Inspection Report

Iso-Tex Diagnostics Inc.
P. O. Box 909
Friendswood, TX 77549

Customer ID: **37111**
Certificate: **74-R-0185**
Site: 001
Iso-Tex Diagnostics Inc.

Type: ROUTINE INSPECTION
Date: Jun-14-2016

2.31 (b) (3) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The unaffiliated member of the IACUC did not attend the last three IACUC meetings held on 5/18/2015, 11/19/2015 and 5/25/2016. The irregular attendance of this required member of the committee does not demonstrate representation of general community interests in the proper care and treatment of animals as intended under the Animal Welfare Act. The unaffiliated member must participate in IACUC activities to signify complete committee membership and function.

Correct by: All future IACUC meetings

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Reports of the IACUC semiannual evaluations of the facility inspections and program review have not been submitted to the Institutional Official for the last three inspections and reviews. No reports were submitted for the 5/18/15, 11/19/15 and 5/25/16 inspections and reviews. The reports shall be updated every six months upon completion of the required semiannual evaluations. Updated reports and submission to the IO is required to ensure appropriate communication is maintained between the IACUC and IO on issues of facility adherence and compliance with AWA regulations and standards.

Correct by: July 16, 2016 for submission of most recent evaluation

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Approved protocol 15-02 using rabbits describes the use of a Ketamine/Xylazine anesthetic cocktail to be administered IM or IV. Discussion with personnel conducting this procedure indicated the drug combination is actually given IP. Deviations from protocols related to minimizing pain and distress can be considered significant changes and shall be reviewed and approved by the IACUC prior to implementation. Consideration of topics for review might include appropriateness of route of drug administration according to established species guidelines.

Prepared By: MARY MOORE, D V M
MARY E MOORE, D V M USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER Inspector 1044
Date: Jun-16-2016

Received By: (b)(6),(b)(7)(c)
Title:
Date: Jun-17-2016

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Correct by: Immediate

2.31 (e) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Approved protocol 15-01 does not contain a complete description of the euthanasia method to be used. Although the protocol states the dosage of Ketamine/Xylazine combination to be given the route of administration of the drugs is not documented. The IACUC must ensure that all protocols contain the information required under the AWA including an appropriate method of euthanasia. Prior to approval the IACUC must confirm that proposed euthanasia activities are conducted using established AVMA guidelines and humane administration.

Correct by: Immediate

2.33 (a)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The most current written program of veterinary care dated June 2015 is incomplete. The information provided under the euthanasia section does not indicate which drug(s), dose or route of administration will be used for the animals at this facility. Since the PVC states that only the registrant will be performing euthanasias it is imperative that a complete description of the procedure and methods is clearly delineated. Assurance must be provided that euthanasia is conducted in accordance with AVMA guidelines.

Correct by: June 30, 2016

2.33 (b) (4)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

*Guinea pigs used under protocol 15 -01 are euthanized using a Ketamine/Xylazine injectable drug combination and is stated to be administered at three times the standard anesthetic dose. According to AVMA 2013 euthanasia guidelines the use of a dissociative anesthetic in combination with an alpha 2 adrenergic agonist should be administered at five times the anesthetic dose standard when used in laboratory animals for euthanasia.

*During discussion with personnel responsible for the above described euthanasia procedure the criteria used to confirm death in the guinea pigs after euthanasia and prior to body disposal could not be provided to this inspector. The individual was asked twice how confirmation of death was determined and no answer was given. AVMA guidelines and industry standard for humane euthanasia mandate that death must always be confirmed using established criteria.

Guidance to principal investigators and personnel involved in the care and use of animals regarding euthanasia must be provided to establish the provision for adequate veterinary care required to be maintained by research facilities. The combination of inadequate euthanasia dosages and lack of confirmation of death prior to body disposal can have painful and distressful consequences for the animals involved. The facility should review euthanasia training, methods and techniques to ensure

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humane handling of animals and adequate veterinary care regarding euthanasia that at least parallels accepted veterinary standards.

Correct by: June 30, 2016

2.36 (a)

ANNUAL REPORT.

The current (2015) annual report was signed by the facility on December 2, 2015 and received in the western regional office on March 26, 2016. A facility that uses or intends to use live animals in research shall submit an annual report to the appropriate regional office on or before December 1 of each calendar year. To comply with the regulations and requirements under the Animal Welfare Act all future annual reports shall be filed by December 1.

Correct by: All future annual report filings

The inspection was conducted with the Quality Assurance Manager and the Inventory Manager.

The exit interview was conducted in person on June 16, 2016 with the Laboratory Manager , Health Physics Specialist and Quality Assurance Manager.

Prepared By: MARY MOORE, D V M

MARY E MOORE, D V M USDA, APHIS, Animal Care **Date:**

Title: VETERINARY MEDICAL OFFICER Inspector 1044 Jun-16-2016

Received By: (b)(6),(b)(7)(c)

Date:

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