# AAVLD Accreditation Audit Report

## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Background and General Findings / Executive Summary</td>
<td>3</td>
</tr>
<tr>
<td>a. Overview / Current accreditation status</td>
<td>3</td>
</tr>
<tr>
<td>b. Response to previous audit and accomplishments</td>
<td>3</td>
</tr>
<tr>
<td>c. Miscellaneous</td>
<td>3</td>
</tr>
<tr>
<td>B. Commendations</td>
<td></td>
</tr>
<tr>
<td>C. Conclusions</td>
<td></td>
</tr>
<tr>
<td>a. Requirements</td>
<td></td>
</tr>
<tr>
<td>b. Recommendations</td>
<td></td>
</tr>
<tr>
<td>c. Suggested Best Practices</td>
<td></td>
</tr>
<tr>
<td>D. Nonconformances</td>
<td></td>
</tr>
</tbody>
</table>
A. BACKGROUND AND GENERAL FINDINGS / EXECUTIVE SUMMARY
   a. Overview / Current Accreditation Status
   b. Response to Previous Audits and Accomplishments
   c. Miscellaneous

B. COMMENDATIONS

C. CONCLUSIONS
   a. Requirements
      1. Respond to the Nonconformances sited in this report in writing, with documentary evidence, by the date requested in the accompanying letter from the Accreditation Committee Chair.
   b. Recommendations
   c. Suggested Best Practices

D. NONCONFORMANCES NOTED DURING SITE VISIT

AAVLD ER: 2.1 Organization, Management and Personnel

Requirement: “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 or laboratory animal diagnostic laboratories supported by the National Institutes of Health.”

Nonconformance: Response:

Requirement: “2.1.2 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.”

Nonconformance: Response:
AAVLD ER: 2.2 Finance and Budget

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

Nonconformance: 
Response:

Requirement: “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.”

Nonconformance: 
Response:

AAVLD ER: 4. Management requirements
4.1 Organization and Management

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

Nonconformance: 
Response:

Requirement: “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.”

Nonconformance: 
Response:

Requirement: “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.”

Nonconformance: 
Response:

Requirement: “4.1.4 The laboratory shall:
a) 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;”
Nonconformance:  
Response:

Requirement: “4.1.4 The laboratory shall:

b) have arrangements to ensure that its management and personnel are free from any undue internal or external commercial, financial and other pressures and influences that may adversely affect the quality of their work;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
c) 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;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
e) specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting the quality of the tests;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
f) provide adequate supervision of testing staff, including trainees, by persons familiar with the tests, their purpose, and the analysis of test results;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
g) 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;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
h) 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;”

Nonconformance:
Response:

Requirement: “4.1.4 The laboratory shall:
i) appoint backups or deputies for key managerial personnel such as the quality manager.”

Nonconformance:
Response:

AAVLD ER: 4.2 Quality system

Requirement: 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 test 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.”

Nonconformance:
Response:

Requirement: “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. The overall objectives shall be set out in a quality policy statement in the quality manual, stating the standard of performance to be achieved and maintained. The quality policy statement shall be issued under the authority of the chief executive.”

Nonconformance:
Response:

Requirement: “4.2.2 It shall include at least the following:
a) a statement of the laboratory management’s intentions with respect to the standard of service it will provide;”

Nonconformance:
Response:

Requirement: “4.2.2 It shall include at least the following:
b) the purpose of the quality system;”

Nonconformance:
Response:

Requirement: “4.2.2 It shall include at least the following:
c) a requirement that all personnel concerned with testing activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;”
Nonconformance: 
Requirement: “4.2.2 It shall include at least the following:
d) the laboratory management’s commitment to good professional practice and quality of its
diagnostic services to its client;”
Nonconformance: 
Response:

Requirement: “4.2.2 It shall include at least the following:
e) the laboratory management’s commitment to compliance with the AAVLD Standard.”
Nonconformance: 
Response:

Requirement: “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.”
Nonconformance: 
Response:

Requirement: “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.”
Nonconformance: 
Response:

AAVLD ER: 4.3 Document Control

Requirement: “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.”
Nonconformance: 
Response:

Requirement: “4.3.2 The laboratory shall have documented policy, 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.’
Nonconformance: 
Response:

Requirement: “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.”
Nonconformance:
American Association of Veterinary Laboratory Diagnosticians, Inc.
Accreditation Audit Report
Lab Name, Dates of site visit

Response:

Requirement: “4.3.4 Documents shall be uniquely identified and accurately cross-referenced.”
Nonconformance:
Response:

Requirement: “4.3.5 Documents shall include page numbers and total number of pages or a mark to signify the end of the document.”
Nonconformance:
Response:

AAVLD ER: 4.4 Review of request or contract

Requirement: “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.”
Nonconformance:
Response:

Requirement: “4.4.2 The review shall also cover any work that is subcontracted by the laboratory.”
Nonconformance:
Response:

AAVLD ER: 4.5 Subcontracting of test services

Requirement: “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.”
Nonconformance:
Response:

Requirement: “4.5.2 The laboratory shall advise the customer of the arrangement.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:
Requirement: “4.5.4 The laboratory shall maintain a list of all subcontractors that it uses for tests.”
Nonconformance:
Response:

AAVLD ER: 4.6 Purchasing services and supplies

Requirement: “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.”
Nonconformance:
Response:

AAVLD ER: 4.7 Complaints

Requirement: “The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.”
Nonconformance:
Response:

AAVLD ER: 4.8 Control of nonconforming testing and test results

Requirement: “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 laboratory shall have procedures for informing clients if test results are questionable or incorrect, particularly if this possibility is identified after test results have been reported to the client. These procedures shall describe who has the authority to withhold test results, implement corrective action, and authorize resumption of work.”
Nonconformance:
Response:

Requirement: “4.8.2 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.
Nonconformance:
Response:

AAVLD ER: 4.9 Corrective and preventive action
Requirement: “4.9.1 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.”
Nonconformance:
Response:

Requirement: “4.9.1 The policy and procedures shall ensure:
a) designation of appropriate authorities responsible for implementation of corrective action(s);”
Nonconformance:
Response:

Requirement: “4.9.1 The policy and procedures shall ensure:
b) investigative procedures are implemented to determine the root cause(s) of the problem;”
Nonconformance:
Response:

Requirement: “4.9.1 The policy and procedures shall ensure:
c) upon identification, appropriate corrective action(s) are implemented;”
Nonconformance:
Response:

Requirement: “4.9.1 The policy and procedures shall ensure:
d) documentation of any required changes to operational procedures;”
Nonconformance:
Response:

Requirement: “4.9.1 The policy and procedures shall ensure:
e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem;”
Nonconformance:
Response:

Requirement: “4.9.1 The policy and procedures shall ensure:
f) when appropriate, areas of activity subject to corrective action are audited in accordance with 4.11.”
Nonconformance:
Response:

Requirement: “4.9.2 The laboratory shall identify potential sources of nonconformance and potential needs for improvement, either technical or with the quality system.
Nonconformance:
Response:

Requirement: “4.9.2 Preventive action procedures shall include:
a) identification and evaluation of potential nonconformance or improvement;”
Nonconformance:
Response:

Requirement: “4.9.2 Preventive action procedures shall include:
b) development and implementation of an action plan, including appropriate controls;”
Nonconformance:
Response:

Requirement: “4.9.2 Preventive action procedures shall include:
c) monitoring of effectiveness in reducing likelihood of nonconformance or in addressing specific needs for improvement.”
Nonconformance:
Response:

AAVLD ER: 4.10 Records

Requirement: “4.10 All laboratory records must be maintained in an effective retrieval system and must be accurate, contemporaneous, attributable and legible. This retrieval system should include a system of classification of diseases. Records should be preserved in accordance with requirements for individual jurisdictions.”
Nonconformance:
Response:

Requirement: “4.10.1 General
The laboratory shall have a records management system.”
Nonconformance:
Response:

Requirement: “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 and preventive action records.”
Nonconformance:
Response:

Requirement: “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 times of records shall be established.”
Nonconformance:
Response:

Requirement: “4.10.1.3 All records shall be held secure and in confidence.”
Nonconformance:
Response:
Requirement: “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.

Nonconformance:
Response:

AAVLD ER: 4.10.2 Technical records

Requirement: “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.”

Nonconformance:
Response:

Requirement: “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.”

Nonconformance:
Response:

Requirement: “4.10.2.3 When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible nor 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.”

Nonconformance:
Response:

AAVLD ER: 4.11 Internal audits

Requirement: “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.”

Nonconformance:
Response:
Requirement: “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).”

Nonconformance:
Response:

Requirement: “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.”

Nonconformance:
Response:

AAVLD ER: 4.12 Management reviews

Requirement: “4.12.1 The quality system and test related activities shall be reviewed by management at least once per year.”

Nonconformance:
Response:

Requirement: “4.12.2 The laboratory shall have a procedure for performing a Management Review.”

Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
   a) suitability of policies and procedures;”

Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
   b) reports from managerial and supervisory personnel;”

Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
   c) reports of recent internal audits;”

Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
   d) corrective and preventive actions;”

Nonconformance:
Response:
Requirement: “4.12.2 The review shall take into consideration:
e) assessments by external bodies;”
Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
f) results of inter-laboratory comparisons or proficiency tests;”
Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
g) changes in the volume and type of work;”
Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
h) client feedback;”
Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
i) complaints;”
Nonconformance:
Response:

Requirement: “4.12.2 The review shall take into consideration:
j) other relevant factors, such as quality control activities, resources and staff training.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

AAVLD ER: 5. Technical requirements

AAVLD ER: 5.1 General
Requirement: “5.1.1 Many factors can affect the reliability of test results. The extent to which these factors contribute to the reliability of test results differs between tests. The laboratory shall take account of these factors in developing or adopting test methods and related procedures for routine use, in the training and qualification of personnel, in the selection and calibration of equipment, and in the assessment of materials and reagents to be used in testing.”
Nonconformance:
Response:

AAVLD ER: 5.2 Personnel

Requirement: “5.2.1 The laboratory shall ensure the initial and ongoing competence of all laboratory personnel to do their assigned work.”
Nonconformance:
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:
Response:

Requirement: “5.2.3 The laboratory shall have a system which ensures the establishment and maintenance of a training program relevant to the present and anticipated needs of the laboratory.”
Nonconformance:
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:
Response:

Requirement: “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.”
Nonconformance:  
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:  
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:  
Response:

Requirement: “5.3.4 Access to and use of areas affecting test results shall be controlled.”
Nonconformance:  
Response:

Requirement: “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.”
Nonconformance:  
Response:

AAVLD ER: 5.4 Test methods

AAVLD ER: 5.4.1 General

Requirement: “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 on 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.”
Nonconformance:  
Response:

Requirement: “5.4.1.2 Test methods shall be approved for use by qualified, authorized personnel, according to established procedures.”
Nonconformance:  
Response:
Requirement: “5.4.1.3 Tests shall be appropriately controlled.”
Nonconformance:
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:
Response:

Requirement: “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.”
Nonconformance:
Response:

AAVLD ER: 5.4.2 Selection of methods

Requirement: “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).”
Nonconformance:
Response:

Requirement: “5.4.2.2 Analysts shall have a record of documented proficiency in the performance of the test. Proficiency shall be documented on an ongoing basis, at appropriate intervals. Assessment of proficiency shall be based on objective data, using blind samples of appropriate number and composition. These samples should be well characterized.”
Nonconformance:
Response:

Requirement: “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 other information sources.”
Nonconformance:
Response:

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
   a) evidence of document control;”
Nonconformance:
Response:

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
   b) relevant references;”
Nonconformance:
Response:
Requirement: “5.4.2.3 In addition, it shall include as appropriate:
c) a description of intended analyte(s) (e.g., antibody) and any quantities or ranges to be
determined (e.g., titer);”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
d) any reference standards or reference materials required (e.g., reference strains, reference
standards for antibody);”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
e) a description of the appropriate matrix or specimen for testing, including species (e.g.,
bovine serum);”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
f) safety considerations, including biocontainment level needed;”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
g) a list of and specifications for equipment, materials, and reagents, including software;”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
h) conditions for acceptance of specimens as fit for testing;”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
i) conditions for specimen identification, collection, handling, transportation and storage;”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
j) conditions for sample preparation;”
Nonconformance: 
Response: 

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
k) a description of the controls used and their acceptance limits;”
Nonconformance: 
Response: 
Requirement: “5.4.2.3 In addition, it shall include as appropriate:
   l) checks to be made prior to beginning the test procedure (e.g., equipment checks and calibrations;”
   
   Nonconformance:
   
   Response:

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
   m) acceptance criteria for results;”
   
   Nonconformance:
   
   Response:

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
   n) 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;”
   
   Nonconformance:
   
   Response:

Requirement: “5.4.2.3 In addition, it shall include as appropriate:
   o) most current description of the test procedure.”
   
   Nonconformance:
   
   Response:

Requirement: “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).”
   
   Nonconformance:
   
   Response:

AAVLD ER: 5.4.3 Validation of test methods

Requirement: “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. While it is preferred that all methods, developed in-house or drawn from reputable collections of standard methods, undergo an in-house validation using an appropriate number of samples from the population of interest, the user is not required to re-validate international or national standard methods, but shall 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 shall provide documented evidence of data on and statistically valid assessment of comparative performance for those assays that are harmonized by interlaboratory comparison to an accepted and validated standard method.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

Requirement: “5.4.3.1 - AND one or more of the following:
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);
3) Published in a peer-reviewed journal with sufficient documentation to establish diagnostic performance and interpretation of results;
4) Documentation of internal or inter-laboratory comparison to an accepted methodology or protocol.”
Nonconformance:
Response:

Requirement: “5.4.3.2 Validation data, including all original observations, calculations, equipment monitoring and calibration records, and archived procedures used to formulate performance characteristics, 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.”
Nonconformance:
Response:

AAVLD ER: 5.4.4 Control of data

Requirement: “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 is secure, retrievable, and approved for use by specified, qualified personnel.”
Nonconformance:
Response:

Requirement: “5.4.4.2 Manual calculations and data transfers shall be subject to appropriate checks in a systematic manner.”
Nonconformance:
Response:

Requirement: “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:
a) 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;”

Nonconformance:
Response:

Requirement: “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:
b) 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;”

Nonconformance:
Response:

Requirement: “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:
c) 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.”

Nonconformance:
Response:

AAVLD ER: 5.5 Equipment

Requirement: “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.”

Nonconformance:
Response:

Requirement: “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.”

Nonconformance:
Response:

Requirement: “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.”

**Nonconformance:**

**Response:**

**Requirement:** “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.”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.4 Each item of equipment used for test activities significant to a test result shall be uniquely identified.”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.5 Records shall be maintained of each item of equipment significant to the tests performed.”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.5 The records shall include at least the following:

a) identity of the item of equipment;”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.5 The records shall include at least the following:

b) manufacturer’s name, type identification, and serial number or other unique identification;”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.5 The records shall include at least the following:

c) verification that equipment complies with the specification;”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.5 The records shall include at least the following:

d) the current location, where appropriate;”

**Nonconformance:**

**Response:**

**Requirement:** “5.5.5 The records shall include at least the following:

e) the manufacturer’s instructions, if available, or reference to their location;”

**Nonconformance:**

**Response:**
Requirement: “5.5.5 The records shall include at least the following:
   f) dates, results and copies of reports and certificates of all calibrations, adjustments,
   acceptance criteria, and the due date of next calibration;”
   Nonconformance: 
   Response: 

Requirement: “5.5.5 The records shall include at least the following:
   g) maintenance carried out to date, and the maintenance plan;”
   Nonconformance: 
   Response: 

Requirement: “5.5.5 The records shall include at least the following:
   h) damage, malfunction, modification or repair to the equipment.”
   Nonconformance: 
   Response: 

Requirement: “5.5.6 Maintenance procedures shall be established.”
   Nonconformance: 
   Response: 

Requirement: “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.”
   Nonconformance: 
   Response: 

Requirement: “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).”
   Nonconformance: 
   Response: 

Requirement: “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.”
   Nonconformance: 
   Response: 

Requirement: “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.”
   Nonconformance: 
   Response:
Requirement: “5.5.11 Test equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate the test results.”
Nonconformance:
Response:

AAVLD ER: 5.6 Measurement traceability

Requirement: “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.”
Nonconformance:
Response:

Requirement: “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:
a) the use of suitable reference standards or materials certified to give a reliable characterization of the material;”
Nonconformance:
Response:

Requirement: “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:
b) mutual-consent standards or methods that are clearly specified and agreed upon by all parties concerned;”
Nonconformance:
Response:

Requirement: “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:
c) participation in a suitable program of interlaboratory comparisons or proficiency testing.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

Requirement: “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).”
Nonconformance:
Response:

Requirement: “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.”

**Nonconformance:**

**Response:**

**Requirement:** “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.”

**Nonconformance:**

**Response:**

**AAVLD ER: 5.7 Specimens**

**Requirement:** “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.”

**Nonconformance:**

**Response:**

**Requirement:** “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.”

**Nonconformance:**

**Response:**

**Requirement:** “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.”

**Nonconformance:**

**Response:**

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

**Nonconformance:**

**Response:**

**AAVLD ER: 5.8 Handling of specimens**

**Requirement:** “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.”

**Nonconformance:**

**Response:**
Requirement: “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).”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

AAVLD ER: 5.9 Ensuring the quality of test results

Requirement: “5.9 Ensuring the quality of test results:
The laboratory shall have quality control procedures for monitoring the validity of test results.”
Nonconformance:
Response:

Requirement: “5.9 This monitoring shall be planned and reviewed and may include, but not be limited to, the following:
a) internal quality control schemes using statistical techniques (e.g., control charts);”
Nonconformance:
Response:

Requirement: “5.9 This monitoring shall be planned and reviewed and may include, but not be limited to, the following:
b) where applicable, use of international reference reagents for preparation of national and/or working standards for internal quality control;”
Nonconformance:
Response:

Requirement: “5.9 This monitoring shall be planned and reviewed and may include, but not be limited to, the following:
c) when practical, replicate tests using the same or different methods;”
Nonconformance: 
Response: 

Requirement: “5.9 This monitoring shall be planned and reviewed and may include, but not be limited to, the following: 
d) correlation of results for different characteristics of a specimen or sample;”
Nonconformance: 
Response: 

Requirement: “5.9 This monitoring shall be planned and reviewed and may include, but not be limited to, the following: 
e) re-testing of retained specimens or samples;”
Nonconformance: 
Response: 

Requirement: “5.9 This monitoring shall be planned and reviewed and may include, but not be limited to, the following: 
f) participation in interlaboratory comparison or proficiency testing programs.”
Nonconformance: 
Response: 

AAVLD ER: 5.10 Reporting test results

Requirement: “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.”
Nonconformance: 
Response: 

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information: 
a) a title (e.g., “Test Report”);”
Nonconformance: 
Response: 

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information: 
b) name and address of laboratory, and, if different, the location where the tests were performed;”
Nonconformance: 
Response: 

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:
c) 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;

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
d) name and address of the client placing the order;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
e) description and unambiguous identification of the specimen(s) tested;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
f) unique identification of the test method(s) used;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
g) date of receipt of specimen(s) and date(s) of performance of the test where relevant to the
validity and application of the results;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
h) test results;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
i) 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;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report
shall include at least the following information:
j) where appropriate and needed, opinions and diagnostic interpretations of the test results;”

Nonconformance:
Response:

Requirement: “5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:
   k) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report.”
Nonconformance:
Response:

Requirement: “5.10.3 Where applicable, the test report shall also include:
   a) date of specimen collection;”
Nonconformance:
Response:

Requirement: “5.10.3 Where applicable, the test report shall also include:
   b) unambiguous identification of specimen source;”
Nonconformance:
Response:

Requirement: “5.10.3 Where applicable, the test report shall also include:
   c) location of collection, including any diagrams, sketches or photographs;”
Nonconformance:
Response:

Requirement: “5.10.3 Where applicable, the test report shall also include:
   d) reference to sampling plan used (see 5.7.1.3.);”
Nonconformance:
Response:

Requirement: “5.10.3 Where applicable, the test report shall also include:
   e) details of any environmental condition during collection that may affect the interpretation of the test results;”
Nonconformance:
Response:

Requirement: “5.10.3 Where applicable, the test report shall also include:
   f) identification of the collection procedure or technique.”
Nonconformance:
Response:

Requirement: “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.”
Nonconformance:
Response:

Requirement: “5.10.5 When the test report contains results of tests performed by
subcontractors, these results shall be clearly identified.”

Nonconformance:
Response:

Requirement: “5.10.6 In the case of transmission of test results and/or interpretations by telex, facsimile or other electronic or electromagnetic means, the requirements of the AAVLD Standard shall be met.”

Nonconformance:
Response:

Requirement: “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.”

Nonconformance:
Response:

Requirement: “5.10.8 When a battery of tests are 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 that is uniquely identified and shall contain a reference to any and all interim reports that it replaces.”

Nonconformance:
Response:

Requirement: “5.10.9 When a material amendment to a test report that has been issued is necessary, a supplement to the test report shall be issued to the client. Such amendments shall be uniquely identified as a supplement, shall contain a reference to the original test report and shall meet all the requirements of the AAVLD Standard.”

Nonconformance:
Response:

Requirement: “5.10.10 When it is necessary to issue a new test report, it shall be uniquely identified and shall contain a reference to the original that it replaces.”

Nonconformance:
Response: