Quality Manual

South Dakota State University (SDSU)

Animal Disease Research and Diagnostic Laboratory (ADRDL)

2022

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Introduction

The Animal Disease Research & Diagnostic Laboratory (ADRDL) has been diligently providing quality veterinary diagnostic services to the state of South Dakota and the region since 1887.

The ADRDL has been continuously accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD) since 1970 as a general, all species laboratory.

The AAVLD is an accreditation body assisting public veterinary diagnostic laboratories in North America to meet or exceed the standards of the World Organization for Animal Health (WOAH) and it provides a periodic independent external evaluation of ADRDL's Quality Management System (QMS) to help it fulfill its commitment of offering quality and reliable veterinary diagnostic services to its clients.

This Quality Manual is a guiding tool for ADRDL employees to build and continually improve its QMS to meet client expectations. The policies contained in this manual and system procedures developed are intended to address the management and technical requirements found in the current version of the AAVLD Essential Requirements. The quality goal of ADRDL is expressed as the quality statement.

ADRDL Quality Statement

The ADRDL at South Dakota State University is committed to provide quality veterinary diagnostic services and sound scientific research to its clients while complying with applicable regulatory and/or AAVLD requirements. The management strongly endorses the implementation and maintenance of a Quality Management System (QMS) that ensures the policies and procedures of the laboratory meet applicable laboratory standards, satisfy the clients' needs, and provide a vehicle for continuous quality improvement. It is a laboratory policy to educate ADRDL employees with its QMS policies and procedures so they can be part of successful QMS at ADRDL.

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Quality Manager

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Head/Director, VBSD/ADRDL

ADRDL Quality Committee

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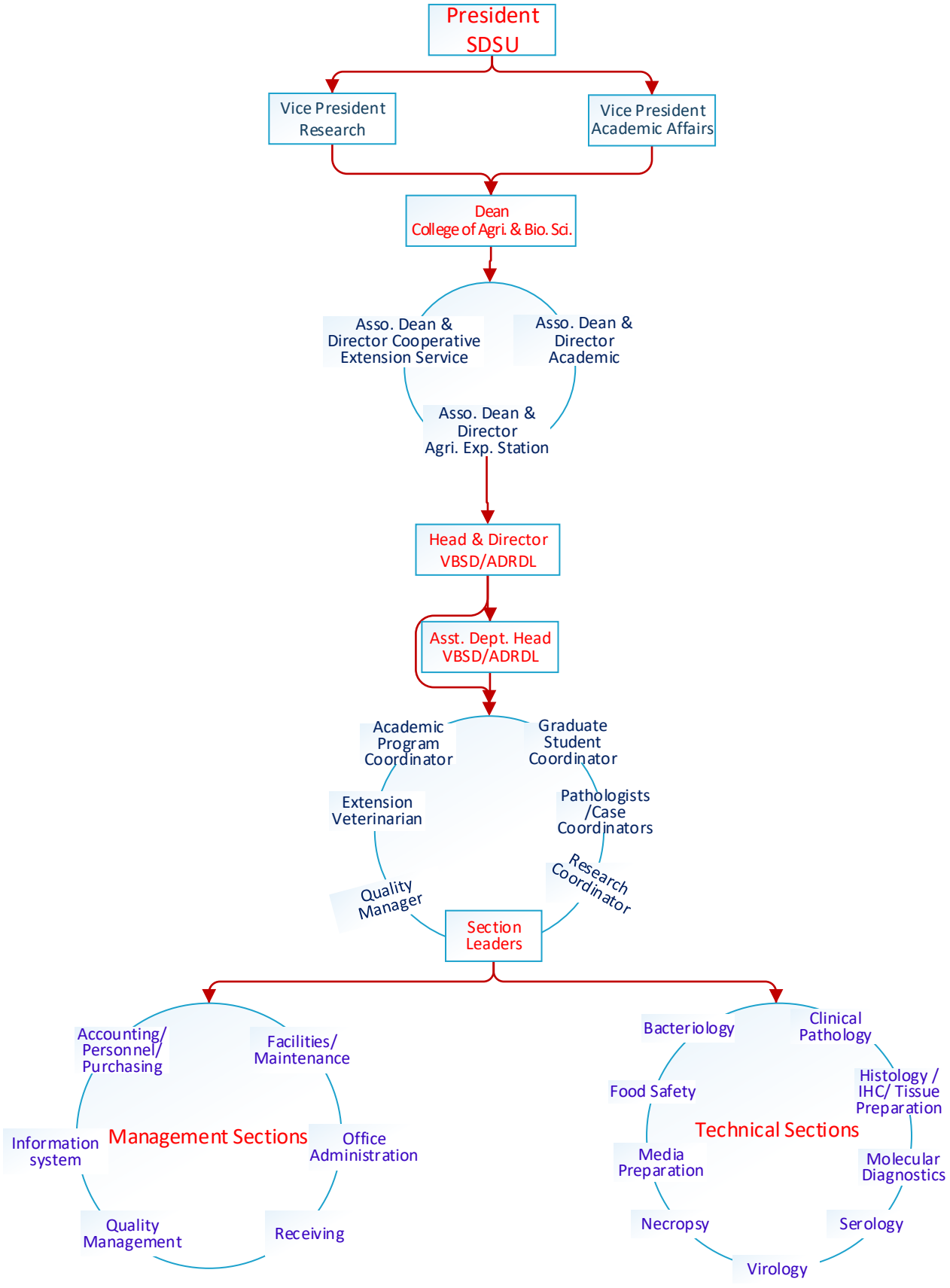
Organization Chart



1. Scope

QMS policies and procedures of this manual are applicable to ADRDL employees performing diagnostic testing and related activities.

2. References:

2.1. “Requirements for an Accredited Veterinary Medical Diagnostic Laboratory”, American Association of Veterinary Laboratory Diagnosticians, Inc., AC-1, Version 2021-01.

3. Terms and Definitions

3.1. Accreditation: A process by which AAVLD gives formal recognition that ADRDL is competent to carry out specific tasks as outlined in accreditation requirements.

3.2. Client – An entity (e.g., person or customer, company, agency, organization, etc.) which seeks diagnostic services from ADRDL.

3.3. 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 actions, risk assessments, analyzing data and setting objectives.

3.4. 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. 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.

3.5. Document – Any information or instruction, in any format or medium that has direct bearing on or effect on the quality of test results (e.g. quality manual, policy, test procedure, work instructions, forms, test methods, worksheets, forms, etc.).

3.6. Specimen: A material submitted by a client for testing, e.g., lung tissue

3.7. Sample – A material that is derived from a specimen and used for testing purposes.

3.8. Policy, n – A written statement of overall intentions and directions defined and endorsed by ADRDL to achieve a specific goal.

3.9. Procedures, n – A specified way to perform an activity. ADRDL test methods are written as Standard Operating Procedures (SOPs).

3.10. 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.

3.11. Quality, n – Quality means fitness for purpose. So no matter what diagnostic service is provided by ADRDL, it must be fit for its purpose. To

be fit for purpose, the diagnostic service must meet client expectations and applicable requirements and be efficient in terms of diagnostic performance.

3.12. Quality assurance, n – Planned program consisting of the required actions to provide adequate confidence that test or testing activity conforms to established technical requirements.

3.13. Quality control, n – Operational techniques and activities that are used to ensure that quality standards are being met.

3.14. Quality Management System (QS): A set of interrelated elements used to implement and direct quality planning, quality control, quality assurance, and quality improvement.

3.15. Record – Any and all written materials that provide proof of compliance with the quality system and evidence that a specified activity has been performed. It could be a paper or digital copy and should be attributable to an individual.

3.16. 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.

4. Management requirements

4.1. Organization and management

4.1.1. The ADRDL is a legally responsible diagnostic laboratory of the VBSD of the College of Agriculture and Biological Sciences at SDSU. SDSU is one of six state supported universities under the direction of the South Dakota Board of Regents. All Board of Regent employees are considered employees of the state of South Dakota. Employee job descriptions are maintained by SD Board of Regents.

4.1.2. The ADRDL's place within SDSU is demonstrated in the VBSD organizational chart, page 5 of this manual. ADRDL sectional organizational charts are prepared as per instructions on creating organizational chart.

4.1.3. Each section has a leader who supervises testing and related activities performed within the section.

4.1.4. During temporary absence of the section leader, section leadership responsibilities will be delegated per the section organizational chart.

4.1.5. The assistant quality manager is the backup person for the quality manager.

4.2. Quality System

4.2.1. The management of the ADRDL is committed to the establishment, implementation, and maintenance of AAVLD compliant QS for the testing and related activities of the department.

4.2.2. This manual is written and approved by the quality committee. It is reviewed periodically by the quality committee. The members of the quality committee are identified on page 4 of this manual.

4.2.3. This manual is available to the staff members of the ADRDL and quality manager provides training to the staff to educate them with the QS policies and procedures.

4.2.4. Diagnostic procedures are written as per the Document Control System (Section 4.3).

4.2.5. Responsibilities of the quality manager:

4.2.5.1. Leads the overall QS in compliance with AAVLD requirements.

4.2.5.2. Maintains the quality manual and QS policies & procedures.

4.2.5.3. Trains the staff for implementation of QS policies & procedures.

4.2.5.4. Schedules, coordinates, and leads the internal audit program to evaluate the QS.

4.2.5.5. Chairs the quality committee.

4.2.5.6. Coordinates laboratory efforts to maintain AAVLD accreditation.

4.2.5.7. Manages documents and records pertaining to the QS.

4.2.6. Section leaders and case coordinators are responsible for ensuring compliance of diagnostic activities performed within their sections with ADRDL QS.

4.2.7. Employees performing diagnostic and related activities are required to adhere to and follow the applicable QS policies and procedures.

4.2.8. Quality committee serves as a management review committee.

4.3. Document control

4.3.1. ADRDL has a document control procedure which describes how to write, approve, review, revise or update, issue, and remove the documents.

4.3.2. It requires following

4.3.2.1. Use of the most current version of the document.

4.3.2.2. Easy accessibility.

4.3.2.3. A system for document identification.

4.3.2.4. It states which personnel are authorized to make document revisions.

4.4. Review of request, tender or contract

4.4.1. The ADRDL has contract review policy which describes a procedure to review the submission contract. The laboratory website provides information to assist the submitting veterinarian / client in test selection and the submission process. The submission forms serve as a tacit agreement / contract between the client and the laboratory. This policy specifies how to evaluate the submission for order errors, how to communicate those errors to the client, how to resolve the submission errors and how to document the resolution process.

4.4.2. Request for outsource testing is also subject to the review process.

4.5. Outsourcing of test services

4.5.1. The ADRDL has a policy for selection of laboratories to use for outsourcing work.

4.6. Purchasing services and supplies

4.6.1. The ADRDL has a procedure for the purchasing of supplies and services that affect the quality of the test. The procedure outlines steps for ordering, receipt, evaluation, use, handling and storage of laboratory reagents and consumables.

4.7. Client complaints

4.7.1. The ADRDL is committed to quality client services. A key component of client service is client complaint resolution. A complaint is defined as a client dissatisfaction for the diagnostic service. Client complaint received by the ADRDL staff is important and is investigated to resolve the issue. A Client Complaint Form is used to document the complaint, action taken and determination if a corrective action is necessary or not. If a corrective action is necessary, steps described in section 4.9.1 are followed.

4.7.1.1. The investigation of such corrective action is linked with the original case report (as applicable) and the concerned parties are notified about the investigation. Data concerning the client complaint resolution process are monitored for quality purposes and reported in the management review. The client complaint resolution procedure involves notification of the quality manager for quality tracking purposes. The final action taken is reviewed and approved by the laboratory director.

4.8. Control of nonconforming testing and test results

4.8.1. The SOPs specify what quality controls are used for the respective test. Acceptance criteria for those quality controls are described in the SOP. When controls are outside of the accepted limits, the person performing the test contacts the bench leader / immediate supervisor, or section leader. Test results are not reported until the supervisory person has investigated the out of limit controls and resolved the issue.

4.8.1.1. Wherever it is not possible to run quality controls along with the test procedure, appropriate steps are taken to ensure the reliability of test results.

4.8.2. When out of limit control values are discovered after the tests have been reported to the client, the investigation process includes re-analyzing the affected samples at no lab fee cost to the client. If the investigation demonstrates that the error in the initial result was significant enough to cause a change in the conclusion of the test, the supervisory staff contacts the section leader. The section leader contacts the client with a corrected report that is attached to the initial report.

4.8.2.1. A corrective action report must be initiated under these circumstances to prevent such incidents from reoccurring.

4.9. Corrective action, risk assessment, and improvements.

4.9.1. When nonconforming testing or failure (e.g., LIMS) or departure from applicable policies and procedures is identified at the ADRDL, section leader or a designated employee investigates the incident. Goal of the corrective action procedure is to take steps to remove the cause of the incident. A corrective action form is used to document the issue, root cause, corrective action, monitoring plan, and outcome of the investigation. The supervisor determines what corrective action is necessary to ensure that quality results are provided to the client. The procedure for corrective action states how long the suggested corrective action will be monitored for effectiveness in preventing a reoccurrence of the incident. A final copy of the corrective action form is given to the quality manager for quality tracking purposes. When appropriate, corrective actions taken for diagnostic activities should be audited as outlined in section 4.11.

4.9.2. Risk Assessment and improvements:

4.9.2.1. ADRDL analyses risks and opportunities (e.g., client feedback) associated with the diagnostic activities to determine their impact.

4.9.2.2. The goal of such analysis is to address potential risk and or explore opportunities to ensure following.

4.9.2.2.1. achieve intended results for the services

4.9.2.2.2. achieve/enhance/improve ADRDL objectives

4.9.2.2.3. prevent or reduce the impact of potential failures on diagnostic services.

4.10. Records

4.10.1. ADRDL has a system for accurate, contemporary, attributable (e.g., who performed the test), and legible records management for diagnostic work (e.g., test reports) and related activities (e.g., training records/internal audits/management reviews). The ADRDL records management procedure

4.10.1.1. specifies how diagnostic case records are uniquely identified, stored to prevent unauthorized access or amendment to data, damage, deterioration, or loss during storage, and how they are discarded. The records storage system ensures that the records are readily retrievable.

4.10.1.2. specifies how records are released and who may receive the records. Record storage and retention practices are designed for information security (e.g., protection against unauthorized access) and confidentiality.

4.10.1.3. outlines a procedure to be followed for correction of paper and electronic diagnostic records.

4.10.1.4. requires that electronic data are backed up periodically.

4.11. Internal Audits

4.11.1. Testing and related activities are periodically audited to verify that the quality policies and procedures are being implemented and are in compliance with appropriate requirements.

4.11.2. The VBSD quality manager is responsible for scheduling and conducting internal audits and reporting the results of the audits to the management and respective sections.

4.11.3. If necessary, qualified employees will be selected and trained to conduct such audits.

4.11.4. Personnel do not audit their own activities.

4.11.5. The intention of internal audits is to identify areas of nonconforming testing so corrective actions can be taken as specified in sections 4.8 and 4.9 of this manual.

4.11.6. The internal audit procedure specifies that a check list is prepared by the auditors to be used in the audit process to document the findings and necessary corrective action. The section supervisor leads the investigative process of corrective actions revealed by the audit and reports findings to the management in a timely manner.

4.11.7. If audit findings reveal that the test results have been compromised, ADRDL will notify affected clients of the erroneous results and actions being taken to address and prevent the problem.

4.12. Management reviews

4.12.1. The VBSD QS is reviewed by the management annually in order to ensure the continuing suitability and effectiveness of quality related activities. The review process considers:

4.12.1.1. status of actions from previous management reviews
4.12.1.2. suitability of policies and procedures
4.12.1.3. reports from managerial and supervisory personnel
4.12.1.4. reports of recent internal audits
4.12.1.5. corrective actions, risk assessments, and improvements
4.12.1.6. assessments by external bodies
4.12.1.7. results of inter-lab comparisons
4.12.1.8. proficiency testing results
4.12.1.9. changes in volume and type of workload
4.12.1.10. client feedback
4.12.1.11. client complaints
4.12.1.12. other relevant issues (e.g., quality assurance activities / staff training, additional resources etc.)

4.12.2. Necessary action items relative to QS improvement and changes are recorded and assigned to the appropriate member of the quality committee for prompt implementation.

5. Technical requirements

5.1. Personnel

5.1.1. ADRDL has specific job descriptions for employees involved in testing and related work.

5.1.2. ADRDL employees, hired for testing and related work, are required to undergo appropriate safety training and understand ADRDL QS policies and procedures to perform testing and related work.

5.1.3. The management of the ADRDL authorizes only individuals that are documented as qualified and competent to do testing and related work.

5.1.4. The ADRDL has a personnel training procedure to ensure the initial and ongoing competence of the personnel involved in testing and related work.

5.1.5. The ADRDL personnel training needs are evaluated during the management review to ensure that present and anticipated needs of the lab are met.

5.2. Accommodations and environmental conditions

5.2.1. The ADRDL facilities have procedures to ensure that the accommodations and environmental conditions do not invalidate the results or adversely affect the quality of diagnostic work.

5.2.2. The ADRDL monitors, records, and controls environmental conditions as required by relevant test procedures and each ADRDL section is responsible for these activities. Areas of importance to monitor are: temperature, biological sterility, humidity, airflow, dust, electromagnetic interference, electrical supply, sound, and vibration levels as appropriate to the concerned test procedures. When necessary, acceptable ranges of the conditions are established and work is kept in abeyance when environmental conditions exceed these ranges.

5.2.3. Incompatible activities are performed in areas with effective physical separation. Measures are taken to prevent cross contamination in all testing areas of the lab.

5.2.4. Access to and use of areas affecting test results is controlled, where appropriate.

5.3. Test methods

5.3.1. General

5.3.1.1. The ADRDL test methods are selected after giving due consideration to factors that impact relevance of the test method and results to specific interpretation or application. These factors include:
- 5.3.1.1.1. suitability of the test method,
- 5.3.1.1.2. acceptability by the scientific and regulatory communities,
- 5.3.1.1.3. acceptability to the clients and
- 5.3.1.1.4. method's feasibility given available laboratory resources.

5.3.1.2. ADRDL test methods are written as SOPs according to document control procedure and used at the bench after they are approved.
- 5.3.1.2.1. Standard templates are available for writing SOPs for ADRDL test methods & Quality System / Administrative / Clerical policies and procedures.
- 5.3.1.2.2. The SOP for the test method contains enough critical and descriptive information such that a trained employee can properly perform the test method within pre-established control limits without reference to external information sources.
- 5.3.1.2.3. Where possible, test methods are appropriately controlled through the use of positive and negative test controls.
- 5.3.1.2.4. Critical activities related to test methods are also written according to the current document control procedure. These critical activities include, but not limited to, equipment operation / calibration / maintenance, personnel training, sample collection, handling, and transportation (where applicable), sample preparation for testing, sample storage and disposal etc.

5.3.1.2.5. Timely updates are received for test methods prepared by national and international standards-setting bodies and other external technical organizations (e.g., National Animal Health Laboratory Network (NAHLN) protocol for Avian Influenza testing). These shall also become controlled documents of the laboratory.

5.3.2. Selection of methods

5.3.2.1. Where possible, the test methods are selected from reputed national or international organization (e.g., NAHLN, CDC, FSIS, Microbiology Laboratory Guide(MLG), etc.).

5.3.2.2. Clients are informed of the test methods (and the rationale, if required) through the user's guide and fee schedule.

5.3.2.3. Test methods are validated before incorporation into the routine diagnostic activities of the ADRDL (See 5.3.3).

5.3.3. Validation of the Test Methods

5.3.3.1. The ADRDL maintains a test method validation procedure which provides guidelines on how to validate a method before it is used for testing purposes.

5.3.3.1.1. This procedure states that the non-standard test methods (modified standard test methods or ADRDL developed test methods) undergo an in-house validation using an appropriate number of samples from the population of interest.

5.3.3.1.2. International or national standard test methods do not require re-validation. However, sources from which such methods are adopted, need to be indicated in respective SOP's reference section.

5.3.3.2. The ADRDL test method validation procedure states that validation data, references and records need to be retained for the entire time the assay is in service and for seven years after the procedure is removed from use.

5.3.4. Control of data

5.3.4.1. The ADRDL has procedures to ensure that

5.3.4.1.1. data related to diagnostic work, whether validation, quality control or diagnostic results are held in a secure system, easy to retrieve, and approved for use.

5.3.4.1.2. there is a systematic check for manual calculations and the data transfers.

5.3.4.1.3. the software developed or modified by the department is documented, validated, and checked for correct function.

5.3.4.1.4. Laboratory Information Management System and interfaces are validated for functionality.

5.3.4.1.5. additions or deletions to such functionalities are also validated before implementation.

5.3.4.1.6. a system is in place to protect the security (e.g., no unauthorized access, tampering, or loss), confidentiality, integrity and retrievability of the data.

5.3.4.1.7. the computers and related equipment are maintained to provide correct operating conditions.

5.4. Equipment, including computers and software

5.4.1. The ADRDL has pertinent equipment required to perform diagnostic services offered to the clients. If equipment outside of permanent control of the lab is used, the ADRDL is required to ensure that the equipment is maintained to comply with this manual.

5.4.2. The equipment and software used for testing purposes are capable of achieving the accuracy required for the concerned procedures.

5.4.3. The ADRDL has a system to ensure that equipment used for test activities, significant to a test result, is uniquely identified.

5.4.4. Only qualified and authorized personnel are allowed to operate equipment and software used for testing purposes. Up to date procedures for equipment operation, work instructions, and relevant manufacturer's manual are maintained and made readily available to appropriate personnel.

5.4.5. Procedures for equipment calibration and maintenance are followed by qualified personnel at specific intervals to ensure that the equipment provides reliable data.

5.4.5.1. The ADRDL equipment maintenance procedures include methods to prevent making adjustments to equipment, both hardware and software, that would invalidate the calibration.

5.4.5.2. When possible, test equipment is labeled with the calibration date and the date when the next calibration is due.

5.4.6. The ADRDL equipment maintenance and calibration procedure specifies following records to be maintained for equipment used for testing activities.

5.4.6.1. the identity of the equipment;

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

5.4.6.3. verification the equipment complies with the specification;

5.4.6.4. current location where appropriate;

5.4.6.5. the manufacturer's instructions, if available, or reference to their location;

5.4.6.6. dates, results and copies of reports and certificates of calibrations, adjustments, acceptance criteria and due date of the next calibration or calibration verification;

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

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

5.4.7. Equipment that is defective or performing outside of specified limits is taken out of service promptly and clearly labeled as non-functional. Such equipment is not used for testing purposes until it has been repaired and shown to perform correctly. The lab determines if a nonconforming test investigation is needed. Any test activity that has been reported to the client and found to be out of compliance needs to be repeated at no cost to the client.

5.4.8. When equipment goes outside of the direct control of the lab, for whatever reason, the ADRDL demonstrates that the equipment is functioning properly before returning it to service.

5.4.9. The ADRDL has procedures to ensure that computers used for collection, processing, recording, reporting, storage, or retrieval of test data, meet the requirements of 5.3.4.1.3 – 5.3.4.1.5

5.5. Measurement traceability

5.5.1. Where applicable, the ADRDL has traceability of measurements to *Systeme International* (SI) units (e.g., calibration of relevant equipment).

5.5.2. Where traceability of the measurements to SI units is not possible, the ADRDL uses the best available means to provide confidence in the results such as:

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

5.5.2.2. Mutual-consent standards or methods that are clearly specified and agreed upon by all parties concerned.

5.5.2.3. Participation in a suitable program of inter-laboratory comparisons or proficiency testing.

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

5.5.4. Biological reference materials are, where possible, traceable to accepted international standards or to OIE reference materials, (ex. International Standard Sera, ATCC bacterial culture etc.).

5.5.5. The ADRDL has defined procedures and schedules intended to maintain confidence in the status of working standards and reference materials.

5.5.6. The ADRDL has procedures for safe handling, transport, storage and use of reference standards and reference materials to prevent contamination or deterioration.

5.6. Specimens

5.6.1. The ADRDL has procedures for the collection of specimens (wherein ADRDL employees are directly involved) to ensure their suitability for testing, processing, storage of specimens. Collection and related procedures are available at the location where the collection is undertaken. The appropriate specimen collection procedures are made available to the clients through the user's guide.

5.6.2. The ADRDL specimen collection procedure specifies recording relevant data and operations as it relates to the quality of the subsequent testing.

5.7. Handling of specimens

5.7.1. The ADRDL has procedures to ensure the integrity of the specimens. These procedures include receiving and forwarding them to appropriate areas, handling (including client instructions), protection, retention and or disposal of samples.

5.7.2. The ADRDL has a system for identifying specimens that ensures no confusion between specimens or derived samples. The identification is retained throughout the life of the specimen and its derived samples in the laboratory and linked to the test report.

5.7.3. Upon receipt of the specimen, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, are recorded. In case of client request to deviate from the standard procedure, a disclaimer is added to the report.

5.7.4. When there is any doubt about the suitability of the specimen for testing purposes, or when the specimen does not conform to the description provided, or if the test method required is not indicated, the ADRDL staff consults client for further instructions before proceeding and records the facts and results of the discussion.

5.8. Ensuring the quality of test results

5.8.1. The ADRDL has procedures for monitoring the validity of test results. These monitoring procedures include;

5.8.1.1. use of test methods selected from reputable organizations (e.g., NAHLN);

5.8.1.2. authorizing only trained employees for testing and related activities;

5.8.1.3. maintenance and calibration of instruments at regular intervals and monitoring equipment performance;

5.8.1.4. use of consumables from reputable sources;

5.8.1.5. when possible, use of internal quality control schemes based on statistical techniques (control charts);

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

5.8.1.7. when practical, replicate tests using the same or different methods or using alternate calibrated instrument;

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

5.8.1.9. retesting of retained specimens or samples;

5.8.1.10. participation in inter-laboratory comparison or proficiency testing programs or using blind samples;

5.8.1.11. result review;

5.8.2. When data from monitoring activities are found to be outside pre-defined criteria, appropriate actions are taken to prevent incorrect results from being reported.

5.9. Reporting Test Results

5.9.1. ADRDL reviews the results before authorizing them for release to appropriate client(s) to ensure accuracy and clarity in accordance with any specific instructions in the test method or contract, to the extent possible.

5.9.2. Each ADRDL test report includes at least the following information:

5.9.2.1. A title (e.g., “PCR MULTIPLEX PRRS”);

5.9.2.2. The complete name and address of the ADRDL and the location where the tests were performed, if different from the main lab;

5.9.2.3. A unique case identification number which appears at the beginning of the report and on each page of the report. The last page indicates a clear identification of the end of the report;

5.9.2.4. Name and address of the client placing the order;

5.9.2.5. Unambiguous identification and description of the sample(s) tested;

5.9.2.6. Unique identification of the test method(s) used;

5.9.2.7. Date the sample was received by the lab and the date the testing was performed;

5.9.2.8. The results of the testing;

5.9.2.9. Reference to specimen collection procedures used by the lab or by the client where these are relevant to the validity or application of the results;

5.9.2.10. Where appropriate and needed, opinions and interpretations of the test results;

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

5.9.3. Where applicable the test report includes:

5.9.3.1. The date of the sample collection;

5.9.3.2. Unambiguous identification of the sample source;

5.9.3.3. Location of collection, including any diagrams, sketches or photographs;

5.9.3.4. Details of any environmental condition during collection that may affect the interpretation of the test results;

5.9.3.5. Identification of collection procedure or technique.

5.9.4. When opinions and interpretations are included in the test report, the basis on which the opinions and interpretations have been made are documented, when appropriate.

5.9.5. When the test report contains results of tests performed by an outsourced lab, the results are clearly identified as performed or provided by the outsourced lab.

5.9.6. Test reports issued (hard copy or electronic format) shall comply with AAVLD reporting requirements.

5.9.7. The test reports are designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse of the report.

5.9.8. Test reports can be issued prior to the completion of all testing. Such reports also have unique identification number. Such reports indicate what tests have been completed, what tests are pending, contain references to any and all preceding reports and comply with AAVLD reporting requirements.

5.9.9. Upon completion of all testing, a final report is issued that is uniquely identified and shall contain a reference to any and all previous reports that the test report replaces.

5.9.10. When changes or addendum to the report needs to be communicated to the client after a test report has been issued, an addendum is issued to the client. Such addendums also are uniquely identified, contain a reference to the test report and comply with applicable reporting requirements.

5.9.11. When it is necessary to issue an additional test report, it is uniquely identified and shall contain a reference to the report it replaces.

6. Revision History

6.1. Updated or added following.

6.1.1. Introduction

6.1.2. Quality statement

6.1.3. Quality committee list

6.1.4. Reference

6.1.5. Definitions for corrective action and risk assessment
6.1.6. Updated 4.9 to include risk assessment and improvements
6.1.7. Updated record, internal audit, and management review sections.

6.2. Minor semantic changes throughout the manual.

“Quality in a service or product is not what you put into it. It is what the client or customer gets out of it.”

- Peter Drucker