United States Department of Agriculture Animal and Plant Health Inspection Service

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Inspection Report

Abbiotec L L C 7985 Dunbrook Road, Ste A San Diego, CA 92126

Customer ID: 329789

> Certificate: 93-R-0569

> > Site: 001 ABBIOTEC, LLC

ROUTINE INSPECTION Type:

Date: 02-AUG-2017

2.31(d)(1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The Rabbit antibody production protocol states that 25 mls of blood will be collected to produce 12-15 mls of serum. Upon review of the bleed schedules, 40 mls of blood were still listed on the project documentation. Individual animal bleed records and weights were not available to confirm that the facility was following the Institutional Animal Care and Use Committee (IACUC) approved protocol. Additional records reviewed were not clear whether the volume collected for a project was serum or whole blood.

The IACUC has not sufficiently reviewed the activities involving animals and departures from the protocol have occurred without approval. The activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee, including monitoring the weight and hematocrit of rabbits when 15% of blood volume is collected to ensure "its health is being maintained". The IACUC has the responsibility to ensure evaluation of procedures that may cause more than momentary pain or distress. The increase in blood volume taken could result in a serious impact on the health of the animals. After approving a protocol, the IACUC should determine that procedures involving animals are conducted in accordance with the protocol and will avoid or minimize discomfort, distress, and pain to the animals unless acceptable justification for the departure is provided in writing.

Correction date: 9 September, 2017

2.32

PERSONNEL QUALIFICATIONS.

Facility records indicate that animal activities for the rabbit antibody production protocol are conducted by a 3rd party company outsourced by the facility that maintains the rabbits. Training records for facility animal caretakers and contracted personnel directly involved in research were not available at the time of inspection. In conjunction with the vague description of blood collection and frequency in the Rabbit protocol, training records are important to ensure that the personnel have a working understanding of the procedures since they are not sufficiently documented in the protocol or Standard Operating Procedures.

Prepared By: FRANK KATHARINE, D V M USDA, APHIS, Animal Care Date:

Title: VETERINARY MEDICAL OFFICER 6091

Received by Title: SENT BY EMAIL Date: 09-AUG-2017

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It is the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties.

Training and instruction must be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facilities responsibilities.

Correction date: 9 September, 2017

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The method of humane euthanasia by the registrant for the animals (including rabbits, goats and llamas) at this facility consists of the inhalation of carbon dioxide gas without prior sedation. There is nothing written in the protocols which justifies this method, especially for the hoofstock. The 2013 AVMA Guidelines for Humane Euthanasia for rabbits state that "while CO2 is an effective method of euthanasia, its use as the sole agent in rabbits results in apparent distress to the rabbit. Premedication with sedative agents will allow for the administration of CO2 for euthanasia". Therefore, the use of CO2 alone as the sole method of euthanasia is not consistent with generally accepted methods of euthanasia for rabbits. A system that follows the currently accepted standards of humane euthanasia must be in place.

Correction date: 9 September, 2017

The animal facility inspection was conducted on August 1st, the records were inspected on August 2nd and an exit interview was conducted with the IACUC Chair.

Prepared By: FRANK KATHARINE, D V M USDA, APHIS, Animal Care Date: 09-AUG-2017

Title: VETERINARY MEDICAL OFFICER 6091

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Customer: 329789 Inspection Date: 02-AUG-17

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
329789	93-R-0569	001	ABBIOTEC, L L C	02-AUG-17

Count Scientific Name Common Name

000008 Oryctolagus cuniculus DOMESTIC RABBIT / EUROPEAN RABBIT

000008 Total