



Systemic Failure in Tuberculosis Screening and Containment in the International Primate Trade Driven by U.S. Importers

PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

June 11, 2025

EXECUTIVE SUMMARY

This report reveals an escalating biosecurity and regulatory crisis: tuberculosis (TB)—including multiple zoonotic strains—has repeatedly entered and spread throughout the United States via imported monkeys destined for use in experimentation. Public records and diagnostic data expose systemic failures in TB screening, quarantine, containment, and disclosure, both internationally and domestically. Despite documented TB outbreaks, federal agencies continue to permit companies, including Charles River Laboratories, Inotiv, Worldwide Primates, and Primate Products Inc., to import monkeys from high-risk overseas suppliers. Charles River Laboratories has concealed infection risks from clients, regulators, and shareholders. These companies are driving a dangerously porous supply chain that prioritizes profit over scientific integrity, public health, and worker safety.

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Key Findings:

- **Multiple Strains of Mycobacteria Among Imported Primates:** From January 2023 to August 2024, monkeys infected with members of the *Mycobacterium tuberculosis* complex (MTBC)—including *M. tuberculosis*, *M. orygis*, *M. caprae*, and *M. bovis*—were identified during and after CDC-mandated quarantine. In addition, two atypical mycobacterial species, *M. avium* and *M. terrae* complex, were also detected. These infections occurred in primates imported from Vietnam, Cambodia, the Philippines, Indonesia, and Mauritius.
- **CDC Knew Yet Continued to Facilitate Imports:** Despite the detection of *M. orygis*—a strain of TB never before seen in U.S. primates—during CDC-mandated quarantine in a 2023 shipment from Vietnam, the CDC **did not halt imports from the implicated supplier.** Charles River continued to source monkeys from this supplier throughout 2023, and *M. orygis* infections were still being detected well into 2024. The CDC failed at the first line of defense.
- **Diagnostic Protocols Repeatedly Failed:** Tuberculin skin tests (TSTs) and serological assays repeatedly produced false negatives when applied to newly imported monkeys, as well as among monkeys in established colonies. In Michigan, monkeys that cleared CDC-mandated quarantine and over a dozen follow-up TB screening tests were later confirmed via necropsy to have **widespread TB infections.** Two laboratory workers tested positive after exposure to the infected monkeys.
- **Domestic Movement Spread TB Between U.S. Facilities:** Infected or latently infected monkeys were **transferred between facilities**, including

Entities:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (U.K.)

cross-country shipments from Houston, TX to Frederick, MD and Reno, NV, distributing TB across colonies and amplifying outbreak risks.

- **Importers Withheld Critical Information from Clients:** Charles River failed to disclose in its [2024](#) and [2025](#) Nonhuman Primate Reports that it had been importing TB-infected monkeys during 2023-2024.
- **Failure to Disclose to Regulators and Shareholders:** Companies have not disclosed these outbreaks or test failures in Securities and Exchange Commission (SEC) filings, despite their potential to impact operations, liability, and revenue, constituting possible material nondisclosure. These failures may also violate CDC import rules, United States Department of Agriculture (USDA) veterinary care standards, and the Animal Welfare Act.

To address the ongoing threat posed by TB-infected primates in the research pipeline, immediate action is required. Imports from foreign suppliers, including Vietnam's Thanh Cong Biological Creature Company and Vina Mekong, tied to TB-positive shipments imported to the U.S. by Charles River Laboratories, must be suspended without delay. The SEC should launch enforcement proceedings against companies that failed to disclose these material biosecurity risks. The CDC and USDA must conduct formal investigations into the collapse of quarantine and screening protocols. Publicly funded institutions that have received TB-infected primates from implicated suppliers, including the U.S. Army Medical Research Institute of Chemical Defense, must immediately suspend procurement and funding relationships. Their colonies are likely compromised and require independent biosecurity audits that do not rely on the same insensitive and non-specific testing schemes that enabled this public health and biosecurity crisis. The Canadian Food Inspection Agency (CFIA), Environment and Climate Change Canada (ECCC) authorities, and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Secretariat must coordinate with U.S. agencies to close enforcement gaps and contain the cross-border spread of this escalating threat.

1. Introduction

Tuberculosis is resurging globally, and the international commercial trade in primates represents a high-risk pipeline for the introduction of novel strains of TB and the spread of this disease. Public records obtained by PETA through a Freedom of Information Act (FOIA) request to the USDA's National Veterinary Services Laboratories (NVSL) reveal ongoing failures to detect, contain, and/or report TB in primates imported into the United States for pharmaceutical/biomedical experimentation.

Tuberculosis is a serious lung disease caused by a group of bacteria known as the *Mycobacterium tuberculosis* complex (MTBC). It spreads through the air when someone with the disease coughs, sneezes, or talks. Most infected humans never get sick—their immune system keeps the bacteria under control, and they are described as having *latent* TB. But about 5 to 10 percent of infected humans will eventually develop active TB.¹ This usually happens months or even years after they were first infected. If it isn't treated with antibiotics, TB can spread from the lungs to other body parts, like the lymph nodes or organs, and become much more dangerous.

¹ Centers for Disease Control and Prevention (2024) CDC fact sheet. Tuberculosis: An overview. https://stacks.cdc.gov/view/cdc/22072/cdc_22072_DS1.pdf

While TB in monkeys is not as well understood as it is in humans, given the biological similarities between the two, the disease likely follows a similar course: the monkey inhales TB bacteria, which infect the lungs. If untreated, the bacteria can multiply and spread over time, often over months, to other organs such as the liver, spleen, and even bones.² Like humans, monkeys can carry *latent* TB infections that show no symptoms.³ These latent infections can become active under stress, transport, or immune suppression conditions—all of which are common in the primate trade and research laboratories.

Because these infections can remain hidden for months or even years, they often escape detection during routine screening, particularly when the animal is not actively shedding bacteria or showing clinical signs. This is a critical failure in the current system: the most commonly used diagnostic tool, the tuberculin skin test (TST), cannot reliably detect latent TB infections. As a result, monkeys may pass through quarantine with undetected infections that later become active, posing serious risks to other animals, laboratory personnel, and the integrity of downstream research.

Despite these risks, the tuberculin skin test (TST)—a tool with well-documented limitations—remains the primary diagnostic method during CDC-mandated quarantine. A series of negative TSTs is required to clear animals for entry into the U.S. experimentation system. However, numerous documented cases have shown that animals who have cleared quarantine later developed active TB, sometimes months later, after being shipped across state lines to other facilities or enrolled in research studies, highlighting both the unreliability of the current screening process and the persistent threat of undetected infection.^{4,5,6,7}

These ongoing failures expose critical gaps in diagnostic accuracy, regulatory oversight, and institutional accountability. The continued use of infected or latently infected animals not only compromises animal welfare and public health, it also undermines the scientific validity of any research based on these compromised models. This report documents how monkeys carrying multiple TB strains entered the U.S. research pipeline, were transferred between facilities, and were cleared through flawed protocols, revealing a systemic breakdown that endangers animals, researchers, and the public. Federal agencies not only fund this system with tens of millions of taxpayer dollars but also accept monkeys from it for use in government-run experiments. In doing

² Lewinsohn DM, Tyeman IS, Frieder M, et al. High resolution radiographic and fine immunologic definition of TB disease progression in the rhesus macaque. *Microbes and Infect.* 2006; 8(11):2587-2598. doi.org/10.1016/j.micinf.2006.07.007

³ Diedrich CR, Mattila JT, Klein E, et al. Reactivation of Latent Tuberculosis in Cynomolgus Macaques Infected with SIV Is Associated with Early Peripheral T Cell Depletion and Not Virus Load. *PLOS ONE.* 2010;5(3):e9611. doi:10.1371/journal.pone.0009611

⁴ Tuberculosis in Imported Nonhuman Primates -- United States, June 1990-May 1993. Accessed April 11, 2025. <https://www.cdc.gov/Mmwr/preview/mmwrhtml/00021299.htm>

⁵ Engel GA, Wilbur AK, Westmark A, Horn D, Johnson J, Jones-Engel L. Naturally acquired Mycobacterium tuberculosis complex in laboratory pig-tailed macaques. *Emerg Microbes Infect.* 2012;1(1):1-5. doi:10.1038/emi.2012.31

⁶ Yee JL, Prongay K, Van Rompay KKA, et al. Tuberculosis detection in nonhuman primates is enhanced by the use of testing algorithms that include an interferon- γ release assay. *Am J Vet Res.* 2022;83(1):15-22. doi:10.2460/ajvr.21.08.0124

⁷ Stockinger DE, Roellich KM, Vogel KW, et al. Primary Hepatic Mycobacterium tuberculosis Complex Infection with Terminal Dissemination in a Pig-Tailed Macaque (*Macaca nemestrina*). *J Am Assoc Lab Anim Sci JAALAS.* 2011;50(2):258-262.

so, they are not just tolerating the risks—they are actively sustaining and expanding a diseased and dangerous supply.

We would also like to call your attention to PETA’s [Vietnam Primate Trade Report](#) and the recent findings documented in Sandy River Research’s independently prepared reports [Unveiling the Dark Side of the Monkey \(Macaque\) Trade](#) and [Deeper Into Darkness-Monkey Trade Exposé](#). Notably, these reports detail the role of Thanh Cong—a major supplier in Vietnam with documented links to tuberculosis and other infectious threats. The recurrence of disease patterns across these investigations underscores a systemic failure to contain biosecurity threats at their source and raises urgent questions about ongoing U.S. government reliance on known high-risk suppliers.

2. Imported Monkeys Arrived Infected with Multiple TB Strains

Records received via FOIA from the USDA’s NVSL confirm the presence of multiple TB strains in monkeys imported from international sources, including Vietnam, Cambodia, Mauritius, the Philippines, and Indonesia. These were not isolated cases; in many instances, multiple monkeys tested positive at the same facility during the same week. Note that TB screening during the CDC-mandated 31-day quarantine at these sites is [conducted under the control of the importing companies](#) themselves, raising serious concerns about conflicts of interest, testing reliability, and the integrity of the quarantine process.

Between January 30, 2023, and August 15, 2024, dozens of monkeys were found to be infected with multiple strains of tuberculosis-causing bacteria at eight CDC-approved quarantine or post-quarantine research facilities (Table 1). These included both members of the *Mycobacterium tuberculosis* complex (MTBC)—such as *M. tuberculosis*, *M. orygis*, *M. caprae*, and *M. bovis*—as well as atypical mycobacterial species like *M. avium* and the *M. terrae* complex. Infections were confirmed at multiple sites, including facilities operated by Charles River Laboratories, which has repeatedly denied the presence of tuberculosis in its monkey colonies.

CRL would have had access to these diagnostic results long before they became publicly available—yet the company continued to deny any TB infections and failed to alert clients, shareholders, or regulators. When finally [compelled to release](#) a public Nonhuman Primate (NHP) report—after months of delay and pressure—CRL omitted any mention of TB outbreaks, despite being fully aware of confirmed cases across multiple facilities. Their public-facing claims that imported monkeys are “disease-free” and that screening protocols are rigorous are flatly contradicted by federal diagnostic data. [Charles River Laboratories states](#) in its annual NHP reports that:

“Our facilities are highly regulated and robustly designed to prevent the transmission of any zoonotic disease. Charles River facilities and processes are designed to comply with state, local and federal health and environmental material requirements. All NHPs imported into our quarantine facilities first undergo a quarantine in the country of origin. The pre-export quarantine includes several pathogen screens and a thorough physical exam conducted by veterinarians. In some cases, Charles River veterinarians help to conduct this pre-export screening. NHPs must meet or exceed the health regulations of the exporting country, the importing country and Charles River’s contract specifications in order to be eligible for export. Imported animals are then further quarantined in our quarantine

facilities as regulated by government agencies and retested to ensure they meet both the government mandates and Charles River’s own specifications for pathogens and health of the animals.”

2.a. NVSL Confirmed Multiple Strains of TB, Including Members of the *Mycobacterium tuberculosis* Complex

Table 1 presents confirmed tuberculosis cases in primates within the U.S. biomedical pipeline between January 2023 and August 2024 based on diagnostic testing conducted by NVSL. Samples were submitted by commercial quarantine and research facilities in cases where TB was suspected, either due to TST findings, clinical signs, necropsy findings, or epidemiological concerns. NVSL identified multiple members of the *Mycobacterium tuberculosis* complex (MTBC), including *M. tuberculosis*, *M. orygis*, *M. caprae*, and *M. bovis*, as well as atypical mycobacterial species such as *M. avium* and the *M. terrae* complex. Infections were confirmed at eight CDC-approved quarantine or post-quarantine research facilities across five states. The table provides facility-specific detail, including the date samples were collected, the number of positive animals, the TB strains detected, and, where available, the exporting country/facility.

Table 1: Facilities, dates, and strains of confirmed TB infections

Exhibit	Facility	Location	Date Sample Collected	Positive Monkeys	MTBC Strain Reported	Known Int'l Origin of Monkeys
1	Charles River Laboratories	Frederick, MD	2023-01-30	2	<i>M. tuberculosis</i> complex	
2	Charles River Laboratories	Frederick, MD	2023-02-27	2	<i>M. tuberculosis</i> complex	
3	Charles River Laboratories	Frederick, MD	2023-12-11	1	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	Thanh Cong, Vietnam
4	Charles River Laboratories	Frederick, MD	2024-01-22	1	<i>M. tuberculosis</i> complex; <i>M. caprae</i>	
5	Charles River Laboratories	Frederick, MD	2024-03-18	1	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	Thanh Cong, Vietnam
6	Charles River Laboratories	Frederick, MD	2024-05-08	1	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	Thanh Cong, Vietnam
7	Charles River Laboratories	Frederick, MD	2024-06-10	2	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	Thanh Cong, Vietnam
8	Charles River Laboratories	Frederick, MD	2024-06-11	1	<i>M. orygis</i>	Thanh Cong, Vietnam
9	Charles River Laboratories	Frederick, MD	2024-06-13	2	<i>M. orygis</i>	
10	Charles River Laboratories	Frederick, MD	2024-07-12	4	<i>M. tuberculosis</i> complex	
11	Charles River Laboratories	Frederick, MD	2024-07-29	3	<i>M. tuberculosis</i> complex	Vina Mekong, Vietnam
12	Charles River Laboratories	Houston, TX	2023-02-06	1	<i>M. orygis</i>	
13	Charles River Laboratories	Houston, TX	2023-02-13	1	<i>M. tuberculosis</i> complex	
14	Charles River Laboratories	Houston, TX	2023-02-20	4	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	Thanh Cong, Vietnam
15	Charles River Laboratories	Houston, TX	2023-02-21	3	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	

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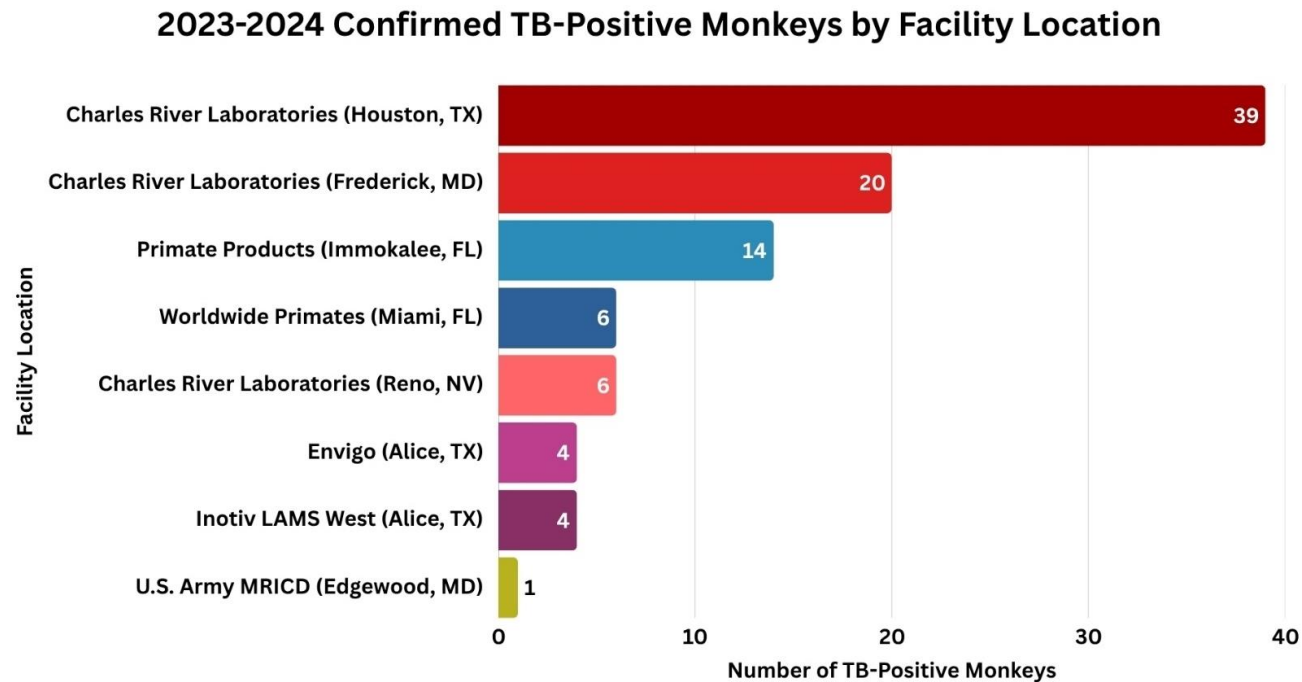
16	Charles River Laboratories	Houston, TX	2023-02-27	1	<i>M. tuberculosis</i> complex	
17	Charles River Laboratories	Houston, TX	2023-03-06	4	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
18	Charles River Laboratories	Houston, TX	2023-03-20	4	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
19	Charles River Laboratories	Houston, TX	2023-03-21	3	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
20	Charles River Laboratories	Houston, TX	2023-04-03	4	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
21	Charles River Laboratories	Houston, TX	2023-04-06	1	<i>M. tuberculosis</i> complex	
22	Charles River Laboratories	Houston, TX	2023-04-11	2	<i>M. tuberculosis</i> complex	
23	Charles River Laboratories	Houston, TX	2023-05-15	1	<i>M. tuberculosis</i> complex	
24	Charles River Laboratories	Houston, TX	2023-05-31	2	<i>M. orygis</i>	Thanh Cong, Vietnam
25	Charles River Laboratories	Houston, TX	2023-11-13	1	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
26	Charles River Laboratories	Houston, TX	2024-01-15	1	<i>M. tuberculosis</i> complex; <i>M. caprae</i>	
27	Charles River Laboratories	Houston, TX	2024-01-29	2	<i>M. tuberculosis</i> complex; <i>M. caprae</i>	
28	Charles River Laboratories	Houston, TX	2024-07-15	4	<i>M. tuberculosis</i> complex	Vina Mekong, Vietnam
29	Charles River Laboratories	Reno, NV	2024-02-23	6	<i>M. tuberculosis</i> complex	CV Primaco, Indonesia
30	Envigo	Alice, TX	2024-03-18	1	<i>M. caprae</i>	
31	Envigo	Alice, TX	2024-04-11	2	<i>M. tuberculosis</i> complex; <i>M. caprae</i>	
32	Envigo	Alice, TX	2024-04-26	1	<i>M. tuberculosis</i> complex	
33	Inotiv LAMS West	Alice, TX	2024-03-30	1	<i>M. tuberculosis</i> complex; <i>M. caprae</i>	

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34	Inotiv LAMS West	Alice, TX	2024-05-06	1	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
35	Inotiv LAMS West	Alice, TX	2024-05-31	1	<i>M. orygis</i>	
36	Inotiv LAMS West	Alice, TX	2024-06-27	1	<i>M. tuberculosis</i> complex; <i>M. orygis</i>	
37	U.S. Army Medical Research Institute of Chemical Defense (MRICD)	Edgewood, MD	2023-06-16	1	<i>M. tuberculosis</i> complex	
38	Primate Products	Immokalee, FL	2023-09-10	1	<i>M. tuberculosis</i> complex	
39	Primate Products	Immokalee, FL	2023-11-30	3	<i>M. tuberculosis</i> complex	
40	Primate Products	Immokalee, FL	2023-12-27	1	<i>M. tuberculosis</i> complex	
41	Primate Products	Immokalee, FL	2024-01-14	1	<i>M. tuberculosis</i> complex	
42	Primate Products	Immokalee, FL	2024-03-05	1	<i>M. tuberculosis</i> complex	
43	Primate Products	Immokalee, FL	2024-07-16	1	<i>M. tuberculosis</i> complex	
44	Primate Products	Immokalee, FL	2024-08-13	3	<i>M. tuberculosis</i> complex	
45	Primate Products	Immokalee, FL	2024-08-15	1	<i>M. tuberculosis</i> complex	
46	Primate Products	Immokalee, FL	2024-09-03	1	<i>M. tuberculosis</i> complex	
47	Primate Products	Immokalee, FL	2024-09-04	1	<i>M. tuberculosis</i> complex	
48	Worldwide Primates	Miami, FL	2023-01-16	1	<i>M. tuberculosis</i> complex	
49	Worldwide Primates	Miami, FL	2023-03-06	1	<i>M. avium</i> ; <i>M. terrae</i> complex	
50	Worldwide Primates	Miami, FL	2023-04-21	1	<i>M. tuberculosis</i> complex; <i>M. bovis</i>	
51	Worldwide Primates	Miami, FL	2023-04-28	1	<i>M. tuberculosis</i> complex; <i>M. bovis</i>	
52	Worldwide Primates	Miami, FL	2023-05-01	1	<i>M. tuberculosis</i> complex; <i>M. bovis</i>	
53	Worldwide Primates	Miami, FL	2023-05-09	1	<i>M. tuberculosis</i> complex; <i>M. bovis</i>	

To make the findings in Table 1 more accessible, Figure 1 displays the number of confirmed TB-positive monkeys per facility during the same period. The visual highlights significant clustering of cases at certain sites, most notably three Charles River Laboratories locations—Houston, Frederick, and Reno—which together accounted for 65 of the confirmed infections. Other facilities with confirmed cases include Primate Products, Worldwide Primates, Envigo, Inotiv LAMS West, and the U.S. Army Medical Research Institute of Chemical Defense (MRICD). This visualization highlights the geographic distribution of confirmed TB cases and shows that the highest numbers occurred at large-scale import and contract research facilities. These facilities serve as distribution hubs within the primate research supply chain, meaning that monkeys, including those with undetected latent TB infections, may be transported across state lines to other research institutions, increasing the potential for wider dissemination of the disease. While the chart captures only confirmed TB cases, the reliance on limited diagnostic tools, such as the TST, means that additional infections may have gone undetected. Asymptomatic or latently infected monkeys could have been transferred to other facilities, posing ongoing challenges for disease containment.

Figure 1 Number of confirmed TB cases by facility, Jan. 2023—Aug. 2024



2.b. Emergence and Persistent Circulation of *M. orygis* in U.S. Primate Research Facilities

Mycobacterium orygis is a zoonotic member of the *Mycobacterium tuberculosis* complex. It has been increasingly implicated in human TB cases globally, raising significant concerns about its ability to infect across species and evade standard diagnostics.⁸ From February to May 2023, an outbreak of *M. orygis*—a TB strain never seen in macaques in the United States—was detected in a shipment of 540 long-tailed macaques originating from Southeast Asia. Thirty-two macaques in

⁸ Hugh BT, Sim EM, Crighton T, et al. Emergence of *Mycobacterium orygis*: novel insights into zoonotic reservoirs and genomic epidemiology. *Front Pub Health*. 2025; 13:1-11. DOI=10.3389/fpubh.2025.1568194

this shipment elicited a positive TST reaction and were euthanized. Additional testing showed that 26 were positive for TB via culture, including animals who had been negative on TST. Further testing during this three-month period identified additional monkeys infected with *M. orygis* among the imported cohort. The remaining macaques in this shipment underwent an extended quarantine period that included additional TSTs before being released from quarantine on August 8, 2023.⁹

Airway bills (see Exhibits 3, 5, 6, 7, 8, 14, and 24) confirm that the macaques involved in the *M. orygis* outbreak originated from Vietnam's Thanh Cong Biological Creature Company (Thanh Cong) and were imported by Charles River Laboratories. Based on facility records, we believe the original shipment from late January 2023 was split upon arrival in the U.S., with approximately half of the animals transferred to Charles River Laboratories' Houston quarantine facility and the other half sent to its Frederick quarantine facility. Some infected monkeys were identified during the original CDC-mandated quarantine (see Exhibit 14). Despite those confirmed TB cases, CRL continued to import macaques from Thanh Cong throughout 2023. As shown in lines 7-9 in Table 1, *M. orygis* was still detected in CRL colonies a year and a half later, including positive animals at its Frederick, MD facility in June 2024, indicating that the outbreak strain persisted and may still be circulating. We have a pending request to the USDA's NSVL for documents related to TB detection from 9/27/2024 to 6/5/2025. Records Thanh Cong provided to CITES indicate that the facility had 646 monkey deaths at their facility in 2023. Mortality on this scale is consistent with disease outbreaks.¹⁰

3. Monkeys Infected with TB Lingered in and were Transferred Between U.S. Facilities

Currently, records that PETA received from the USDA's NSVL show the movement of TB-infected or exposed monkeys between CRL facilities, creating clear opportunities for cross-contamination between facilities and subsequent outbreaks. On February 23, 2024, two long-tailed macaques housed at CRL's Reno facility tested positive for *M. tuberculosis* complex. These monkeys, originally supplied by CV Primaco in Indonesia, arrived at CRL's Houston Facility in September 2022 and were later transferred across the country (see Exhibit 29). While they may have been infected prior to import, it is also possible they acquired TB after arriving in the U.S., highlighting both the risk of undetected latent infection and the vulnerability of CRL's internal biosecurity systems. Either scenario underscores a critical breakdown: infected monkeys were moved between facilities and introduced into new colonies, spreading a pathogen that should have been identified and contained.

3.a. Undetected TB Progression and Dissemination Within U.S. Colonies: The Case of Monkey 2007090

⁹ Swisher SD, Taetzsch SJ, Laughlin ME, et al. Outbreak of *Mycobacterium orygis* in a Shipment of Cynomolgus Macaques Imported from Southeast Asia — United States, February–May 2023. *MMWR Morb Mortal Wkly Rep.* 2024;73(7):145-148. doi:10.15585/mmwr.mm7307a2

¹⁰ CITES presentation from Viet Nam concerning trade in *Macaca fascicularis* in response to Resolution conf 17.7 on review of animal specimens reported as produced in Captivity, February 3-8, 2025. Pg 7, Facility 3. <https://cites.org/sites/default/files/documents/E-SC78-Inf-14.pdf>

Another monkey, 2007090, originating from Thanh Cong in Vietnam and shipped to CRL's Frederick, MD facility in October 2023, was euthanized in May 2024 due to a five-month history of weight loss, nasal discharge, and an overall poor prognosis (see Exhibit 6). Although repeatedly non-reactive to the TST, necropsy revealed lung nodules, enlarged lymph nodes, and kidney lesions consistent with TB. Culture confirmed the presence of both *M. tuberculosis* complex and *M. orygis*, and direct PCR testing for TB DNA yielded positive results in multiple organs. The diagnostic results from monkey 2007090 tell a clear story of disease progression. Moderate quantities of TB bacterial DNA were found in the lungs, with slightly lower levels in the spleen, lymph nodes, and liver. This organ-specific gradient reflects a classic path of untreated TB infection: initial pulmonary (lung) colonization, followed by gradual dissemination to secondary organs over several months—precisely the pattern seen in human cases. This case reinforces what is already well-established in human medicine and is increasingly undeniable in primates: TB can evade detection by TST and spread silently within a host before manifesting as an advanced, disseminated disease. Two monkeys from the same October 2023 shipment tested positive in December 2023 (see Exhibit 3) and March 2024 (see Exhibit 5), while an additional four monkeys tested positive in May and June 2024 (see Exhibits 6, 7, and 8). Considering that these confirmed TB-infected monkeys were among the more than 700 monkeys CRL imported from Thanh Cong and transported to the U.S. on Bluebird Nordic Airlines (See Exhibit 3), it is unclear how many of the remaining monkeys are carrying latent TB, or how many have been distributed to facilities and clients in North America.

3.b. Laboratory Workers Exposed: The Michigan Outbreak

In early 2023, a separate TB outbreak occurred at Northern Biomedical Research in Norton Shores, Michigan, triggered by three wild-caught long-tailed macaques originally imported from Mauritius, through Florida. According to documents obtained via FOIA from the Michigan Department of Agriculture & Rural Development, two laboratory workers tested positive following exposure and were referred for medical evaluation and treatment (see Exhibit 54).¹¹

Figure 2. A portion of the FOIA documents received on May 18, 2023, from the Michigan Department of Agriculture and Rural Development

From: [Schalow, Michele \(MDARD\)](#)
To: [Lenda, Catherine \(MDARD\)](#)
Subject: My Updates from Today's TB Call
Date: Wednesday, February 22, 2023 8:54:00 AM

Tuberculosis

- We are responding to an outbreak of tuberculosis (*Mycobacterium tuberculosis*) at a facility involving at least 3 macaques.
- The macaques were wild caught in Mauritius, imported into Florida, and then imported into Michigan.
- Additional primates were exposed and are under quarantine.
- Information to MDARD is that other animals associated with the importation from Mauritius to the United States were also found to have tuberculosis.

¹¹ Hicks J P. Infected monkeys at Michigan research lab threaten health and science. *M Live*. <https://www.mlive.com/public-interest/2023/06/infected-monkeys-at-michigan-research-lab-threaten-health-and-science.html>. June 21, 2023. Accessed May 28, 2025.

3.c. Mauritius-Origin *M. bovis* Outbreak Escaped Detection Despite Multimodal Testing, Resulted in Laboratory Worker Exposure

In late 2023, a veterinary pathology abstract presented at the American College of Veterinary Pathologists Annual Meeting documented the Michigan outbreak. It exposed the fundamental inadequacy of current diagnostic protocols for detecting latent or emerging TB in nonhuman primates.¹² According to the report, four wild-caught, Mauritius-origin cynomolgus macaques had cleared all CDC-mandated entry requirements, including three consecutive negative tuberculin skin tests (TSTs) during the 31-day federal quarantine period. Over the following 17 months, the animals tested negative on six additional TSTs, interferon gamma release assays (IFN- γ), two independent serology assays, and thoracic radiographs.

Seven months after the last TST, one macaque developed signs of active disease, including lethargy and respiratory distress. Three others remained asymptomatic but later tested TST-positive. All four monkeys were euthanized. Necropsy revealed widespread caseogranulomas across the lungs, liver, spleen, and lymph nodes. While acid-fast staining did not detect organisms, PCR confirmed *M. tuberculosis* complex DNA in three of the four monkeys. Culture isolation succeeded in one case, and whole genome sequencing performed by the Michigan Department of Health and Human Services identified the pathogen as *M. bovis*.

The most plausible explanation is that these monkeys harbored latent TB infections that reactivated over time, likely triggered by the stress of transport, social disruption, or assignment to a study protocol. A recent study found that even minor interventions, such as routine cage transfers, can cause measurable physiological stress and suppress immune responses in cynomolgus macaques.¹³ The Michigan outbreak underscores how these common research practices may act as immunological tipping points—reactivating latent TB in animals presumed to be disease-free and exposing both other primates and laboratory personnel to a dangerous and preventable pathogen.

3.d. A Systemic Threat: Infected Monkeys Circulating Through U.S. Research Facilities

The Michigan case is not an isolated failure—it is a warning sign. Monkeys imported into the U.S., cleared through flawed quarantine protocols, are then introduced into company-owned colonies where they are housed, handled, and often mixed with other animals—before being sold and shipped to research institutions nationwide. Although publicly available Certificates of Veterinary Inspection (CVIs) represent only a sliver of total shipments, PETA was able to use CVIs to trace monkey sales from Texas’ Charles River Laboratories, Envigo, and Inotiv facilities and Florida’s Primate Products and Worldwide Primates to facilities around the country. During the known high-risk windows in 2023-2024, these primate importers transported monkeys by common carriers to Northern Biomedical Research in Michigan, Labcorp in Wisconsin, Lovelace Biomedical Research Institute in New Mexico, the United States Army Medical Research Institute of Infectious Diseases in Maryland and the University of Texas Medical Branch (see Exhibit 55).

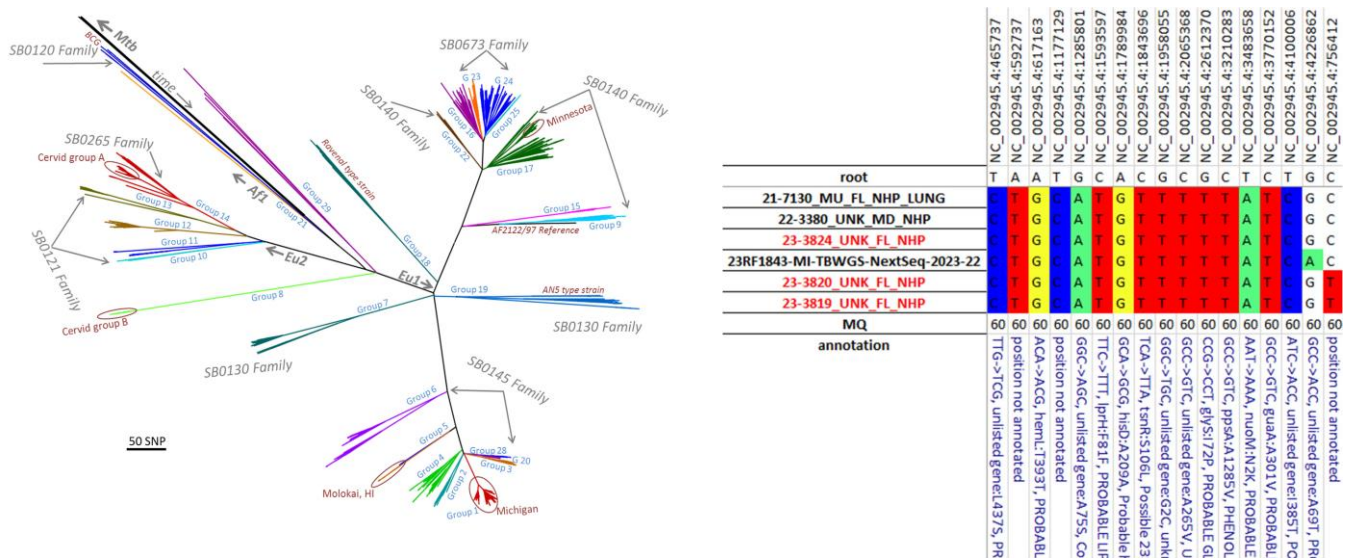
¹² Gerras A, Bolin S, Mani R, Sledge D. 2023 *Disseminated Tuberculosis In A Group Of Cynomolgus Macaques*. Pg 27. https://cdn.ymaws.com/www.acvp.org/resource/resmgr/2023_annual_meeting/2023_accepted_abstracts.pdf

¹³ Capitanio JP, Tancredi DJ, Zarrabi J, VandeVoort C, Walker CK. Cortisol and Catecholamine Concentrations Are Affected by Repeated Relocations of Adult Female Rhesus Monkeys (*Macaca mulatta*). *Am J Primatol*. 2025;87(6):e70050. doi:10.1002/ajp.70050

These documented transfers are almost certainly the tip of the iceberg—not only for 2023–2024, but for the years preceding and following. For example, in 2023, Worldwide Primates submitted spleen, liver, kidney, and lung tissues from a long-tailed macaque in their facility to the USDA NVSL (Exhibit 52). Figure 3 shows that genotyping and phylogenetic analyses conducted by NVSL revealed that the 2023 monkey was infected with the same distinctive strain of *M. bovis* that had been detected at Worldwide Primate during an outbreak in 2021 that included a monkey who originated from Mauritius (21-7130_MU_FL_NHP_LUNG). The results from NVSL also indicate that the same distinctive strain of *M. bovis* was detected in a monkey in Maryland in 2022 (22-3380_UNK_MD_NHP). Simply put, the same strain of *M. bovis* had been circulating at Worldwide Primates since at least 2021, and during that period, countless monkeys were moved in and out of Worldwide Primates.

What we can see is alarming. What remains hidden—shielded by regulatory loopholes, inconsistent testing, and institutional silence—is almost certainly worse. Tuberculosis continues to circulate through the primate supply chain, with infected or exposed monkeys routinely transported between facilities on commercial carriers and across state lines. Federal oversight has failed to contain the spread, quantify the risk, or protect public health and national biosecurity from the consequences of this ongoing breakdown.

Figure 3. A report prepared in 2023 by USDA NVSL confirmed that a macaque housed at Worldwide Primates was infected with the same distinctive strain of *M. bovis* had been circulating in the facility since 2021. In 2022 a monkey in Maryland was found to be infected with the same strain.



4. Screening Protocols Failed Repeatedly

The CDC's continued reliance on the outdated and scientifically inadequate tuberculin skin test (TST) as the cornerstone of tuberculosis screening in recently imported nonhuman primates presents a serious public health risk. The TST, developed nearly a century ago, has long been recognized in research and veterinary communities as insensitive and nonspecific, particularly in primates.¹⁴ It frequently fails to detect both latent and active TB infections, especially in animals recently subjected to the compounded immunological stress of capture, transport, pre-shipment vaccination, and new housing conditions. A 2022 retrospective analysis of Mauritius-origin macaques in CDC-mandated quarantine made this clear:¹⁵

“The process of preparing an animal for intercontinental transport, including vaccination, may suppress the response to tuberculin, which, for example, is the case when an animal is measles vaccinated within 28 days of a TST. This would eliminate or minimize an animal's response to tuberculin causing a probable false negative reaction... Stress during and after recent shipping is a well-known and documented phenomenon... This stress response may suppress the immune system allowing a recrudescence of latent TB. Reactivation of latent TB may not be diagnosed with the TST until after an animal has cleared CDC quarantine.”

This finding is not hypothetical—it's borne out in real-world failures. USDA NVSL records show multiple cases where PCR confirmed TB infection, but cultures were negative, highlighting the limitations of relying on growth-based diagnostics. Moreover, facility records and NVSL submission data suggest that diagnostic escalation typically occurs only if a monkey exhibits overt clinical signs or generates a TST reaction graded 3/5 or higher. As a result, many infected animals may never be tested beyond the initial TSTs, and latent infections can go entirely undetected. The *M. bovis* outbreak at Northern Biomedical Research in Michigan underscores the consequences. Four wild-caught Mauritius-origin macaques underwent 17 months of intensive surveillance with multimodal testing and were still only diagnosed on postmortem after one of them became clinically ill. These failures illustrate a central truth: even the most comprehensive current protocols are not sufficient to detect tuberculosis in primates. Monkeys may pass federal quarantine and be distributed to research facilities while harboring transmissible TB. This undermines biosecurity and jeopardizes the health of laboratory personnel, other animals, and the scientific validity of downstream research.

5. Regulatory and Ethical Breaches

5.a. Public Health Risk

The findings in this report reveal not just operational lapses but a fundamental collapse of federal oversight, most notably by the CDC, in preventing the importation and spread of tuberculosis

¹⁴ Yee JL, Prongay K, Van Rompay KKA, et al. (2022). Tuberculosis detection in nonhuman primates is enhanced by use of testing algorithms that include an interferon- γ release assay, *Amer. J. Vet. Res.*, 83(1): 15-22.

¹⁵ Panarella M, Hursh S (2022) A retrospective analysis of the tuberculin skin test reactions of a single source population of Mauritian *Macaca fascicularis* held in quarantine during 2017. *PLOS One*, 17(4): e0265942.

through the U.S. primate research pipeline. Monkeys infected with multiple TB strains have entered the country, cleared CDC-mandated quarantine, and been transported across state lines to biosafety level 2 and 3 (BSL-2/3) facilities. In many cases, facility staff were unaware they were housing infected animals until weeks or months later.

Despite its well-documented failures in detecting latent and active TB in stressed animals, the CDC continues to rely on the nearly century-old tuberculin skin test (TST) as its primary screening tool for imported primates. This outdated method, paired with an overly narrow trigger for further diagnostics, has allowed TB-infected animals to move freely through the U.S. biomedical pipeline. The result: personnel, animals, and downstream research facilities are repeatedly exposed to a preventable, airborne zoonotic disease.

The CDC has long acknowledged the zoonotic risk of importing wildlife but has repeatedly failed to act. According to a 2023 report from the U.S. Government Accountability Office (GAO), the CDC has known since at least 2007 that its animal import regulations may be inadequate. Despite issuing an advance notice of proposed rulemaking that year, citing risks from wild animal imports and admitting that its framework was reactive rather than preventive, the agency abandoned its plans to strengthen oversight.

In 2008, CDC officials testified that this reactive posture was insufficient to stop zoonotic diseases from entering the U.S. Yet in 2014, and again in the years since, the agency opted against issuing stronger regulations, citing "competing priorities." The GAO 2023 report explicitly criticized this failure, stating:

"CDC has not comprehensively identified and characterized risks related to imported wildlife... Its current approach—to act after an outbreak occurs, rather than proactively—may not suffice to ensure that reasonable steps are being taken to prevent the introduction of zoonotic diseases into the U.S."

In May 2023, the GAO recommended that the CDC conduct a comprehensive risk assessment focused on high-priority wildlife imports, such as nonhuman primates. The CDC refused, and in its formal response, the agency *did not concur*.¹⁶

The result is clear: despite years of internal warnings and external recommendations, the CDC has maintained a regulatory regime that invites the outbreaks it is supposed to prevent. The ongoing circulation of tuberculosis-infected monkeys in U.S. research facilities is not just a biosecurity failure—it's a policy failure, driven by institutional inertia and willful disregard for known risks.

5.b. Breach of Disclosure Obligations and Legal Risk

Despite the gravity of these incidents, companies involved in the importation and sale of tuberculosis-infected primates—including Charles River Laboratories—have failed to disclose

¹⁶ United States Government Accountability Office Report to Congressional Committees. Zoonotic Diseases: Federal Actions Needed to Improve Surveillance and Better Assess Human Health Risks Posed by Wildlife. <https://www.gao.gov/products/gao-23-105238#:~:text=GAO%20is%20making%20five%20recommendations,disease%20risks%20for%20imported%20wildlife>

them in filings, U.S. Securities and Exchange Commission (SEC) proxy statements, annual reports, or investor communications. This lack of transparency raises serious concerns under federal securities law. The SEC requires disclosing material risks that could impact operational stability, legal exposure, or investor decision-making.¹⁷ The recurrence of TB outbreaks and the failures in screening and containment meet that threshold— silence in the face of these facts may constitute a breach of SEC regulations. It also undermines the public’s right to know that federally regulated facilities are importing a dangerous pathogen and failing to contain it.

In addition to potential SEC violations, these failures may also breach the Animal Welfare Act, which mandates adequate veterinary care and disease control.¹⁸ This report documents multiple cases in which facilities failed to appropriately diagnose and treat serious illnesses, reflecting a breakdown in veterinary oversight that may constitute a violation of federal standards, putting animals and personnel at risk.

Critically, these actions may also violate CDC import regulations, which are designed to prevent the entry and spread of communicable diseases through strict quarantine and post-arrival monitoring. Yet infected monkeys have repeatedly cleared quarantine and been transported across state lines, sometimes without TB being detected until much later, if at all.

The continued importation and use of potentially infected animals, despite well-documented risks, reflects a systemic failure of regulatory compliance and ethical responsibility. Companies that cannot guarantee their colonies are TB-free, that continue to import infected primates, and that fail to alert clients or regulators to this reality are perpetuating a fundamentally unsafe supply chain.

There is currently no federal mechanism to verify the health status of animals once they leave quarantine, no requirement to disclose infections to clients or the public, and no accountability for failures that threaten human health, animal welfare, and scientific integrity.

¹⁷ SEC Securities Disclosure: Background and Policy Issues. Accessed May 22, 2025.
<https://www.congress.gov/crs-product/IF11256>

¹⁸ 42 CFR 71.53 -- Requirements for importers of nonhuman primates. Accessed May 22, 2025.
<https://www.ecfr.gov/current/title-42/part-71/section-71.53>

Exhibit 1

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE

1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

(b) (6)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

Charles River Laboratories

EMAIL ADDRESS

(b) (6) crl.com

OWNER CITY

Frederick

STATE/COUNTRY

MD/USA

PHONE NUMBER

(b) (6)

FAX NUMBER

(b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Frederick

STATE/COUNTRY

MD/USA

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6)

Frederick, MD 21701

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

7. NUMBER IN HERD/FLOCK AFFECTED

8. NUMBER IN HERD/FLOCK DEAD

9. EXAMINATIONS REQUESTED

Mycobacterium Culture
Mycobacterium PCR
Mycobacterium Identification
Rule in/out TB

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

01/30/2023

12. AUTHORIZED BY

14. COUNTRY OF ORIGIN

(b) (6)

15. REFERRAL NUMBER

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

20. NUMBER OF ANIMALS SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary)

23. SIGNATURE OF SUBMITTER AND

(b) (6)

2/14/23

0

23-005146

MB

02/16/2023
602163



CONDITION

PRIORITY

DISTRIBUTION

RECEIVED BY

(b) (6)

VS FORM 10-4
AUG 2009

24-08898_000608

Date: February 14th 2023

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis* / (b) (4) origin ** Quarantine Samples **

Item Name	Quantity	Date sample Derived	Packing
(b) (4)	LN, spleen, liver and lung	(b) (4)	Dry Ice
	LN, spleen, liver and lung		Dry Ice

4. Date Shipped: (b) (4)

5. FedEx Tracking# (b) (6)

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

Signature of Supervisor *J*

SEE CONDITIONS OF SALE/WARRANTY

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: **(b) (4)**

07 February 2023

History:

Customer: **Charles River Frederick - Quarantine**
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID **(b) (4)**

Animal had a 5/5 TB reaction at 72 hours and was euthanized. Necropsy performed by submitter found mildly enlarged tracheobronchial lymph nodes. No other significant findings.

Microscopic Diagnoses:

#1 **(b) (4)** Lymph node (tracheobronchial): Adenitis, necrotizing/abscess, mild, multifocal.

Acid Fast Stain (TBLN): Two acid fast bacilli noted within TBLN lesion.

Arteries (liver, kidney, intestine): Arteritis/vasculitis, lymphocytic, neutrophilic, mild/moderate, multifocal.

Stomach: Lymphocytic infiltrates, mucosal, mild, diffuse.

Large intestine: GALT hyperplasia, moderate, multifocal.

Lung (fragment), Lymph node (mesenteric), Heart, Liver, Kidney, Urinary bladder, Small intestine: Within normal limits.

Comment:

The tracheobronchial lymph node lesion and finding of very few acid fast bacilli was consistent with a diagnosis of Mycobacteriosis. There was also evidence of multiorgan arteritis and lymphocytic gastritis. Spleen was not submitted with the order.

(b) (6)

24-08898_000610



National Veterinary Services Laboratories

FINAL REPORT

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

Laboratory Test Report

Owner

Charles River Laboratories

Frederick, MD

Animal Location

Frederick County MD

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:

23-005146

NFC Control Number:

19823017715

Date Collected:

01/30/2023

Date Received:

02/15/2023

Date Completed:

08/16/2023

Collected By:

[REDACTED]

Purpose:

TB-10-4

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 12979 Case #: TB23-01491 Sample: LN Specimen Type: Lymph Node Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.64131927

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all other isolates in the NVSL Database. The isolate has acquired a single SNP from the most recent common ancestor. See the attached Genotyping Report.

Animal ID: 12979 **Case #:** TB23-01492 **Sample:** Spleen **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 12979 **Case #:** TB23-01493 **Sample:** Liver **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Inhibited Ct = U

Interpretation: The PCR reaction was inhibited; the test result was not valid. Retesting will be necessary for a valid result.

Animal ID: 12979 **Case #:** TB23-01494 **Sample:** Lung **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.38423538

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

07 February 2023

History:

Customer: Charles River Frederick - Quarantine
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Animal had 4/5 TB reaction at 72 hours and was euthanized. Necropsy conducted by the submitter found tracheobronchial lymph nodes were enlarged with purulent material on cut surface. A firm, 5mm nodule was noted in lung.

Microscopic Diagnoses:

#1 (b) (4) Lymph node (tracheobronchial): Adenitis, necrotizing/abscess, mild, multifocal.

Acid Fast Stain (TBLN): Small numbers of acid-fast positive bacilli present within the lesions.

Lung, Heart, Liver, Spleen, Kidney, Urinary Bladder, Adrenal Gland, Stomach, Small Intestine,

Large Intestine, Lymph node (mesenteric): Within normal limits.

Acid Fast Stain (lung): Negative.

Comment:

The enlarged and purulent tracheobronchial lymph node noted at necropsy correlated microscopically to necrosis and abscess of the lymph nodes with intralesional acid fast bacilli. This lesion was consistent with Mycobacteriosis. Other tissues examined were considered within normal limits, including the lung for which a nodular lesion was not identified.

(b) (6)

24-08898_000612

Animal ID: 26352 **Case #:** TB23-01495 **Sample:** LN **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.87466431

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 26352 **Case #:** TB23-01496 **Sample:** Spleen **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 26352 **Case #:** TB23-01497 **Sample:** Liver **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 26352 Case #: TB23-01498 Sample: Lung Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.76572227

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all other isolates in the NVSL Database. The isolate has the same SNP as the most recent common ancestor to the isolates on this report and has acquired 2 SNPs from sharing the common ancestor to this outbreak. See the attached Genotyping Report.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 2

Date: March 13th 2023

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis*/ (b) (4) origin ** Quarantine Samples **

- | 3. Item Name | Quantity | Date sample Derived | Packing |
|--------------|----------------------------|---------------------|---------|
| (b) (4) | LN, spleen, liver and lung | 2/27/23 | Dry Ice |
| | LN, spleen, liver and lung | 2/27/23 | Dry Ice |

4. Date Shipped: Ship on (b) (4)

5. FedEx Tracking# (b) (6)

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

SEE CONDITIONS OF SALE/WARRANTY

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Please consider the environment before printing this email note.

(b) (5) Necropsy - (b) (4)

From Date

02/27/2023 13:44:21

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)



Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
02/27/2023 13:43:46	Date Out	02/27/2023 13:43:46
02/27/2023 13:51:28	Died during quarantine	Yes
02/27/2023 13:43:46	Euthanasia Method	IV Phenytoin/Pentobarbital
02/27/2023 13:43:46	Euthanasia Reason	Other
01/17/2023	In-Shipment #	(b) (4)
02/27/2023 13:43:46	Location at Stock Out - Path	

Clinical History

Animal had TB test administered on 2/22/23 on the right eye. At 72 hours, the animal was noted to have a grade 3/5 TB reaction, which was confirmed by the veterinarian. Therefore, humane euthanasia was elected and a complete necropsy according to the Death In Quarantine algorithm was performed.

Tentative Diagnosis

Gross Description

The carcass of a (b) (4) in good body condition (BCS 2.5/5; Wt: 1.9kg) was examined. There was mild bruising and edema of the right eyelid present. All other findings were unremarkable. No gross findings consistent with tuberculosis.

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin



Abnormal Skin Description

mild bruising and edema of the right eyelid

Oral



Abnormal Oral Cavity Description

(b) (4) - Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4) Necropsy (b) (4)

Microbiology

Pending

Other Diagnostic Test

Histopathology

Pending

Final Diagnosis

Event Comment

Document(s)



Pathology Report

LTM Order #: (b) (4)

28 February 2023

History:

Customer: Charles River Frederick - Quarantine
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Animal had 4/5 reaction to TB test 24, 48, and 72 hours and was euthanized. Necropsy was performed by submitter with no significant findings.

Microscopic Diagnoses:

#1 (ID (b) (4)) Lymph node (tracheobronchial) and associated connective tissue: Abscess, moderate, multifocal.

Acid fast Stain (TBLN): A rare acid-fast bacillus was noted in the necrotic debris of the TBLN lesion.

Gram Stain (TBLN): Negative for bacteria.

Spleen, Lymph nodes (mesenteric), Lung, Heart, Liver, Kidney, Urinary bladder, Pancreas,

Small intestine, Stomach, Large intestine: Within normal limits.

Comment:

The microscopic lesions in the tracheobronchial lymph node and associated connective tissue were consistent with Mycobacteriosis. Acid fast stains revealed a single bacillus. No other significance lesions were noted.

(g) (q)

(b) (4) - Necropsy - (b) (4)

From Date

02/13/2023 11:11:47

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
02/13/2023 11:07:18	Date Out	02/13/2023 11:07:18
02/14/2023 07:38:16	Died during quarantine	Yes
02/13/2023 11:07:18	Euthanasia Method	IV Phenytoin/Pentobarbital
02/13/2023 11:07:18	Euthanasia Reason	Other
01/17/2023	In-Shipment #	(b) (4)
02/13/2023 11:07:18	Location at Stock Out - Path	

Clinical History

Animal had TB test administered on 02/09/2023 on the left eye. At 24, 48 and 72 hours, the animal was noted to have a grade 4/5 TB reaction, which was confirmed by the veterinarian. Humane euthanasia was elected and a complete necropsy according to the Death in Quarantine algorithm was performed.

Tentative Diagnosis

Gross Description

The carcass of a (b) (4) in good body condition (BCS 2.5/5; Wt : 2.1kg) was examined. There was mild erythema and edema of the left eyelid present. The tracheobronchial lymph nodes were diffusely enlarged with purulent material on cut surface. There was a nodule palpated in the lung tissue; upon dissection it appeared to be an enlarged lymph node with no purulent material on cut surface.

Gross Findings: Check box by tissue examined. Describe if abnormal.

(b) (4) - Necropsy - (b) (4)

Skin



Abnormal Skin Description

Left upper eyelid moderately erythematous and edematous with scant scabbing along lid margin laterally

Oral



Abnormal Oral Cavity Description

Lymph Nodes



Abnormal Lymph Nodes Description

Enlarged tracheobronchial lymph nodes with purulent debris on cut surface

Respiratory System



Abnormal Respiratory System Description

1cm nodule in lung, lymph node consistency, no material on cut surface

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



(b) (4) - Necropsy - (b) (4)

Skeletal Muscle

Bone Marrow

Brain



Skin



Skin - Description



Other

Other - Description

Mesenteric LN



Microbiology

Other Diagnostic Test

Histopathology

Final Diagnosis

Event Comment

Document(s)



Animal ID: 20942 **Case #:** TB23-02392 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 20942 **Case #:** TB23-02393 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.10472107

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 13325 **Case #:** TB23-02394 **Sample:** 5 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.98841476

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 13325 **Case #:** TB23-02395 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 33.80635452

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all other isolates in the NVSL Database. The isolate has acquired a single SNP from the most recent common ancestor. See the attached Genotyping Report.

Animal ID: 13325 **Case #:** TB23-02396 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 13325 **Case #:** TB23-02397 **Sample:** 8 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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APPENDIX – GENOTYPING REPORT

15 August 2023

Accession:

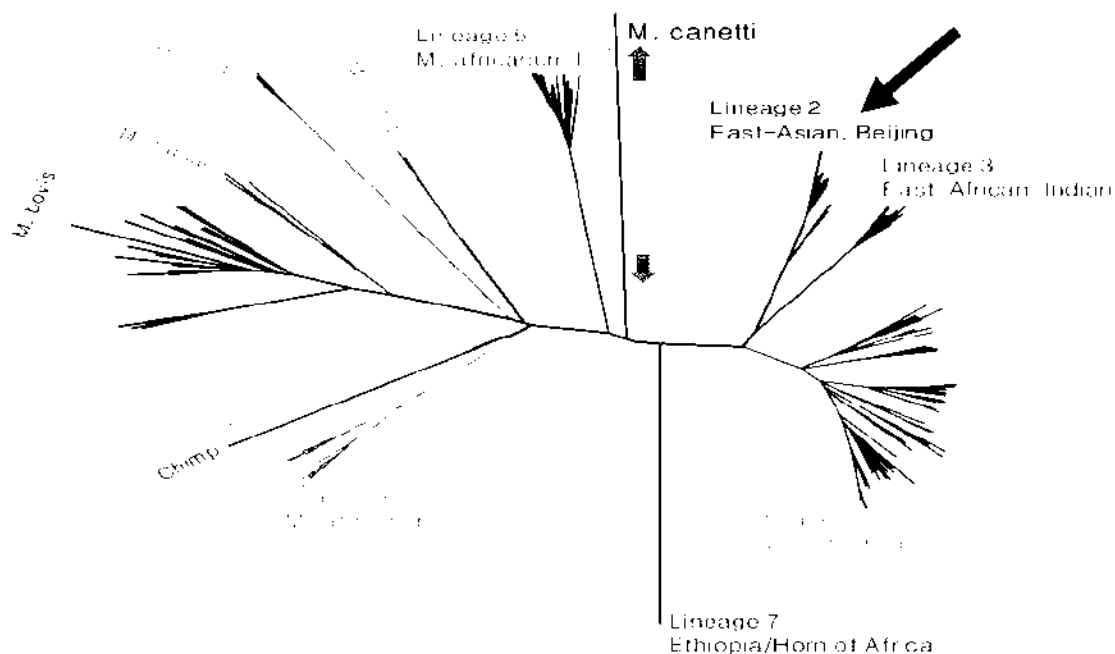
23-005146

23-008085

23-006500

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium tuberculosis* lineage 2. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



APPENDIX – GENOTYPING REPORT

15 August 2023

Accession:

23-005146

23-008085

23-006500

Figure 2. Abbreviated Tree of *M. tuberculosis* lineage 2. The isolates from these accessions are shown in red. Isolates indicated by the bracket share the same SNP pattern and have acquired a single SNP from sharing the most recent common ancestor (red arrow) with 23-1498 & 22-7400. All isolates indicated below are from the same outbreak.

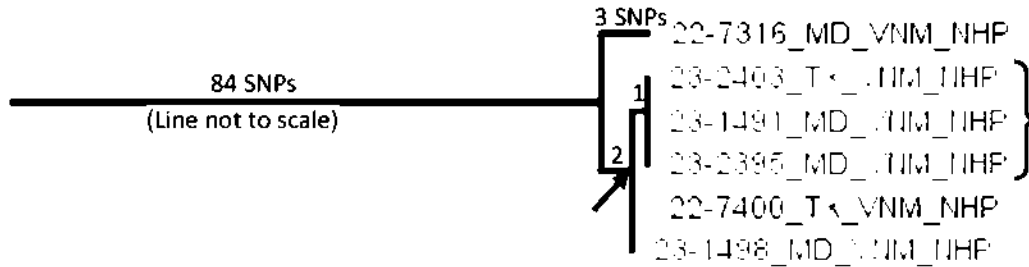


Table 1: Abbreviated SNP table of isolates from this outbreak. Three isolates (23-2403, 23-1491, 23-2395) have acquired a single SNP (arrow) from sharing the most recent common ancestor (blue bracket) with two other isolates. The isolates in this outbreak (shown below) have acquired 84 SNPs (bracket only partially shown) from the nearest common ancestor in the NVSL database.

root	NC_000962.3:3978820	NC_000962.3:4001269	NC_000962.3:4002861	NC_000962.3:4136888	NC_000962.3:4153283	NC_000962.3:4156287	NC_000962.3:4158458	NC_000962.3:4186690	NC_000962.3:4195450	NC_000962.3:4231160	NC_000962.3:4252749	NC_000962.3:4305747	NC_000962.3:4328194	NC_000962.3:4350042	NC_000962.3:4350043	NC_000962.3:4371246	NC_000962.3:2323585	NC_000962.3:2954634	NC_000962.3:3786116	NC_000962.3:1688413	NC_000962.3:2038752	NC_000962.3:33807547
22-7316_MD_VNM_NHP		A	A	A	A	A	A	A	A	A				G	G		G					
22-7400_TX_VNM_NHP		A	A	A	A	A	A	A	A	A				G	G		G	A	C	G		
23-1498_MD_VNM_NHP		A	A	A	A	A	A	A	A	A				G	G		G	A	C	G		
23-2403_TX_VNM_NHP		A	A	A	A	A	A	A	A	A				G	G		G	A	C	G		
23-1491_MD_VNM_NHP		A	A	A	A	A	A	A	A	A				G	G		G	A	C	G		
23-2395_MD_VNM_NHP		A	A	A	A	A	A	A	A	A				G	G		G	A	C	G		
MQ	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60
annotation	GGG->GGT, PPLT3:V3:G25:4:G	GGG->TGT, PPLT3:V3:G28:4:G	GAC->AAC, PPLT3:V3:G40:4:G	CGC->CAC, unlisted gene:	G-C->AIC, ask:53:61, asp	CGC->CAC, dhaC:V183H,	position not annotated	TTG>TTA, unlisted gene:	GGG->GAG, nmtr:G4L, H	CGC->CAC, unlisted gene:	IAC->TAA, fadL35:Y555	position not annotated	CGC->TGC, ethR:R216C, H	CTC->TTC, eccC11:406F,	CTC->CTC, eccC11:1406R,	CAT->CTA, eccD2:V3:G41:Q	ACG->ACC, eobH:1137L, L	CGA->CGC, unlisted gene:	GTC->GIG, unlisted gene:	GAA->GGA, lplL158G, ecc	position not annotated	CGA->AGA, acfA1:R643R,

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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AMENDED REPORT

Laboratory Test Report**Owner**

Charles River Laboratories

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:**23-008085****NFC Control Number:**

19823020892

Date Collected:

02/27/2023

Date Received:

03/14/2023

Date Completed:

08/16/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 20942 Case #: TB23-02390 Sample: 1 Specimen Type: Lymph Node Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 20942 Case #: TB23-02391 Sample: 2 Specimen Type: Spleen Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 20942 **Case #:** TB23-02392 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 20942 **Case #:** TB23-02393 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.10472107

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 13325 **Case #:** TB23-02394 **Sample:** 5 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.98841476

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 13325 **Case #:** TB23-02395 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 33.80635452

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all other isolates in the NVSL Database. The isolate has acquired a single SNP from the most recent common ancestor. See the attached Genotyping Report.

Exhibit 3

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE

1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

Charles River Laboratories - Frederick

EMAIL ADDRESS

OWNER CITY

STATE/COUNTRY

(b) (6) srl.com

Frederick

MD/USA

PHONE NUMBER

FAX NUMBER

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

PREMISES ID

(b) (6)
Frederick, MD 21701

COUNTY

STATE/COUNTRY

Frederick

MD/USA

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

7. NUMBER IN HERD/FLOCK AFFECTED

Mycobacterium Culture
Mycobacterium PCR
Mycobacterium Identification
Rule in/out TB

8. NUMBER IN HERD/FLOCK DEAD

10. COLLECTED BY

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL In-lab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

11. DATE COLLECTED

12/11/2023

12. AUTHORIZED BY

14. COUNTRY OF ORIGIN

15. REFERRAL NUMBER

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

20. NUMBER OF ANIMALS SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary)

SAMPLE NOT VERIFIED

23. (b) (6)

24 - 000204
MB

CONDITION

PRIORITY

USE ONLY

RECEIVED

01/03/2024

502163

VS FORM 10-4
AUG 2009

24-08898_001019

Date: January 2nd 2024

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis*/ (b) (4) origin ** Quarantine Samples **

Item Name	Quantity	Date sample Derived	Packing
(b) (7)(F)	LN, spleen, liver and lung	12/11/23	Dry Ice
	LN, spleen, liver and lung	12/11/23	Dry Ice
	LN, spleen, liver and lung	12/11/23	Dry Ice

4. Date Shipped: Ship on 1/2/2024 for delivery on morning of 1/3/2024

5. FedEx Tracking# (b) (6)

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

Signature of Supervisor

SEE CONDITIONS OF SALE/WARRANTY

Bravo-Garcia, Doris - MRP-APHIS

From: (b) (6) <(b) (6)@crl.com>
Sent: Friday, December 29, 2023 7:34 AM
To: APHIS-NVSL Case Coordinator - APHIS; Bravo-Garcia, Doris - MRP-APHIS; Lehman, Kimberly - MRP-APHIS; MRP-APHIS-MB-CaseManagement
Cc: (b) (6) (b) (6) (b) (6)
Subject: [External Email] Permission to ship NHP samples
Attachments: (b) (4)

[External Email]

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Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send (b) (4) HP tissue samples for Mycobacterium testing on Tuesday, 1/2/24 for arrival on Wednesday, 1/3/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send packing forms and AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4))

What was the date that they left the originating country? 10/21/23

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – see attached report

Cause of Death? Euthanized due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Thank you,

(b) (6) (b) (6) DVM

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

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Frederick | Charles River
Frederick, MD 21701

(b) (6) iver.com

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Bravo-Garcia, Doris - MRP-APHIS

From: (b) (6) <(b) (6)@crl.com>
Sent: Friday, December 29, 2023 9:21 AM
To: Thacker, Tyler - MRP-APHIS; APHIS-NVSL Case Coordinator - APHIS; Bravo-Garcia, Doris - MRP-APHIS; Lehman, Kimberly - MRP-APHIS; MRP-APHIS-MB-CaseManagement
Cc: (b) (6) (b) (6) (b) (6)
Subject: RE: [External Email]Permission to ship NHP samples
Attachments: (b) (4)

Thank you, Tyler.

We receive (b) (4) histopathology report. We would like to submit an additional sample on Tuesday, 1/2/24 for a (b) (6). Please see attached histopathology and filovirus report.
Happy New Year!
(b) (6)

From: Thacker, Tyler - MRP-APHIS <tyler.thacker@usda.gov>
Sent: Friday, December 29, 2023 9:07 AM
To: Del Castillo-Pratts, Dania <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) (b) (6)@crl.com>; (b) (6) (b) (6)@crl.com>; (b) (6) (b) (6)@crl.com>
(b) (6)@crl.com>
[External Email]Permission to ship NHP samples

WARNING: This message was sent by an external party. Report suspicious messages via the "Report Phishing" button in Outlook.

Please go ahead and ship these animals. Please send the tracking number as you usually do.
Tyler

From: (b) (6) <(b) (6)@crl.com>
Sent: Friday, December 29, 2023 7:34 AM
To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6)@crl.com>; (b) (6)@crl.com>; (b) (6)@crl.com>
Subject: [External Email]Permission to ship NHP samples

[External Email]

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Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send [redacted] NHP tissue samples for Mycobacterium testing on Tuesday, 1/2/24 for arrival on Wednesday, 1/3/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send packing forms and AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)
What was the date that they left the originating country? 10/21/23
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Was animals exposed to animals from other sources? No
Was a complete necropsy and with histology done on this animal? Yes
If so, can you provide those results? – see attached report
Cause of Death? Euthanized due to TB suspect
Was the animal showing any abnormal symptoms prior to death? No

Thank you,

(b) (6)
(b) (6)
(b) (6)
(b) (6)
(b) (6)
(b) (6)
(b) (6)
(b) (6)
(b) (6)
Frederick | Charles River
Frederick, MD 21701
(b) (6)
crl.com | www.criver.com
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Pathology Report

LTM Order #: (b) (4)

27 December 2023

History:

Customer: Charles River Frederick - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

The animal was euthanized after a Grade 3/5 TB reaction at 72 hours. Necropsy was performed by the submitter and found 0.5 cm nodule on left liver lobe and splenomegaly.

Microscopic Diagnoses:

#1: Liver: Inflammatory nodule around a central parasite-like structure. Inflammation is eosinophilic centrally with macrophages peripherally.

Spleen: Lymphoid hyperplasia, moderate, multifocal.

Brown pigment, intracellular, histiocytic, moderate, multifocal.

Lung, Lymph nodes (tracheobronchial), Heart, Urinary bladder, Kidney, Lymph nodes (mesenteric), Adrenal gland, Stomach, Small intestine, Large intestine: Within normal limits.

Acid-fast stain (lung, TBLN, Liver): Negative for acid-fast bacteria.

Comment:

The grossly observed focal liver nodule correlated microscopically to an inflammatory nodule around what is likely to be a parasitic cyst. There was little other structure to be more specific about the parasite. Splenomegaly correlated to lymphoid hyperplasia. The spleen also had abundant dark brown pigment of uncertain origin. There were no microscopic lesions to suggest infection with Mycobacteriosis. Acid fast stains of lung, TBLN, and liver were negative. The microscopic lesions were considered incidental.

(b) (4)

Pathology Report

LTM Order # (b) (4)

27 December 2023

History:

Customer: Charles River Frederick - Quarantine
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

The animal was euthanized after a grade 3/5 TB reaction at 72 hours. Necropsy was performed by the submitter and found no significant lesions.

Microscopic Diagnoses:

#1 (b) (4): Lung, Liver, Spleen, Lymph node (tracheobronchial), Heart, Urinary bladder, Kidney, Lymph nodes (mesenteric), Stomach, Small intestine, Large intestine: Within normal limits.

Acid-fast stain (lung, TBLN): Negative for acid-fast bacteria.

Comment:

There were no significant microscopic lesions in the examined tissues. There were no microscopic changes to suggest Mycobacteriosis.

(b) (6)

Pathology Report

LTM Order # (b) (4)

29 December 2023

History:

Customer: Charles River Frederick - Quarantine
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

This animal was euthanized after a grade 5/5 TB reaction at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes with caseous exudate and mild splenomegaly.

Microscopic Diagnoses:

#1 (b) (4) Lung: Abscess, moderate, focal with associated pleural/subpleural edema, marked, focally extensive.

Acid-fast Stain (lung): Few acid-fast positive bacilli noted in the pulmonary abscess lesion.

Lymph node (tracheobronchial): Abscess, mild with moderate peripheral lymphocytosis.

Acid-fast Stain (TBLN): No acid-fast organisms were noted.

Spleen: Lymphoid hyperplasia, mild, multifocal.

Small intestine: Lymphocytes, mucosal, mild, diffuse.

Liver, Heart, Lymph nodes (mesenteric), Kidney, Urinary bladder, Stomach, Large intestine:
Within normal limits.

Comment:

History, gross and microscopic pulmonary and TBLN lesions, and the presence of acid-fast bacteria support a diagnosis of Mycobacteriosis in this animal.

(b) (6)

Frederick

Animal ID: 2008158 **Case #:** TB24-00246 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 2008158 **Case #:** TB24-00247 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 2006081 **Case #:** TB24-00248 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 30.40438461

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.**Animal ID:** 2006081 **Case #:** TB24-00249 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Frederick

Animal ID: 2006081 **Case #:** TB24-00250 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.3601532

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2006081 **Case #:** TB24-00251 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate**Mycobacterium orygis****Direct PCR** for M. tuberculosis complex - IS1081

Detected Ct = 34.20948029

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895190811	
Trans_mode	AIR	

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895438020	
Trans_mode	AIR	

Exhibit 4

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for this information collection are 0579-0040, 0579-0050, 0579-0101, 0579-0146, and 0579-0189. The time required to complete this information collection is estimated to average 25 hours to 1 hour per response including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0040, 0050, 0101,
0146, and 0189

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE
1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

(b) (6) (b) (6)

EMAIL ADDRESS

(b) (6) cml.com

PHONE NUMBER

(b) (6)

FAX NUMBER

(b) (6)

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6)
Frederick, MD 21701

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

Charles River Laboratories - Frederick

OWNER CITY

Frederick

STATE/COUNTRY

MD/USA

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Frederick

STATE/COUNTRY

MD/USA

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

Mycobacterium Culture
Mycobacterium PCR
Mycobacterium Identification
Rule in/out TB

7. NUMBER IN HERD/FLOCK AFFECTED

8. NUMBER IN HERD/FLOCK DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

01/22/2024

12. AUTHORIZED BY

13. PURPOSE OF SUBMISSION (See instructions for definitions)

- ☐ Interstate Movement ☐ Import ☒ TB ☐ Reagent Evaluation
☐ Export ☐ FAD/EP Diagnostic ☐ General Diagnostic ☐ NVSL Intra-lab
☐ Pre-import ☐ Surveillance ☐ Developmental Research

14. COUNTRY
(b) (6) (b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

- ☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

- ☐ Blood ☐ Feces ☐ Parasite ☐ Serum ☒ Tissue (Specify) ☐ Whole Animal ☐ Other (Specify)
☐ Culture ☐ Feed ☐ Plant ☐ Soil ☐ Urine ☐ Fetus
☐ Extract ☐ Milk ☐ Semen ☐ Swab (Specify) ☐ Water ☐ DNA/RNA

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

- ☐ Cattle ☐ Goat ☐ Chicken ☐ Bison ☐ Fish ☒ Other (Specify)
☐ Swine ☐ Horse ☐ Turkey ☐ Deer (Specify) ☐ Environment
☐ Sheep ☐ Donkey ☐ Other bird (Specify) ☐ Elk ☐ Reagent

20. NUMBER OF ANIMALS SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
	(b) (4)								

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary)

SAMPLE NOT VERIFIED

23. SIGNATURE

(b) (6)

24 - 003073
MB

CONDITION ☒ PRIORITY 3 NVSL USE ONLY DISTRIBUTION RECEIVED (b) (6) (b) (6) (b) (6)

01/30/2024
30321

VS FORM 10-4
AUG 2009

24-08898_001043

Date: January 29th 2024

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis* (b)(4) ↑ ** Quarantine Samples **

- | 3. Item Name | Quantity | Date sample Derived | Packing |
|--------------|----------------------------|---------------------|---------|
| (b) (4) | LN, spleen, liver and lung | 1/22/24 | Dry Ice |

4. Date Shipped: Ship on 1/29/2024 for delivery on morning of 1/30/2024

5. FedEx Tracking#

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

Signature of Supervisor

SEE CONDITIONS OF SALE/WARRANTY

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order #: (b) (4)

26 January 2024

History:

Customer: Charles River Frederick - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Fixed tissues submitted from an animal had a 4/5 reaction at 72 hours to TB test. The animal was euthanized and necropsy was performed by the submitter. Significant changes included a caseous nodule on the lung.

