REQUIREMENTS FOR AN ACCREDITED VETERINARY MEDICAL DIAGNOSTIC LABORATORY

AMERICAN ASSOCIATION OF VETERINARY LABORATORY DIAGNOSTICIANS, INC.

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MISSION STATEMENT

The purpose of the AAVLD accreditation program is to accredit public veterinary diagnostic laboratories in North America relative to technical and operational competence compatible with appropriate standards and to provide an administrative assessment.

OBJECTIVES OF THE ACCREDITATION PROGRAM

- To provide a mechanism for objectively accrediting veterinary diagnostic laboratories
- To continuously emphasize the importance of excellence in veterinary diagnostic service
- To periodically evaluate and modify the accreditation process
- To keep laboratories cognizant of current technological advances in diagnostic veterinary medicine
- To keep laboratories informed of the impact of legislative mandates and other regulatory actions
- To promote adequate training of specialists in diagnostic veterinary medicine
- To encourage hiring of dedicated and innovative diagnosticians with appropriate training and experience
- To encourage acquisition and maintenance of facilities suitable and adequate to provide quality services
- To promote appropriate quality system programs
- To assist veterinary diagnostic laboratories to align with applicable aspects of the current version of ISO:IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories.

1. CLASSIFICATION

1.1. There are two types of accreditation: accredited and provisionally accredited.

1.2. An accredited laboratory is one that is capable of providing a full range of diagnostic services year-round in a majority of the following essential disciplines: necropsy, histopathology, clinical pathology, bacteriology, virology, mycology, parasitology, serology and toxicology. It is mandatory that a full-service laboratory offer necropsy, histopathology, bacteriology, and virology on site. Mechanisms must exist for referral of those services not directly offered by the laboratory. The Accreditation Committee will evaluate the appropriateness of essential services referred to other laboratories.

NOTE: Bacteriology and virology disciplines may be represented by molecular diagnostic service that include identification of microbial genomes and their translated gene products (partial or whole).

1.3. A provisionally accredited laboratory is one that does not fully meet the AAVLD Accreditation Requirements. A provisionally accredited laboratory is given a period of time to correct the deficiencies noted. Provisionally accredited laboratories are required to document progress through periodic reports.

2. ADMINISTRATIVE REQUIREMENTS

2.1. Organization, Management and Personnel

2.1.1. Diagnostic laboratories reviewed for accreditation may be administered by a State/Provincial Department of Agriculture, a University, an Agricultural Experiment Station, a State/Provincial Department of Health, or by various combinations of such public institutions. The Committee does not review commercial laboratories.

2.1.2. The laboratory personnel shall be able to provide competence in all management and technical groups evaluated for accreditation. Minimum training levels are listed by laboratory position in Appendix 1, Personnel Qualifications.

2.2. Finance and Budget

2.2.1. The overall budget will be evaluated on the basis of salaries for personnel, operations, equipment, maintenance, travel, information technology, and continuing education. The laboratory shall have sufficient resources to meet the requirements for accreditation as indicated in the support for the various disciplines and the overall administrative function of the laboratory.

2.2.2. As diagnostic laboratories are a vital part of disease surveillance and monitoring, finances must be available to sustain these assignments. Since these laboratories serve the public good, surveillance resources are not intended to be self-sufficient financially and require public financial support commensurate with the public good derived.

3. ACCREDITATION PROCESS

3.1. The AAVLD Accreditation Committee will consider all written applications for an accreditation site visit from qualifying public laboratories, as described in the administrative requirements.

3.2. The AAVLD Accreditation Committee will evaluate each laboratory for compliance with its own statement of Quality Management objectives and the established criteria set by the AAVLD Accreditation Program.

3.3. Each accredited laboratory will be requested to provide an annual update at the time of dues payment that outlines changes in Chief Administrator or administrative structure, or any major changes in personnel, physical facilities, equipment, or budget that could affect accreditation status.

3.4. Steps of the Accreditation process:

3.4.1. Applications are considered confidential by the Committee.

3.4.2. The AAVLD Accreditation Committee reviews the application and the laboratory's Quality Management System documents. If the status, application and Quality Management System of the laboratory are satisfactory, a site visit will be performed.

3.4.3. A site visit will be conducted according to the Accreditation Site Visit Procedures set forth by the AAVLD Accreditation Program.

3.4.4. The site visit team provides written and oral reports and recommendations to the AAVLD Accreditation Committee.

3.4.5. The Committee may make changes to the written report and recommendations and determines the classification status of the laboratory.

3.4.6. Reports, which are confidential information, are sent to the laboratory director.

3.4.7. Accreditation is time-limited. Laboratories are reaccredited periodically through reapplication. Accreditation may be withheld or withdrawn if the laboratory fails to meet the Requirements of the current version of the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory.

SPECIFIC REQUIREMENTS

4. Management Requirements

4.1. Organization and Management

4.1.1. The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

4.1.2. The laboratory shall be organized and shall operate in such a way that it meets the requirements of this Standard whether carrying out work in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.3. The laboratory shall have a clearly defined organizational system and structure. This shall be supported with organizational charts and job descriptions. Organizational charts shall indicate key personnel and the laboratory's place within the larger organization. Relationships between management, technical operations, support services and quality activities shall be specified.

4.1.4. The laboratory shall:

4.1.4.1. have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and to initiate actions to prevent or minimize such departures;

4.1.4.2. have policies and procedures to ensure the ongoing impartiality of its management and personnel such that they are free from any undue internal or

external commercial, financial or other pressures and influences that may adversely affect the quality of their work or diminish confidence in their competence, judgment or operational integrity.

4.1.4.3. have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results. These procedures shall ensure:

4.1.4.3.1. Policies are extended to external personnel who have access to confidential client information.

4.1.4.3.2. Client complaints are kept confidential.

4.1.4.3.3. The client is notified when information is required to be released for any reason, except when released to federal, state or provincial, or local regulatory agencies.

4.1.4.4. specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting the quality of the tests;

4.1.4.5. provide adequate supervision of testing staff, including trainees, by persons familiar with the tests, their purpose and the analysis of test results;

4.1.4.6. have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

4.1.4.7. appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

4.1.4.8. appoint backups or deputies for key managerial personnel such as the quality manager.

NOTE: In laboratories with a small number of personnel, individuals may have more than one function, and it may be impractical to appoint deputies for every function.

