



## Inspection Report

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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: 14-JUL-2021

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### 2.32(a) Critical

#### Personnel qualifications.

Four female cynomolgus macaques approximately 2 years of age were given an improper dose of a test article which resulted in euthanasia of the animals. An IACUC approved protocol involving cynomolgus macaques called for an initial dose of a test article to be given at 30 mg/kg and lowered to 15 mg/kg on day 15; however, on day 15 of the study, four cynomolgus macaques were given the original 30 mg/kg dose rather than the intended reduced dose amount of 15 mg/kg. The animals were given the incorrect dose due to a technician error. The dosing error was immediately discovered, and a veterinarian was notified. Due to the potential adverse effects of the high dose, veterinary staff elected to euthanize the four animals to prevent unnecessary pain and discomfort. The animals were euthanized and sent to necropsy on day 18.

Deviations from a protocol can result in unnecessary pain or death. It is the responsibility of the research facility to ensure that all personnel involved in animal care, treatment, and use are qualified to perform their duties to preclude such adverse events.

Correct from this time forward.

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**Prepared By:** DIANE FORBES

USDA, APHIS, Animal Care

**Date:**

04-NOV-2021

**Title:** VETERINARY MEDICAL  
OFFICER

**Received by Title:** Attending Veterinarian

**Date:**

04-NOV-2021



## Inspection Report

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### 2.33(b)(1) Critical

#### Attending veterinarian and adequate veterinary care.

One adult domestic pig had a broken limb and received inadequate veterinary care. On 21 Oct 2020 a 1-year old female Yorkshire pig (#1111), weighing 44.57 kg, was found not bearing weight on her left hindlimb. Staff reported the animal preferred to be in a recumbent position and was reluctant to stand. The initial veterinary exam confirmed the lameness but found no wounds, bruising, or apparent trauma. The animal was placed on pain medication and when lameness didn't improve, the pain medication was increased 2 days later. On 26 Oct 2020 the animal was still non-weight bearing and there was mild swelling of the limb; moderate inflammation above the stifle was observed 4 days later. On 4 Nov 2020, a Computed Tomography (CT) scan revealed an "oblique fracture to the left femur with bony callus formation". It took 15 days to obtain imaging diagnostics on this animal. The pig remained on the study until it was completed and was euthanized on 11 Nov 2020.

The research facility must maintain a program of veterinary care that provides adequate staffing, facilities, equipment, and services to ensure proper monitoring and diagnostics of animals and immediate intervention is required to prevent a serious animal welfare issue. Failure to provide adequate personnel and resources could negatively impact animal welfare.

Correct from this time forward by ensuring that there is adequate staffing, facilities, equipment, and services so that all animals utilized in study procedures are adequately diagnosed and treated.

### 2.38(f)(1) Critical

#### Miscellaneous.

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A male cynomolgus macaque approximately 2 years of age sustained an arm fracture during nasogastric dosing of the test article. The fracture occurred on 5 Mar 2021 while positioning the animal within the procedure cage. The employee manually restrained the non-sedated animal by grasping the macaque by the right forearm to position the animal. The animal struggled during the physical restraint, which resulted in a mid-diaphyseal fracture of the radius and ulna. According to the facility, the torque applied by the employee to the animal's limb during positioning most likely resulted in this injury.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

Corrective and preventative actions have been instituted by the facility. These include modification of the procedure to prohibit grasping of the animal's arm below the elbow. The procedure cage has also been modified to minimize animal risk when used for smaller nonhuman primates. And finally, the facility is providing increased oversight and a more experienced staff to conduct dosing.

Correct from this time forward.

### **3.125(a) Critical Facilities, general.**

The flooring in eight pig enclosures housing eight adult domestic pigs (1 pig per enclosure) was determined to be structurally unsafe. The facility technicians stated they saw the metal grates (26 x 47 inches) in multiple enclosures displaced in the mornings and repositioned the grates without reporting this as a maintenance problem. In reference to an adult female Yorkshire pig (#1111) who sustained a broken femur, the observation log on 05 Nov 2020 for this individual

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pig stated that the animal was "Laying down unwilling to get up. Possible no access to water grate was up blocking lixit."

The facility technicians eventually verbally conveyed to the attending veterinarian on 13 Nov 2020 that some of the pigs would lift the grate edges with their snout and lift the metal grates off the floor. The veterinary staff was not aware of the structural deficiency in the observation log which was reported on 05 Nov 2020 and it is unknown when exactly these pigs began displacing the metal grates in their enclosures.

Pig enclosures must be constructed and maintained to protect the health and well-being of the animals. The enclosures must also be constructed of appropriate material and strength for the animals involved to prevent injury.

The cages that allow animals to remove the flooring have been removed from use.

To be corrected immediately.

This inspection and exit interview were conducted with the facility representatives.

Additional Inspectors:

NAOMI SISMOUR, 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	14-JUL-2021

Count	Scientific Name	Common Name
000002	<i>Macaca mulatta</i>	RHESUS MACAQUE
001879	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000016	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000184	<i>Canis lupus familiaris</i>	DOG ADULT
002081	<b>Total</b>	