Microscopic Diagnoses:

#1 (b) (4) Lung, Lymph node (tracheobronchial): Granuloma, early formation, mild, multifocal.

Acid Fast Stain (lung, TBLN): Acid fast organism noted associated with lung lesion.

Heart, Liver, Spleen, Kidney, Urinary bladder, Lymph node (mesenteric), Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

Although only a single acid-fast organism was noted, the history, gross, and microscopic lesions were suggestive of Mycobacteria. Organisms are generally few (or none) with tuberculosis. No other significant lesions were noted.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report**Owner**

Charles River Laboratories

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:**24-003073****NFC Control Number:**

19824015881

Date Collected:

01/22/2024

Date Received:

01/30/2024

Date Completed:**Collected By:**

[REDACTED]

Purpose:

TB-10-4

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 29067 **Case #:** TB24-01341 **Sample:** 1 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.4547348

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 29067 **Case #:** TB24-01342 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.08194733

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 29067 **Case #:** TB24-01343 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 29067 **Case #:** TB24-01344 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 26.2626915

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 5

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE
1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

(b) (6)

Charles River Laboratories - Frederick

EMAIL ADDRESS

OWNER CITY

STATE/COUNTRY

(b) (6) @crl.com

Frederick

MD/USA

PHONE NUMBER

FAX NUMBER

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

PREMISES ID

(b) (6)

COUNTY

STATE/COUNTRY

Frederick, MD 21701

Frederick

MD/USA

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

7. NUMBER IN HERD/FLOCK AFFECTED

Mycobacterium Culture
Mycobacterium PCR
Mycobacterium Identification
Rule in/out TB

8. NUMBER IN HERD/FLOCK DEAD

Expiration Date:

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

03/18/2024

12. AUTHORIZED BY

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

(b) (4)

SAMPLED

2 (Cynomolgus)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary)

23. SIGNATURE

(b) (6)

NVSL USE ONLY

24 - 009789

MB

04/03/2024

502163



CONDITION

DI

PRIORITY

3

NVSL USE ONLY

DISTRIBUTION

(b) (6)

RECEIVED

(b) (6)

VS FORM 10-4
AUG 2009

24-08898_001188

Date: April 2, 2024

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis* (b) (4) origin ** Quarantine Samples **

- | 3. Item Name | Quantity | Date sample Derived | Packing |
|--------------|----------------------------|---------------------|---------|
| (b) (4) | LN, spleen, liver and lung | 3/18/24 | Dry Ice |
| | LN, spleen, liver and lung | 3/18/24 | Dry Ice |

4. Date Shipped: Ship on 4/2/2024 for delivery on morning of 4/3/2024

5. FedEx Tracking#

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

Signature of Supervisor

SEE CONDITIONS OF SALE/WARRANTY

Mobile (b) (6)

From: (b) (6) <(b) (6)@crl.com>

Sent: Monday, April 1, 2024 2:10 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: [External Email]Permission to ship NHP samples

Some people who received this message don't often get email from (b) (6)@crl.com. [Learn why this is important](#)

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send ^{MRP} NHP tissue samples for Mycobacterium testing on tomorrow, 4/2/24 for arrival on Wednesday, 4/3/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? 10/21/23

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – Please see attached histopathology report

Cause of Death? Euthanized due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Thank you,

(b) (6) (b) (6) DVM

Director of North America Quarantine Veterinary Services

(b) (6)

(b) (6)

Frederick | Charles River

(b) (6)

Frederick, MD 21701

P: (b) (6)

F: (b) (6)

(b) (6)

[crl.com](mailto:(b) (6)@crl.com) | www.criver.com

24-08898_001190



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report

Owner

Charles River Laboratories - Frederick

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:

24-009789

NFC Control Number:

19824023204

Date Collected:

03/18/2024

Date Received:

04/03/2024

Date Completed:

Collected By:

[REDACTED]
General Diagnostic

Purpose:

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1909052 **Case #:** TB24-04222 **Sample:** 1 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 37.26548004

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Frederick

Animal ID: 1909052 **Case #:** TB24-04223 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.67060471

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1909052 **Case #:** TB24-04224 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1909052 **Case #:** TB24-04225 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.40238953

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2104157 **Case #:** TB24-04226 **Sample:** 5 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895190811	
Trans_mode	AIR	

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895438020	
Trans_mode	AIR	

Exhibit 6

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE

1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

(b) (6)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com

OWNER CITY

Frederick

STATE/COUNTRY

MD/USA

PHONE NUMBER

(b) (6)

FAX NUMBER

(b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

(b) (6)

Frederick, MD 21701

COUNTY

Frederick

STATE/COUNTRY

MD/USA

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

Mycobacterium Culture

Mycobacterium PCR

Mycobacterium Identification

Rule in/out TB

10. COLLECTED BY

(b) (6)

7. NUMBER IN HERD/FLOCK AFFECTED

11. DATE COLLECTED

05/08/2024

8. NUMBER IN HERD/FLOCK DEAD

12. AUTHORIZED BY

14. COUNTRY OF ORIGIN

(b) (4)

15. REFERRAL NUMBER

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

20. NUMBER OF ANIMALS SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary).

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE

NVSL USE ONLY

24 - 018314
MB

NVSL USE ONLY

CONDITION

03

PRIORITY

3

DISTRIBUTION

(b) (6)

RECEIVED BY

(b) (6)

VS FORM 10-4
AUG 2009

502183
08/26/2024



24-08898_001280

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Initial Pathology Report

LTM Order #: (b) (4)

12 June 2024

History:

Customer: Charles River Frederick - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Animal had a 5-month history of weight loss and bouts of anorexia for 3 weeks that responded to supportive care. Just before euthanasia (due to poor condition and prognosis), she was found with severe mucoid discharge from left nostril. One month ago, she had some periocular swelling following TB test, that resolved by the final read. Necropsy was performed by the submitter and found nodular granulomatous lung changes and tracheobronchial lymph nodes mildly enlarged with caseous center. Mesenteric lymph node was mildly enlarged and caseous. Kidneys had multifocal, white, millimeter sized foci through. Spleen was small.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, moderate, multifocal.

Acid Fast Stain (lung): Negative for acid-fast organisms.

Tracheobronchial lymph node (TBLN): Granuloma, moderate, multifocal.

Acid Fast Stain (TBLN): Positive for intralesional acid-fast bacilli.

Kidney: Granuloma, mild, multifocal.

Acid Fast Stain (kidney): PDG.

Mass lesion (unidentified tissue, possibly MLN): Granuloma, moderate, multifocal, and coalescing with central mineralization.

24-08898_001281

Acid Fast Stain (mass): PDG.

Small intestine: Granuloma, murals, moderate, multifocal.

Mononuclear infiltrates, mucosal, mild, multifocal with mucosal and submucosal edema, blunting and fusing of villi.

Large intestine: Lymphocytic infiltrates, mucosal, mild, multifocal.

Urinary bladder: Lymphocytic infiltrate, mucosa, minimal.

Liver: Inflammation, parenchymal, mononuclear, minimal, multifocal.

Stomach: Yeast, luminal, mild, diffuse (consistent with Candida).

Spleen, Heart : Within normal limits.

Comment:

The gross and microscopic lesions of the lung and TBLN were consistent with Mycobacteria, supported by finding acid-fast bacilli in the TBLN lesion. These findings are consistent with a diagnosis of Mycobacteriosis. Interestingly in this case, several other major organs appear to have similar granuloma lesions. Additional acid-fast stains will be performed and the report will be updated, just to document additional presence of bacteria. Additional staining will not change the initial impression of Mycobacteriosis in this animal.

(b) (6)

From: (b) (6)
To: Bravo-Garcia, Doris - MRP-APHIS; Lehman, Kimberly - MRP-APHIS; MRP-APHIS-MB-CaseManagement
Cc: (b) (6) (b) (6) (b) (6)
Subject: [External Email] Request Permission to ship NHP samples
Date: 70 AM
Attachments: (b) (4)

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;
Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send NHP tissue samples for Mycobacterium testing on today, 6/20/24 for arrival on Thursday, 6/21/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? 10/21/23

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – Please see attached histopathology report

Cause of Death?

- (b) (4) – failure to thrive and respiratory signs.
- Euthanized due to TB suspect

Was the animal showing any abnormal symptoms prior to death? (b) (4) weight loss, respiratory signs and bouts of anorexia

Thank you,

(b) (6) (b) (6) DVM
(b) (6)
(b) (6)
(b) (6) Frederick | Charles River
(b) (6) Frederick, MD 21701
P: (b) (6) | F: (b) (6)
(b) (6) crl.com | www.criver.com
[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Confidentiality Notice: The information contained in this email and any attachments are confidential and may contain privileged and/or proprietary information. This email is intended for the use of the addressee only. If you are not the intended recipient, you are strictly prohibited from copying, distributing or using this email or the information contained in it. If you received this email in error, please notify the sender immediately by email or telephone, and destroy any copies, electronic, paper or otherwise.

24-08898_001287



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report

Owner

Charles River Laboratories

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:

24-018314

NFC Control Number:

19824033266

Date Collected:

05/08/2024

Date Received:

06/25/2024

Date Completed:

Collected By:

[REDACTED]
General Diagnostic

Purpose:

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2007090 **Case #:** TB24-07706 **Sample:** 1 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.07153511

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2007090 **Case #:** TB24-07707 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 26.20966339

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2007090 **Case #:** TB24-07708 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 29.89596748

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2007090 **Case #:** TB24-07709 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 23.80890846

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895190811	
Trans_mode	AIR	

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895438020	
Trans_mode	AIR	

Exhibit 7

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for this information collection are 0579-0040, 0579-0090, 0579-0101, 0579-0146, and 0579-0189. The time required to complete this information collection is estimated to average 25 hours to 1 hour per response including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0040, 0090, 0101,
0146, and 0189

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE

1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

(b) (6) (b) (6)

Charles River Laboratories

E-MAIL ADDRESS

(b) (6) crl.com

OWNER CITY

Frederick

STATE/COUNTRY

MD/USA

PHONE NUMBER

(b) (6)

FAX NUMBER

(b) (4)

4. LOCATION OF ANIMALS

PREMISES ID

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6)
Frederick, MD 21701

COUNTY

Frederick

STATE/COUNTRY

MD/USA

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

7. NUMBER IN HERD/FLOCK AFFECTED

Mycobacterium Culture
Mycobacterium PCR
Mycobacterium Identification
Rule in/out TB

10. COLLECTED BY

(b) (6)

8. NUMBER IN HERD/FLOCK DEAD

11. DATE COLLECTED

06/10/2024

12. AUTHORIZED BY

14. COUNTRY OF ORIGIN

(b) (4)

15. REFERRAL NUMBER

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary)

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE

NVSL USE ONLY

CONDITION

D1

PRIORITY

3

NVSL USE ONLY

DISTRIB

(b) (6)

CEIVED BY

(b) (6)

24 - 018315
MB

VS FORM 10-4
AUG 2009

502163
06/26/2024



24-08898_001288

Pathology Report

LTM Order #: (b) (4)

22 June 2024

History:

Customer: Charles River Frederick - Quarantine
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

This animal had a 3/5 TB reaction at 24, 48, and 72 hours and was euthanized. Necropsy conducted by the submitter found nodule on the lung with caseous material.

Microscopic Diagnoses:

#1 (b) (4): Lung: Granuloma, moderate, focal.

Tracheobronchial lymph nodes (TBLN): Granuloma, mild, multifocal.

Acid Fast Stain (lung, TBLN): Positive for intralésional acid-fast bacilli.

Liver, Spleen, Heart, Lymph node (mesenteric), Kidney, Urinary bladder, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions and presence of acid-fast bacilli is consistent with the diagnosis of Mycobacteriosis in this animal.

(b) (6)

Pathology Report

LTM Order #: (b) (4)

22 June 2024

History:

Customer: Charles River Frederick - Quarantine
Strain: Not-Specified
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

This animal had a 4/5 TB reaction and was euthanized. Necropsy was conducted by the submitter and found a lung nodule and caseous material in the tracheobronchial lymph node (TBLN). Omentum was adhered to intestines.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, moderate, focal.

Acid Fast Stain (lung): Positive for acid-fast bacilli.

Tracheobronchial Lymph node (TBLN): Granuloma, marked, multifocal to coalescing.

Lymphoid hyperplasia, moderate.

Acid Fast Stain (TBLN): Negative for acid-fast bacilli.

Stomach: Gastritis, lymphocytic, mild, multifocal.

Liver, Spleen, Heart, Lymph node (mesenteric), Kidney, Urinary bladder, Pancreas, Small intestine, Large intestine: Within normal limits.

Comment:

The nature of the lung and TBLN lesions were consistent with Mycobacteriosis in this animals. Finding of acid-fast bacilli in the lung supports the diagnosis. The gastric change was considered incidental.

(b) (6)

From: (b) (6)
To: [Lehman, Kimberly - MRP-APHIS](#); [Bravo-Garcia, Doris - MRP-APHIS](#); [MRP-APHIS-MB-CaseManagement](#)
Cc: (b) (6) (b) (6) (b) (6)
Subject: RE: [External Email]Request Permission to ship NHP samples
Date: Monday, June 24, 2024 7:52:22 AM
Attachments: [image001.png](#)

(b) (4)

Hi Kim,

We also plan to send today tissue samples from (b) (6) additional NHP for Mycobacterium testing for arrival on Tuesday, 6/25/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? 10/21/23

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – Please see attached histopathology report

Cause of Death? – TB Suspect

Was the animal showing any abnormal symptoms prior to death? No

From: (b) (6) <Claire.Porter@crl.com>
Sent: Thursday, June 20, 2024 1:39 PM
To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; (b) (6) <(b) (6)@crl.com>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) (b) (6) @crl.com>; (b) (6) (b) (6) @crl.com>
Subject: RE: [External Email]Request Permission to ship NHP samples

Good afternoon Kim,

Yes, we will hold these samples to ship on Monday 6/24 for Tuesday 6/25 arrival. We will provide a tracking number on Monday 6/24.

Thank you,

(b) (6) (b) (6) (b) (6)

24-08898_001299

MB.caseManager@usda.gov>

Cc: (b) (6) (b) (6) @crl.com>; (b) (6) (b) (6) @crl.com>; (b) (6) (b) (6) @crl.com>

Subject: [External Email]Request Permission to ship NHP samples

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send NHP tissue samples for Mycobacterium testing on today, 6/20/24 for arrival on Thursday, 6/21/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? 10/21/23

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – Please see attached histopathology report

Cause of Death?

- (b) (4) failure to thrive and respiratory signs.
- (b) (4) Euthanized due to TB suspect

Was the animal showing any abnormal symptoms prior to death? (b) (4) – weight loss, respiratory signs and bouts of anorexia

Thank you,

(b) (6) (b) (6) DVM
Director of North America Quarantine Veterinary Services

(b) (6)
(b) (6) Frederick | Charles River
(b) (6) Frederick, MD 21701

P: (b) (6) | F: (b) (6)
(b) (6) crl.com | www.criver.com
[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

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24-08898_001300



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report

Owner

Charles River Laboratories

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:

24-018315

NFC Control Number:

19824033267

Date Collected:

06/10/2024

Date Received:

06/25/2024

Date Completed:

Collected By:

[REDACTED]
General Diagnostic

Purpose:

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1907065 **Case #:** TB24-07710 **Sample:** 1 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1907065 **Case #:** TB24-07711 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1907065 **Case #:** TB24-07712 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1907065 **Case #:** TB24-07713 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 30.93237686

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Animal ID: 2109271 **Case #:** TB24-07714 **Sample:** 5 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 22.56388474

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Animal ID: 2109271 **Case #:** TB24-07715 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.87171936

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2109271 **Case #:** TB24-07716 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2109271 **Case #:** TB24-07717 **Sample:** 8 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 30.93165207

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895190811	
Trans_mode	AIR	

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895438020	
Trans_mode	AIR	

Exhibit 8

Date: July 10, 2024

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis* (b) (4) origin ** Quarantine Samples **

3. Item Name	Quantity	Date sample Derived	Packing
(b) (4)	LN, spleen, liver and lung	6/11/24	Dry Ice
(b) (4)	LN, spleen, liver and lung	6/11/24	Dry Ice
(b) (4)	LN, spleen, liver and lung	6/24/24	Dry Ice

4. Date Shipped: Ship on 7/10/2024 for delivery on morning of 7/11/2024

5. FedEx Tracking#

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

Signature of Supervisor

SEE CONDITIONS OF SALE/WARRANTY

From: (b) (6)
To: Bravo-Garcia, Doris - MRP-APHIS; Lehman, Kimberly - MRP-APHIS; MRP-APHIS-MB-CaseManagement
Cc: (b) (6) (b) (6) (b) (6)
Subject: [External Email]FW: Request Permission to ship NHP samples
Date: Wednesday, July 10, 2024 12:36:05 PM
Attachments: (b) (4)

[External Email]

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Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send (b) (6) NHP tissue samples for Mycobacterium testing on today, 7/10/24 for arrival on Thursday, 7/11/24. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? 10/21/23

How many animals were in the group imported (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – Please see attached histopathology report

Cause of Death?

- (b) (4) TB suspect
- (b) (4) Positive IFN gamma test
- (b) (4) positive IFN gamma test

Was the animal showing any abnormal symptoms prior to death? No

Thank you,

(b) (6) (b) (6) DVM
Director of North America Quarantine Veterinary Services

(b) (6)
(b) (6) Frederick | Charles River
(b) (6) Frederick, MD 21701

P: (b) (6) | F: (b) (6)
(b) (6) crl.com | www.criver.com
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24-08898_001315

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order #: (b) (4)

22 June 2024

History:

Customer: Charles River Frederick - Quarantine

Strain: Not-Specified

Species: Non-Human Primate (NHP)

Notes: animal ID (b) (4)

This animal had a positive result on (b) (4) and was euthanized. Necropsy was performed by the submitter and found mildly enlarged spleen.

Microscopic Diagnoses:

#1 (b) (4) Stomach: Gastritis, lymphocytic, mild, diffuse.

Lung, Lymph node (tracheobronchial, mesenteric), Liver, Spleen, Heart, Kidney, Urinary bladder, Small intestine, Large intestine: Within normal limits.

Acid Fast Stain (lung, TBLN): Negative for acid-fast organisms.

Comment:

There were no microscopic lesions suggestive of Mycobacteriosis. Acid fast stains of lung and TBLN were performed for thoroughness in the absence of lesions and no organisms were found. Gastritis was considered incidental.

(b) (4)

24-08898_001316

Pathology Report

LTM Order # (b) (4)

28 June 2024

History:

Customer: Charles River Frederick - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

This animal had negative intradermal TB test and intermediate (b) (4) and low body condition despite supportive care. It was euthanized and necropsy was conducted by the submitter and found gas-filled stomach, mild splenomegaly and enlarged left adrenal gland. Axillary lymph nodes were discolored black considered associated with tattoo.

Microscopic Diagnoses:

#1 (b) (4) Stomach: Gastritis, lymphocytic, moderate, diffuse.

Liver: Vacuolation, hepatocellular, moderate, diffuse.

Spleen: Eosinophilic material, central, minimal, focal.

Urinary bladder: Cystitis, lymphocytic, mild with few intraluminal bacteria.

Lung, Kidney, Adrenal gland, Lymph node (mesenteric), Heart, Small intestine, Large intestine:

Within normal limits.

Tracheobronchial lymph node (TBLN): Not present.

Comment:

A definitive cause of this animal's poor condition was uncertain, although the gastric and/or urinary lesions may have played a role. There were no microscopic lesions consistent with Mycobacteriosis. The TBLN was not present in the sections. The tissue submitted as TBLN was adipose tissue. We sectioned deep into the block, but lymph node was not found. When LN are normal, they can be challenging to find grossly.

(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order #: (b) (4)

05 July 2024

History:

Customer: Charles River Frederick - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

This animal had a 4/5 reading on dermal TB test at 24, 48, and 72 hours and was euthanized. Necropsy was performed by the submitter and found lung adhesions, an enlarged tracheobronchial lymph node (TBLN) with caseous center, two small plaques on the liver.

Microscopic Diagnoses:

#1 (b) (4) Lymph node (tracheobronchial): Granuloma, mild, multifocal.

Acid Fast Stain (TBLN): Few, intralesional acid-fast bacilli present.

Lung: Pleural thickening, fibrous, mild, multifocal.

Acid Fast Stain (lung): Negative.

Stomach: Lymphocytic infiltrates, mucosal, mild, multifocal.

Spleen, Heart, Liver, Kidney, Lymph nodes (mesenteric), Small intestine, Large intestine,

Urinary bladder: Within normal limits.

Comment:

The clinical history, gross and microscopic lesions in the TBLN are consistent with a diagnosis of Mycobacteriosis in this animal.

(b) (6)

24-08898_001326

Animal ID: 2007108 **Case #:** TB24-08185 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2007108 **Case #:** TB24-08186 **Sample:** 8 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2103136 **Case #:** TB24-08187 **Sample:** 9 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.76255417

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Animal ID: 2103136 **Case #:** TB24-08188 **Sample:** 10 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2103136 **Case #:** TB24-08189 **Sample:** 11 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 2103136 **Case #:** TB24-08190 **Sample:** 12 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Results authorized by:**Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov**Help Us Help You**

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895190811	
Trans_mode	AIR	

Details		✕
Date	2023-10-17	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY(MACACA FASCICULARIS)#&VN	
Value_usd	5467500	
Unit_price_usd	15187.5	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE - HOANG DONG COMMUNE - LANG SON CITY - LANG SON.,	
Exporter_phone	84	
Exporter_fax		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	15187.5	
Value_dclr	5467500	
Currency_dclr	USD	
Exchange_rate_vnd	24270	
Value_vnd	1.326962E+11	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	305895438020	
Trans_mode	AIR	

Exhibit 9



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report

Owner

Charles River Laboratories Frederick

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:

24-017181

NFC Control Number:

19824031987

Date Collected:

Date Received:

06/13/2024

Date Completed:

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2003090 **Case #:** TB24-07198 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 32.77476501**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2003090 **Case #:** TB24-07199 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 37.26292801**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2003090 **Case #:** TB24-07200 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2003090 **Case #:** TB24-07201 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 33.4708252**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2110043 **Case #:** TB24-07202 **Sample:** 5 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2110043 **Case #:** TB24-07203 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2110043 **Case #:** TB24-07204 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2110043 **Case #:** TB24-07205 **Sample:** 8 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2007010 **Case #:** TB24-07206 **Sample:** 9 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.57047272

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2007010 **Case #:** TB24-07207 **Sample:** 10 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2007010 **Case #:** TB24-07208 **Sample:** 11 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2007010 **Case #:** TB24-07209 **Sample:** 12 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 33.64281845

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Animal ID: 2110045 **Case #:** TB24-07210 **Sample:** 13 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Exhibit 10

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report**Owner**

Charles River Laboratories Frederick

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:**24-022513****NFC Control Number:**

19824037878

Date Collected:

07/12/2024

Date Received:

08/07/2024

Date Completed:**Collected By:**[REDACTED]
General Diagnostic**Purpose:****Referral/Retain Tag Number:**

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 33572 **Case #:** TB24-08822 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081**Detected** **Ct = 27.1042366**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33572 **Case #:** TB24-08823 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081**Detected** **Ct = 36.15092087**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33572 **Case #:** TB24-08824 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 35.83751678**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33572 **Case #:** TB24-08825 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 26.5355854**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37676 **Case #:** TB24-08826 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37676 **Case #:** TB24-08827 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37676 **Case #:** TB24-08828 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37676 **Case #:** TB24-08829 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37616 **Case #:** TB24-08830 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.11271667

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37616 **Case #:** TB24-08831 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37616 **Case #:** TB24-08832 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37616 **Case #:** TB24-08833 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37636 **Case #:** TB24-08834 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37636 **Case #:** TB24-08835 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37636 **Case #:** TB24-08836 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37636 **Case #:** TB24-08837 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.3802681

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37660 **Case #:** TB24-08838 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37720 **Case #:** TB24-08844 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 37720 **Case #:** TB24-08845 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 24693 **Case #:** TB24-08846 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 25.5363369

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 24693 **Case #:** TB24-08847 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 24693 **Case #:** TB24-08848 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Inhibited Ct = U

Interpretation: The PCR reaction was inhibited; the test result was not valid. Retesting will be necessary for a valid result.

Animal ID: 24693 Case #: TB24-08849 Sample: 4 Specimen Type: Lung Species: Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.46081924

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 11

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE

1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

(b) (6) (b) (6)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

Charles River Laboratories - Frederick

EMAIL ADDRESS

(b) (6) cri.com

OWNER CITY

Frederick

STATE/COUNTRY

MD/USA

PHONE NUMBER

(b) (6)

FAX NUMBER

(b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Frederick

STATE/COUNTRY

MD/USA

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6)
Frederick, MD 21701

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

Mycobacterium Culture

Mycobacterium PCR

Mycobacterium Identification

Rule in/out TB

7. NUMBER IN HERD/FLOCK AFFECTED

8. NUMBER IN HERD/FLOCK DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

07/29/2024

12. AUTHORIZED BY

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

21. IDENTIFICATION (See instructions <250 samples per form)

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary).

SAMPLE NOT VERIFIED

23. SIGNATURE OF

(b) (6)

NVSL USE ONLY

COLLECTION

PRIORITY

VS FORM 10-4
AUG 2009

(b) (6)

24-024085
MB

08/22/2024
602183

24-08898_001397

Date: August 21, 2024

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis*/ (b) (4) origin ** Quarantine Samples **

3. Item Name	Quantity	Date sample Derived	Packing
(b) (4)	LN, spleen, liver and lung	7/29/24	Dry Ice
	LN, spleen, liver and lung	7/29/24	Dry Ice
	LN, spleen, liver and lung	7/29/24	Dry Ice

4. Date Shipped: Ship on 8/21/2024 for delivery on morning of 8/22/2024

5. FedEx Tracking#

(b) (6)

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)

Signature of Supervisor

SEE CONDITIONS OF SALE/WARRANTY

Bravo-Garcia, Doris - MRP-APHIS

From: (b) (6) <(b) (6)@crl.com>
Sent: Wednesday, August 21, 2024 12:12 PM
To: Bravo-Garcia, Doris - MRP-APHIS; Lehman, Kimberly - MRP-APHIS; MRP-APHIS-MB-CaseManagement
Cc: (b) (6); (b) (6)
Subject: [External Email] Permission to ship NHP samples
Attachments: (b) (4)

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**,
Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send ^{NHP} NHP tissue samples for Mycobacterium testing on today, 8/21 for arrival on Thursday, 8/22. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? 06/28/24

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? – Please see attached histopathology report

Cause of Death? – TB Suspect

Was the animal showing any abnormal symptoms prior to death? No

Thank you,

(b) (6) (b) (6) DVM
Director of North America Quarantine Veterinary Services
(b) (6)
(b) (6) Frederick | Charles River
(b) (6) Frederick, MD 21701
P: (b) (6) | F: (b) (6)
(b) (6) crl.com | www.criver.com
[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

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Pathology Report

LTM Order # (b) (4)

09 August 2024

History:

Customer: Charles River Frederick - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

This animal had a 4/5 TB react at 72 hours and was euthanized. Necropsy was performed by the submitter and found a lung nodule slightly enlarged tracheobronchial lymph node (TBLN) both with caseous center.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, mild, focal.

Lymph node (TBLN): Granuloma, minimal, multifocal.

Abscess, chronic, marked, focally extensive.

Acid Fast Stain (lung, TBLN): Positive for acid-fast bacilli in the TBLN lesion. No organisms noted in the lung.

Heart, Liver, Spleen, Kidney, Adrenal gland, Lymph node (mesenteric), Urinary bladder, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions were consistent with a diagnosis of mycobacteriosis in this animal.

(b) (6)

Pathology Report

LTM Order # (b) (4)

14 August 2024

History:

Customer: Charles River Frederick - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4) TB suspects

This animal had a grade 4/5 reaction to TB test at 72 hours and was euthanized. Necropsy was performed by the submitter and found a lung nodule and enlarged tracheobronchial lymph node (TBLN) with caseous center.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, pedunculated at lung margin, mild, focal.

Tracheobronchial lymph node: Granuloma, moderate, multifocal.

Liver: Granuloma, mild, focal.

Spleen: Granuloma, mild, focal.

Acid Fast stain (lung, TBLN, Liver, Spleen): Negative for acid fast organisms.

Heart, Kidney, Urinary bladder, Lymph node (mesenteric), Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions were consistent with a diagnosis of mycobacteriosis in this animal.

(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order # (b) (6)

14 August 2024

History:

Customer: Charles River Frederick - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

This animal has a grade 3/5 TB reaction at 72 hours and was euthanized. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph node (TBLN) with caseous center and a nodule on lung.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, moderate, focal.

Lymph node (TBLN): Granuloma, moderate, multifocal.

Acid Fast stain (lung, TBLN): Positive for intralesional acid fast bacillus in the lung. TBLN was negative.

Lymph node (mesenteric): Lymphoid hyperplasia, mild, multifocal.

Heart, Liver, Spleen, Kidney, Urinary bladder, Stomach, Small intestine, Pancreas, Large intestine: Within normal limits.

Comment:

The microscopic lesions were consistent with a diagnosis of mycobacteriosis in this animal.

(b) (6)

24-08898_001410



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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PARTIAL

Laboratory Test Report

Owner

Charles River Laboratories - Frederick

Frederick, MD

Animal Location

Frederick County MD, US

Submitter - 502163

Charles River Laboratories

8501 Progress Drive

Frederick, MD 21701

FAX #: 240-529-0640

Phone #: [REDACTED]

Accession Number:

24-024085

Date Collected:

07/29/2024

Date Received:

08/22/2024

Date Completed:

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is not a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 37698 **Case #:** TB24-10108 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 32.2521553**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37698 **Case #:** TB24-10109 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Frederick

Animal ID: 37698 **Case #:** TB24-10110 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Animal ID: 37698 **Case #:** TB24-10111 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Direct PCR for *M. tuberculosis* complex - IS1081

Detected Ct = 26.39938545

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37036 **Case #:** TB24-10112 **Sample:** 5 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for *M. tuberculosis* complex - IS1081

Detected Ct = 27.32958603

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37036 **Case #:** TB24-10113 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey,
Cynomolgus

Direct PCR for *M. tuberculosis* complex - IS1081

Detected Ct = 33.05519104

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 37036 **Case #:** TB24-10114 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Frederick

Animal ID: 37036 **Case #:** TB24-10115 **Sample:** 8 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33891 **Case #:** TB24-10116 **Sample:** 9 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 25.61090851

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33891 **Case #:** TB24-10117 **Sample:** 10 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33891 **Case #:** TB24-10118 **Sample:** 11 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33891 **Case #:** TB24-10119 **Sample:** 12 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.0704422

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Frederick

Animal ID: 37036 **Case #:** TB24-10133 **Sample:** 13 **Specimen Type:** Heart **Species:** Monkey, Cynomolgus**Direct PCR** for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Heart sample for animal 37036 was received but not listed on the submission form.**

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Details		×
Date	2024-06-25	
Exporter_id	3800232291	
Exporter	VINA MEKONG GROUP	
Importer	CHARLES RIVER LABORATORIES, INC.	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY. (116 MALE, 173 FEMALE) (SCIENTIFIC NAME: MACACA FASCICULARIS)#&VN	
Value_usd	216750	
Unit_price_usd	750	
Qty_unit	UNC (ANIMALS)	
Qty	289	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	VIETNAM	
Des_port		
Exporter_address	THANH HIEP HAMLET, THANH BAC COMMUNE, TAN BIEN DISTRICT, TAY NINH PROVINCE, VIETNAM,	
Exporter_phone	0908 007799	
Exporter_fax		
Exporter_mail		
Exporter_contact	HUỖNH HỮU DỮNG	
Exporter_vn	CÔNG TY TNHH MỘT THÀNH VIÊN VINA MEKONG	
Exporter_type	ORDINARY EXPORT	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG. (116 CON ĐỰC, 173 CON CÁI) (TÊN KHOA HỌC: MACACA FASCICULARIS)#&VN	
Unit_price_dclr	750	
Value_dclr	216750	
Currency_dclr	USD	
Exchange_rate_vnd	25247	
Value_vnd	5472287250	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	306527209460	
Trans_mode	AIR	

Details		✕
Date	2024-06-25	
Exporter_id	3800232291	
Exporter	VINA MEKONG GROUP	
Importer	CHARLES RIVER LABORATORIES, INC.	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY, (180 MALE, 180 FEMALE) (SCIENTIFIC NAME: MACACA FASCICULARIS)#&VN	
Value_usd	270000	
Unit_price_usd	750	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	VIETNAM	
Des_port		
Exporter_address	THANH HIEP HAMLET, THANH BAC COMMUNE, TAN BIEN DISTRICT, TAY NINH PROVINCE, VIETNAM,	
Exporter_phone	0908 007799	
Exporter_fax		
Exporter_mail		
Exporter_contact	HUỖNH HỮU DŨNG	
Exporter_vn	CÔNG TY TNHH MỘT THÀNH VIÊN VINA MEKONG	
Exporter_type	ORDINARY EXPORT	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG. (180 CON ĐỰC, 180 CON CÁI) (TÊN KHOA HỌC: MACACA FASCICULARIS)#&VN	
Unit_price_dclr	750	
Value_dclr	270000	
Currency_dclr	USD	
Exchange_rate_vnd	25247	
Value_vnd	6816690000	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	306527166650	
Trans_mode	AIR	

Exhibit 12

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-1" for definitions.

1. SUBMITTER NAME (including Business Name) (b) (6) Charles River Laboratories		2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) crl.com (b) (6) crl.com		OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6)	FAX NO. (b) (6)	4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047		PREMISES ID	
		COUNTY Harris	STATE/COUNTRY TX/US

5. PAYMENT METHOD	
<input type="checkbox"/> USER FEE ACCOUNT NO.	<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars)
	<input checked="" type="checkbox"/> CF CAI X

6. HERD/FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 02/06/23
8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)
13. PURPOSE OF SUBMISSION (See instructions for definitions)		14. COUNTRY OF ORIGIN/DESTINATION (b) (4)
<input type="checkbox"/> Interstate Movement	<input type="checkbox"/> Import	<input checked="" type="checkbox"/> TB
<input type="checkbox"/> Export	<input type="checkbox"/> FAD/EP Diagnostic	<input type="checkbox"/> Reagent Evaluation
<input type="checkbox"/> Pre-Import	<input type="checkbox"/> Surveillance	<input type="checkbox"/> NVSL Intralab
	<input type="checkbox"/> General Diagnostic	
	<input type="checkbox"/> Developmental Research	

16. PRESERVATION	
<input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input checked="" type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)	
17. SPECIMENS SUBMITTED ("X" applicable item(s))	
<input type="checkbox"/> Blood	<input type="checkbox"/> Feces
<input type="checkbox"/> Culture	<input type="checkbox"/> Parasite
<input type="checkbox"/> Extract	<input type="checkbox"/> Feed
<input type="checkbox"/> Milk	<input type="checkbox"/> Plant
<input type="checkbox"/> Semen	<input type="checkbox"/> Soil
<input type="checkbox"/> Swab (specify)	<input type="checkbox"/> Tissue (specify)
<input type="checkbox"/> Urine	<input type="checkbox"/> Whole Animal
<input type="checkbox"/> Water	<input type="checkbox"/> Fetus
	<input type="checkbox"/> DNA/RNA
	<input type="checkbox"/> Other (specify)
	<input type="checkbox"/> TBLN; Lung; Nodule
18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)	
19. SPECIES OR SOURCE ("X" ONLY one)	
<input type="checkbox"/> Cattle	<input type="checkbox"/> Goat
<input type="checkbox"/> Swine	<input type="checkbox"/> Chicken
<input type="checkbox"/> Sheep	<input type="checkbox"/> Horse
<input type="checkbox"/> Donkey	<input type="checkbox"/> Turkey
<input type="checkbox"/> Other bird (specify)	<input type="checkbox"/> Bison
	<input type="checkbox"/> Deer (specify)
	<input type="checkbox"/> Elk
	<input type="checkbox"/> Fish
	<input type="checkbox"/> Environment
	<input checked="" type="checkbox"/> Other (specify)
	<input type="checkbox"/> Reagent
	<input type="checkbox"/> Cynomolgus
	<input type="checkbox"/> Macaque
20. NUMBER OF ANIMALS SAMPLED (b) (4)	

21. IDENTIFICATION (See instructions <250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary)

see attached necropsy report

SAMPLE NOT VERIFIED

23. DATE OF SUBMISSION (b) (6) 2/6/23	24-08898_00059
CONDITION DI	PRIORITY 3
DISTRIBUTION (b) (6)	RECEIVED BY (b) (6)
VS FORM 10-1 AUG 2009	

23-004180
MB

02/07/2023
30321

I also wanted to note that the samples sent 1/30 to arrive 1/31 did not arrive until today due to weather/shipping issues from the shipping companies. I am not sure how you had these samples packaged (ie ice pack or dry ice), but would recommend re-submission of samples if possible. If re-submission is not possible, please let us know and we will try our best with the samples we have. Thank you!

Kim

Kimberly A Lehman, DVM, MPH, DACVPM
Supervisory Veterinary Medical Officer
Director's Office
USDA-APHIS-VS-D&B-NVSL
1920 Dayton Ave
Ames, IA 50010
Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov

From: (b) (6) <(b) (6)@crl.com>
Sent: Monday, February 6, 2023 12:47 PM
To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>
Subject: [External Email]Request Permission to ship NHP Samples

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;
Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing today (2/6/23) for arrival tomorrow (2/7/23). Please let us know if you are agreeable to this. The necropsy report is attached. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)
Where did the animals originate from? (b) (4)
What was the date that they left the originating country? (b) (4)
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Was animals exposed to animals from other sources? No
Was a complete necropsy and with histology done on this animal? Yes
If so, can you provide those results?

- Gross necropsy revealed: Moderate bruise superior palpebra left eye. 3mm firm translucent nodule ventromedial left cranial lung lobe. Moderately enlarged tracheobronchial lymph nodes.
- Histopathology pending

Cause of Death? Euthanasia with pentobarbital IV
Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

(b) (6)
(b) (6)
(b) (6) Houston | Charles River
(b) (6) Road, Houston, TX 77047
(b) (6)
(b) (6) cri.com | www.criver.com
LinkedIn | Twitter | Facebook | Eureka
Pronouns: she, her, hers

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(b) (4) Necropsy - (b) (4)

From Date

02/06/2023 12:18:07

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

VSH / (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/06/2023 12:17:01	Date Out	02/06/2023 12:17:01
02/06/2023 12:17:01	Location at Stock Out - Path	(b) (4)
02/06/2023 12:33:06	Died during quarantine	Yes
02/06/2023 12:17:01	Euthanasia Reason	See necropsy report
02/06/2023 12:17:01	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4) At 72h read of 2nd of 5 quarantine TB tests, pt reported for grade 3 reaction. No other significant history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin



Abnormal Skin Description

Moderate bruise superior palpebra left eye

Oral



Abnormal Oral Cavity Description

(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Moderately enlarged tracheobronchial lymph nodes

Respiratory System



Abnormal Respiratory System Description

3mm firm translucent nodule ventromedial left cranial lung lobe

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) Necropsy - (b) (4)

Other

Other - Description



adrenal, lung nodule

Microbiology

TB microbiology- pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: **(b) (4)**

15 February 2023

History:

Customer: Charles River Houston - Quarantine
Species: Non-Human Primate (NHP)
Notes: Animal ID **(b) (4)**

This animal had a 3/5 TB test at 72 hours on the second round of quarantine TB testing. Necropsy was performed by the submitter. Moderately enlarged tracheobronchial lymph nodes (TBLN) were noted. A 3mm translucent nodule was on left lung.

Microscopic Diagnoses:

#1 **(b) (4)**: Lung (nodule): Abscess, mild, focal.

Acid Fast Stain (lung nodule): Moderate numbers of acid-fast bacilli present within the lesion.

Intestines: Lymphoid hyperplasia of GALT, mild, multifocal.

Heart, Lung, Thymus, Liver, Spleen, Kidney, Stomach, Adrenal gland, Adipose tissue: Within normal limits.

Comment:

The lung nodule noted at necropsy correlated microscopically to an inflammatory lesion containing acid fast bacilli. This lesion was consistent with Mycobacteriosis. No TBLN was found in examined tissues, but thymus was. It may be that thymus was misidentified as TBLN, which may explain the gross comment of enlargement. The TBLN is often the best tissue for finding TB lesions. None the less, with the pulmonary nodule the diagnosis of Mycobacteriosis can be made.

(9) (q)

24-08898_000607

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-004180****Animal Location**

Harris County TX, US

NFC Control Number:

19823016665

Date Collected:

02/06/2023

Date Received:

02/07/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1912015 **Case #:** TB23-01110 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.15179062

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 1912015 **Case #:** TB23-01111 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.36365891

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1912015 **Case #:** TB23-01112 **Sample:** 3 **Specimen Type:** Granuloma, Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 21.33502007

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

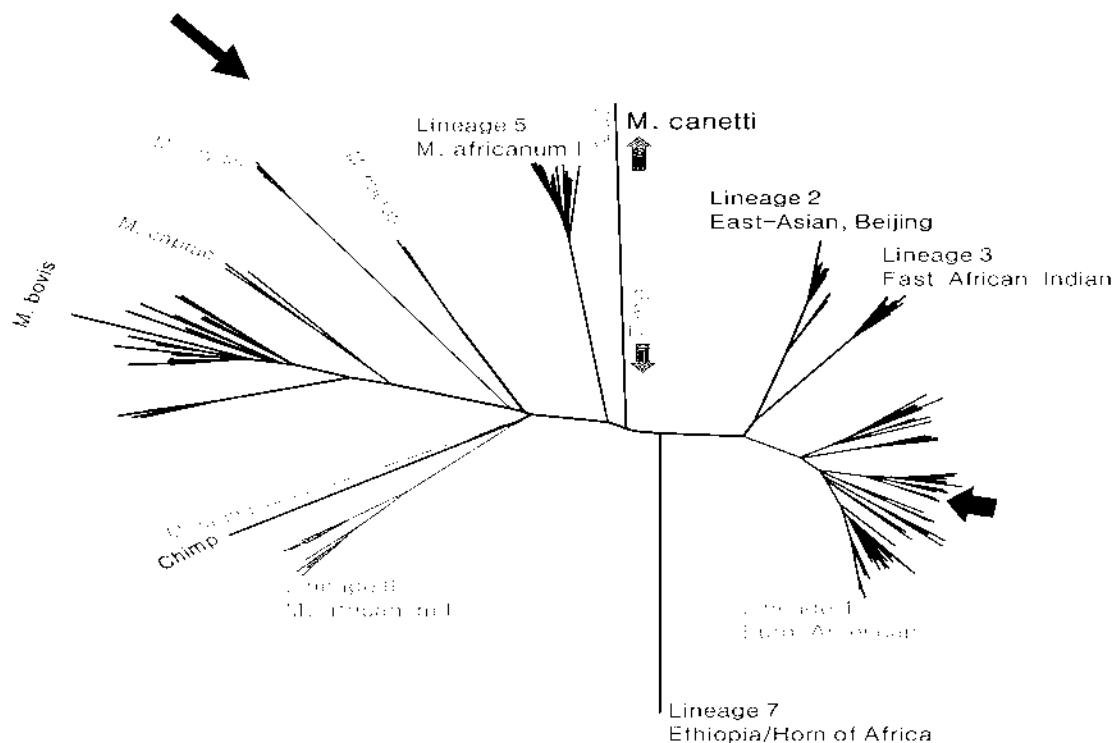
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



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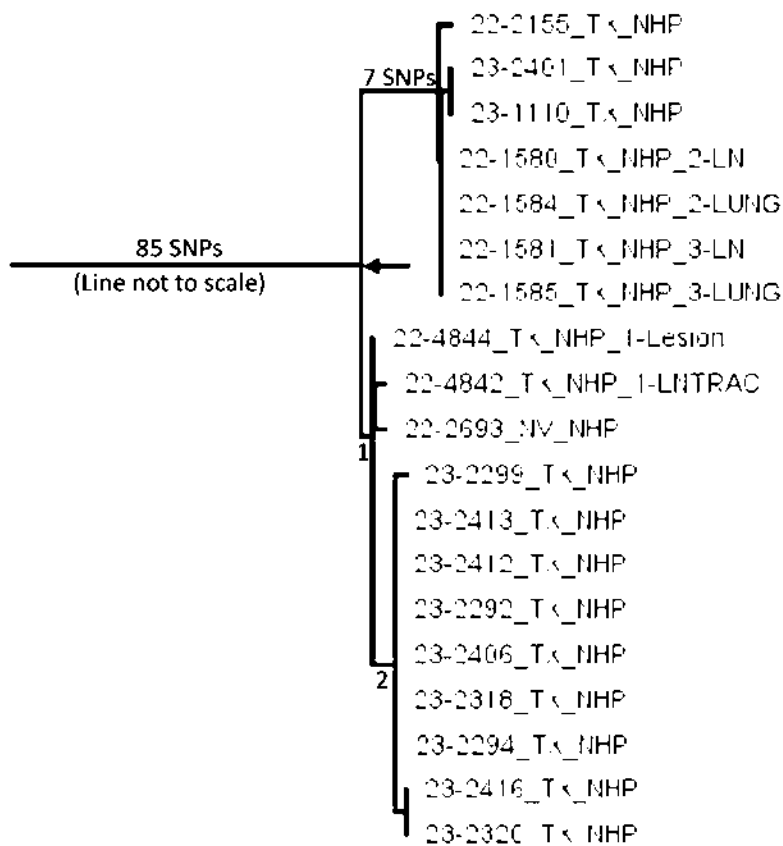
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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PO Box 844

Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:
Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3150708	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3230370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4073545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487			
root	G	T	C	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	G	A	A	G	G	A	G	G	A	A	G	G	A	A	C	G	A	A	G	C	G	T	G	G	T	G
22-1580 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G	
22-1581 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G	
22-1581 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G	
22-1585 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G	
22-2155 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	A	C	G	T	G	G	T	G	
23-2401 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G	
23-1110 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G	
22-2693 NV NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	G	G	T	G	
22-4844 TX NHP 1 lesion	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	G	G	T	G	
22-4847 TX NHP 1 ENTRAC	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	G	G	T	G	
23-2413 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	G	
23-2412 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	G	
23-2292 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	G	
23-2406 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	G	
23-2318 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	G	
23-2299 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	A	G	
23-2294 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	R	
23-2416 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	A	
23-2320 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	A	A	G	C	T	A	A	T	A	

Exhibit 13

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send two NHP samples for Mycobacterium testing on Tuesday, February 14th for arrival Wednesday, February 15th. Please let us know if you are agreeable to this. The necropsy reports are attached. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes, see attached reports

If so, can you provide those results?

- Necropsy report:
- (b) (4) – Mild to moderate enlarged tracheobronchial lymph nodes.
- (b) (4) – Mild to moderate enlarged tracheobronchial lymph nodes and 1 0.5cm firm nodule in the right lung lobe.

Cause of Death? Euthanasia due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

Regards,

(b) (6)

(b) (6)

Frederick | Charles River
Frederick, MD 21701

(b) (6)

(b) (6) pcrf.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

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OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

(b) (6) Charles River Laboratories

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

EMAIL ADDRESS

(b) (6) @crl.com (b) (6) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO.

(b) (6)

FAX NO.

(b) (6)

MAILING ADDRESS (Street, City, State, ZIP Code)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

(b) (6) Houston, TX 77047

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD
Number: 4866 9110 0011 4879
Exp. Date: 09/24

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

11. DATE COLLECTED

02/13/23

8. NO. IN HERD/FLOCK
DEAD

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement ☐ Import ☒ TB ☐ Reagent Evaluation
☐ Export ☐ FAD/EP Diagnostic ☐ General Diagnostic ☐ NVSL Intralab
☐ Pre-Import ☐ Surveillance ☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood ☐ Feces ☐ Parasite ☐ Serum ☒ Tissue (specify) ☐ Whole Animal ☐ Other (specify)
☐ Culture ☐ Feed ☐ Plant ☐ Soil ☐ Urine ☐ Fetus TBLN; Lung; (b) (4)
☐ Extract ☐ Milk ☐ Semen ☐ Swab (specify) ☐ Water ☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle ☐ Goat ☐ Chicken ☐ Bison ☐ Fish ☒ Other (specify)
☐ Swine ☐ Horse ☐ Turkey ☐ Deer (specify) ☐ Environment Cynomolgus
☐ Sheep ☐ Donkey ☐ Other bird (specify) ☐ Elk ☐ Reagent Macaque

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

2/14/23 Email from (b) (6) with
updated submission form for ID correction KAL

23. NVSL USE ONLY

(b) (6) 02.13.23

CONDITION PRIORITY DISTRIBUTION RECEIVED BY

VS FORM 10-4
AUG 2009

24-08898_000622

(b) (4) Necropsy (b) (4)

From Date

02/13/2023 14:30:30

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (4) (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/13/2023 14:28:19	Date Out	02/13/2023 14:28:19
02/13/2023 14:28:19	Location at Stock Out - Path	(b) (4)
02/13/2023 14:58:08	Died during quarantine	Yes
02/13/2023 14:28:19	Euthanasia Reason	See necropsy report
02/13/2023 14:28:19	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

(b) (4) origin macaca fascicularis male animal with grade 4 positive TB reaction.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Oral

Abnormal Oral Cavity Description



Lymph Nodes

Abnormal Lymph Nodes Description



enlarged tracheobronchial lymph nodes

(b) (4) - Necropsy - (b) (4)

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

Two cassettes, one labelled ? and the other ?? --->?: found along mid trachea, above the bifurcation --->?: found around RT lung bronchus, appeared to contain yellow discharge.

(b) (4) - Necropsy (b) (4)

Microbiology

Mycobacterium culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

01 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. (b) (4) origin *Macaca fascicularis* male with grade 4 positive TB reaction. Necropsy was conducted by the submitter. Unidentified tissue with yellow discharge noted near right bronchus. No other significant findings.

Microscopic Diagnoses:

#1: Connective tissue (collected near right lung bronchus): Abscess, mild, focal.

Acid Fast (connective tissue): Few acid-fast bacilli are noted within the lesion.

Lung, Thymus, Liver, Small intestine, Heart, Spleen: Within normal limits.

Comment:

The tissue labeled with “??” was an abscess lesion in connective tissue, perhaps was or was adjacent to a lymph node. The microscopic appearance of the lesion and presence of acid-fast bacteria considered with the history is consistent with a diagnosis of Mycobacteriosis. The tissue labeled with “?” was thymus.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005150****Animal Location**

Harris County TX, US

NFC Control Number:

19823017719

Date Collected:

02/13/2023

Date Received:

02/15/2023

Date Completed:

04/19/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 22059 **Case #:** TB23-01499 **Sample:** TBLN **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22059 **Case #:** TB23-01500 **Sample:** Lung **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081**Detected** Ct = 35.39421082

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Exhibit 14

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and 333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

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(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) crl.com (b) (6) crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6), Houston, TX 77047

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED
02/20/23

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN;lung;liver;

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

heart

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SUBMITTER USE DATE

(b) (6)

NVSL USE ONLY

CONDITION

PRIORITY

DIS

(b) (6)

RECEIVED BY

(b) (6)

23 - 005859

MB

502739
02/22/2023

VS FORM 10-4
AUG 2009

24-08898_000674

Re: [External Email]Request Permission to ship NHP Samples 4 of 8 02.21.23

Lehman, Kimberly MRP APHIS <Kimberly.Lehman@usda.gov>

Tue 2/21/2023 4:48 PM

To: (b) (6) <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS
<NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

We will accept samples from (b) (4). Thank you for the information. Please send us the tracking number and the histopathology results when you have it please

Kim Lehman

Kimberly A Lehman, DVM, MPH, DACVPM
Supervisory Veterinary Medical Officer
Director's Office
USDA-APHIS-VS-D&B-NVSL
1920 Dayton Ave
Ames, IA 50010
Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov

From: (b) (6) <(b) (6)@crl.com>

Sent: Tuesday, February 21, 2023 4:27 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Subject: [External Email]Request Permission to ship NHP Samples 4 of 8 02.21.23

[External Email]

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Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report has been attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment: (b) (4)
Where did the animals originate from? (b) (4)
What was the date that they left the originating country? (b) (4)
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Was animals exposed to animals from other sources? No

24-08898 000675

Was a complete necropsy and with histology done on this animal? **Yes**

If so, can you provide those results?

- **Gross necropsy revealed**
 - mild erythema and swelling of superior palpebra OD
 - enlarged tracheobronchial lymph nodes (1.5cm)
 - Adhesions noted on serosal surface of lungs bilateral adhering to thoracic wall.
 - Generalized congested and consolidated right lung with multifocal to coalescing irregularly shaped off white masses, which are caseous upon incision.
 - Laterodorsal aspect of the left caudal lung lobe has a 5mm tan solid mass.
 - Single pinpoint white raised lesion on serosal surface of heart just distal to circumflex artery.
 - Seven 3mm multifocal hard white nodules found through hepatic parenchyma
- **Histopathology pending**

Cause of Death? **Euthanasia via IV pentobarbital**

Was the animal showing any abnormal symptoms prior to death? **No**

Please let me know if you need any other information.

Thank you,

(b) (6)

(b) (6) | Charles River

P: (b) (6) | M: (b) (6)

(b) (6) [crl.com](#) | [www.criver.com](#)

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

(b) (4) - Necropsy - (b) (4)

From Date

02/20/2023 21:02:34

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/20/2023 20:58:10	Date Out	02/20/2023 20:58:10
02/20/2023 20:58:10	Location at Stock Out - Path	(b) (4)
02/21/2023 16:22:51	Died during quarantine	Yes
02/20/2023 20:58:10	Euthanasia Reason	See necropsy report.
02/20/2023 20:58:10	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) Grade 3 TST at 72 hr read OD. No other significant clinical history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema and swelling of superior palpebra OD.

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

enlarged tracheobronchial lymph nodes (1.5cm)

Respiratory System



Abnormal Respiratory System Description

Adhesions noted on serosal surface of lungs bilateral adhering to thoracic wall. Generalized congested and consolidated right lung with multifocal to coalescing irregularly shaped off white masses, which are caseous upon incision. Laterodorsal aspect of the left caudal lung lobe has a 5mm tan solid mass.

Cardiovascular System



Abnormal Cardiovascular System Description

Single pinpoint white raised lesion on serosal surface of heart just distal to circumflex artery.

Gastrointestinal System



Abnormal Gastrointestinal System Description

Seven 3mm multifocal hard white nodules found through hepatic parenchyma

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



(b) (4) Necropsy (b) (4)

Skeletal Muscle

Bone Marrow

Brain



Skin



Skin - Description



Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Pathology Report

LTM Order #: (b) (4)

08 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain:
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine necropsy for Houston. Animal had grade 3 TAT as 72 hours. Necropsy performed by the submitter found enlarged tracheobronchial lymph node (TBLN) and adhesions of the lung to thoracic wall. several caseous white lung masses, single pin pint lesion on heart, several 3mm nodules in liver.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, marked, focally extensive/multifocal.

Acid Fast Stain (lung, liver): Small numbers of acid-fast bacilli in lung and liver lesions.

Liver: Granuloma, mild, multifocal.

Spleen: Inflammation, histiocytic with several multinucleated giant cells, mild, focal.

Heart: Hyalinized material, nodular, epicardial, with peripheral chronic inflammation, mild, focal.

Large intestine: *Balantidium coli*, luminal, minimal.

Hyalinized material, nodular, outer muscular layer, peripheral chronic inflammation, mild, focal.

Stomach: Lymphocytic gastritis, moderate, focally extensive.

Lymph nodes (TBLN, mesenteric), Kidney, Urinary bladder, Adrenal gland, Small intestines,

Pancreas: Within normal limits.

Comment:

The microscopic lesions in lung, liver and spleen were consistent with Mycobacteriosis. Acid Fast staining was positive in lung and liver. The small nodule noted on the epicardium and large intestinal serosa were similar and may represent parasitic granuloma. This and other changes not

LTM Order Number (b) (4) age 2 of 2

connected to Mycobacteriosis were considered incidental.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005859****Animal Location**

Harris County TX, US

NFC Control Number:

19823018475

Date Collected:

02/20/2023

Date Received:

02/22/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1701012 **Case #:** TB23-02293 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.72643661

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1701012 Case #: TB23-02294 Sample: 2 Specimen Type: Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 20.94334412

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 1701012 Case #: TB23-02295 Sample: 3 Specimen Type: Liver Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1701012 Case #: TB23-02296 Sample: 4 Specimen Type: Heart Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.8776207

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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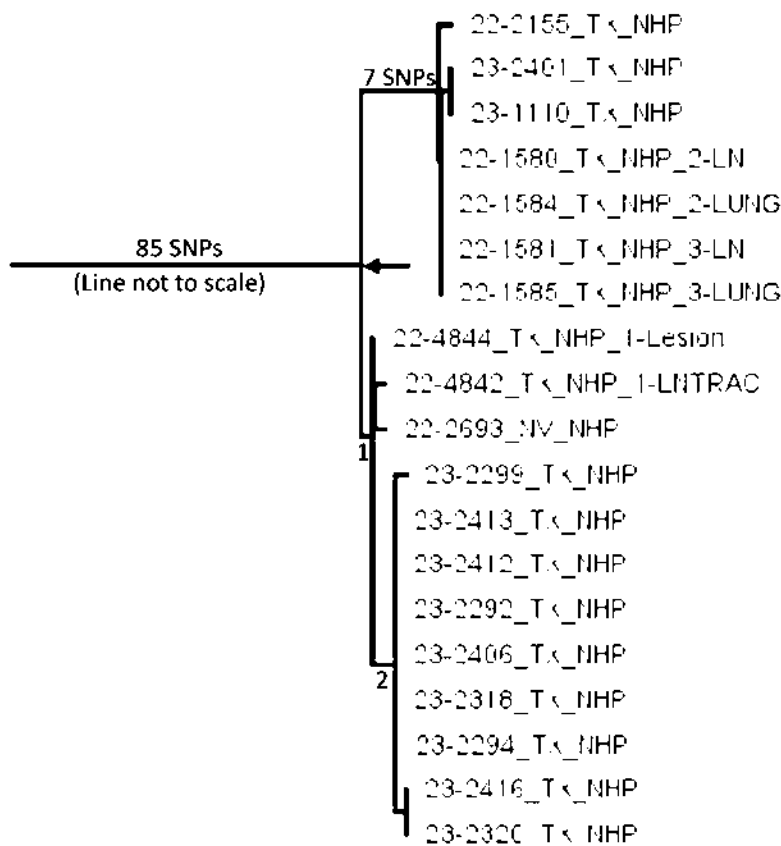
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3156208	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3236370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487			
root	G	T	T	C	A	G	G	A	A	A	C	T	G	G	T	C	A	T	A	A	G	G	A	A	G	G	G	G	A	A	A	C	G	A	A	G	C	G	T	G	G	T	G		
22-1580 TX NHP 2 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G	
22-1581 TX NHP 2 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G	
22-1581 TX NHP 3 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G	
22-1585 TX NHP 3 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G	
22-2155 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		A	C	G	T	G	G	T	G	
23-2401 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	G		T	G	G	T	G	
23-1110 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	G		T	G	G	T	G	
22-2693 NV NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	G	G	T	G
22-4844 TX NHP 1 lesion	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	G	G	T	G
22-4847 TX NHP 1 ENTRAC	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	G	G	T	G
23-2413 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	G
23-2412 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	G
23-2292 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	G
23-2406 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	G
23-2318 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	G
23-2299 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	A	G
23-2294 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	R
23-2416 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	A
23-2320 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	G		A	C		G	A	A	G	C		T	A	A	T	A

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OMB Approved
0579-0090, 0579-0101
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) (b) (6) Charles River Laboratories		2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) .crl.com (b) (6) .crl.com		OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6) FAX NO. 713-433-6971		4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047		PREMISES ID	
		COUNTY Harris	STATE/COUNTRY TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO. ☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

6. FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 02/20/23
8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)
13. PURPOSE OF SUBMISSION (See instructions for definitions)		14. COUNTRY OF ORIGIN/DESTINATION (b) (4)
<input type="checkbox"/> Interstate Movement <input type="checkbox"/> Import <input checked="" type="checkbox"/> TB <input type="checkbox"/> Reagent Evaluation <input type="checkbox"/> Export <input type="checkbox"/> FAD/EP Diagnostic <input type="checkbox"/> General Diagnostic <input type="checkbox"/> NVSL Intralab <input type="checkbox"/> Pre-Import <input type="checkbox"/> Surveillance <input type="checkbox"/> Developmental Research		15. REFERRAL NUMBER

16. PRESERVATION
☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))	18. TOTAL NUMBER OF SPECIMENS SUBMITTED
<input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (specify) <input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus TBLN; Lung; liver (b) (4) <input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (specify) <input type="checkbox"/> Water <input type="checkbox"/> DNA/RNA	

19. SPECIES OR SOURCE ("X" ONLY one)	20. NUMBER OF ANIMALS SAMPLED
<input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (specify) <input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (specify) <input type="checkbox"/> Environment Cynomolgus <input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (specify) <input type="checkbox"/> Elk <input type="checkbox"/> Reagent Macaque (b) (4)	

21. IDENTIFICATION (See instructions <250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
	(b) (4)								

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE (b) (6) 2/24/23	NVSL USE ONLY
CONDITION D	PRIORITY 3
DISTRIBUTION (b) (6)	RECEIVED BY (b) (6)

23 - 005858
MB

VS FORM 10-4
AUG 2009

602739
02/22/2023

24-08898_000663

Re: [External Email]Request Permission to ship NHP Samples 3 of 8 02.21.23

Lehman, Kimberly MRP APHIS <Kimberly.Lehman@usda.gov>

Tue 2/21/2023 4:47 PM

To: (b) (6) <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS
<NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

We will accept samples from (b) (4). Thank you for the information. Please send us the tracking number and the histopathology results when you have it please

Kim Lehman

Kimberly A Lehman, DVM, MPH, DACVPM

Supervisory Veterinary Medical Officer

Director's Office

USDA-APHIS-VS-D&B-NVSL

1920 Dayton Ave

Ames, IA 50010

Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov

From: (b) (6) <(b) (6)@crl.com>

Sent: Tuesday, February 21, 2023 4:16 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Subject: [External Email]Request Permission to ship NHP Samples 3 of 8 02.21.23

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report is attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment: (b) (4)
Where did the animals originate from? (b) (4)
What was the date that they left the originating country? (b) (4)
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Was animals exposed to animals from other sources? No

24-08898 000664

Was a complete necropsy and with histology done on this animal? **Yes**

If so, can you provide those results?

- Gross necropsy revealed mild erythema and swelling of superior palpebra OD, enlarged tracheobronchial lymph nodes measuring 1.3-1.5cm, 0.5 cm tan solid irregularly shaped smooth mass on medioventral aspect of cranial left lung lobe, on incision mass has a yellow tan center.
- Histopathology pending

Cause of Death? **Euthanasia via IV pentobarbital**

Was the animal showing any abnormal symptoms prior to death? **No**

Please let me know if you need any other information.

Thank you,

(b) (6)

(b) (6)

Charles River

(b) (6)

(b) (6)

(b) (6)

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Pronouns: she, her, hers

(b) (4) Necropsy (b) (4)

From Date 02/20/2023 15:52:46 Reference # (b) (4) Registered ☒

Domain Animal Activity Necropsy

Animal ID (b) (4) Status Performed Performed by (b) (6) (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/20/2023 14:20:25	Date Out	02/20/2023 14:20:25
02/20/2023 14:20:25	Location at Stock Out - Path	(b) (4)
02/23/2023 15:56:24	Died during quarantine	Yes
02/20/2023 14:20:25	Euthanasia Reason	See necropsy report.
02/20/2023 14:20:25	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) during quarantine TST, pt found to have grade 3 reaction OD. No other significant clinical history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin **Abnormal Skin Description**
☒ mild erythema and swelling of superior palpebra OD.

Oral **Abnormal Oral Cavity Description**
☐

(b) (4)

Necropsy

(b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

enlarged tracheobronchial lymph nodes measuring 1.3-1.5cm.

Respiratory System



Abnormal Respiratory System Description

0.5cm tan solid irregularly shaped smooth mass on medioventral aspect of cranial left lung lobe, on incision mass has a yellow tan center.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

one focal hard white 1mm nodule in parenchyma of right medial hepatic lobe

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) Necropsy (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Charles River Research Animal Diagnostic Services

(g) (q)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

04 March 2023

History:

Customer: Charles River Houston - Quarantine

Strain:

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine necropsy for Houston. Found to have grade 3 reaction to OD. Necropsy was performed by submitter and found enlarged tracheobronchial lymph node (TBLN) and 0.5cm mass on lung lobe.

Microscopic Diagnoses:

#1 (b) (4) Lung: Abscess, mild, focal.

Acid Fast Stain (lung): Positive for small numbers of acid-fast bacilli.

Spleen, TBLN, Liver, Kidney, Adrenal gland, Urinary bladder, Heart, Stomach, Small intestines,

Large intestines: Within normal limits.

Comment:

The pulmonary lesions were consistent with Mycobacteriosis with acid fast noted within the pulmonary lesions. Mesenteric lymph node was not submitted.

(g) (q)

24-08898_000669

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005858****Animal Location**

Harris County TX, US

NFC Control Number:

19823018474

Date Collected:

02/20/2023

Date Received:

02/22/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:

This is a billable case.

This test has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1806008 **Case #:** TB23-02317 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result**Isolate****Acid fast bacteria recovered****Mycobacterium tuberculosis complex****Direct PCR for M. tuberculosis complex - IS1081**

Detected Ct = 28.90727234

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1806008 **Case #:** TB23-02318 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 24.89655113

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 1806008 **Case #:** TB23-02319 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

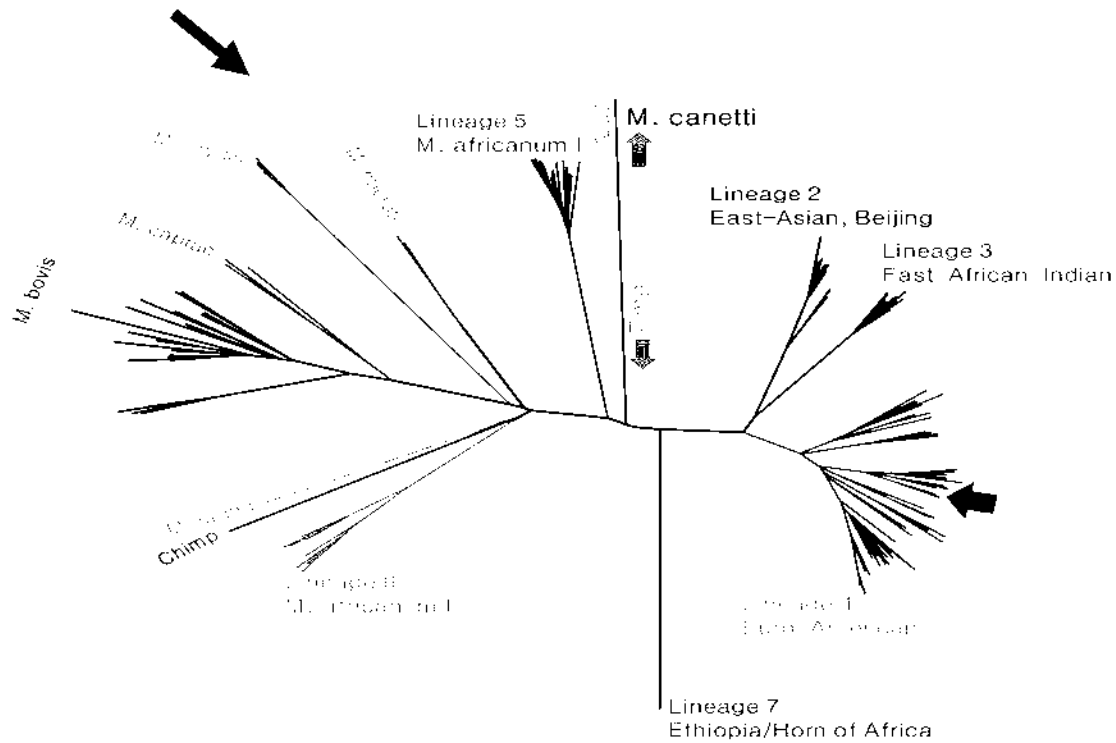
(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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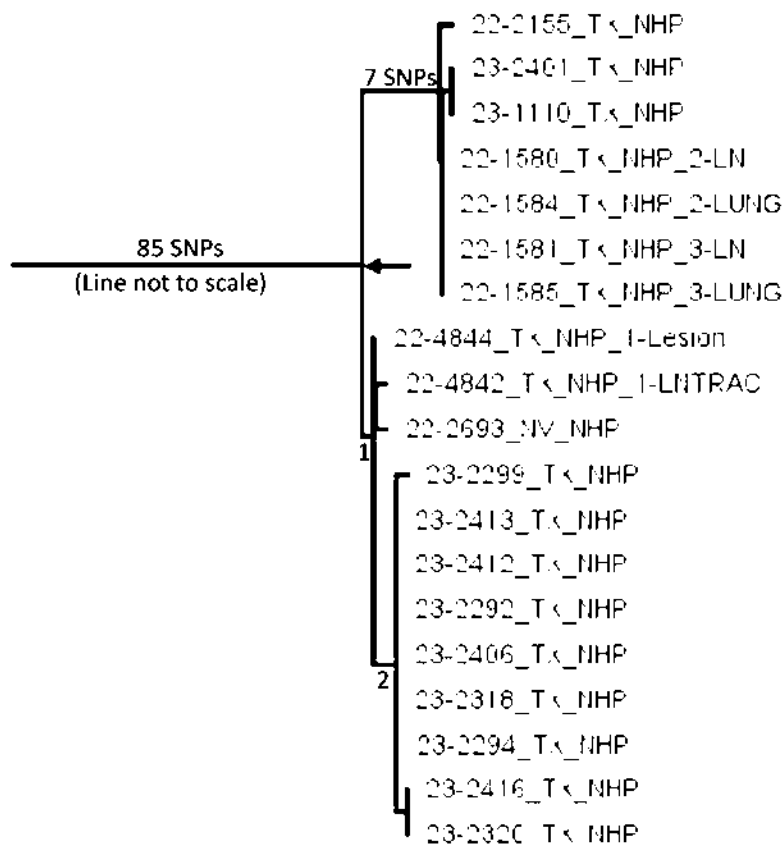
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:
Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3150708	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3230370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4073545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487			
root	G	T	C	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	A	G	G	A	A	G	G	A	A	G	A	A	C	G	A	A	G	C	G	T	G	G	T	G		
22-1580 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	C	G	T	G	G	T	G	
22-1581 TX NHP 2 UNG	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	C	G	T	G	G	T	G	
22-1581 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	C	G	T	G	G	T	G	
22-1585 TX NHP 3 UNG	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	C	G	T	G	G	T	G	
22-2155 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	A	C	G	T	G	G	T	G
23-2401 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	G	G	T	G	G	T	G	
23-1110 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G	A	G		A	G	G	G	T	G	G	T	G	
22-2693 NV NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	G	G	T	G				
22-4844 TX NHP 1 lesion	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	G	G	T	G				
22-4847 TX NHP 1 ENTRAC	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	G	G	T	G				
23-2413 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	G				
23-2412 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	G				
23-2292 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	G				
23-2406 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	G				
23-2318 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	G				
23-2299 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	A	G				
23-2294 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	R				
23-2416 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	A				
23-2320 TX NHP	G	A	G	G	A	A	G	G	A	A	G	G	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C		T	A	A	T	A				

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com (b) (6) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6) Houston, TX 77047

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED
02/20/23

12. AUTHORIZED BY

(b) (6)

7. NO. IN HERD/FLOCK AFFECTED

8. NO. IN HERD/FLOCK DEAD

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung;

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE OF

X

(b) (6)

2/21/23

9

NVSL USE ONLY

CONDITION

PRIORITY 3

DIST

(b) (6)

RECEIVED BY

(b) (6)

23 - 005856
MB

502739
02/22/2023

VS FORM 10-4
AUG 2009

24-08898_000642

(b) (4) - Necropsy (b) (4)

From Date

02/20/2023 10:47:05

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (4)

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/20/2023 10:46:29	Date Out	02/20/2023 10:46:29
02/20/2023 10:46:29	Location at Stock Out - Path	(b) (4)
02/21/2023 14:51:31	Died during quarantine	Yes
02/20/2023 10:46:29	Euthanasia Reason	See necropsy report
02/20/2023 10:46:29	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

(b) (4) fascicularis arrived at site 01.15.23. At 72h read of TB test reported for grade 3 reaction. No other significant history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



moderately erythematous super palpebra OS.

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Two moderately enlarged tracheobronchial lymph nodes, approx 1 cm and 1.5 cm

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4) Necropsy (b) (4)

Microbiology

TB microbiology pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Re: [External Email]Request Permission to ship NHP Samples 1 of 8 02.21.23

Lehman, Kimberly MRP APHIS <Kimberly.Lehman@usda.gov>

Tue 2/21/2023 4:51 PM

To: (b) (6) <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS
<NvslCaseCoordinator@usda.gov>; (b) (6) (b) (6)@crl.com (b) (6)
(b) (6)@crl.com (b) (6)@crl.com (b) (6)@crl.com (b) (6)@crl.com
<(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

We will accept samples from (b) (4). Thank you for the information. Please send us the tracking number, filovirus testing results and the histopathology results when you have it please.

Kim Lehman

Kimberly A Lehman, DVM, MPH, DACVPM

Supervisory Veterinary Medical Officer

Director's Office

USDA-APHIS-VS-D&B-NVSL

1920 Dayton Ave

Ames, IA 50010

Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov

From: (b) (6) <(b) (6)@crl.com>

Sent: Tuesday, February 21, 2023 2:59 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; (b) (6)
<(b) (6)@crl.com>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; (b) (6)
<(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>;
(b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Subject: [External Email]Request Permission to ship NHP Samples 1 of 8 02.21.23

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday, February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report is attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment: (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

24-08898 000646

Was a complete necropsy and with histology done on this animal? **Yes**

If so, can you provide those results?

- Gross necropsy revealed a moderately erythematous superior palpebra OS and two moderately enlarged tracheobronchial lymph nodes, approx. 1 cm and 1.5 cm
- Histopathology pending

Cause of Death? **Euthanasia via IV pentobarbital**

Was the animal showing any abnormal symptoms prior to death? **No**

Please let me know if you need any other information.

Thank you,

(b) (6)

(b) (6)

Charles River

(b) (6)

(b) (6)

(b) (6)

cri.com | www.criver.com

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Pronouns: she, her, hers

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005856****Animal Location**

Harris County TX, US

NFC Control Number:

19823018472

Date Collected:

02/20/2023

Date Received:

02/22/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

TB-10-4

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2002040 **Case #:** TB23-02401 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.61135674

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 2002040 **Case #:** TB23-02402 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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APPENDIX – GENOTYPING REPORT

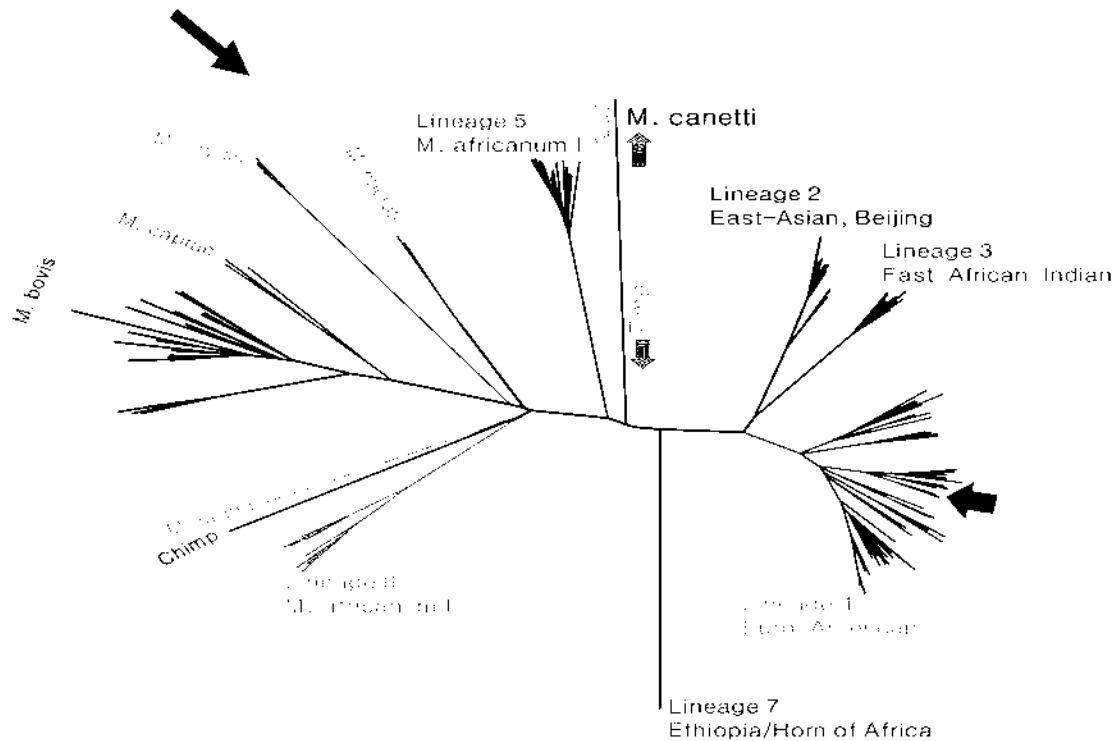
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



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22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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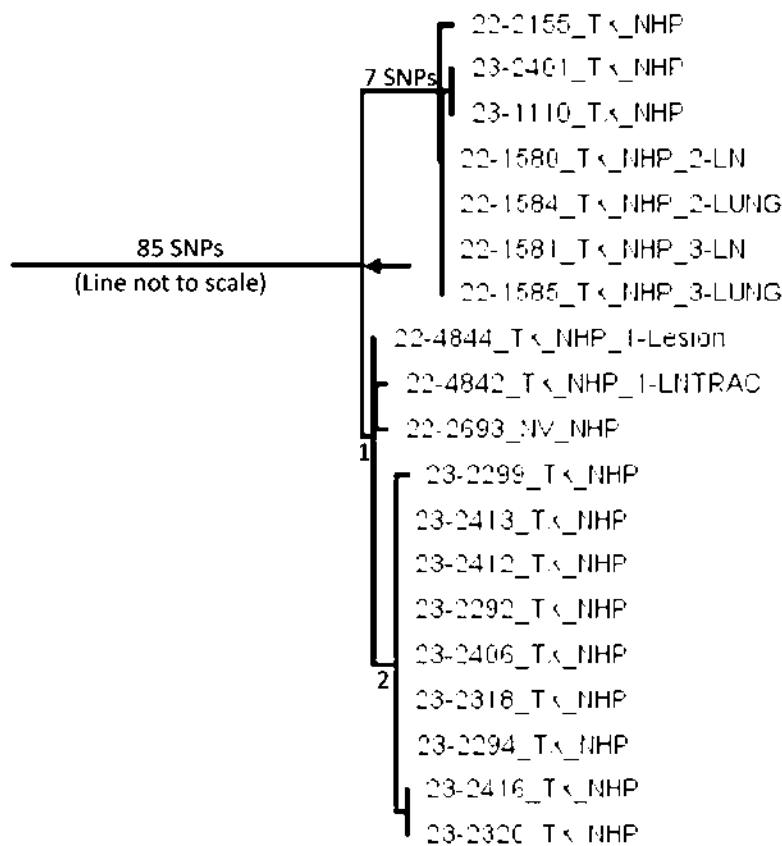
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3150708	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3230370	NC_000962.3:3293637	NC_000962.3:3340841	NC_000962.3:33449065	NC_000962.3:33453785	NC_000962.3:33496294	NC_000962.3:33627787	NC_000962.3:33801458	NC_000962.3:33957533	NC_000962.3:33984291	NC_000962.3:34068655	NC_000962.3:34073545	NC_000962.3:34091916	NC_000962.3:34119052	NC_000962.3:34144714	NC_000962.3:34199069	NC_000962.3:34259800	NC_000962.3:34313309	NC_000962.3:34387015	NC_000962.3:34407309	NC_000962.3:34410735	NC_000962.3:3489395	NC_000962.3:3489396	NC_000962.3:3494566	NC_000962.3:34687213	NC_000962.3:32952996	NC_000962.3:33467800	NC_000962.3:34364853	NC_000962.3:3171922	NC_000962.3:33347753	NC_000962.3:32874747	NC_000962.3:32080995	NC_000962.3:3130886	NC_000962.3:33428942	NC_000962.3:33461421	NC_000962.3:31594487				
root	G	T	C	A	G	G	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	G	A	T	G	G	G	A	A	A	C	G	A	A	G	C	G	T	G	G	T	G			
22 1580 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	G	G	T	G	G	T	G				
22 1581 TX NHP 2 UNG	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	G	G	T	G	G	T	G				
22 1581 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	G	G	T	G	G	T	G				
22 1585 TX NHP 3 UNG	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	G	G	T	G	G	T	G				
22 2155 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	A	C	G	T	G	G	T	G			
23 2401 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	G	G	T	G	G	T	G				
23 1110 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	G	A	G	G	G	T	G	G	T	G				
22 2693 NV NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G
22 4844 TX NHP 1 lesion	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G
22 4847 TX NHP 1 ENTRAC	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	G	G	T	G	
23 2413 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23 2412 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23 2292 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23 2406 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23 2318 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23 2299 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	A	G
23 2294 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	R
23 2416 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	A
23 2320 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	G	A	A	G	A	A	G	G	A	A	G	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	A

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OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) (b) (6) Charles River Laboratories	2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) .crl.com (b) (6) .crl.com	OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6) FAX NO. (b) (6)	4. LOCATION OF ANIMALS PREMISES ID	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047	COUNTY Harris	STATE/COUNTRY TX/US

5. PAYMENT METHOD

<input type="checkbox"/> USER FEE ACCOUNT NO.	<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars)	<input checked="" type="checkbox"/> CREDIT CARD
---	---	---

6. HERD/FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 02/20/23
8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)				14. COUNTRY OF ORIGIN/DESTINATION (b) (4)
<input type="checkbox"/> Interstate Movement	<input type="checkbox"/> Import	<input checked="" type="checkbox"/> TB	<input type="checkbox"/> Reagent Evaluation	
<input type="checkbox"/> Export	<input type="checkbox"/> FAD/EP Diagnostic	<input type="checkbox"/> General Diagnostic	<input type="checkbox"/> NVSL Intralab	
<input type="checkbox"/> Pre-Import	<input type="checkbox"/> Surveillance	<input type="checkbox"/> Developmental Research		

16. PRESERVATION	15. REFERRAL NUMBER
<input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input checked="" type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)	

17. SPECIMENS SUBMITTED ("X" applicable item(s))	18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)
<input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus <input type="checkbox"/> DNA/RNA	
<input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (specify) <input type="checkbox"/> Water	

19. SPECIES OR SOURCE ("X" ONLY one)	20. NUMBER OF ANIMALS SAMPLED (b) (4)
<input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (specify)	
<input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (specify) <input type="checkbox"/> Environment <input type="checkbox"/> Reagent	
<input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (specify) <input type="checkbox"/> Elk	

21. IDENTIFICATION (See instructions <250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).
see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE X (b) (6) 2/21/23 9	23 - 005854 MB 02/22/2023 602739
CONDITION D1 PRIORITY 3 NVSL USE ONLY (b) (6) RECEIVED BY (b) (6)	
VS FORM 10-4 AUG 2009	

24-08898_000631

Thu 3/2/2023 4:48 PM

Pathology report for 2011071.

Sent: Tuesday, February 21, 2023 4:51 PM

Subject: Re: [External Email]Request Permission to ship NHP Samples 2 of 8 02.21.23

Kim Lehman

Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov

1/2

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results?

- Gross necropsy revealed moderately erythematous superior palpebra OD, enlarged tracheobronchial lymph nodes, 3mm firm solid tan nodule in medial aspect of caudal left lung lobe parenchyma
- Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

Thank you,

(b) (6)

Charles River

(b) (6)

(b) (6)

@crl.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

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(b) (4) Necropsy (b) (4)

From Date

02/20/2023 12:26:01

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (4)

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (6), (b) (4), (b) (7)(C)
02/20/2023 12:25:28	Date Out	02/20/2023 12:25:28
02/20/2023 12:25:28	Location at Stock Out - Path	(b) (4)
02/21/2023 15:04:24	Died during quarantine	Yes
02/20/2023 12:25:28	Euthanasia Reason	See necropsy report
02/20/2023 12:25:28	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

(b) (4) (b) (4) Macaca fascicularis arrived on site 01,15,23. At 72h read of TB test, animal reported for grade 3 reaction. No other significant history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Moderately erythematous superior palpebra OD.

Oral

Abnormal Oral Cavity Description



(b) (6), (b) (4), (b) (5)

Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Enlarged tracheobronchial lymph nodes

Respiratory System



Abnormal Respiratory System Description

3 mm firm solid tan nodule in medial aspect caudal left lung lobe parenchyma

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4) - Necropsy - (b) (4)

Microbiology

TB microbiology pending

Other Diagnostic Test

(b) (4)

Histopathology

results pending

Final Diagnosis

Event Comment

Document(s)



Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order # (b) (4)

01 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine necropsy for Houston (b) (4) (b) (4) origin *Macaca fascicularis* arrived (b) (4). Grade 3 reaction at 72 hours on TB test. Necropsy was performed by submitter found enlarged TBLN and 3mm tan nodule on left lung. No other significant lesions.

Microscopic Diagnoses:

(b) (4): Lung: Nodule of inflammatory cell infiltrates, marginal, mild, focal.

Acid Fast Stain (lung, TBLN): Negative for organisms.

Spleen, Lymph node (TBLN), Liver, Kidney, Heart, Adrenal gland, Urinary bladder, Stomach,

Small intestine, Large intestine: Within normal limits.

Comment:

There were no microscopic lesions to suggest Mycobacteriosis. The small lung nodule was inflammatory and chronic but not consistent with abscess/granuloma.

(b) (6)

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005854****Animal Location**

Harris County TX, US

NFC Control Number:

19823018470

Date Collected:

02/20/2023

Date Received:

02/22/2023

Date Completed:

10/04/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2011071 **Case #:** TB23-02399 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all the isolates in the NVSL Database. This isolate is a *Mycobacterium orygis*. This isolate has the same SNP pattern as the majority of the isolates in the branch. See Genotyping report.

Animal ID: 2011071 **Case #:** TB23-02400 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.25179291

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
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APPENDIX – GENOTYPING REPORT

4 October 2023

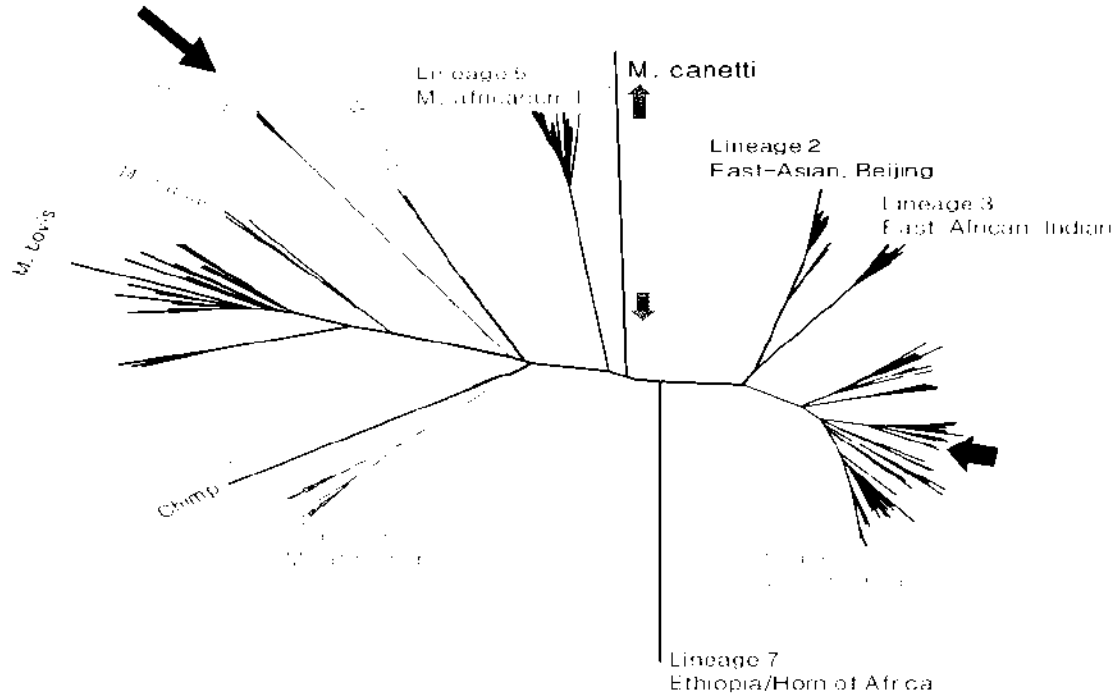
Accession:

23-012103

23-005854

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.





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APPENDIX – GENOTYPING REPORT

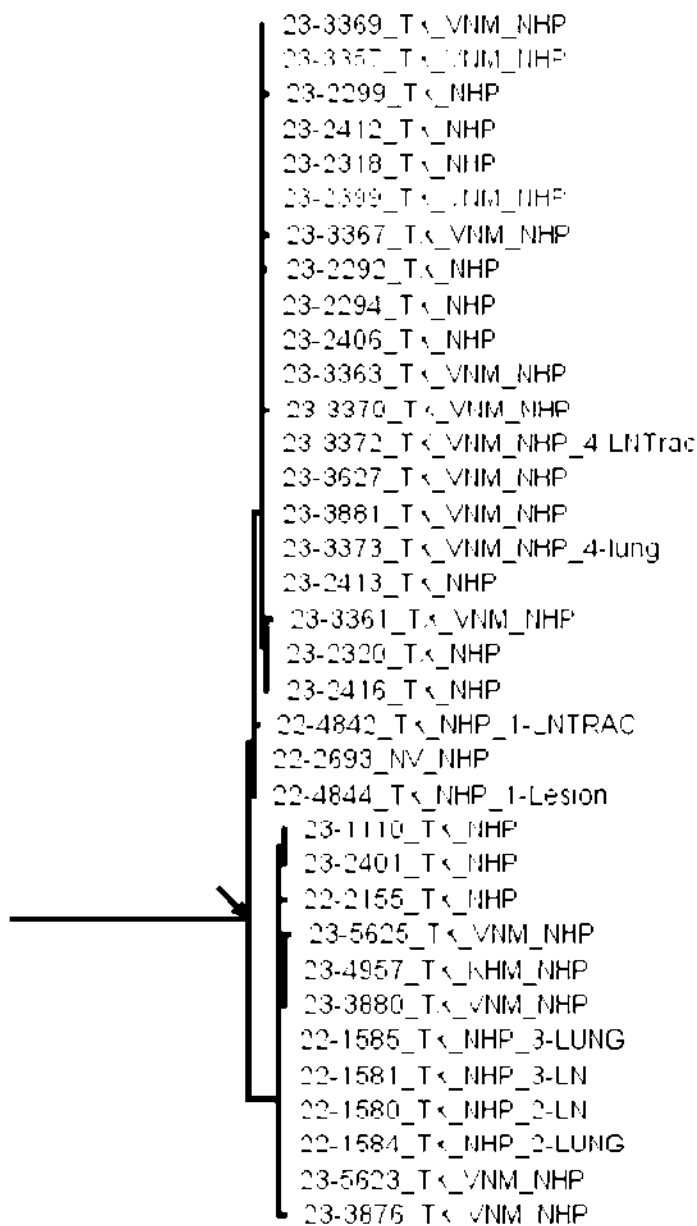
4 October 2023

Accession:

23-012103

23-005854

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. The two isolates associated with these submissions are in red. These two isolates have the same SNP pattern as the majority of the isolates in this branch.





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APPENDIX – GENOTYPING REPORT

4 October 2023

Accession:

23-012103

23-005854

Table 1: Abbreviated SNP table of NVSL Group Orygis. Isolates 23-3357 and 23-2399 have the same SNP pattern as the majority (bracket) of the isolates from this branch (see Figure 1).

	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259860	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:2874747	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:3010690	NC_000962.3:4317051	NC_000962.3:1594487	NC_000962.3:3332273
root	T	A	A	G	G	G	A	T	G	G	G	G	G	T	G	A	G	G
23-2292_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3369_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3357_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2412_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2318_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2399_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3372_TX_VNM_NHP_4-LNTrac		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3627_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3881_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3373_TX_VNM_NHP_4-lung		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2413_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2406_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3363_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2299_TX_NHP		G	G	A	A	A	G			A		A	A	A	G	A	G	G
23-3367_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	A	A	G	G
23-3370_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	G	G	G
23-2294_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	R	G
23-2320_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	A	G
23-2416_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	A	G
23-3361_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	A	A

Details		✕
Date	2023-01-11	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC.	
Hs_code	01061100	
Product_description	LON G-TAILED MONKEY (MACACA FASCICULARIS)#&EN	
Value_usd	3132000	
Unit_price_usd	5800	
Qty_unit	UNC (ANIMALS)	
Qty	540	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE, HOANG DON G COMMUNE, LANG SON CITY, LANG SON PROVINCE, VIETNAM,	
Exporter_phone		
undefined		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Load_port_vn		
Commodity_vn	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	5800	
Value_dclr	3132000	
Currency_dclr	5800	
Exchange_rate_vnd	23340	
Value_vnd	73100880000	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	3052800437400	
Trans_mode	AIR	

Exhibit 15

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

CMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) crl.com (b) (6) crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. 713-433-6971

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

02/21/23

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

(b) (6)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung;

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

2

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS
SAMPLED

1

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE

X

(b) (6)

2/21/23

0

23 - 005857
MB

CONDITION

D1

PRIORITY

3

DIST

(b) (6)

RECEIVED BY

(b) (6)

502739
02/22/2023

VS FORM 10-4
AUG 2009

24-08898_000653

[External Email] Request Permission to ship NHP Samples 8 of 8 02.21.23

(b) (6) <(b) (6)@crl.com>

Tue 2/21/2023 5:09 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov> (b) (6)
 <(b) (6)@crl.com>; Bravo Garcia, Doris MRP APHIS <doris.m.bravo@usda.gov> (b) (6)
 <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6)
 <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com>; Lehman, Kimberly MRP APHIS
 <Kimberly.Lehman@usda.gov> (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-
 CaseManagement <NVSL.MB.caseManager@usda.gov>

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report is attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)

Where did the animals originate from (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results?

- Gross necropsy revealed
 - minor erythema, mild swelling superior right palpebra
 - severe adhesions between thoracic wall, diaphragm and serosal surface of lungs. Ventromedial aspect of right cranial lung lobe has a 5mm tan irregularly shaped mass that is casseous upon incision
- Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

This is the last animal that was necropsied today.

Thank you,

(b) (6)
 (b) (6) Charles River
 (b) (6) (b) (6)
 (b) (6) crl.com | www.criver.com
[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)
 Pronouns: she, her, hers

24-08898 000654

(b) (4) - Necropsy (b) (4)

From Date

02/21/2023 16:56:59

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/21/2023 15:14:44	Date Out	02/21/2023 15:14:44
02/21/2023 15:14:44	Location at Stock Out - Path	(b) (4)
02/21/2023 17:03:41	Died during quarantine	Yes
02/21/2023 15:14:44	Euthanasia Reason	See necropsy report
02/21/2023 15:14:44	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

PT arrived at facility (b) (4) pt reported for grade 3 TST OD at 72h read.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



minor erythema, mild swelling superior right palpebra

Oral

Abnormal Oral Cavity Description



Lymph Nodes

Abnormal Lymph Nodes Description



(b) (4) - Necropsy - (b) (4)

Respiratory System



Abnormal Respiratory System Description

Severe adhesions between thoracic wall, diaphragm and serosal surface of lungs. Ventromedial aspect of right cranial lung lobe has a 5mm tan irregularly shaped mass that is caseous upon incision.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4) - Necropsy - (b) (4)

Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

01 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain:
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine necropsy for Houston. Grade 3 TST PD at 72 hour read. Necropsy was performed by submitter found severe adhesions between thoracic wall, diaphragm, and serosal surface of lungs. 5mm tan irregularly shaped mass with caseous center.

Microscopic Diagnoses:

#1 (b) (4) Lung: Abscess/granuloma, mild, focal.

Acid Fast Stain (lung): Few acid-fast bacilli associated with pulmonary lesions.

Large intestine: Balantidium coli, luminal.

Lymph node (TBLN), Liver, Spleen, Heart, Kidney, Adrenal gland, Urinary bladder, Stomach,

Small intestines: Within normal limits.

Comment:

The lung lesion with intralesional acid-fast bacilli were consistent with Mycobacteriosis. No other significant changes were noted.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005857****Animal Location**

Harris County TX, US

NFC Control Number:

19823018473

Date Collected:

02/21/2023

Date Received:

02/22/2023

Date Completed:

05/22/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1908039 **Case #:** TB23-02291 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 33.45985794

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1908039 Case #: TB23-02292 Sample: 2 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

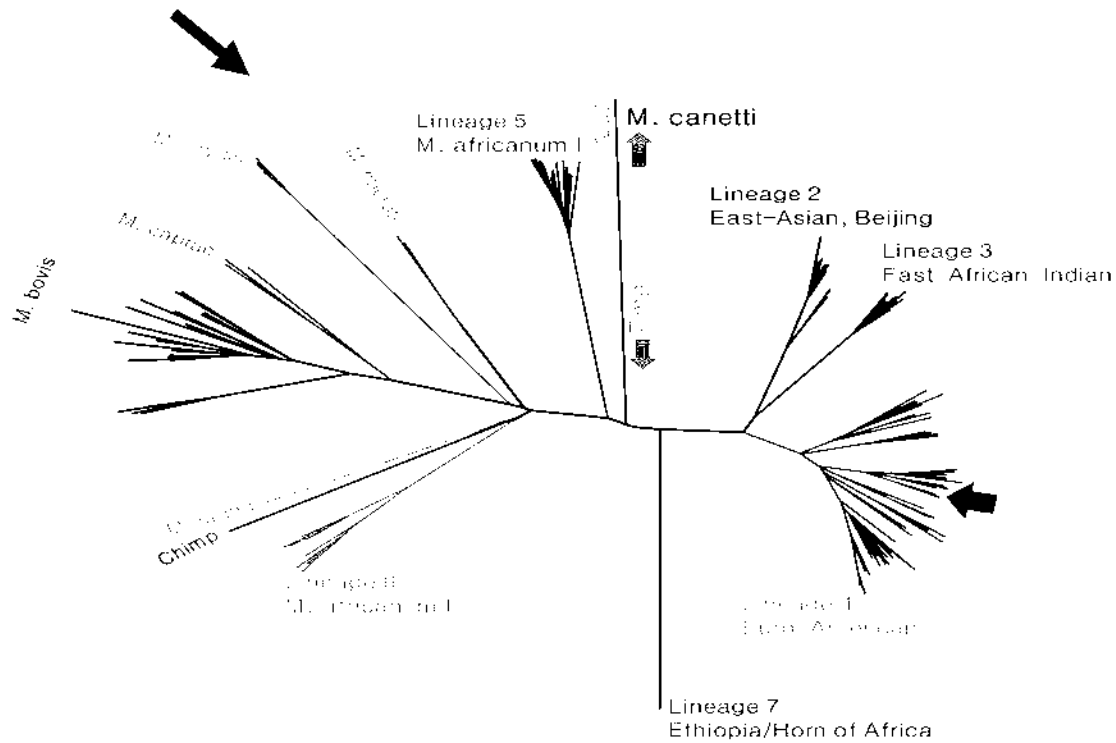
(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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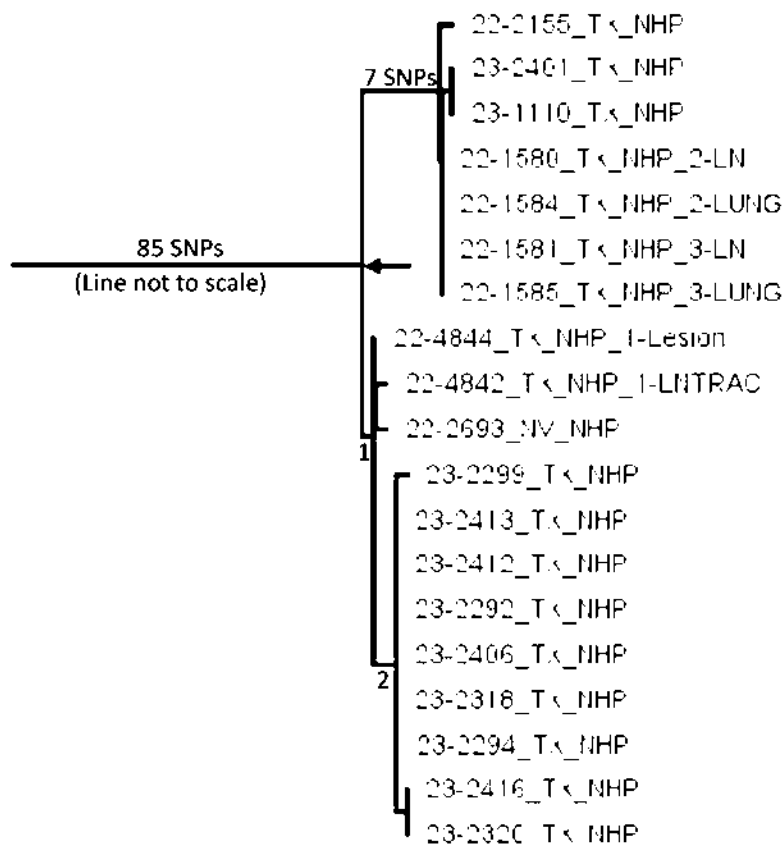
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:
Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3150708	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3230370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4073545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487		
root	G	T	C	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	A	G	G	A	A	G	G	A	A	G	A	A	C	G	A	A	G	C	G	T	G	G	T	G	
22-1580 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	G	C	G	T	G	G	T	G
22-1581 TX NHP 2 LUNG	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	G	C	G	T	G	G	T	G	
22-1581 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	G	C	G	T	G	G	T	G	
22-1585 TX NHP 3 LUNG	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	G	C	G	T	G	G	T	G	
22-2155 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	C	G	T	G	G	T	G	
23-2401 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	G	G	T	G	G	T	G		
23-1110 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	A	G	A	A	G	A	A	G	A	G	G	G	T	G	G	T	G		
22-2693 NV NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G					
22-4844 TX NHP 1 lesion	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G					
22-4847 TX NHP 1 ENTRAC	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G					
23-2413 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G					
23-2412 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G					
23-2292 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G					
23-2406 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G					
23-2318 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G					
23-2299 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	A	G					
23-2294 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	R					
23-2416 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	A					
23-2320 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	A					

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OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE

OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com (b) (6) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

MAILING ADDRESS (Street, City, State, ZIP Code)

COUNTY

Harris

STATE/COUNTRY

TX/US

(b) (6) Houston, TX 77047

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

11. DATE COLLECTED

02/21/23

8. NO. IN HERD/FLOCK
DEAD

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Faces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung;

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

Stomach

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

(b) (4)

20. NUMBER OF ANIMALS
SAMPLED

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23 - 005862

MB

23. SUBMITTER'S DATE

(b) (6)

2/21/23

NVSL USE ONLY

CONDITION

PRIORITY

(b) (6)

RECEIVED BY

(b) (6)

502739

02/22/2023

VS FORM 10-4
AUG 2009

24-08898_000697

[External Email] Request Permission to ship NHP Samples 7 of 8 02.21.23

(b) (6) <(b) (6)@crl.com>

Tue 2/21/2023 5:04 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov> (b) (6)
 <(b) (6)@crl.com>; Bravo Garcia, Doris MRP APHIS <doris.m.bravo@usda.gov> (b) (6)
 <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6)
 <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com>; Lehman, Kimberly MRP APHIS
 <Kimberly.Lehman@usda.gov> (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-
 CaseManagement <NVSL.MB.caseManager@usda.gov>

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report is attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results?

- Gross necropsy revealed
 - Superior right palpebra moderately erythematous and swollen, crusted, scabbed and ulcerated.
 - 2cm tracheobronchial lymph node as tracheal carina, with caseous center upon incision.
 - 3mm tan mass on medial aspect of left caudal lung lobe. Upon incision, the center is caseous.
 - Generalized multifocal pinpoint white raised lesions subserosa of stomach, more lesions seen on the lesser curvature than the greater curvature.
- Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

Thank you,

(b) (6)

(b) (6) | Charles River

P: (b) (6) | M: (b) (6)

(b) (6) | crl.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

24-08898 000698

(b) (4) Necropsy (b) (4)

From Date

02/21/2023 16:43:05

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/21/2023 15:14:44	Date Out	02/21/2023 15:14:44
02/21/2023 15:14:44	Location at Stock Out - Pat	(b) (4)
02/21/2023 16:56:54	Died during quarantine	Yes
02/21/2023 15:14:44	Euthanasia Reason	See necropsy report
02/21/2023 15:14:44	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) Grade 5 TST OD at 72hr read. No other significant clinical history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Superior right palpebra moderately erythematous and swollen, crusted, scabbed and ulcerated.

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

2cm tracheobronchial lymph node as tracheal carina; with caseous center upon incision.

Respiratory System



Abnormal Respiratory System Description

3mm tan mass on medial aspect of left caudal lung lobe. Upon incision, the center is casseous.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Generalized multifocal pinpoint white raised lesions subserosa of stomach, more lesions seen on the lesser curvature than the greater curvature.

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) Necropsy (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

07 March 2023

History:

Customer: Charles River Houston - Quarantine

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine necropsy for Houston B test at 72 hours. Necropsy was performed by submitter found caseous tracheobronchial lymph node and lung mass, and pinpoint raised white lesion of stomach.

Microscopic Diagnoses:

#1 (b) (4) Lung, tracheobronchial lymph node (TBLN): Abscess, mild, focal.

TBLN: Lymphoid hyperplasia, mild, multifocal.

Acid Fast Stain (Lung, TBLN): Negative for organisms.

Stomach: Parasitic nodule, submucosa, focal.

Spleen, Urinary bladder, Liver, Heart, Kidney, Small intestines, Large intestines: Within normal limits.

Comment:

Although acid-fast organisms were not found, the history, gross, and microscopic changes are strongly suggestive of Mycobacteriosis in this animal. There was an incidental parasitic nodule in the stomach. Definitive identification was not possible but larval helminth was considered. Mesenteric lymph node was not submitted.

(b) (6)

24-08898_000702

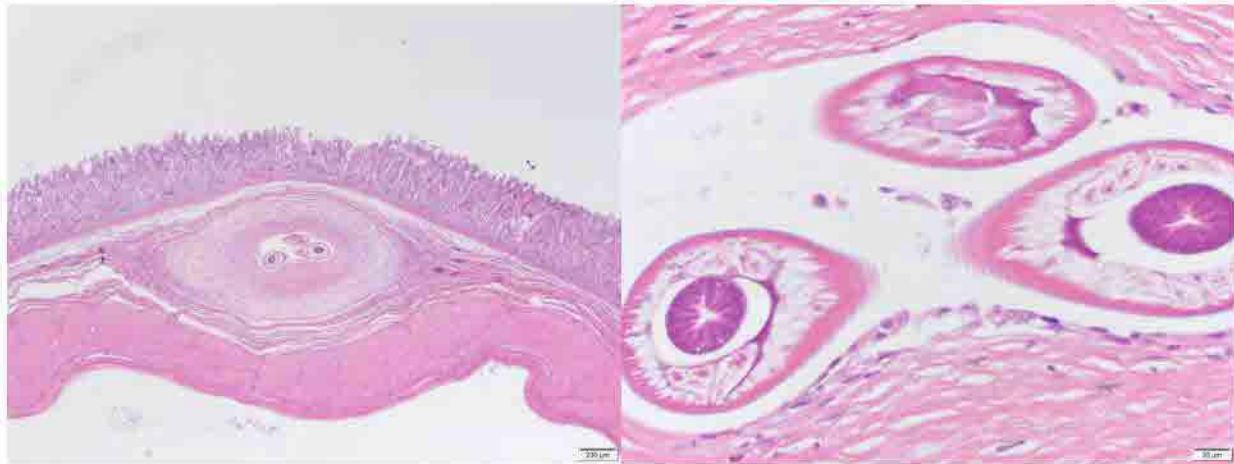


Figure 1: Photomicrograph, Stomach with incidental parasitic nodule. Left: 40X Right: 400X, H&E

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005862****Animal Location**

Harris County TX, US

NFC Control Number:

19823018478

Date Collected:

02/21/2023

Date Received:

02/22/2023

Date Completed:

05/22/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2005034 **Case #:** TB23-02320 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.93312454

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 2005034 **Case #:** TB23-02321 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 22.97507668

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2005034 **Case #:** TB23-02322 **Sample:** 3 **Specimen Type:** Stomach **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

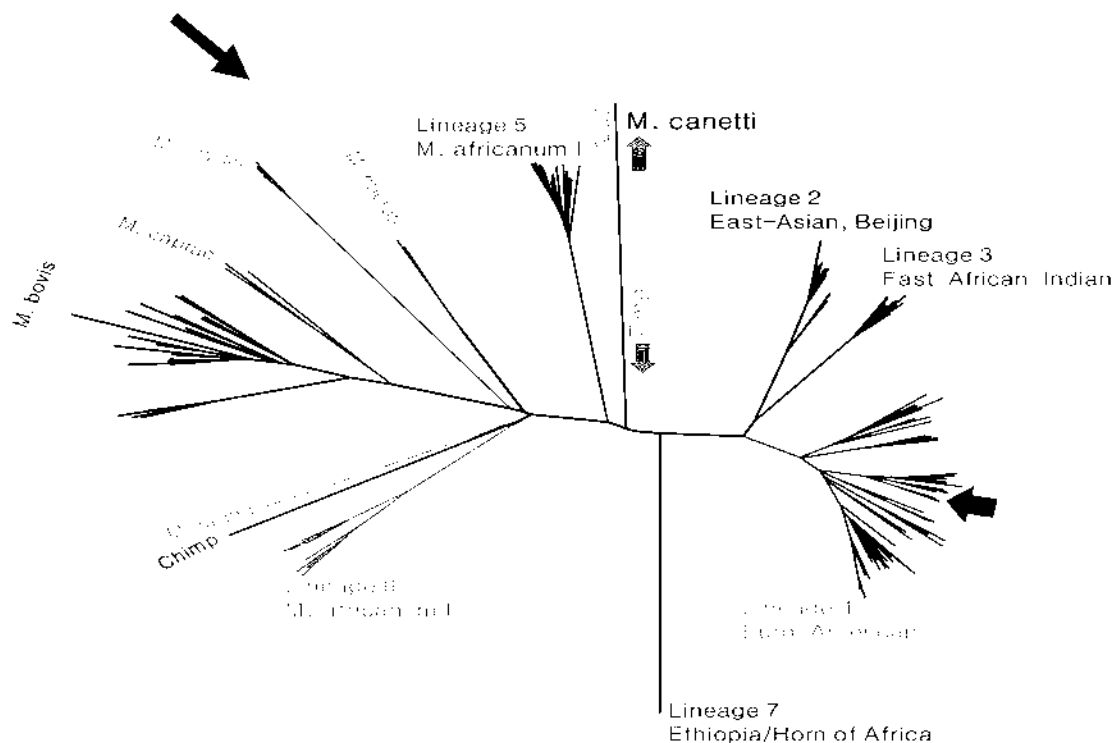
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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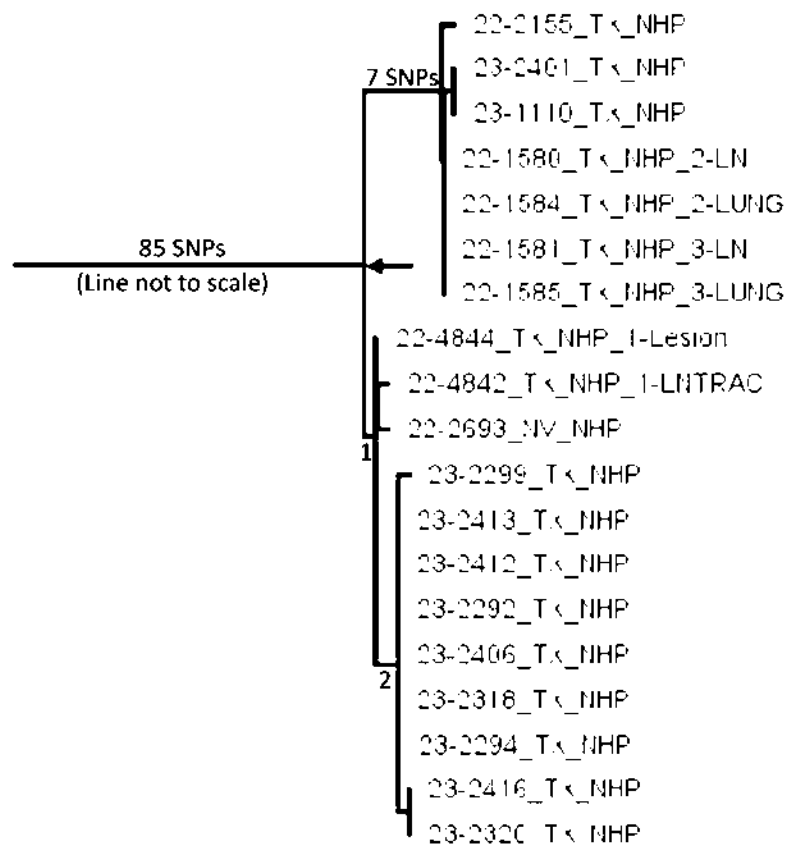
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:
Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3150708	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3230370	NC_000962.3:3293637	NC_000962.3:3340841	NC_000962.3:33449065	NC_000962.3:33453785	NC_000962.3:33496294	NC_000962.3:33627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4073545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:33467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:33347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:33428942	NC_000962.3:1461421	NC_000962.3:1594487		
root	G	T	C	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	A	G	G	A	A	G	G	A	A	G	G	A	A	C	G	A	A	G	C	G	T	G	G	T	G
22-1580 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G
22-1581 TX NHP 2 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G
22-1581 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G
22-1585 TX NHP 3 UN	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G
22-2155 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	A	C	G	T	G	G	T	G
23-2401 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G
23-1110 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	A	G	A	G	A	G	G	C	G	T	G	G	T	G
22-2693 NV NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G
22-4844 TX NHP 1 lesion	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G
22-4847 TX NHP 1 ENTRAC	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	G	G	T	G
23-2413 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23-2412 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23-2292 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23-2406 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23-2318 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	G
23-2299 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	A	G
23-2294 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	R
23-2416 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	A
23-2320 TX NHP	G	A	G	G	A	A	G	G	A	A	A	G	G	G	G	G	G	G	G	A	A	A	G	A	A	G	A	A	G	A	C	A	A	C	G	A	A	G	C	T	A	A	T	A

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

4. EMAIL ADDRESS

(b) (6) @crl.com (b) (6) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. 741-433-5846

FAX NO.

(b) (6)

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6) Houston, TX 77047

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD

Exp. date

Exp. date

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

7. NO. IN HERD/FLOCK AFFECTED

8. NO. IN HERD/FLOCK DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED
02/21/23

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ TBLN; Lung; liver

☐ DNA/RNA

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

☐ Reagent

☐ Cynomolgus

☐ Macaque

☐ Other (specify)

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

☐ Elk

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23.

(b) (6)

2/21/23

Q

23 - 005861
MB

CONDITION

PRIORITY

3

DIST

(b) (6)

RECEIVED BY

(b) (6)

VS FORM 10-4
AUG 2009

502739
02/22/2023

24-08898_000686

Re: [External Email]Request Permission to ship NHP Samples 6 of 8 02.21.23

Lehman, Kimberly MRP APHIS <Kimberly.Lehman@usda.gov>

Tue 2/21/2023 4:53 PM

To: (b) (6) <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS
<NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;
(b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

We will accept samples from (b) (4). Thank you for the information. Please send us the tracking number and the histopathology when you have it please.

Kim Lehman

Kimberly A Lehman, DVM, MPH, DACVPM
Supervisory Veterinary Medical Officer
Director's Office
USDA-APHIS-VS-D&B-NVSL
1920 Dayton Ave
Ames, IA 50010
Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov

From: (b) (6) <(b) (6)@crl.com>

Sent: Tuesday, February 21, 2023 4:49 PM

To: APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Subject: [External Email]Request Permission to ship NHP Samples 6 of 8 02.21.23

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report is attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)
Where did the animals originate from? (b) (4)
What was the date that they left the originating country? (b) (4)
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Was animals exposed to animals from other sources? No

24-08898 000687

Was a complete necropsy and with histology done on this animal? **Yes**

If so, can you provide those results?

- **Gross necropsy revealed**
 - ulceration, scabbing, moderate erythema and swelling superior palpebra OD
 - At the hilum of the left lung lobe, a 2-3cm irregularly shaped tracheobronchial lymph node that has a mixed casseous and purulent center upon incision. Other enlarged tracheobronchial lymph nodes noted measuring at most 1.2cm.
 - Well defined line of demarcation in cranial left lung lobe where distal half is hypermic. At the center of the line of demarcation there is a 1.5cm botryoid tan mass, that is casseous upon incision.
 - Eighteen multifocal 1-2mm hard white nodules throughout hepatic parenchyma.
- **Histopathology pending**

Cause of Death? **Euthanasia via IV pentobarbital**

Was the animal showing any abnormal symptoms prior to death? **No**

Please let me know if you need any other information.

Thank you,

(b) (6)

(b) (6) | Charles River

P: (b) (6) | M: (b) (6)

(b) (6) [crj.com](mailto:(b) (6)@crj.com) | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

(b) (4) Necropsy (b) (4)

From Date

02/21/2023 16:28:18

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/21/2023 15:14:44	Date Out	02/21/2023 15:14:44
02/21/2023 15:14:44	Location at Stock Out - Path	(b) (4)
02/21/2023 16:46:56	Died during quarantine	Yes
02/21/2023 15:14:44	Euthanasia Reason	See necropsy report
02/21/2023 15:14:44	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4) Pt reported for grade 5 reaction OD at 72hr TST read. No other significant clinical history.

Tentative Diagnosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



ulceration, scabbing, moderate erythema and swelling superior palpebra OD

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

At the hilum of the left lung lobe, a 2-3cm irregularly shaped tracheobronchial lymph node that has a mixed caseous and purulent center upon incision. Other enlarged tracheobronchial lymph nodes noted measuring at most 1.2cm.

Respiratory System



Abnormal Respiratory System Description

Well defined line of demarcation in cranial left lung lobe where distal half is hyperemic. At the center of the line of demarcation there is a 1.5cm botryoid tan mass, that is caseous upon incision.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Eighteen multifocal 1-2mm hard white nodules throughout hepatic parenchyma.

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Liver



Stomach



Ileum



Lung



Spleen



Duodenum



Colon



Heart Muscle



Kidney



Jejunum



Bladder



(b) (4) Necropsy - (b) (4)

Skeletal Muscle

Bone Marrow

Brain



Skin



Skin - Description



Other

Other - Description



Microbiology

TB culture pending.

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Pathology Report

LTM Order #: (b) (4)

08 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain:
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine necropsy for Houston. Grade 5 reaction at 72 hours TST. Necropsy performed by submitter found purulent tracheobronchial lymph node (TBLN), lung mass with caseous center, numerous hard, white nodules in liver.

Microscopic Diagnoses:

#1 (b) (4) Lung, TBLN: Abscess, moderate, multifocal.

Acid Fast Stain(lung, TBLN): Small numbers of acid-fast positive bacilli noted in lesions of lung and TBLN.

Liver: Hyalinized and degenerative material with peripheral mixed inflammation, mild, focal (parasitic granuloma).

Stomach: Lymphocytic gastritis, mild, focally extensive.

Spleen, Urinary bladder, Heart, Kidney, Mesenteric lymph node, Small intestine, Large intestines: Within normal limits.

Comment:

The microscopic lesions in the lung and TBLN were consistent with Mycobacteriosis and contained acid-fast bacteria. The liver nodule was an incidental parasite granuloma. The stomach change was incidental as well.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-005861****Animal Location**

Harris County TX, US

NFC Control Number:

19823018477

Date Collected:

02/21/2023

Date Received:

02/22/2023

Date Completed:

05/22/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2008032 **Case #:** TB23-02299 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 22.99157906

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 2008032 **Case #:** TB23-02300 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 30.94801903

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2008032 **Case #:** TB23-02301 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 16

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

SPECIMEN SUBMISSION

PAGE
OF☒ Check if wildlife (no owner)

TX/US

TX/US

☒ Chen

15. REFERRAL NUMBER

TBLN, Lung, Liver

Synthetic Muscle

IDENTIFICATION

Sex

(b) (4)

see attached necropsy report

23-006500

MB

02/28/2023

502739

VS FORM 10-4

AUG 2009

24-08898 000708

24-08898_000708

Supervisory Veterinary Medical Officer**Director's Office****USDA-APHIS-VS-D&B-NVSL****1920 Dayton Ave****Ames, IA 50010****Ph: (515) 337-6335 | Kimberly.Lehman@usda.gov****From:** (b) (6) <(b) (6)@crl.com>**Sent:** Monday, February 27, 2023 11:26 AM**To:** Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>**Cc:** (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>**Subject:** [External Email]Request Permission to ship NHP Samples

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send an NHP sample for Mycobacterium testing today (2/27/23) for arrival tomorrow (2/28/23). Please let us know if you are agreeable to this. The necropsy report is attached. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported (b) (4)

Have any cohorts died of unknown causes? **No**Was animals exposed to animals from other sources? **No**Was a complete necropsy and with histology done on this animal? **Yes**

If so, can you provide those results?

- **Gross necropsy revealed: enlarged tracheobronchial lymph node (1.5cm), 0.8cm firm solid tan nodule in parenchyma of dorsomedial aspect of right caudal lung lobe, lungs diffusely hemorrhagic, 0.3cm cream colored firm solid nodule in parenchyma of right medial hepatic lobe. Upon incision, center is tan.**
- **Histopathology pending**

Cause of Death? **Euthanasia with pentobarbital IV**Was the animal showing any abnormal symptoms prior to death? **No**

Please let me know if you need any other information.

24-08898 000709

(b) (6) DVM, RLATG

(b) (6) ouston | Charles River

(b) (6) Road, Houston, TX 77047

(b) (6) crl.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

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(b) (4) Necropsy (b) (4)

From Date

02/27/2023 10:58:00

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6), (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
02/27/2023 10:56:52	Date Out	02/27/2023 10:56:52
02/27/2023 10:56:52	Location at Stock Out - Path	(b) (4)
02/27/2023 11:09:24	Died during quarantine	Yes
02/27/2023 10:56:52	Euthanasia Reason	See necropsy report
02/27/2023 10:56:52	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt had grade 3 TST at 72h read, no other significant clinical history.

Tentative Diagnosis

r/o TB

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Enlarged tracheobronchia lymph node (1.5cm)

Respiratory System



Abnormal Respiratory System Description

0.8cm firm solid tan nodule in parenchyma of dorsomedial aspect of right caudal lung lobe. Lungs diffusely hemorrhagic.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

0.3cm cream colored firm solid nodule in parenchyma of right medial hepatic lobe. Upon incision, center is tan.

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



(b) (4) Necropsy (b) (4)

Skin

Skin - Description



Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6) 2/27/23 (b) (6)

Pathology Report

LTM Order #: (b) (4)

14 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had a grade 3 TST at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph node (TBLN) and a firm nodule on the right lung lobe, and hepatic lobe.

Microscopic Diagnoses:

#1: Lung: Abscess, mild, focal.

Acid Fast Stain (lung): Positive for moderate numbers of acid-fast bacilli.

Liver: Granuloma, mild, focal.

Acid Fast Stain (liver): Negative.

Spleen, Adrenal gland, Urinary bladder, Kidney, Heart, Stomach, Small intestines, Large intestines: Within normal limits.

Comment:

The microscopic lesions were consistent with Mycobacteriosis. Acid fast staining highlighted acid-fast bacilli in the pulmonary lesion.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-006500****Animal Location**

Harris County TX, US

NFC Control Number:

19823019175

Date Collected:

02/27/2023

Date Received:

02/28/2023

Date Completed:

08/16/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 21807 **Case #:** TB23-02403 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recoveredMycobacterium tuberculosis
complex**Direct PCR for M. tuberculosis complex - IS1081**

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all other isolates in the NVSL Database. The isolate has acquired a single SNP from the most recent common ancestor. See the attached Genotyping Report.

Animal ID: 21807 **Case #:** TB23-02404 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

If you would like Whole Genome Sequencing (WGS) performed with a genotype analysis the cost is \$103 per isolate. Please email NVSL-MB.caseManager@usda.gov <mailto:NVSL-MB.caseManager@usda.gov> if you would like to request this analysis.

Animal ID: 21807 **Case #:** TB23-02405 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

15 August 2023

Accession:

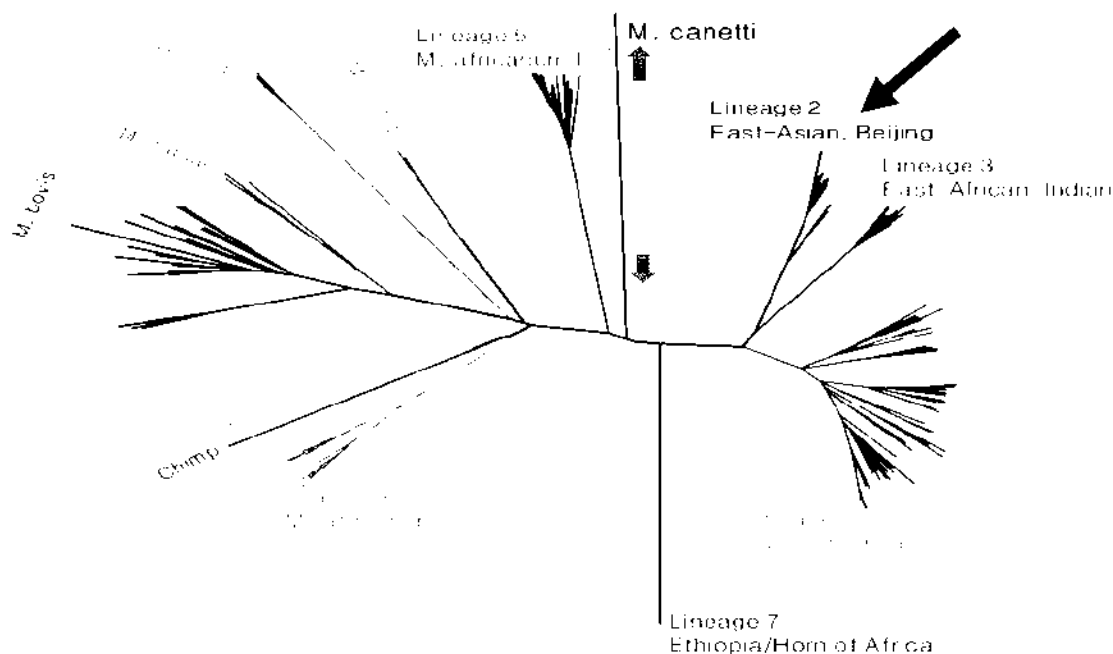
23-005146

23-008085

23-006500

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium tuberculosis* lineage 2. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



APPENDIX – GENOTYPING REPORT

15 August 2023

Accession:

23-005146

23-008085

23-006500

Figure 2. Abbreviated Tree of *M. tuberculosis* lineage 2. The isolates from these accessions are shown in red. Isolates indicated by the bracket share the same SNP pattern and have acquired a single SNP from sharing the most recent common ancestor (red arrow) with 23-1498 & 22-7400. All isolates indicated below are from the same outbreak.

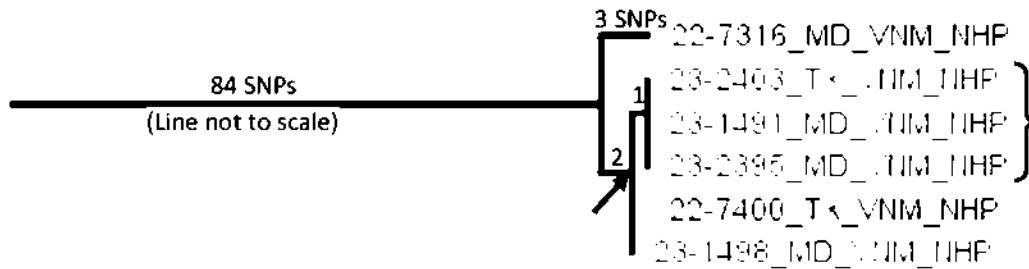


Table 1: Abbreviated SNP table of isolates from this outbreak. Three isolates (23-2403, 23-1491, 23-2395) have acquired a single SNP (arrow) from sharing the most recent common ancestor (blue bracket) with two other isolates. The isolates in this outbreak (shown below) have acquired 84 SNPs (bracket only partially shown) from the nearest common ancestor in the NVSL database.

root	NC_000962.3:39/18820	NC_000962.3:400/1269	NC_000962.3:400/2861	NC_000962.3:413/6888	NC_000962.3:415/3283	NC_000962.3:415/6287	NC_000962.3:415/8458	NC_000962.3:418/6690	NC_000962.3:419/5450	NC_000962.3:423/1160	NC_000962.3:425/2749	NC_000962.3:430/5747	NC_000962.3:432/8194	NC_000962.3:435/0042	NC_000962.3:435/0043	NC_000962.3:437/1246	NC_000962.3:232/3585	NC_000962.3:295/4634	NC_000962.3:378/6116	NC_000962.3:168/8413	NC_000962.3:203/8752	NC_000962.3:380/547
22-7316 MD_VNM_NHP		A	A	A	A	A	A	A	A	A					G	G		G				
22-7400 TX_VNM_NHP		A	A	A	A	A	A	A	A	A					G	G		G	A	C	G	
23-1498 MD_VNM_NHP		A	A	A	A	A	A	A	A	A					G	G		G	A	C	G	
23-2403 TX_VNM_NHP		A	A	A	A	A	A	A	A	A					G	G		G	A	C	G	
23-1491 MD_VNM_NHP		A	A	A	A	A	A	A	A	A					G	G		G	A	C	G	
23-2395 MD_VNM_NHP		A	A	A	A	A	A	A	A	A					G	G		G	A	C	G	
MQ	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	
annotation	GGG->GG,1GG,1PPE,3:G524G	GGG->1GG,fadL30:L280W	GAC->AAC,fadD3:D409N	CGC->CAC,unlisted gene:	G-C->AIC,ask:5356i,asp	CGC->CAC,dnaG-V183H,	position not annotated	11G>11A,unlisted gene:	GGG->GAG,nmrR:G4L,H	CGC->CAC,unlisted gene:	CGC->1AA,fadL35:Y555	position not annotated	CGC->1GC,ethR:R216C,H	CTC->1TC,ecfCB11:406F,	CGC->ACAG,ecfCB2:V364Q,	ACG->ACG,ecfCB1:1131L,H	CGA->CGC,unlisted gene:	GTC->GIG,unlisted gene:	GAA->GGA,1pL1:1586,ec	position not annotated	CGA->AGA,acfA1:R643R,	

Exhibit 17

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

(b) (6) Charles River Laboratories

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

EMAIL ADDRESS

(b) (6) crl.com (b) (6) crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

MAILING ADDRESS (Street, City, State, ZIP Code)

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CRED.
CARD

CC

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None ☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE

X

(b) (6)

3/23/23 3/6/23

23 - 007330

MB

CONDITION

PRIORITY

VS FORM 10-4

VS FORM 10-4

AUG 2009

(b) (6)

(b) (6)

30821
03/07/2023



24-08898_000730

[External Email]RE: Request to ship NHP Samples 2 of 5

(b) (6) <(b) (6)@crl.com>

Mon 3/6/2023 5:13 PM

To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP APHIS MB CaseManagement <NVSL MB.caseManager@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com>

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

My apologies. The dates should read Monday, March 6, 2023 for shipping for arrival Tuesday, March 7, 2023.

From: (b) (6)

Sent: Monday, March 6, 2023 3:33 PM

To: Lehman, Kimberly A - APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>; Bravo Garcia, Doris M - APHIS <doris.m.bravo@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: Request to ship NHP Samples 2 of 5

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report has been attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results? Gross necropsy revealed mild erythema and swelling of superior palpebra OS. Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

Thank you,

(b) (6)

24-08898 000731

(b) (6)

Houston | Charles River

(b) (6)

Road, Houston, TX 77047

(b) (6)

(b) (6)

[crl.com](#) | [www.criver.com](#)

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

(b) (4) Necropsy (b) (4)

From Date

03/06/2023 11:31:53

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update

(b) (4)

Name

Value

In-Shipment #

(b) (4)

03/06/2023 11:29:25

Date Out

03/06/2023 11:29:25

03/06/2023 11:29:25

Location at
Stock Out - Pat.

(b) (4)

03/06/2023 11:38:40

Died during
quarantine

Yes

03/06/2023 11:29:25

Euthanasia
Reason

TB Reactor

03/06/2023 11:29:25

Euthanasia
Method

IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) t had grade 3 TST OS at 72hr read. No other significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema and swelling of the left superior palpebra

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4) - Necropsy (b) (4)

Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

22 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Euthanized because of grade 3 TB test at 72 hours. Necropsy was conducted by the submitter.

Microscopic Diagnoses:

#1: Lymph node (tracheobronchial): Abscess, mild, multifocal.

Lymphoid hyperplasia, mild, multifocal.

Acid fast stain (TBLN): Positive for small numbers of acid-fast organisms within the abscess lesions.

Large intestine: *Balantidium coli*, luminal, moderate.

Lung, Liver, Spleen, Heart, Kidney, Adrenal gland, Urinary bladder, Stomach, Small intestine,

Lymph node (mesenteric): Within normal limits.

Comment:

The TBLN lesions and presence of acid-fast organisms was consistent with the diagnosis of Mycobacteriosis. No other significant lesions were noted.

(b) (6)



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report

Owner

Houston, TX

Accession Number:

23-007331

Animal Location

Harris County TX, US

NFC Control Number:

19823020072

Date Collected:

03/06/2023

Date Received:

03/07/2023

Date Completed:

05/22/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1803006 **Case #:** TB23-02413 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 30.51751709

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 1803006 Case #: TB23-02414 Sample: 1 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.85004425

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

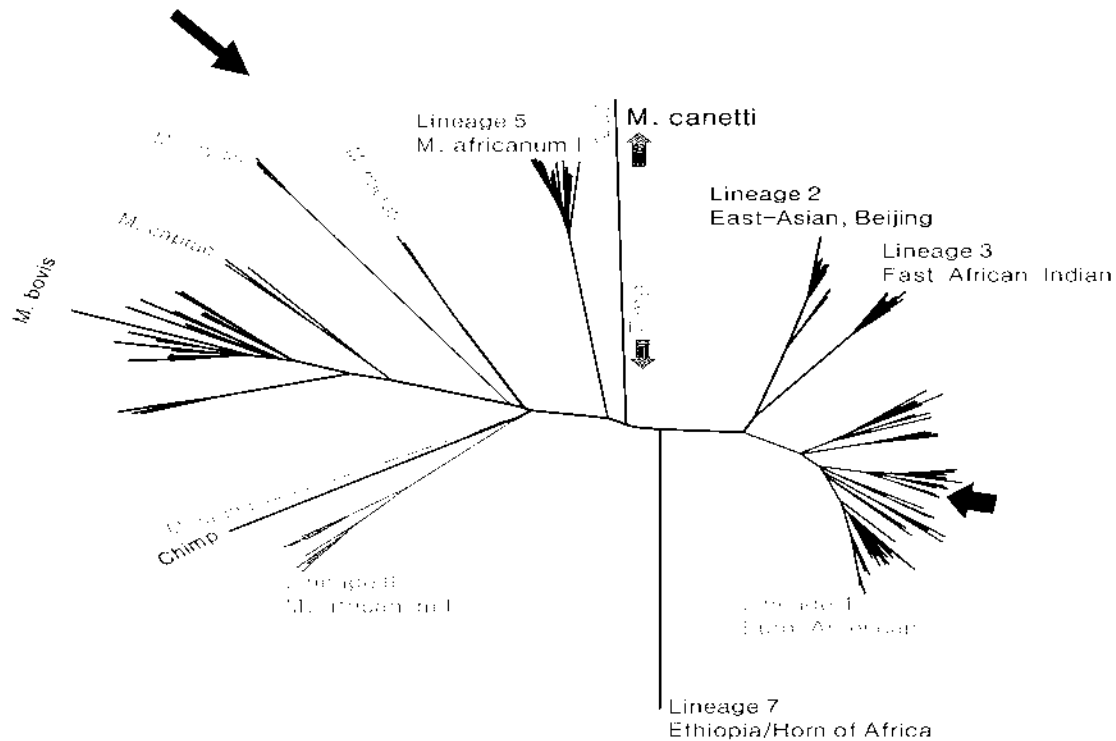
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



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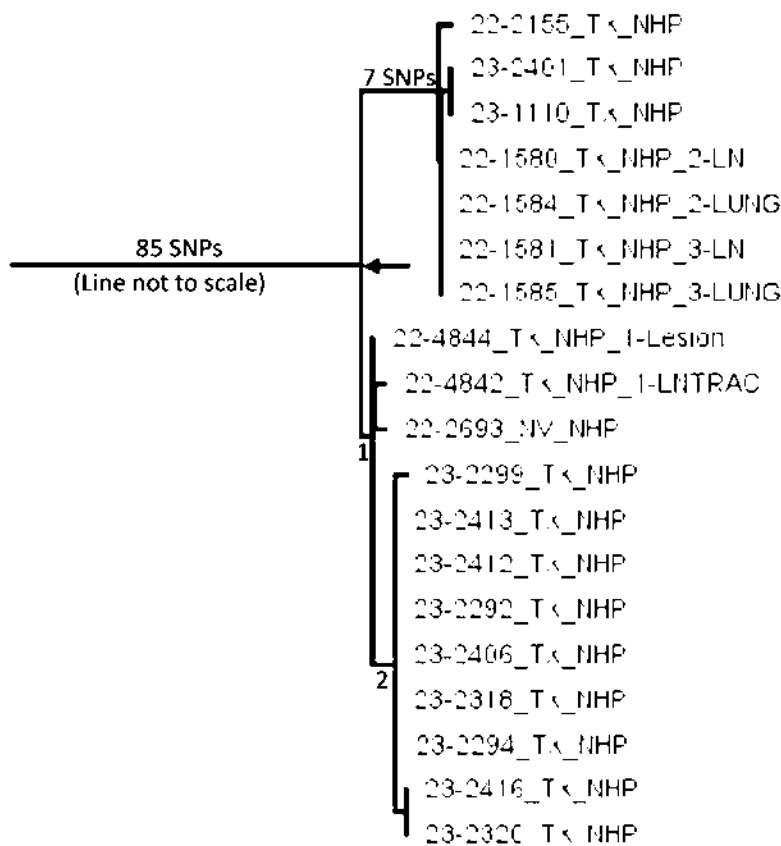
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3156208	NC_000962.3:3180991	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3236370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487	
root	G	T	T	C	A	G	G	A	A	A	C	T	G	G	T	C	A	T	A	A	G	G	A	G	A	G	G	G	A	A	A	C	G	A	A	G	C	G	T	G	G	T	G
22-1580 TX NHP 2 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 2 UNG	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 3 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		G	C	G	T	G	G	T	G
22-1585 TX NHP 3 UNG	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		G	C	G	T	G	G	T	G
22-2155 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		A	C	G	T	G	G	T	G
23-2401 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		G	G	T	G	G	T	G	
23-1110 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	A	G		A	G		G	G	T	G	G	T	G	
22-2693 NV NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	G	G	T	G		
22-4844 TX NHP 1 lesion	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	G	G	T	G		
22-4847 TX NHP 1 ENTRAC	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	G	G	T	G		
23-2413 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2412 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2292 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2406 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2318 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2299 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	A	G		
23-2294 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	R		
23-2416 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	A		
23-2320 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	A		

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com (b) (6) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6) FAX NO. 713-433-6971

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6) Houston, TX 77047

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

cc

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED
03/06/23

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung; Liver

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE

(b) (6)

(Y)

23 - 007323 .Y
MB

CONDITION

PRIORITY

NVSL USE ONLY

DISTRIBUTION

RECEIVED BY

VS FORM 10-4
AUG 2009

(b) (6)

03/07/2023
30321

24-08898_000719

Pronouns: she, her, hers

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Please consider the environment before printing this email note

From: (b) (6) <(b) (6)@crl.com>

Sent: Monday, March 6, 2023 5:09 PM

To: Lehman, Kimberly A - APHIS <Kimberly.Lehman@usda.gov>; Bravo Garcia, Doris M - APHIS <doris.m.bravo@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: Request to Ship NHP Samples 5 of 5

Good evening,

We would like to send an NHP sample for Mycobacterium testing Monday, March 6, 2023 for arrival Tuesday, March 7, 2023. Please let us know if you are agreeable to this. The necropsy report has been attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment: (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating (b) (4) y? (b) (4)

How many animals were in the group imported (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results?

- Gross necropsy revealed mild erythema and moderate swelling of left superior palpebra. Three enlarged tracheobronchial lymph nodes (1.0cm, 1.3cm, 1.4cm n length). Generalized red, hemorrhagic appearance of lungs. In the parenchyma of the right middle lung lobe there is a firm, black, irregularly shaped mass that has a tan center. Generalized multifocal white to tan firm cavitary nodules within the parenchyma of the liver, upon incision some lesions appeared hollow, some have a yellow-brown exudate, and others had a solid hemorrhagic center. Between the inferior vena cava and caudal liver lobe, there is a pyramidal tan mass.
- Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

Thank you,

(b) (6) DVM, RLATG

24-08898 000720

(b) (6)

Houston | Charles River

(b) (6)

Road, Houston, TX 77047

(b) (6)

(b) (6)

[crl.com](#) | [www.criver.com](#)

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

(b) (4) Necropsy (b) (4)

From Date

03/06/2023 16:43:19

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/06/2023 16:42:27	Date Out	03/06/2023 16:42:27
03/06/2023 16:42:27	Location at Stock Out - Path	(b) (4)
03/06/2023 17:02:14	Died during quarantine	Yes
03/06/2023 16:42:27	Euthanasia Reason	TB Reactor
03/06/2023 16:42:27	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) t had grade 4 TST OS at 72h read. No significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema and moderate swelling of left superior palpebra

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

three enlarged tracheobronchial lymph nodes (1.0cm, 1.3cm, 1.4cm in length)

Respiratory System



Abnormal Respiratory System Description

generalized red, hemorrhagic appearance of lungs. In the parenchyma of the right middle lung lobe there is a firm, black, irregularly shaped mass that has a tan center.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

generalized multifocal white to tan firm cavitary nodules within the parenchyma of the liver, upon incision some lesions appeared hollow, some have a yellow-brown exudate, and others had a solid hemorrhagic center. Between the inferior vena cava and caudal liver lobe, there is a pyramidal tan mass.

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



(b) (4) Necropsy (b) (4)

Skeletal Muscle



Skin



Other



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

23 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Euthanized for grade 4 TST at 72 hours. Necropsy was performed by submitter and found enlarged tracheobronchial lymph nodes, mass lesion on lung and liver.

Microscopic Diagnoses:

#1: Lung: Abscess, mild, focal.

Acid-fast stain (lung): Positive for acid-fast organisms within the lung lesion.

Liver: Abscess, moderate, multifocal.

Acid-fast stain (liver): Negative for organisms.

Gram Stain (liver): Negative for organisms.

Spleen, Kidney, Adrenal glands, Urinary bladder, Small intestine, Large intestine, Stomach:
Within normal limits.

Comment:

The lung and liver lesions and presence of intrapulmonary acid-fast organisms was consistent with a diagnosis of Mycobacteriosis. No other significant lesions were noted.

