

*American Association
of
Veterinary Laboratory Diagnosticians
Accreditation Committee
Accreditation Audit Report*

Montana Veterinary Diagnostic Laboratory
Bozeman, Montana

December 3-5, 2012

NAMES OF AUDITORS

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AAVLD Accreditation Audit Report

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A. BACKGROUND AND GENERAL FINDINGS / EXECUTIVE SUMMARY

a. Overview / Current Accreditation Status

The Montana Veterinary Diagnostic Laboratory (MVDL) is a full service laboratory offering a range of diagnostic services for domestic and wild animals. The laboratory has all sections required by the American Association of Veterinary Laboratory Diagnosticians (AAVLD) Requirements. It does not offer toxicology diagnostics, and refers a range of assays to outside laboratories. The MVDL is administered as a unit under the Montana Department of Livestock (DOL) through the Board of Livestock (BOL), who is represented by their Executive Officer, Mr. Christian MacKay. Dr. A. William (Bill) Layton serves as the Director of the MVDL. Ms. Tess Moore is the Quality Manager. Dr. Layton also functions as the professional level supervisor of the Histology, Clinical Pathology, Serology, and Milk Testing sections, while the Bacteriology, Virology, and Molecular Diagnostics sections are overseen by Dr. D.J. (Jeff) Marshall, a pathologist who also performs necropsies and histopathological evaluations of necropsy and mail-in fixed tissues. Dr. Stephen Smith is the third MVDL pathologist. The Information Technology Supervisor, Mr. Jim Newhall, reports to the Board of Livestock Executive Officer through the State Information Technology Office. A total of 21 additional staff positions are identified on the MVDL Organizational Chart. The Director, Section Supervisors and Quality Manager all meet minimum and in some cases preferred qualifications as described in the AAVLD Requirements.

In FY 2011-2012, the laboratory reported a total of 278,122 laboratory tests. In the past 5 years, total testing levels increased from a 232,044 in FY08 to 297,818 in FY10, and then decreased to the current level. The increase and subsequent testing decrease results in large part to fluctuations in the brucellosis serology testing as a part of the Montana State and federal brucellosis surveillance programs in the Greater Yellowstone Area, and increased *Tritrichomonas foetus* real time PCR testing as part of the Montana bull testing surveillance program. The MVDL is a National Animal Health Laboratory Network (NAHLN) member laboratory and receives funding from USDA/APHIS/VS NAHLN that is used to support the full time Quality Manager.

The MVDL budget sources include state general funds, state livestock per capita tax, outside contract and grant funding, and laboratory fees. The total budget for FY13 is \$1,959,636. This is a decrease of \$88,531 from FY12, resulting from a decrease in both annual base adjustment and "new proposals" to the FY10 and FY11 base levels. A fee increase was requested and approved by the Board of Livestock last year. However, the Governor froze all state fee increases, so it was not implemented. Fees have not risen since 2008.

The Montana Veterinary Diagnostic Laboratory was last reviewed October 28-30, 2007 by AAVLD auditors Ron Lewis (Chair), Dave Zeman, and Barbara Powers. Prior to that visit the laboratory was provisionally accredited. Provisional accreditation was continued for one year subsequent to the 2007 site review findings, and has been continued on an annual basis by the Accreditation Committee since that time.

2012 Audit

The Montana Veterinary Diagnostic Laboratory was audited December 3-5, 2012 by AAVLD auditors Terry McElwain (Chair), Barbara Martin, and Laura Torchin. The application was complete and all required and requested quality documents were provided in advance, including the Application and the MVDL Quality Manual, Process Flow Documents, System SOPs, Auditor Checklist, Sample Case Reports, 2011 Management Review, and a newsletter. An opening meeting was conducted with available laboratory personnel on December 3. Every testing section in the laboratory was reviewed partially or in whole by the full site review team on December 3-4. A closing meeting was held on December 5. The site review team met with Dr. Layton and Ms. Moore on December 5.

Auditing was performed with reference to the AAVLD Requirements for Accreditation of a Veterinary Medical Diagnostic Laboratory, Version 6.1, the MVDL Quality Manual Version 6.1, dated November 2, 2012, and to current process flow documents, system SOPs and technical SOPs. Since the current quality management system is in revision at this time (see below), case and record audits dated prior to implementation of the current system were audited with reference to the system and technical SOP's in place at that time. Both vertical and horizontal audits were performed; internal audits (when available), nonconformances, corrective actions, records, reports and other documents were reviewed, and laboratory technical and professional staff members were interviewed. Specific nonconformances found are listed below.