4.2. Quality system

4.2.1. The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range and volume of testing it undertakes. The laboratory management shall document its policies, systems, programs, procedures and instructions to enable the laboratory to ensure to the extent possible, the quality of the tests and diagnostic interpretations it

generates. Documentation used in this quality system shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2. The laboratory management shall define and document the policies and objectives to be achieved by implementing the quality system. The laboratory management shall ensure that these policies and objectives are documented in a quality manual.

4.2.3. The quality manual shall include or make reference to the supporting procedures, including technical procedures. It shall outline the structure of the documentation used in the quality system. The quality manual shall be maintained up to date.

4.2.4. The quality manual shall define the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the AAVLD Standard.

4.3. Document Control

4.3.1. The document control system shall ensure that only the current version of the correct document is in use in the laboratory and that documents needed for staff to perform their work are available at the work location.

4.3.2. The laboratory shall have documented policies, procedures and/or work instructions that describe how laboratory documents affecting the quality of tests, including test methods, are reviewed, approved, issued, updated, revised, amended, retained or archived and discarded. Procedures shall be reviewed and approved by authorized, qualified staff.

4.3.3. Changes to documents shall be identified clearly and reviewed and approved by an authorized, qualified officer, administrator or supervisor having access to pertinent background information concerning the change.

4.3.4. Documents shall be uniquely identified and accurately cross-referenced.

4.3.5. Documents shall include page numbers and total number of pages or a mark to signify the end of the document,

NOTE: In this context "document" means any information or instructions, in any format or medium, that have direct bearing on or affect the quality of test results and includes not only the quality manual, policies, procedures and instructions, but also test methods, worksheets, forms, international standards, and regulations.

4.4. Review of request or contract

4.4.1. The laboratory shall have documented policy and procedures that describe how the laboratory ensures that it is capable of and has the capacity for doing particular testing. The procedures shall ensure adequate review of the proposed work with laboratory staff and the client. The laboratory shall keep a record of the review and of client agreement.

4.4.2. The review shall also cover any work that is subcontracted or referred by the laboratory. The laboratory shall advise the client what laboratory the sample/specimen will be sent to for testing. Advisement can occur pre or post submission (e.g. phone, website, fee schedule, test report)

NOTE: Please refer to the AAVLD Glossary of Terms for definitions of Subcontracted and Referral tests.

4.5. Subcontracting of test services

4.5.1. When a laboratory offers tests that are subcontracted, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting or agency arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with the AAVLD Requirements or ISO 17025 for the work in question.

4.5.2. The laboratory shall advise the customer of the arrangement.

4.5.3. The laboratory is not responsible for documenting that the subcontracting lab is competent when the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.4. The laboratory shall maintain a list of all subcontractors that it uses for tests.

4.6. Purchasing services and supplies

The laboratory shall have a policy and procedures to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of test results. These procedures shall include a description of the criteria for selection, evaluation, use, handling and storage of materials and reagents having an effect or potential effect on test results.

4.7. Complaints

4.7.1. The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties and shall ensure that:

4.7.1.1. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

4.7.1.2. The client shall be kept informed of the progress made on the complaint and of its resolution.

4.7.1.3. All complaints are reviewed and approved by someone not involved in the original laboratory activity in question.

4.8. Control of nonconforming testing and test results

4.8.1. The laboratory shall have a policy and procedures that ensure that nonconforming testing (conditions that exist which have or could adversely affect the reliability of test results) is detected and promptly corrected. The procedure shall ensure that:

4.8.1.1. Clients are notified if questionable or incorrect test results have been reported.

4.8.1.2. An evaluation of the impact on previous work is assessed.

4.8.1.3. The responsibility and authority to stop work, withhold test results, implement corrective action and authorize resumption of work is defined.

4.8.2. The laboratory shall retain records of nonconforming work and actions taken.

4.8.3. When a serious issue or a risk to the quality of test results is identified the laboratory shall ensure that appropriate corrective action procedures given in 4.9 shall be promptly implemented.

4.9. Corrective action, Risk assessment and Improvements

4.9.1. Corrective Action

The laboratory shall have a policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system have been identified. The policy and procedures shall ensure:

4.9.1.1. designation of appropriate authorities responsible for implementation of corrective action(s);

4.9.1.2. investigative procedures are implemented to determine the root cause(s) of the problem;

4.9.1.3. upon identification, appropriate corrective action(s) are implemented;

4.9.1.4. documentation of any required changes to operational procedures;

4.9.1.5. once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and

4.9.1.6. when appropriate, areas of activity subject to corrective action are audited in accordance with 4.11.

NOTE: Special internal audits need only be initiated when a serious issue or risk to the quality of test results or integrity of the quality system has been the subject of corrective action.

4.9.2. Risk Assessment

4.9.2.1. The laboratory shall consider the risks and opportunities associated with its activities in order to:

4.9.2.1.1. assure the quality management system can achieve its intended results;

4.9.2.1.2. enhance opportunities to achieve the purpose and objectives of the laboratory;

4.9.2.1.3. prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

4.9.2.1.4. achieve improvement.

4.9.2.2. The laboratory shall plan:

4.9.2.2.1. actions to address these risks and opportunities;

4.9.2.2.2. how to integrate and implement the actions into its quality management system;

4.9.2.2.3. how to evaluate the effectiveness of these actions.

4.9.2.3. Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

4.9.3. Improvement

4.9.3.1. The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

4.9.3.2. The laboratory shall seek feedback, both positive and negative, from its clients. The feedback shall be analyzed and used to improve the quality management system, laboratory activities and customer service.

4.10. Records

All laboratory records must be maintained in an effective retrieval system and must be accurate, contemporaneous, attributable and legible. Records should be preserved in accordance with requirements for individual jurisdictions.

4.10.1. General - The laboratory shall have a records management system.

4.10.1.1. The laboratory shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews, as well as, corrective action records.

4.10.1.2. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention of records shall be consistent with contractual obligations.

NOTE: Records may be in the form of various types of media, such as hard copy or electronic media.

4.10.1.3. All records shall be held secure and in confidence.

4.10.1.4. The laboratory shall have procedures to protect and back up data and records held on computers at all times and to prevent unauthorized access to or amendment of data or records on computers.

4.10.2. Technical records

4.10.2.1. The laboratory shall retain for a defined period of time original observations, derived data, calibration records, staff records, a copy of each test report issued and any other information necessary to recreate the activity. The records for each test shall contain sufficient information to facilitate identification of factors affecting the quality of test results and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel.

4.10.2.2. Observations, data and calculation shall be clearly and permanently recorded and identifiable to the specific test at the time they are made.