(b) (6)

24-08898_000729

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-007323****Animal Location**

Harris County TX, US

NFC Control Number:

19823020064

Date Collected:

03/06/2023

Date Received:

03/07/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1811020 **Case #:** TB23-02406 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 29.56841469

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Animal ID: 1811020 **Case #:** TB23-02407 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1811020 **Case #:** TB23-02408 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

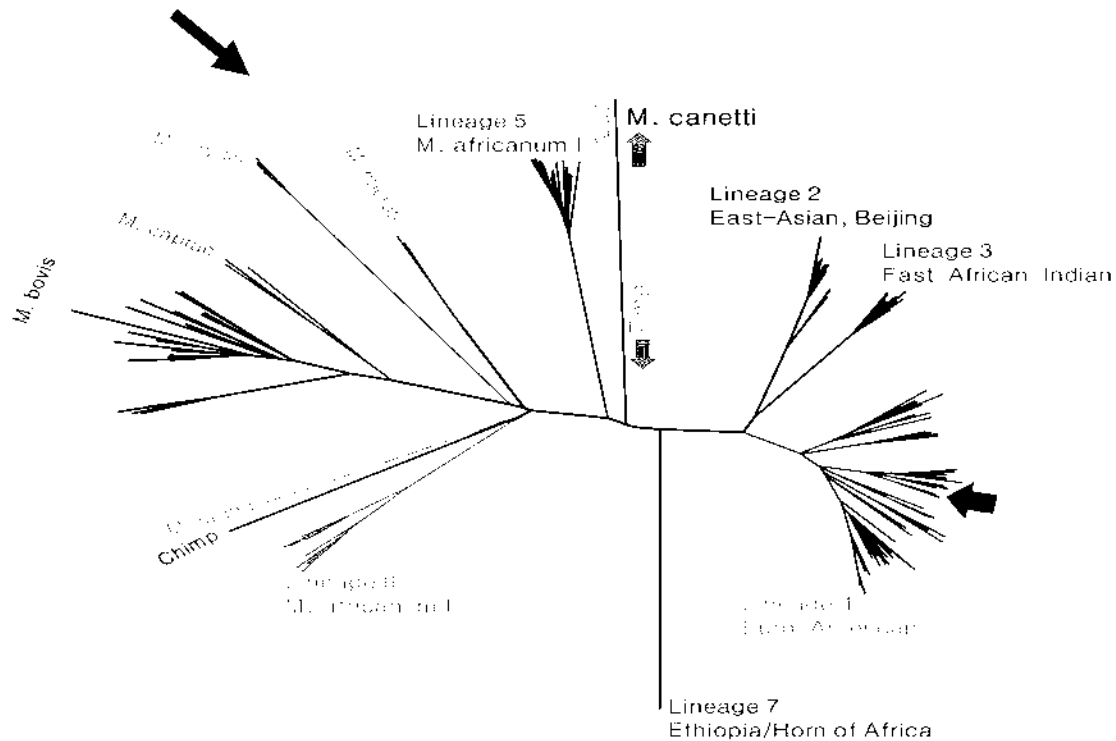
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

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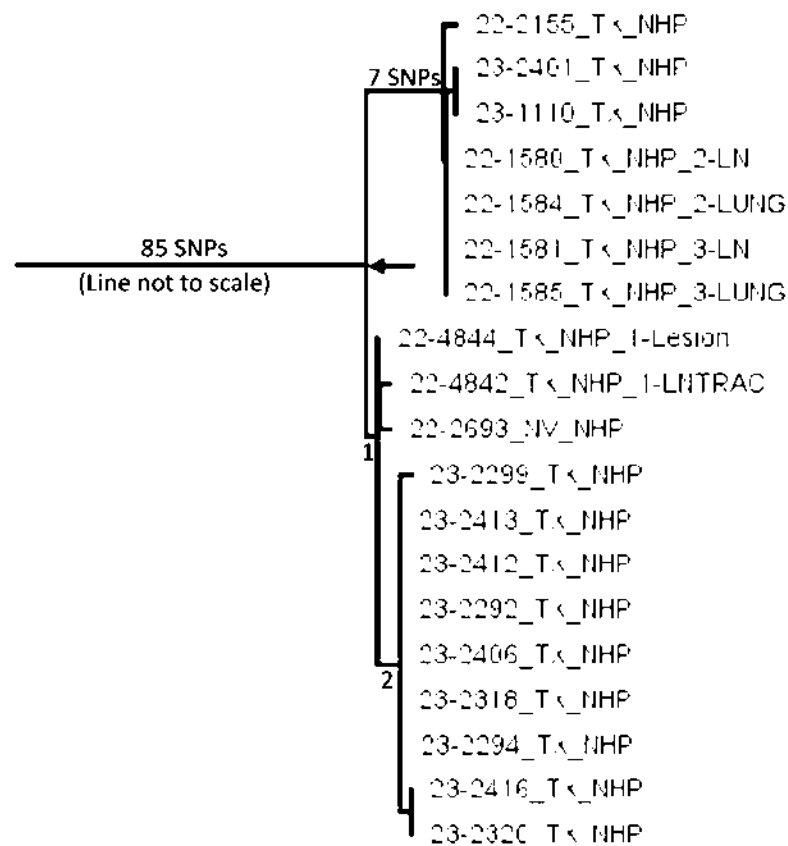
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3156208	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3236370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487	
root	G	T	T	C	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	A	G	G	A	G	G	A	A	G	A	A	C	G	A	A	G	C	G	T	G	G	T	G
22-1580 TX NHP 2 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 2 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 3 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G
22-1585 TX NHP 3 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	C	G	T	G	G	T	G
22-2155 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		A	C	G	T	G	G	T	G
23-2401 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	G	T	G	G	T	G	
23-1110 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	G		A	G		G	G	T	G	G	T	G	
22-2693 NV NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	G	G	T	G		
22-4844 TX NHP 1 lesion	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	G	G	T	G		
22-4847 TX NHP 1 ENTRAC	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	G	G	T	G		
23-2413 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2412 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2292 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2406 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2318 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	G		
23-2299 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	A	G		
23-2294 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	R		
23-2416 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	A		
23-2320 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G	A	A	G	C			T	A	A	T	A		

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name) (b) (6) Charles River Laboratories		2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) @crl.com (b) (6) @crl.com		OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6)	FAX NO. (b) (6)	4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047		PREMISES ID	COUNTY Harris
			STATE/COUNTRY TX/US

5. PAYMENT METHOD <input type="checkbox"/> USER FEE ACCOUNT NO. <input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars) <input checked="" type="checkbox"/> CREDIT CARD CC		6. HERD/FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
		7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 03/06/23
		8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)
13. PURPOSE OF SUBMISSION (See instructions for definitions) <input type="checkbox"/> Interstate Movement <input type="checkbox"/> Import <input checked="" type="checkbox"/> TB <input type="checkbox"/> Reagent Evaluation <input type="checkbox"/> Export <input type="checkbox"/> FAD/EP Diagnostic <input type="checkbox"/> General Diagnostic <input type="checkbox"/> NVSL Intralab <input type="checkbox"/> Pre-Import <input type="checkbox"/> Surveillance <input type="checkbox"/> Developmental Research				14. COUNTRY OF ORIGIN/DESTINATION (b) (4)
				15. REFERRAL NUMBER

16. PRESERVATION <input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input checked="" type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)				18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)	
17. SPECIMENS SUBMITTED ("X" applicable item(s)) <input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (specify) <input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus TBLN; Lung <input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (specify) <input type="checkbox"/> Water <input type="checkbox"/> DNA/RNA					
19. SPECIES OR SOURCE ("X" ONLY one) <input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (specify) <input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (specify) <input type="checkbox"/> Environment Cynomolgus <input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (specify) <input type="checkbox"/> Elk <input type="checkbox"/> Reagent Macaque				20. NUMBER OF ANIMALS SAMPLED (b) (4)	

21. IDENTIFICATION (See instructions <250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary)

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE (b) (6) 3/6/23		23 - 007331 MB	
CONDITION DI	PRIORITY 3	DISTRIBUTION (b) (6)	RECEIVED BY (b) (6)
VS FORM 10-4 AUG 2009		30321 03/07/2023	

24-08898_000741

[External Email]RE: Request Permission to ship NHP Samples 3 of 5

(b) (6) <(b) (6)@crl.com>

Mon 3/6/2023 5:13 PM

To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP APHIS MB CaseManagement <NVSL MB.caseManager@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com>

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

My apologies. The dates should read Monday, March 6, 2023 for shipping for arrival Tuesday, March 7, 2023.

From: (b) (6)

Sent: Monday, March 6, 2023 3:52 PM

To: Lehman, Kimberly A - APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>; Bravo Garcia, Doris M - APHIS <doris.m.bravo@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: Request Permission to ship NHP Samples 3 of 5

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report has been attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results?

- Gross necropsy revealed severe erythema, mild swelling of left superior palpebra. Two enlarged tracheobronchial lymph nodes (both 1.3cm in length). 2mm firm tan solid nodule in parenchyma of ventral aspect of middle right lung lobe. 4mm x 5mm firm red-tan solid mass with yellow center upon incision on dorsolateral aspect of right caudal lung lobe. Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

24-08898 000742

Thank you,

(b) (6)

(b) (6)

Houston | Charles River

(b) (6)

Road, Houston, TX 77047

(b) (6)

(b) (6)

[crl.com](#) | [www.criver.com](#)

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

- Necropsy

(b) (4)

From Date

03/06/2023 15:34:25

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/06/2023 15:33:39	Date Out	03/06/2023 15:33:39
03/06/2023 15:33:39	Location at Stock Out - Path	(b) (4)
03/06/2023 15:46:42	Died during quarantine	Yes
03/06/2023 15:33:39	Euthanasia Reason	TB Reactor
03/06/2023 15:33:39	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) Noted to have missing Right Hand D4P3 missing on entry exam. Pt had grade 3 TST OS at 72h. No significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



severe erythema, mild swelling of left superior palpebra.

Oral

Abnormal Oral Cavity Description



- Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Two enlarged tracheobronchial lymph nodes (both 1.3cm in length)

Respiratory System



Abnormal Respiratory System Description

2mm firm tan solid nodule in parenchyma of ventral aspect of middle right lung lobe. 4mm x 5mm firm red-tan solid mass with yellow center upon incision on dorsolateral aspect of right caudal lung lobe.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Third phalanx of right hand digit 4 is missing.

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



- Necropsy - (b) (4)

Skin

Skin - Description



Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

3/6/23

(b) (6)

Pathology Report

LTM Order #: (b) (4)

22 March 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Euthanized due to a grade 3 on TB test at 72 hours. Necropsy was performed by submitter and found enlarged tracheobronchial lymph nodes (TBLN), mass in lung.

Microscopic Diagnoses:

#1 (b) (4): Lung: Abscess, mild, multifocal.

Lymph node (TBLN): Abscess/granuloma, mild, multifocal.

Lymphoid hyperplasia, mild, multifocal.

Acid Fast Stain (lung, TBLN): Small numbers of acid-fast organisms present in both lung and TBLN lesions.

Stomach: Lymphocytic infiltrates, mucosal, mild, diffuse (lymphocytic gastritis).

Large intestine: *Balantidium coli*, luminal, minimal.

Liver, Spleen, Urinary bladder, Heart, Kidney, Adrenal gland, Small intestine: Within normal limits.

Comment: The microscopic lesions in the lung and TBLN and the presence of acid-fast organisms within those lesions was consistent with the diagnosis of Mycobacteriosis. This animal also had mild lymphocytic gastritis.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-007332****Animal Location**

Harris County TX, US

NFC Control Number:

19823020073

Date Collected:

03/06/2023

Date Received:

03/07/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1906014 **Case #:** TB23-02415 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recoveredMycobacterium tuberculosis
complex**Direct PCR for M. tuberculosis complex - IS1081**

Detected Ct = 23.81841278

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1906014 Case #: TB23-02416 Sample: 2 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

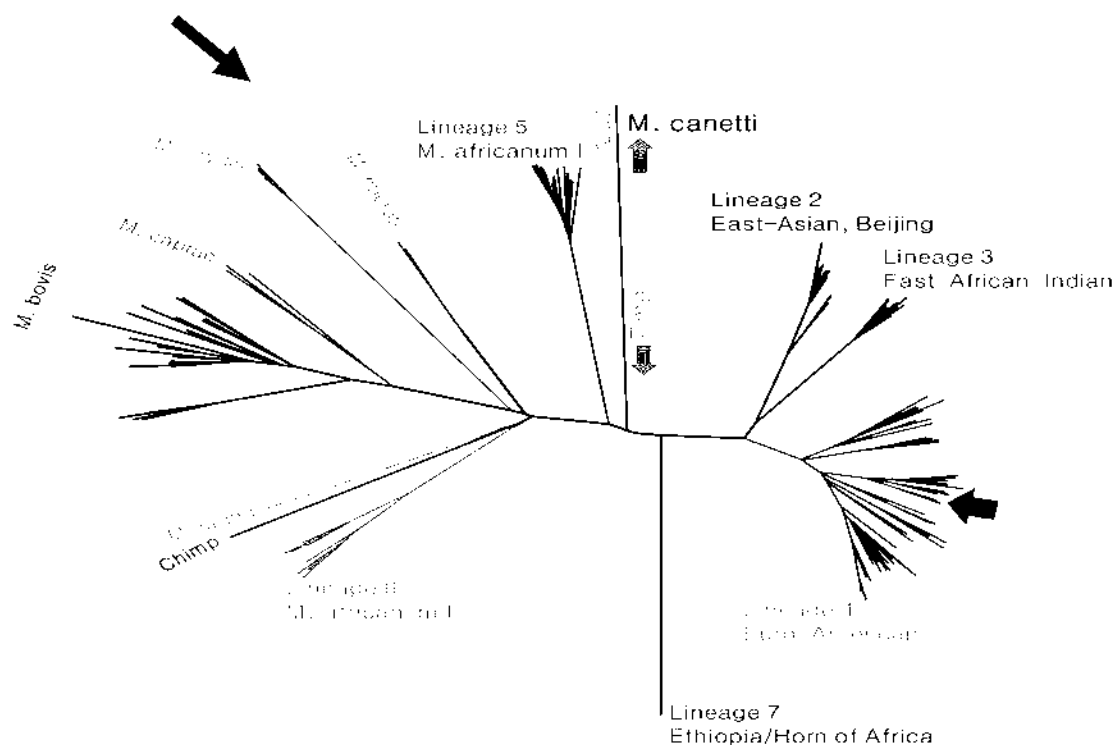
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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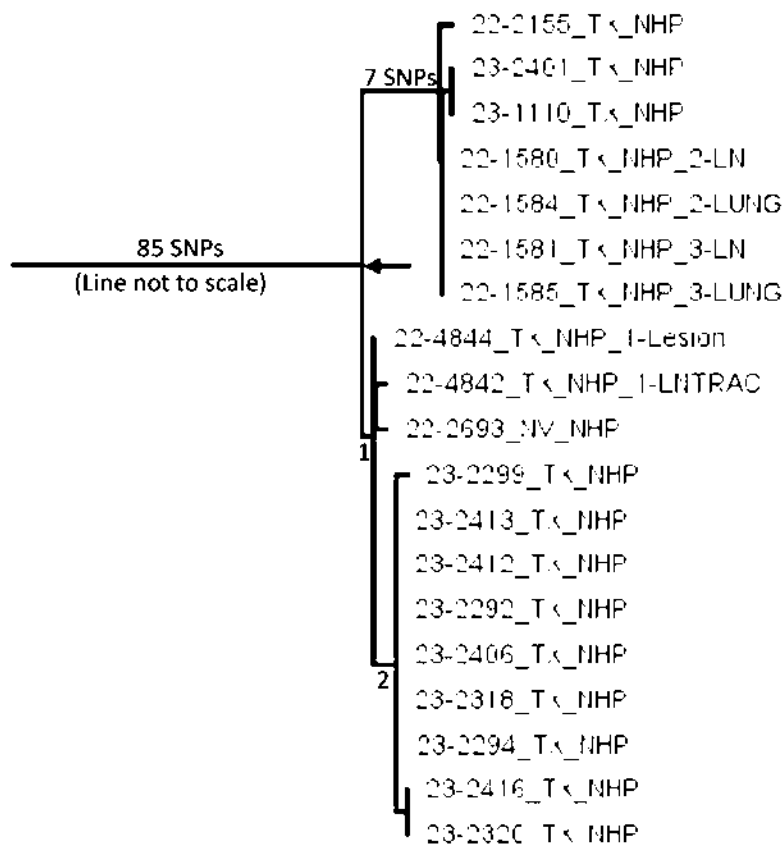
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





National Veterinary Services Laboratories

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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3156208	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3236370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487		
root	G	T	T	C	A	G	G	A	A	A	C	T	G	G	T	C	A	T	A	A	G	G	G	A	T	G	G	G	A	A	C	G	A	A	G	C	G	T	G	G	T	G		
22-1580 TX NHP 2 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 2 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 3 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		G	C	G	T	G	G	T	G
22-1585 TX NHP 3 UN	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		G	C	G	T	G	G	T	G
22-2155 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		A	C	G	T	G	G	T	G
23-2401 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		G	G		T	G	G	T	G
23-1110 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G		A	A	G		A	G		G	G		T	G	G	T	G
22-2693 NV NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	G	G	T	G
22-4844 TX NHP 1 lesion	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	G	G	T	G
22-4847 TX NHP 1 ENTRAC	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	G
23-2413 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	G
23-2412 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	G
23-2292 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	G
23-2406 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	G
23-2318 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	G
23-2299 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	A	G
23-2294 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	R
23-2416 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	A
23-2320 TX NHP	G	A		G	G	A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A		A	C	G	A	A	G	C				T	A	A	T	A

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE

OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

(b) (6) Charles River Laboratories

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

EMAIL ADDRESS

(b) (6) crl.com (b) (6) crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. 713-433-6971

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

CC

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

03/06/23

12. AUTHORIZED BY

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE

X

(b) (6)

3/6/23

Ⓢ

23-007332
MB

CONDITION

PRIORITY

DISTRIBUTION

RECEIVED BY

VS FORM 10-4
AUG 2009

(b) (6)

(b) (6)

30321
03/07/2023

MB

24-08898_000752

[External Email]RE: Request Permission to Ship NHP samples 4 of 5

(b) (6) <(b) (6)@crl.com>

Mon 3/6/2023 5:12 PM

To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>; APHIS NVSL Case Coordinator APHIS <NvslCaseCoordinator@usda.gov>; MRP APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com> (b) (6) <(b) (6)@crl.com>

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

My apologies. The dates should read Monday, March 6, 2023 for shipping for arrival Tuesday, March 7, 2023

From: (b) (6)

Sent: Monday, March 6, 2023 4:04 PM

To: Lehman, Kimberly A - APHIS <Kimberly.Lehman@usda.gov>; Bravo Garcia, Doris M - APHIS <doris.m.bravo@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: Request Permission to Ship NHP samples 4 of 5

Good afternoon,

We would like to send an NHP sample for Mycobacterium testing on Tuesday February 21, 2023 for arrival on Wednesday, February 22, 2023. Please let us know if you are agreeable to this. The necropsy report has been attached to this email. We will send submission and packing forms when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Signalment: (b) (4)

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes

If so, can you provide those results?

- Gross necropsy revealed 5mm x 3mm pale pink firm nodule with yellow center upon incision in parenchyma of dorsal aspect of right middle lung lobe.
- Histopathology pending

Cause of Death? Euthanasia via IV pentobarbital

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

Thank you,

24-08898 000753

(b) (6)

(b) (6)

Houston | Charles River

(b) (6)

Road, Houston, TX 77047

(b) (6)

(b) (6)

crl.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

(b) (4) - Necropsy (b) (4)

From Date

03/06/2023 15:54:36

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/06/2023 15:52:35	Date Out	03/06/2023 15:52:35
03/06/2023 15:52:35	Location at Stock Out - Path	(b) (4)
03/06/2023 15:59:14	Died during quarantine	Yes
03/06/2023 15:52:35	Euthanasia Reason	TB Reactor
03/06/2023 15:52:35	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) Pt had grade 3 TST OS at 72hr read. No significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema and swelling of left superior palpebra

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Respiratory System



Abnormal Respiratory System Description

5mm x 3mm pale pink firm nodule with yellow center upon incision in parenchyma of dorsal aspect of right middle lung lobe.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4) Necropsy - (b) (4)

Microbiology

PCR culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

3/6/23

(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

22 March 2023

History:

Customer: Charles River Houston - Quarantine

Strain: *Macaca fascicularis*

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal was euthanized due to grade 3 TB reaction at 72 hours. Necropsy was performed by the submitter found a mass lesion on the lung.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, moderate, focal.

Lymph node (tracheobronchial): Granuloma, mild, focal.

Acid Fast Stain (lung, TBLN): Two acid-fast organisms were noted in the lung lesion. TBLN was negative.

Liver, Spleen, Urinary bladder, Heart, Kidney, Adrenal gland, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The lung and TBLN lymph node lesions and the presence of frequent acid-fast organisms were consistent with a diagnosis of Mycobacteriosis. No other significant findings were noted.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-007330****Animal Location**

Harris County TX, US

NFC Control Number:

19823020071

Date Collected:

03/06/2023

Date Received:

03/07/2023

Date Completed:

05/22/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2009024 **Case #:** TB23-02411 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2009024 Case #: TB23-02412 Sample: 2 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for *M. tuberculosis* complex - IS1081

Detected Ct = 24.99202156

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced then compared to all other isolates in the NVSL database. It was determined that this isolate was *Mycobacterium orygis* a member of the *Mycobacterium tuberculosis* complex. See attached genotyping report for more information.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

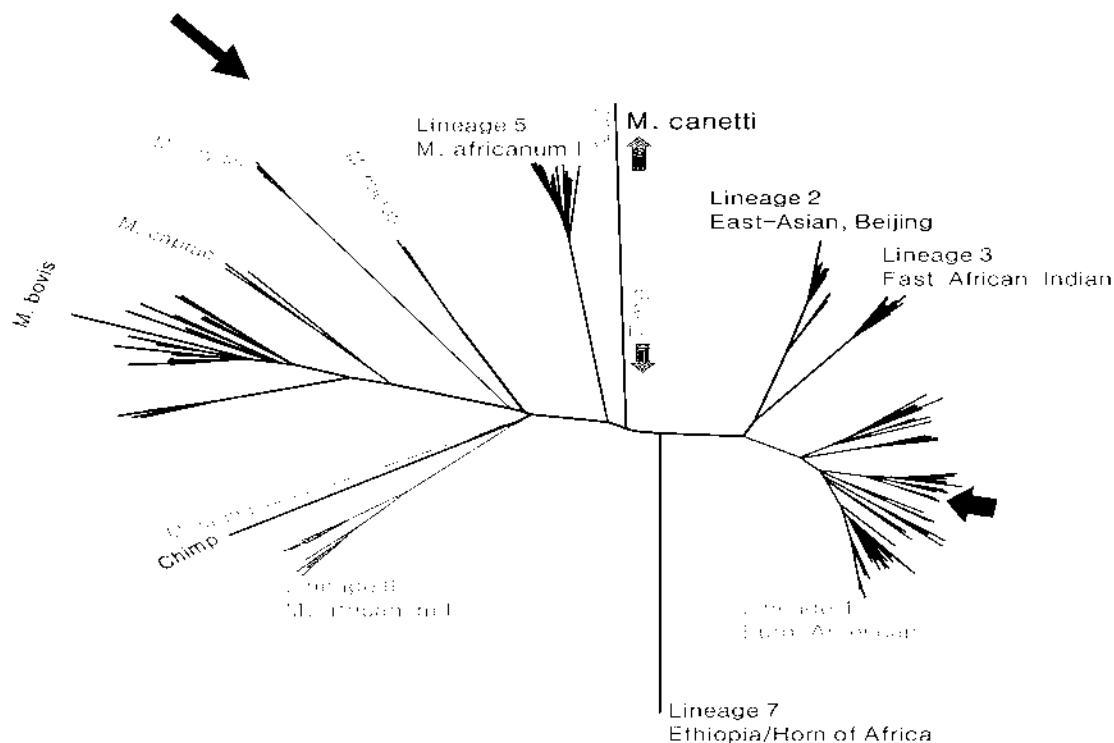
19 May 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Accession	Sample
22-005735	22-1580	23-004180	23-1110
22-005735	22-1581	23-005857	23-2292
22-005735	22-1584	23-005859	23-2294
22-005735	22-1585	23-005861	23-2299
22-007914	22-2155	23-005858	23-2318
22-010967	22-2693	23-005862	23-2320
22-020430	22-4842	23-005856	23-2401
22-020430	22-4844	23-007323	23-2406
		23-007330	23-2412
		23-007331	23-2413
		23-007332	23-2416



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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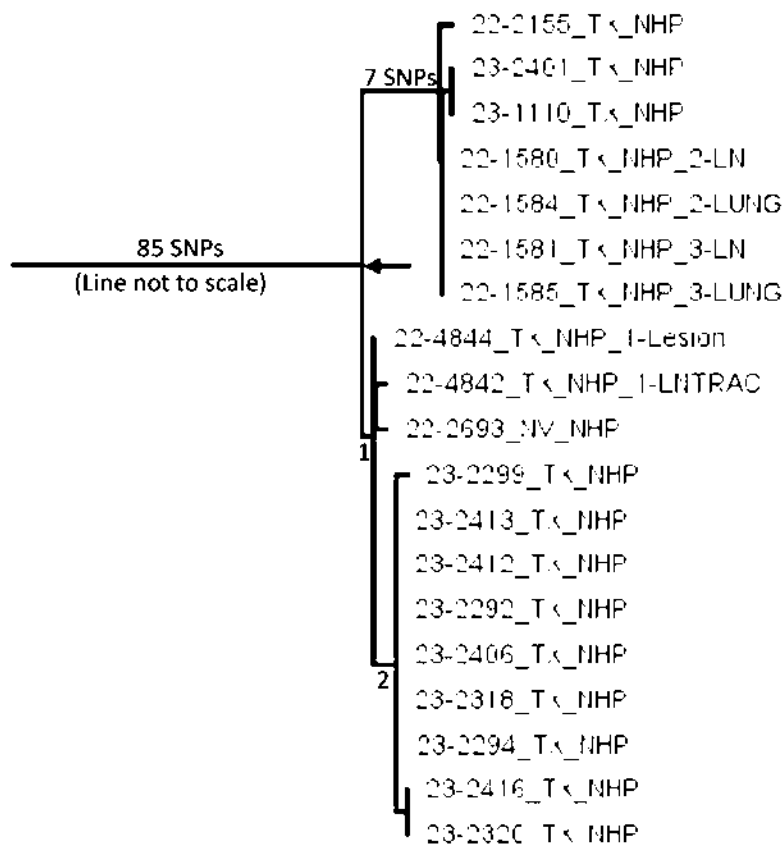
APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. All isolates from this outbreak share with 8 SNPs from sharing the most recent common ancestor (red arrow) for this outbreak. There are two distinct groups represented by the blue and red branches. The isolates on the blue all share a common ancestor that has acquired 7 SNPs (see also Table 2) from the most recent common ancestor to the outbreak. These isolates are within 1 SNP of each other. The isolates in the red bracket share a single SNP from sharing the most recent common ancestor to the outbreak. The isolates in the red branch are within 3 SNPs of each other. The significance of this finding is that transmission may have occurred within these groups, but not between them.





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APPENDIX – GENOTYPING REPORT

19 May 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. The isolates in blue (matching the blue branch, Figure 2) all share a single common ancestor (blue bracket). Isolates in red (matching red branch, Figure 2) share a common ancestor (red arrow). The isolates from this outbreak are with in 8 SNPs from sharing the most recent common ancestor to this outbreak (black bracket, abbreviated).

	NC_000962.3:303007G	NC_000962.3:3114933	NC_000962.3:3156208	NC_000962.3:3180995	NC_000962.3:3187937	NC_000962.3:3228002	NC_000962.3:3236370	NC_000962.3:3293637	NC_000962.3:3440841	NC_000962.3:3449065	NC_000962.3:3453785	NC_000962.3:3496294	NC_000962.3:3627787	NC_000962.3:3801458	NC_000962.3:3957533	NC_000962.3:3984291	NC_000962.3:4068655	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259800	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:489395	NC_000962.3:489396	NC_000962.3:794566	NC_000962.3:1687213	NC_000962.3:2952996	NC_000962.3:3467800	NC_000962.3:4364853	NC_000962.3:171922	NC_000962.3:3347753	NC_000962.3:2874747	NC_000962.3:2080995	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:1594487	
root	G	T	C	A	G	G	A	G	G	A	A	C	T	G	G	T	C	A	T	A	A	G	G	A	G	G	G	G	A	A	A	C	G	A	A	G	C	G	T	G	G	T	G
22-1580 TX NHP 2 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 2 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		G	C	G	T	G	G	T	G
22-1581 TX NHP 3 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		G	C	G	T	G	G	T	G
22-1585 TX NHP 3 UN	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		G	C	G	T	G	G	T	G
22-2155 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		A	C	G	T	G	G	T	G
23-2401 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		G	G	T	G	G	T	G	
23-1110 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	A	G	G	A	G		A	G		G	G	T	G	G	T	G	
22-2693 NV NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	G	G	T	G	
22-4844 TX NHP 1 lesion	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	G	G	T	G	
22-4847 TX NHP 1 ENTRAC	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	G	G	T	G	
23-2413 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	G	
23-2412 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	G	
23-2292 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	G	
23-2406 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	G	
23-2318 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	G	
23-2299 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	A	G	
23-2294 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	R	
23-2416 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	A	
23-2320 TX NHP	G	A		G	G		A	A	G	G		A	A	A	G	G	G		G	G	A	A	A	G		A	C	A	A	C	G		A	A	G	C		T	A	A	T	A	

Exhibit 18

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) (b) (6) Charles River Laboratories		2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) @crl.com (b) (6) @crl.com		OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6)	FAX NO. (b) (6)	4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047		PREMISES ID	COUNTY Harris
		STATE/COUNTRY TX/US	

5. PAYMENT METHOD		
<input type="checkbox"/> USER FEE ACCOUNT NO.	<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars)	<input checked="" type="checkbox"/> CREDIT CARD

6. HERD/FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 03/20/23
8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)
13. PURPOSE OF SUBMISSION (See instructions for definitions)		14. COUNTRY OF ORIGIN/DESTINATION (b) (4)
<input type="checkbox"/> Interstate Movement <input type="checkbox"/> Import <input checked="" type="checkbox"/> TB <input type="checkbox"/> Reagent Evaluation		
<input type="checkbox"/> Export <input type="checkbox"/> FAD/EP Diagnostic <input type="checkbox"/> General Diagnostic <input type="checkbox"/> NVSL Intralab		
<input type="checkbox"/> Pre-Import <input type="checkbox"/> Surveillance <input type="checkbox"/> Developmental Research		

15. PRESERVATION
<input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input checked="" type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))	18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)
<input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus TBLN; Lung	
<input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (specify) <input type="checkbox"/> Water <input type="checkbox"/> DNA/RNA	

19. SPECIES OR SOURCE ("X" ONLY one)	20. NUMBER OF ANIMALS SAMPLED (b) (4)
<input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (specify)	
<input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (specify) <input type="checkbox"/> Environment Cynomolgus	
<input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (specify) <input type="checkbox"/> Elk <input type="checkbox"/> Reagent Macaque	

21. IDENTIFICATION (See instructions - 250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

(b) (6)

4-18-23

SAMPLED & TESTED

X		NVSL USE ONLY	
CONDITION DE	PRIORITY 3	DISTRIBUTION (b) (6)	RECEIVED BY (b) (6)
VS FORM 10-4 AUG 2009			

23-012107
MB

502739
04/19/2023

24-08898_000814

(b) (4) Necropsy (b) (4)

From Date

03/20/2023 15:50:27

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)



Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/20/2023 12:56:16	Date Out	03/20/2023 12:56:16
03/20/2023 12:56:16	Location at Stock Out - Path	(b) (4)
03/21/2023 09:08:43	Died during quarantine	Yes
03/20/2023 12:56:16	Euthanasia Reason	TB Reactor
03/20/2023 12:56:16	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4) Pt reported for grade 3 TST OD at 72h read. No other significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Mild swelling and erythema with minor scaling of right superior palpebra. Yellow bruise left medial proximal thigh.

(b) (4) - Necropsy (b) (4)

Oral

Abnormal Oral Cavity Description



Lymph Nodes

Abnormal Lymph Nodes Description



enlarged tracheobronchial lymph nodes measuring from 5mm to 1.7cm.

Respiratory System

Abnormal Respiratory System Description



Cardiovascular System

Abnormal Cardiovascular System Description



Gastrointestinal System

Abnormal Gastrointestinal System Description



Urinary System

Abnormal Urinary System Description



Reproductive System

Abnormal Reproductive System Description



Endocrine System

Abnormal Endocrine System Description



Nervous System

Abnormal Nervous System Description



Musculoskeletal System

Abnormal Musculoskeletal System Description



Tissues Fixed

Tracheobronchial Lymph Node

Lung

Heart Muscle



Liver

Spleen

Kidney



Stomach

Duodenum

Jejunum



Ileum

Colon

Bladder



Skeletal Muscle

Bone Marrow

Brain



Skin

Skin - Description



(b) (4) Necropsy - (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order # (b) (4)

06 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had grad 3 TST at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes (TBLN).

Microscopic Diagnoses:

#1 (b) (4) Lung: Anthracosis, mild, multifocal.

Large intestine: *Balantidium coli*, luminal, minimal.

TBLN, Spleen, Liver, Urinary bladder, Kidney, Adrenal gland, Heart, Stomach, Small intestine:
Within normal limits.

Comment:

There were no microscopic lesions to suggest Mycobacteriosis. Acid-fast stains were performed and examined for the lung and TBLN and were negative for acid-fast organisms. There were no significant microscopic findings.

(b) (4)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner****Accession Number:****23-012108****Animal Location****Harris County TX****NFC Control Number:**

19823025373

Date Collected:**03/20/2023****Date Received:**

04/19/2023

Date Completed:

08/23/2023

Submitter - 502739**Charles River Laboratories**

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Collected By:**Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1808008 **Case #:** TB23-03368 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1808008 Case #: TB23-03369 Sample: 2 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 13 other isolates in this outbreak. See attached Genotyping report.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

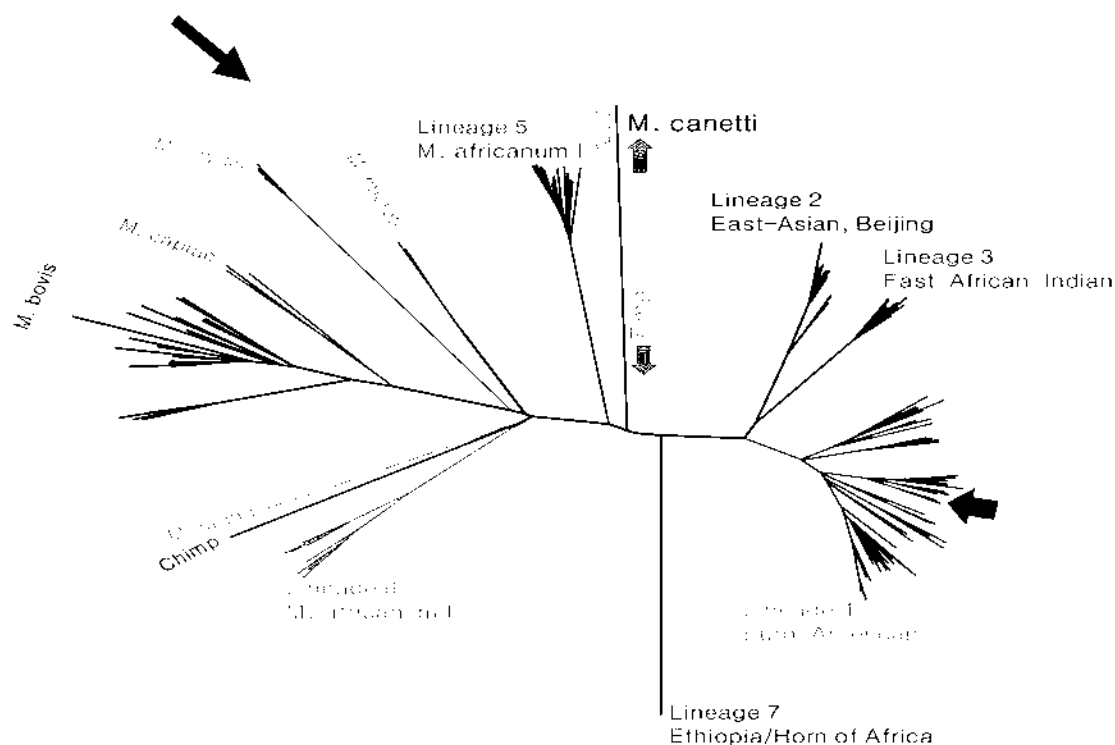
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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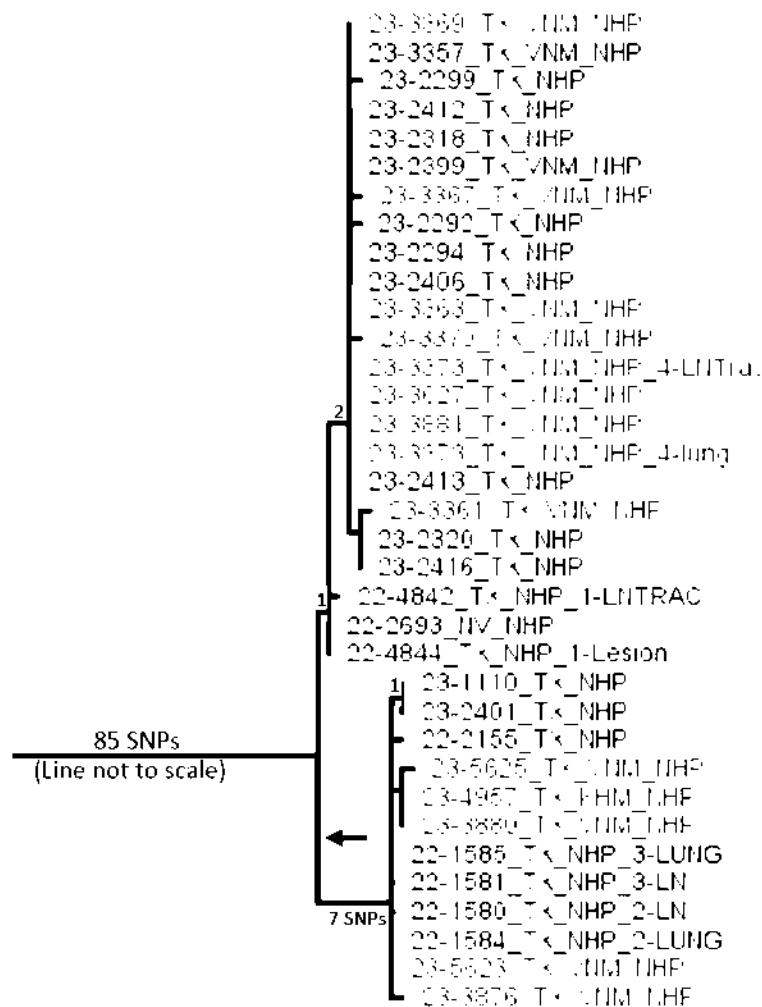
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) (b) (6) Charles River Laboratories		2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) @crl.com (b) (6) @crl.com		OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6) FAX NO. (b) (6)		4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047		PREMISES ID	COUNTY Harris
			STATE/COUNTRY TX/US

5. PAYMENT METHOD

<input type="checkbox"/> USER FEE ACCOUNT NO.	<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars)	<input checked="" type="checkbox"/> CREDIT CARD ce
---	---	---

6. HERD/FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 03/20/23
8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)
13. PURPOSE OF SUBMISSION (See instructions for definitions)		14. COUNTRY OF ORIGIN/DESTINATION (b) (4)
<input type="checkbox"/> Interstate Movement <input type="checkbox"/> Import <input checked="" type="checkbox"/> TB <input type="checkbox"/> Reagent Evaluation <input type="checkbox"/> Export <input type="checkbox"/> FAD/EP Diagnostic <input type="checkbox"/> General Diagnostic <input type="checkbox"/> NVSL Intralab <input type="checkbox"/> Pre-Import <input type="checkbox"/> Surveillance <input type="checkbox"/> Developmental Research		NUMBER

16. PRESERVATION <input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input checked="" type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)		18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)
17. SPECIMENS SUBMITTED ("X" applicable item(s)) <input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (specify) <input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus TBLN; Lung (b) (4) <input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (specify) <input type="checkbox"/> Water <input type="checkbox"/> DNA/RNA		
19. SPECIES OR SOURCE ("X" ONLY one) <input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (specify) <input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (specify) <input type="checkbox"/> Environment Cynomolgus (b) (4) <input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (specify) <input type="checkbox"/> Ek <input type="checkbox"/> Reagent Macaque		20. NUMBER OF ANIMALS SAMPLED (b) (4)

21. IDENTIFICATION (See instructions \$250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

23. SIGNATURE OF SUBMITTER AND DATE (b) (6) 4-18-23		23-012108 MB
CONDITION VS FORM 10-4 AUG 2009	PRIORITY 3	NVSL USE ONLY DISTRIBUTION (b) (6)

24-08898_000823

502739
04/19/2023

(b) (4) Necropsy - (b) (4)

From Date

03/20/2023 08:32:11

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6) (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/20/2023 08:15:57	Date Out	03/20/2023 08:15:57
03/20/2023 08:15:57	Location at Stock Out - Path	(b) (4)
03/21/2023 09:05:52	Died during quarantine	Yes
03/20/2023 08:15:57	Euthanasia Reason	TB Reactor
03/20/2023 08:15:57	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4) Pt reported for grade 3 TST at 72h read. No other significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema and swelling right superior palpebra. Red bruise proximal medial left thigh.

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Respiratory System



Abnormal Respiratory System Description

5mm red-tan spheroid nodule in parenchyma of left caudal lung lobe in ventral aspect. Upon incision, there is white viscous discharge in the center.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

(b) (4)

Necropsy

(b) (4)

Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

06 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had a grade 3 TST at 72 hours. Necropsy was conducted by the submitter and found nodule on the lung.

Microscopic Diagnoses:

#1 (b) (4) Lung: Abscess, mild, focal.

Acid Fast Stain (lung): Moderate numbers of acid-fast bacilli present in the lung lesion.

Lymph node (TBLN): Lymphoid hyperplasia, mild, multifocal.

Large intestine: *Balantidium coli*, minimal.

Spleen, Liver, Adrenal gland, Urinary bladder, Heart, Kidney, Stomach, Small intestine: Within normal limits.

Comment:

The pulmonary lesion and presence of intralesional acid-fast organisms was consistent with a diagnosis of Mycobacteriosis. There were no other significant lesion.

(b) (6)

**National Veterinary Services Laboratories**

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AMENDED REPORT

Laboratory Test Report**Owner****Accession Number:****23-012107****Animal Location****Harris County TX, US****NFC Control Number:**

19823025372

Date Collected:**03/20/2023****Date Received:**

04/19/2023

Date Completed:

08/23/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 502739**Charles River Laboratories**

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1907049 **Case #:** TB23-03366 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1907049 Case #: TB23-03367 Sample: 2 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has acquired a single SNP from sharing a the most recent common ancestor with 13 other isolates from this outbreak. See attached Genotyping report.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

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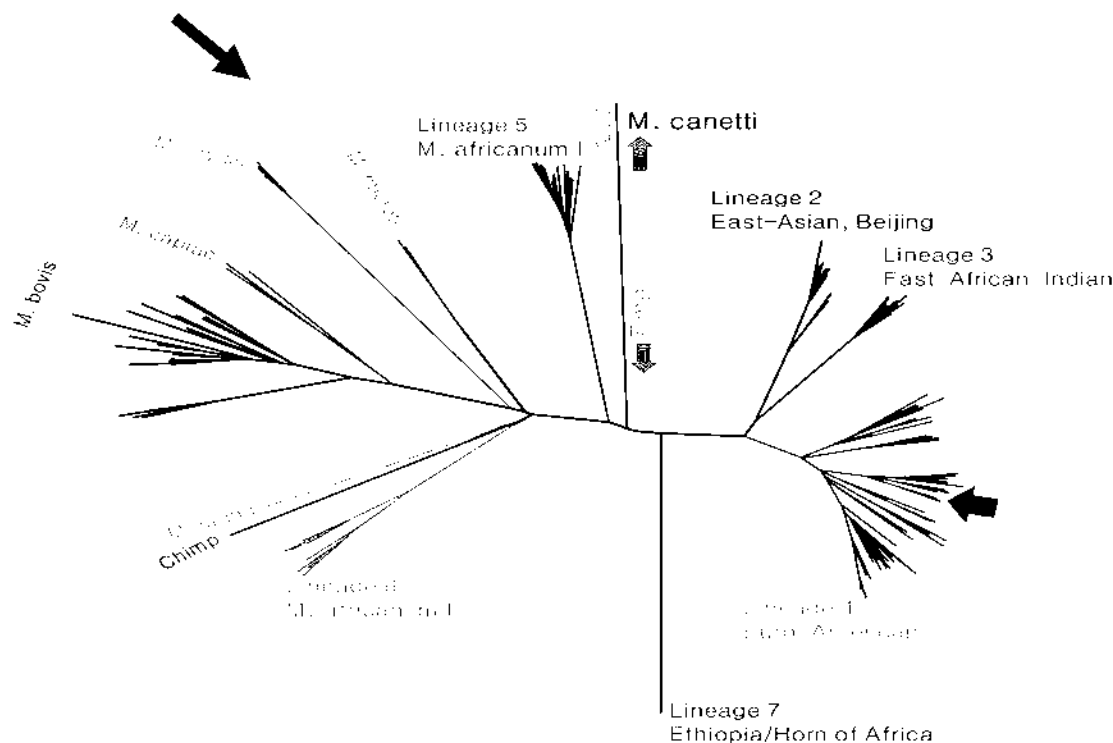
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



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23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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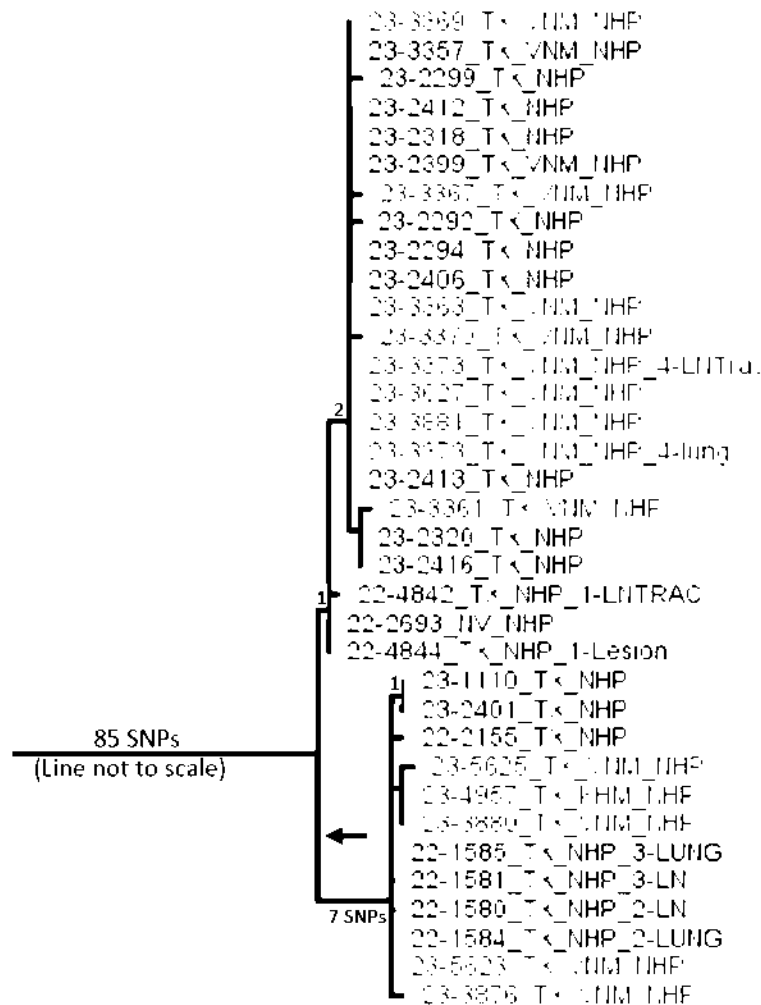
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. oryzae* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

(b) (4) Necropsy (b) (4)

From Date

03/20/2023 12:57:34

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/20/2023 12:56:16	Date Out	03/20/2023 12:56:16
03/20/2023 12:56:16	Location at Stock Out - Path	(b) (4)
03/21/2023 09:10:20	Died during quarantine	Yes
03/20/2023 12:56:16	Euthanasia Reason	TB Reactor
03/20/2023 12:56:16	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4) Pt reported for grade 5 TST OD at 72h read. No other significant clinical history.

Tentative Diagnosis

r/o tuberculosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



superior right palpebra severely swollen, moderately erythematous with yellow crusting.

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

enlarged tracheobronchial lymph nodes measuring between 1.0- 1.5cm. The largest tracheobronchial lymph node abnormal conformation, upon incision there are multifocal solid white nodules.

Respiratory System



Abnormal Respiratory System Description

5mm tan irregularly shaped nodule in the parenchyma of the caudal left lung lobe in the dorsomedial aspect. Upon incision, there are multifocal solid white nodules.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

missing third phalanx of digit 3 on left hand,

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



(b) (4) Necropsy (b) (4)

Skin

Skin - Description



Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order # (b) (4)

05 April 2023

History:

Customer: Charles River Houston - Quarantine

Strain: *Macaca fascicularis*

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had grade 5 TST at 72 hour read. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes (TBLN) with white nodules, a tan lung nodule.

Microscopic Diagnoses:

#1 (b) (4) lymph node (TBLN): Granuloma, moderate.

Lung: Abscess, mild, focal.

Acid Fast Stain (lung, TBLN): Positive for small numbers of acid-fast bacilli in the lymph node and pulmonary lesions.

Stomach: Lymphocytic infiltrates, mild, diffuse (lymphocytic gastritis).

Spleen, Liver, Heart, Kidney, Adrenal gland, Urinary bladder, Pancreas, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions in the TBLN and lung, as well as the presence of lesion-associated acid-fast organisms is consistent with Mycobacteriosis. The gastritis was considered incidental.

(b) (6)

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AMENDED REPORT

Laboratory Test Report**Owner****Accession Number:****23-012109****Animal Location****Harris County TX, US****NFC Control Number:**

19823025374

Date Collected:**03/20/2023****Date Received:**

04/19/2023

Date Completed:

08/23/2023

Submitter - 502739**Collected By:****Purpose:**

General Diagnostic

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2003029 **Case #:** TB23-03370 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result**Isolate****Acid fast bacteria recovered****Mycobacterium orygis****Direct PCR** for M. tuberculosis complex - IS1081**Detected** Ct = 27.31910324

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has acquired a single SNP from sharing a the most recent common ancestor with 13 other isolates from this outbreak. See attached Genotyping report.

Animal ID: 2003029 **Case #:** TB23-03371 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.49000168

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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APPENDIX – GENOTYPING REPORT

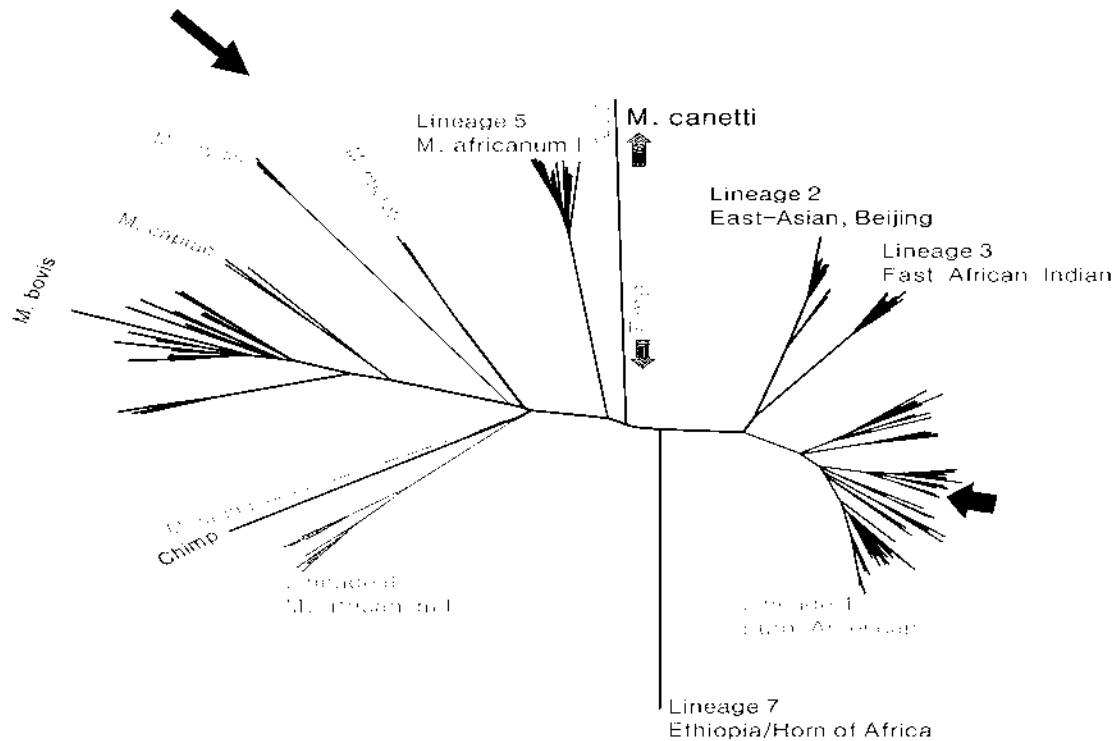
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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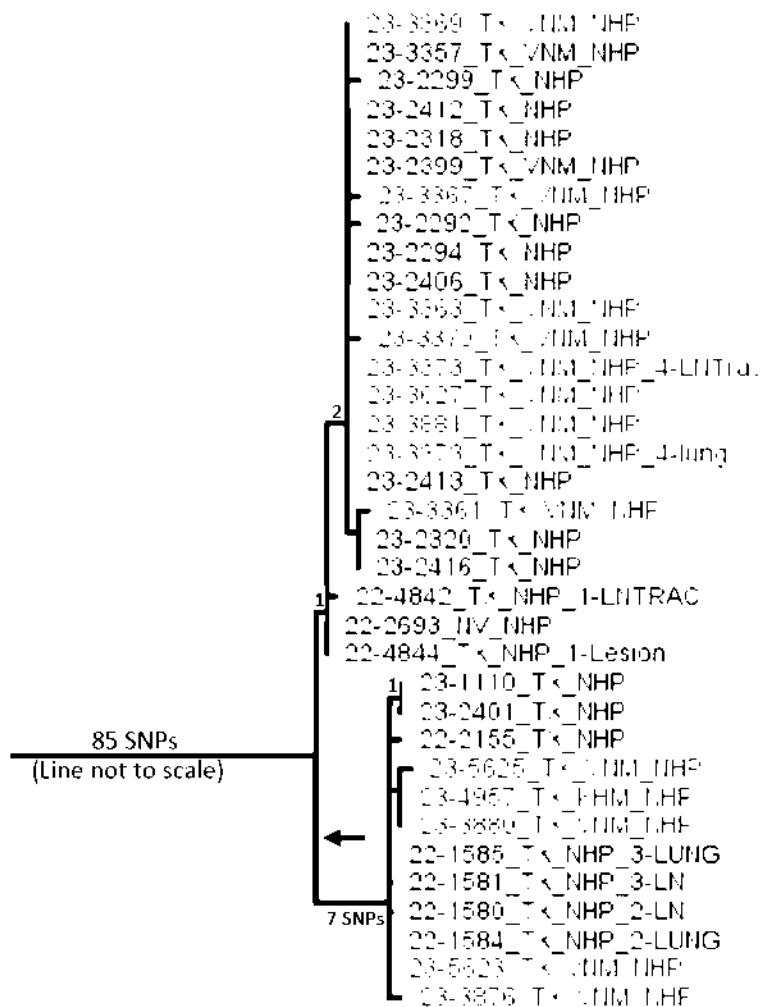
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	A	A	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com (b) (6) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

MAILING ADDRESS (Street, City, State, ZIP Code)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

6. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD
Number
Exp. Da

CC

7. NO. IN HERD/FLOCK AFFECTED

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

11. DATE COLLECTED
03/20/23

12. AUTHORIZED BY

(b) (6)

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

18. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus
Macaque

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)	(b) (4)			F					

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

(b) (6)

4-18-23

CONDITION

VS FORM 10-4
AUG 2009

PRIORITY

3

NVSL USE ONLY

DISTRIBUTION

(b) (6)

RECEIVED BY

(b) (6)

23-012110
MB

502739
04/19/2023

24-08898_000846

(b) (4) - Necropsy - (b) (4)

From Date

03/20/2023 15:58:28

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment	(b) (4)
03/20/2023 12:56:16	Date Out	03/20/2023 12:56:16
03/20/2023 12:56:16	Location at Stock Out - Path	(b) (4)
03/21/2023 09:12:22	Died during quarantine	Yes
03/20/2023 12:56:16	Euthanasia Reason	TB Reactor
03/20/2023 12:56:16	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) Pt reported for grade 3 TST OD at 72h read. No other significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema and swelling of right superior palpebra.

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

enlarged tracheobronchial lymph nodes measuring from 5mm to 1.2cm.

Respiratory System



Abnormal Respiratory System Description

5mm red-tan spheroid nodule in parenchyma of left caudal lung lobe at ventral aspect. Upon incision, there was multifocal off-white areas in the center.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) - Necropsy - (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

06 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: *Macaca fascicularis*
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had a grade 3 TST at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph node and lung nodule.

Microscopic Diagnoses:

#1 (b) (4) Lung, TBLN: Abscess, mild, focal.

Acid Fast Stain (lung, TBLN): Small numbers of acid-fast bacilli are present in both pulmonary and lymphoid lesions.

Lymph nodes (mesenteric), Adrenal gland, Heart, Liver, Urinary bladder, Kidney, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions and intralesional acid-fast organisms were consistent with Mycobacteriosis. There were no other significant microscopic lesions.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner****Accession Number:****23-012110****Animal Location****Harris County TX****NFC Control Number:**

19823025375

Date Collected:**03/20/2023****Date Received:**

04/19/2023

Date Completed:

08/23/2023

Submitter - 502739**Collected By:****Purpose:**

General Diagnostic

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2007040 **Case #:** TB23-03372 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result**Isolate****Acid fast bacteria recovered****Mycobacterium orygis****Direct PCR** for M. tuberculosis complex - IS1081**Detected** Ct = 21.38571739

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 13 other isolates in this outbreak. See attached Genotyping report.

Animal ID: 2007040 Case #: TB23-03373 Sample: 2 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result**Isolate**

Acid fast bacteria recovered

**Mycobacterium tuberculosis
complex****Direct PCR** for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 13 other isolates in this outbreak. See attached Genotyping report.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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APPENDIX – GENOTYPING REPORT

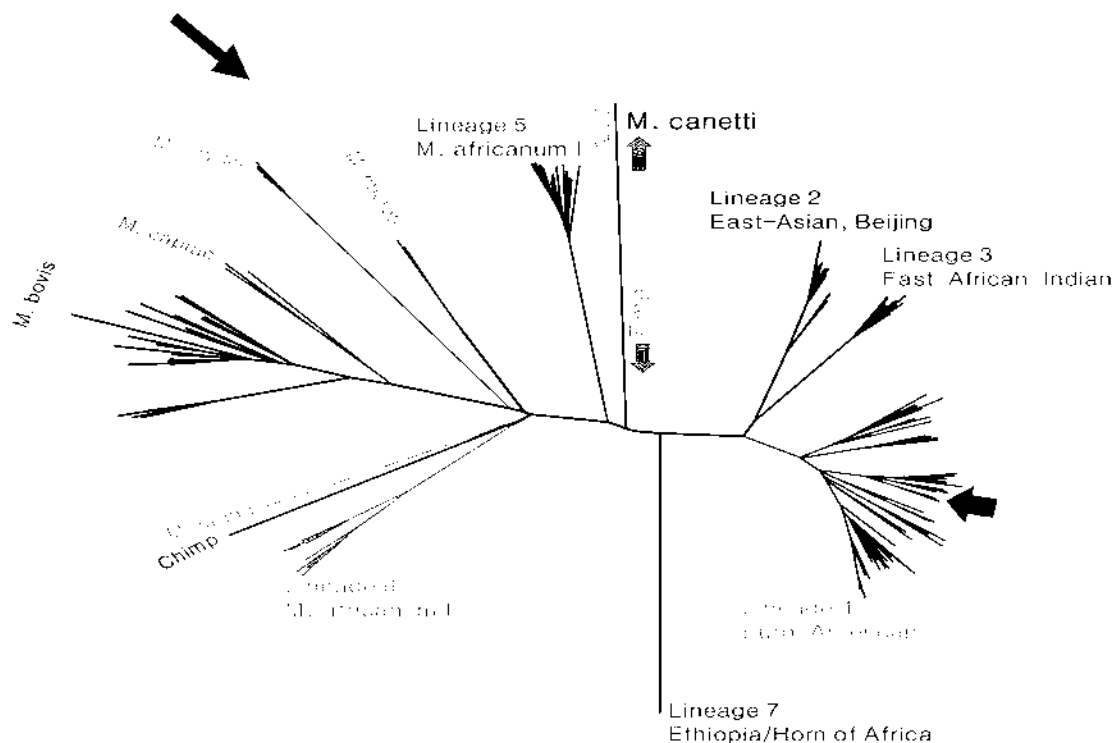
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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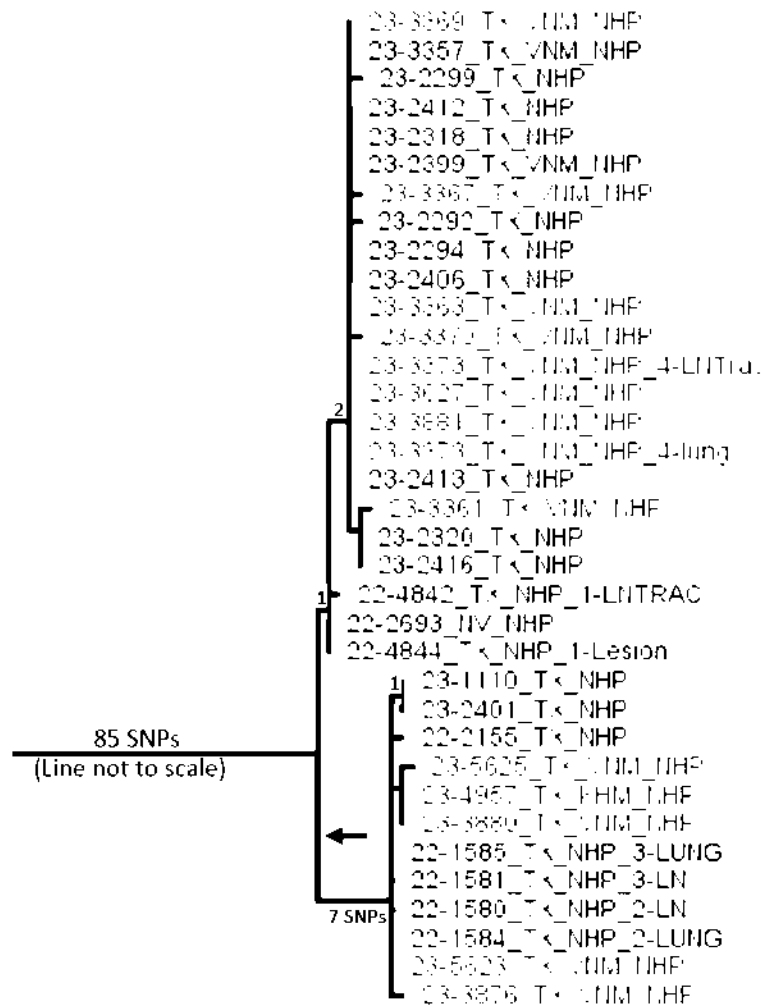
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. oryzae* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

Exhibit 19

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com (b) (6) crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD

CC

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

(b) (4) HERD/FLOCK
AFFECTED

Culture; PCR

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

03/21/23

12. AUTHORIZED BY

(b) (6)

13. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung; Liver

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

(b) (4)

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions - 250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

(b) (6)

4-18-23

23-012106

23-012106
MB

X

CONDITION

PRIORITY

NVSL USE ONLY

DISTRIBUTION

RECEIVED BY

VS FORM 10-4
AUG 2009

3

(b) (6)

①

502739
04/19/2023

24-08898_000805

(b) (4) - Necropsy (b) (4)

From Date

03/21/2023 16:41:19

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6) (b) (6)

Properties

Date of Last Update

Name

Value

(b) (4)

In-Shipment #

(b) (4)

03/21/2023 16:40:29

Date Out

03/21/2023 16:40:29

03/21/2023 16:40:29

Location at
Stock Out -
Path

(b) (4)

03/21/2023 17:24:27

Died during
quarantine

Yes

03/21/2023 16:40:29

Euthanasia
Reason

TB Reactor

03/21/2023 16:40:29

Euthanasia
Method

IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4) Pt reported for grade 3 TST OD at 72 hr read. No other significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



minor erythema and mild swelling right superior palpebra

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

enlarged tracheobronchial lymph nodes measuring between 4mm and 1.4cm. The largest tracheobronchial lymph nodes has white discharge in the center upon incision.

Respiratory System



Abnormal Respiratory System Description

adhesions from the ventral aspect of the left cranial and caudal lung lobes to the thoracic wall and mediastinum appreciated upon opening the thoracic cavity. A 2mm hard white, chalky nodule on the ventral aspect of left caudal lung lobe. Upon blunt dissection of the lung lobe from adhering to the thoracic wall, so of the chalky hard white nodule remained adhered to the thoracic wall. A 4mm solid firm nodule with a tan perimeter and off white center is embedded in the parenchyma of the right middle lung lobe.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

7mm x 6mm area of infarction at edge of right middle hepatic lobe

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung

Heart Muscle

Liver



Spleen

Kidney

(b) (4) - Necropsy - (b) (4)

Stomach



Ileum



Skeletal Muscle



Skin



Other



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order # (b) (4)

11 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had grade 3 TST at 72 hours. Gross necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes, pulmonary lesions and nodules, presumed liver infarction.

Microscopic Diagnoses:

#1 (b) (4) TBLN: Granuloma, mild, multifocal.

Lung: Mineralization, vascular, moderate, focal.

Thickened pleura, mild, multifocal.

Granuloma, mild, focal.

Acid Fast stain (TBLN, Lung): Positive for small numbers of acid-fast organisms in the lymph node

Liver: Vacuolation, hepatocellular, moderate, focally extensive (hepatic lipidosis).

Spleen, Heart, Kidney, Stomach, Urinary bladder, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions with intralesional acid-fast organism was consistent with Mycobacteriosis. The gross liver lesion was likely correlated to a focus of lipidosis. No infarction was noted. No other significant lesions were noted.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report**Owner****Accession Number:****23-012106****Animal Location****Harris County TX****NFC Control Number:**

19823025371

Date Collected:**03/21/2023****Date Received:**

04/19/2023

Date Completed:

08/23/2023

Submitter - 502739**Collected By:****Purpose:**

General Diagnostic

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1807016 **Case #:** TB23-03363 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result**Isolate****Acid fast bacteria recovered****Mycobacterium orygis****Direct PCR** for M. tuberculosis complex - IS1081**Detected** Ct = 30.37460327

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 13 other isolates in this outbreak. See attached Genotyping report.

Animal ID: 1807016 **Case #:** TB23-03364 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 29.36946106

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1807016 **Case #:** TB23-03365 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

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Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

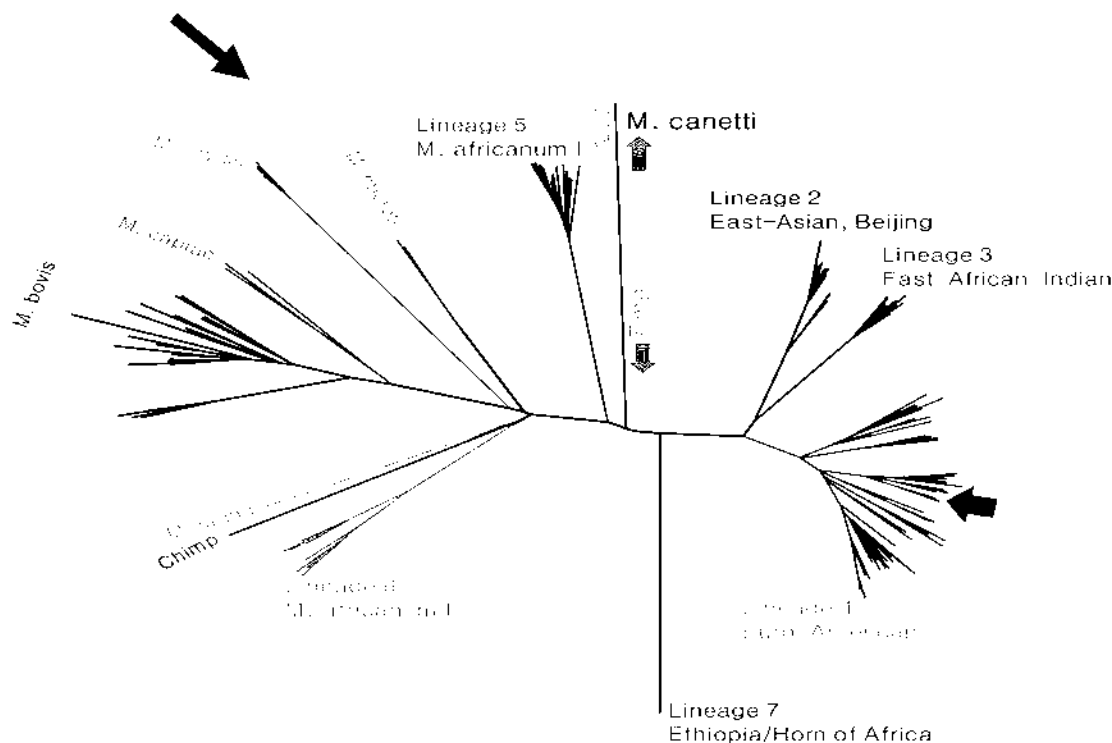
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



National Veterinary Services Laboratories

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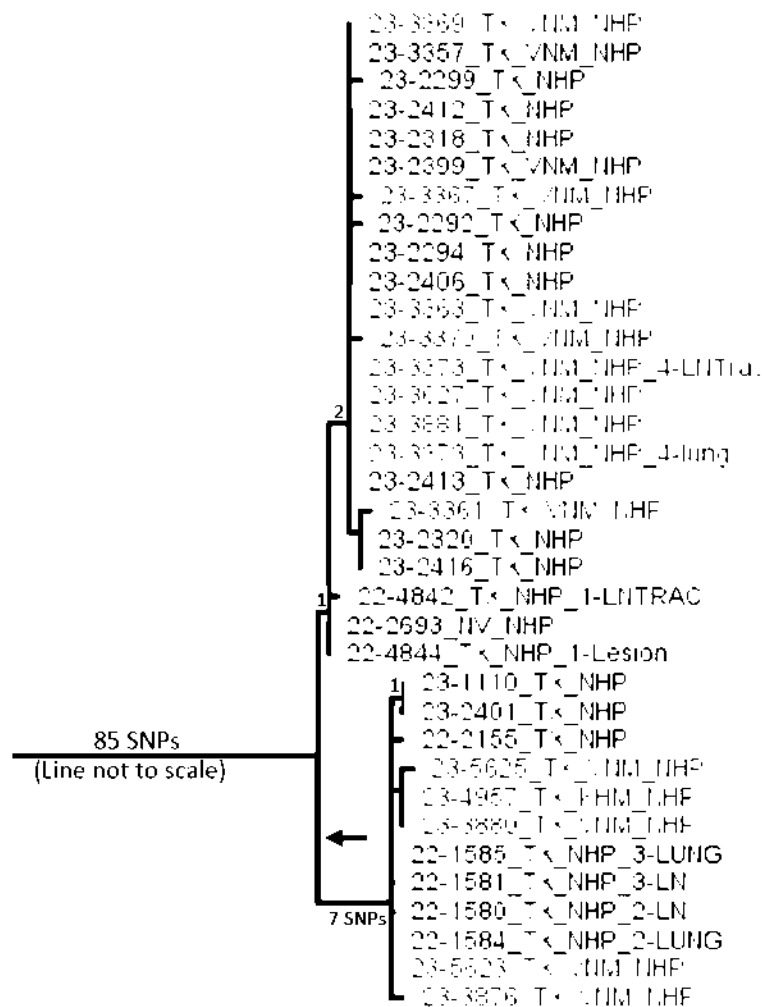
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) @crl.com (b) (4) @crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CRED
CARD

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

11. DATE COLLECTED

03/21/23

8. NO. IN HERD/FLOCK
DEAD

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung;
Stomach; Spleen

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus
Macaque

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

23. SIGNATURE OF SUBMITTER AND DATE

X

23-012103

MB

CONDITION

PRIORITY

NVSL USE ONLY

DISTRIBUTION

RECEIVED BY

VS FORM 10-4
AUG 2009

04/19/2023
502739

24-08898_000787

(b) (4) Necropsy (b) (4)

From Date 03/21/2023 15:20:00 Reference # (b) (4) Registered ☒

Domain Animal Activity Necropsy

Animal ID (b) (4) Status Performed Performed by (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
03/21/2023 15:19:29	Date Out	03/21/2023 15:19:29
03/21/2023 15:19:29	Location at Stock Out - Path	(b) (4)
03/21/2023 16:05:12	Died during quarantine	Yes
03/21/2023 15:19:29	Euthanasia Reason	TB Reactor
03/21/2023 15:19:29	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

(b) (4) male cynomolgus macaque arriving at facility (b) (4) Grade 3 TST OD at 72h read. No other significant history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin ☒ Abnormal Skin Description mild erythema and swelling of RT superior palpebra

Oral ☒ Abnormal Oral Cavity Description

(b) (4) - Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

3 enlarged tracheobronchial lymph nodes: 1x.5; 1.5x.5 and 1.5x1.5 cm² with light gray/off white round inclusions, approx 2mm, 2 gray tracheobronchial lymph nodes approx 4mm and 8mm with dark gray hue

Respiratory System



Abnormal Respiratory System Description

Two lung nodules, firm, embedded in lung parenchyma, with light pink/off white core, 3mm

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

multiple round, firm, smooth nodule/bullae-like lesion snear cardiac region

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



(b) (4) Necropsy (b) (4)

Skin

Skin - Description



Other

Other - Description



spleen - milky white flat nodules ranging from 0.5-2mm visible on the splenic capsule. Lesion 1 - splenic nodule Lesion 2 - cardiac stomach nodule Lesion 3 - lung nodule Lesion 4 - dark TBLN

Microbiology

Other Diagnostic Test

Histopathology

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order #: (b) (4)

11 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had grade 3 TST at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes (TBLN), lung nodules, milky-colored spleen and focal nodule in stomach.

Microscopic Diagnoses:

#1 (b) (4) TBLN: Abscess, moderate, multifocal.

Lymphoid hyperplasia with foci of macrophages, mild, multifocal and occasional multinucleated giant cell.

Acid Fast Stain (TBLN): Positive for small numbers of acid-fast bacilli in TBLN lesion.

Lung (fragment): Inflammatory cells, mononuclear, mild, focal near margin.

Lung (Acid Fast): Negative.

Stomach: Increase gastric mucosal associated lymphoid tissue, mild, multifocal.

Heart, Liver, Kidney, Spleen, Urinary bladder, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic change in the TBLN and positive findings on Acid fast stain were consistent with Mycobacteriosis. Grossly noted gastric nodules may correlate to intestinal lymphoid aggregates (GALT).

(b) (6)

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-012103****Animal Location**

Harris County TX, US

NFC Control Number:

19823025368

Date Collected:

03/21/2023

Date Received:

04/19/2023

Date Completed:

10/04/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 502739

Charles River Laboratories

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1907017 Case #: TB23-03355 Sample: Lesion 1 Specimen Type: SPLEEN, LESION**Species: Monkey, Cynomolgus**

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1907017 Case #: TB23-03356 Sample: Lesion 2 Specimen Type: STOMACH, LESION**Species: Monkey, Cynomolgus**

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1907017 **Case #:** TB23-03357 **Sample:** Lesion 3 **Specimen Type:** Granuloma, Lung
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and compared to all the isolates in the NVSL Database. This isolate is a *Mycobacterium orygis*. This isolate has the same SNP pattern as the majority of the isolates in the branch. See Genotyping report.