The site review team met confidentially with the Board of Livestock and Dr. Marty Zaluski, State Veterinarian on December 4, 2012. Board of Livestock members present included the following individuals:

Christian Mackay, Executive Officer
Janet French (Board Chair and Beef Producer)
Brett DeBruycker (Beef Producer)
John Lehfeldt (Sheep Producer)

Four other members of the Board representing cattle (2), dairy (1), and swine (1) were not present. The site review team had a very frank and productive discussion with the Board of Livestock and State Veterinarian, who uniformly support the laboratory and recognize that the aged physical facility cannot continue to serve the laboratory and State of Montana in the future. The Board reviewed past efforts to acquire funding for a new facility, and outlined current efforts to develop a public/private partnership with the Montana State University Foundation Innovation Campus for design and construction of a new laboratory facility. The site visit team would like to express their thanks to the MVDL Director and Quality Manager for their assistance in arranging these meetings, and to the Board of Livestock and State Veterinarian for taking the time to meet with the auditors. Without exception, members of the Board of Livestock and State Veterinarian valued, were supportive and appreciative of the work of the MVDL.

Note: It was difficult to evaluate this requirement for the entire system due to the current transition occurring in the quality system. All training records are being converted to a new format, which has not been adopted or fully implemented in all sections yet. The training records were inconsistent from section to section. When the quality system was first established, there was no mechanism established to "grandfather" in the current personnel. As a result, initial competency training records did not exist for many personnel.

Response:

Requirement: "5.2.2 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing and diagnostic interpretation, and the management shall authorize only staff who are documented as qualified and competent to do testing and related work."

Nonconformance:

All sections: on new training form, supervisors are authorizing themselves as competent to perform testing and related work.

Histology: current training form is being filled out electronically. Cannot determine if supervisor actually authorized personnel to perform testing or if personnel typed in initials and printed form on their own (see SOP training record for Document ID 5.4.700.110)

Virology: unable to locate completed competency records for technician. A sheet was started with name of technician but technician was never authorized as qualified and competent.

Response:

AAVLD ER: 5.3 Accommodation and environmental conditions

Requirement: "5.3 Accommodation and environmental conditions: All aspects of the physical facilities must provide an appropriate environment for the conduct of the activities of all disciplines required for laboratory accreditation. Laboratories, offices, storage space and animal holding rooms shall be clean, maintained in good repair and be adequate in number and size for intended function of the laboratory. Adequate lighting and ventilation shall be provided. Safety, biosafety, biocontainment, and biosecurity features shall be incorporated as a part of the physical facility."

Nonconformance:

Receiving: Hood used for mixing of formalin to working dilution not certified since 12/14/2006. (Note: this equipment was labeled as out of service during site visit.)

Response:

Requirement: "5.3.2 The laboratory shall monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, radiation, humidity, airflow, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Test activities shall be stopped when the environmental conditions jeopardize the test results."

Nonconformance:

Molecular :Clean Rm Freezer range (-18 – -22 degrees). Log contained several out of range temps with no indication of action taken. (For example June 25th temp was recorded as -23 degrees C.)

Bacteriology: The form for monitoring the temperature of the Frigidare refrigerator indicated a range of 2-4.5C. The temperature was 1C on 9 days with no indication that action was taken.

Histology: The form for monitoring the temperature of Kenmore freezer indicated a low limit (-40) but not the upper limit. It was determined by the Quality Manager that the upper range was indicated on the form, but because of the font size did not print. 82 of 104 temperatures were above the acceptable high temperature with no record that action was taken.

Histology: The form for monitoring the temperature of the Kelvinator refrigerator indicated that the temperature was out of range on one day with no record that action was taken.

Receiving: The form for monitoring the temperature in the Hobart refrigerator indicated the ranges for 2-4.5C. the temperature was out of range (5C) on 3 days with no record that action was taken.

Virology: No range of acceptable temperature noted on environmental recording form for Forma Freezer 3551; as a result, all temperatures recorded other than -80C were out of range with no action taken.

Response:

Requirement: “5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.”

Nonconformance:

Milk Quality: samples being stored in same unit as positive control material and media with no measures to prevent cross-contamination (e.g. store in secondary container).

Response:

AAVLD ER: 5.4 Test methods

AAVLD ER: 5.4.1 General

Requirement: “5.4.1.2 Test methods shall be approved for use by qualified, authorized personnel, according to established procedures.”

Nonconformance:

Molecular: The validation data for a PCR for *Tritrichomonas foetus* was available, however there was no documentation that the procedure had been approved for use.

Response:

Requirement: “5.4.1.4 The laboratory shall have written instructions for all tests and related procedures used in its routine activities, the calibration and operation of all relevant equipment, and the collection, handling, transport and storage of specimens and preparation of samples for testing.”

Nonconformance:

Serology: no instructions or training record on how to perform monthly in-house calibration of ELISA reader #4050

Bacteriology: