



Inspection Report

Altasciences Preclinical Seattle LLC
6605 Merrill Creek Parkway
Everett, WA 98203

Customer ID: **505169**
Certificate: **91-R-0075**
Site: 001
ALTASCIENCES PRECLINICAL
SEATTLE LLC

Type: ROUTINE INSPECTION
Date: 08-FEB-2022

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

The IACUC reviewed and approved Protocol 104221-10, which omitted pertinent characteristics of a test article to be delivered via subcutaneous injection. Beagles on this protocol were noted to vocalize and exhibit signs of pain upon injection of the test article. Upon testing, it was determined that the pH of the test article was 4. The vocalizing and signs of pain did not occur after adjustment of the pH to 6.5-7.5 for subsequent administrations of the test article.

It is important that proposals to conduct animal activity contain enough detail for the IACUC to determine if the likelihood of pain or discomfort exists and to consider if/how pain and discomfort might be limited to that which is unavoidable for the conduct of scientifically valuable research. The registrant must ensure that all protocols reviewed by the IACUC contain a complete description of use, including pertinent information regarding test article characteristics and routes of administration, in order to help anticipate and, if possible, mitigate preventable pain or discomfort.

TO BE CORRECTED BY 03/01/2022.

2.31(e)(4)

Institutional Animal Care and Use Committee (IACUC).

The IACUC reviewed and approved Protocol 47321-34, which contained information indicating the likelihood for pain caused by experimental procedures but did not contain a literature search for alternatives, provisions for humane

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endpoints, or specific measures to treat or mitigate pain and suffering. Two beagles, identified as #4518731 and #4527349, developed oral ulcerations, inappetance and lethargy which required veterinary intervention. It is important that proposals to conduct animal activity contain a description of the procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals. The registrant must ensure that all protocols reviewed by the IACUC contain this complete description to enable the Committee to properly review and deliberate the proposed activities.

TO BE CORRECTED BY 03/01/2022.

2.33(b)(3)

Attending veterinarian and adequate veterinary care.

- One female Cynomolgus macaque (tattoo 212186) has complete hair loss on the upper back and half of the lower back as well as patches of alopecia on the head and thighs. The alopecia covers approximately 65% of the animal's body.
- One male Cynomolgus macaque (tattoo 211819) has significant alopecia to the lower back and lateral torso as well as small patches of alopecia on the legs and arms. The alopecia covers approximately 75% of the animal's body.
- One female Cynomolgus macaque (tattoo 8054293312) has hair loss over most of its head as well as on its upper left arm. The left leg has diffuse alopecia and the right leg is completely hairless. The alopecia covers approximately 35% of the animal's body.
- One Cynomolgus macaque (tattoo 211987) has alopecia covering its entire body.

The facility's guidelines for alopecia require that any animal showing greater than 25% alopecia be reported for behavioral assessment. There were no medical or behavioral records showing that the alopecia in these animals was observed by caretakers or reported to the veterinary or behavioral staff.

Additionally, the various components of the facility's veterinary recordkeeping system are disjointed, making it very difficult

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for inspectors and the facility's veterinarians to find, piece together, and completely follow individual cases and notes to determine the status and final outcomes. Although the new electronic record system was introduced and is in use with plans for further improvements, it currently is not functioning in a practical manner. The system does not efficiently facilitate vital communications between the various animal husbandry, behavioral and veterinary staff.

Effective daily observations allow the facility to assess the health of the animals, including any injuries, behavioral problems, or compatibility issues. Timely reporting of new conditions is important to prevent worsening of any problems and to ensure proper care. The facility must observe all animals daily and then ensure an effective mechanism of direct and frequent communication with the attending veterinarian so that timely and accurate information on problems of health, behavior, and well-being are conveyed and so that the medical conditions of the animals can be evaluated and documented by the veterinarian. A corrective plan with a reasonable timeline for completion must be developed and initiated.

TO BE CORRECTED BY 03/01/2022.

3.13(a)

Veterinary care for dogs.

The written program of veterinary care (PVC) is incomplete. There is no plan for sampling dogs for blood parasites or external/internal parasites, including the number of animals to be sampled. There is also no treatment plan for blood or intestinal/external parasites, and the details and schedule of monitoring for and addressing any issues with the haircoat, skin, eyes and teeth are not included. In addition, the current PVC states that physical examinations by the veterinarian will occur, "At least every 12 months +/- one month." Parasites are a common cause of disease in dogs and if not detected and properly treated, can lead to serious illness and even death. Without a schedule for monitoring the haircoat, skin, eyes and teeth, problems may go unnoticed and not be treated quickly, leading to discomfort or worsening of the condition. Prolonging the interval between hands-on physical examinations by the veterinarian can delay the detection

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and treatment of physical or behavioral problems that could arise and go unnoticed by non-veterinarian staff.

The facility must develop and follow a complete, appropriate program of veterinary care for dogs. The program of veterinary care must include plans for sampling and treatment for blood parasite and internal/external parasites, specific plans for monitoring of the haircoat, skin, eyes and teeth, and provision of a hands-on physical examination by the veterinarian no less than every 12 months. The missing information must be added to the program of veterinary care to ensure the animals are receiving adequate veterinary care.

TO BE CORRECTED BY 03/11/2022.

3.80(b)(1)

Primary enclosures.

One male Cynomolgus macaque (SSAN 3005) is being housed in a cage that does not meet minimum space requirements. The cage measurements meet the requirements for Group 3 nonhuman primates; however, based on his weight, this macaque should be housed in caging that meets minimum requirements for Group 4 nonhuman primates. Weight records for this animal show that he has weighed above 10 kilograms since early January and his most recent weight on 2/6/2022 was 10.27 kilograms. This animal was moved into a larger cage during the inspection.

Housing that does not meet minimum space requirements can cause stress to the animal and limit natural behaviors.

Housing for all nonhuman primates must meet the minimum space requirements outlined in 3.80(b)(1).

TO BE CORRECTED BY 02/21/2022.

3.84(a)

Cleaning, sanitization, housekeeping, and pest control.

In one of the facility's rooms, 5 of the 12 built-in holding enclosures containing Cynomolgus macaques have a solid, brown to white material accumulated on the inside and outside of the enclosure walls in numerous places. Because these housing pens are built-in and non-mobile, they cannot be cleaned through the cage wash. The husbandry supervisor

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confirmed that the last sanitization of the caging in that room was documented as being performed the day prior and agreed that it appeared the cleaning and sanitation had not been done well based on the amount and character of the accumulation present at the time of inspection. The supervisor ordered the enclosures be re-cleaned and sanitized, which was completed at the time of inspection.

Accumulation of fecal material, food waste and other debris encourages soiling of the animals and contamination of food. All indoor primary enclosures for non-human primates must be cleared from excreta and food waste as often as necessary to prevent accumulation of feces and waste, to prevent the non-human primates from becoming soiled, and to reduce disease hazards, insects, pests and odors.

TO BE CORRECTED BY 02/21/2022.

This inspection was conducted from 2/8/2022 to 2/10/2022 and the exit interview was conducted on 2/10/2022 with facility representatives.

Additional Inspectors:

KATIE PRICE, VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
505169	91-R-0075	001	ALTASCIENCES PRECLINICAL SEATTLE LLC	08-FEB-2022

Count	Scientific Name	Common Name
001915	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000018	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000227	<i>Canis lupus familiaris</i>	DOG ADULT
002160	Total	