Animal ID: 1907017 **Case #:** TB23-03358 **Sample:** Lesion 4 **Specimen Type:** LNTRAC, LESION
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

APPENDIX – GENOTYPING REPORT

4 October 2023

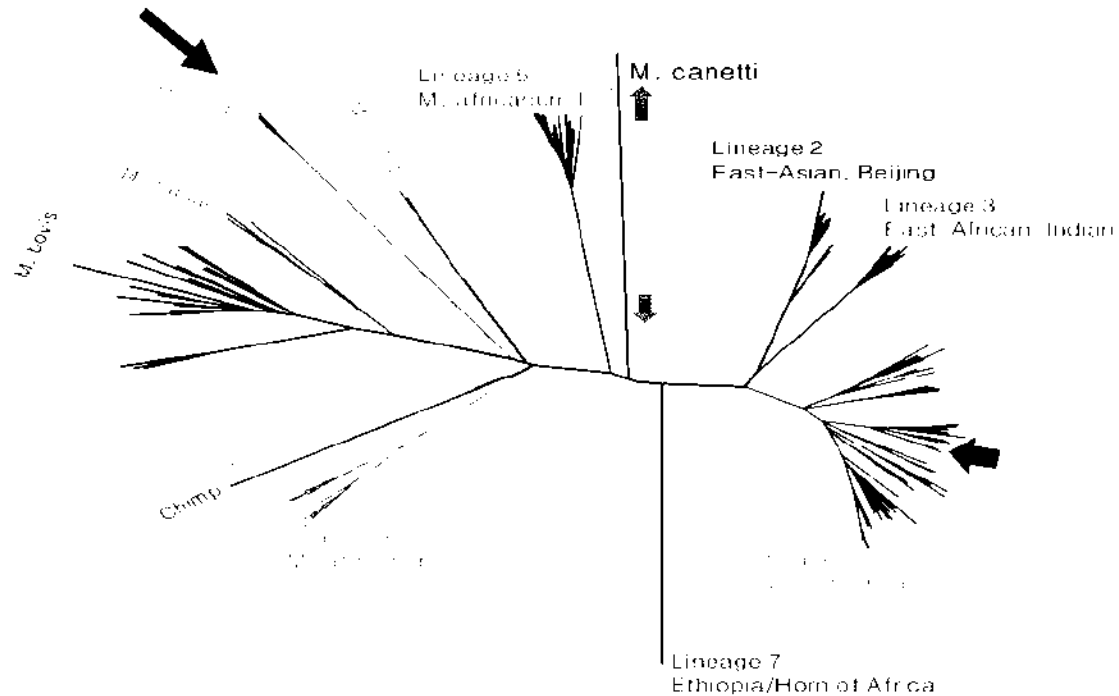
Accession:

23-012103

23-005854

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.





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APPENDIX – GENOTYPING REPORT

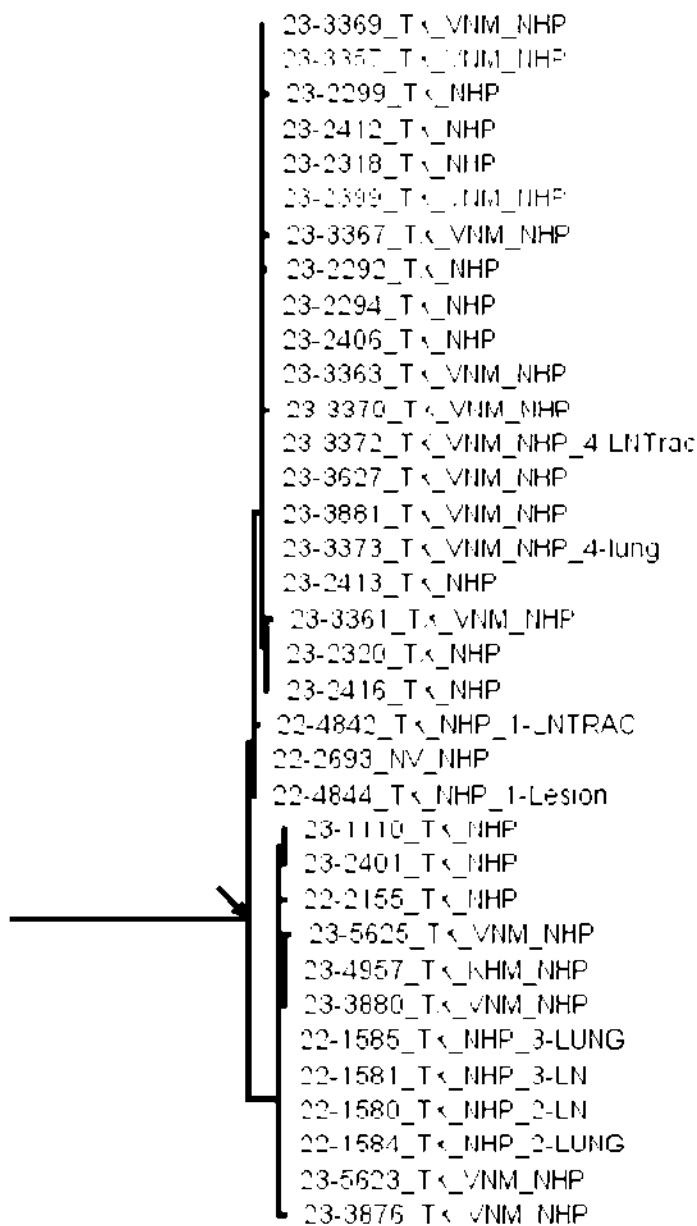
4 October 2023

Accession:

23-012103

23-005854

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. The two isolates associated with these submissions are in red. These two isolates have the same SNP pattern as the majority of the isolates in this branch.





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APPENDIX – GENOTYPING REPORT

4 October 2023

Accession:

23-012103

23-005854

Table 1: Abbreviated SNP table of NVSL Group Orygis. Isolates 23-3357 and 23-2399 have the same SNP pattern as the majority (bracket) of the isolates from this branch (see Figure 1).

	NC_000962.3:4079545	NC_000962.3:4091916	NC_000962.3:4119052	NC_000962.3:4144714	NC_000962.3:4199069	NC_000962.3:4259860	NC_000962.3:4313309	NC_000962.3:4387015	NC_000962.3:4407309	NC_000962.3:4410735	NC_000962.3:2874747	NC_000962.3:130886	NC_000962.3:3428942	NC_000962.3:1461421	NC_000962.3:3010690	NC_000962.3:4317051	NC_000962.3:1594487	NC_000962.3:3332273
root	T	A	A	G	G	G	A	T	G	G	G	G	G	T	G	A	G	G
23-2292_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3369_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3357_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2412_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2318_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2399_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3372_TX_VNM_NHP_4-LNTrac		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3627_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3881_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3373_TX_VNM_NHP_4-lung		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2413_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2406_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-3363_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	G	G
23-2299_TX_NHP		G	G	A	A	A	G			A		A	A	A	G	A	G	G
23-3367_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	A	A	G	G
23-3370_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	G	G	G
23-2294_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	R	G
23-2320_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	A	G
23-2416_TX_NHP		G	G	A	A	A	G			A		A	A	T	G	A	A	G
23-3361_TX_VNM_NHP		G	G	A	A	A	G			A		A	A	T	G	A	A	A

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

11 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Grade 3 TST at 72 hours. Gross necropsy performed by the submitter found enlarged tracheobronchial lymph node (TBLN) and gastric ulcers.

Microscopic Diagnoses:

#1 (b) (4) TBLN: Granuloma, moderate, focally extensive.

Acid Fast Stain (TBLN): Positive for acid-fast bacilli associated with the lymphoid lesion.

Lung, Spleen, Stomach, Heart, Liver, Kidney, Urinary bladder, Small intestine, Large intestine:
Within normal limits.

Comment:

The TBLN microscopic lesion and intralesional acid fast bacilli were consistent with a diagnosis of Mycobacteriosis. Gastric ulcers were not noted in the sections. No other significant lesions were found.

(b) (6)

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-013240****Animal Location**

Harris County TX, US

NFC Control Number:

19823026641

Date Collected:

03/21/2023

Date Received:

04/28/2023

Date Completed:

08/23/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1708008 **Case #:** TB23-03627 **Sample:** 1 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 13 other isolates in this outbreak. See attached Genotyping report.

Samples from this animal were also received under Accession 23-012104.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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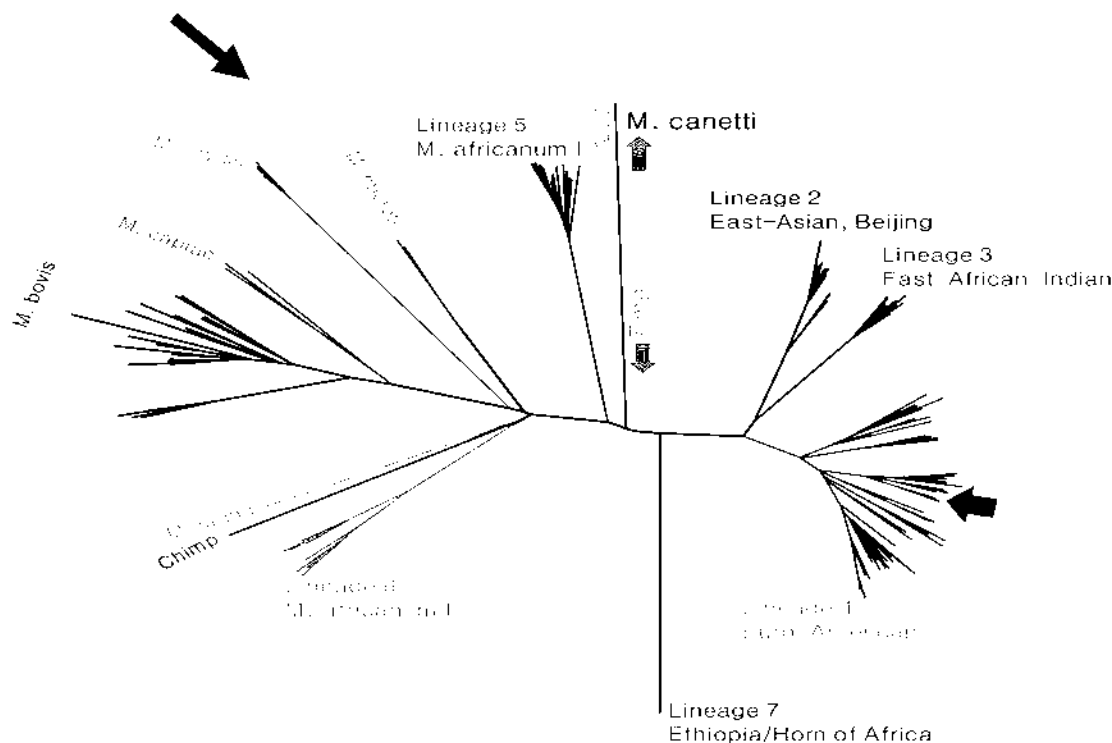
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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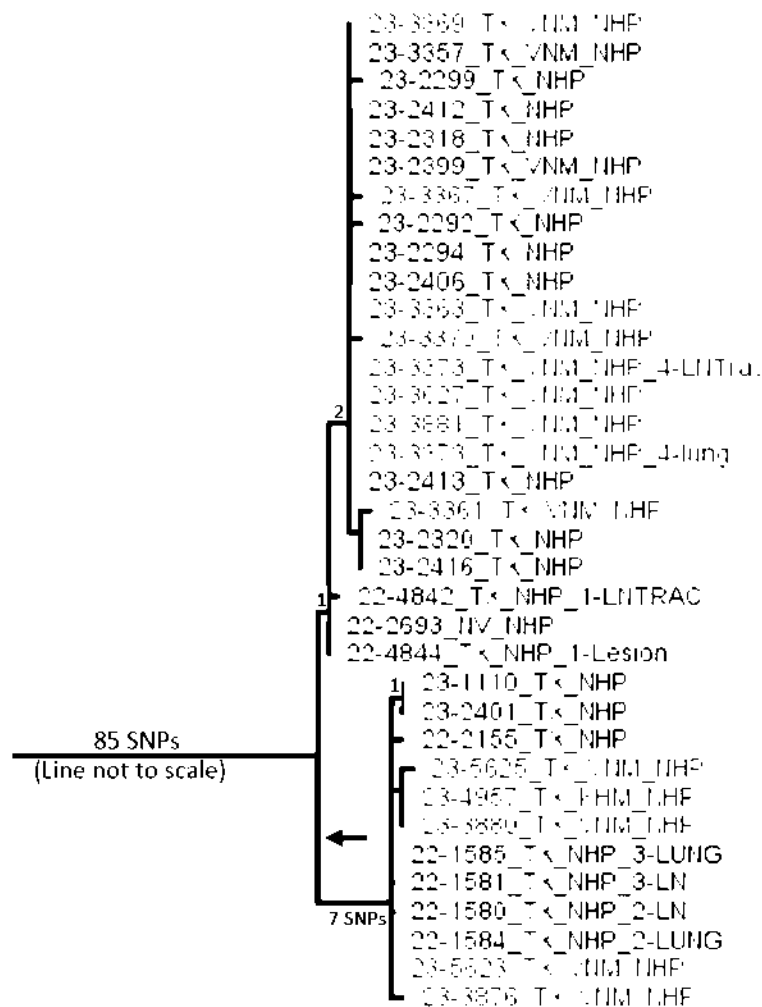
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 208099.5	NC_000962.3 48939.5	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

Exhibit 20

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0080, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0080, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0080, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) (b) (6) Charles River Laboratories		2. NVSL SUBMITTER ID	3. NAME OF OWNER <input checked="" type="checkbox"/> Check if wildlife (no owner)
EMAIL ADDRESS (b) (6) crl.com (b) (6) crl.com		OWNER CITY Houston	STATE/COUNTRY TX/US
PHONE NO. (b) (6) FAX NO. (b) (6)		4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Houston, TX 77047		PREMISES ID	COUNTY Harris
			STATE/COUNTRY TX/US

5. PAYMENT METHOD		
<input type="checkbox"/> USER FEE ACCOUNT NO.	<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in US dollars)	<input checked="" type="checkbox"/> CREDIT CARD Num' <u>u</u> Exp. <u>u</u>
6. HERD/FLOCK SIZE (b) (4)	9. EXAMINATIONS REQUESTED Culture; PCR	10. COLLECTED BY (b) (6)
7. NO. IN HERD/FLOCK AFFECTED		11. DATE COLLECTED 04/03/23
8. NO. IN HERD/FLOCK DEAD		12. AUTHORIZED BY (b) (6)
13. PURPOSE OF SUBMISSION (See instructions for definitions)		
<input type="checkbox"/> Interstate Movement <input type="checkbox"/> Import <input checked="" type="checkbox"/> TB <input type="checkbox"/> Reagent Evaluation		
<input type="checkbox"/> Export <input type="checkbox"/> FAD/EP Diagnostic <input type="checkbox"/> General Diagnostic <input type="checkbox"/> NVSL Intralab		
<input type="checkbox"/> Pre-Import <input type="checkbox"/> Surveillance <input type="checkbox"/> Developmental Research		

16. PRESERVATION <input type="checkbox"/> None <input type="checkbox"/> Ice Pack <input checked="" type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)		
17. SPECIMENS SUBMITTED ("X" applicable item(s))		18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)
<input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (specify)		
<input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus TBLN; Lung		
<input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (specify) <input type="checkbox"/> Water <input type="checkbox"/> DNA/RNA		
19. SPECIES OR SOURCE ("X" ONLY one)		20. NUMBER OF ANIMALS SAMPLED (b) (4)
<input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (specify)		
<input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (specify) <input type="checkbox"/> Environment Cynomolgus Macaque		
<input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (specify) <input type="checkbox"/> Elk <input type="checkbox"/> Reagent		

21. IDENTIFICATION (See instructions - 250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

(b) (6)		4-18-23		23-012105 MB	
CONDITION DI	PRIORITY 3	NVSL USE ONLY DISTRIBUTION MB	RECEIVED BY (b) (6)	602739 04/19/2023	
VS FORM 10-4 AUG 2009					
24-08898_000796					

(b) (4) Necropsy - (b) (4)

From Date 04/03/2023 11:38:56 Reference # (b) (4) Registered ☒

Domain Animal Activity Necropsy

Animal ID (b) (4) Status Performed Performed by (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment	(b) (4)
04/03/2023 11:38:02	Date Out	04/03/2023 11:38:02
04/03/2023 11:38:02	Location at Stock Out - Path	(b) (4)
04/06/2023 12:34:04	Died during quarantine	Yes
04/03/2023 11:38:02	Euthanasia Reason	TB Reactor
04/03/2023 11:38:02	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Patient arrived at facility (b) (4) Pt had grade 4 TST at 72h read. No clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description

☒

mild swelling and moderate erythema with scaling of the left superior palpebra

Oral

Abnormal Oral Cavity Description

☒

(b) (4) - Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

three enlarged tracheobronchial lymphs measuring from 1.0cm to 1.3 cm in length. Off-white multifocal irregularly shaped nodules are in the center upon incision.

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) Necropsy (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order # (b) (4)

14 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy. The animal had a grade 4 TST at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes (TBLN).

Microscopic Diagnoses:

#1 (b) (4) Lymph node (TBLN): Granuloma, mild, multifocal.

Acid Fast Stain (TBLN): Positive for infrequent acid-fast organism in the TBLN lesion.

Lung, Liver, Spleen, Heart, Kidney, Adrenal gland, Urinary bladder, Stomach, Small intestine, Large intestine, Pancreas: Within normal limits.

Comment:

The lymph node lesion and presence of acid-fast bacteria were consistent with a diagnosis of Mycobacteriosis in this animal.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner****Accession Number:****23-012105****Animal Location****Harris County TX, US****NFC Control Number:**

19823025370

Date Collected:**04/03/2023****Date Received:**

04/19/2023

Date Completed:

08/23/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 502739**Charles River Laboratories**

305 Alameda Genoa Rd

Houston, TX 77047

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1901032 **Case #:** TB23-03361 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result**Isolate****Acid fast bacteria recovered****Mycobacterium orygis****Direct PCR** for M. tuberculosis complex - IS1081

Detected Ct = 24.55780602

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has acquired a 2 SNPs from sharing a the most recent common ancestor with 13 other isolates from this outbreak. See attached Genotyping report.

Animal ID: 1901032 **Case #:** TB23-03362 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 37.1288147

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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APPENDIX – GENOTYPING REPORT

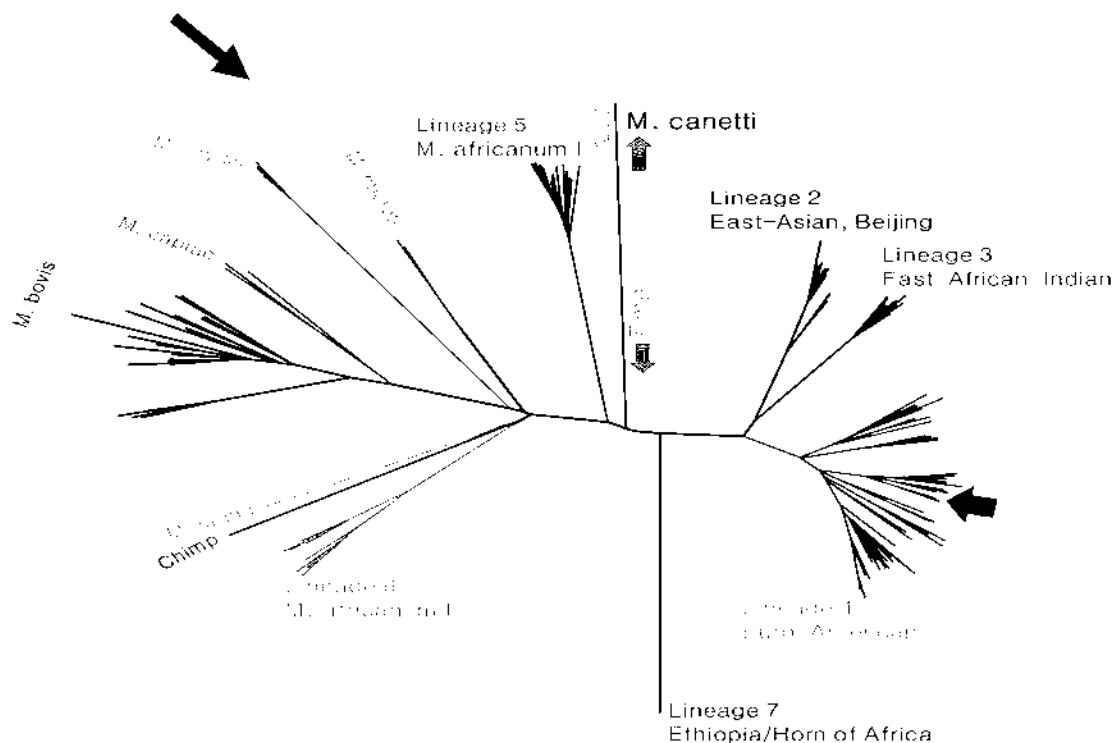
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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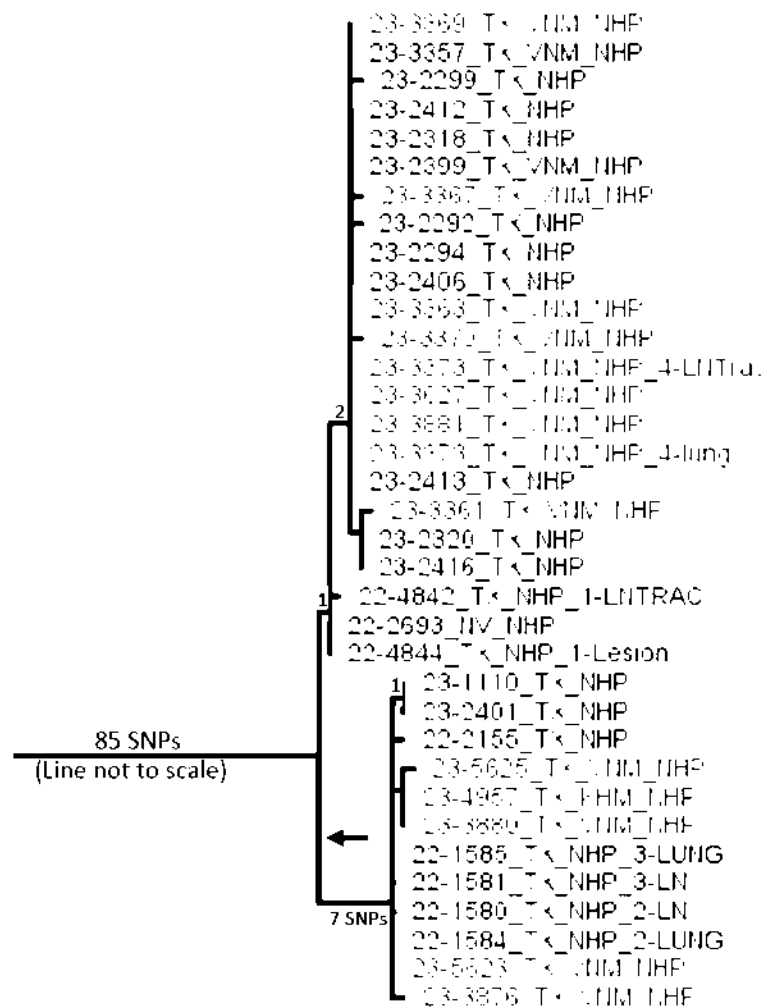
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. oryzae* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 208099.5	NC_000962.3 48939.5	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	A	A	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G

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OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

OWNER CITY

STATE/COUNTRY

(b) (6) .crl.com (b) (6) .crl.com

Houston

TX/US

PHONE NO.

FAX NO.

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

PREMISES ID

COUNTY

STATE/COUNTRY

Harris

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

10. COLLECTED BY

(b) (4)

Culture; PCR

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

11. DATE COLLECTED
04/03/23

8. NO. IN HERD/FLOCK
DEAD

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

12. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Food

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

(b) (4)

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions: Use additional sheets if necessary).

see attached necropsy report

23. SIGNATURE OF SUBMITTER AND DATE

X

NVSL USE ONLY

CONDITION

PRIORITY

DIST

(b) (6)

23-014320

MB

30321
05/09/2023



VS FORM 10-4
AUG 2009

24-08898_000867

(b) (4) - Necropsy - (b) (4)

From Date

04/03/2023 15:48:39

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6) (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
04/03/2023 15:21:18	Date Out	04/03/2023 15:21:18
04/03/2023 15:21:18	Location at Stock Out - Path	(b) (4)
04/06/2023 12:44:04	Died during quarantine	Yes
04/03/2023 15:21:18	Euthanasia Reason	TB Reactor
04/03/2023 15:21:18	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

(b) (4) origin animal arriving at facility (b) (4) Reported for Grade 3 TST OS at 72h read. No other significant clinical history.

Tentative Diagnosis

r/o Mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



mild erythema minor swelling of left superior palpebra

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

three enlarged tracheobronchial lymph nodes measuring 0.8cm-1.8cm in length. The largest lymph node had an off-white solid nodule in the center upon incision.

Respiratory System



Abnormal Respiratory System Description

focal 0.6cm irregularly shaped tan mass in parenchyma of right middle lung lobe. The center was off-white upon incision.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



(b) (4) - Necropsy - (b) (4)

Skin

Skin - Description



Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

19 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4) *

Quarantine Necropsy. Grade 3 TST at 72 hours. Necropsy was performed by the submitter and found enlarged tracheobronchial lymph nodes (TBLN) and a lung nodule.

Microscopic Diagnoses:

#1 (b) (4) Lung: Abscess, moderate, focal.

TBLN: Abscess/granuloma, moderate, multifocal.

Acid Fast Stain (lung, TBLN): Small numbers of intralesional acid-fast bacilli in lung and TBLN lesions.

Large intestine: Balantidium coli, luminal, mild.

Liver, Spleen, Heart, Kidney, Adrenal gland, Urinary bladder, Stomach, Small intestine: Within normal limits.

Comment:

The pulmonary and TBLN lesions with intralesional acid-fast bacilli are consistent with Mycobacteriosis. B. coli is incidental.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-014325****Animal Location**

Harris County TX, US

NFC Control Number:

19823027961

Date Collected:

04/03/2023

Date Received:

05/09/2023

Date Completed:

07/19/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1905020 **Case #:** TB23-03883 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081**Detected** **Ct = 26.71939468**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1905020 **Case #:** TB23-03884 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 644, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) crl.com (b) (6) crl.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

DATE

04/03/23

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

23. SIGNATURE OF SUBMITTER AND DATE

X

CONDITION

PRIORITY

NVSL USE ONLY
DISTR

(b) (6)

VS FORM 10-4
AUG 2009

23-014324
MB

30321
05/09/2023

24-08898_000920

- Necropsy - (b) (4)

From Date

04/03/2023 15:41:27

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6), (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
04/03/2023 15:20:52	Date Out	04/03/2023 15:20:52
04/03/2023 15:20:52	Location at Stock Out - Path	(b) (4)
04/06/2023 12:41:29	Died during quarantine	Yes
04/03/2023 15:20:52	Euthanasia Reason	TB Reactor
04/03/2023 15:20:52	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

(b) (4) origin cynomolgus macaque arriving at facility (b) (4) Reported for Grade 3 TST OS at 72h read. No other significant clinical history.

Tentative Diagnosis

r/o Mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Oral

Abnormal Oral Cavity Description



- Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

1.1cm enlarged tracheobronchial lymph node

Respiratory System



Abnormal Respiratory System Description

3mmx2mm tan discolored area of parenchyma of left caudal lung lobe. 5mm x4mm tan discolored area of parenchyma of right caudal lung lobe.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

- Necropsy - (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

Histopathology results pending.

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order # (b) (4)

19 April 2023

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy. Grade 3 TST at 72 hours. Necropsy performed by the submitter found enlarged tracheobronchial lymph nodes (TBLN) and two tan areas on lung lobes.

Microscopic Diagnoses:

#1 (b) (4) TBLN: Abscess, mild, multifocal with aggregates of macrophages.

Acid fast stain (TBLN): Positive for moderate numbers of acid-fast bacilli in the lesion.

Large intestine: Lymphocytic infiltrates, mucosal, moderate, diffuse (lymphocytic enteritis).

Lung, Liver, Spleen, Heart, Kidney, Adrenal gland, Stomach, Small intestine, Urinary bladder:

Within normal limits.

Comment:

The microscopic lesion in the TBLN and the presence of intralesional acid-fast bacilli was consistent with the diagnosis of Mycobacteriosis. Lymphocytic colitis was also noted.

(b) (6)

Bravo-Garcia, Doris - MRP-APHIS

From: (b) (6) <(b) (6)@crl.com>
Sent: Thursday, May 4, 2023 10:42 AM
To: Lehman, Kimberly - MRP-APHIS; APHIS-NVSL Case Coordinator - APHIS; Bravo-Garcia, Doris - MRP-APHIS
Cc: (b) (6)
Subject: [External Email] Request to ship NHP Samples
Attachments: (b) (4)

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;
Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send (b) (4) NHP samples for Mycobacterium testing on Thursday, May 4th to arrive Friday, May 5th. Please let us know if you are agreeable to this. The necropsy, histopathology and filovirus reports are attached for animal IDs# (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) and (b) (4)

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)
What was the date that they left the originating country? (b) (4)
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Were animals exposed to animals from other sources? No
Was a complete necropsy and with histology done on this animal? Yes, see attached reports
If so, can you provide those results?

1. (b) (4)
 - a. Necropsy findings:
 - i. moderate erythema, moderate swelling, and erosion of left superior palpebra.
 - ii. four enlarged tracheobronchial lymph nodes measuring 0.5- 1.0cm in length. the largest lymph node had two off-white solid nodule in the center upon incision.
 - iii. hemorrhagic appearance of parenchyma of caudal lung lobes bilaterally
 - b. Histopath:
 - i. The microscopic lesions in the lung and TBLN and presence of acid-fast bacteria in the TBLN were consistent with the diagnosis of Mycobacteriosis.
2. (b) (4)
 - a. Necropsy findings:
 - i. 1.1cm enlarged tracheobronchial lymph node.

- ii. 3mmx2mm tan discolored area of parenchyma of left caudal lung lobe. 5mm x4mm tan discolored area of parenchyma of right caudal lung lobe.
 - b. Histopath:
 - i. The microscopic lesion in the TBLN and the presence of intralesional acid-fast bacilli was consistent with the diagnosis of Mycobacteriosis.
- 3. (b) (4)
 - a. Necropsy findings:
 - i. mild erythema minor swelling of left superior palpebra
 - ii. three enlarged tracheobronchial lymph nodes measuring 0.8cm-1.8cm in length. The largest lymph node had an off-white solid nodule in the center upon incision.
 - iii. irregularly shaped tan mass in parenchyma of right middle lung lobe. The center was off-white upon incision.
 - b. Histopath:
 - i. The pulmonary and TBLN lesions with intralesional acid-fast bacilli are consistent with Mycobacteriosis.
- 4. (b) (4)
 - a. Necropsy findings:
 - i. a focal pinpoint solid white nodule in parenchyma of right middle hepatic lobe.
 - b. Histopath:
 - i. There were no microscopic lesions to suggest this animal had Mycobacteriosis. The grossly described liver nodule was not identified microscopically; however, a single pinpoint-sized lesion is likely clinically irrelevant.
- 5. (b) (4)
 - a. Necropsy findings:
 - i. Mild erythema and moderate swelling of right superior palpebra
 - ii. Mildly enlarged tracheobronchial lymph nodes (2-3mm).
 - b. Histopath
 - i. There were no microscopic changes to suggest Mycobacteriosis. Acid fast stains of the lung and TBLN were negative for organisms.
- 6. (b) (4)
 - a. Necropsy findings
 - i. 0.7cm x 0.6cm ulceration with minor bleeding and granulation tissue on lateral left elbow. 0.5cm x 0.5cm ulceration with minor bleeding and granulation bed on lateral right carpus.
 - ii. Multiple enlarged tracheobronchial lymph nodes measuring from 1.0cm- 1.9cm in length. Some had white chunky center on cut surface. Enlarged lymph nodes on the omentum near the lesser curvature of the stomach.
 - iii. The right cranial lung lobe has a 1.7cm x 2.5cm pale, firm irregularly shaped area with a well demarcated dark red area at the distal periphery. On incision, the lung parenchyma appears necrotic with areas ranging from dark red/ black to red and tan. Similar lesion are found throughout the parenchyma of all other lung lobes, varying in size.
 - iv. The spleen is 7cm x 3.5cm x 2.5cm and is diffusely affected by multifocal to coalescing caseous necrosis. Very little normal parenchyma is apparent.
 - v. Multifocal 1mm firm solid white nodules throughout the parenchyma of all liver lobes. The pancreas is enlarged.
 - vi. White caseous exudate was observed within the right carpal joint capsule and extending through a rent into deep muscle tissue of flexor carpi ulnaris and covered by a bed of granulation tissue on the superficial aspect of the muscle. White caseous exudate is also noted within bone of the left ulna at the olecranon, extending to the joint capsule through a rent which is covered by granulation tissue.

b. Histopath:

- i. Despite the absence of acid-fast bacteria, the microscopic lesions are very suggestive of Mycobacteriosis in multiple major organs. The lesions are chronic with abundant macrophages, multinucleated giant cells, and mineralization which may explain the absence of organisms that are often difficult to find. Several other lesions were noted and considered incidental.

7. (b) (4)

- a. No abnormalities on necropsy
- b. There were no microscopic changes considered to be consistent with Mycobacteriosis. Acid fast stains of lung and TBLN were negative for organisms.

Cause of Death? Euthanasia due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

(b) (6)

(b) (6) Houston | Charles River

(b) (6) Houston, TX 77047

(b) (6) cri.com | www.criver.com

LinkedIn | Twitter | Facebook | Eureka

Pronouns: she, her, hers

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-014324****Animal Location**

Harris County TX, US

NFC Control Number:

19823027960

Date Collected:

04/03/2023

Date Received:

05/09/2023

Date Completed:

08/23/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1906028 **Case #:** TB23-03881 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recoveredMycobacterium tuberculosis
complex**Direct PCR for M. tuberculosis complex - IS1081**

Detected Ct = 21.34055328

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 13 other isolates in this outbreak. See attached Genotyping report.

Animal ID: 1906028 **Case #:** TB23-03882 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.9028511

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

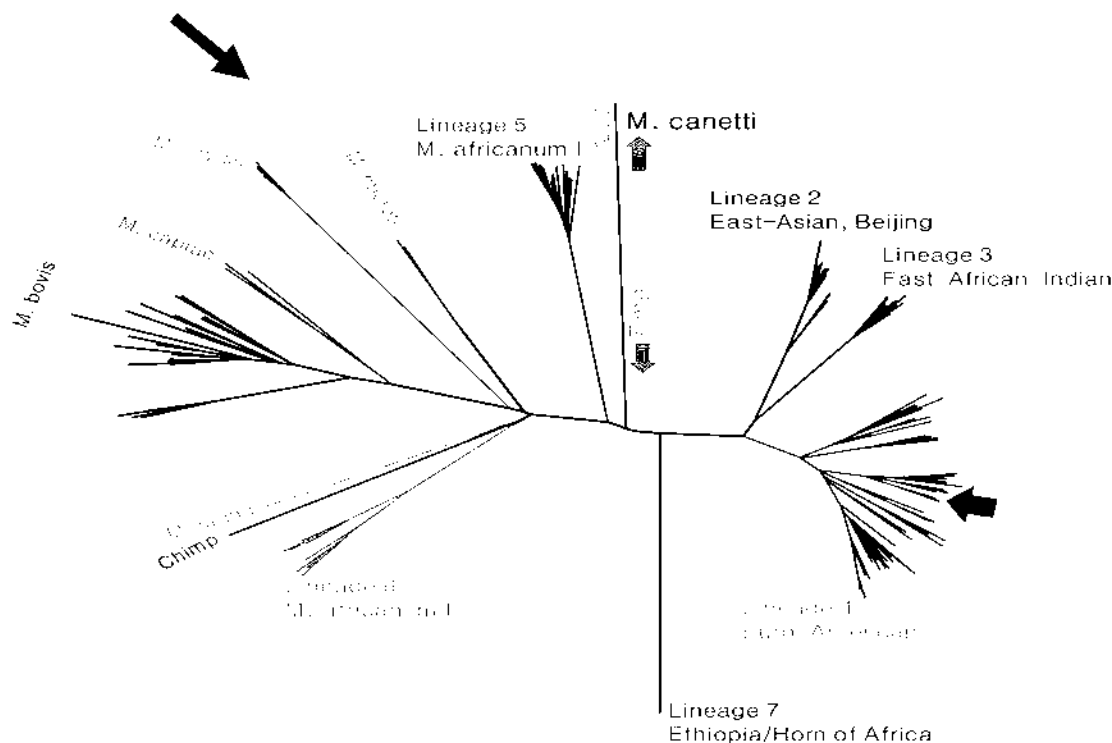
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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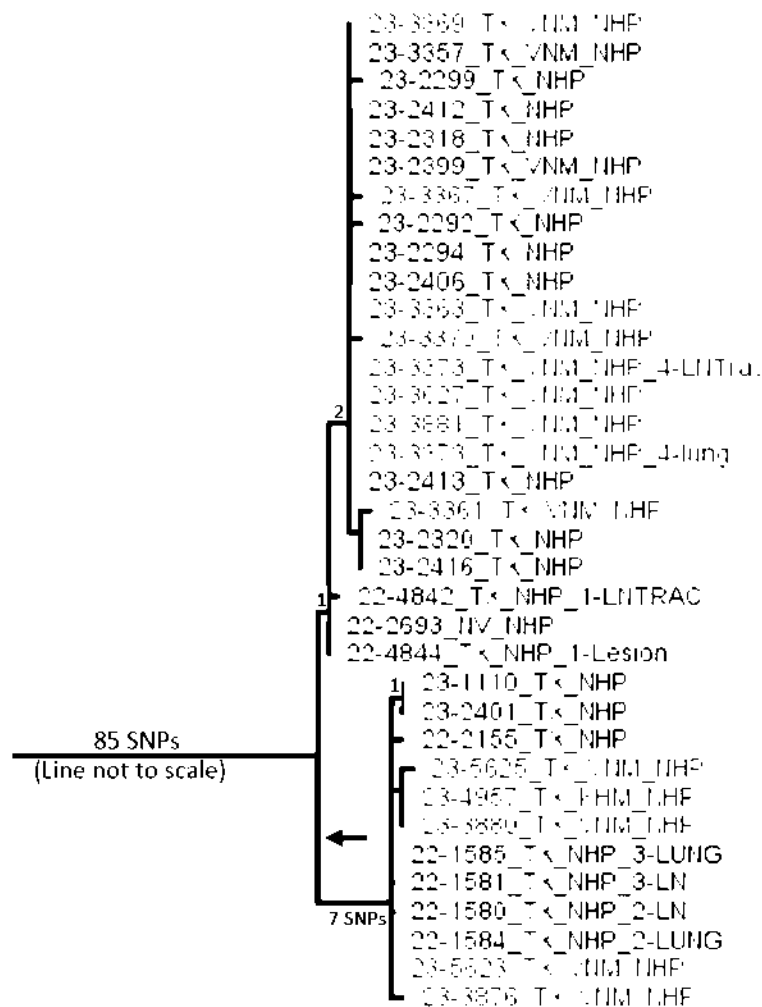
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7526 Fax: 515-337-7315

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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 208099.5	NC_000962.3 48939.5	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G

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NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

OWNER CITY

STATE/COUNTRY

(b) (6) crl.com (b) (6) crl.com

Houston

TX/US

PHONE NO. (b) (6) FAX NO. (b) (6)

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

PREMISES ID

COUNTY

STATE/COUNTRY

(b) (6) Houston, TX 77047

Harris

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

(b) (4)

Culture; PCR

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

04/03/23

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus
Macaque

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

23. SIGNATURE OF SUBMITTER AND DATE

X

CONDITION

PRIORITY

NVSL USE ONLY

VS FORM 10-4

AUG 2009

(b) (6)

23 - 014325
MB

30321
05/09/2023



24-08898_000932

(b) (4) - Necropsy - (b) (4)

From Date

04/03/2023 13:47:58

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

VSH / (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
04/03/2023 13:46:16	Date Out	04/03/2023 13:46:16
04/03/2023 13:46:16	Location at Stock Out - Path	(b) (4)
04/06/2023 12:37:20	Died during quarantine	Yes
04/03/2023 13:46:16	Euthanasia Reason	TB Reactor
04/03/2023 13:46:16	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Patient arrived at facility (b) (4) Patient had grade 5 TST at 72h read. No significant clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



moderate erythema, moderate swelling, and erosion of left superior palpebra.

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

four enlarged tracheobronchial lymph nodes measuring 0.5- 1.0cm in length, the largest lymph node had two off-white solid nodule in the center upon incision.

Respiratory System



Abnormal Respiratory System Description

hemorrhagic appearance of parenchyma of caudal lung lobes bilaterally

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) - Necropsy - (b) (4)

Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order #: (b) (4)

19 April 2023

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy. Animal had a grade 5 TST at 72 hours. A necropsy was performed by the submitter and found enlarged tracheal bronchial lymph nodes (TBLN) and red lung.

Microscopic Diagnoses:

#1 (b) (4) TBLN: Granuloma, mild, multifocal.

Acid Fast Stain (TBLN): Positive for infrequent acid fast organism within TBLN lesion.

Lung: Focal inflammation with lymphocytes and multinucleated giant cells, adjacent to bronchus, mild, focal.

Edema, moderate, diffuse.

Acid Fast Stain (lung): Negative.

Colon: Balantidium coli, luminal, mild.

Heart, Liver, Spleen, Kidney, Adrenal gland, Urinary bladder, Small intestine: Within normal limits.

Stomach: Not present in section.

Comment:

The microscopic lesions in the lung and TBLN and presence of acid-fast bacteria in the TBLN were consistent with the diagnosis of Mycobacteriosis. Balantidium coli finding was incidental.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-014320****Animal Location**

Harris County TX, US

NFC Control Number:

19823027956

Date Collected:

04/03/2023

Date Received:

05/09/2023

Date Completed:

07/10/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2005051 **Case #:** TB23-03871 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081**Detected** **Ct = 34.18938065**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2005051 **Case #:** TB23-03872 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Exhibit 21

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

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(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) cri.com (b) (6) cri.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO.

(b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

Exp. date: 12/31/23

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

11. DATE COLLECTED

4/6/23

8. NO. IN HERD/FLOCK
DEAD

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☐ Tissue (specify)

☐ Whole Animal

☒ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung;
Omentum; Spleen

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

(b) (7)(F)

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus
Macaque

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

20. NUMBER OF ANIMALS
SAMPLED

(b) (7)(F)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (7)(F)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary)

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE

X

23 - 020233

MB

CONDITION

DI

PRIORITY

3

NVSL USE ONLY

(b) (6)

30321

07/06/2023



VS FORM 10-4
AUG 2009

24-08898_000960

(b) (4) Necropsy (b) (4)

(b) (6)

From Date

04/06/2023 13:10:13

Reference #

(b) (4)

Registered

V-08238

4/6/2023

Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
04/06/2023	Date Out	04/06/2023
04/06/2023	Location at Stock Out - Path	(b) (4)
04/06/2023 14:03:34	Died during quarantine	Yes
04/06/2023	Euthanasia Reason	Other
04/06/2023	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Animal arrived on (b) (4) and remained in a CDC quarantine for the duration of time. No significant clinical history.

Tentative Diagnosis

Gross Description

The carcass of (b) (4) in good body condition was examined. Fibrous tissue noted on chest cavity with lungs adhered to the chest wall. A 1cm granulomatous lesion noted attached to the right caudal lung lobe. Multiple small (<0.025cm) granulomatous lesion noted throughout the omentum. Omentum was adhered to the bladder and a 3cm granulomatous lesion noted adhered to the descending colon. Suspect splenomegaly noted. All other findings were unremarkable.

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description

☒

Oral

Abnormal Oral Cavity Description

☒

(b) (4) - Necropsy - (b) (4)

Lymph Nodes

Abnormal Lymph Nodes Description



Respiratory System

Abnormal Respiratory System Description



Cardiovascular System

Abnormal Cardiovascular System Description



Gastrointestinal System

Abnormal Gastrointestinal System Description



Urinary System

Abnormal Urinary System Description



Reproductive System

Abnormal Reproductive System Description



Endocrine System

Abnormal Endocrine System Description



Nervous System

Abnormal Nervous System Description



Musculoskeletal System

Abnormal Musculoskeletal System Description



Tissues Fixed

Tracheobronchial Lymph Node

Lung

Heart Muscle



Liver

Spleen

Kidney



Stomach

Duodenum

Jejunum



Ileum

Colon

Bladder



Skeletal Muscle

Bone Marrow

Brain



Skin

Skin - Description



Other

Other - Description



granulomatous lesions

(b) (4) - Necropsy - (b) (4)

Microbiology

None

Other Diagnostic Test

None

Histopathology

Fixed tissue submitted for Histopathology

Final Diagnosis

Event Comment

Document(s)



Pathology Report

LTM Order #: 2023021858

28 April 2023

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy. Necropsy was conducted by the submitter and found fibrous tissue on the lung surface and a 1cm granulomatous lesion in the lung, multiple small granulomatous lesions in the omentum, urinary bladder.

Microscopic Diagnoses:

#1 (b) (4) Omental masses: Abscess/granuloma, chronic, mineralization, marked, multifocal.

Acid fast stain (masses, lung, lymph node): Negative.

Lung, Liver, Spleen, Lymph node (bronchial): Within normal limits.

Comment:

While the omental masses had some features suggestive of Mycobacteriosis, no organisms were found on acid fast stains and neither was the location a common presentation of Mycobacteriosis in these quarantine animals. The extensive mineralization may represent a more chronic lesion. Since Mycobacteriosis cannot be ruled out, I would consider the lesions in this animal suspicious.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-020233****Animal Location**

Harris County TX, US

NFC Control Number:

19823034743

Date Collected:

04/06/2023

Date Received:

07/06/2023

Date Completed:

09/15/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1909027 **Case #:** TB23-05630 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1909027 **Case #:** TB23-05631 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081**Detected** Ct = 35.20380783

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1909027 **Case #:** TB23-05632 **Sample:** 3 **Specimen Type:** Tissue **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Specimen: Omentum

Animal ID: 1909027 **Case #:** TB23-05633 **Sample:** 4 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 25.86735916

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1909027 **Case #:** TB23-05634 **Sample:** 5 **Specimen Type:** Tissue **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Specimen: Abnormal tissue #2

There was a discrepancy with this submission. Submission form says 4 samples were sent but 5 samples were received.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 22

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE

OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

OWNER CITY

STATE/COUNTRY

Houston

TX/US

PHONE NO (b) (6)

FAX NO (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

STATE/COUNTRY

Harris

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

(b) (4)

Culture; PCR

7. NO. IN HERD/FLOCK
AFFECTED

8. NO. IN HERD/FLOCK
DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

04/11/23

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

21. IDENTIFICATION (See instructions <250 samples per form)

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

23. SIGNATURE OF SUBMITTER AND DATE

X

CONDITION

PRIORITY

NVSL
DISTR

(b) (6)

VS FORM 10-4
AUG 2009

23 - 014323

MB

30321
05/09/2023

24-08898_000908

- Necropsy - (b) (4)

From Date

04/11/2023 15:17:53

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6) (b) (6)

Properties

Date of Last Update

Name

Value

(b) (4)

In-Shipment #

(b) (4)

04/11/2023 15:16:56

Date Out

04/11/2023 15:16:56

04/11/2023 15:16:56

Location at
Stock Out -
Path

(b) (4)

04/14/2023 13:36:38

Died during
quarantine

Yes

04/11/2023 15:16:56

Euthanasia
Reason

Other

04/11/2023 15:16:56

Euthanasia
Method

IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4). Decreased range of motion of stifles noted on entry physical examination. No other clinical history. Pt presents for euthanasia due to (b) (4).

(b) (4)

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Oral

Abnormal Oral Cavity Description



- Necropsy - ACT2300018573

Lymph Nodes



Abnormal Lymph Nodes Description

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

Other



Other - Description

- Necropsy - (b) (4)

Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

29 April 2023

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy. Euthanized due to (b) (4). Necropsy was performed by the submitter with no findings.

Microscopic Diagnoses:

#1 (b) (4) Stomach: Lymphocytic infiltrates, mucosal, mild, diffuse (lymphocytic gastritis).

Small intestine: Dilated lacteals, mild, multifocal.

Lung, Lymph node (tracheobronchial), Liver, Spleen, Heart, Kidney, Adrenal gland, Urinary bladder, Large intestine, Pancreas: Within normal limits.

Acid Fast Stain (lung, tracheobronchial lymph node): Negative for acid fast organisms.

Comment:

There were no microscopic changes considered to be consistent with Mycobacteriosis. Acid fast stains of lung and TBLN were negative for organisms. Other microscopic changes were considered incidental.

(b) (6)



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report

Owner

Houston, TX

Accession Number:

23-014323

Animal Location

Harris County TX, US

NFC Control Number:

19823027959

Date Collected:

04/11/2023

Date Received:

05/09/2023

Date Completed:

08/23/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1908009 **Case #:** TB23-03880 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 2 other isolates and has acquired a single SNP from sharing a the most recent common ancestor with 6 other isolates from this outbreak. See attached Genotyping report.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

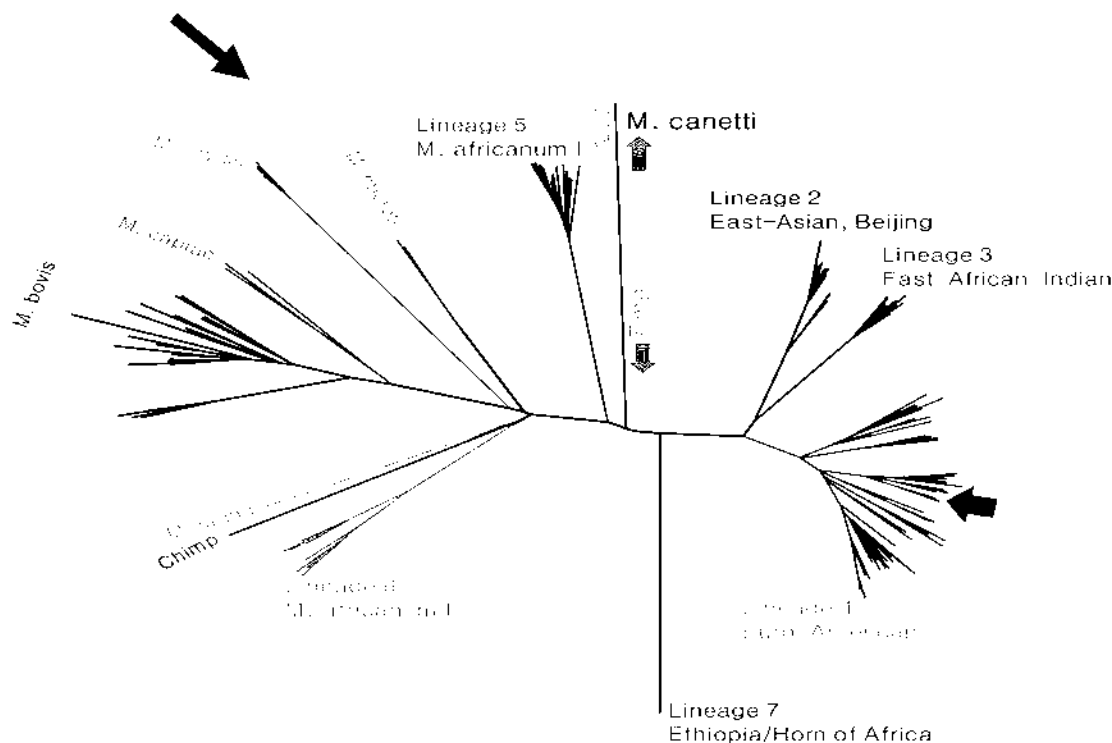
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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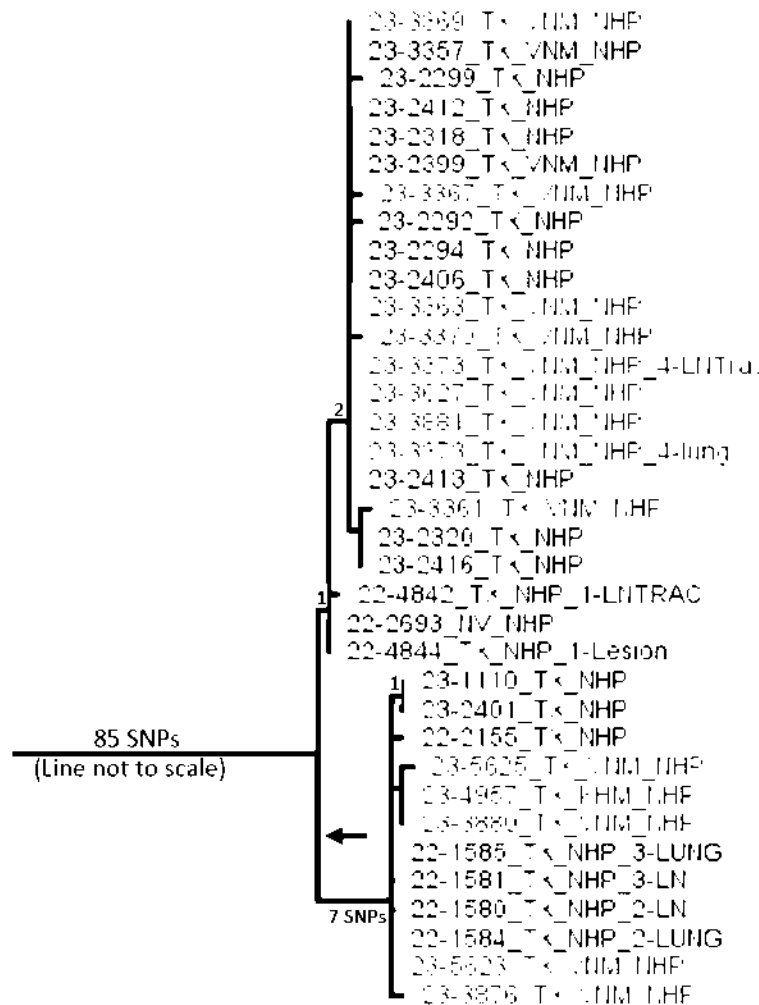
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 208099.5	NC_000962.3 48939.5	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G

Attachments:

[illegible]

Subject: [External Email]Request to ship NHP Samples

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

What was the date that they left the originating country? (b) (4)

24-08898 000876

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes, see attached reports

If so, can you provide those results?

1. (b) (4)

a. Necropsy findings:

- i. moderate erythema, moderate swelling, and erosion of left superior palpebra.
- ii. four enlarged tracheobronchial lymph nodes measuring 0.5-1.0cm in length. the largest lymph node had two off-white solid nodule in the center upon incision.
- iii. hemorrhagic appearance of parenchyma of caudal lung lobes bilaterally

b. Histopath:

- i. The microscopic lesions in the lung and TBLN and presence of acid-fast bacteria in the TBLN were consistent with the diagnosis of Mycobacteriosis.

2. (b) (4)

a. Necropsy findings:

- i. 1.1cm enlarged tracheobronchial lymph node.
- ii. 3mmx2mm tan discolored area of parenchyma of left caudal lung lobe. 5mm x4mm tan discolored area of parenchyma of right caudal lung lobe.

b. Histopath:

- i. The microscopic lesion in the TBLN and the presence of intralesional acid-fast bacilli was consistent with the diagnosis of Mycobacteriosis.

3. (b) (4)

a. Necropsy findings:

- i. mild erythema minor swelling of left superior palpebra
- ii. three enlarged tracheobronchial lymph nodes measuring 0.8cm-1.8cm in length. The largest lymph node had an off-white solid nodule in the center upon incision.
- iii. irregularly shaped tan mass in parenchyma of right middle lung lobe. The center was off-white upon incision.

b. Histopath:

- i. The pulmonary and TBLN lesions with intralesional acid-fast bacilli are consistent with Mycobacteriosis.

4. (b) (4)

a. Necropsy findings:

- i. a focal pinpoint solid white nodule in parenchyma of right middle hepatic lobe.

b. Histopath:

- i. There were no microscopic lesions to suggest this animal had

Mycobacteriosis. The grossly described liver nodule was not identified microscopically; however, a single pinpoint-sized lesion is likely clinically irrelevant.

5. (b) (4)

a. Necropsy findings:

- i. Mild erythema and moderate swelling of right superior palpebra
- ii. Mildly enlarged tracheobronchial lymph nodes (2-3mm).

b. Histopath

- i. There were no microscopic changes to suggest Mycobacteriosis. Acid fast stains of the lung and TBLN were negative for organisms.

6. (b) (4)

a. Necropsy findings

- i. 0.7cm x 0.6cm ulceration with minor bleeding and granulation tissue on lateral left elbow. 0.5cm x 0.5cm ulceration with minor bleeding and granulation bed on lateral right carpus.
- ii. Multiple enlarged tracheobronchial lymph nodes measuring from 1.0cm- 1.9cm in length. Some had white chunky center on cut surface. Enlarged lymph nodes on the omentum near the lesser curvature of the stomach.
- iii. The right cranial lung lobe has a 1.7cm x 2.5cm pale, firm irregularly shaped area with a well demarcated dark red area at the distal periphery. On incision, the lung parenchyma appears necrotic with areas ranging from dark red/ black to red and tan. Similar lesion are found throughout the parenchyma of all other lung lobes, varying in size.
- iv. The spleen is 7cm x 3.5cm x 2.5cm and is diffusely affected by multifocal to coalescing caseous necrosis. Very little normal parenchyma is apparent.
- v. Multifocal 1mm firm solid white nodules throughout the parenchyma of all liver lobes. The pancreas is enlarged.
- vi. White caseous exudate was observed within the right carpal joint capsule and extending through a rent into deep muscle tissue of flexor carpi ulnaris and covered by a bed of granulation tissue on the superficial aspect of the muscle. White caseous exudate is also noted within bone of the left ulna at the olecranon, extending to the joint capsule through a rent which is covered by granulation tissue.

b. Histopath:

- i. Despite the absence of acid-fast bacteria, the microscopic lesions are very suggestive of Mycobacteriosis in multiple major organs. The lesions are chronic with abundant macrophages, multinucleated giant cells, and mineralization which may explain the absence of organisms that are often difficult to find. Several other lesions were noted and considered incidental.

7. (b) (4)

- a. No abnormalities on necropsy
- b. There were no microscopic changes considered to be consistent with Mycobacteriosis. Acid fast stains of lung and TBLN were negative for organisms.

Cause of Death? Euthanasia due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

(b) (6)

(b) (6) Houston | Charles River

(b) (6) Houston, TX 77047

(b) (6) crl.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

Bravo-Garcia, Doris - MRP-APHIS

From: (b) (6) <(b) (6)@crl.com>
Sent: Thursday, May 4, 2023 10:42 AM
To: Lehman, Kimberly - MRP-APHIS; APHIS-NVSL Case Coordinator - APHIS; Bravo-Garcia, Doris - MRP-APHIS
Cc: (b) (6)
Subject: [External Email] Request to ship NHP Samples
Attachments: (b) (4)

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;
Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send (b) (4) NHP samples for Mycobacterium testing on Thursday, May 4th to arrive Friday, May 5th. Please let us know if you are agreeable to this. The necropsy, histopathology and filovirus reports are attached for animal IDs# (b) (4) (b) (4) (b) (4) (b) (6) (b) (4) (b) (4) and (b) (4)

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes, see attached reports

If so, can you provide those results?

1. (b) (4)

a. Necropsy findings:

- i. moderate erythema, moderate swelling, and erosion of left superior palpebra.
- ii. four enlarged tracheobronchial lymph nodes measuring 0.5- 1.0cm in length. the largest lymph node had two off-white solid nodule in the center upon incision.
- iii. hemorrhagic appearance of parenchyma of caudal lung lobes bilaterally

b. Histopath:

- i. The microscopic lesions in the lung and TBLN and presence of acid-fast bacteria in the TBLN were consistent with the diagnosis of Mycobacteriosis.

2. (b) (4)

a. Necropsy findings:

- i. 1.1cm enlarged tracheobronchial lymph node.

- ii. 3mmx2mm tan discolored area of parenchyma of left caudal lung lobe. 5mm x4mm tan discolored area of parenchyma of right caudal lung lobe.
 - b. Histopath:
 - i. The microscopic lesion in the TBLN and the presence of intralesional acid-fast bacilli was consistent with the diagnosis of Mycobacteriosis.
3. (b) (4)
- a. Necropsy findings:
 - i. mild erythema minor swelling of left superior palpebra
 - ii. three enlarged tracheobronchial lymph nodes measuring 0.8cm-1.8cm in length. The largest lymph node had an off-white solid nodule in the center upon incision.
 - iii. irregularly shaped tan mass in parenchyma of right middle lung lobe. The center was off-white upon incision.
 - b. Histopath:
 - i. The pulmonary and TBLN lesions with intralesional acid-fast bacilli are consistent with Mycobacteriosis.
4. (b) (4)
- a. Necropsy findings:
 - i. a focal pinpoint solid white nodule in parenchyma of right middle hepatic lobe.
 - b. Histopath:
 - i. There were no microscopic lesions to suggest this animal had Mycobacteriosis. The grossly described liver nodule was not identified microscopically; however, a single pinpoint-sized lesion is likely clinically irrelevant.
5. (b) (4)
- a. Necropsy findings:
 - i. Mild erythema and moderate swelling of right superior palpebra
 - ii. Mildly enlarged tracheobronchial lymph nodes (2-3mm).
 - b. Histopath
 - i. There were no microscopic changes to suggest Mycobacteriosis. Acid fast stains of the lung and TBLN were negative for organisms.
6. (b) (4)
- a. Necropsy findings
 - i. 0.7cm x 0.6cm ulceration with minor bleeding and granulation tissue on lateral left elbow. 0.5cm x 0.5cm ulceration with minor bleeding and granulation bed on lateral right carpus.
 - ii. Multiple enlarged tracheobronchial lymph nodes measuring from 1.0cm- 1.9cm in length. Some had white chunky center on cut surface. Enlarged lymph nodes on the omentum near the lesser curvature of the stomach.
 - iii. The right cranial lung lobe has a 1.7cm x 2.5cm pale, firm irregularly shaped area with a well demarcated dark red area at the distal periphery. On incision, the lung parenchyma appears necrotic with areas ranging from dark red/ black to red and tan. Similar lesion are found throughout the parenchyma of all other lung lobes, varying in size.
 - iv. The spleen is 7cm x 3.5cm x 2.5cm and is diffusely affected by multifocal to coalescing caseous necrosis. Very little normal parenchyma is apparent.
 - v. Multifocal 1mm firm solid white nodules throughout the parenchyma of all liver lobes. The pancreas is enlarged.
 - vi. White caseous exudate was observed within the right carpal joint capsule and extending through a rent into deep muscle tissue of flexor carpi ulnaris and covered by a bed of granulation tissue on the superficial aspect of the muscle. White caseous exudate is also noted within bone of the left ulna at the olecranon, extending to the joint capsule through a rent which is covered by granulation tissue.

b. Histopath:

- i. Despite the absence of acid-fast bacteria, the microscopic lesions are very suggestive of Mycobacteriosis in multiple major organs. The lesions are chronic with abundant macrophages, multinucleated giant cells, and mineralization which may explain the absence of organisms that are often difficult to find. Several other lesions were noted and considered incidental.

7. (b) (4)

- a. No abnormalities on necropsy
- b. There were no microscopic changes considered to be consistent with Mycobacteriosis. Acid fast stains of lung and TBLN were negative for organisms.

Cause of Death? Euthanasia due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

Charles River

Houston, TX 77047

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Pronouns: she, her, hers

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE

OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

OWNER CITY

STATE/COUNTRY

(b) (6) crl.com (b) (6) crl.com

Houston

TX/US

PHONE NO. (b) (6) FAX NO. (b) (6)

4. LOCATION OF ANIMALS

MAILING ADDRESS (include city, state, ZIP Code)

PREMISES ID

COUNTY

STATE/COUNTRY

(b) (6) Houston, TX 77047

Harris

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER

(Enclosed, payable to USDA in US dollars)

X

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

10. COLLECTED BY

(b) (4) Culture; PCR

(b) (6)

7. NO. IN HERD/FLOCK AFFECTED

11. DATE COLLECTED

04/11/23

8. NO. IN HERD/FLOCK DEAD

12. AUTHORIZED BY

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (specify)

☐ Whole Animal

☐ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN, Lung,

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

Spleen, Liver,

Muscle

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS SAMPLED

(b) (4)

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).
see attached necropsy report.

23. SIGNATURE OF SUBMITTER AND DATE

X

CONDITION

PRIORITY

NVSL USE ONLY

DISTRIBUTION

VS FORM 10-4

AUG 2009

(b) (6)

23-014322
MB

30321
05/09/2023

24-08898_000883

- Necropsy - (b) (4)

From Date

04/11/2023 15:17:53

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
04/11/2023 15:16:56	Date Out	04/11/2023 15:16:56
04/11/2023 15:16:56	Location at Stock Out - Path	(b) (4)
04/14/2023 13:38:56	Died during quarantine	Yes
04/11/2023 15:16:56	Euthanasia Reason	Other
04/11/2023 15:16:56	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility on (b) (4). On entry exam a firm, enlarged spleen and a laceration of the left elbow were noted. Follow up ultrasonography was scheduled to occur following release from quarantine. The left elbow laceration healed and resolved within 1 week with topical gentamicin treatment. On 3/31/23 pt was reported for L elbow wound. Upon examination of sedated animal, L elbow had 2cm ulcerated wound with minor bleeding. A similar lesion was noted on the right lateral wrist. The elbow wound was clipped and flushed with sterile saline. Administered ceftiofur SQ and buprenorphine SR SQ. Recheck of the lesions on 4/6/23 revealed a scab present on L lateral elbow. The R wrist is swollen and eroded. DVM evaluation was scheduled for the next sedated event. Pt presents for euthanasia due to (b) (4).

Tentative Diagnosis

r/o mycobacteriosis

- Necropsy - (b) (4)

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description

☒

0.7cm x 0.6cm ulceration with minor bleeding and granulation tissue on lateral left elbow. 0.5cm x 0.5cm ulceration with minor bleeding and granulation bed on lateral right carpus.

Oral

Abnormal Oral Cavity Description

☐

Lymph Nodes

Abnormal Lymph Nodes Description

☒

Multiple enlarged tracheobronchial lymph nodes measuring from 1.0cm- 1.9cm in length. Some had white chunky center on cut surface. Enlarged lymph nodes on the omentum near the lesser curvature of the stomach.

Respiratory System

Abnormal Respiratory System Description

☒

The right cranial lung lobe has a 1.7cm x 2.5cm pale, firm irregularly shaped area with an well demarcated dark red area at the distal periphery. On incision, the lung parenchyma appears necrotic with areas ranging from dark red/ black to red and tan. Similar lesion are found throughout the parenchyma of all other lung lobes, varying in size.

Cardiovascular System

Abnormal Cardiovascular System Description

☒

The spleen is 7cm x 3.5cm x 2.5cm and is diffusely affected by multifocal to coalescing caseous necrosis. Very little normal parenchyma is apparent.

Gastrointestinal System

Abnormal Gastrointestinal System Description

☒

Multifocal 1mm firm solid white nodules throughout the parenchyma of all liver lobes. The pancreas is enlarged.

Urinary System

Abnormal Urinary System Description

☐

Reproductive System

Abnormal Reproductive System Description

☐

- Necropsy - (b) (4)

Endocrine System



Nervous System



Musculoskeletal System



Abnormal Endocrine System Description

Abnormal Nervous System Description

Abnormal Musculoskeletal System Description

White caseous exudate was observed within the right carpal joint capsule and extending through a rent into deep muscle tissue of flexor carpi ulnaris and covered by a bed of granulation tissue on the superficial aspect of the muscle. White caseous exudate is also noted within bone of the left ulna at the olecranon, extending to the joint capsule through a rent which is covered by granulation tissue.

Tissues Fixed

Tracheobronchial Lymph Node



Liver



Stomach



Ileum



Skeletal Muscle



Skin



Other



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Lung



Spleen



Duodenum



Colon



Bone Marrow



Skin - Description

Other - Description

left olecranon bone.

Heart Muscle



Kidney



Jejunum



Bladder



Brain



- Necropsy - ACT2300018573

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order #: (b) (4)

29 April 2023

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy. Euthanized due to (b) (4) screening result. Necropsy was performed by the submitter and found caseous joint lesions, enlarged tracheobronchial lymph nodes, enlarged gastric lymph nodes, dark red area on lung, caseous spleen and hepatic nodules. Rule out tuberculosis.

Microscopic Diagnoses:

#1 (b) (4) Lung, Spleen, Lymph node (tracheobronchial), Liver, Skeletal muscle, connective tissue: Granuloma, marked, multifocal and coalescing with central mineralization.
Acid Fast stain (lung, Spleen, TBLN, Liver): Negative for acid-fast organism.
Adrenal gland: Nodular hyperplasia, cortical, mild, focal.
Mineralization, vascular, mural, mild, focal.
Stomach: Lymphocytic infiltrates, mucosal, mild, diffuse (lymphocytic gastritis).
Large intestine: Balantidium coli, luminal, mild.
Kidney, Heart, Urinary bladder, Small intestine: Within normal limits.

Comment:

Despite the absence of acid-fast bacteria, the microscopic lesions are very suggestive of Mycobacteriosis in multiple major organs. The lesions are chronic with abundant macrophages, multinucleated giant cells, and mineralization which may explain the absence of organisms that are often difficult to find. Several other lesions were noted and considered incidental.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-014322****Animal Location**

Harris County TX, US

NFC Control Number:

19823027958

Date Collected:

04/11/2023

Date Received:

05/09/2023

Date Completed:

08/23/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1908037 **Case #:** TB23-03875 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recoveredMycobacterium tuberculosis
complex**Direct PCR for M. tuberculosis complex - IS1081**

Detected Ct = 32.87908173

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

If you would like Whole Genome Sequencing (WGS) performed with a genotype analysis the cost is \$117 per isolate. Please email NVSL-MB.caseManager@usda.gov <mailto:NVSL-MB.caseManager@usda.gov> if you would like to request this analysis.

Animal ID: 1908037 **Case #:** TB23-03876 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 22.81538391

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has acquired a single SNP from sharing a the most recent common ancestor with 6 other isolates from this outbreak. See attached Genotyping report.

Animal ID: 1908037 **Case #:** TB23-03877 **Sample:** 3 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 29.31061745

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

If you would like Whole Genome Sequencing (WGS) performed with a genotype analysis the cost is \$117 per isolate. Please email NVSL-MB.caseManager@usda.gov <mailto:NVSL-MB.caseManager@usda.gov> if you would like to request this analysis.

Animal ID: 1908037 **Case #:** TB23-03878 **Sample:** 4 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.054245

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1908037 **Case #:** TB23-03879 **Sample:** 5 **Specimen Type:** Muscle **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.85630035

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



National Veterinary Services Laboratories

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APPENDIX – GENOTYPING REPORT

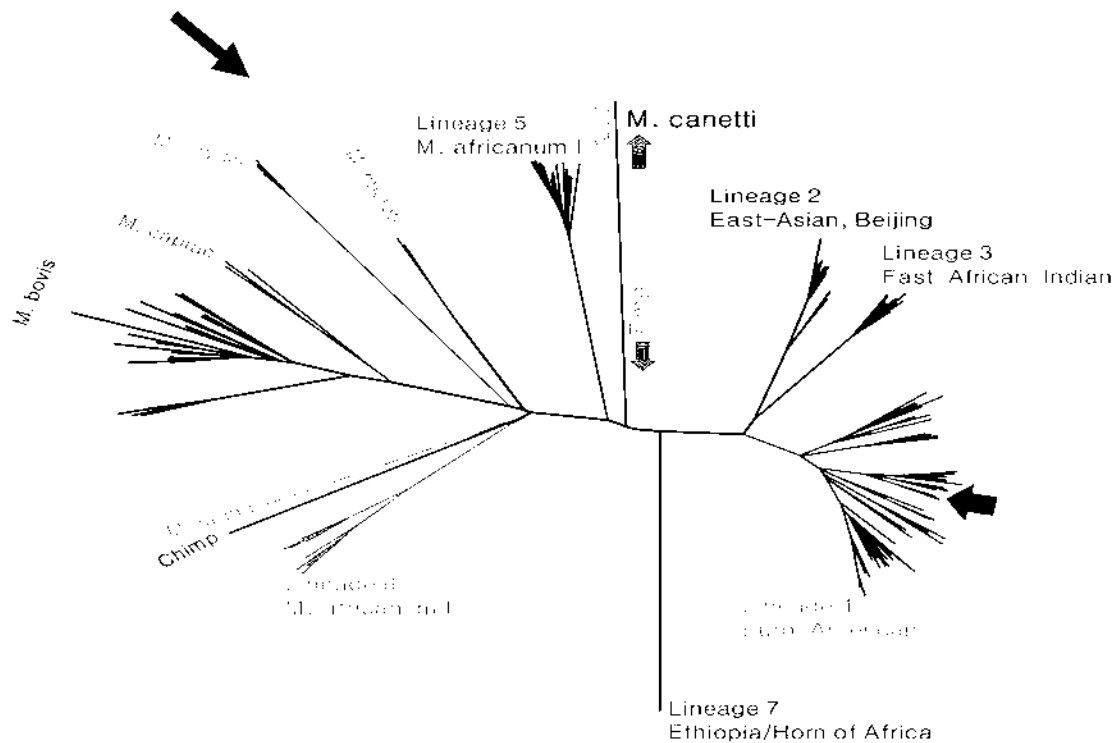
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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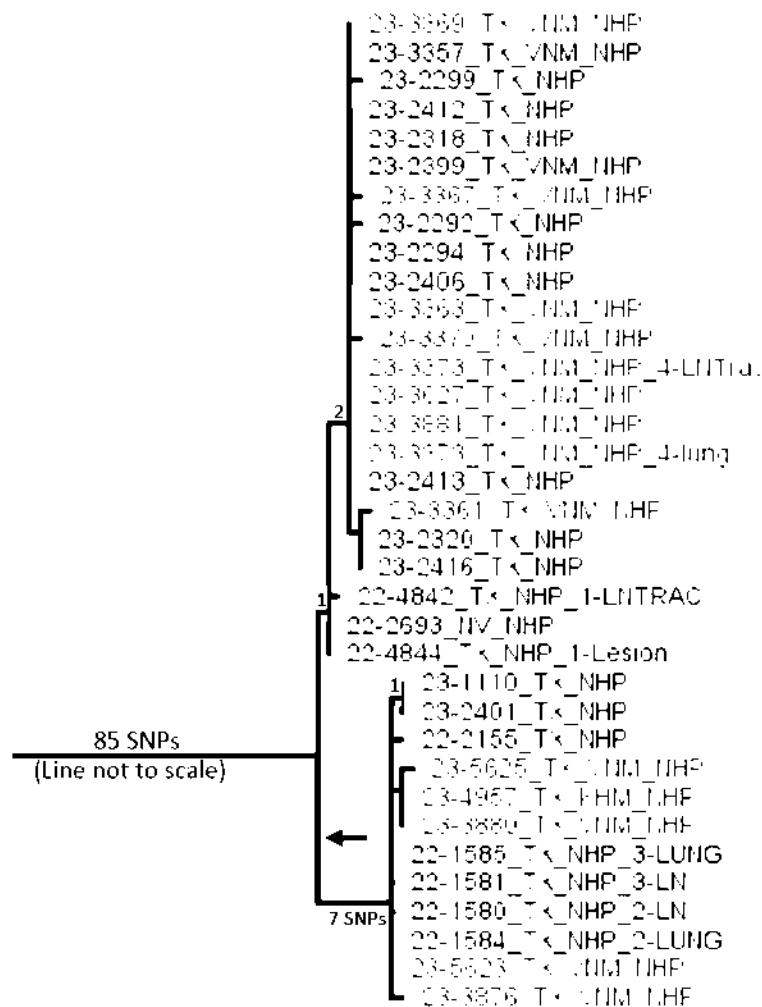
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

Exhibit 23

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

(b) (6) Charles River Laboratories

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

EMAIL ADDRESS

(b) (6) cri.com (b) (6) cri.com

OWNER CITY

Houston

STATE/COUNTRY

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

PREMISES ID

MAILING ADDRESS (Street, City, State, ZIP Code)

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT
CARD

Exp. Date: --

6. HERD/FLOCK SIZE

(b) (6)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

7. NO. IN HERD/FLOCK
AFFECTED

11. DATE COLLECTED
5/15/2023

8. NO. IN HERD/FLOCK
DEAD

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☐ Tissue (specify)

☐ Whole Animal

☒ Other (specify)

18. TOTAL NUMBER OF
SPECIMENS SUBMITTED

(b) (4)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung; Liver

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

20. NUMBER OF ANIMALS
SAMPLED

(b) (4)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus
Macaque

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

(b) (6)

23 - 017496

MB

CONDITION

PRIORITY

3

NVSL USE ONLY

DIS

(b) (6)

VS FORM 10-4
AUG 2009

06/07/2023
30321

24-08898_000948

[External Email]Request to ship NHP samples

(b) (6) <(b) (6)@crl.com>

Tue 6/6/2023 10:02 AM

To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; Bravo-Garcia, Doris - MRP-APHIS <doris.m.bravo@usda.gov>

Cc: (b) (6)@crl.com> (b) (6)@crl.com> (b) (6)@crl.com> (b) (6)@crl.com> (b) (6)@crl.com> (b) (6)@crl.com> (b) (6)@crl.com>

3 attachments (731 KB)

(b) (4)

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Good morning,

We would like to send NHP samples for Mycobacterium testing on Tuesday, June 6 to arrive on Wednesday June 7. Please let us know if you are agreeable to this. The necropsy, histopathology and filovirus reports are attached for animal ID# (b) (4)

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)

What was the date that they left the originating country? (b) (4)

How many animals were in the group imported? (b) (4)

Have any cohorts died of unknown causes? No

Was animals exposed to animals from other sources? No

Was a complete necropsy and with histology done on this animal? Yes, see attached reports

If so, can you provide those results?

1. (b) (4)
 - a. Necropsy findings: Abnormalities on gross necropsy include: Moderate erythema and moderate-severe swelling of superior palpebra right eye. Enlarged tracheobronchial lymph nodes (1.0 cm- 1.8cm). Two light tan translucent firm irregularly shaped nodule embedded in the parenchyma of the right middle lung lobe, measuring 0.5 cm x 0.6cm (largest nodule) and 0.2cm x 0.2cm. Upon cut surface, nodule is solid and homogenous. Two 0.1 cm slightly raised white spots on serosal surface of liver, one on the caudate lobe and one the left liver lobe.
 - b. Histopath:
 - i. The characteristic microscopic lesions and the positive acid-fast stain were consistent with a diagnosis of Mycobacteriosis in this animal. Nephritis was considered incidental.

Cause of Death? Euthanasia due to TB suspect

Was the animal showing any abnormal symptoms prior to death? No

Please let me know if you need any other information.

24-08898 000949

Kind regards,

(b) (6)

(b) (6) Houston | Charles River

(b) (6) Houston, TX 77047

(b) (6)

(b) (6) @cri.com | www.criver.com

[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

Pronouns: she, her, hers

(b) (4) - Necropsy - (b) (4)

From Date

05/15/2023 12:02:30

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6), (b) (6)

Properties

Date of Last Update	Name	Value
(b) (4)	In-Shipment #	(b) (4)
05/15/2023 11:59:57	Date Out	05/15/2023 11:59:57
05/15/2023 11:59:57	Location at Stock Out - Path	(b) (4)
05/22/2023 17:15:11	Died during quarantine	Yes
05/15/2023 11:59:57	Euthanasia Reason	TB Reactor
05/15/2023 11:59:57	Euthanasia Method	IV Phenytoin/Pentobarbital

Clinical History

Pt arrived at facility (b) (4). Tail trauma noted at intake physical examination and healed as expected. Pt has grade 5 TST OD at 72hr. No other clinical history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Moderate erythema and moderate-severe swelling of superior palpebra right eye

Oral

Abnormal Oral Cavity Description



(b) (4) Necropsy (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

enlarged tracheobronchial lymph nodes (1.0 cm- 1.8cm)

Respiratory System



Abnormal Respiratory System Description

two light tan translucent firm irregularly shaped nodule embedded in the parenchyma of the right middle lung lobe, measuring 0.5 cm x 0.6cm (largest nodule) and 0.2cm x 0.2cm. Upon cut surface, nodule is solid and homogenous.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Two 0.1 cm slightly raised white spots on serosal surface of liver, one on the caudate lobe and one on the left liver lobe.

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



(b) (4) - Necropsy - (b) (4)

Skin

Skin - Description



Other

Other - Description



Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (4)

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order #: (b) (4)

02 June 2023

History:

Customer: Charles River Houston - Quarantine

Strain: *Macaca fascicularis*

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston-The animal had a grade 5 TST at 72 hours and was euthanized. Necropsy was performed by the submitter and found tan nodule in the lung, raised white spots on serosal liver, and enlarged tracheobronchial lymph node.

Microscopic Diagnoses:

#1 (b) (4) Lung, Tracheobronchial lymph node: Granuloma, moderate, multifocal with multinucleated giant cells; occasional central necrosis.

Acid Fast Stain (lung, TBLN): Very few acid-fast bacilli noted in lung lesion. TBLN negative.

Liver: Granuloma with multinucleated giant cells, mild, focal.

Kidney: Nephritis, interstitial, lymphocytic, minimal, multifocal.

Spleen, Heart, Adrenal Gland, Urinary bladder, Stomach, Pancreas, Small intestine, Large intestine and associated lymph node: Within normal limits.

Comment:

The characteristic microscopic lesions and the positive acid-fast stain were consistent with a diagnosis of Mycobacteriosis in this animal. Nephritis was considered incidental.

(b) (4)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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AMENDED REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-017496****Animal Location**

Harris County TX, US

NFC Control Number:

19823031698

Date Collected:

05/15/2023

Date Received:

06/07/2023

Date Completed:

08/23/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1901034 **Case #:** TB23-04957 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recoveredMycobacterium tuberculosis
complex**Direct PCR for M. tuberculosis complex - IS1081**

Detected Ct = 31.78379822

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 2 other isolates and has acquired a single SNP from sharing a the most recent common ancestor with 6 other isolates from this outbreak. See attached Genotyping report.

Animal ID: 1901034 **Case #:** TB23-04958 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 27.94769859

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 1901034 **Case #:** TB23-04959 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

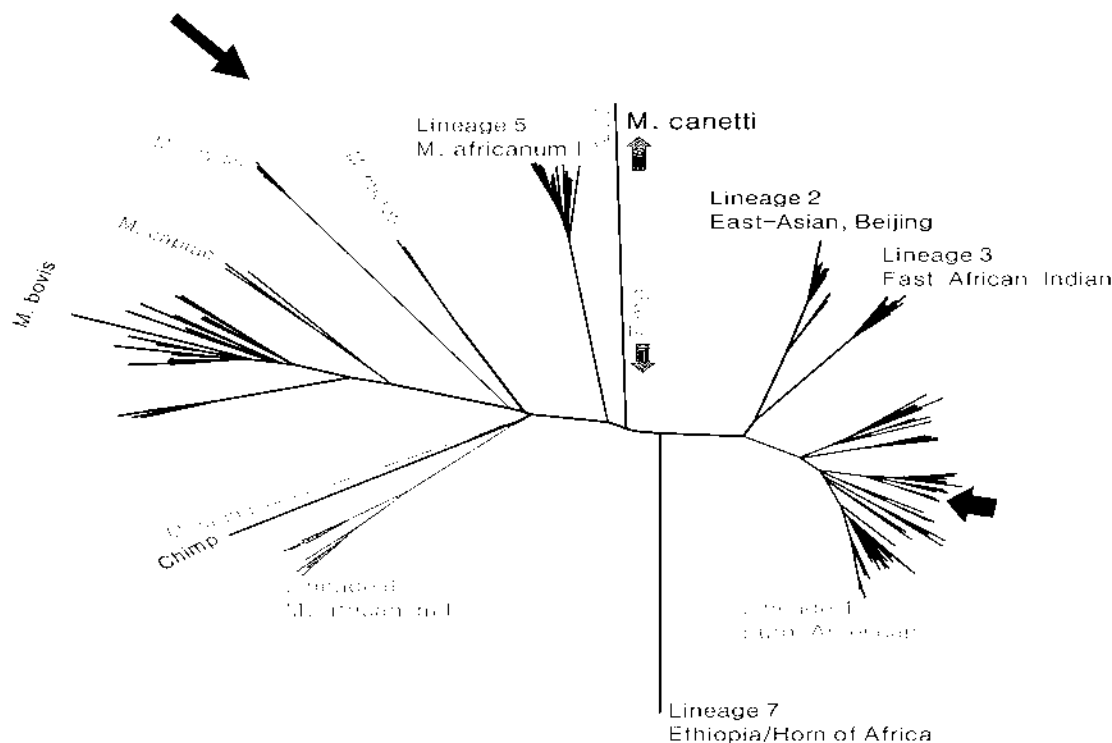
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



National Veterinary Services Laboratories

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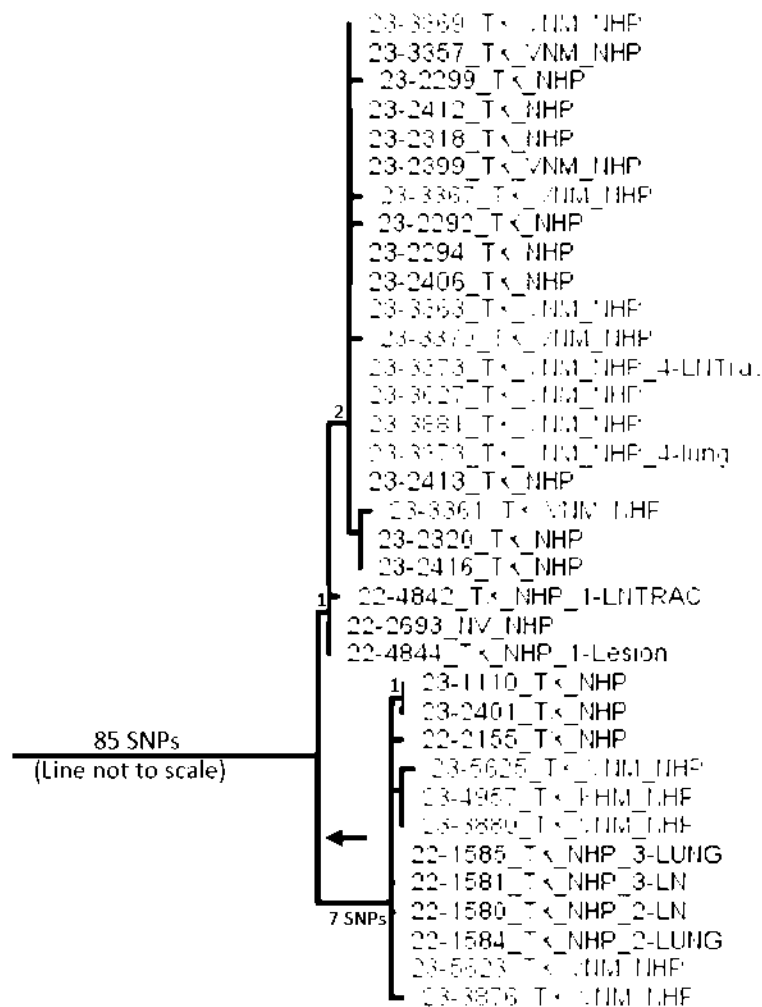
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 208099.5	NC_000962.3 48939.5	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	A	A	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

Exhibit 24

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average 5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name)

2. NVSL SUBMITTER ID

3. NAME OF OWNER

☒ Check if wildlife (no owner)

(b) (4) Charles River Laboratories

EMAIL ADDRESS

OWNER CITY

STATE/COUNTRY

(b) (6) @crl.com (b) (6) @crl.com

Houston

TX/US

PHONE NO. (b) (6)

FAX NO. (b) (6)

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

PREMISES ID

COUNTY

STATE/COUNTRY

(b) (6) Houston, TX 77047

Harris

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD

Num:
Exp. E.

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

10. COLLECTED BY

(b) (4)

Culture; PCR

(b) (6)

7. NO. IN HERD/FLOCK AFFECTED

11. DATE COLLECTED
5/31/23

8. NO. IN HERD/FLOCK DEAD

(b) (6)

12. AUTHORIZED BY

13. PURPOSE OF SUBMISSION (See instructions for definitions)

14. COUNTRY OF ORIGIN/DESTINATION

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☐ Tissue (specify)

☐ Whole Animal

☒ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN; Lung

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS SAMPLED

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE

X

23 - 020234

MB

CONDITION

PRIORITY 3

DISTRI (b) (4)

VED BY (b) (4)

VS FORM 10-4
AUG 2009

30321
07/06/2023



24-08898_000968

(b) (4) - Necropsy - (b) (4)

From Date

05/31/2023 14:36:45

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6) (b) (6)

Properties

Date of Last Update	Name	Value
05/31/2023 14:44:56	Died during quarantine	Yes
05/31/2023 13:57:27	Date Out	05/31/2023 13:57:27
05/31/2023 13:57:27	Location at Stock Out - Path	(b) (4)
05/31/2023 13:57:27	Euthanasia Reason	TB Reactor
05/31/2023 13:57:27	Euthanasia Method	IV Phenytoin/Pentobarbital
01/15/2023	In-Shipment #	(b) (4)

Clinical History

(b) (4) cynomolgus macaque arriving at facility 01.15.23. Grade 4 TST OS at 72h read. No other significant history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



OS upper palpebra erythematous with layer of dried crusted serum

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Two moderately enlarged tracheobronchial lymph nodes with cream colored 2mm solid nodules inside.

Respiratory System



Abnormal Respiratory System Description

One firm beige nodule found within lung parenchyma, also containing 1-2mm nodules.

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) - Necropsy - (b) (4)

Other



Other - Description

Lesion 1 - cut lymph node with 2mm cream colored nodules
Lesion 2 - cut beige lung nodule

Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Pathology Report

LTM Order #: (b) (4)

09 June 2023

History:

Customer: Charles River Houston - Quarantine

Strain:

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had a grade 4 TST at 72 hours and was euthanized. Necropsy conducted by the submitter found two moderately enlarged tracheobronchial lymph nodes (TBLN) and one lung nodule.

Microscopic Diagnoses:

#1 (b) (4) Lymph node (not clearly identified): Granuloma, moderate, focal.

Lung: Lymphocytic foci with few macrophages, mild, multifocal (2); with mild edema.

Acid-Fast Stain (lung, lymph node): Negative for acid fast organisms.

Lymph node, Spleen, Liver, Adrenal gland, Heart, Kidney, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The lymph node lesion was highly suggestive of Mycobacteriosis although acid-fast bacilli were not noted. Considering the history and microscopic changes, Mycobacteriosis should not be excluded from the differential.

(b) (6)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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FINAL REPORT

Laboratory Test Report**Owner**

Houston, TX

Accession Number:**23-020234****Animal Location**

Harris County TX, US

NFC Control Number:

19823034744

Date Collected:

05/31/2023

Date Received:

07/06/2023

Date Completed:

09/08/2023

Collected By:**Purpose:**

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1809008 **Case #:** TB23-05622 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 1809008 Case #: TB23-05623 Sample: 2 Specimen Type: Lesion/Exudate Species:
Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Sample was labeled Lesion.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 6 other isolates and shares a the most recent common ancestor with 5 other isolates from this outbreak. See attached Genotyping report.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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APPENDIX – GENOTYPING REPORT

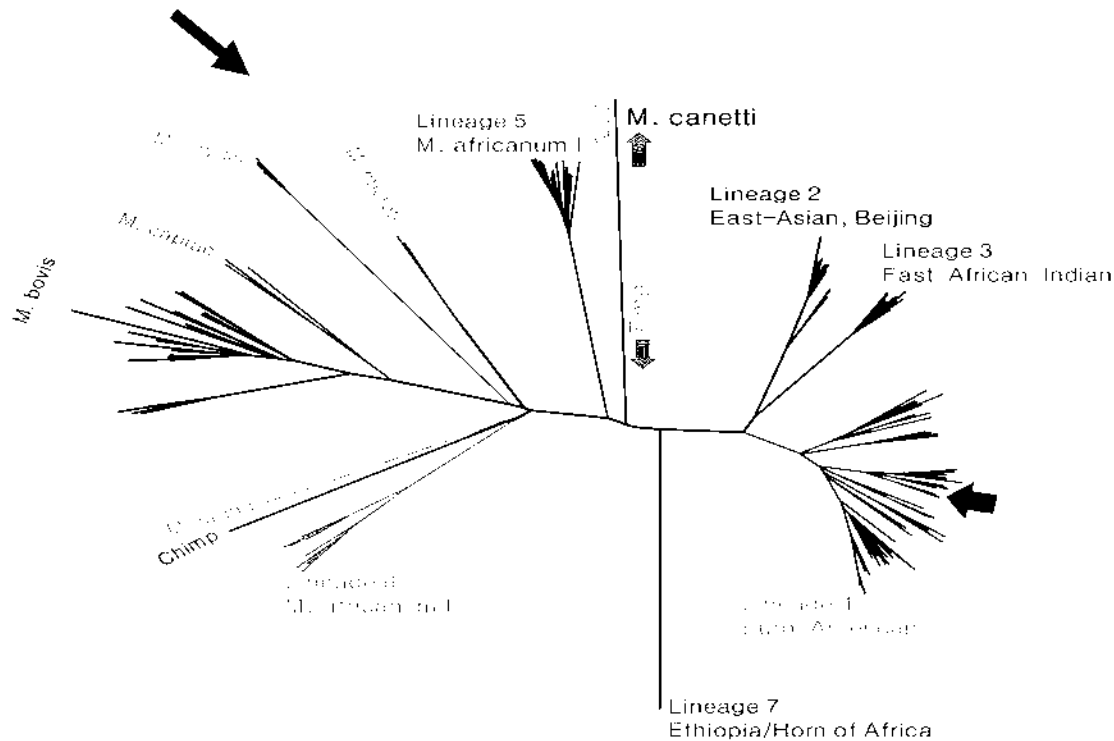
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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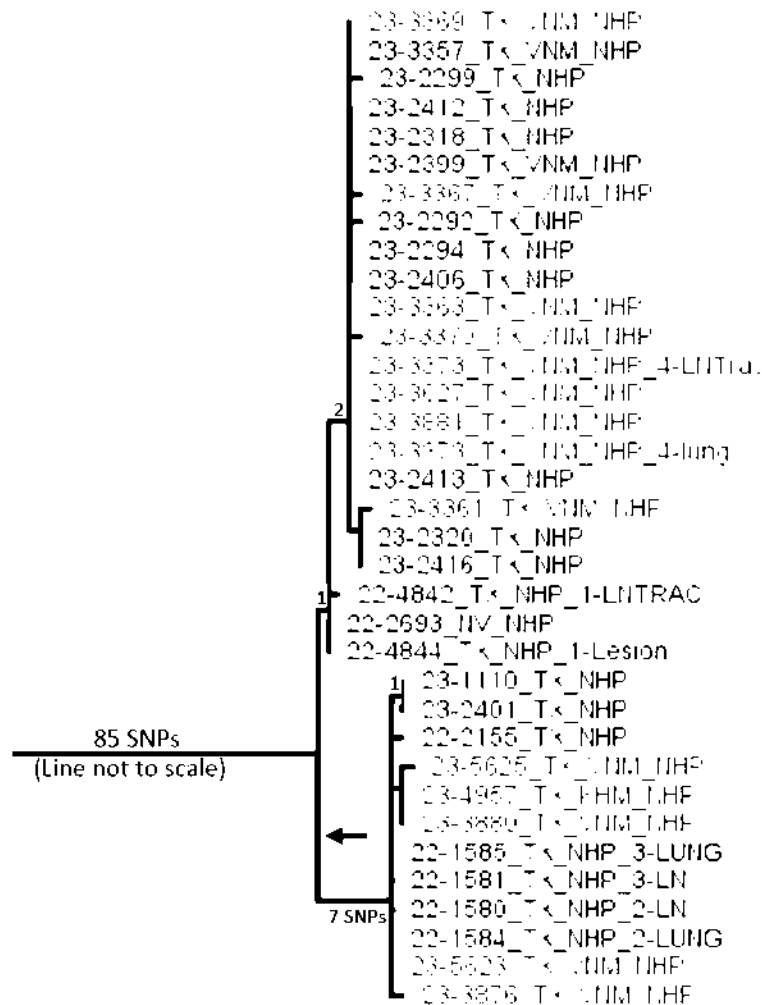
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 2080993	NC_000962.3 489393	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 108721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628	
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3369_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3357_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2412_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2318_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2399_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2292_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3627_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3881_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2413_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2406_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3363_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2299_TX_NHP	G	A	A	A	G			A		A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3367_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3370_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2294_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-3361_TX_VNM_NHP	G	A	A	A	G			A		A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G	
23-2320_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G	
23-2416_TX_NHP	G	A	A	A	G			A		A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G	
22-2693_NV_NHP	G	A	A	A	G			A		G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
22-4844_TX_NHP_1-Lesion	G	A	A	A	G			A		G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G			A		G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G	
22-1585_TX_NHP_3-LUNG	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	G
23-1110_TX_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			G	G	T	G
23-2401_TX_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			G	G	T	G
22-2155_TX_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	A	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G		G
23-4957_TX_KHM_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G		G
23-3880_TX_VNM_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G		G
23-3876_TX_VNM_NHP	G	A	A	A	G			A		G	G	G	T	G	A	G	G	T	A	G	G	A	G			C	G	T	A

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0090, 0101, and 0212. The time required to complete this information collection is estimated to average .5 hours per response for 0579-0090, 1 hour per response for 0579-0101, and .333 hours per response for 0579-0212, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0090, 0579-0101,
and 0579-0212

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
(515) 337-7514

SPECIMEN SUBMISSION

PAGE
OF

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (including Business Name) 2. NVSL SUBMITTER ID 3. NAME OF OWNER ☒ Check if wildlife (no owner)

(b) (6) Charles River Laboratories

EMAIL ADDRESS

(b) (6) crl.com (b) (6) crl.com

PHONE NO. (b) (6)

FAX NO. (b) (6)

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6) Houston, TX 77047

OWNER CITY

Houston

STATE/COUNTRY

TX/US

4. LOCATION OF ANIMALS

PREMISES ID

COUNTY

Harris

STATE/COUNTRY

TX/US

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in US dollars)

☒ CREDIT CARD
Ex. CC

6. HERD/FLOCK SIZE

(b) (4)

9. EXAMINATIONS REQUESTED

Culture; PCR

10. COLLECTED BY

(b) (6)

7. NO. IN HERD/FLOCK AFFECTED

11. DATE COLLECTED

5/31/23

8. NO. IN HERD/FLOCK DEAD

(b) (6)

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

12. COUNTRY OF ORIGIN/DESTINATION

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None ☐ Ice Pack ☒ Dry Ice ☐ Formalin ☐ Borax ☐ Alcohol ☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☐ Tissue (specify)

☐ Whole Animal

☒ Other (specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

TBLN

☐ Extract

☐ Milk

☐ Semen

☐ Swab (specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (specify)

☐ Environment

Cynomolgus

☐ Sheep

☐ Donkey

☐ Other bird (specify)

☐ Elk

☐ Reagent

Macaque

20. NUMBER OF ANIMALS SAMPLED

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID

Animal ID

Breed

Age

Sex

Sample ID

Animal ID

Breed

Age

Sex

(b) (4)

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets if necessary).

see attached necropsy report

SAMPLE NOT VERIFIED

23. SIGNATURE OF SUBMITTER AND DATE

X

NVSL USE ONLY

CONDITION

PRIORITY 3

DISTRIBUTION

RECEIVED

(b) (6)

(b) (6)

VS FORM 10-4
AUG 2009

23-020236
MB

30321
07/08/2023



24-08898_000980

(b) (4) - Necropsy - (b) (4)

From Date

05/31/2023 14:30:59

Reference #

(b) (4)

Registered



Domain

Animal

Activity

Necropsy

Animal ID

(b) (4)

Status

Performed

Performed by

(b) (6) (b) (6)

Properties

Date of Last Update	Name	Value
05/31/2023 14:48:33	Died during quarantine	Yes
05/31/2023 13:57:27	Date Out	05/31/2023 13:57:27
05/31/2023 13:57:27	Location at Stock Out - Path	(b) (4)
05/31/2023 13:57:27	Euthanasia Reason	TB Reactor
05/31/2023 13:57:27	Euthanasia Method	IV Phenytoin/Pentobarbital
01/15/2023	In-Shipment #	(b) (4)

Clinical History

(b) (4) cynomolgus macaque arriving at facility 01.15.23. Grade 5 TST OS at 72h read. No other significant history.

Tentative Diagnosis

r/o mycobacteriosis

Gross Description

Gross Findings: Check box by tissue examined. Describe if abnormal.

Skin

Abnormal Skin Description



Moderate bruising present on OS upper palpebra

Oral

Abnormal Oral Cavity Description



(b) (4) - Necropsy - (b) (4)

Lymph Nodes



Abnormal Lymph Nodes Description

Cluster of enlarged tracheobronchial lymph nodes encircling the trachea with 2mm tan nodules inside. Cluster measured approximately 20 mm^2

Respiratory System



Abnormal Respiratory System Description

Cardiovascular System



Abnormal Cardiovascular System Description

Gastrointestinal System



Abnormal Gastrointestinal System Description

Urinary System



Abnormal Urinary System Description

Reproductive System



Abnormal Reproductive System Description

Endocrine System



Abnormal Endocrine System Description

Nervous System



Abnormal Nervous System Description

Musculoskeletal System



Abnormal Musculoskeletal System Description

Tissues Fixed

Tracheobronchial Lymph Node



Lung



Heart Muscle



Liver



Spleen



Kidney



Stomach



Duodenum



Jejunum



Ileum



Colon



Bladder



Skeletal Muscle



Bone Marrow



Brain



Skin



Skin - Description

(b) (4) - Necropsy - (b) (4)

Other



Other - Description

Lesion 1. cut lymph node with nodules inside

Microbiology

TB culture pending

Other Diagnostic Test

(b) (4)

Histopathology

pending

Final Diagnosis

Event Comment

Document(s)



(b) (6)

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Tel: 877-274-8371 Fax: 978-658-7698

Pathology Report

LTM Order # (b) (4)

09 June 2023

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

Quarantine Necropsy for Houston. Animal had a grade 5 TST at 72 hours and was euthanized. Necropsy was performed by the submitter and found cluster of tracheobronchial lymph nodes with tan nodules.

Microscopic Diagnoses:

#1 (b) (4) Lymph nodes (around trachea): Lymphocytic and histiocytic infiltrative nodules, connective tissue around trachea/lung, mild, multifocal.

Lymph node ("cut"): Abscess, marked, diffuse.

Acid Fast Stain (LN): Rare acid-fast bacilli found within the lesion.

Lung, Spleen, Heart, Adrenal gland, Urinary bladder, Kidney, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic lesions in the lymph nodes, rare acid-fast bacteria, and history were consistent with a diagnosis of Mycobacteriosis in this animal.

(b) (6)



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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FINAL REPORT

Laboratory Test Report

Owner

Houston, TX

Accession Number:

23-020236

Animal Location

Harris County TX, US

NFC Control Number:

19823034746

Date Collected:

05/31/2023

Date Received:

07/06/2023

Date Completed:

08/23/2023

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Submitter - 30321

Charles River Laboratories

305 Alameda-Genoa Rd.

Houston, TX 77047

FAX #: 713-433-6971

Phone #: 713-433-5846

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 1908035 **Case #:** TB23-05625 **Sample:** 1 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

WGS Results

Genomic DNA from this isolate was sequenced and then compared to all isolates in the USDA database. This isolate has the same SNP pattern as 2 other isolates and has acquired a single SNP from sharing a the most recent common ancestor with 6 other isolates from this outbreak. See attached Genotyping report.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>



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APPENDIX – GENOTYPING REPORT

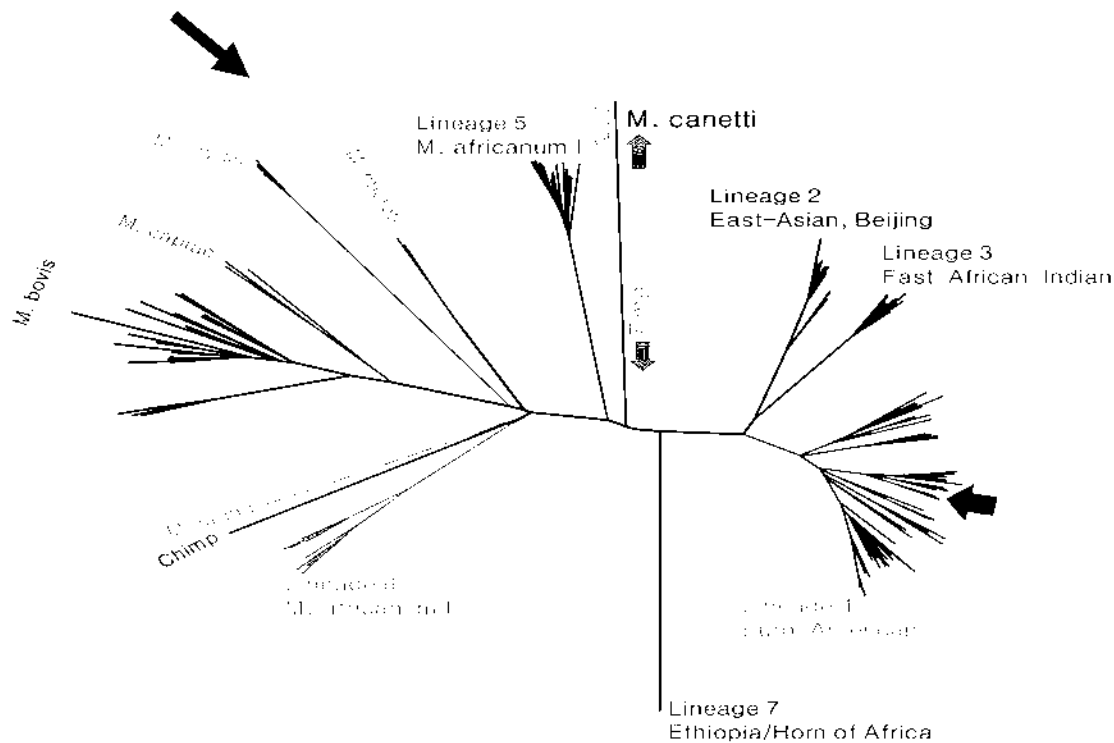
19 August 2023

Accession:

Various

WGS Genotyping results

Figure 1. The isolates recovered from these cynomolgus monkeys was *Mycobacterium orygis*. The red arrow indicates where *M. orygis* falls on the mycobacterium family tree.



Accession	Sample	Animal
23-012105	23-3361	1901032
23-012106	23-3363	1807016
23-12107	23-3367	1907049
23-012108	23-3369	1808008
23-012109	23-3370	2003029
23-012110	23-3372	2007040
23-12110	23-3373	2007040
23-013240	23-3627	1708008
23-014322	23-3876	1908037
23-014323	23-3880	1908009
23-014324	23-3881	1906028
23-017496	23-4957	1901034
23-020234	23-5623	1809008
23-020236	23-5625	1908035



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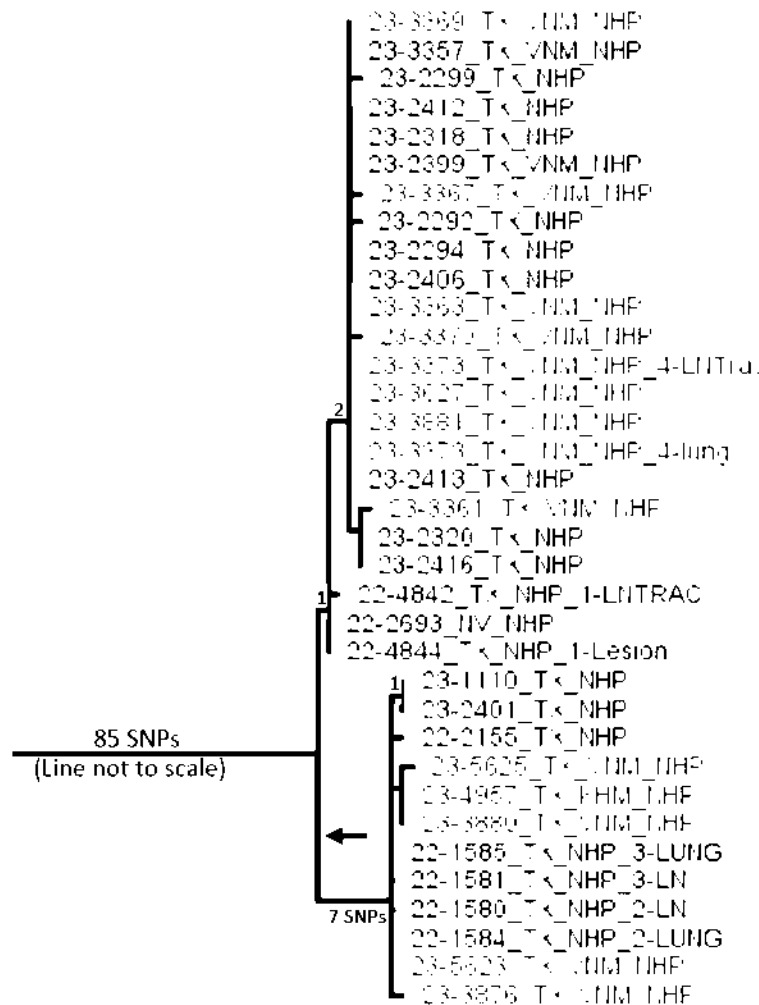
APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Figure 2. Abbreviated Tree of *M. orygis* isolates in NVSL database. Isolates from this outbreak share a common ancestor (red arrow) that has acquired 85 SNPs from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group has acquired 7 SNPs (blue branch) from the common ancestor, while all isolates in the other group (red branch) share a single SNP (blue arrow, see Table 2). All isolates within these groups are within 4 SNPs of each other. Although all of these isolates share a common ancestor, these data would suggest that there are two separate transmission events taking place represented by the two groups. Note, the 2022 isolates have acquired 2 SNPs from the common ancestor to the whole outbreak and match the ancestor to the isolates in the red branch including all the 2023 isolates in that branch.





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APPENDIX – GENOTYPING REPORT

19 August 2023

Accession:

Various

Table 1: Abbreviated SNP table of group. Isolates from this outbreak share a common ancestor that has acquired 85 SNPs (red bracket, not all SNPs shown) from sharing a common ancestor with other isolates in the NVSL database. The outbreak can be divided into two groups. One group (blue shading) has acquired 7 SNPs (blue bracket) from the common ancestor, while all isolates in the other group (red shading) share a single SNP (red arrow).

	NC_000962.3 411905.2	NC_000962.3 414471.4	NC_000962.3 419906.9	NC_000962.3 425986.0	NC_000962.3 431330.9	NC_000962.3 438701.5	NC_000962.3 440730.9	NC_000962.3 441073.5	NC_000962.3 467474.7	NC_000962.3 130886	NC_000962.3 342894.2	NC_000962.3 1461421	NC_000962.3 3010690	NC_000962.3 431705.1	NC_000962.3 1594487	NC_000962.3 333227.3	NC_000962.3 208099.5	NC_000962.3 48939.5	NC_000962.3 489396	NC_000962.3 794566	NC_000962.3 168721.3	NC_000962.3 2952996	NC_000962.3 3467800	NC_000962.3 436483.3	NC_000962.3 334775.3	NC_000962.3 171922	NC_000962.3 549934	NC_000962.3 3269628
root	A	G	G	A	A	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3369_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3357_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2412_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2318_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2399_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2292_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3372_TX_VNM_NHP_4-LNTrac	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3627_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3881_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3373_TX_VNM_NHP_4-lung	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2413_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2406_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3363_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2299_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	A	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3367_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	A	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3370_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	G	G	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2294_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	R	G	T	C	A	A	C	G	A	A	C	G	T	G
23-3361_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	A	T	C	A	A	C	G	A	A	C	G	T	G
23-2320_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
23-2416_TX_NHP	G	A	A	A	G	A	A	A	A	A	A	T	G	A	A	G	T	C	A	A	C	G	A	A	C	G	T	G
22-2693_NV_NHP	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4844_TX_NHP_1-Lesion	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-4842_TX_NHP_1-LNTRAC	G	A	A	A	G	A	A	A	A	G	G	T	G	A	G	G	T	C	A	A	C	G	A	A	C	G	T	G
22-1585_TX_NHP_3-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1581_TX_NHP_3-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1580_TX_NHP_2-LN	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-1584_TX_NHP_2-LUNG	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5623_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-1110_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-2401_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
22-2155_TX_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-5625_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-4957_TX_KHM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3880_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	G
23-3876_TX_VNM_NHP	G	A	A	A	G	A	A	A	A	G	G	G	T	G	A	G	G	T	A	G	G	A	G	A	C	G	T	A

Details		✕
Date	2023-01-11	
Exporter_id	4900255858	
Exporter	THANH CONG BIOLOGICAL CREATURE CO., LTD	
Importer	CHARLES RIVER LABORATORIES, INC.	
Hs_code	01061100	
Product_description	LON G-TAILED MONKEY (MACACA FASCICULARIS)#&EN	
Value_usd	3132000	
Unit_price_usd	5800	
Qty_unit	UNC (ANIMALS)	
Qty	540	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	UNITED STATES	
Des_port		
Exporter_address	HOANG THUY VILLAGE, HOANG DON G COMMUNE, LANG SON CITY, LANG SON PROVINCE, VIETNAM,	
Exporter_phone		
undefined		
Exporter_mail		
Exporter_contact	NGUYỄN THÀNH CÔNG	
Exporter_vn	CÔNG TY CỔ PHẦN SINH VẬT KỸ THUẬT THÀNH CÔNG - JINGANG	
Load_port_vn		
Commodity_vn	CON KHỈ ĐUÔI DÀI SỐNG(MACACA FASCICULARIS)#&VN	
Unit_price_dclr	5800	
Value_dclr	3132000	
Currency_dclr	5800	
Exchange_rate_vnd	23340	
Value_vnd	73100880000	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	3052800437400	
Trans_mode	AIR	

Exhibit 25

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report**Owner**Charles River Laboratories
Houston, TX**Animal Location**

Houston County TX

Submitter - 30321Charles River Laboratories
305 Alameda-Genoa Rd.
Houston, TX 77047
FAX #: 713-433-6971
Phone #: 713-433-5846**Accession Number:****23-038824****NFC Control Number:**

19824010031

Date Collected:

11/13/2023

Date Received:

12/08/2023

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 2110071 **Case #:** TB23-10643 **Sample:** 1 **Specimen Type:** Lymph Node **Species:**

Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.09831238

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 2110071 **Case #:** TB23-10644 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus**Mycobacterial Culture Result**

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081Not Detected Ct =
Undetermined

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2110071 **Case #:** TB23-10645 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct =

Undetermined

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2110071 **Case #:** TB23-10646 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct =

Undetermined

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 2110071 **Case #:** TB23-10647 **Sample:** 5 **Specimen Type:** Tissue **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.42901611

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Exhibit 26

Animal ID: 29678 **Case #:** TB24-01347 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 29678 **Case #:** TB24-01348 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 29077 **Case #:** TB24-01349 **Sample:** 5 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.76292992

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 29077 **Case #:** TB24-01350 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 29077 **Case #:** TB24-01351 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.26185608

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 29077 **Case #:** TB24-01352 **Sample:** 8 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.34337807

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 29077 **Case #:** TB24-01353 **Sample:** 9 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 29077 **Case #:** TB24-01354 **Sample:** 10 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 29.49106216

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Animal ID: 29077 **Case #:** TB24-01355 **Sample:** 11 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.33911896

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

The number of samples on the submission form do not match the number of samples received. Total of 7 samples received for animal 29077.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 27

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order # (b) (4)

06 February 2024

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4) Quarantine Necropsy

Animal had a 4/5 TB score during 2nd TB test in quarantine. It was euthanized and necropsied by the submitter. Findings included mildly enlarged tracheobronchial lymph nodes and a lung nodule.

Microscopic Diagnoses:

#1 (b) (4) Lung: Granuloma, mild, focal

Acid-fast Stain (lung): Positive for acid fast organism.

Liver, Lymph node (tracheobronchial, mesenteric), Heart, Spleen, Kidney, Urinary bladder,

Stomach, Small intestine, Large intestine: Within normal limits.

Acid Fast stain (TBLN): Negative for organisms.

Comment:

The history and pulmonary lesion are consistent with Mycobacteriosis. No other significant lesions were noted.

(b) (6)

24-08898_001099



National Veterinary Services Laboratories

PARTIAL

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

Laboratory Test Report

Owner

Charles River Laboratories
Houston, TX

Animal Location

TX, US

Submitter - 503902

Pratts
Charles River Laboratories
305 Alameda-Genoa Rd
Houston, TX 77047
FAX #: 240-529-0640
Phone #:

Accession Number:

24-004193

NFC Control Number:

19824017091

Date Collected:

01/29/2024

Date Received:

02/08/2024

Date Completed:

Collected By:

Purpose:

TB-10-4

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 32292 **Case #:** TB24-01945 **Sample:** 1 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32292 **Case #:** TB24-01946 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32292 **Case #:** TB24-01947 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32292 **Case #:** TB24-01948 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 33.76313019

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 32292 **Case #:** TB24-01949 **Sample:** 5 **Specimen Type:** Lesion/Exudate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.66385841

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Pathology Report

LTM Order #: (b) (4)

06 February 2024

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

Quarantine Necropsy-Animal had a 5/5 TB reaction at 72 hours and was euthanized. Necropsy was conducted by the submitter and found enlarged left axillary lymph node with purulent material and skin wound on left hand, 3rd digit,. Tracheobronchial lymph nodes were mildly enlarged. The heart was globoid with thinner right ventricle. Few pigmented nodules noted on the omentum.

Microscopic Diagnoses:

#1 (b) (4) Lymph nodes (presumed axillary): Lymphadenitis, suppurative, necrotizing, lytic, marked, diffuse.

Acid Fast stain (Lymph nodes, axillary): Small numbers of acid-fast bacilli associated with lymph node lesions.

Adipose tissue, abdominal: Granuloma, resolving with gold/brown pigment containing macrophages and peripheral eosinophilic (parasitic granuloma).

Lung, Liver, Lymph node (tracheobronchial, mesenteric), Heart, Spleen, Urinary bladder,

Kidney, Stomach, Intestines: Within normal limits.

Acid Fast stain (lung, TBLN): Negative for organisms.

Comment: The axillary lymph node lesions were likely secondary to the digit lesion described in the history. The lesions were consistent with Mycobacteriosis. The omental nodules noted grossly correlated to resolving parasitic nodules. Some black pigment was associated with lung, lymph nodes, and spleen was of uncertain origin or significance.

(b) (6)

Animal ID: 33868 **Case #:** TB24-01950 **Sample:** 1 **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.70177078

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33868 **Case #:** TB24-01951 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.15059662

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33868 **Case #:** TB24-01952 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.09268188

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33868 **Case #:** TB24-01953 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33868 **Case #:** TB24-01954 **Sample:** 5 **Specimen Type:** Lesion/Exudate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.50719833

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33868 **Case #:** TB24-01955 **Sample:** 6 **Specimen Type:** Tissue **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.73898315

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

The sample container was labeled digit with lesion.

In addition to LN, spleen, liver, and lung, a phalange (digit) was received for animal ID 33868 . It was not captured on the submission form.

Exhibit 28

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7514

SPECIMEN SUBMISSION

PAGE
1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name)

(b) (6)

2. NVSL SUBMITTER ID

3. NAME OF OWNER ☐ Check if wildlife (No owner)

Charles River Laboratories

EMAIL ADDRESS

(b) (6) cri.com

OWNER CITY

Houston

STATE/COUNTRY

TX/USA

PHONE NUMBER

(b) (6)

FAX NUMBER

(b) (6)

4. LOCATION OF ANIMALS

MAILING ADDRESS (Street, City, State, ZIP Code)

(b) (6)

Houston, TX 77047

PREMISES ID

COUNTY

Georgia

STATE/COUNTRY

TX/USA

5. PAYMENT METHOD

☐ USER FEE ACCOUNT NO.

☐ CHECK/MONEY ORDER
(Enclosed, payable to USDA in U.S. dollars)

☒ Credit Card Number: On File

Expiration Date:

6. HERD/FLOCK SIZE

9. EXAMINATIONS REQUESTED

7. NUMBER IN HERD/FLOCK AFFECTED

Mycobacterium Culture
Mycobacterium PCR
Mycobacterium Identification
Rule in/out TB

8. NUMBER IN HERD/FLOCK DEAD

10. COLLECTED BY

(b) (6)

11. DATE COLLECTED

07/15/2024

12. AUTHORIZED BY

13. PURPOSE OF SUBMISSION (See instructions for definitions)

☐ Interstate Movement

☐ Import

☒ TB

☐ Reagent Evaluation

☐ Export

☐ FAD/EP Diagnostic

☐ General Diagnostic

☐ NVSL Intralab

☐ Pre-Import

☐ Surveillance

☐ Developmental Research

14. COUNTRY OF ORIGIN

(b) (4)

15. REFERRAL NUMBER

16. PRESERVATION

☐ None

☐ Ice Pack

☒ Dry Ice

☐ Formalin

☐ Borax

☐ Alcohol

☐ Other (Specify)

17. SPECIMENS SUBMITTED ("X" applicable item(s))

☐ Blood

☐ Feces

☐ Parasite

☐ Serum

☒ Tissue (Specify)

☐ Whole Animal

☐ Other (Specify)

☐ Culture

☐ Feed

☐ Plant

☐ Soil

☐ Urine

☐ Fetus

☐ Extract

☐ Milk

☐ Semen

☐ Swab (Specify)

☐ Water

☐ DNA/RNA

19. SPECIES OR SOURCE ("X" ONLY one)

☐ Cattle

☐ Goat

☐ Chicken

☐ Bison

☐ Fish

☒ Other (Specify)

☐ Swine

☐ Horse

☐ Turkey

☐ Deer (Specify)

☐ Environment

☐ Sheep

☐ Donkey

☐ Other bird (Specify)

☐ Elk

☐ Reagent

21. IDENTIFICATION (See instructions <250 samples per form)

IDENTIFICATION

Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (4)									

Date: August 14, 2024

Biological Products Packing List

1. Contact Name: United States Department of Agriculture
Animal and Plant Health Inspection Services
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010
Phone: 515-337-7514

2. Species/Origin: *Macaca fascicularis* (b) (4) origin ** Quarantine Samples **

3. Item Name	Quantity	Date sample Derived	Packing
(b) (4)	LN, spleen, liver and lung	7/15/24	Dry Ice
(b) (4)	LN, spleen, liver and lung	7/15/24	Dry Ice
(b) (4)	LN, spleen, liver and lung	7/15/24	Dry Ice
(b) (4)	LN, spleen, liver and lung	7/15/24	Dry Ice

4. Date Shipped: Ship on 8/14/2024 for delivery on morning of 8/15/2024

5. FedEx Tracking (b) (7)(F)

6. Warning:

The tissues above are derived from non-human primates in a CDC-registered quarantine facility. Except when specifically requested, the donor non-human primates are not tested for presence/absence of antibody to any disease. If donor animal is required to be tested for any disease agent then the specifics must be notified in writing and prior confirmation on availability and price of testing obtained when placing the order.

The tissues from non-human primates may harbor known or yet unknown naturally occurring biohazards and should be appropriately handled by the user.

(b) (6)
Signature of Supervisor

SEE CONDITIONS OF SALE/WARRANTY

From: (b) (6) <(b) (6)@crl.com>
Sent: Wednesday, August 14, 2024 8:14 AM
To: Bravo Garcia, Doris M - APHIS <doris.m.bravo@usda.gov>; Kimberly Lehman <Kimberly.Lehman@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) <(b) (6)@crl.com> (b) (6)@crl.com>
Subject: Request Permission to ship NHP samples

Good morning,

We would like to send (b) (6) HP tissue samples for Mycobacterium testing on today, 8/14 for arrival on Thursday, 8/15. Please let us know if you are agreeable to this. Please see attached histopathology and filovirus report. We will send the AWB when the shipping label is created.

National Veterinary Services Lab Information for NHP samples submitted:

Where did the animals originate from? (b) (4)
What was the date that they left the originating country? 06/28/24
How many animals were in the group imported? (b) (4)
Have any cohorts died of unknown causes? No
Was animals exposed to animals from other sources? No
Was a complete necropsy and with histology done on this animal? Yes
If so, can you provide those results? – Please see attached histopathology report
Cause of Death? – TB Suspect
Was the animal showing any abnormal symptoms prior to death? No

Thank you,

(b) (6) (b) (6) DVM
Director of North America Quarantine Veterinary Services
(b) (6)
(b) (6) Frederick | Charles River
(b) (6) Frederick, MD 21701
P: (b) (6) | F: (b) (6)
(b) (6) [crl.com](mailto:(b) (6)@crl.com) | www.criver.com
[LinkedIn](#) | [Twitter](#) | [Facebook](#) | [Eureka](#)

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Please consider the environment before printing this email note.

Charles River Research Animal Diagnostic Services

(b) (6)

Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order #: (b) (4)

02 August 2024

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

This animal had a grade 3/5 TB reaction at 48 and 72 hours and was euthanized. Necropsy was conducted by the submitter and found nodular lesions on the lung, tracheobronchial lymph node, liver, and spleen.

Microscopic Diagnoses:

#1 (b) (4) Lung, Tracheobronchial lymph node, Liver, Spleen: Granuloma, mild/moderate/marked, multifocal.

Acid fast stain (lung, TBLN, Liver, Spleen): Positive for intralesional acid-fast bacilli in the spleen. Other tissues were negative.

Heart, Kidney, Lymph node (mesenteric), Urinary bladder, Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic changes are consistent with a diagnosis of Mycobacteriosis in this animal.

(b) (4)

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

PARTIAL

Laboratory Test Report**Owner**Charles River Laboratories
Houston, TX**Animal Location**

TX, US

Submitter - 503903Pratts
Charles River Laboratories
305 Alameda-Genoa Rd.
Houston, TX 77047**Accession Number:****24-023332****NFC Control Number:**

19824038777

Date Collected:

07/15/2024

Date Received:

08/15/2024

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 32810 **Case #:** TB24-09333 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081**Detected** **Ct = 26.26446533**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 32810 **Case #:** TB24-09334 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081**Not Detected** **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32810 **Case #:** TB24-09335 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32810 **Case #:** TB24-09336 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.75315857

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33666 **Case #:** TB24-09337 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.33961868

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33666 **Case #:** TB24-09338 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33666 **Case #:** TB24-09339 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Pathology Report

LTM Order #: (b) (4)

02 August 2024

History:

Customer: Charles River Houston - Quarantine

Strain: Macaca fascicularis

Species: Non-Human Primate (NHP)

Notes: Animal ID (b) (4)

This animal had a grade 4/5 TB reaction at 72 hours and was euthanized. Necropsy was performed by the submitter and found lung nodule with caseous center and mildly enlarged tracheobronchial lymph node (TBLN).

Microscopic Diagnoses:

#1 (b) (4) Lung, Tracheobronchial lymph node (TBLN): Granuloma, mild/moderate, focal to coalescing.

Acid Fast Stain (lung, TBLN): Positive for intralesional acid-fast bacilli.

Spleen, Liver, Heart, Kidney, Lymph node (mesenteric), Small intestine, Large intestine, Urinary bladder (no mucosa): Within normal limits.

Stomach: not present in examined tissues.

Comment:

The microscopic changes in this animal were consistent with a diagnosis of Mycobacteriosis.

(b) (6)

Animal ID: 22853 **Case #:** TB24-10136 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22853 **Case #:** TB24-10137 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33258 **Case #:** TB24-10138 **Sample:** 5 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 23.17875671

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33258 **Case #:** TB24-10139 **Sample:** 6 **Specimen Type:** Spleen **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33258 **Case #:** TB24-10140 **Sample:** 7 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33258 **Case #:** TB24-10141 **Sample:** 8 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22853 **Case #:** TB24-10230 **Sample:** 9 **Specimen Type:** Tissue **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33258 **Case #:** TB24-10231 **Sample:** 10 **Specimen Type:** Tissue **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

2 additional samples labeled "abnormal tissue" one for each animal. This was not caught during check in of samples.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Charles River Research Animal Diagnostic Services

(b) (6) Wilmington, MA 01887 USA

Email: (b) (6)@crl.com

Pathology Report

LTM Order # (b) (4)

05 August 2024

History:

Customer: Charles River Houston - Quarantine
Strain: Macaca fascicularis
Species: Non-Human Primate (NHP)
Notes: Animal ID (b) (4)

This animal had a grade 3/5 TB reaction at 48 and 72 hours and was euthanized. Necropsy was performed by the submitter and found a lung nodule and slightly enlarged tracheobronchial lymph node.

Microscopic Diagnoses:

#1 (b) (4) Lung, Tracheobronchial lymph node (TBLN): Granuloma, mild, multifocal.
Acid Fast Stain (lung, TBLN): Positive for intralesional acid-fast bacillus in the TBLN. Negative for organisms in the lung.
Large intestine: Herniated Peyer's patch with associated inflammation with gold/brown pigment-containing macrophages, mild, focal.
Liver, Spleen, Heart, Urinary bladder, Kidney, Lymph node (mesenteric), Stomach, Small intestine, Large intestine: Within normal limits.

Comment:

The microscopic changes were consistent with a diagnosis of Mycobacteriosis. The intestinal change was considered incidental.

(b) (6)

24-08898_001380

Animal ID: 32810 **Case #:** TB24-09335 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32810 **Case #:** TB24-09336 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.75315857

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33666 **Case #:** TB24-09337 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.33961868

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 33666 **Case #:** TB24-09338 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33666 **Case #:** TB24-09339 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33666 **Case #:** TB24-09340 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33673 **Case #:** TB24-09341 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33673 **Case #:** TB24-09342 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33673 **Case #:** TB24-09343 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33673 **Case #:** TB24-09344 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 34030 **Case #:** TB24-09345 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 27.77874565**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 34030 **Case #:** TB24-09346 **Sample:** 2 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 35.43774033**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 34030 **Case #:** TB24-09347 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 34030 **Case #:** TB24-09348 **Sample:** 4 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 34.3151474**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 34030 **Case #:** TB24-09349 **Sample:** 5 **Specimen Type:** Tissue **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 27.96220398**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Details		×
Date	2024-06-25	
Exporter_id	3800232291	
Exporter	VINA MEKONG GROUP	
Importer	CHARLES RIVER LABORATORIES, INC.	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY. (116 MALE, 173 FEMALE) (SCIENTIFIC NAME: MACACA FASCICULARIS)#&VN	
Value_usd	216750	
Unit_price_usd	750	
Qty_unit	UNC (ANIMALS)	
Qty	289	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctr	VIETNAM	
Des_port		
Exporter_address	THANH HIEP HAMLET, THANH BAC COMMUNE, TAN BIEN DISTRICT, TAY NINH PROVINCE, VIETNAM,	
Exporter_phone	0908 007799	
Exporter_fax		
Exporter_mail		
Exporter_contact	HUỖNH HỮU DŨNG	
Exporter_vn	CÔNG TY TNHH MỘT THÀNH VIÊN VINA MEKONG	
Exporter_type	ORDINARY EXPORT	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG. (116 CON ĐỰC, 173 CON CÁI) (TÊN KHOA HỌC: MACACA FASCICULARIS)#&VN	
Unit_price_dclr	750	
Value_dclr	216750	
Currency_dclr	USD	
Exchange_rate_vnd	25247	
Value_vnd	5472287250	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	306527209460	
Trans_mode	AIR	

Details		✕
Date	2024-06-25	
Exporter_id	3800232291	
Exporter	VINA MEKONG GROUP	
Importer	CHARLES RIVER LABORATORIES, INC.	
Hs_code	01061100	
Product	LIVE LONG-TAILED MONKEY, (180 MALE, 180 FEMALE) (SCIENTIFIC NAME: MACACA FASCICULARIS)#&VN	
Value_usd	270000	
Unit_price_usd	750	
Qty_unit	UNC (ANIMALS)	
Qty	360	
Weight_kg		
Origin_country	VIETNAM	
Load_port		
Des_ctry	VIETNAM	
Des_port		
Exporter_address	THANH HIEP HAMLET, THANH BAC COMMUNE, TAN BIEN DISTRICT, TAY NINH PROVINCE, VIETNAM,	
Exporter_phone	0908 007799	
Exporter_fax		
Exporter_mail		
Exporter_contact	HUỖNH HỮU DŨNG	
Exporter_vn	CÔNG TY TNHH MỘT THÀNH VIÊN VINA MEKONG	
Exporter_type	ORDINARY EXPORT	
Importer_address	CHARLES RIVER, LABORATORIES, FREDERICK, 8501 PROGRESS, DRIVE FREDERICK, MD21701, MARYLAND, US,	
Load_port_vn		
Commodity	CON KHỈ ĐUÔI DÀI SỐNG. (180 CON ĐỰC, 180 CON CÁI) (TÊN KHOA HỌC: MACACA FASCICULARIS)#&VN	
Unit_price_dclr	750	
Value_dclr	270000	
Currency_dclr	USD	
Exchange_rate_vnd	25247	
Value_vnd	6816690000	
Incoterms	FOB	
Payment	KC	
Transport	AIR	
Carrier		
Bill_no	306527166650	
Trans_mode	AIR	

Exhibit 29

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
NATIONAL VETERINARY SERVICES LABORATORIES
P.O. BOX 844, 1920 DAYTON AVENUE, AMES, IA 50010
515-337-7266

SPECIMEN SUBMISSION

PAGE
1 OF 1

INSTRUCTIONS: Use a separate form for each species and each owner/broker. See "Instructions for Completing VS Form 10-4" for definitions.

1. SUBMITTER NAME (Including Business Name) (b) (6) Charles Rivers Laboratories	2. NVSL SUBMITTER ID	3. NAME OF OWNER <input type="checkbox"/> Check if wildlife (No owner) Charles Rivers Laboratories
EMAIL ADDRESS (b) (6) @crl.com	OWNER CITY Reno	STATE/COUNTRY NV
PHONE NUMBER (b) (6) FAX NUMBER (b) (6)	4. LOCATION OF ANIMALS	
MAILING ADDRESS (Street, City, State, ZIP Code) (b) (6) Reno, NV 89511	PREMISES ID	COUNTY Washoe
		STATE/COUNTRY NV

5. PAYMENT METHOD		
<input type="checkbox"/> USER FEE ACCOUNT NO.	<input type="checkbox"/> CHECK/MONEY ORDER (Enclosed, payable to USDA in U.S. dollars)	<input checked="" type="checkbox"/> Credit Card Number: Expiration Date:
6. HERD/FLOCK (b) (4)	9. EXAMINATIONS REQUESTED TB Culture - Cynomolgus monkey TB suspect tissues, stored in dry ice in 15ml conicals.	10. COLLECTED BY (b) (6)
7. NUMBER IN HERD/FLOCK AFFECTED (b) (4)		11. DATE COLLECTED 02/23/2024
8. NUMBER IN HERD/FLOCK DEAD (b) (4)		12. AUTHORIZED BY
13. PURPOSE OF SUBMISSION (See instructions for definitions)		14. COUNTRY OF ORIGIN / DESTINATION (b) (4)
<input type="checkbox"/> Interstate Movement <input type="checkbox"/> Import <input checked="" type="checkbox"/> TB <input type="checkbox"/> Reagent Evaluation	<input type="checkbox"/> Export <input type="checkbox"/> FAD/EP Diagnostic <input type="checkbox"/> General Diagnostic <input type="checkbox"/> NVSL Intralab	15. REFERRAL NUMBER AT00199
<input type="checkbox"/> Pre-Import <input type="checkbox"/> Surveillance <input type="checkbox"/> Developmental Research		

16. PRESERVATION <input type="checkbox"/> None <input checked="" type="checkbox"/> Ice Pack <input type="checkbox"/> Dry Ice <input type="checkbox"/> Formalin <input type="checkbox"/> Borax <input type="checkbox"/> Alcohol <input type="checkbox"/> Other (Specify)		18. TOTAL NUMBER OF SPECIMENS SUBMITTED (b) (4)
17. SPECIMENS SUBMITTED ("X" applicable item(s))		
<input type="checkbox"/> Blood <input type="checkbox"/> Feces <input type="checkbox"/> Parasite <input type="checkbox"/> Serum <input checked="" type="checkbox"/> Tissue (Specify) <input type="checkbox"/> Whole Animal <input type="checkbox"/> Other (Specify)	<input type="checkbox"/> Culture <input type="checkbox"/> Feed <input type="checkbox"/> Plant <input type="checkbox"/> Soil <input type="checkbox"/> Urine <input type="checkbox"/> Fetus	
<input type="checkbox"/> Extract <input type="checkbox"/> Milk <input type="checkbox"/> Semen <input type="checkbox"/> Swab (Specify) <input type="checkbox"/> Water <input type="checkbox"/> DNA/RNA		
19. SPECIES OR SOURCE ("X" ONLY one)		20. NUMBER OF ANIMALS SAMPLED (b) (4)
<input type="checkbox"/> Cattle <input type="checkbox"/> Goat <input type="checkbox"/> Chicken <input type="checkbox"/> Bison <input type="checkbox"/> Fish <input checked="" type="checkbox"/> Other (Specify) Non-human Primate	<input type="checkbox"/> Swine <input type="checkbox"/> Horse <input type="checkbox"/> Turkey <input type="checkbox"/> Deer (Specify) <input type="checkbox"/> Environment	
<input type="checkbox"/> Sheep <input type="checkbox"/> Donkey <input type="checkbox"/> Other bird (Specify) <input type="checkbox"/> Elk <input type="checkbox"/> Reagent		

21. IDENTIFICATION (See instructions <250 samples per form)					IDENTIFICATION				
Sample ID	Animal ID	Breed	Age	Sex	Sample ID	Animal ID	Breed	Age	Sex
(b) (6) (b) (4) (b) (4)					(b) (6) (b) (4) (b) (4)				
					SAMPLE NOT VERIFIED				

22. ADDITIONAL DATA (History, clinical signs, post mortem findings, remarks, tentative diagnosis, special instructions. Use additional sheets, if necessary).
Due to suspected positive and positive tuberculin test results, (b) (4) were euthanized. Standard set of tissues collected. At necropsy, nodules, focal to multifocal, were observed in the liver (b) (4), lung (b) (4), and spleen (b) (4). Additionally, multiple adhesions were observed between the cranial lung lobes and the thoracic cavity for (b) (4), and multifocal pale foci were observed in the lung of (b) (4). Lymph node enlargement was also observed in (b) (4) (tracheobronchial), (b) (4) (tracheobronchial), (b) (4) (axillary and tracheobronchial), and (b) (4) (pancreatic).

(b) (6)		11 Mar 2024		24 - 007413	
CONDITION		PRIORITY		MB	
VS FORM 10-4 FEB 2021		3		03/12/2024 21897	
(b) (6)		(b) (6)			

24-08898_001168

WARNING



BIOHAZARD

Enclosed are non-human primate blood or tissue products. These products, even if frozen, can carry and transmit potentially lethal diseases to humans (Herpes B, etc.)

It is strongly recommended that you treat these products as if they were humans samples (gloves, face mask, eye protection, etc.) and that you dispose of such products in biohazard containers.

Contact the following for recommended post exposure procedures:

- NIH B Virus Resource Laboratory 404-651-0808

OR

- The Environmental Health and Safety Division
Charles River Laboratories
Preclinical Services – Nevada

(b) (6)

Reno, NV 89511

(b) (7)(A)

Shipping Manifest

Domestic and International

charles river

To Be Completed By Submitter:

TO: Name, Title: United States Department of Agriculture Company: Animal & Plant Health Inspection Service National Veterinary Services Laboratories Address: P.O. Box 844, 1920 Dayton Avenue Ames, IA 50010 Phone: 515-337-7514 Fax: _____ Email: _____		Date Of Shipment: 11-Mar-2024 Study Number: (b) (4) Sponsor Study Number: _____ Courier Service: <input checked="" type="checkbox"/> FedEx Next Day <input type="checkbox"/> am <input type="checkbox"/> FedEx Int'l Express <input type="checkbox"/> FedEx 2nd Day <input type="checkbox"/> UPS <input type="checkbox"/> am <input type="checkbox"/> FedEx Ground <input type="checkbox"/> World Courier <input type="checkbox"/> Other (Specify): _____	
FROM: Name, Title: (b) (6) Company: Charles River Laboratories Address: Preclinical Services, Nevada (b) (6) Reno, NV 89511 Phone: (b) (6) Fax: _____ Email: _____@crl.com		Purpose of Shipment: <input type="checkbox"/> Return <input type="checkbox"/> Analysis <input checked="" type="checkbox"/> Evaluation <input type="checkbox"/> Archive <input type="checkbox"/> Other: _____	
Samples/Specimens/Items Shipped: <input checked="" type="checkbox"/> Tissue(s) <input type="checkbox"/> Bone Marrow <input type="checkbox"/> Test/Control Article(s) <input type="checkbox"/> Serum <input type="checkbox"/> Paraffin Block(s) <input type="checkbox"/> Formulation Sample(s) <input type="checkbox"/> Plasma <input type="checkbox"/> Slide(s) Fixed <input type="checkbox"/> Culture Swab(s) <input type="checkbox"/> Urine <input type="checkbox"/> Slide(s) Unfixed <input type="checkbox"/> Document(s) <input type="checkbox"/> Feces <input type="checkbox"/> Whole Blood <input type="checkbox"/> CD(s) <input type="checkbox"/> Other (Specify): _____		Shipping Conditions: <input checked="" type="checkbox"/> Dry Ice _____ kg <input type="checkbox"/> Formalin <input type="checkbox"/> Ambient <input type="checkbox"/> Alcohol <input type="checkbox"/> Blue Ice <input type="checkbox"/> Ethanol <input type="checkbox"/> Other (Specify): _____	
Documents Required to Accompany Shipment: <input type="checkbox"/> Original CITES Permit <input type="checkbox"/> C.O.T. <input type="checkbox"/> 3-177 Declaration of Exportation <input type="checkbox"/> T.M.I.S. <input type="checkbox"/> Customs Invoice <input type="checkbox"/> T.A.S.D.S. <input type="checkbox"/> Blood Collection Record / Hardcopy <input type="checkbox"/> C.O.A. <input type="checkbox"/> Blood Collection Record / Electronic <input type="checkbox"/> MSDS/SDS <input type="checkbox"/> Health Certificate <input type="checkbox"/> P.O. <input type="checkbox"/> Other (specify): _____		Species: <input type="checkbox"/> Human <input type="checkbox"/> Canine <input type="checkbox"/> Rodent (Rat) <input type="checkbox"/> Rodent Other <input type="checkbox"/> Lagomorph (Rabbits) <input checked="" type="checkbox"/> Non Human Primate (Cynomolgus) <input type="checkbox"/> Non Human Primate Other: <input type="checkbox"/> Other (Specify): _____	
Shipping Notification: _____@crl.com _____@crl.com		Comments: _____ _____ _____	
Number of Boxes: 1		Shipment Submitted By (Initial and Date): SN 11 Mar 2024	

To Be Completed By Shipping Department:

(b) (6) _____ Date: 11 Mar 2024		Total Box(es): 1	
To Be Completed By Recipient: After Completing Section, Please Fax, Mail, or Email back to CRL.			
Date Received: _____ Received By (print name): _____ Received By (signature): _____ Condition Upon Receipt: <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor (Check One)		Waybill/Job/Tracking Number: AFFIX TRACKING LABEL HERE	

(b) (4)

01170

Shipment Inventory D

charles river

Study Number: (b) (4)
 Sponsor Number: (b) (4)
 Test System: Monkey (MNKY)
 Sample Matrix: Tissues
 Storage Condition at Set to maintain 2°C
 Destination: to 8°
 Total Number of Samples: (b) (4)

(b) (4)	Date	23-Feb-2024
(b) (4)	Tissue for TB Culture in 15 mL conical (liver x1, lung x1, spleen x1, tracheobronchial LN x1, cervical LN x1, inguinal LN x1, axillary LN x1)	(b) (4)
3608-10007	Number of Samples per Timepoint	

N/A = Not Applicable, M = Male, F = Female, Unsex = Unsexed, S = Sex, -/- = No sample available, Other:

*Two additional samples from: lung and pancreatic LN

From: (b) (6) <(b) (6)@crl.com>
Sent: Monday, March 11, 2024 10:32 AM
To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>
Subject: RE: TB Suspect Tissue Shipment (b) (4)

To whom it may concern:

For study number (b) (4) samples for TB diagnostics will be shipped on dry ice today, 11 Mar 2024 for receipt on 12 Mar 2024 via FedEx. You will be receiving an email with the tracking information later today.

Shipment will contain (b) (4) (b) (4) onicals of frozen tissue split between 2 boxes.

Please see the attached manifest for shipping details and inventory.

Thank you,

(b) (6)

(b) (6)
(b) (6)
(b) (6) | Charles River
(b) (6) Reno, NV 89511
P: (b) (6) | F: (b) (6)
(b) (6) @crl.com | www.criver.com
she/her/hers

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From: (b) (6)
Sent: Tuesday, March 5, 2024 2:59 PM
To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>
Subject: RE: [External Email]TB Suspect Tissue Shipmen (b) (4)

Good afternoon Kim,

Below are the histopathology results for your review:

Due to suspected positive and positive tuberculosis skin test reactions, (b) (4) were euthanized. Tissues collected at necropsy for light microscopic evaluation included liver, lung, lymph nodes (axillary, cervical, and tracheobronchial), and spleen, as well as any tissues with macroscopic observations.

At necropsy, nodules, focal to multifocal, were observed in the liver (Animal Nos. (b) (4)) and (b) (4) lung (Animal No. (b) (4) and spleen (Animal No. (b) (4) Additionally, multiple adhesions were observed between the cranial lung lobes and the thoracic cavity for Animal No. (b) (4) and multifocal pale foci were observed in the lung

24-08898 001172

of Animal No. (b) (4). Lymph node enlargement was also observed in Animal Nos. (b) (4) (tracheobronchial), (b) (4) (tracheobronchial), (b) (4) (axillary and tracheobronchial), and (b) (4) (pancreatic). Granulomatous inflammation, consistent with Mycobacterial infection, was observed in various tissues in Animal Nos. (b) (4), (b) (4), and (b) (4) and correlated with the macroscopic observations of nodules in the liver, lung, and spleen, and with tracheobronchial lymph node enlargement (Animal Nos. (b) (4) and (b) (4)). Granulomatous inflammation was like that described in Animal No. (b) (4) and was characterized by focal and/or multifocal to coalescing granulomas with central cores of lytic necrosis surrounded by epithelioid macrophages, multinucleated giant cells, lesser neutrophils, lymphocytes, and plasma cells, and circumferential fibrous connective tissue. Variable mineralization within granulomas was often observed. Acid-fast staining of tissues revealed very rare acid-fast positive bacilli in the tracheobronchial lymph node of Animal Nos. (b) (4), (b) (4), and (b) (4) and in the liver of Animal No. 0389F.

Please let us know when we can ship the frozen tissues for analysis.

Thank you,

(b) (6)

J. Norcross, BS RLATg

(b) (6) | Charles River

(b) (6) Reno, NV 89511

P: (b) (6) | F: (b) (6)

(b) (6) [crl.com](mailto:(b) (6)@crl.com) | www.criver.com

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From: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>

Sent: Friday, February 23, 2024 11:48 AM

To: (b) (6) <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS

<NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>; (b) (6)

<(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>

Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6)

<(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>;

(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6)

<(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6)

(b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: Re: [External Email]TB Suspect Tissue Shipment (b) (4)

WARNING: This message was sent by an external party. Report suspicious messages via the "Report Phishing" button in Outlook.

Thank you for confirming the samples are tissues. Yes, please freeze the samples then ship frozen so they arrive at NVSL on a Monday-Thursday. This will allow us to avoid another freeze-thaw cycle. Thanks!

Kim

- 1) General: Description of animal (age, species, gender, etc.) and ID:

a. Animal Number Gender Age
(b) (4)

- 2) Where did the animal originate from (b) (4)
3) Were the non-human primates under quarantine? Yes
a. If yes, please describe (b) (4)
4) What was the date that it left the originating country? 24 Sep 2022
5) How many animals were in the group imported (b) (4)
6) Was it exposed to animals from other sources? No
7) Was a complete necropsy and with histology done on these animals? Complete necropsy performed, histology pending
a. If so can you provide those results (please e-mail)? Yes, when completed
8) How did they die? All animals euthanized
9) Was it showing any abnormal symptoms prior to death? Positive test results
10) Have any cohorts died of unknown causes? One animal died on 09 Feb 2024 due to low appetite and abnormal blood values, lesions identified at necropsy were confirmed as TB at histology.

Thank you,

(b) (6)

J. Norcross, BS RLATg

(b) (6) | Charles River

(b) (6) Reno, NV 89511

P: (b) (6) | F: (b) (6)

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24-08898 001174

Bravo-Garcia, Doris - MRP-APHIS

From: Lehman, Kimberly - MRP-APHIS
Sent: Tuesday, March 5, 2024 8:46 PM
To: (b) (6) APHIS-NVSL Case Coordinator - APHIS; MRP-APHIS-MB-CaseManagement
Cc: (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
Subject: Re: [External] ct Tissue Shipment (b) (4)

Thank you for the information. We can receive the samples. Please send the tracking number when it is available ensuring the frozen tissues arrive at NVSL on a Monday through Thursday.

Kim



Kimberly A Lehman, DVM, MPH, DACVPM
Director, Diagnostic Bacteriology & Pathology Laboratory
USDA-APHIS-VS-D&B-NVSL-DBPL
1920 Dayton Ave
Ames, IA 50010
Office 515-337-6335
Mobile 515-357-0580

From: (b) (6) <(b) (6)@crl.com>
Sent: Tuesday, March 5, 2024 4:59 PM
To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>
Subject: RE: [External Email]TB Suspect Tissue Shipment (b) (4)

Good afternoon, Kim

Below are the histopathology results for your review:

Due to suspected positive and positive tuberculosis skin test reactions, (b) (4) were euthanized. Tissues collected at necropsy for light microscopic evaluation included liver, lung, lymph nodes (axillary, cervical, and tracheobronchial), and spleen, as well as any tissues with macroscopic observations.

At necropsy, nodules, focal to multifocal, were observed in the liver (Animal Nos. (b) (4) and (b) (4) lung (Animal No. (b) (4) and spleen (Animal No. (b) (4). Additionally, multiple adhesions were observed between the cranial lung lobes and the thoracic cavity for Animal No. (b) (4) and multifocal pale foci were observed in the lung of Animal No. (b) (4). Lymph node enlargement was also observed in Animal Nos. (b) (4) (tracheobronchial), (b) (4) (tracheobronchial), (b) (4) (axillary and tracheobronchial), and (b) (4) (pancreatic). Granulomatous inflammation, consistent with Mycobacterial infection, was observed in various tissues in Animal Nos. (b) (4) (b) (4) (b) (4) and (b) (4) and correlated with the macroscopic observations of nodules in the liver, lung, and spleen, and with tracheobronchial lymph node enlargement (Animal Nos. (b) (4) and (b) (4). Granulomatous inflammation was like that described in Animal No. (b) (4) and was characterized by focal and/or multifocal to coalescing granulomas with central cores of lytic necrosis surrounded by epithelioid macrophages, multinucleated giant cells, lesser neutrophils, lymphocytes, and plasma cells, and circumferential fibrous connective tissue. Variable mineralization within granulomas was often observed. Acid-fast

staining of tissues revealed very rare acid-fast positive bacilli in the tracheobronchial lymph node of Animal Nos. (b) (4) and (b) (4) and in the liver of Animal No (b) (4)

Please let us know when we can ship the frozen tissues for analysis.

Thank you,

(b) (6)

J. Norcross, BS RLATg

(b) (6) | Charles River

(b) (6) eno, NV 89511

P: (b) (6) | F: (b) (6)

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From: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>

Sent: Friday, February 23, 2024 11:48 AM

To: (b) (6) <(b) (6)@crl.com>; APHIS-NVSL Case Coordinator - APHIS <NvslCaseCoordinator@usda.gov>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; MRP-APHIS-MB-CaseManagement <NVSL-MB.caseManager@usda.gov>
Cc: (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>; (b) (6) <(b) (6)@crl.com>

Subject: Re: [External Email]TB Suspect Tissue Shipment (CRL (b) (4))

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Thank you for confirming the samples are tissues. Yes, please freeze the samples then ship frozen so they arrive at NVSL on a Monday-Thursday. This will allow us to avoid another freeze-thaw cycle. Thanks!

Kim



Kimberly A Lehman, DVM, MPH, DACVPM

Director, Diagnostic Bacteriology & Pathology Laboratory

USDA-APHIS-VS-D&B-NVSL-DBPL

1920 Dayton Ave

Ames, IA 50010

Office 515-337-6335

Mobile (b) (6)

From: (b) (6) <(b) (6)@crl.com>

Sent: Friday, February 23, 2024 1:43 PM

To: Lehman, Kimberly - MRP-APHIS <Kimberly.Lehman@usda.gov>; APHIS-NVSL Case Coordinator - APHIS

24-08898_001176

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

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PARTIAL

Laboratory Test Report**Owner**

Charles Rivers Laboratories

Reno, NV

Animal Location

Washoe County NV

Submitter - 21897

Charles River Laboratories

6995 Longley Lane

Reno, NV 89511

FAX #: 713-433-6971

Accession Number:**24-007413****NFC Control Number:**

19824020613

Date Collected:

02/23/2024

Date Received:

03/12/2024

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:

AT00199

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.**Animal ID:** 1507-1755F **Case #:** TB24-03417 **Sample:** 1 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 1507-1755F **Case #:** TB24-03418 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 1507-1755F **Case #:** TB24-03419 **Sample:** 3 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 1507-1755F **Case #:** TB24-03420 **Sample:** 4 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Animal ID: 1507-1755F **Case #:** TB24-03421 **Sample:** 5 **Specimen Type:** Lymph Node, Cervical
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 1507-1755F **Case #:** TB24-03422 **Sample:** 6 **Specimen Type:** Lymph Node, Inguinal
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 1507-1755F **Case #:** TB24-03423 **Sample:** 7 **Specimen Type:** Lymph Node, Axillary
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 2603-1542F **Case #:** TB24-03424 **Sample:** 8 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: 2603-1542F **Case #:** TB24-03425 **Sample:** 9 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 2603-1542F **Case #:** TB24-03426 **Sample:** 10 **Specimen Type:** Spleen **Species:**
Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: 2603-1542F **Case #:** TB24-03427 **Sample:** 11 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be
released at a later date.

Animal ID: 2603-1542F **Case #:** TB24-03428 **Sample:** 12 **Specimen Type:** Lymph Node, Cervical
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 2603-1542F **Case #:** TB24-03429 **Sample:** 13 **Specimen Type:** Lymph Node, Inguinal
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 2603-1542F **Case #:** TB24-03430 **Sample:** 14 **Specimen Type:** Lymph Node, Axillary
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03431 **Sample:** 15 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03432 **Sample:** 16 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03433 **Sample:** 17 **Specimen Type:** Spleen **Species:**
Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03434 **Sample:** 18 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03435 **Sample:** 19 **Specimen Type:** Lymph Node, Cervical
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03436 **Sample:** 20 **Specimen Type:** Lymph Node, Inguinal
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3501-0088F **Case #:** TB24-03437 **Sample:** 21 **Specimen Type:** Lymph Node, Axillary
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3502-0389F **Case #:** TB24-03467 **Sample:** 22 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: 3502-0389F **Case #:** TB24-03468 **Sample:** 23 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3502-0389F **Case #:** TB24-03469 **Sample:** 24 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Animal ID: 3502-0389F **Case #:** TB24-03470 **Sample:** 25 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Animal ID: 3502-0389F **Case #:** TB24-03471 **Sample:** 26 **Specimen Type:** Lymph Node, Cervical **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3502-0389F **Case #:** TB24-03472 **Sample:** 27 **Specimen Type:** Lymph Node, Inguinal **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3502-0389F **Case #:** TB24-03473 **Sample:** 28 **Specimen Type:** Lymph Node, Axillary **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3503-0491F **Case #:** TB24-03474 **Sample:** 29 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3503-0491F **Case #:** TB24-03475 **Sample:** 30 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3503-0491F **Case #:** TB24-03476 **Sample:** 31 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3503-0491F **Case #:** TB24-03477 **Sample:** 32 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Animal ID: 3503-0491F **Case #:** TB24-03478 **Sample:** 33 **Specimen Type:** Lymph Node, Cervical **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3503-0491F **Case #:** TB24-03479 **Sample:** 34 **Specimen Type:** Lymph Node, Inguinal **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3503-0491F **Case #:** TB24-03480 **Sample:** 35 **Specimen Type:** Lymph Node, Axillary **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03481 **Sample:** 36 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03482 **Sample:** 37 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03483 **Sample:** 38 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03484 **Sample:** 39 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03485 **Sample:** 40 **Specimen Type:** Lymph Node, Cervical **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03486 **Sample:** 41 **Specimen Type:** Lymph Node, Inguinal
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3604-1736F **Case #:** TB24-03487 **Sample:** 42 **Specimen Type:** Lymph Node, Axillary
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3607-1540F **Case #:** TB24-03495 **Sample:** 43 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: 3607-1540F **Case #:** TB24-03496 **Sample:** 44 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3607-1540F **Case #:** TB24-03497 **Sample:** 45 **Specimen Type:** Spleen **Species:**
Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: 3607-1540F **Case #:** TB24-03498 **Sample:** 46 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be
released at a later date.

Animal ID: 3607-1540F **Case #:** TB24-03499 **Sample:** 47 **Specimen Type:** Lymph Node, Cervical
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: 3607-1540F **Case #:** TB24-03500 **Sample:** 48 **Specimen Type:** Lymph Node, Inguinal
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3607-1540F **Case #:** TB24-03501 **Sample:** 49 **Specimen Type:** Lymph Node, Axillary
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: 3608-1685F **Case #:** TB24-03502 **Sample:** 50 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 3608-1685F **Case #:** TB24-03503 **Sample:** 51 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Animal ID: 3608-1685F **Case #:** TB24-03504 **Sample:** 52 **Specimen Type:** Spleen **Species:**
Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: 3608-1685F **Case #:** TB24-03505 **Sample:** 53 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: 3608-1685F **Case #:** TB24-03506 **Sample:** 54 **Specimen Type:** Lymph Node, Cervical
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: 3608-1685F **Case #:** TB24-03507 **Sample:** 55 **Specimen Type:** Lymph Node, Inguinal
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: 3608-1685F **Case #:** TB24-03508 **Sample:** 56 **Specimen Type:** Lymph Node, Axillary**Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex**Animal ID:** 3608-1685F **Case #:** TB24-03509 **Sample:** 57 **Specimen Type:** Lymph Node **Species:**

Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Sample labeled as Pancreatic lymph node.

There was a discrepancy on this animal. Submission form notes 9 samples, but only 8 samples were received. The additional lung sample listed on the submission form was not received.

Last sample #58 was not recieved

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 30



National Veterinary Services Laboratories

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Laboratory Test Report

Owner

Envigo Global Services

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 502278

Envigo Global Services

925 County Road 381

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-010072

NFC Control Number:

19824023534

Date Collected:

03/18/2024

Date Received:

04/05/2024

Date Completed:

07/11/2024

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 24710VM **Case #:** TB24-04571 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 24710VM **Case #:** TB24-04572 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32021VM **Case #:** TB24-04573 **Sample:** 3 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 31928VM **Case #:** TB24-04574 **Sample:** 4 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 31928VM **Case #:** TB24-04575 **Sample:** 5 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

In future submissions, please request Identification: Mycobacterium Tuberculosis Complex Only or Whole
Genome Sequencing (WGS) on the submission form.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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Exhibit 31



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FINAL REPORT

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Laboratory Test Report

Owner

Envigo Global Services

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 502278

Envigo Global Services

925 County Road 381

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-010878

NFC Control Number:

19824024480

Date Collected:

04/11/2024

Date Received:

04/12/2024

Date Completed:

07/11/2024

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 30456VM **Case #:** TB24-05158 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.52798843

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

If you would like Whole Genome Sequencing (WGS) performed with a genotype analysis the cost is \$ 117 per isolate. Please email NVSL-MB.caseManager@usda.gov if you would like to request this analysis.

In future submissions, please request MTBC only or WGS on the submission form.

Animal ID: 30456VM **Case #:** TB24-05159 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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Laboratory Test Report

Owner

Envigo Global Services

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 502278

Envigo Global Services

925 County Road 381

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-010878

NFC Control Number:

19824024480

Date Collected:

04/11/2024

Date Received:

04/12/2024

Date Completed:

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 30456VM **Case #:** TB24-05158 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.52798843

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.



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PARTIAL

Laboratory Test Report

Owner

Envigo Global Services

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 502278

Envigo Global Services

925 County Road 381

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-016453

NFC Control Number:

19824031139

Date Collected:

04/11/2024

Date Received:

06/06/2024

Date Completed:

Collected By:

[REDACTED]

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 33301VM **Case #:** TB24-06876 **Sample:** 1 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 33301VM Case #: TB24-06877 Sample: 2 Specimen Type: Lymph Node,
Tracheobronchial Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 26.73980713

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Samples were received in the same bag. Bag was labeled 33301VM and A5-59. Please send tissues in separate bags on future submissions.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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FINAL REPORT

Laboratory Test Report**Owner**

Envigo Global Services

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 502278

Envigo Global Services

925 County Road 381

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:**24-017362****NFC Control Number:**

19824032186

Date Collected:

04/26/2024

Date Received:

06/14/2024

Date Completed:

08/19/2024

Collected By:**Purpose:**

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 32471VM **Case #:** TB24-07320 **Sample:** 1 **Specimen Type:** Lung **Species:** Monkey

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 32471VM **Case #:** TB24-07321 **Sample:** 2 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081**Detected** Ct = 34.04652786

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Exhibit 33



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PARTIAL

Laboratory Test Report

Owner

Envigo Global Services

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 502278

Envigo Global Services

925 County Road 381

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-018658

NFC Control Number:

19824033642

Date Collected:

03/30/2024

Date Received:

06/27/2024

Date Completed:

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 30193VM **Case #:** TB24-07854 **Sample:** 1 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.87753677

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 30193VM **Case #:** TB24-07855 **Sample:** 2 **Specimen Type:** Lymph Node,
Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium caprae

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 25.39388084

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Please note, the TBLN and lung were received together in the same bag. Please send tissues in separate bags on future submissions.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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Laboratory Test Report

Owner

INOTIV LAMS West-Alice

Alice, TX

Animal Location

Jim Wells County TX, US

Submitter - 504116

Inotiv Lams West - Alice

2103 FM 625

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-014350

NFC Control Number:

19824028720

Date Collected:

05/06/2024

Date Received:

05/16/2024

Date Completed:

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 230428 Case #: TB24-05951 Sample: 1 Specimen Type: Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 19.78899384

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 230428 Case #: TB24-05952 Sample: 2 Specimen Type: Tissue Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 20.67435265

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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Laboratory Test Report

Owner

Inotiv Lams West- Alice

Alice

Animal Location

Jim Wells County TX, US

Submitter - 504116

Inotiv Lams West - Alice

2103 FM 625

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:

24-018531

NFC Control Number:

19824033496

Date Collected:

05/31/2024

Date Received:

06/26/2024

Date Completed:

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 230383 **Case #:** TB24-07763 **Sample:** 1 **Specimen Type:** Lymph Node, Tracheobronchial
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

MTBC dPCR could not be performed due to sample size.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Animal ID: 230383 Case #: TB24-07764 Sample: 2 Specimen Type: Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Please note, the TBLN and lung were received together in the same bag. Please send tissues in separate bags on future submissions.

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

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PARTIAL

Laboratory Test Report**Owner**

Inotiv Lams West-Alice

Alice

Animal Location

Jim Wells County TX, US

Submitter - 504116

Inotiv Lams West - Alice

2103 FM 625

Alice, TX 78332

Phone #: [REDACTED]

Accession Number:**24-020040****NFC Control Number:**

19824035165

Date Collected:

06/27/2024

Date Received:

07/12/2024

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 230416 Case #: TB24-08219 Sample: 1 Specimen Type: Heart Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 230416 Case #: TB24-08220 Sample: 2 Specimen Type: Liver Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 230416 **Case #:** TB24-08221 **Sample:** Composite **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

This sample is a composite of the following samples

Animal ID: 230416 **Sample:** 4 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus **Client Reference ID:**

Animal ID: 230416 **Sample:** 3 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus **Client Reference ID:**

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.72674942

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 230416 **Case #:** TB24-08222 **Sample:** Composite **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

This sample is a composite of the following samples

Animal ID: 230416 **Sample:** 6 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus **Client Reference ID:**

Animal ID: 230416 **Sample:** 5 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus **Client Reference ID:**

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 27.85548973

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 230416 **Case #:** TB24-08223 **Sample:** Composite **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

This sample is a composite of the following samples

Animal ID: 230416 **Sample:** 8 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus **Client Reference ID:**

Animal ID: 230416 **Sample:** 7 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus **Client Reference ID:**

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium orygis

Direct PCR for *M. tuberculosis* complex - IS1081

Detected Ct = 29.31106758

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.caseManager@usda.gov

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AMENDED REPORT

Laboratory Test Report

***** This is a confidential report intended for official use only. *****

Owner

MRICD

Edgewood, MD US

Accession Number:

23-020402

Submitter

US Army Medical Research Institute of Chemical
Defense (USAMRICD)
8350 Ricketts Point Rd
Aberdeen Proving Ground, MD 21010
Phone #: 4-4-4

Date Collected:

06/16/2023

Date Received:

07/07/2023

Date Completed:

7/13/2023

Collected By:

Erica Barkei

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is not a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: C20166 Case # PS-23P5115 Sample: 23-0863 Specimen Type: Fixed Tissue
Species: Monkey, Cynomolgus ID Type: Animal identification devices were not received

PCR Analysis

A polymerase chain reaction (PCR) test was performed on formalin fixed tissue using primers for IS 6110 to identify *Mycobacterium tuberculosis* complex species, 16S rDNA to identify *Mycobacterium avium* species, and IS900 to identify *Mycobacterium avium* subspecies *paratuberculosis*.

Results:

M. tuberculosis complex:

IS6110- positive

M. avium:

16S rDNA- negative

IS900- negative

Comments:

The sample was positive for *M. tuberculosis* complex IS6110 DNA.

Jennifer L. Johnson, D.V.M.

Pathology Section

Diagnostic Bacteriology and Pathology Laboratory

Histopathology Analysis

24-08898_001464

Exhibit 38

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

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FINAL REPORT

Laboratory Test Report**Owner**

Immokalee, FL

Accession Number:**23-029043****Animal Location**

Collier County FL, US

NFC Control Number:

19823044491

Date Collected:

09/10/2023

Date Received:

09/27/2023

Date Completed:**Collected By:**

General Diagnostic

Purpose:**Referral/Retain Tag Number:****Submitter - 30234**

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 3821 **Case #:** TB23-08213 **Sample:** 3281**Specimen Type:** Heart **Species:** Monkey, Cynomolgus**Mycobacterial Culture Result**

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 24.36781502

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

The genomic DNA from this isolate was sequenced and then compared to all other isolates in the NVSL Database. This isolate was determined to be *Mycobacterium tuberculosis* Linage 4. Two isolates were sequenced from this animal; they had the same SNP pattern. These isolates were not closely related to other isolates in the NVSL Database. See attached Genotyping Report.

Animal ID: 3821 **Case #:** TB23-08214 **Sample:** 3281
Specimen Type: Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 29.44291115

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

WGS Results

The genomic DNA from this isolate was sequenced and then compared to all other isolates in the NVSL Database. This isolate was determined to be *Mycobacterium tuberculosis* Linage 4. Two isolates were sequenced from this animal; they had the same SNP pattern. These isolates were not closely related to other isolates in the NVSL Database. See attached Genotyping Report.

Animal ID: 3821 **Case #:** TB23-08215 **Sample:** 3281
Specimen Type: Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 25.93148994

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 3821 **Case #:** TB23-08216 **Sample:** 3281
Specimen Type: Bone Marrow **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Animal ID: 3821 **Case #:** TB23-08217 **Sample:** 3281
Specimen Type: Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.62060547

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 39

**National Veterinary Services Laboratories**

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Laboratory Test Report**Owner**

Immokalee, FL

Accession Number:**23-038726****Animal Location**

Collier County FL, US

NFC Control Number:

19824009935

Date Collected:

11/30/2023

Date Received:

12/08/2023

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Submitter - 30234

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

Referral/Retain Tag Number:

Indonesia

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 3675 **Case #:** TB23-10681 **Sample:** 1 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3675 **Case #:** TB23-10682 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3675 **Case #:** TB23-10683 **Sample:** 3 **Specimen Type:** Intestine **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3675 **Case #:** TB23-10684 **Sample:** 4 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.6449585

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 3675 **Case #:** TB23-10685 **Sample:** 5 **Specimen Type:** Other - Specify in Comments **Species:** Monkey, Cynomolgus

Sample Not tested

NOT_TESTED

Sample was received but will not be processed due to type of sample. Spine sample can not be processed.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

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Laboratory Test Report**Owner**

Immokalee, FL

Accession Number:**23-038730****Animal Location**

Collier County FL, US

NFC Control Number:

19824009939

Date Collected:

11/30/2023

Date Received:

12/08/2023

Date Completed:**Collected By:**

General Diagnostic

Purpose:**Referral/Retain Tag Number:**

Indonesia

Submitter - 30234

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: N-AA2600 **Case #:** TB23-10693 **Sample:** 1 **Specimen Type:** Heart **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-AA2600 **Case #:** TB23-10694 **Sample:** 2 **Specimen Type:** Colon **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-AA2600 **Case #:** TB23-10695 **Sample:** 3 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.55322647

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: N-AA2600 **Case #:** TB23-10696 **Sample:** 4 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-AA2600 **Case #:** TB23-10697 **Sample:** 5 **Specimen Type:** Intestine **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.59397507

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: N-AA2600 **Case #:** TB23-10698 **Sample:** 6 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 31.84888649

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: N-AA2600 **Case #:** TB23-10699 **Sample:** 7 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Direct M. tuberculosis complex PCR from feces was reported under Acc# 23-038183.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology & Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.caseManager@usda.gov

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Laboratory Test Report**Owner**

Immokalee, FL

Accession Number:**23-038729****Animal Location**

Collier County FL, US

NFC Control Number:

19824009938

Date Collected:

11/30/2023

Date Received:

12/08/2023

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Submitter - 30234

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

Referral/Retain Tag Number:

Indonesia

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: N-FA4680 **Case #:** TB23-10686 **Sample:** 1 **Specimen Type:** Heart **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4680 **Case #:** TB23-10687 **Sample:** 2 **Specimen Type:** Colon **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4680 **Case #:** TB23-10688 **Sample:** 3 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4680 **Case #:** TB23-10689 **Sample:** 4 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4680 **Case #:** TB23-10690 **Sample:** 5 **Specimen Type:** Intestine **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4680 **Case #:** TB23-10691 **Sample:** 6 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Tissue Grinding/Homogenate-After isolating *M. tuberculosis* we re-ran a PCR from the lung homogenate.

Direct PCR for *M. tuberculosis* complex - IS1081

Detected Ct = 31.91794395

Interpretation: *Mycobacterium tuberculosis* complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: N-FA4680 **Case #:** TB23-10692 **Sample:** 7 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Animal ID: N-FA4680 **Case #:** TB23-11225 **Sample:** 13 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

M. tuberculosis complex DNA was Detected from the feces on direct PCR under Accession# 23-038183 (sample 13). We decided to culture the feces with the tissues from this animal.

Direct *M. tuberculosis* complex PCR from feces was reported under Acc# 23-038183.

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Exhibit 40

**National Veterinary Services Laboratories**

PO Box 844

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FINAL REPORT

Laboratory Test Report**Owner**Primate Products, LLC
Immokalee, FL**Accession Number:****23-040956****Animal Location**

Hendry County FL, US

Date Collected:**12/27/2023****Date Received:**

12/28/2023

Date Completed:

03/21/2024

Submitter - 30234Primate Products
PO Box 1588
Immokalee, FL 34143
FAX #: 239-867-2030
Phone #: 239-867-2020**Collected By:****Purpose:**

Development / Research

Referral/Retain Tag Number:**This is not a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: AI-AA9908 **Case #:** TB24-00186 **Sample:** 2 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA0486 **Case #:** TB24-00187 **Sample:** 3 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA3164 **Case #:** TB24-00224 **Sample:** 40 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4937 **Case #:** TB24-00225 **Sample:** 41 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4947 **Case #:** TB24-00264 **Sample:** 42 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4943 **Case #:** TB24-00265 **Sample:** 43 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 36.76406479

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: N-FA4943 **Case #:** TB23-11195 **Sample:** 43 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Direct PCR** for M. tuberculosis complex - IS6110

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** N-FB2703 **Case #:** TB23-11196 **Sample:** 45 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Direct PCR** for M. tuberculosis complex - IS6110

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** N-FA4716 **Case #:** TB23-11197 **Sample:** 46 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS6110

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Direct PCR** for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Exhibit 41



National Veterinary Services Laboratories

FINAL REPORT

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Laboratory Test Report

Owner

Immokalee, FL

Accession Number:

24-004119

Animal Location

Collier County FL, US

NFC Control Number:

19824017009

Date Collected:

01/14/2024

Date Received:

02/08/2024

Date Completed:

04/12/2024

Collected By:

Dr. Estefaney Lemus

Purpose:

TB-10-4

Submitter - 30234

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 3203755202 **Case #:** TB24-02087 **Sample:** 32037552 **Specimen Type:** Feces **Species:** Marmoset (not otherwise specified)

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 34.80725098**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Direct PCR for Johne's IS900

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium avium subspecies paratuberculosis DNA was not detected in the sample.

Direct PCR for M. tuberculosis complex - IS6110

Detected **Ct = 36.401474**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

There was a discrepancy with this sample. The sample container was labeled as 320375205. The submission form listed the Sample ID as 32037552 and the Animal ID as 3203755202.

Cycle Threshold (Ct) provides an estimate of the amount of M. avium subsp. paratuberculosis (MAP) DNA in the fecal material. Generally, the lower the number, the more DNA in the fecal material. MAP DNA can then be correlated to the number of organisms shed in the fecal material.

General guidelines are as follows:

<25 Ct = Very Heavy Fecal Shedder

<30 Ct = Heavy Fecal Shedder

<33 Ct = Moderate Fecal Shedder

<36 Ct = Light Fecal Shedder

<40 Ct = Suspect Fecal Shedder - DNA was detected, but at a low level. Without epidemiological information, correlation to fecal culture is not consistent.

Undetermined (U) = No MAP DNA was detected

Exhibit 42



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FINAL REPORT

Laboratory Test Report

Owner

Primate Products LLC
Immokalee, FL

Animal Location

Hendry County FL, US

Submitter - 30234

Primate Products
PO Box 1588
Immokalee, FL 34143
FAX #: 239-867-2030
Phone #: 239-867-2020

Accession Number:

24-006970

NFC Control Number:

19824020106

Date Collected:

03/05/2024

Date Received:

03/07/2024

Date Completed:

07/01/2024

Collected By:

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Fecal samples for mycobacterial culture and direct PCR is not ideal. Mycobacterium tuberculosis complex (MTBC) direct PCR and culture from feces has not been validated by NVSL. Results are provided for supplemental purposes only; interpretation is determined by the submitter. All samples were tested by PCR using both the IS6110 and IS1081 primer pairs. See results below.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 7151475089 **Case #:** TB24-05033 **Sample:** 7151475089 **Specimen Type:** Feces
Species: Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Direct PCR for M. tuberculosis complex - IS6110

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3555 **Case #:** TB24-05037 **Sample:** 3555 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Direct PCR** for M. tuberculosis complex - IS6110

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 6258 **Case #:** TB24-05038 **Sample:** 6258 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.34186935

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.**Direct PCR** for M. tuberculosis complex - IS6110

Detected Ct = 32.02885437

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.**Animal ID:** 5710 **Case #:** TB24-05039 **Sample:** 5710 **Specimen Type:** Feces **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Direct PCR** for M. tuberculosis complex - IS6110

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 21-950 **Case #:** TB24-05470 **Sample:** 21-950 **Specimen Type:** Gastric Aspirate**Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 3307 **Case #:** TB24-05471 **Sample:** 3307 **Specimen Type:** Gastric Aspirate **Species:**

Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 3555 **Case #:** TB24-05472 **Sample:** 3555 **Specimen Type:** Gastric Aspirate **Species:**

Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.**Animal ID:** 6258 **Case #:** TB24-05473 **Sample:** 6258 **Specimen Type:** Gastric Aspirate **Species:**

Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.63565636

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.**Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.**



National Veterinary Services Laboratories

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Ames, Iowa 50010

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PARTIAL

Laboratory Test Report

Owner	Accession Number:	24-015398
Animal Location	NFC Control Number:	19824029903
	Date Collected:	05/23/2024
	Date Received:	05/28/2024
	Date Completed:	
Submitter - 30234	Collected By:	
Primate Products	Purpose:	General Diagnostic
PO Box 1588		
Immokalee, FL 34143		
FAX #: 239-867-2030	Referral/Retain Tag Number:	
Phone #: 239-867-2020		

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 6258 **Case #:** TB24-06538 **Sample:** 1 **Specimen Type:** Heart **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 6258 **Case #:** TB24-06539 **Sample:** 2 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 6258 **Case #:** TB24-06540 **Sample:** 3 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 6258 **Case #:** TB24-06541 **Sample:** 4 **Specimen Type:** Spleen **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Animal ID: 6258 **Case #:** TB24-06542 **Sample:** 5 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 6258 Case #: TB24-06543 Sample: 6 Specimen Type: Granuloma Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 21.87897682

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6258 Case #: TB24-06544 Sample: 7 Specimen Type: Granuloma, Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

(This new section will be updated periodically with tips for submitters.)

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<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

Exhibit 43

**National Veterinary Services Laboratories**

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

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PARTIAL

Laboratory Test Report**Owner**

Primate Products, LLC

Immokalee, FL

Animal Location

Hendry County FL, US

Submitter - 30261

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

Accession Number:**24-020374****NFC Control Number:**

19824035536

Date Collected:

07/16/2024

Date Received:

07/17/2024

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: DRPZ4-21-1250D-A **Case #:** TB24-08389 **Sample:** DRPZ4-21-125D-A **Specimen Type:** Lymph Node **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Bag labeled TBON.

Animal ID: DRPZ4-21-1250D-A **Case #:** TB24-08390 **Sample:** DRPZ4-21-125D-A **Specimen Type:** LUNG, LIVER, SPLEEN, HEART **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Bag was not labeled.**24-08898_000543**

Page 1 of 2

Date Generated: 9/13/2024

Animal ID: DRPZ4-21-1250D-A **Case #:** TB24-08391 **Sample:** DRPZ4-21-125D-A **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 30.49057007

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Bag labeled Tracheobronchial.

Whole genome sequencing (WGS) was performed. The genotype report with analysis will be released at a later date.

Sample types did not match what was listed on the submission form. Please make sure all samples are labeled with Animal ID and bags are identified properly.

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

Help Us Help You

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Exhibit 44

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Laboratory Test Report**Owner**Primate Products, LLC
Immokalee, FL**Animal Location**

Hendry County FL, US

Submitter - 30261Primate Products
PO Box 1588
Immokalee, FL 34143
FAX #: 239-867-2030
Phone #: 239-867-2020**Accession Number:****24-022992****NFC Control Number:**

19824038392

Date Collected:**Date Received:**

08/13/2024

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 8412021953C **Case #:** TB24-11455 **Sample:** 1 **Specimen Type:** Gastric Aspirate
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: N-FA4231 **Case #:** TB24-11456 **Sample:** 2 **Specimen Type:** Gastric Aspirate **Species:**
Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: L22-199 **Case #:** TB24-11457 **Sample:** 3 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 31.60825157**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 3146 **Case #:** TB24-11458 **Sample:** 4 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3166 **Case #:** TB24-11459 **Sample:** 5 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3384 **Case #:** TB24-11460 **Sample:** 6 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3563 **Case #:** TB24-11461 **Sample:** 7 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected **Ct = U**

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3559 **Case #:** TB24-11462 **Sample:** 8 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3260 **Case #:** TB24-11463 **Sample:** 9 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 4338 **Case #:** TB24-11464 **Sample:** 10 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: NV1810 **Case #:** TB24-11465 **Sample:** 11 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 32.62742996

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 9868 **Case #:** TB24-11466 **Sample:** 12 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: V220672 **Case #:** TB24-11472 **Sample:** 18 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: V220762 **Case #:** TB24-11473 **Sample:** 19 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 34.9008522

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: V220689 **Case #:** TB24-11474 **Sample:** 20 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 9872002374 **Case #:** TB24-11475 **Sample:** 21 **Specimen Type:** Gastric Aspirate
Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: NV870 **Case #:** TB24-11476 **Sample:** 22 **Specimen Type:** Gastric Aspirate **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Exhibit 45

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FINAL REPORT

Laboratory Test Report**Owner**Primate Products, LLC
Immokalee, FL**Animal Location**

Hendry County FL, US

Submitter - 30261Primate Products
PO Box 1588
Immokalee, FL 34143
FAX #: 239-867-2030
Phone #: 239-867-2020**Accession Number:****24-023425****NFC Control Number:**

19824038872

Date Collected:

08/15/2024

Date Received:

08/16/2024

Date Completed:

09/05/2024

Collected By:**Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 22-856 Case #: TB24-09884 Sample: 1 Specimen Type: Swab, Nasal Species:
Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-577 Case #: TB24-09885 Sample: 2 Specimen Type: Swab, Nasal Species:
Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-517 **Case #:** TB24-09901 **Sample:** 18 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-364 **Case #:** TB24-09902 **Sample:** 19 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-463 **Case #:** TB24-09903 **Sample:** 20 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-185 **Case #:** TB24-09904 **Sample:** 21 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 35.53935242

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 22-189 **Case #:** TB24-09905 **Sample:** 22 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Exhibit 46

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Laboratory Test Report**Owner**

Primate Products, LLC

Immokalee, FL

Animal Location

Hendry County FL, US

Submitter - 30261

Primate Products

PO Box 1588

Immokalee, FL 34143

FAX #: 239-867-2030

Phone #: 239-867-2020

Accession Number:**24-025369****NFC Control Number:**

19824041112

Date Collected:

09/03/2024

Date Received:

09/05/2024

Date Completed:**Collected By:****Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 6283 **Case #:** TB24-11282 **Sample:** 3 **Specimen Type:** Nasal Swab/Wash **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081**Detected****Ct = 33.68982315**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11265 **Sample:** 4 **Specimen Type:** Colon **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081**Detected****Ct = 29.95207596**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11266 **Sample:** 5 **Specimen Type:** Ileum **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 28.89402962**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11267 **Sample:** 6 **Specimen Type:** Jejunum **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 34.04347229**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11268 **Sample:** 7, Duodenum **Specimen Type:** Tissue **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 23.80960083**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11269 **Sample:** 8 **Specimen Type:** Stomach **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 25.81292725**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11270 **Sample:** 9 **Specimen Type:** Bladder **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 31.84786797**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11271 **Sample:** 10 **Specimen Type:** Heart **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 27.38121033**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11272 **Sample:** 11 **Specimen Type:** Spleen **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 30.8716526**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11273 **Sample:** 12 **Specimen Type:** Lung **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 24.04654884**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11274 **Sample:** 13 **Specimen Type:** Kidney **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 28.93192863**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 6283 **Case #:** TB24-11275 **Sample:** 14 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected **Ct = 30.54443741**

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Exhibit 47

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FINAL REPORT

Laboratory Test Report**Owner**Primate Products, LLC
Immokalee, FL**Animal Location**

Hendry County FL, US

Submitter - 30261Primate Products
PO Box 1588
Immokalee, FL 34143
FAX #: 239-867-2030
Phone #: 239-867-2020**Accession Number:****24-025371****NFC Control Number:**

19824041114

Date Collected:

09/04/2024

Date Received:

09/05/2024

Date Completed:

09/11/2024

Collected By:**Purpose:**

General Diagnostic

Referral/Retain Tag Number:**This is a billable case.**

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 4807 Case #: TB24-11120 Sample: 1 Specimen Type: Swab, Nasal Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3124 Case #: TB24-11121 Sample: 2 Specimen Type: Swab, Nasal Species: Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3080 **Case #:** TB24-11127 **Sample:** 8 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 3065 **Case #:** TB24-11128 **Sample:** 9 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 5703C **Case #:** TB24-11129 **Sample:** 10 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 9210 **Case #:** TB24-11130 **Sample:** 11 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 24.19102669

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Animal ID: 9232 **Case #:** TB24-11131 **Sample:** 12 **Specimen Type:** Swab, Nasal **Species:** Monkey, Cynomolgus

Direct PCR for M. tuberculosis complex - IS1081

Detected Ct = 28.0759182

Interpretation: Mycobacterium tuberculosis complex DNA was detected in the sample. The Ct value along with other test results and epi information are required to determine the status of the animal.

Exhibit 48

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FINAL REPORT

Laboratory Test Report**Owner**

Worldwide Primates, Inc.

Miami, FL

Animal Location

Miami-Dade County FL, US

Submitter - 24078

Worldwide Primates, Inc

PO Box 971279

Miami, FL 33197

Phone #: 305-378-9585

Accession Number:**23-001868****NFC Control Number:**

19823014123

Date Collected:

01/16/2023

Date Received:

01/18/2023

Date Completed:

05/24/2023

Collected By:**Purpose:**

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.**Animal ID:** 9839537483 **Case #:** TB23-00539 **Sample:** 1 **Specimen Type:** Lung **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis

Whole genome sequencing (WGS) is being performed. The genotype report with analysis will be released at a later date.

Animal ID: 9839537483 **Case #:** TB23-00540 **Sample:** 2 **Specimen Type:** Intestine **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 9839537483 **Case #:** TB23-00541 **Sample:** 3 **Specimen Type:** Intestine **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 9839537483 **Case #:** TB23-00542 **Sample:** 4 **Specimen Type:** Liver **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 9839537483 **Case #:** TB23-00571 **Sample:** 5 **Specimen Type:** Gastric Wash **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Animal ID: 9839537483 **Case #:** TB23-00543 **Sample:** 6 **Specimen Type:** Lymph Node, Mediastinal **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Animal ID: 9839537483 **Case #:** TB23-00544 **Sample:** 8 **Specimen Type:** Kidney **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Animal ID: 9839537483 **Case #:** TB23-00545 **Sample:** 9 **Specimen Type:** Heart **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Animal ID: 9839537483 **Case #:** TB23-00546 **Sample:** 9 **Specimen Type:** Lymph Node, Mesenteric **Species:** Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Results authorized by:

Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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APPENDIX – GENOTYPING REPORT

24 May 2023

Accession:

23-001868

Figure 1. Low resolution tree of *Mycobacterium tuberculosis* complex isolates. The isolate of interest is in Linage 2 identified by the red arrow.

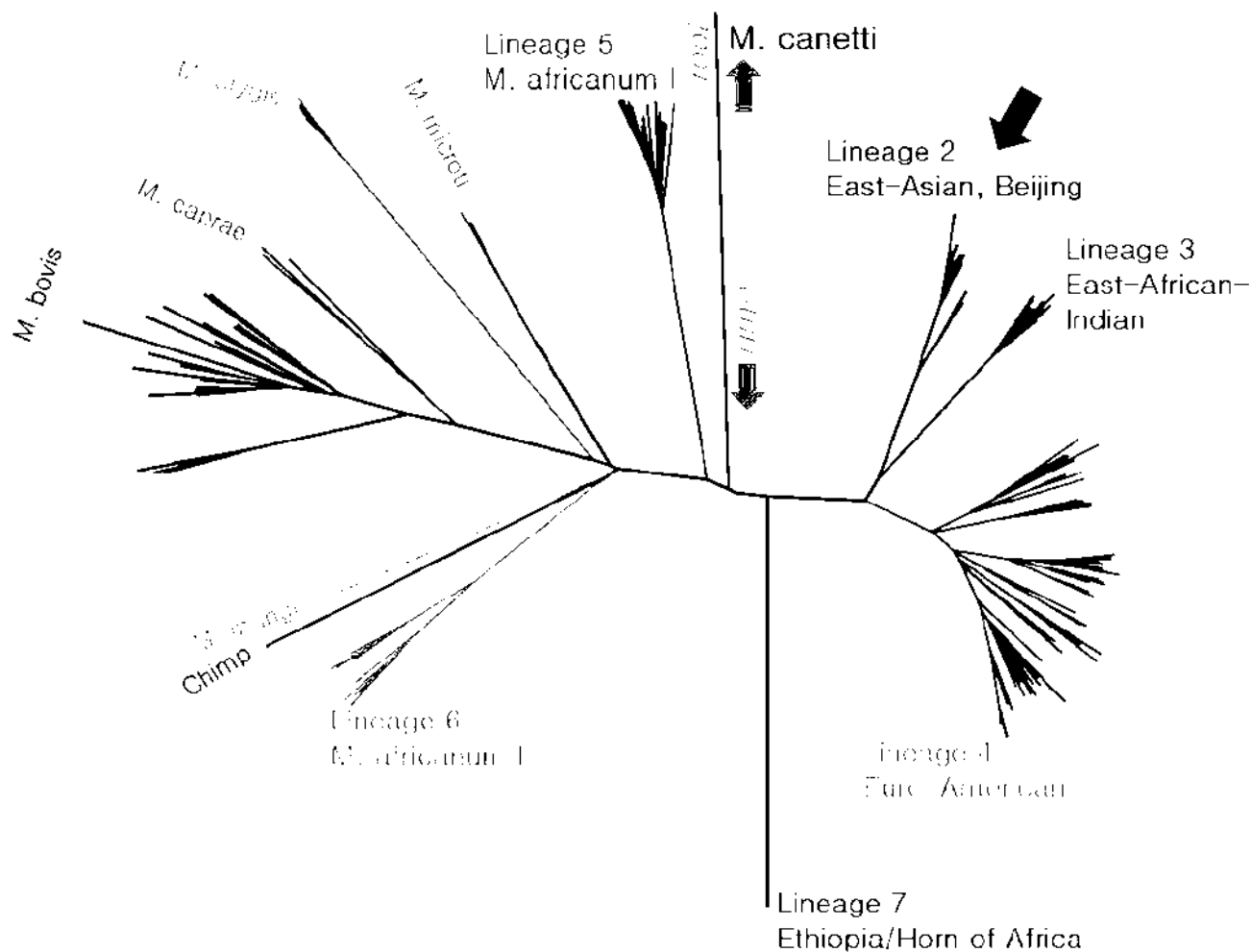




Figure 2: Select phylogenetic tree. The Mtb isolates collect from the lung and mediastinal lymph node from one individual submitted to NVSL (red). They have gained a single SNP from sharing the most recent common ancestor (blue arrow) with isolate 22-7555 from the same submitter. And ancestor from these isolates have gained a single SNP from sharing a common ancestor (blue arrow) with 22-7735 also from the same submitter. These data show that these three animals are part of the same outbreak.

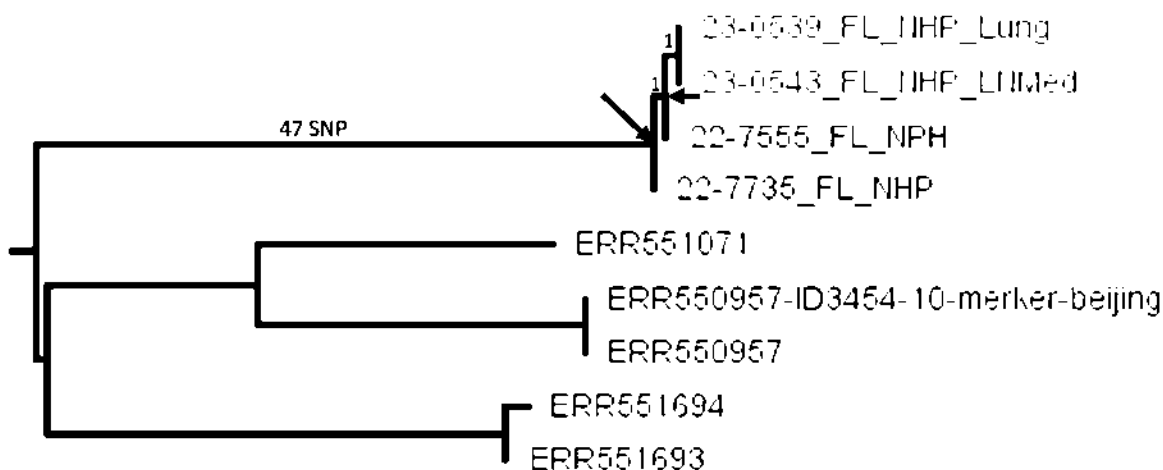


Table 1: Abbreviated SNP Table of group 2B. The two isolates from this animal had the same SNP pattern (red label) and have gained a single SNP (blue arrow) from sharing the most recent common ancestor with 22-7555. The ancestor to these three had gained a single SNP (red arrow) from sharing a common ancestor with 22-7735.

	NC_000962.3:2280610	NC_000962.3:2280815	NC_000962.3:2318436	NC_000962.3:2384006	NC_000962.3:2433510	NC_000962.3:2801128	NC_000962.3:2871516	NC_000962.3:3044668	NC_000962.3:3183189	NC_000962.3:3203356	NC_000962.3:3255493	NC_000962.3:3442753	NC_000962.3:3588245	NC_000962.3:3597680	NC_000962.3:3597692	NC_000962.3:3690493	NC_000962.3:3820064	NC_000962.3:4143216	NC_000962.3:4287697	NC_000962.3:4312512	NC_000962.3:4322485	NC_000962.3:4391572	NC_000962.3:4405379	NC_000962.3:2564515	NC_000962.3:2594759
root	C	G	T	C	C	C	G	C	A	C	G	C	G	G	G	A	G	C	C	C	G	G	C		
23-0539 FL NHP Lung		A			G	G	A	G			A				A		A		A		A	A	G		
23-0543 FL NHP LNIMed		A			G	G	A	G			A				A		A		A		A	A	G		
22-7555 FL NPH		A			G	G	A	G			A				A		A		A		A	A	G		
22-7735 FL NHP		A			G	G	A	G			A				A		A		A		A	A	G		

Exhibit 49

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FINAL REPORT

Laboratory Test Report**Owner**

Worldwide Primates, Inc.

Miami, FL

Animal Location

Miami-Dade County FL, US

Submitter - 24078

Worldwide Primates, Inc

PO Box 971279

Miami, FL 33197

Phone #: 305-378-9585

Accession Number:**23-007354****NFC Control Number:**

19823020096

Date Collected:

03/06/2023

Date Received:

03/07/2023

Date Completed:

05/09/2023

Collected By:

S. Salinas

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

Mycobacterium tuberculosis complex direct PCR has not been validated by NVSL for this species or sample type. The sensitivity and specificity of the test is unknown. Culture results should be used for all official purposes.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: 22-469 Case #: TB23-02382 Sample: 030623_01 Specimen Type: Adrenal Gland
Species: Monkey, Rhesus Macaque

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-469 Case #: TB23-02383 Sample: 030623_01 Specimen Type: Lung Species:
Monkey, Rhesus Macaque

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-469 **Case #:** TB23-02384 **Sample:** 030623_01 **Specimen Type:** Lymph Node, Tracheobronchial **Species:** Monkey, Rhesus Macaque

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium avium subsp. *hominissuis*

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Isolate identification was carried out by sequencing regions of the 16s and *rpoB* genes then comparing the sequence to known isolates. For mycobacteria, *rpoB* is generally more discriminatory than 16S. See attached reports for additional details.

Animal ID: 22-469 **Case #:** TB23-02385 **Sample:** 030623_01 **Specimen Type:** Lymph Node, Cervical **Species:** Monkey, Rhesus Macaque

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium terrae complex

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Isolate identification was carried out by sequencing regions of the 16s and *rpoB* genes then comparing the sequence to known isolates. For mycobacteria, *rpoB* is generally more discriminatory than 16S. See attached reports for additional details.

Animal ID: 22-469 **Case #:** TB23-02386 **Sample:** 030623_01 **Specimen Type:** Lymph Node, Mesenteric **Species:** Monkey, Rhesus Macaque

Mycobacterial Culture Result

No Isolation Made

Direct PCR for *M. tuberculosis* complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: *Mycobacterium tuberculosis* complex DNA was not detected in the sample.

Animal ID: 22-469 **Case #:** TB23-02387 **Sample:** 030623_01 **Specimen Type:** Liver **Species:**
Monkey, Rhesus Macaque

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Inhibited Ct = U

Interpretation: The PCR reaction was inhibited; the test result was not valid. Retesting will be necessary for a valid result.

Animal ID: 22-469 **Case #:** TB23-02388 **Sample:** 030623_01 **Specimen Type:** Kidney **Species:**
Monkey, Rhesus Macaque

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Animal ID: 22-469 **Case #:** TB23-02389 **Sample:** 030623_01 **Specimen Type:** Spleen **Species:**
Monkey, Rhesus Macaque

Mycobacterial Culture Result

No Isolation Made

Direct PCR for M. tuberculosis complex - IS1081

Not Detected Ct = U

Interpretation: NEGATIVE: Mycobacterium tuberculosis complex DNA was not detected in the sample.

Results authorized by: Dr. Tyler C. Thacker, Section Head, Mycobacteria and Brucella Section
NVSL MB General Phone: 515-337-7526
NVSL MB Email: NVSL-MB.caseManager@usda.gov

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Exhibit 50



National Veterinary Services Laboratories

FINAL REPORT

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Laboratory Test Report

Owner

Worldwide Primates, Inc.

Miami, FL

Animal Location

Miami-Dade County FL, US

Submitter - 24078

Worldwide Primates, Inc
PO Box 971279

Miami, FL 33197

Phone #: 305-378-9585

Accession Number:

23-013239

NFC Control Number:

19823026640

Date Collected:

04/21/2023

Date Received:

04/28/2023

Date Completed:

02/09/2024

Collected By:

GA

Purpose:

TB-10-4

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: BC177 Case #: TB23-03817 Sample: BC177 Specimen Type: Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Animal ID: BC177 Case #: TB23-03818 Sample: BC177 Specimen Type: Liver Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Animal ID: BC177 Case #: TB23-03819 Sample: BC177 Specimen Type: Spleen Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium bovis

WGS Results

Genomic DNA was sequenced and compared to all other isolates in the NVSL Database. This isolate has the same SNP pattern as another isolate submitted to NVSL at the same time from the same submitter. These isolates have acquired a single SNP from sharing the most recent common ancestor to this outbreak. See attached Genotyping Report.



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FINAL REPORT

Laboratory Test Report

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Owner

Worldwide Primates, Inc.
Miami, FL

Submitter

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
Phone #: 305-378-9585

Accession Number:

23-013239

NFC Control Number:

19823026640

Date Collected:

04/21/2023

Date Received:

04/28/2023

Date Completed:

05/10/2023

Collected By:

GA

Purpose:

Tuberculosis

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: BC177 Case # PS-23P3992 Sample: BC177 Specimen Type: Fixed Tissue Species: Monkey, Cynomolgus ID Type: Animal identification devices were not received

PCR Analysis

A polymerase chain reaction (PCR) test was performed on formalin fixed tissue using primers for IS6110 to identify *Mycobacterium tuberculosis* complex species, 16S rDNA to identify *Mycobacterium avium* species, and IS900 to identify *Mycobacterium avium* subspecies *paratuberculosis*.

Results:

M. tuberculosis complex:

IS6110- positive

M. avium:

16S rDNA- negative

IS900- negative

Comments:

The sample was positive for *M. tuberculosis* complex IS6110 DNA.

Jennifer L. Johnson, D.V.M.

Pathology Section

Diagnostic Bacteriology and Pathology Laboratory

24-08898_000212



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FINAL REPORT

Laboratory Test Report

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Owner

Worldwide Primates, Inc.
Miami, FL

Submitter

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
Phone #: 305-378-9585

Accession Number:

23-013239

NFC Control Number:

19823026640

Date Collected:

04/21/2023

Date Received:

04/28/2023

Date Completed:

05/10/2023

Collected By:

GA

Purpose:

Tuberculosis

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: BC177 Case # PS-23P3992 Sample: BC177 Specimen Type: Fixed Tissue Species: Monkey, Cynomolgus ID Type: Animal identification devices were not received

PCR Analysis

A polymerase chain reaction (PCR) test was performed on formalin fixed tissue using primers for IS6110 to identify *Mycobacterium tuberculosis* complex species, 16S rDNA to identify *Mycobacterium avium* species, and IS900 to identify *Mycobacterium avium* subspecies *paratuberculosis*.

Results:

M. tuberculosis complex:

IS6110- positive

M. avium:

16S rDNA- negative

IS900- negative

Comments:

The sample was positive for *M. tuberculosis* complex IS6110 DNA.

Jennifer L. Johnson, D.V.M.

Pathology Section

Diagnostic Bacteriology and Pathology Laboratory

24-08898_001455

Exhibit 51



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Laboratory Test Report

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Owner

Worldwide Primates, Inc
Miami, FL

Submitter

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
Phone #: 305-378-9585

Accession Number:

23-013633

NFC Control Number:

19823027116

Date Collected:

04/28/2023

Date Received:

05/02/2023

Date Completed:

05/10/2023

Collected By:

GA

Purpose:

Tuberculosis

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: SB655 **Case #** PS-23P3991 **Sample:** SB655 **Specimen Type:** Fixed Tissue **Species:** Monkey, Cynomolgus **ID Type:** Animal identification devices were not received

PCR Analysis

A polymerase chain reaction (PCR) test was performed on formalin fixed tissue using primers for IS6110 to identify *Mycobacterium tuberculosis* complex species, 16S rDNA to identify *Mycobacterium avium* species, and IS900 to identify *Mycobacterium avium* subspecies *paratuberculosis*.

Results:

M. tuberculosis complex:

IS6110- positive

M. avium:

16S rDNA- negative

IS900- negative

Comments:

The sample was positive for *M. tuberculosis* complex IS6110 DNA.

Jennifer L. Johnson, D.V. M.

Pathology Section

Diagnostic Bacteriology and Pathology Laboratory

Histopathology Analysis

24-08898_001459



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Laboratory Test Report

Owner

Worldwide Primates, Inc
Miami, FL

Animal Location

Miami-Dade County FL, US

Submitter - 24078

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
Phone #: 305-378-9585

Accession Number:

23-013633

NFC Control Number:

19823027116

Date Collected:

04/28/2023

Date Received:

05/02/2023

Date Completed:

02/09/2024

Collected By:

GA

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: SB655 Case #: TB23-03824 Sample: SB655 Specimen Type: Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium bovis

WGS Results

Genomic DNA was sequenced and compared to all other isolates in the NVSL Database. This isolate has the same SNP pattern as the most recent common ancestor to the current outbreak and an isolate submitted in 2021 by the same submitter. See attached Genotyping Report.

Animal ID: SB655 Case #: TB23-03825 Sample: SB655 Specimen Type: Spleen Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis complex

Animal ID: SB655 Case #: TB23-03826 Sample: SB655 Specimen Type: Liver Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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APPENDIX – GENOTYPING REPORT

1 July 2023

Accession:

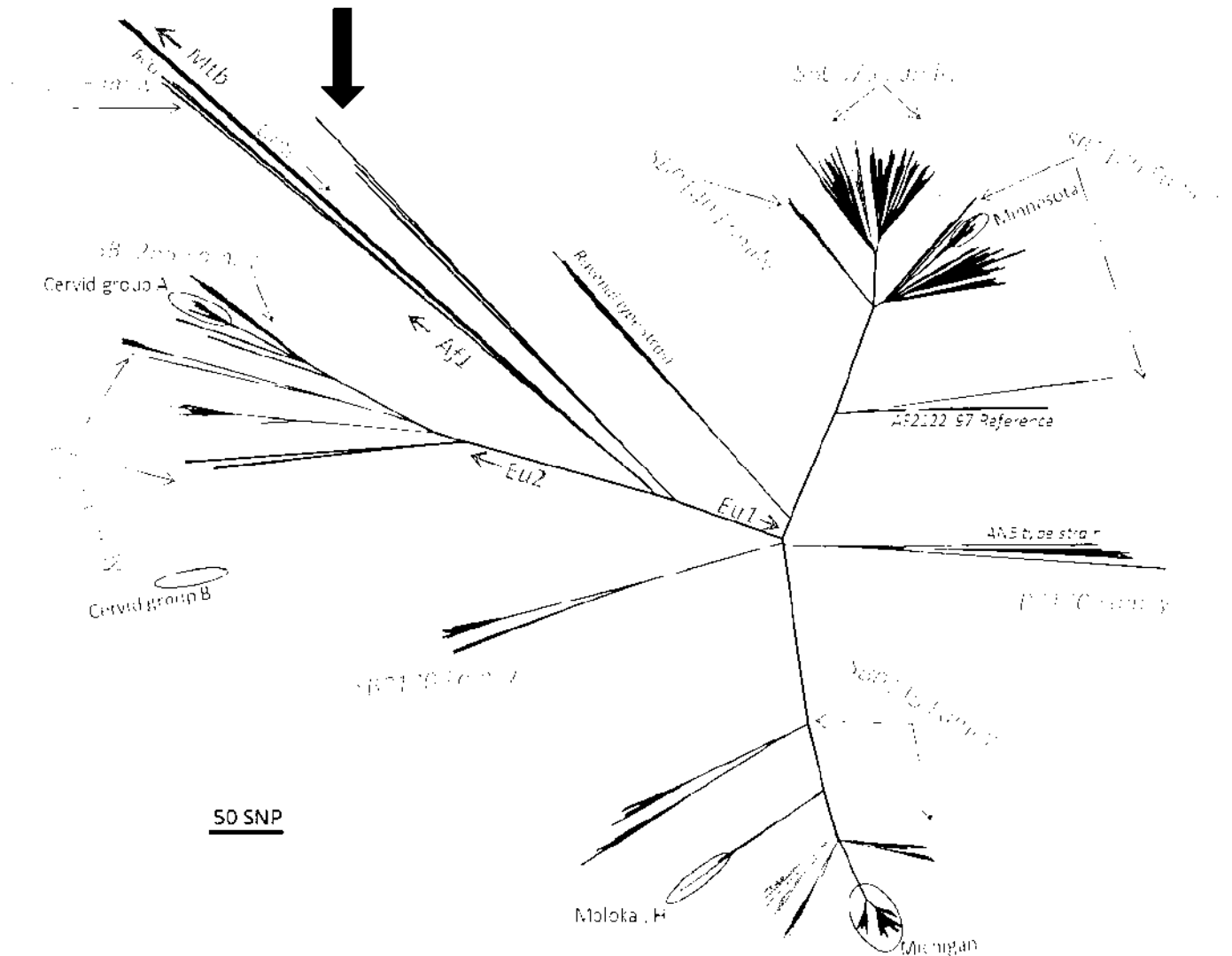
23-013239

23-13632

23-013633

WGS Genotyping results

Figure 1. The genotype of the *M. bovis* isolates recovered from submitted tissues belong to group 29. The red arrow indicates the location of this group of isolates.



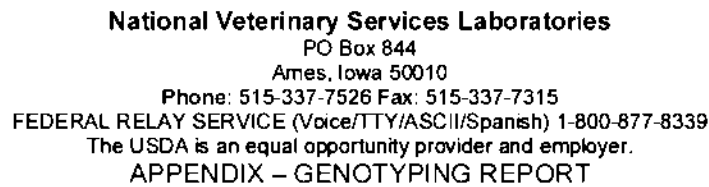


Figure 2. Abbreviated Phylogenetic tree and SNP Table of group 29. These isolates belong to the same outbreak that includes previously submitted sample from the same submitter (21-7130). 23-3824 has the same genotype as 21-7130 and 23-3380 as well as the most recent common ancestor (red arrow & bracket) to this outbreak. The isolates 23-3819 & 23-3820 have acquired a single SNP (blue arrow) from the most recent common ancestor. These data indicate that these isolates are part of a single outbreak.

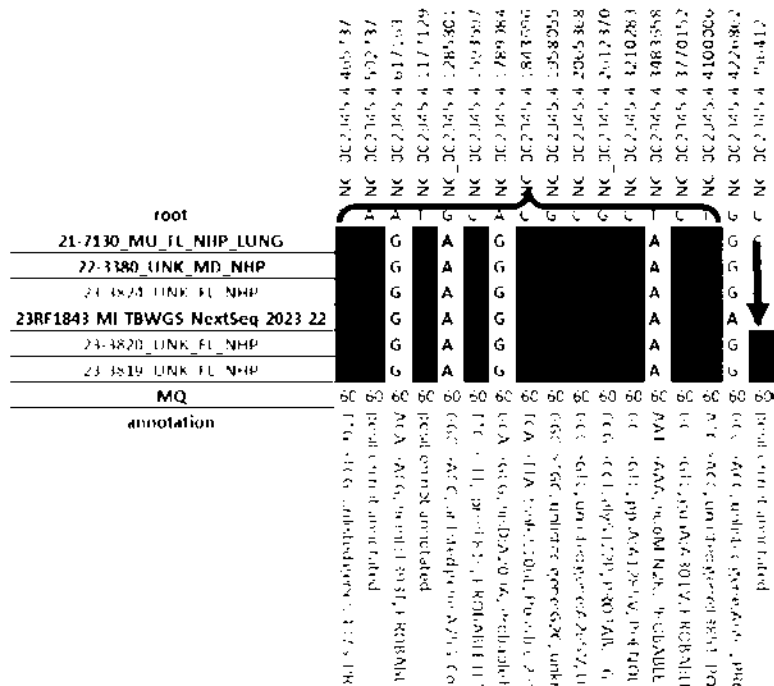
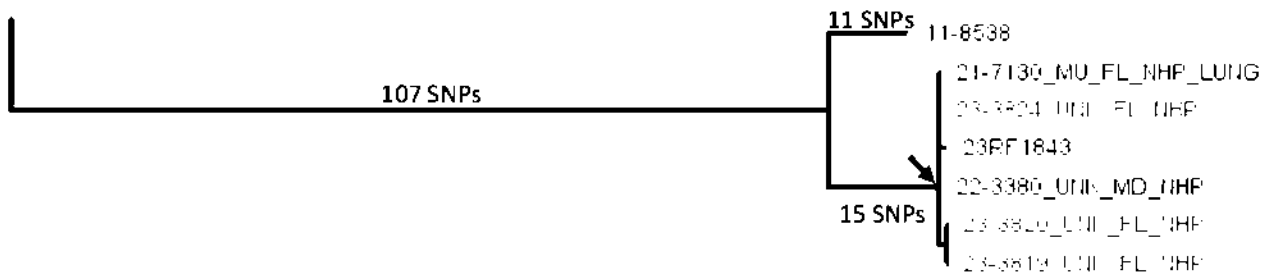


Exhibit 52

NVSL Report - Accession#23-013632,Purpose:GEN_DIAG,Exam Req:TB sent to
garias@wwwprimates.com

NVSL Case Coordinator <NVSLCASECOORDINATOR@USDA.GOV>

Fri 2/9/2024 4:16 PM

To:garias@wwwprimates.com <garias@wwwprimates.com>

 1 attachments (1,009 KB)

23-013632_MB_FI_REPT_02-09-2024-04-15-28-PM.pdf;

Submitter Name: Sonia T Salinas

Submitter Company: Worldwide Primates, Inc

Referral Number:

FAD Number:

Accession: 23-013632

Date Received: 05/02/2023 12:05:16 PM

Purpose: General Diagnostic

Exam(s) Requested: TB

Submitter State: FL

Owner State: FL

Animal State: FL

Species: [Monkey, Cynomolgus]

**National Veterinary Services Laboratories**

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FINAL REPORT

Laboratory Test Report**Owner**Worldwide Primates, Inc
Miami, FL**Animal Location**

Miami-Dade County FL, US

Submitter - 24078Dr. Sonia T. Salinas
Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
Phone #: 305-378-9585**Accession Number:****23-013632****NFC Control Number:**

19823027115

Date Collected:

05/01/2023

Date Received:

05/02/2023

Date Completed:

02/09/2024

Collected By:

GA

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.**Animal ID:** SB373 **Case #:** TB23-03820 **Sample:** SB373 **Specimen Type:** Spleen **Species:**
Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium bovis

WGS Results

Genomic DNA was sequenced and compared to all other isolates in the NVSL Database. This isolate has the same SNP pattern as another isolate submitted to NVSL at the same time from the same submitter. These isolates have acquired a single SNP from sharing the most recent common ancestor to this outbreak. See attached Genotyping Report.

Animal ID: SB373 **Case #:** TB23-03821 **Sample:** SB373 **Specimen Type:** Liver **Species:** Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: SB373 Case #: TB23-03822 Sample: SB373 Specimen Type: Kidney Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Animal ID: SB373 Case #: TB23-03823 Sample: SB373 Specimen Type: Lung Species: Monkey, Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis complex

Results authorized by:

Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

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APPENDIX – GENOTYPING REPORT

1 July 2023

Accession:

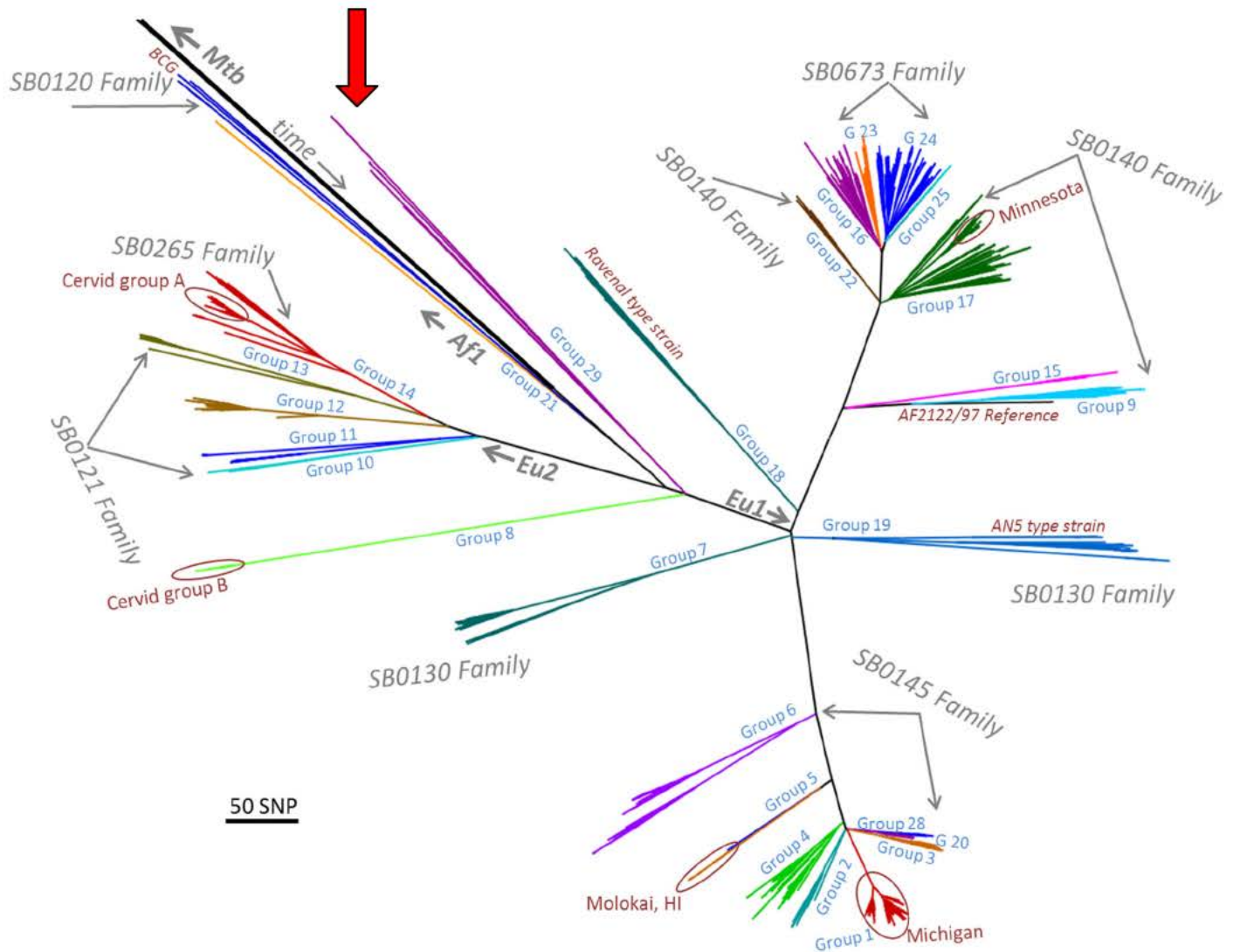
23-013239

23-13632

23-013633

WGS Genotyping results

Figure 1. The genotype of the *M. bovis* isolates recovered from submitted tissues belong to group 29. The red arrow indicates the location of this group of isolates.





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Ames, Iowa 50010

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APPENDIX – GENOTYPING REPORT

1 July 2023

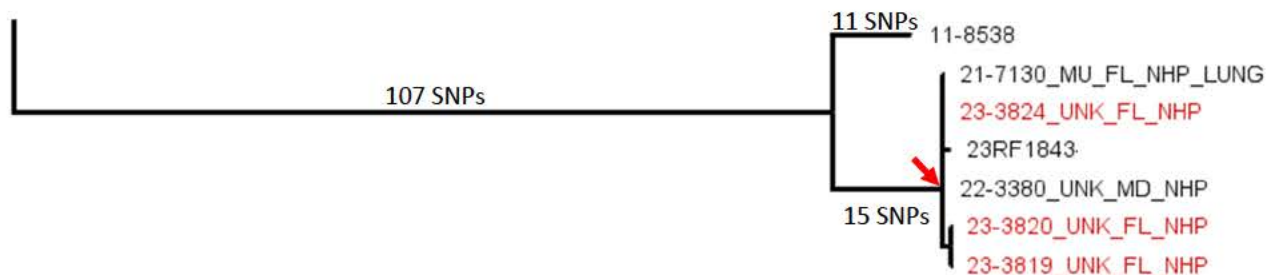
Accession:

23-013239

23-13632

23-013633

Figure 2. Abbreviated Phylogenetic tree and SNP Table of group 29. These isolates belong to the same outbreak that includes previously submitted sample from the same submitter (21-7130). 23-3824 has the same genotype as 21-7130 and 23-3380 as well as the most recent common ancestor (red arrow & bracket) to this outbreak. The isolates 23-3819 & 23-3820 have acquired a single SNP (blue arrow) from the most recent common ancestor. These data indicate that these isolates are part of a single outbreak.



	NC_002945.4:465737	NC_002945.4:592737	NC_002945.4:617163	NC_002945.4:1177129	NC_002945.4:1285801	NC_002945.4:1593597	NC_002945.4:1789984	NC_002945.4:1843696	NC_002945.4:1958055	NC_002945.4:2065368	NC_002945.4:2612370	NC_002945.4:3210283	NC_002945.4:3483658	NC_002945.4:3770152	NC_002945.4:4100006	NC_002945.4:4226862	21-7130_MU_FL_NHP_LUNG	22-3380_UNK_MD_NHP	23-3824_UNK_FL_NHP	23RF1843-MI-TBWGS-NextSeq-2023-22	23-3820_UNK_FL_NHP	23-3819_UNK_FL_NHP	MQ	annotation
root	A	A	T	G	C	A	C	G	C	G	C	T	C	T	G	C								
21-7130_MU_FL_NHP_LUNG	T	G	A	T	G	T	T	T	T	T	T	A	T	T	T	T								
22-3380_UNK_MD_NHP	T	G	A	T	G	T	T	T	T	T	T	A	T	T	T	T								
23-3824_UNK_FL_NHP	T	G	A	T	G	T	T	T	T	T	T	A	T	T	T	T								
23RF1843-MI-TBWGS-NextSeq-2023-22	T	G	A	T	G	T	T	T	T	T	T	A	T	T	T	T								
23-3820_UNK_FL_NHP	T	G	A	T	G	T	T	T	T	T	T	A	T	T	T	T								
23-3819_UNK_FL_NHP	T	G	A	T	G	T	T	T	T	T	T	A	T	T	T	T								
MQ	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60
annotation	TTG->TCG, unlisted gene:LA373, PR	position not annotated	ACA->ACG, hemL:1393T, PROBABL	position not annotated	GGC->AGC, unlisted gene:A755, Co	TTC->TTT, lprH:F81F, PROBABLE UP	GCA->GCG, hsdA:209A, Probable f	TCA->TTA, tsnR:S106L, Possible 23:	GGC->TGC, unlisted gene:A265V, U	GGC->GTC, unlisted gene:A265V, U	CCG->CCT, glyS:172P, PROBABLE GL	GCC->GTC, ppsA:A1285V, PHENOL	AAI->AAA, nuoM:N2K, PROBABLE	GCC->GTC, guaA:A301V, PROBABLE	ATC->ACC, unlisted gene:A69T, PR	GCC->ACC, unlisted gene:1385T, PO								

Exhibit 53



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FINAL REPORT

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII-Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

Laboratory Test Report

Owner

Worldwide Primates, Inc
Miami, FL

Animal Location

FL, US

Submitter - 503464

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
FAX #: 786-391-1342
Phone #:

Accession Number:

23-014475

NFC Control Number:

19823028151

Date Collected:

05/09/2023

Date Received:

05/10/2023

Date Completed:

09/09/2024

Collected By:

GA

Purpose:

TB-10-4

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: UG792 Case #: TB23-04509 Sample: 1 Specimen Type: Lung Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium bovis

DNA from this isolate was sequenced and compared to all M. bovis isolates in the NVSL database. This isolate belongs to group 29 and matches other isolates of non-human primate origin indicating this isolate is part of a single event continuing since at least 2021. Please see the attached whole genome sequence (WGS) report for further details.

Animal ID: UG792 Case #: TB23-04510 Sample: 2 Specimen Type: Liver Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Acid fast bacteria recovered

Isolate

Mycobacterium tuberculosis
complex

Animal ID: UG792 Case #: TB23-04511 Sample: 3 Specimen Type: Spleen Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

Isolate

Acid fast bacteria recovered

Mycobacterium tuberculosis
complex

Animal ID: UG792 Case #: TB23-04512 Sample: 4 Specimen Type: Kidney Species: Monkey,
Cynomolgus

Mycobacterial Culture Result

No Isolation Made

Results authorized by: Dr. Kimberly A Lehman, DVM, MPH, DACVPM, Director, Diagnostic Bacteriology
& Pathology Laboratory Phone: 515-337-7526 Email: NVSL-MB.
caseManager@usda.gov

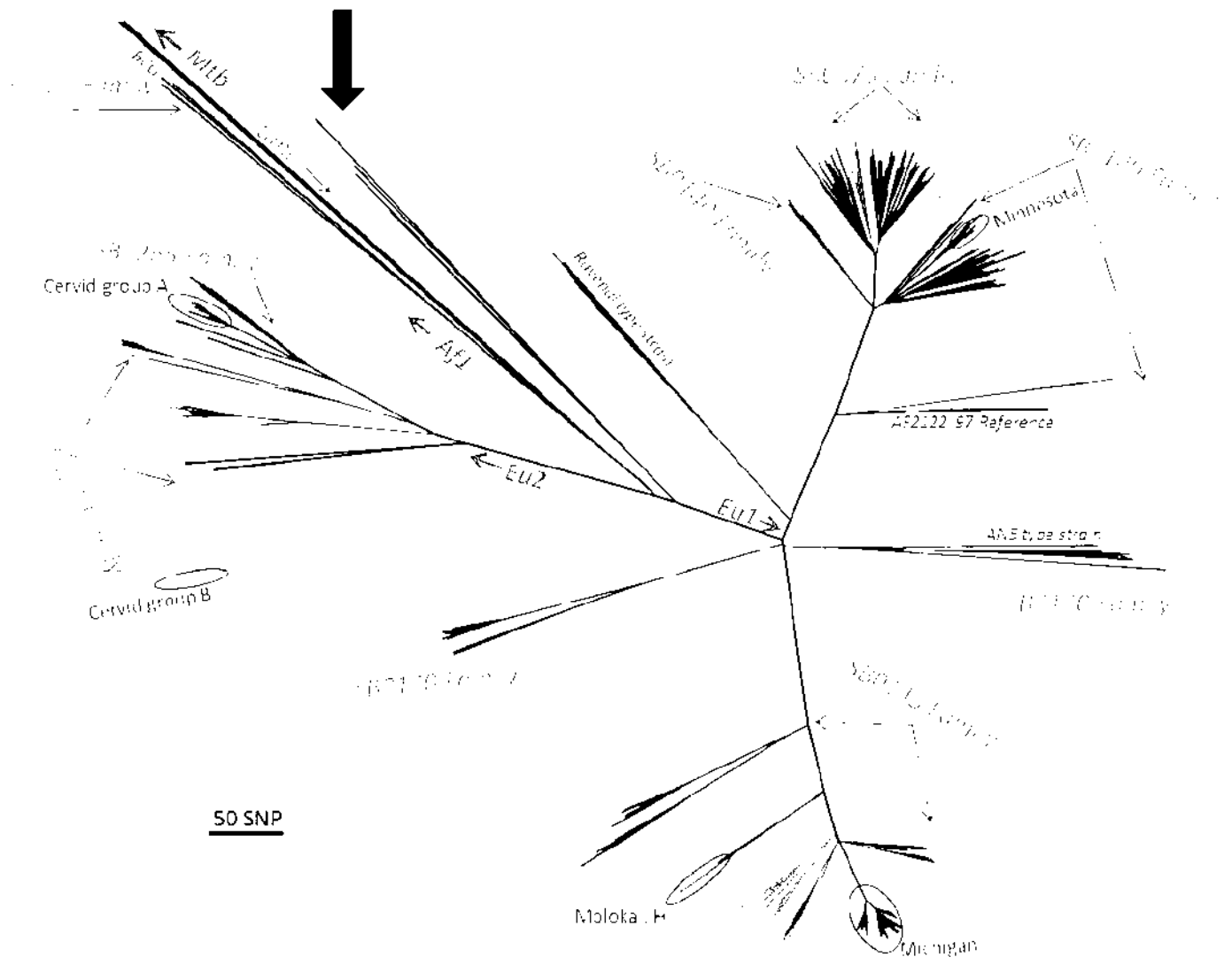
Help Us Help You

(This new section will be updated periodically with tips for submitters.)

Try the new NCAH Portal for VS Form 10-4 submissions to NVSL! For more information, please click or visit:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/portal>

WGS Genotyping results

Figure 1. The genotype of the *M. bovis* isolates recovered from submitted tissues belong to group 29. The red arrow indicates the location of this group of isolates.





National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

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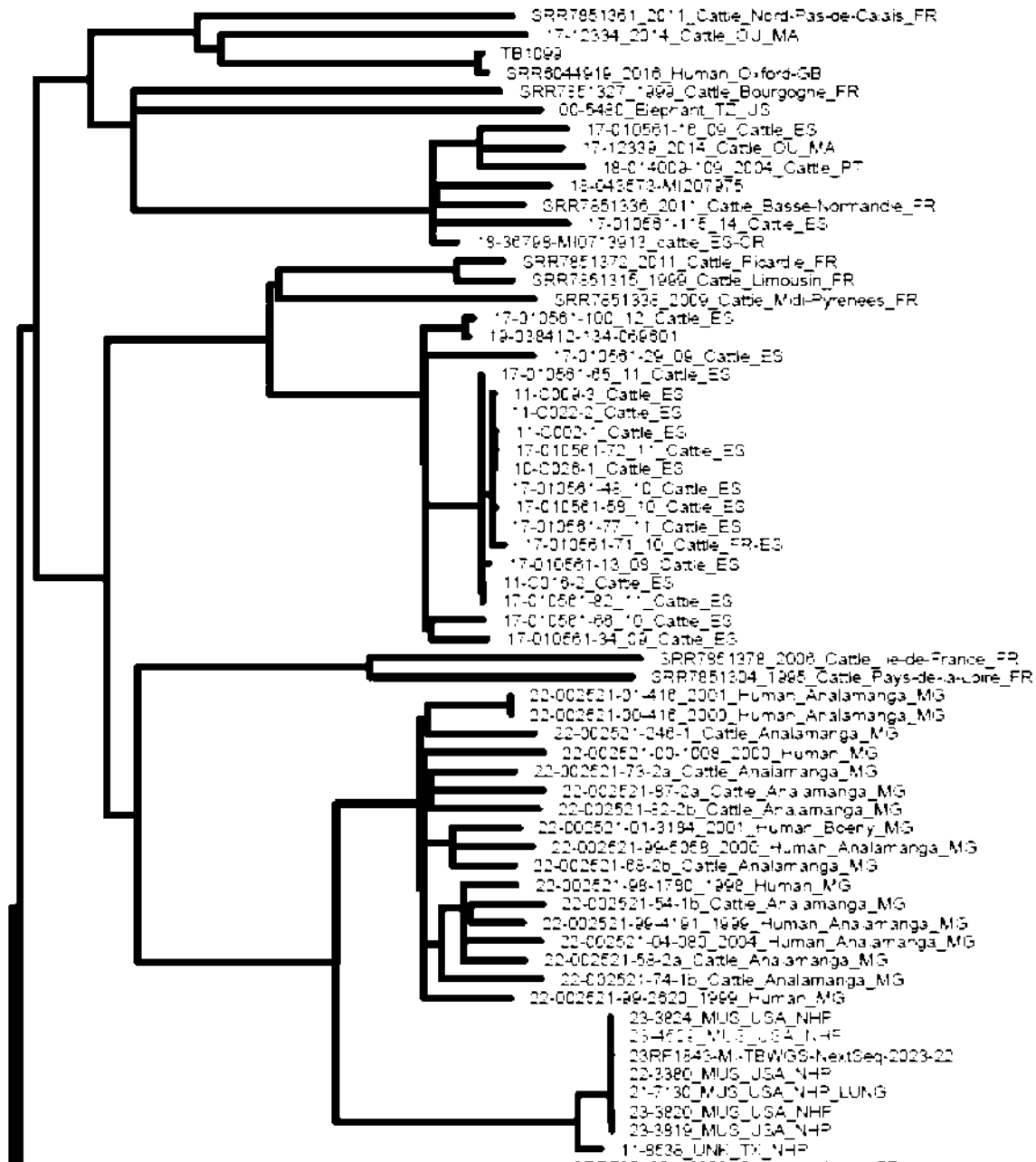
APPENDIX – GENOTYPING REPORT

4 Aug 2024

Accession:

23-014475

Figure 2. Abbreviated Phylogenetic tree and SNP Table of group 29. The isolate of interest is in red font. These data indicate that these isolates are part of a single outbreak that has been continuing since at least 2021.





National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

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4 Aug 2024

Accession:

23-014475

APPENDIX – GENOTYPING REPORT

Figure 3. SNP table detailing the relationship between isolates. This isolate recovered is indistinguishable from three other non-human primate isolates.

	root										
	11-8538_UNK_TX_NHP	21-7130_MUS_USA_NHP_LUNG	22-3380_MUS_USA_NHP	23-4509_MUS_USA_NHP	23-3824_MUS_USA_NHP	23RF1843-MI-TBWGS-NextSeq-2023-22	23-3819_MUS_USA_NHP	23-3820_MUS_USA_NHP	MQ	annotation	
NC_002945.4:156411	C	C	C	C	C	C	C	C	60	position not annotated	
NC_002945.4:422688	G	G	G	G	G	G	G	G	60	GCC >ACC, unlisted gene:A69I, PROBABLL CONSLRVLD IN ILGRAL MLMBRANL PR	
NC_002945.4:410000	T	T							60	AIC >ACC, unlisted gene:I385I, POSSIBLL LGASL, nonsynonymous	
NC_002945.4:377015	C	C							60	GGC >GAC, guaA:G226D, PROBABLL GMP SYNTHASE [GLUTAMINL HYDROLYZING	
NC_002945.4:348365	T	T	A	A	A	A	A	A	60	AAI >AAA, nuoM:N2K, PROBABLL NADH DLHYDROGLNASL I {CHAIN M} NUOK {N	
NC_002945.4:321023	C	C							60	GCC >GIC, ppsA:A1285V, PHLNOLPHIOCLROL SYNTHLSIS 1YPL I POLYKLIDL SYN	
NC_002945.4:261231	G	G							60	CGG >AGG, glyS:R393R, PROBABLL GLYCYL tRNA SYNTHLASE GLYS (GLYCINL tRNA	
NC_002945.4:206536	C	C							60	GCC->GIC, unlisted gene:A265V, UPF0/49 protein Rv1823, nonsynonymous	
NC_002945.4:195805	G	G							60	GGC->IGC, unlisted gene:G2C, unknown protein, nonsynonymous	
NC_002945.4:184365	C	C							60	ICA->TAA, tsnR:S106L, Possible 23S rRNA methyltransferase tsnR, nonsynonymou	
NC_002945.4:178993	A	A	G	G	G	G	G	G	60	GCA->GCG, hisD:A209A, Probable histidinol dehydrogenase HisD (HDH), silent mut	
NC_002945.4:159355	C	C							60	TTC->TTT, lprH:F81F, PROBABLL LIPOPROTEIN LPRH, silent mutation	
NC_002945.4:128580	G	G	A	A	A	A	A	A	60	GCC->GCI, unlisted gene:A154A, Conserved alanine and proline rich protein, silent	
NC_002945.4:117117	T	T							60	position not annotated	
NC_002945.4:617165	A	A	G	G	G	G	G	G	60	ACA->ACG, hemL:I393I, PROBABLL GLUTAMATE-1-SEMIALDEHYDL 2,1-AMINOM	
NC_002945.4:592731	A	A							60	position not annotated	
NC_002945.4:465731	T	T							60	TTG->TCG, unlisted gene:L437S, PROBABLL TRANSCRIPTIONAL REGULATORY PROI	
NC_002945.4:274220	C	C	C	C	C	C	C	C	60	GGC->GGI, pepN:G214G, PROBABLL AMINOPEPTIDASE N PLPN {LYSYLAMINOPEP	
NC_002945.4:269833	C	C	C	C	C	C	C	C	60	CCG->CCA, unlisted gene:P18P, BQ202/_MB2452C, silent mutation	
NC_002945.4:268465	G	A	G	G	G	G	G	G	60	GCC->GCI, unlisted gene:A272A, DNA internalization-related competence protein	
NC_002945.4:265594	C		C	C	C	C	C	C	60	GCG->GCA, rpfD:A83A, PROBABLL RLSUSCITATION-PROMOTING FACTOR RPF-D, si	
NC_002945.4:174795	G		C	C	C	C	C	C	60	IGG->TCG, frdBC:W33S, probable fumarate reductase [membrane anchor subunit	
NC_002945.4:171270	C		C	C	C	C	C	C	60	CGT->CAT, pks5:R1376H, Probable polyketide synthase pks5, nonsynonymous	
NC_002945.4:167425	G	A	G	G	G	G	G	G	60	CGC->TGC, unlisted gene:R55C, CONSLRVLD HYPOTHELICAL PROTEIN, nonsynony	
NC_002945.4:141893	C	G	C	C	C	C	C	C	60	GAC >CAC, embR:D315H, PROBABLL TRANSCRIPTIONAL REGULATORY PROTEIN LI	
NC_002945.4:101905	A	G	A	A	A	A	A	A	60	GTC >GCC, unlisted gene:V45A, POSSIBLL DIOXYGLNASL, nonsynonymous	
NC_002945.4:397984	C		C	C	C	C	C	C	60	CCG >TCG, unlisted gene:P252S, POSSIBLL DLHYDROGLNASL/RLDUCTASL, nonsyn	
NC_002945.4:4685	A	G	A	A	A	A	A	A	60	GCA >GCG, unlisted gene:A84A, Zn ribbon containing, possibly RNA binding prote	
NC_002945.4:434940	G	A	A	A	A	A	A	A	60	position not annotated	



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report

***** This is a confidential report intended for official use only. *****

Owner

Worldwide Primates, Inc
Miami, FL

Submitter

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
FAX #: 786-391-1342
Phone #:

Accession Number:

23-014475

NFC Control Number:

19823028151

Date Collected:

05/09/2023

Date Received:

05/10/2023

Date Completed:

05/26/2023

Collected By:

GA

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: UG792 Case # PS-23P4107 Sample: UG792 Specimen Type: Fixed Tissue Species: Monkey, Cynomolgus ID Type: Animal identification devices were not received

PCR Analysis

A polymerase chain reaction (PCR) test was performed on formalin fixed tissue using primers for IS 6110 to identify *Mycobacterium tuberculosis* complex species, 16S rDNA to identify *Mycobacterium avium* species, and IS900 to identify *Mycobacterium avium* subspecies *paratuberculosis*.

Results:

M. tuberculosis complex:

IS6110- positive

M. avium:

16S rDNA- negative

IS900- negative

Comments:

The sample was positive for *M. tuberculosis* complex IS6110 DNA.

Jennifer L. Johnson, D.V.M.

Pathology Section

Diagnostic Bacteriology and Pathology Laboratory

Histopathology Analysis

Tissue Examined Lung

Tissue Examined Liver

24-08898_000272



National Veterinary Services Laboratories

PO Box 844

Ames, Iowa 50010

Phone: 515-337-7514 Fax: 515-337-7938

FEDERAL RELAY SERVICE (Voice/TTY/ASCII/Spanish) 1-800-877-8339

The USDA is an equal opportunity provider and employer.

AMENDED REPORT

Laboratory Test Report

***** This is a confidential report intended for official use only. *****

Owner

Worldwide Primates, Inc
Miami, FL

Submitter

Worldwide Primates, Inc
PO Box 971279
Miami, FL 33197
FAX #: 786-391-1342
Phone #: 305-982-8677

Accession Number:

23-014475

NFC Control Number:

19823028151

Date Collected:

05/09/2023

Date Received:

05/10/2023

Date Completed:

05/26/2023

Collected By:

GA

Purpose:

General Diagnostic

Referral/Retain Tag Number:

This is a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Animal ID: UG792 Case # PS-23P4107 Sample: UG792 Specimen Type: Fixed Tissue Species: Monkey, Cynomolgus ID Type: Animal identification devices were not received

PCR Analysis

A polymerase chain reaction (PCR) test was performed on formalin fixed tissue using primers for IS 6110 to identify *Mycobacterium tuberculosis* complex species, 16S rDNA to identify *Mycobacterium avium* species, and IS900 to identify *Mycobacterium avium* subspecies *paratuberculosis*.

Results:

M. tuberculosis complex:

IS6110- positive

M. avium:

16S rDNA- negative

IS900- negative

Comments:

The sample was positive for *M. tuberculosis* complex IS6110 DNA.

Jennifer L. Johnson, D.V.M.

Pathology Section

Diagnostic Bacteriology and Pathology Laboratory

Histopathology Analysis

Tissue Examined Lung

Tissue Examined Liver

24-08898_001462

Accession: **23-014475** Owner: Worldwide Primates, Inc

Referral/Tag Number:

Tissue Examined Kidney

Tissue Examined Spleen

Diagnosis Mycobacteriosis - compatible

Pathologist Jennifer L. Johnson, DVM

Mycobacterial cultures are pending, and these results will be reported separately.

Results authorized by: Dr. Aaron Lehmkuhl, Head, Pathology Section
NVSL PL PS General Phone: 515-337-7912

24-08898_001463

Exhibit 54

From: Schalow, Michele (MDARD)

Sent: Wednesday, February 22, 2023 9:07 AM

To: Schumacher, Kayleen (MDARD) <SchumacherK1@michigan.gov>

Subject: Information for the Weekly Update

Rabies/Animal Bites

- Sloth bite
 - MDARD was asked by a Saginaw County for guidance and to officially quarantine a sloth that bit a child during a paid encounter at a pet shop.
 - MDARD issued a 30-day quarantine for the sloth on Friday and animal control is monitoring the quarantine.
 - Little is known about rabies in sloths. The local health department has the authority to order euthanasia if an animal has bitten a person, but did not want to do that for this case. In some species, such as dogs and cats, an animal that is biting due to rabies will get sicker and die within 10 days of the bite. We advised 30 days of isolation/quarantine out of an abundance of caution.
 - As the sloth was being exhibited and a patron bitten, MDARD also alerted the United States Department of Agriculture (USDA), Animal Care (AC) to the situation.
 - MDARD regularly gets asked for guidance in handling biting animals when an animal bites a person or other animal, especially if the animal is a livestock or exotic animal species.
- We were notified that a county animal control was allowing an animal owner to opt out of isolating their animal if it bit the owner or another animal. This is a concern as an animal that is biting could have rabies and could spread rabies. State law requires all animal bites to a person be reported to the local health department within 24 hours and the compendium be followed (which typically is euthanasia and testing or isolation for 10 days). Could be other animal controls that are doing this. If staff hear about this, it is a good idea to discuss the concerns with this practice.
- No reported cases of rabies for 2023 so far!

Brucellosis

- We have been alerted to two new cases of brucellosis
 - Case 1
 - 3-year-old intact female mixed breed dog from Jackson County
 - Case 2:
 - 1.5-year-old spayed female Beagle from Ingham County.
 - Both cases involved dogs acquired from out-of-state rescues. Both dogs had a history of chronic neck or back pain and were referred to Michigan State University's (MSU) Neurology Service and were subsequently confirmed to have the disease. One dog also had a history of muscle spasms and the other had a history of a shifting leg lameness.
 - The dogs are quarantined and MDARD is conducting an epidemiologic investigation to look for further exposures.

Leptospirosis

- To date, for calendar year 2023, we have had 3 cases reported, 2 from Macomb and 1 from Wayne Counties.
- None were vaccinated against the disease.

Strangles

- As of February 23, 2023, we have had 8 cases of strangles reported for 2023 from seven different counties: Bay, Livingston, Macomb, Ottawa, Shiawassee (2), St Joseph, and Van Buren.

Tuberculosis

- We are responding to an outbreak of tuberculosis (*Mycobacterium tuberculosis*) at a facility involving at least 3 macaques.

- The macaques were wild caught in Mauritius, imported into Florida, and then imported into Michigan.
- Additional primates were exposed and are under quarantine.
- Information to MDARD is that other animals associated with the importation from Mauritius to the United States were also found to have tuberculosis.

Disposers and Transporters of Dead Animals/Bodies of Dead Animals Act

- Two out of 14 annual inspections have been completed as of February 21st. The due date for inspections is August 11, 2023.

New pet shop in metro-Detroit

- MDARD has been responding to several calls and email from the public concerned over a new pet shop, Puppygram, that open in Berkley, Michigan recently.
- Pet shop appears to be part of a small chain of pet shops in the Midwest United States.
- Concern mainly related to animal welfare and licensing. Overall, seems they do not want the pet shop there.
- As a reminder, MDARD is not currently licensing and inspecting pet shops. Concern related to animal welfare should be directed to local animal control/law enforcement.

Large Carnivore Breeding Update

- As a reminder, it is illegal to breed large carnivores in Michigan unless a person has a zoo with MDARD. There are a lot of requirements that must be met for a license!
- There are currently 5 licenses, each to breed a specified pair of large carnivores together.
- Animals licensed to breed include tigers, polar bears, snow leopards, and lions.
- Four of the licenses were issued by MDARD within the prior 2 month.
- The zoos are actively breeding the animals so hopefully we will hear about babies in the near future!

Michele Schalow, DVM (she, her, hers)

Companion Animal, Exotic Animal, and Equine Program Manager

Michigan Department of Agriculture and Rural Development (MDARD)

Animal Industry Division (AID)

Office: 517-284-5688

Cell: 517-243-1592

Exhibit 55



CERTIFICATE OF VETERINARY INSPECTION

CERTIFICATE NUMBER

58-038294-335655-0

Contact State of Destination for Movement Requirements and Certificate Validity - Certificate is valid for thirty days from date of inspection

☐ INTERNATIONAL☐ REGULAR HEALTH MAINTENANCE PROGRAM☐ 72 Hour HoldINSPECTION DATE
Jan 28 2023ISSUE DATE
Jan 30 2023SHIP DATE
Jan 31 2023

ENTRY PERMIT #

BRAND INSPECTION FORM #

BRAND INSPECTION ISSUE DATE

NAME Worldwide Primates, Inc.			PHONE # 305-378-9585		NAME USAMRIID			PHONE # 301-402-3957		NAME Wildlife Transportation Facili			PHONE # 301-471-3580				
PHYSICAL ADDRESS 16450 SW 180th Street			PREMISES I.D.		PHYSICAL ADDRESS Bldg 1408, 1425 Porter Street			PREMISES I.D.		PHYSICAL ADDRESS PO Box 967							
CITY Miami		STATE FL	ZIP 33187	COUNTY Miami Dade		CITY Fort Detrick		STATE MD	ZIP 21702	COUNTY Frederick		CITY Stevensville	STATE MD	ZIP 21666	COUNTY Queen Anne		
EMAIL1			EMAIL2			EMAIL1			EMAIL2			EMAIL1			EMAIL2		
NAME Worldwide Primates, Inc.			Same as above - <input type="checkbox"/>			NAME USAMRIID			Same as above - <input type="checkbox"/>			Origin of Shipment GPS Coordinates Latitude Longitude					
PHYSICAL ADDRESS 16450 SW 180th Street						PHYSICAL ADDRESS Bldg 1408, 1425 Porter Street						TEST RECORDS - Are legible copies of official charts (with individual animals identified and animals that are not shipped lined out) attached to all copies? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
CITY Miami		STATE FL	ZIP 33187	COUNTY Miami Dade		CITY Fort Detrick		STATE MD	ZIP 21702	COUNTY Frederick		Herd / Flock #		Record # <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
# in Shipment		0	Small Animals	0	Cervids	0	Purpose(s) of Movement (check all that apply)			Intra-state	Carrier	Flock / Herd Free For		Current State / Area Status			
<input type="checkbox"/> Beef Cattle		0	<input type="checkbox"/> Dairy Cattle	0	<input type="checkbox"/> Camelids	0	<input type="checkbox"/> Show <input type="checkbox"/> Pet <input type="checkbox"/> Training			<input type="checkbox"/>	<input type="checkbox"/> Air <input checked="" type="checkbox"/> Truck <input type="checkbox"/> Mail	<input checked="" type="checkbox"/> TB Free <input type="checkbox"/> John's <input type="checkbox"/> NPPI		Tuberculosis <input type="checkbox"/> Free <input type="checkbox"/> MAA <input type="checkbox"/> MA			
<input type="checkbox"/> Horses		0	<input type="checkbox"/> Sheep	0	<input type="checkbox"/> Semen/Embryos	0	<input type="checkbox"/> Race <input type="checkbox"/> Breeding <input type="checkbox"/> Slaughter			<input type="checkbox"/>	<input type="checkbox"/> Boat <input type="checkbox"/> Rail <input type="checkbox"/> Car	<input type="checkbox"/> Bruc. <input type="checkbox"/> Scrapie <input type="checkbox"/> PRV		Brucellosis <input type="checkbox"/> Free <input type="checkbox"/> Class A			
<input type="checkbox"/> Goats		0	<input type="checkbox"/> Swine	0	<input type="checkbox"/> Aquaculture	0	<input type="checkbox"/> Rodeo <input type="checkbox"/> Feeding <input type="checkbox"/> Medical			<input checked="" type="checkbox"/>	<input type="checkbox"/> Other	<input type="checkbox"/> Trich <input type="checkbox"/> EIA <input type="checkbox"/> Other		<input type="checkbox"/> PRV Free <input type="checkbox"/> Other			
<input type="checkbox"/> Avian		0	<input type="checkbox"/> Dogs & Cats	0	<input type="checkbox"/> Other	0	<input type="checkbox"/> Sale <input type="checkbox"/> Grazing <input checked="" type="checkbox"/> Other (specify below)			<input checked="" type="checkbox"/>							

VETERINARY CERTIFICATION STATEMENTS:	**These documents are proprietary and may contain client, patient, financial and/or trade secret information. Release is not authorized without permission of consignor / shipper.**														
	WWP USDA license# 58-B-0542														

Line #	Qty	Species	OFFICIAL/FEDERAL EAR TAG # REGISTRATION TATTOO OR OTHER PERMANENT IDENTIFICATION *** You may place up to four unique animal identifiers with a comma between each entry ***	Age	Breed	Sex	Bruc Vac Tatto o	Test Date	Test	Accession #	Result +/-	Lab	Other
1		OTH	DrpL7-29D-C	>3 Y	Macaca fascicularis	Male		01/17/2023	TB test		N		
2		OTH	DrpZ39-37C-B-B	>3 Y	Macaca fascicularis	Male		1/17/2023	TB test		N		
3		OTH	DrpZ7-49B-M	>3 Y	Macaca fascicularis	Male		01/17/2023	TB test		N		
4		OTH	DRPZ7-97B-H	>3 Y	Macaca fascicularis	Male		01/17/2023	TB test		N		

VETERINARY CERTIFICATION - I certify, as an accredited veterinarian that the above described animals have been inspected by me and that they are not showing signs of infectious, contagious and/or communicable disease (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.										OFFICIAL OFFICE USE ONLY				
SIGNATURE 			NAME Horatiu Vinerean		STATE OF LICENSE FL		ADDRESS 16450 SW 180th Street			LICENSE# VM11076		CATEGORY I		
DATE Jan 30 2023			USDA ACCR.# 038294		Miami FL		33187							



OFFICIAL CERTIFICATE OF VETERINARY INSPECTION

CERTIFICATE NUMBER

58-038294-335655-0

Name of Consignor/Owner			Worldwide Primates, Inc.			Name of Consignee/Owner			USAMRIID			Vet Name: Horatiu Vinerean			# in Movement			0			Date			Jan 30 2023		
Line #	Qty	Species	OFFICIAL/FEDERAL EAR TAG # REGISTRATION TATTOO OR OTHER PERMANENT IDENTIFICATION *** You may place up to four unique animal identifiers with a comma between each entry ***			Age	Breed	Sex	Bruc Vac Tatto o	Test Date	Test	Accession #	Result +/-	Lab	Other											
5		OTH	DrpZ9-84C-F			>3 Y	Macaca fascicularis	Male		01/17/2023	TB test		N													

IMPORTATION PERMIT NO. 4811



NEW MEXICO DEPARTMENT OF GAME & FISH
LE FIELD OPERATIONS DIVISION
SPECIAL USE PERMITS PROGRAM
ONE WILDLIFE WAY
SANTA FE, NM 87507
Office: (505) 476-8064
Email: DGF.Permits@dgf.nm.gov

THIS PERMIT IS VALID FROM THE DATE ISSUED THROUGH: April 28, 2023

Under authority of the statutes of the State of New Mexico, permission is hereby given to:

NAME:		FEE PAID: \$300.00 on 2/10/2022
BUSINESS NAME:	Lovelace Biomedical Research Institute	EMAIL: lbriar@lovelacebiomedical.org
ADDRESS:	2425 Ridgecrest Dr. SE	FAX: 505-348-4722
CITY, STATE, ZIP:	Albuquerque, NM 87108	PHONE: 505-348-9600

To import into the State of New Mexico: 5 Cynos crab-eating macaque (*Macaca fascicularis*).

From: World Wide Primates: 16450 SW 180th St., Miami FL 33187; USDA 58-B-0542.

The following disposition will be made of the above-named imported species:

Lovelace Biomedical Research Institute Facility on KAFB, Albuquerque, NM 87115 for Scientific Research.

On File: Containment/confinement plan indicating where and how the species will be maintained; the animals will reside on Military reservation. USDA #85-R-0003, Health Certificates only valid for ten days, permit will be issued upon receipt of valid Health Certification.

THIS PERMIT SHALL ACCOMPANY THE SHIPMENT

The importer agrees to accept this permit subject to NM Statute Ch. 17 and the regulations of the State Game Commission and binds him or herself to faithful observance of said regulations. By exercising the rights of this permit, he/she acknowledges that the animals brought into New Mexico under its provisions, and all their subsequent progeny, will be subject to State laws and rules.

Michael B. Sloane, Director

March 28, 2023

Date Issued

I certify that the information on this permit is true and accurate. I also certify that I have read and understand the provisions of this permit and agree to abide by them.

Permittee's Signature

Date

ALL FEDERAL, CITY AND COUNTY RULES, REGULATIONS AND ORDINANCES MUST BE ADHERED TO.

(This permit is invalid unless a copy, signed and dated by the permittee, is returned to the New Mexico Department of Game and Fish.)

- ☐ For your files
☐ Please sign and return

IMPORTATION PERMIT APPLICATION ZOO / SCIENTIFIC / EDUCATION



NEW MEXICO DEPARTMENT OF GAME & FISH
FIELD OPERATIONS DIVISION
SPECIAL USE PERMITS PROGRAM
P.O. BOX 25112
SANTA FE, NM 87504
505-476-8064 / Fax 505-476-8133
Email: DGF.Permits@state.nm.us

Application Fee Structure:

Importation of non-domesticated animals per calendar year (1/1 to 12/31)
Class 1: 1 to 5 animals.....\$25.00
Class 2: 6 to 99 animals.....\$75.00
Class 3: greater than 100 animals...\$300.00
Other: per application, one time use...\$20.00

FOR DEPT. USE ONLY

Check # _____
Amount \$ _____
Date ____/____/____
Initials _____
☐ Health Certificate or
☐ AZA accredited

Application must be submitted at least two (2) weeks prior to proposed importation. Missing documentation may substantially delay the application process. Importation approval is not guaranteed. A valid permit must be issued before lawful entry into the State of New Mexico.

APPLICANTS NAME	Lovelace Biomedical Research Institute	EMAIL	lbriar@lovelacebiomedical.org
BUSINESS NAME	same as above	WEBSITE	lovelacebiomedical.org
ADDRESS (mailing)	2425 Ridgecrest Dr SE	ADDRESS (physical)	Area Y bldg 9217, Kirtland AFB East
CITY, STATE, ZIP	Albuquerque NM 87108		Albuquerque NM 87115
TELEPHONE (Cell)	5059179968	(Office)	5053489600

Requested date of entry into the State of New Mexico: 06Apr2023

SPECIES REQUESTED TO BE IMPORTED			QUANTITY Note (S or N) Spayed or Neutered		
*Group	Common Name	Scientific Name (family, genus, species, sub sp.)	Males	Females	Mix/ Unknown
	Cynos	Macaca fascicularis	5		

*Group- refers to restrictiveness on the importation species list

For additional animals, attach or email the list

SUPPLIER INFORMATION		Health Certificate or License Type
Suppliers Name	Wold Wide Primates Inc	One or more of the following is mandatory prior to entry (attach copies to application).
Business Name	same as above	Health Certificate from an accredited veterinarian
Address	16450 SW 180th St	AZA or Rearing Facility Inspection certificate of health from an accredited veterinarian
City, ST, Zip	Miami FL 33187	USDA Class A, B or C Licenses
Telephone / Fax	1-305-378-9585	USFWS Federal Permits
Email / Website	stsalina@wwprimates.com	Other Licenses held (in-state/out-of-state)
License Type/No.	58-B-0542	National Poultry Improvement Plan # (NPIP)

By signing below, applicants understand that if any animal show signs of an infectious or contagious disease, it will be quarantined and the animals may be destroyed as deemed necessary by authorized agents of the Zoo, NMDGF or USFWS.

28Mar2023

Signature of applicant

Date

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for this information collection are 0579-0036 and 0579-0333. The time required to complete this information collection is estimated to average .25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

No dog, cat, nonhuman primate, or additional kinds or classes of animals designated by USDA regulation shall be delivered to any intermediate handler or carrier for transportation in commerce, unless accompanied by a health certificate executed and issued by a licensed veterinarian (7 U.S.C. 21.43.9; CFR, Subchapter A, Part 2).

OMB APPROVED
0579-0036
0579-0333

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

UNITED STATES INTERSTATE AND INTERNATIONAL
CERTIFICATE OF HEALTH EXAMINATION
FOR SMALL ANIMALS

WARNING: Anyone who makes a false, fictitious, or fraudulent statement on this document, or uses such document knowing it to be false, fictitious, or fraudulent may be subject to a fine of not more than \$10,000 or imprisonment of not more than 5 years or both (18 U.S.C. 1001).

1. TYPE OF ANIMAL SHIPPED (select one only)

☐ Dog ☐ Cat ☐ Other _____
☒ Nonhuman Primate ☐ Ferret ☐ Rodent

2. CERTIFICATE NUMBER - OFFICIAL USE ONLY

23-005

3. TOTAL NUMBER OF ANIMALS

4. PAGE

1 of 1

5. NAME, ADDRESS, AND TELEPHONE NUMBER OF OWNER (CONSIGNOR)

World Wide Primates
16450 SW 180th St
Miami, FL 33187
3053789585

6. NAME, ADDRESS, AND TELEPHONE NUMBER OF RECIPIENT AT DESTINATION (CONSIGNEE)

LoveLace Biomedical Research Institute
2425 Ridgecrest Dr. SE
Albuquerque, NM 87108

USDA License/or Registration Number (if applicable) 58-B-0542

7. ANIMAL IDENTIFICATION

NAME, AND/OR TATTOO NUMBER OR OTHER IDENTIFICATION	BREED - COMMON OR SCIENTIFIC NAME	AGE	SEX	COLOR OR DISTINCTIVE MARKS OR MICROCHIP
(1) 4803	Macaca Fascicularis	A	M	Brown
(2) 4942	Macaca Fascicularis	A	M	Brown
(3) 5695	Macaca Fascicularis	A	M	Brown
(4) 4853	Macaca Fascicularis	A	M	Brown
(5) 8322	Macaca Fascicularis	A	M	Brown
(6)				

8. PERTINENT VACCINATION, TREATMENT, AND TESTING HISTORY

RABIES VACCINATION
☐ 1 YEAR ☐ 2 YEARS ☐ 3 YEARS

Vaccination Date	Product	Date	Product Type and/or Results
		3/27/2023	TBT NEGATIVE LOT#453X
		3/27/2023	TBT NEGATIVE LOT#453X
		3/27/2023	TBT NEGATIVE LOT#453X
		3/27/2023	TBT NEGATIVE LOT#453X
		3/27/2023	TBT NEGATIVE LOT#453X
		3/28/23	

9. REMARKS OR ADDITIONAL CERTIFICATION STATEMENTS (WHEN REQUIRED)

VETERINARY CERTIFICATION: I certify that the animals described in box 7 have been examined by me this date, that the information provided in box 8 is true and accurate to the best of my knowledge, and that the following findings have been made ("X" applicable statements).

☐ I have verified the presence of the microchip, if a microchip is listed in box 7.

☒ I certify that the animal(s) described above and on continuation sheet(s), if applicable, have been inspected by me on this date and appear to be free of any infectious or contagious diseases and to the best of my knowledge, exposure thereto, which would endanger the animal or other animals or would endanger public health.

☒ To my knowledge, the animal(s) described above and on continuation sheet(s) if applicable, originated from an area not quarantined for rabies and has/have not been exposed to rabies.

ENDORSEMENT FOR INTERNATIONAL EXPORT (IF NEEDED)

PRINTED NAME OF USDA VETERINARIAN

NAME, ADDRESS, AND TELEPHONE NUMBER OF ISSUING VETERINARIAN

Donna Steiner, DVM, MS
PO BOX 1588
IMMOKALEE, FL 34142

LICENSE NUMBER AND STATE

VM3749FL

Accredited ☒ Yes ☐ No
If yes, please complete below

NATIONAL ACCREDITATION NUMBER
054812

NOTE: International shipments may require certification by an accredited veterinarian.

SIGNATURE OF USDA VETERINARIAN Apply USDA Seal or Stamp here

DATE

SIGNATURE OF ISSUING VETERINARIAN

DATE

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for this information collection are 0579-0036 and 0579-0333. The time required to complete this information collection is estimated to average .25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

No dog, cat, nonhuman primate, or additional kinds or classes of animals designated by USDA regulation shall be delivered to any intermediate handler or carrier for transportation in commerce, unless accompanied by a health certificate executed and issued by a licensed veterinarian (7 U.S.C. 21.43.9; CFR, Subchapter A, Part 2).

OMB APPROVED
0579-0036
0579-0333

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

UNITED STATES INTERSTATE AND INTERNATIONAL
CERTIFICATE OF HEALTH EXAMINATION
FOR SMALL ANIMALS

WARNING: Anyone who makes a false, fictitious, or fraudulent statement on this document, or uses such document knowing it to be false, fictitious, or fraudulent may be subject to a fine of not more than \$10,000 or imprisonment of not more than 5 years or both (18 U.S.C. 1001).

1. TYPE OF ANIMAL SHIPPED (select one only)

☐ Dog ☐ Cat ☐ Other _____
☒ Nonhuman Primate ☐ Ferret ☐ Rodent

3. TOTAL NUMBER OF ANIMALS

2. CERTIFICATE NUMBER - OFFICIAL USE ONLY

23-037

4. PAGE

1 of 2

5. NAME, ADDRESS, AND TELEPHONE NUMBER OF OWNER (CONSIGNOR)

Primate Products, LLC
34200 Doctors Hammock Rd.
Immokalee, FL 34142
2398672020

6. NAME, ADDRESS, AND TELEPHONE NUMBER OF RECIPIENT AT DESTINATION (CONSIGNEE)

LoveLace Biomedical Research Institute
2425 Ridgcrest, Dr. SE
Albuquerque, NM 87108

USDA License/or Registration Number (if applicable) 58-B-0542

7. ANIMAL IDENTIFICATION

NAME, AND/OR TATTOO NUMBER OR OTHER IDENTIFICATION	BREED - COMMON OR SCIENTIFIC NAME	AGE	SEX	COLOR OR DISTINCTIVE MARKS OR MICROCHIP
(1) L22-144	Macaca Fascicularis	J	F	Brown
(2) L22-158	Macaca Fascicularis	J	F	Brown
(3) L22-238	Macaca Fascicularis	J	F	Brown
(4) L22-240	Macaca Fascicularis	J	F	Brown
(5) L22-116	Macaca Fascicularis	J	F	Brown
(6) L22-226	Macaca Fascicularis	J	F	Brown

8. PERTINENT VACCINATION, TREATMENT, AND TESTING HISTORY

RABIES VACCINATION		OTHER VACCINATIONS, TREATMENT, AND/OR TESTS AND RESULTS	
<input type="checkbox"/> 1 YEAR <input type="checkbox"/> 2 YEARS <input type="checkbox"/> 3 YEARS			
Vaccination Date	Product	Date	Product Type and/or Results
		9/26/2023	TBT NEGATIVE LOT#453X
		9/26/2023	TBT NEGATIVE LOT#453X
		9/26/2023	TBT NEGATIVE LOT#453X
		9/26/2023	TBT NEGATIVE LOT#453X
		9/18/2023	TBT NEGATIVE LOT#453X
		9/18/2023	TBT NEGATIVE LOT#453X

9. REMARKS OR ADDITIONAL CERTIFICATION STATEMENTS (WHEN REQUIRED)

VETERINARY CERTIFICATION: I certify that the animals described in box 7 have been examined by me this date, that the information provided in box 8 is true and accurate to the best of my knowledge, and that the following findings have been made ("X" applicable statements).

☐ I have verified the presence of the microchip, if a microchip is listed in box 7.

☒ I certify that the animal(s) described above and on continuation sheet(s), if applicable, have been inspected by me on this date and appear to be free of any infectious or contagious diseases and to the best of my knowledge, exposure thereto, which would endanger the animal or other animals or would endanger public health.

☒ To my knowledge, the animal(s) described above and on continuation sheet(s) if applicable, originated from an area not quarantined for rabies and has/have not been exposed to rabies.

ENDORSEMENT FOR INTERNATIONAL EXPORT (IF NEEDED)

PRINTED NAME OF USDA VETERINARIAN

NAME, ADDRESS, AND TELEPHONE NUMBER OF ISSUING VETERINARIAN

Donna Steiner, DVM, MS
PO BOX 1588
IMMOKALEE, FL 34142

LICENSE NUMBER AND STATE
VM3749FL

Accredited ☒ Yes ☐ No
If yes, please complete below

NATIONAL ACCREDITATION NUMBER
054812

NOTE: International shipments may require certification by an accredited veterinarian.

SIGNATURE OF USDA VETERINARIAN Apply USDA Seal or Stamp here

DATE

SIGNATURE OF ISSUING VETERINARIAN

DATE

<div>U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICES UNITED STATES INTERSTATE AND INTERNATIONAL CERTIFICATE OF HEALTH EXAMINATION FOR SMALL ANIMALS (Continuation Sheet)</div>						<div>WARNING THIS DOCUMENT IS PROPRIETARY, IT MAY CONTAIN FINANCIAL AND/OR TRADE SECRET INFORMATION, RELEASE IS NOT AUTHORIZED WITHOUT PERMISSION OF ISSUER</div>				<div>1. CERTIFICATE NUMBER (Insert certificate no. from page 1) 23-037</div>	
<div>3. NAME, ADDRESS AND TELEPHONE NUMBER OF OWNER/CONSIGNOR Primate Products, LLC 34200 Doctors Hammock Rd. Immokalee, FL 34142 239-867-2020</div>						<div>4. NAME, ADDRESS AND TELEPHONE NUMBER OF CONSIGNEE LoveLace Biomedical Research Institute 2425 Ridgecrest, Dr. SE Albuquerque, NM 87108</div>					
<div>5. ANIMAL IDENTIFICATION (To be completed by owner/consignor)</div>						<div>6. VACCINATION HISTORY (To be completed by Veterinarian)</div>					
COMPLETE USDA TAG. COLLAR AND/OR TATTOO NUMBER		BREED - COMMON OR SCIENTIFIC NAME	AGE	SEX	COLOR OR DISTINCTIVE MARKS	RABIES Killed Virus Live Virus		D-H-L		OTHER VACCINATIONS, TEST OR TREATMENT	
						Date	Product	Date	Product	Date	Type/Result
7	L22-82	Macaca Fascicularis	J	F	Brown					9/18/2023	TBT NEGATIVE LOT#453X
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
24											
25											
26											
27											



CERTIFICATE OF VETERINARY INSPECTION

CERTIFICATE NUMBER

58-038294-360199-3

Contact State of Destination for Movement Requirements and Certificate Validity - Certificate is valid for thirty days from date of inspection

☐ INTERNATIONAL☐ REGULAR HEALTH MAINTENANCE PROGRAM☐ 72 Hour HoldINSPECTION DATE
Nov 08 2023ISSUE DATE
Nov 09 2023SHIP DATE
Nov 13 2023

ENTRY PERMIT #

BRAND INSPECTION FORM #

BRAND INSPECTION ISSUE DATE

NAME Worldwide Primates, Inc		PHONE # 305-378-9585	NAME UTMB		PHONE #	NAME JKL Secure Freight		PHONE # 775-761-3631
PHYSICAL ADDRESS 16450 SW 180th Street		PREMISES I.D.	PHYSICAL ADDRESS 11th and Strand		PREMISES I.D.	PHYSICAL ADDRESS PO Box 18950		
CITY Miami	STATE FL	ZIP 33187	CITY Galveston	STATE TX	ZIP 77555	CITY Reno	STATE NV	ZIP 89511
COUNTRY USA		COUNTRY USA		COUNTRY USA		COUNTRY USA		
NAME Worldwide Primates, Inc		NAME UTMB		Origin of Shipment GPS Coordinates Latitude Longitude		TEST RECORDS - Are legible copies of official charts (with individual animals identified and animals that are not shipped lined out) attached to all copies?		
PHYSICAL ADDRESS 16450 SW 180th Street		COUNTRY USA	PHYSICAL ADDRESS 11th and Strand		COUNTRY USA	Herd / Flock #		Record #
CITY Miami	STATE FL	ZIP 33187	CITY Galveston	STATE TX	ZIP 77555	YES NO		
# in Shipment		Purpose(s) of Movement (check all that apply)		Carrier		Flock / Herd Free For		Current State / Area Status
<input type="checkbox"/> Beef Cattle		<input type="checkbox"/> Show		<input type="checkbox"/> Air		<input checked="" type="checkbox"/> TB Free		Tuberculosis
<input type="checkbox"/> Dairy Cattle		<input type="checkbox"/> Sale		<input type="checkbox"/> Truck		<input type="checkbox"/> John's		Free
<input type="checkbox"/> Sheep		<input type="checkbox"/> Training		<input type="checkbox"/> Mail		<input type="checkbox"/> NPIP		MAA
<input type="checkbox"/> Swine		<input type="checkbox"/> Race		<input type="checkbox"/> Boat		<input type="checkbox"/> Bruc.		MA
<input type="checkbox"/> Dogs & Cats		<input type="checkbox"/> Breeding		<input type="checkbox"/> Rail		<input type="checkbox"/> Scrapie		NA
		<input type="checkbox"/> Rodeo		<input type="checkbox"/> Car		<input type="checkbox"/> PRV		Class A
		<input type="checkbox"/> Feeding		<input checked="" type="checkbox"/> Land		<input type="checkbox"/> Trich		Class B
		<input type="checkbox"/> Medical		<input type="checkbox"/> Other		<input type="checkbox"/> EIA		Class C
		<input type="checkbox"/> Personal Travel/Transit				<input type="checkbox"/> Other		GYA, DSA (Class A)
		<input type="checkbox"/> Companion Animal						PRV Free
		<input checked="" type="checkbox"/> Other (specify below)						Other

VETERINARY CERTIFICATION STATEMENTS:	***These documents are proprietary and may contain confidential client, patient, financial and or trade secret information. Release is not authorized without permission of consignor/shipper. ***
--------------------------------------	--

Line #	Qty	Species	OFFICIAL/FEDERAL EAR TAG # REGISTRATION TATTOO OR OTHER PERMANENT IDENTIFICATION *** You may place up to four unique animal identifiers with a comma between each entry ***	Age	Breed	Sex	Bruc Vac Tatto o	Test Date	Test	Accession #	Res ult +/-	Lab	Other
1		OTH	000187093	>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N		
2		OTH	320375153	>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N		
3		OTH	000187137	>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N		
4		OTH	000187113	>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N		

VETERINARY CERTIFICATION - I certify, as an accredited veterinarian that the above described animals have been inspected by me and that they are not showing signs of infectious, contagious and/or communicable disease (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.		OFFICIAL OFFICE USE ONLY	
SIGNATURE 	NAME Horatiu Vinerean	STATE OF LICENSE FL	
PHONE 3053789585	ADDRESS 16450 SW 180th Street	LICENSE# VM11076	
E-MAIL sales@wwprimates.com	Miami	FL	33187
DATE Nov 09 2023	USDA ACCR.# 038294		



OFFICIAL CERTIFICATE OF VETERINARY INSPECTION

CERTIFICATE NUMBER

58-038294-360199-3

Name of Consignor/Owner			Worldwide Primates, Inc			Name of Consignee/Owner			UTMB			Vet Name: Horatiu Vinerean			# in Movement			0			Date			Nov 09 2023		
Line #	Qty	Species	OFFICIAL/FEDERAL EAR TAG # REGISTRATION TATTOO OR OTHER PERMANENT IDENTIFICATION *** You may place up to four unique animal identifiers with a comma between each entry ***			Age	Breed	Sex	Bruc Vac Tatto o	Test Date	Test	Accession #	Result +/-	Lab	Other											
5		OTH	000187020			>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N													
6		OTH	000071763			>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N													
7		OTH	320560797			>3 Y	Callithrix jacchus	Female		10/19/2023	TB test	453X	N													
8		OTH	320560795			>3 Y	Callithrix jacchus	Male		10/19/2023	TB test	453X	N													
9		OTH	320481929			>3 Y	Callithrix jacchus	Male		10/19/2023	TB test	453X	N													
10		OTH	000187094			>3 Y	Callithrix jacchus	Male		10/19/2023	TB test	453X	N													
11		OTH	000187141			>3 Y	Callithrix jacchus	Male		10/19/2023	TB test	453X	N													
12		OTH	320560798			>3 Y	Callithrix jacchus	Male		10/19/2023	TB test	453X	N													
13		OTH	320560777			>3 Y	Callithrix jacchus	Male		10/19/2023	TB test	453X	N													



Texas Animal Health Commission
2105 Kramer Ln
PO Box 12966
Austin, TX 78711
Phone: 512-719-0700
Fax: 512-719-0729

<http://www.tahc.state.tx.us/regs/entry.html>

CERTIFICATE OF VETERINARY INSPECTION

Contact State of Destination for Movement Requirements and Certificate Validity
FOR FOREIGN SHIPMENTS (Outside United States or Leaving United States) USE FEDERAL FORM
For Interstate Travel - Certificate Valid for 30 days from Inspection

CERTIFICATE NUMBER

24-TX-21605359

INSPECTION DATE	ISSUE DATE	ENTRY PERMIT NUMBER	BRAND INSPECTION NUMBER & ISSUE DATE
2024-03-12	2024-03-19	N/A	

ORIGIN OF SHIPMENT	CONSIGNOR, PRESENT OWNER OF SHIPMENT	DESTINATION OF SHIPMENT	CONSIGNEE, NEW OWNER OF SHIPMENT	CARRIER, TRANSPORTER
Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	Northern Biomedical Research 1210 Pontaluna Spring Lake, MI 49456 Phone: 231-759-2333 PIN/LID: /	Northern Biomedical Research 1210 Pontaluna Spring Lake, MI 49456 Phone: 231-759-2333 PIN/LID: /	Envigo Envigo 2541 Daniels Street Madison, WI 53718 Phone: 608/556-3358 PIN/LID: /


SPECIES - NUMBER IN SHIPMENT	PURPOSE(S) OF MOVEMENT	CARRIER TYPE	HERD STATUS NUMBER	HERD FREE FOR	CURRENT STATE/AREA STATUS
Cynomolgus () - 13 animals	Sale	Truck/Trailer			

REMARKS/ADDITIONAL CERTIFICATION STATEMENTS
Shipping Date: 2024-03-19

Name: Primates Age: 29-30 months Color: brown Gender: Multiple Genders (Mixed) Breed: Primates Head Count: 13

Official ID Types: Animal Id, Sex IDs: FR444D, F BC226B, F FR1123A, F NR141A, F NV455B, M NR225A, M FR265A, M NV472A, M FR923B, M UG698B, M BC811A, M FR983A, M AP640E, M
--

Remarks: Order#17784 TB placed on 05Mar24 TB Negative on 08Mar24 Lot#454X

OWNER / AGENT STATEMENT	VETERINARIAN'S SIGNATURE:	Pablo Hidalgo
The animals in this shipment are those certified to and listed on this certificate.	This is a legally binding equivalent of a handwritten signature.	925 County Road 381 Alice, TX 78332 Phone: 361-661-6111
Signature _____ Date _____		
OFFICIAL USE ONLY The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.	VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.	License Number and State: 13446 - TX National Accreditation Number: 073564

Michigan Department of
AGRICULTURE
& Rural Development
Reviewed by Nicole Ballreich
Electronic Certificate

March 29, 2024

RECEIVED

By Nicole Ballreich at 2:29 pm, Mar 29, 2024



Texas Animal Health Commission
2105 Kramer Ln
PO Box 12966
Austin, TX 78711
Phone: 512-719-0700
Fax: 512-719-0729

<http://www.tahc.state.tx.us/regs/entry.html>

CERTIFICATE OF VETERINARY INSPECTION

Contact State of Destination for Movement Requirements and Certificate Validity
FOR FOREIGN SHIPMENTS (Outside United States or Leaving United States) USE FEDERAL FORM
For Interstate Travel - Certificate Valid for 30 days from Inspection

CERTIFICATE NUMBER

24-TX-21605372

INSPECTION DATE	ISSUE DATE	ENTRY PERMIT NUMBER	BRAND INSPECTION NUMBER & ISSUE DATE
2024-03-12	2024-03-19	N/A	

ORIGIN OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /		CONSIGNOR, PRESENT OWNER OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /		DESTINATION OF SHIPMENT Northern Biomedical Research 1210 Pontaluna Spring Lake, MI 49456 Phone: 231-759-2333 PIN/LID: /		CONSIGNEE, NEW OWNER OF SHIPMENT Northern Biomedical Research 1210 Pontaluna Spring Lake, MI 49456 Phone: 231-759-2333 PIN/LID: /		CARRIER, TRANSPORTER Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /			
SPECIES - NUMBER IN SHIPMENT Cynomolgus () - 9 animals		PURPOSE(S) OF MOVEMENT Sale		CARRIER TYPE Truck/Trailer		HERD STATUS NUMBER		HERD FREE FOR		CURRENT STATE/AREA STATUS	

REMARKS/ADDITIONAL CERTIFICATION STATEMENTS

Shipping Date: 2024-03-19

Name: Primates | Age: 28-29 months | Color: brown | Gender: Multiple Genders (Mixed) | Breed: Primates | Head Count: 9

Official ID Types: Animal Id, Sex | IDs:

EC390A, F | UG455B, F | MB551A, F | BC864A, F | SB147D, M | SB313B, M | VL252B, M | MB295B, M | FR540A, M

Remarks: Order#17781 TB placed on 26Feb24 TB Negative on 29Feb24 Lot#454X

OWNER / AGENT STATEMENT	VETERINARIAN'S SIGNATURE:	Pablo Hidalgo
The animals in this shipment are those certified to and listed on this certificate.	This is a legally binding equivalent of a handwritten signature.	925 County Road 381 Alice, TX 78332 Phone: 361-661-6111
Signature _____ Date _____	 Pablo Hidalgo 2024-03-19 08:14:48 CDT	License Number and State: 13446 - TX National Accreditation Number: 073564
OFFICIAL USE ONLY	VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.	
The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.		



Reviewed by Nicole Ballreich
Electronic Certificate

March 29, 2024

RECEIVED

By Nicole Ballreich at 2:30 pm, Mar 29, 2024



Texas Animal Health Commission
2105 Kramer Ln
PO Box 12966
Austin, TX 78711
Phone: 512-719-0700
Fax: 512-719-0729

<http://www.tahc.state.tx.us/regs/entry.html>

CERTIFICATE OF VETERINARY INSPECTION

Contact State of Destination for Movement Requirements and Certificate Validity
FOR FOREIGN SHIPMENTS (Outside United States or Leaving United States) USE FEDERAL FORM
For Interstate Travel - Certificate Valid for 30 days from Inspection

CERTIFICATE NUMBER

24-TX-21920553

INSPECTION DATE	ISSUE DATE	ENTRY PERMIT NUMBER	BRAND INSPECTION NUMBER & ISSUE DATE
2024-05-03	2024-05-07	24-131	

ORIGIN OF SHIPMENT Charles River Laboratories 305 Almeda Genoa Road Houston, TX 77047 Harris County Phone: 713-433-5845 PIN/LID: /		CONSIGNOR, PRESENT OWNER OF SHIPMENT Charles River Laboratories 305 Almeda Genoa Road Houston, TX 77047 Harris County Phone: 713-433-5845 PIN/LID: /		DESTINATION OF SHIPMENT Heather Gengo 34200 Doctors Hammock Rd Immokalee, FL 34142 Phone: 305-378-9585 PIN/LID: /		CONSIGNEE, NEW OWNER OF SHIPMENT Heather Gengo 34200 Doctors Hammock Rd Immokalee, FL 34142 Phone: 305-378-9585 PIN/LID: /		CARRIER, TRANSPORTER JKL Secure Freight PO Box 18950 Reno, NV 89511 Phone: 775-461-3631 PIN/LID: /			
SPECIES - NUMBER IN SHIPMENT macaca Fascicularis () - 113 animals		PURPOSE(S) OF MOVEMENT Primates received will be used for permitted purposes		CARRIER TYPE Truck/Trailer		HERD STATUS NUMBER		HERD FREE FOR		CURRENT STATE/AREA STATUS	
REMARKS/ADDITIONAL CERTIFICATION STATEMENTS USDA License 14-R-0144 To my knowledge, the animal(s) described below and on continuation sheet(s) if applicable, originated from an area not quarantined for rabies and has/have not been exposed to rabies Shipping Date: 2024-05-08											

Name: WWP | **Age:** 5-6yrs | **Color:** | **Gender:** Multiple Genders (Mixed) | **Breed:** Cynomolgus | **Head Count:** 113

Official ID Types: Tattoo, Gender, Last TBT Date | **IDs:**

1759, F, 4/22/2024 | 1758, F, 4/22/2024 | 1738, F, 4/22/2024 | 1726, F, 4/22/2024 | 1707, F, 4/22/2024 | 1706, F, 4/22/2024 | 1705, F, 4/22/2024 | 1651, F, 4/22/2024 | 1618, F, 4/22/2024 | 1592, F, 4/22/2024 | 1585, F, 4/22/2024 | 1562, F, 4/22/2024 | 1551, F, 4/22/2024 | 1534, F, 4/22/2024 | 1531, F, 4/22/2024 | 1523, F, 4/22/2024 | 1518, F, 4/22/2024 | 1517, F, 4/22/2024 | 1503, F, 4/22/2024 | 1496, F, 4/22/2024 | 1494, F, 4/22/2024 | 1490, F, 4/22/2024 | 1488, F, 4/22/2024 | 1483, F, 4/22/2024 | 1115, F, 4/22/2024 | 1067, F, 4/22/2024 | 1058, F, 4/22/2024 | 1052, F, 4/22/2024 | 1050, F, 4/22/2024 | 1048, F, 4/22/2024 | 1012, F, 4/22/2024 | 1011, F, 4/22/2024 | 1003, F, 4/22/2024 | 1000, F, 4/22/2024 | 0997, F, 4/22/2024 | 0995, F, 4/22/2024 | 0968, F, 4/22/2024 | 0876, F, 4/22/2024 | 0874, F, 4/22/2024 | 0854, F, 4/22/2024 | 0853, F, 4/22/2024 | 0850, F, 4/22/2024 | 0813, F, 4/22/2024 | 0811, F, 4/22/2024 | 0802, F, 4/22/2024 | 0781, F, 4/22/2024 | 0697, F, 4/22/2024 | 0622, F, 4/22/2024 | 0606, F, 4/22/2024 | 0474, F, 4/22/2024 | 0452, F, 4/22/2024 | 0445, F, 4/22/2024 | 0333, F, 4/22/2024 | 0298, F, 4/22/2024 | 0016, F, 4/22/2024 | 0015, F, 4/22/2024 | 1766, M, 4/22/2024 | 1762, M, 4/22/2024 | 1756, M, 4/22/2024 | 1747, M, 4/22/2024 | 1739, M, 4/22/2024 | 1737, M, 4/22/2024 | 1734, M, 4/22/2024 | 1729, M, 4/22/2024 | 1721, M, 4/22/2024 | 1719, M, 4/22/2024 | 1714, M, 4/22/2024 | 1708, M, 4/22/2024 | 1703, M, 4/22/2024 | 1701, M, 4/22/2024 | 1699, M, 4/22/2024 | 1691, M, 4/22/2024 | 1688, M, 4/22/2024 | 1679, M, 4/22/2024 | 1677, M, 4/22/2024 | 1672, M, 4/22/2024 | 1671, M, 4/22/2024 | 1669, M, 4/22/2024 | 1667, M, 4/22/2024 | 1657, M, 4/22/2024 | 1647, M, 4/22/2024 | 1632, M, 4/22/2024 | 1611, M, 4/22/2024 | 1610, M, 4/22/2024 | 1598, M, 4/22/2024 | 1586, M, 4/22/2024 | 1574, M, 4/22/2024 | 1528, M, 4/22/2024 | 1522, M, 4/22/2024 | 1519, M, 4/22/2024 | 1511, M, 4/22/2024 | 1504, M, 4/22/2024 | 1482, M, 4/22/2024 | 1480, M, 4/22/2024 | 1479, M, 4/22/2024 | 1063, M, 4/22/2024 | 1061, M, 4/22/2024 | 0884, M, 4/22/2024 | 0882, M, 4/22/2024 | 0855, M, 4/22/2024 | 0806, M, 4/22/2024 | 0790, M, 4/22/2024 | 0786, M, 4/22/2024 | 0607, M, 4/22/2024 | 0567, M, 4/22/2024 | 0508, M, 4/22/2024 | 0415, M, 4/22/2024 | 0331, M, 4/22/2024 | 0326, M, 4/22/2024 | 0070, M, 4/22/2024 | 0065, M, 4/22/2024 | 0020, M, 4/22/2024 | 0011, M, 4/22/2024

Remarks:

Tests

Name	Type	Lab	Test Date	Accession	Result Date	Result
Tuberculosis	454X		2024-04-22		2024-04-25	Negative



Texas Animal Health Commission
2105 Kramer Ln
PO Box 12966
Austin, TX 78711
Phone: 512-719-0700
Fax: 512-719-0729

<http://www.tahc.state.tx.us/regs/entry.html>

CERTIFICATE OF VETERINARY INSPECTION

Contact State of Destination for Movement Requirements and Certificate Validity
FOR FOREIGN SHIPMENTS (Outside United States or Leaving United States) USE FEDERAL FORM
For Interstate Travel - Certificate Valid for 30 days from Inspection

CERTIFICATE NUMBER

24-TX-21920553

INSPECTION DATE 2024-05-03	ISSUE DATE 2024-05-07	ENTRY PERMIT NUMBER 24-131	BRAND INSPECTION NUMBER & ISSUE DATE 1
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OWNER / AGENT STATEMENT The animals in this shipment are those certified to and listed on this certificate. Signature _____ Date _____	VETERINARIAN'S SIGNATURE: This is a legally binding equivalent of a handwritten signature. <i>Serena Young</i> Serena Young 2024-05-07 15:11:38 CDT	Serena Young 305 Alameda-Genoa Road Houston, TX 77047 Phone: 240-529-0503 License Number and State: 18850 - TX National Accreditation Number: 056286
OFFICIAL USE ONLY The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.	VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.	



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CERTIFICATE NUMBER

24-TX-22504911

INSPECTION DATE 2024-09-11	ISSUE DATE 2024-09-16	ENTRY PERMIT NUMBER 35CT06244-BP6	BRAND INSPECTION NUMBER & ISSUE DATE
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ORIGIN OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	CONSIGNOR, PRESENT OWNER OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	DESTINATION OF SHIPMENT Labcorp Early Development Labs Inc. 3301 Kinsman Blvd. Madison, WI 53704 Phone: 608-310-2517 PIN/LID: /	CONSIGNEE, NEW OWNER OF SHIPMENT Labcorp Early Development Labs Inc. 3301 Kinsman Blvd. Madison, WI 53704 Phone: 608-310-2517 PIN/LID: /	CARRIER, TRANSPORTER Envigo RMS LLC Envigo RMS LLC 2541 Daniels Street Madison, WI 53718 Phone: 608/556-3358 PIN/LID: /
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SPECIES - NUMBER IN SHIPMENT Cynomolgus () - 4 animals	PURPOSE(S) OF MOVEMENT Transfer	CARRIER TYPE Truck/Trailer	HERD STATUS NUMBER	HERD FREE FOR	CURRENT STATE/AREA STATUS
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REMARKS/ADDITIONAL CERTIFICATION STATEMENTS

Shipping Date: 2024-09-16

Name: Primates | Age: 34-37 months | Color: Brown | Gender: Multiple Genders (Mixed) | Breed: Primates | Head Count: 4

Official ID Types: Animal Id, Sex | IDs:

A21125, M | A21189, M | A21106, F | A21087, F

Remarks: Order#17878 TB placed on 03Sep24 TB Negative on 06Sep24 Lot#457X

Brand Description: 74-B-0332 / Order# 17878

OWNER / AGENT STATEMENT The animals in this shipment are those certified to and listed on this certificate. Signature _____ Date _____	VETERINARIAN'S SIGNATURE: This is a legally binding equivalent of a handwritten signature. <i>Paul Makidon, DVM, PhD, DACLAM</i> Paul Makidon 2024-09-16 07:18:29 CDT	Paul Makidon 925 County Road 381 Alice, TX 78332 Phone: 361-661-6111 License Number and State: 18199 - TX National Accreditation Number: 051727
OFFICIAL USE ONLY The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.	VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.	



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For Interstate Travel - Certificate Valid for 30 days from Inspection

CERTIFICATE NUMBER

24-TX-22505363

INSPECTION DATE 2024-09-11	ISSUE DATE 2024-09-16	ENTRY PERMIT NUMBER 35CT06244-BP6	BRAND INSPECTION NUMBER & ISSUE DATE
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ORIGIN OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	CONSIGNOR, PRESENT OWNER OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	DESTINATION OF SHIPMENT Labcorp Early Development Labs Inc. 3301 Kinsman Blvd. Madison, WI 53704 Phone: 608-310-2517 PIN/LID: /	CONSIGNEE, NEW OWNER OF SHIPMENT Labcorp Early Development Labs Inc. 3301 Kinsman Blvd. Madison, WI 53704 Phone: 608-310-2517 PIN/LID: /	CARRIER, TRANSPORTER Envigo RMS LLC Envigo RMS LLC 2541 Daniels Street Madison, WI 53718 Phone: 608/556-3358 PIN/LID: /
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SPECIES - NUMBER IN SHIPMENT Cynomolgus () - 14 animals	PURPOSE(S) OF MOVEMENT Transfer	CARRIER TYPE Truck/Trailer	HERD STATUS NUMBER	HERD FREE FOR	CURRENT STATE/AREA STATUS
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REMARKS/ADDITIONAL CERTIFICATION STATEMENTS Shipping Date: 2024-09-16
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Name: Primates Age: 69-88 Months Color: Brown Gender: Male Breed: Primates Head Count: 14

Official ID Types: Animal Id, Sex IDs: B10186, M B10304, M B07799, M BB06223, M BB06472, M B07767, M B07876, M B06279, M B07699, M B06396, M B14733, M B10430, M B06499, M B13266, M

Remarks: Order#17794 TB placed on 20Aug24 TB Negative on 23Aug24 Lot#457X Brand Description: 74-B-0332 / Order# 17794
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OWNER / AGENT STATEMENT The animals in this shipment are those certified to and listed on this certificate. Signature _____ Date _____	VETERINARIAN'S SIGNATURE: This is a legally binding equivalent of a handwritten signature. <i>Paul Makidon, DVM, PhD, DACLAM</i> Paul Makidon 2024-09-16 08:57:21 CDT	Paul Makidon 925 County Road 381 Alice, TX 78332 Phone: 361-661-6111 License Number and State: 18199 - TX National Accreditation Number: 051727
OFFICIAL USE ONLY The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.	VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.	



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CERTIFICATE NUMBER

24-TX-22504957

INSPECTION DATE 2024-09-11	ISSUE DATE 2024-09-16	ENTRY PERMIT NUMBER 35CT06244-BP6	BRAND INSPECTION NUMBER & ISSUE DATE
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ORIGIN OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	CONSIGNOR, PRESENT OWNER OF SHIPMENT Envigo Global Services Inc 925 CR 381 Alice, TX 78332 Phone: 361-661-6014 PIN/LID: /	DESTINATION OF SHIPMENT Labcorp Early Development Labs Inc. 3301 Kinsman Blvd. Madison, WI 53704 Phone: 608-310-2517 PIN/LID: /	CONSIGNEE, NEW OWNER OF SHIPMENT Labcorp Early Development Labs Inc. 3301 Kinsman Blvd. Madison, WI 53704 Phone: 608-310-2517 PIN/LID: /	CARRIER, TRANSPORTER Envigo RMS LLC Envigo RMS LLC 2541 Daniels Street Madison, WI 53718 Phone: 608/556-3358 PIN/LID: /
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SPECIES - NUMBER IN SHIPMENT Cynomolgus () - 39 animals	PURPOSE(S) OF MOVEMENT Transfer	CARRIER TYPE Truck/Trailer	HERD STATUS NUMBER	HERD FREE FOR	CURRENT STATE/AREA STATUS
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REMARKS/ADDITIONAL CERTIFICATION STATEMENTS

Shipping Date: 2024-09-16

Name: Primates | Age: 48-92 Months | Color: Brown | Gender: Female | Breed: Primates | Head Count: 39

Official ID Types: Animal Id, Sex | IDs:

B15439, F | B15678, F | B15267, F | B15468, F | B15383, F | B15463, F | B15195, F | B15443, F | B18316, F | B15213, F | B18461, F | B18230, F | B18477, F | B08042, F | B07987, F | B18571, F | B07396, F | B15187, F | B18749, F | B10850, F | B08126, F | B07611, F | B14166, F | B08027, F | B15475, F | B15380, F | B15527, F | B18528, F | B15357, F | B15415, F | B15368, F | B09093, F | B08090, F | B18246, F | B18551, F | B07384, F | B04151, F | B15413, F | B18529, F

Remarks: Order#17885 TB placed on 05Sep24 TB Negative on 08Sep24 Lot#457X

Brand Description: 74-B-0332 / Order# 17885

OWNER / AGENT STATEMENT The animals in this shipment are those certified to and listed on this certificate. Signature Date	VETERINARIAN'S SIGNATURE: This is a legally binding equivalent of a handwritten signature. <i>Paul Makidon, DVM, PhD, DACLAM</i> Paul Makidon 2024-09-16 08:24:25 CDT	Paul Makidon 925 County Road 381 Alice, TX 78332 Phone: 361-661-6111
OFFICIAL USE ONLY The Veterinarian issuing this certificate is accredited and has been authorized to inspect animals and issue certificates.	VETERINARIAN CERTIFICATION - I certify, as an accredited Veterinarian, that the above animals have been inspected by me and that they are not showing signs of infectious, contagious, and/or communicable disease, (except where noted). The vaccinations and results of tests are indicated on the certificate. To the best of my knowledge, the animals listed on this certificate meet the state of destination and federal interstate requirements. No further warranty is made or implied.	License Number and State: 18199 - TX National Accreditation Number: 051727