4.10.2.3. When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible or deleted) and the correct value entered alongside. All such alterations to records shall be dated, signed or initialed by the person making the correction. In the case of computer collected data, similar measures shall be taken to avoid loss or change of original data.

4.10.2.4. Technical records held in the Laboratory Information Management system (LIMS) shall be protected from unauthorized access and safeguarded against tampering and loss.

4.11. Internal audits

4.11.1. The laboratory shall periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and the AAVLD Standard. The internal audit program shall address all elements of the quality system, including testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities, except when it can be demonstrated that an effective audit can be carried out.

NOTE: In laboratories with a small number of personnel, effective internal audits may not be feasible. In such cases, it may be appropriate for two or more laboratories to cooperate in auditing each other.

4.11.2. When audit findings cast doubt on the effectiveness of the operations or on the quality of the laboratory's test results, the laboratory shall take timely and effective corrective and where appropriate preventive action, and shall notify clients in

writing if investigations show that the laboratory results may have been affected (see 4.8).

4.11.3. The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these corrective actions are discharged within an appropriate and agreed-upon time frame.

4.12. Management reviews

4.12.1. The quality system and test-related activities shall be reviewed by management at least once per year.

4.12.2. The laboratory shall have a procedure for performing a Management Review. The review shall take into consideration:

4.12.2.1. suitability of policies and procedures;

4.12.2.2. reports from managerial and supervisory personnel;

4.12.2.3. status of actions from previous management reviews;

4.12.2.4. reports of recent internal audits;

4.12.2.5. corrective actions;

4.12.2.6. assessments by external bodies;

4.12.2.7. results of inter-laboratory comparisons or proficiency tests;

4.12.2.8. changes in the volume and type of work;

4.12.2.9. client feedback;

4.12.2.10. complaints;

4.12.2.11. improvements;

4.12.2.12. risk assessment;

4.12.2.13. other relevant factors, such as quality control activities, resources and staff training.

4.12.3. Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed-upon time frame.

4.12.4. This review and subsequent activities shall ensure the continuing suitability and effectiveness of the quality management system and shall ensure the introduction of necessary changes and improvements.

5. Technical requirements

5.1. Space holder to preserve document format

5.2. Personnel

5.2.1. The laboratory shall ensure:

5.2.1.1. the initial and ongoing competence of laboratory personnel to do their assigned work using objective criteria.
NOTE: Examples of objective criteria include proficiency testing, inter-laboratory comparisons, reference sample panels, replicate testing of quality control materials and continuing education.

5.2.1.2. laboratory personnel understand the significance of deviation from laboratory procedures.

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.

5.2.3. The laboratory shall have a system that ensures the establishment and maintenance of a training program relevant to the present and anticipated needs of the laboratory.

5.2.4. The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

5.2.4.1. develop, modify, verify and validate methods and any planned deviations;

5.2.4.2. analyze results, including statements of conformity or opinions and interpretations; and;

5.2.4.3. review, authorize and report results.

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 the 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.

5.3.1. Laboratory facilities for testing, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of tests. The laboratory shall ensure that the environment does not invalidate the results or adversely affect the required quality of any testing activity.

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.

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.

5.3.4. Access to and use of areas affecting test results shall be controlled.

5.3.5. The laboratory shall ensure the establishment and maintenance of safety, biosafety, biocontainment and biosecurity programs relevant to present and anticipated needs. The programs will provide staff training and address all necessary elements to ensure a safe work environment.

5.4. Test methods

5.4.1. General

5.4.1.1. The laboratory shall use appropriate test methods and related procedures for all animal disease diagnostic testing activities. Consideration shall be given to all factors that impact the relevance of the test method and test results to a specific diagnostic interpretation or application. These factors include the suitability of the test method, its acceptability by the scientific and regulatory communities, its acceptability to the client and its feasibility given available laboratory resources. See 5.4.3.1 note.

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

5.4.1.3. Tests shall be appropriately controlled.

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.

5.4.1.5. Laboratories using test methods prepared by national and international standards-setting bodies and other external technical organizations shall have a system to receive updates of these methods in a timely manner.

NOTE: International, regional or national standards or other recognized specifications that contain sufficient and concise information on any of the above subjects do not need to be rewritten as internal procedures if these standards are published in a way that they can be used as published by the operating staff in a laboratory. Consideration may need to be given to providing additional documentation for optional steps in the assay or additional details. As with all test methods, they shall be subject to document control (see 4.3).

5.4.2. Selection of methods

5.4.2.1. The client shall be informed of the test method chosen and if required, the laboratory shall provide the client with the rationale used in making this choice (see 5.4.1.1).

5.4.2.2. The laboratory shall demonstrate, using objective criteria, that it can properly perform standard methods prior to introducing diagnostic tests. Records of verification shall be retained. If the standard methods change, the verification must be repeated.

5.4.2.3. Test methods shall contain enough critical and descriptive information such that experienced personnel can properly perform the test within pre-established control limits without reference to information sources outside the laboratory's document control system. In addition, they shall include as appropriate:

5.4.2.3.1. evidence of document control;

5.4.2.3.2. relevant references;

5.4.2.3.3. a description of intended analyte(s) (e.g., antibody) and any quantities or ranges to be determined (e.g., titer);

5.4.2.3.4. any reference standards or reference materials required (e.g., reference strains, reference standards for antibody);

5.4.2.3.5. a description of the appropriate matrix or specimen for testing, including species (e.g., bovine serum);

5.4.2.3.6. safety considerations, including biocontainment level needed;

5.4.2.3.7. a list of and specifications for equipment, materials and reagents, including software;

5.4.2.3.8. conditions for acceptance of specimens as fit for testing;

5.4.2.3.9. conditions for specimen identification, collection, handling, transportation and storage;

5.4.2.3.10. conditions for sample preparation;

5.4.2.3.11. a description of the controls used and their acceptance limits;

5.4.2.3.12. checks to be made prior to beginning the test procedure (e.g., equipment checks and calibrations);

5.4.2.3.13. acceptance criteria for results;

5.4.2.3.14. data to be recorded and the method of analysis/transformation, presentation, and/or interpretation (e.g., how an absorbance reading is transformed and interpreted as a positive or negative result relative to a cut-off) and recording; and

5.4.2.3.15. the most current description of the test procedure.

5.4.2.4. The test method shall be validated before it is incorporated into the routine diagnostic activities of the laboratory. The same prerequisite applies to an existing assay that has been modified if the modification affects the performance characteristics of the assay (see 5.4.3).

5.4.3. Validation of test methods

5.4.3.1. A test method, whether an international or national standard method, a harmonized method or developed in-house, shall be considered appropriate for routine diagnostic purposes if it has been validated, where possible, according to the principles outlined in the OIE Manual of Standards for Diagnostic Tests and Vaccines or other related OIE references. It is preferred for all methods, whether developed in-house or drawn from reputable collections of standard methods, that the laboratory should be able to define, at least through reference to public or private documentation, the analytical sensitivity and specificity, accuracy and precision, diagnostic sensitivity and specificity and other parameters relevant to the use of the test method in the user's laboratory. The user is not required to re-validate international or national standard methods.

NOTE: Test methods may be classified as "validated for use" by meeting the following criteria.

5.4.3.1.1. Ongoing documentation of internal or inter-laboratory performance using known reference standard(s) for the species and/or diagnostic specimen(s) of interest,

AND one or more of the following:

5.4.3.1.2. Endorsed or published by reputable technical organization (e.g.: OIE Manual of Standards for Diagnostic Tests and Vaccines, US Food and Drug Administration's Bacteriologic Analytic Methods, Bergey's Manual of Determinative Bacteriology, American Society of Microbiology Manual of Clinical Laboratory Immunology, American Association of Avian Pathologists Isolation and Identification of Avian Pathogens, EPA protocols, American Fisheries Society Bluebook, AOAC, NAHLN);

5.4.3.1.3. Published in a peer-reviewed journal with sufficient documentation to establish diagnostic performance and interpretation of results;

5.4.3.1.4. Documentation of internal or inter-laboratory comparison to an accepted methodology or protocol.

5.4.3.2. Validation data, including all original observations, calculations, equipment monitoring and calibration records, archived procedures used to formulate performance characteristics, and a statement on validity of the method, detailing its fitness for the intended use shall be retained by the laboratory for at least as long as the assay is used for diagnostic purposes and for at least seven years after the assay has been retired from use.

NOTE: Depending on client needs, the laboratory may be required to define

other diagnostic performance indicators such as positive and negative predictive values of the test. Such indicators may be particularly relevant to certain diagnostic applications or test populations.

5.4.4. Control of data

5.4.4.1. The laboratory shall ensure, using appropriate procedures that all data resulting from test validation and all data relating to test results are secure, retrievable, and approved for use by specified, qualified personnel.

5.4.4.2. Manual calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.4.3. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

5.4.4.3.1. computer software, modified or developed by the user, is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use, i.e., the laboratory shall implement and document changes to control procedures such that these activities can be recreated and an audit trail is established;

5.4.4.3.2. The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any additions or deletions of functionality, they shall be authorized, documented and validated before implementation. This includes extensions to commercial off-the-shelf software.

5.4.4.3.3. procedures are established and implemented for protecting the security, integrity, and retrievability of data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

5.4.4.3.4. computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.

5.4.4.4. The laboratory information management system(s) shall be:

5.4.4.4.1. protected from unauthorized access;

5.4.4.4.2. safeguarded against tampering and loss;

5.4.4.4.3. operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides

conditions which safeguard the accuracy of manual recording and transcription;

5.4.4.4.4. maintained in a manner that ensures the integrity of the data and information.

5.4.4.5. Failures in the laboratory information management system to operate as expected are subject to the non-conforming work process.

5.4.4.6. When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure the provider or operator of the system complies with all applicable requirements of this document.

NOTE: Commercial software, excluding LIMS, in general use within its designed application range may be considered sufficiently validated.

5.5. Equipment

The laboratory shall possess or have access to all equipment necessary for the correct performance of all services. All equipment shall be identified, properly maintained and calibrated with maintenance and calibration procedures documented.

5.5.1. The laboratory shall be furnished with all items of test and related equipment required for the correct performance of the tests. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this AAVLD standard are met.

5.5.2. Equipment and its software used for diagnostic activities shall be capable of achieving the accuracy required and shall comply with specifications relevant to the procedures concerned. Calibration programs shall be established for key equipment where these properties have a significant effect on the results.

5.5.3. Equipment shall be operated by authorized, qualified personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4. Each item of equipment used for test activities significant to a test result shall be uniquely identified.

5.5.5. Records shall be maintained of each item of equipment significant to the tests performed. The records shall include at least the following:

5.5.5.1. identity of the item of equipment;

5.5.5.2. manufacturer's name, type identification and serial number or other unique identification;

5.5.5.3. verification that equipment complies with the specification;

5.5.5.4. the current location, where appropriate;

5.5.5.5. the manufacturer's instructions, if available;

5.5.5.6. dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and the due date of next calibration;

5.5.5.7. maintenance carried out to date and the maintenance plan;

5.5.5.8. damage, malfunction, modification or repair to the equipment.

5.5.6. Maintenance procedures shall be established.

5.5.7. Equipment calibrations shall be performed by qualified personnel using procedures appropriate to intended use, accuracy and precision required, and at appropriate intervals as historical data indicate.

5.5.8. Equipment that has been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service, clearly labeled or marked and appropriately stored until it has been repaired and shown to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and shall institute the "Control of nonconforming work" procedure (4.8).

5.5.9. Whenever practical, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration or verification and the date when the next calibration or verification is due.

5.5.10. When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.11. Test equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate the test results.

5.6. Measurement traceability

5.6.1. Where indicated and when possible, the laboratory shall have traceability of all measurements, including the calibration of equipment to Standard International (SI) units.

5.6.2. Where traceability to SI units of measurement is not possible, the best available means for providing confidence in the results shall be applied, such as:

5.6.2.1. the use of suitable reference standards or materials certified to give a reliable characterization of the material;

5.6.2.2. mutual-consent standards or methods that are clearly specified and agreed upon by all parties concerned;

5.6.2.3. participation in a suitable program of interlaboratory comparisons or proficiency testing.

5.6.3. Reference equipment, standards or materials used in conjunction with testing activities shall be handled, maintained and stored in a manner that ensures proper performance and/or accuracy.

5.6.4. Biological reference material shall, where possible, be traceable to accepted international standards or to OIE reference materials (e.g., International Standard Sera).

5.6.5. Checks needed to maintain confidence in the status of working standards and reference materials shall be carried out according to defined procedures and schedules.

5.6.6. The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.7. Specimens

5.7.1. General

The laboratory shall have procedures for the collection of specimens to ensure that they are both appropriate to the test being undertaken and suitable for testing.

NOTE: This applies to veterinary diagnostic laboratories only when the laboratory is directly responsible for specimen collection.

5.7.1.1. The laboratory shall have procedures for the collection, processing where indicated and preservation of specimens. Collection and related procedures shall be available at the location where collection is undertaken.

5.7.1.2. The laboratory shall have procedures for recording relevant data and operations relating to specimen collection that forms part of the test that is undertaken, whether the collection is performed by laboratory staff or by the client. Records shall include the collection procedure used, identification of the collector, environmental conditions (if relevant) and diagrams or other means to identify the collection location as necessary (e.g., in the case of tissue specimens) and, if appropriate, the statistics that sampling procedures are based upon.

5.7.1.3. When sampling from populations, as appropriate, the laboratory shall have a statistically defined plan for sample collection.

NOTE: While the laboratory may provide relevant scientific and/or statistical input into the development of sampling plans for the testing of animal populations, the development of these plans does not fall within the AAVLD Accreditation Requirements.

5.8. Handling of specimens

5.8.1. The laboratory shall have procedures which ensure the integrity of specimens. These shall include transportation, receipt, handling, protection, retention and/or disposal of specimens. Handling instructions provided by the client with the specimen shall be considered.

5.8.2. The laboratory shall have a system for identifying specimens that ensure no confusion between specimens or derived samples. The identification shall be retained throughout the life of the specimen and its derived samples in the laboratory and linked to the test report (5.10).

5.8.3. Upon receipt of the specimen, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, shall be recorded. If there has been a departure from specifications, then the samples should not be considered fit to test. However, if the client requests an item to be tested after acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

5.8.4. When there is any doubt as to the suitability of a specimen for testing purposes, or when a specimen does not conform to the description provided, or if the test method required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the facts and results of that discussion.

5.9. Ensuring the quality of test results

5.9.1. The laboratory shall have quality control procedures for monitoring the validity of test results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

5.9.1.1. internal quality control schemes using statistical techniques (e.g., control charts);

5.9.1.2. where applicable, use of international reference reagents for preparation of national and/or working standards for internal quality control;

5.9.1.3. when practical, replicate tests using the same or different methods;

5.9.1.4. correlation of results for different characteristics of a specimen or sample;

5.9.1.5. re-testing of retained specimens or samples;

5.9.1.6. participation in interlaboratory comparison or proficiency testing programs;

5.9.1.7. functional check(s) of measuring and testing equipment;

5.9.1.8. intermediate checks on measuring equipment;

5.9.1.9. review of reported results;

5.9.1.10. testing of blind sample(s);

5.9.1.11. use of alternative instrumentation that has been calibrated to provide traceable results.

5.9.2. Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

NOTE: The validity of test results is influenced by both technical competence and assay performance characteristics. If the validity of test results is called into question, it is important to be able to distinguish between the two. A test may demonstrate appropriate process control but poor diagnostic performance or vice versa.

5.10. Reporting test results

5.10.1. The results of each test performed by the laboratory shall be reported accurately, clearly, unambiguously and objectively and in accordance with any specific instructions in the test method or contract. The results shall be reviewed and authorized prior to reporting.

5.10.2. Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:

5.10.2.1. a title (e.g., "Test Report");

5.10.2.2. name and address of laboratory, and if different, the location where the tests were performed;

5.10.2.3. unique identification (see 5.8.2.) at the beginning and on each page of the test report to ensure that the page is recognized as a part of the test report and a clear identification of the end of the report;

5.10.2.4. name and address of the client placing the order;

5.10.2.5. description and unambiguous identification of the specimen(s) tested;

5.10.2.6. unique identification of the test method(s) used;

5.10.2.7. date of receipt of specimen(s) where relevant to the validity and application of the results;

5.10.2.8. the date(s) of performance of the laboratory testing where relevant to the validity and application of results;

5.10.2.9. test results;

5.10.2.10. reference to specimen collection procedures used by the laboratory or by the client where these are relevant to the validity or application of the results;

5.10.2.11. where appropriate and needed, opinions and diagnostic interpretations of the test results;

5.10.2.12. the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report.

5.10.3. Where applicable, the test report shall also include:

5.10.3.1. date of specimen collection;

5.10.3.2. unambiguous identification of specimen source;

5.10.3.3. location of collection, including any diagrams, sketches or photographs;

5.10.3.4. reference to sampling plan used (see 5.7.1.3.);

5.10.3.5. details of any environmental condition during collection that may affect the interpretation of the test results;

5.10.3.6. identification of the collection procedure or technique.

5.10.4. When opinions and diagnostic interpretations are included in the test report, the laboratory shall document the basis upon which the opinions and interpretations have been made.

NOTE: When the results of a battery of tests are considered in formulating an opinion or making a diagnostic interpretation, it may be necessary to describe for the client, the rationale behind the sequence of testing and the decision making process (e.g., presumptive vs. definitive tests or screening vs. confirmatory tests).

5.10.5. When the test report contains results of tests performed by subcontractors or referral laboratories, these results shall be clearly identified.

5.10.6. Transmission of test results and/or interpretations whether in hardcopy or electronic format shall meet the requirements of the AAVLD Standard.

5.10.7. The report format shall be designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

5.10.8. When a battery of tests is to be performed and results reported as available, interim test reports shall be issued to the client. These reports shall indicate tests completed and tests pending. Such reports shall be uniquely identified as interim test reports, shall contain a reference to any and all preceding interim reports and shall meet all the requirements of the AAVLD Standard. Upon completion of all testing, a final test report shall be issued.

5.10.9. When an issued report needs to be changed, or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

5.10.10. When it is necessary to issue a new test report (e.g. amended or addended) for whatever reason, it shall be uniquely identified and shall contain a reference to the original that it replaces.

Document Revision Summary

Version 4.3 - 10/19/09

- Entire document: Removed "Essential" from "Essential Requirements"
- Entire document: Added Table of Contents
- Objectives of the Accreditation Program, last bullet: Changed date of OIE document from 2002 to 2008
- Section 1.1: Changed "will be" to "are"
- Section 1.3: In the second sentence, changed "shall be" to "is" Last sentence, changed "will be" to "are"
- Section 1.4: Removed section
- Section 3.4.1: Removed "The AAVLD Accreditation Application is provided as Appendix 1."
- Specific Requirements: Changed date of OIE document from 2002 to 2008
- Attachment 1: Removed the Application from Requirements and made it a separate document
- Personnel Qualifications: Removed 4th column from table

Version 5.0 - 9/14/10

- Entire document: Grammatical corrections
- Table of Contents: Added Appendices 1 and 2, corrected page numbers
- Section 1.2: Added "year-round" after "a full range of diagnostic services"
- Section 5.7.1 Note: Replaced "sample" with "specimen"
- Appendix 1, page 3: In * replaced "medical" with "veterinary"
- Appendix 2: Added new appendix: Glossary of Terms

Version 6.0 - 10/10/11

- Section 4.3.3: Changed the word "Amendments" to "Changes" and deleted the words "in the text"
- Section 4.3.5: New section
- Section 4.5: Deleted "The client shall be informed of and agree to any subcontracting of work."
- Sections 4.5.1-4.5.4: New sections
- Appendix 1
    - Quality Manager: Minimum Qualifications: Deleted "in a biological science related field"
- Section Heads: Minimum Qualifications:
    - Toxicology: Deleted "and 3 years experience" and replaced with "and 2 years experience or DVM and Diplomate ABVT"
    - Bacteriology: Added "DVM"

Version 6.1 - 6/1/12

- Appendix 1
    - Pages 23 and 24: Add fourth column, List Actual Qualifications tab, to table

Version 6.2 - 10/5/14

- Section 2.2.1: Changed "library" to "information technology"
- Section 3.4.2: Added "and the laboratory's Quality Management System documents"
- Section 3.4.3: Added "Accreditation", deleted "AAVLD", "and Accreditation Audit Report", added "set forth by AAVLD", deleted "SOP 102.1"
- Specific Requirements: Deleted entire section
- Section 4.2.2.c : Added "laboratory", deleted "concerned with testing activities within the laboratory"
- Section 5.2.1: Added "using objective criteria. Note: Examples of objective criteria may include proficiency testing, inter-laboratory comparisons, reference sample panels, replicate testing of quality control materials and continuing education".
- Section 5.4.2.2: Added "using objective criteria", deleted "confirmation" added "verification".
- Section 5.4.2.3: Deleted "other", added "outside the laboratories document control system".
- Section 5.4.4.1: Deleted "is" added "are
- Section 5.10.6: Deleted "In the case of", added "whether in hardcopy or", deleted by telex, facsimile or other", added

"format shall meet", deleted "or by electromagnetic means" and "shall be met".

- Glossary Terms Added:
  - "Test Method: specific procedure; synonymous with assay e.g. ELISA, cELISA, PCR, real time PCR".
  - "Test: the use of a test method (assay, specific procedure) within a specific context, i.e. diagnosis of a disease. Test refers to the specific target (i.e. infectious agent, antigen, antibody, analyte) plus the specific procedure used, e.g. EIA antibody ELISA, Porcine Parvovirus PCR
  - Verification: Added "The process of determining accuracy using a reference standard; e.g." Deleted "The process of", added "the internal process to determine if a laboratory can perform a validated assay and obtain expected results.

Version 2016-07 – 07/28/2016

- Personnel Qualification, Appendix 1: Revised entire document
- Naming convention: Revised document number to "AC-1" and revised version number to year and month of Accreditation Committee meeting when revision approved
- Section 2.1.2:
  - Removed: "The director/chief administrative officer shall be a veterinarian. The laboratory personnel shall be able to provide competence in all testing groups evaluated for accreditation. Minimum training levels are listed in the section on personnel qualifications in Appendix I."
  - Added: "The laboratory personnel shall be able to provide competence in all management and technical groups evaluated for accreditation. Minimum training levels are listed by laboratory position in Appendix 1, Personnel Qualifications."

Version 2018-07 – 07/31/2018

- Appendix 2 – Glossary of Terms: Added new terms for referral tests and subcontracted tests
  - **Subcontracted Tests:** Any test request currently offered by the laboratory that is received from the client where the laboratory is unable to perform for whatever reason (e.g. excessive workload, lack of personnel, need for further expertise or other temporary incapacity). Subcontracted reports will be sent back to the laboratory for inclusion in their report.
  - **Referral Tests:** Any test request not currently offered by the laboratory. The laboratory must advise the client what laboratory the sample/specimen will be sent to for testing. Advisement can occur pre or post submission (e.g. phone, website, fee schedule, test report). Referral reports may be sent back to the laboratory for inclusion in their report.
- Section 4.4.2:
  - Removed: The review shall also cover any work that is subcontracted by the laboratory.
  - Added: The review shall also cover any work that is subcontracted **or referred** by the laboratory.
- Section 4.4: added note at end of section
  - NOTE: Please refer to the AAVLD Glossary of Terms for definitions of Subcontracted and Referral tests.
- Section 4.5 Subcontracting of test services: added note at end of section
  - NOTE: Referral testing (as defined by the AAVLD Glossary of Terms) does not fall under section 4.5 (Subcontracting of Test Services). Refer to AAVLD 4.4 (Review of Request and Contract).
- Section 5.10.5:
  - Removed: 5.10.5 When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.
  - Added: 5.10.5 When the test report contains results of tests performed by **subcontractors or referral laboratories**, these results shall be clearly identified.

Version 2021-01 – 08/06/2019

- Cover page: Updated version number
- Document Footer : Updated version number
- Table of Contents: Updated page numbers
- Objectives of the Accreditation Program: Updated last bullet indicating alignment with ISO:IEC 17025 and removed reference to OIE standard
- Section 1.2: Changed "full service" to "full-service"

- Section 1.2: Added note
- Section 1.3: Revised definition of a provisionally accredited laboratory
- Section 2.1.1: Removed reference to NIH supported laboratories
- Section 3.2:
    - Changed “meets to “compliant with”
    - Changed “Accreditation Committee” to AAVLD Accreditation Program
- Section 3.4.3:
    - Changed “guidelines” to “procedures”
    - Changed AAVLD to the AAVLD Accreditation Program.
- Section 3.4.7: Changed “AAVLD Accreditation Committee to “current version of the AAVLD Requirements for an Accredited Veterinary Medical Diagnostic Laboratory”
- Section 4.1.4.b:
    - Changed “arrangements” to “policies and procedures”
    - Added “ongoing impartiality”
    - Combined 4.1.4b with 4.1.4.4
- Section 4.1.4.c:
    - Extended confidentiality to external personnel
    - Added client complaints are kept confidential
    - Added requirement for client notification when confidential information is released
- Section 4.1.4.d: was removed
- Section 4.1.4.e: was renumbered as 4.1.4.4
- Section 4.1.4.f: was renumbered as 4.1.4.5
- Section 4.1.4.g: was renumbered as 4.1.4.6
- Section 4.1.4.h: was renumbered as 4.1.4.7
- Section 4.1.4.i: was renumbered as 4.1.4.8
- Section 4.2.2: removed requirement for a quality policy statement
- Section 4.7.1:
    - Added the requirement of informing the client of progress made
    - Added a required review and approval of complaint resolution
- Section 4.8.1:
    - Clarified client notification
    - Clarified responsibility for withholding test results and resumption of work.
- Section 4.8.2: Added record requirement for non-conforming work and action taken
- Section 4.8.2: Old 4.8.2 was renumbered as 4.8.3
- Section 4.9: Preventive action removed
- Section 4.9.2: Added Risk Assessment section
- Section 4.9.3: Added Improvement section
- Section 4.10: Removed requirement for the ability to pull records by disease
- Section 4.10.1.2: Added that retention times are consistent with contractual obligations
- Section 4.10.2.4 Added specific reference to LIMS records
- Section 4.12.2:
    - Added status of actions from previous management reviews
    - Removed preventive actions
    - Added improvements
    - Added risk assessments
- Section 5.1: Removed the General reference to factors that can affect the reliability of test results.
- Section 5.1: Section has been reserved to maintain numbering.
- Section 5.2.2: Added requirement that lab personnel understand the significance of deviation.
- Section 5.2.4: Added specific authorization of personnel language.
- Section 5.4.2.2: Added records requirement for verification of methods.
- Section 5.4.3.1: Reworded the paragraph and removed the requirement for documentary evidence of data on and statistically valid assessment of comparative performance for assays harmonized by interlaboratory comparison.
- Section 5.4.3.2: Added the requirement for a statement on validity of the method, detailing its fitness for the intended use.
- Section 5.4.4.3: Added 5.4.4.3.2 specific to laboratory information management system(s).
- Section 5.4.4.3: Note was moved to 5.4.4.6 with language change to exclude laboratory information system(s)
- Section 5.4.4.4: Added specific to laboratory information management system(s).
- Section 5.4.4.5: Added to specify that failures in laboratory information management system(s) are subject to nonconforming work process.

- Section 5.4.4.6: was added for laboratory information management systems which are maintained off-site or through an external provider.
- Section 5.8.1: Added handling instructions provided with the item shall be considered.
- Section 5.8.3: Added requirement for a disclaimer on the test report when a client requests testing on a sample which deviates from specified conditions.
- Section 5.9.1: Added items 5.9.1.7 – 5.9.1.11 as additional planned and reviewed options.
- Section 5.9.2: Added requirement to take appropriate action if the planned review activities are found to be outside pre-defined criteria.
- Section 5.10.1: Added that results shall be reviewed and authorized prior to reporting.
- Section 5.10.2.8: Added the date(s) of performance of the testing where relevant.
- Section 5.10.9: Revised to clarify. Includes clear identification of the change and reason for the change on the report.
- Appendix 2, Glossary of Terms: added definitions for Risk Assessment and Impartiality.

Appendix 1

PERSONNEL QUALIFICATIONS[1]

POSITION	MINIMUM QUALIFICATIONS	PREFERRED QUALIFICATIONS	LIST OF ACTUAL QUALIFICATIONS
Administration			
Director/ Chief Administrator	DVM* and advanced degree in relevant field of study + 5 years veterinary diagnostic laboratory or relevant work experience + 5 years directing / supervising experience. Experience could include practice management, regulatory/policy, finance or quality management	DVM* and PhD with specialty board certification + 5 years veterinary diagnostic laboratory or relevant work experience + 5 years directing / supervising experience. Experience could include practice management, regulatory/policy, finance or quality management	
Quality Manager	BS or BA** + 2 years QA experience.	MS or PhD in a science related field, and documented advanced QA training, and QA certification.	
Section Heads			
Anatomic and Clinical Pathology	DVM* and MS in pathology **OR** DVM* with completion of a pathology residency program **+** 5 years veterinary diagnostic laboratory or relevant work experience.	DVM* and PhD in pathology + Diplomate ACVP + 5 years veterinary diagnostic laboratory or relevant work experience	
Toxicology	DVM* and MS in toxicology **OR** Relevant PhD + 2 years veterinary diagnostic laboratory experience **OR** DVM* and Diplomate of ABVT	DVM* and PhD in toxicology + Diplomate ABVT + 5 years veterinary diagnostic laboratory experience	

POSITION	MINIMUM QUALIFICATIONS	PREFERRED QUALIFICATIONS	LIST OF ACTUAL QUALIFICATIONS
Bacteriology Virology	MS or PhD degree in relevant science related field + 2 years veterinary diagnostic laboratory or relevant work experience **OR** DVM* and Diplomate ACVM + 2 years veterinary diagnostic laboratory experience	DVM* and PhD + Diplomate ACVM + 5 years veterinary diagnostic laboratory or relevant work experience	
Serology Molecular Diagnostics	MS or PhD degree in relevant science related field + 2 years veterinary diagnostic laboratory or relevant work experience	DVM* and PhD + Diplomate ACVM + 5 years veterinary diagnostic laboratory or relevant work experience	
Analytical Chemistry	MS degree in chemistry + 2 years veterinary diagnostic laboratory or relevant work experience	PhD degree in chemistry + Board Certified (ABT) + 5 years veterinary diagnostic laboratory or relevant work experience.	
Professional Staff			
Anatomic and Clinical Pathologists	DVM* and MS in pathology **OR** DVM* with completion of a pathology residency program	DVM* and PhD in pathology + Diplomate ACVP + 5 years veterinary diagnostic laboratory experience	
Epidemiologists	MS or PhD + 2 years veterinary diagnostic laboratory or relevant work experience	DVM* and MS or PhD + ACVPM Board Certification + 5 years veterinary diagnostic laboratory or relevant work experience	

POSITION	MINIMUM QUALIFICATIONS	PREFERRED QUALIFICATIONS	LIST OF ACTUAL QUALIFICATIONS
Diagnosticians	DVM* + 2 years veterinary diagnostic laboratory or relevant work experience	DVM* with advanced training in appropriate discipline + 5 years veterinary diagnostic laboratory or relevant work experience	
Technical/ Clerical Staff			
Laboratory Technicians: Histotechnology, Bacteriology, Clinical Pathology, Necropsy, Toxicology, Serology, Virology or Molecular Dx.	High school + 2 years veterinary diagnostic laboratory or relevant work experience; **OR** Compliance with existing state or university policies.	BS/MT/VT/HT/HTL (as appropriate) + 2 years veterinary diagnostic laboratory or relevant work experience	
Medical Records Technician	High school + 2 years veterinary diagnostic laboratory experience; **OR** Compliance with existing state or university policies	BS + 2 years veterinary diagnostic laboratory experience and certification	

1. The Accreditation Committee will consider exceptions to personnel qualifications on a case-by-case basis. Justifications of an exemption for specific personnel qualifications will be evaluated during a regularly scheduled full site visit to a laboratory.

*Or equivalent /comparable veterinary degree.
**Or equivalent/comparable science degree.

Appendix 2 **Glossary of Terms**

Accreditation: A process by which an authoritative body (accreditation body) gives formal recognition that an organization or person is competent to carry out specific tasks as outlined in accreditation requirements.

Accuracy: The level of agreement between a test value and the expected value for a reference standard, control, or known activity or titer; closeness to the true value.

Addend (ed): Item of additional material.

Amend (ed): Item of changed or corrected material

Assessment: A process of collecting and analyzing data in a systematic way to determine the compliance of an organization with specific accreditation requirements.

Audit finding: The result(s) of the evaluation between collected audit evidence and audit criteria.

Calibration: The process of adjusting the accuracy of a piece of equipment to a NIST calibrated standard.

Competence: The demonstrated ability to get the correct result by possessing the required skill, knowledge, qualification or capacity.

Continuous improvement: A set of recurring activities that an organization carries out in order to enhance its ability to meet requirements. Some of these activities may include audits, management reviews, corrective and preventive actions, analyzing data and setting objectives.

Control chart: A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted. Control charts may be used to evaluate shifts and trends within a controlled process (e.g. test method).

Corrective action*:* The steps taken to reduce or eliminate the cause of an existing nonconformity or other undesirable situation. Corrective actions prevent *recurrence* of nonconformities. See also Preventive Action. Note: An initial correction is the immediate step taken to fix a detected nonconformity or get a process back under control prior to conducting the root cause analysis of a corrective action.

Document: From AAVLD Requirements pg. 23 - **"NOTE:** In this context "document" means any information or instructions, in any format or medium, that have direct bearing on or affect the quality of test results, and includes not only the quality manual, policy, procedures, and instructions, but also test methods, worksheets, forms, international standards, and regulations."

Effectiveness: The state of having produced a decided on or desired effect. The extent to which planned activities are realized and planned results achieved.

Guideline: A document stating recommendations or suggestions.

Improvement: The positive effect of a process change effort.

Internal (first party) audit: An on-site inspection of a process or quality system to ensure compliance with specific requirements. The auditors who conduct first party audits are employees of the organization being audited.

Interim Report: Test report(s) issued before all testing is completed (i.e. preliminary report)

Impartiality: Objectivity existing in a laboratory to ensure that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory.

ISO:IEC: International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Management system: The organizational structure, responsibilities, procedures, processes and resources for implementing policy and achieving objectives.

Management review: An evaluation of the suitability, adequacy, and effectiveness of an organization's quality policy and quality objectives, address resource needs and look for opportunities for improvement.

Measurement Traceability: The ability to identify and trace the history, distribution, location, and application of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

NIST (National Institute of Standards and Technology): An agency of the U.S. Department of Commerce that develops and promotes measurements, standards and technology.

Nonconformance (noncompliance): The failure to comply with a specified requirement.

Objective evidence: The evidence supporting the existence or verity of something. It may be obtained through observation, measurement, test, or other means.

Policy: An overarching plan (direction), used for the basis of making decisions, and for achieving an organization's goals.

Precision: The aspect of measurement that addresses repeatability or consistency when an identical item is measured several times - precise does not equal accurate.

Process: A set of interrelated work activities characterized by a set of specific inputs that make up a procedure for a set of specific outputs.

Process control: The method for keeping a process within accepted boundaries by minimizing variation.

Quality assurance: A planned program consisting of the actions necessary to provide confidence that a test or testing activity conforms to established technical requirements.

Quality control: The operational activities used to ensure that quality standards are being met.

Quality management system: A set of interrelated or interacting elements that organizations use to implement and direct quality planning, quality control, quality assurance, and quality improvement.

Quality manual: A document specifying the quality management system of an organization. A Quality Manual may vary in detail and format in order to suit the size and complexity of an organization.

Record: Any and all written materials that provide proof of compliance with the quality system and evidence that a specified activity has been performed. They may be in hard copy or electronic form and should be attributable to an individual.

Referral Tests: Any test request not currently offered by the laboratory.

Reliability: The ability of an item to perform a required function under stated conditions for a stated period of time.

Repeatability: The variation in measurements taken by a single person or instrument on the same item and under the same conditions (e.g. running a sample in triplicate).

Reproducibility: The ability of a test or method to be accurately reproduced, or *replicated* (e.g. running a sample for a given method on two different days or by two different analysts).

Risk Assessment: The process for establishing a basis in a laboratory for increasing the effectiveness of the quality management system to improve results and prevent negative effects.

Root cause: The initiating reason for the presence of a defect or problem. When removed or corrected, the nonconformance is eliminated.

Root cause analysis: The process of problem solving used to identify the underlying or initiating source of a nonconformance.

Sample: Material that is derived from a specimen and used for testing purposes.

Sensitivity (diagnostic): Proportion of known infected reference animals that test positive in the assay (infected animals that test negative are considered to have false-negative results).

Specification: The requirements, to which a given service must conform, usually stated in a document.

Specificity (diagnostic): Proportion of known uninfected reference animals that test negative in an assay (uninfected reference animals that test positive are considered to have false-positive results).

Specimen: Material submitted for testing, e.g., carcass, whole blood, serum, and urine.

Subcontracted Tests: Any test request currently offered by the laboratory that is received from the client where the laboratory is unable to perform for whatever reason (e.g. excessive workload, lack of personnel, need for further expertise or other temporary incapacity). Subcontracted reports will be sent back to the laboratory for inclusion in their report.

Test Method: Specified procedure used for diagnostic testing.

Test: The use of a test method (assay, specific procedure) within a specific context, i.e. diagnosis of a disease. Test refers to the specific target (i.e. infectious agent, antigen, antibody, analyte) plus the specific procedure used, e.g. EIA antibody ELISA, Porcine Parvovirus PCR

Trend: The measure of a variable's tendency, over time, to increase, decrease or remain unchanged. It is typically represented graphically or through statistical means.

Validation: The act of confirming, through objective evidence, that the requirements which define an intended use or application have been met. The process through which a test method is confirmed to be fit for the intended purpose.

Verification: The process of determining accuracy using a reference standard; e.g. comparing the accuracy of a piece of equipment to a NIST calibrated reference standard; the internal process to determine if a laboratory can perform a validated assay and obtain expected results.