
ARIZONA VETERINARY DIAGNOSTIC LABORATORY

QUALITY MANUAL

June 12, 2015

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2.0 Document Structure

The quality manual has been prepared by the Arizona Veterinary Diagnostic Laboratory (AzVDL) as part of the Quality Assurance/Quality Control Program for use by personnel in the conduct of their business. The manual describes the QA/QC Program and the objectives of AzVDL as listed in the Director's Quality Policy Statement. The documentation is comprised of the Quality Manual and current Standard Operating Procedures:

Quality Manual

System Procedures

Q-Quality

Q001 through Q020

A-Administrative

A001 through A031

F-Facility

F003 through F046

Laboratory Procedures

B-Bacteriology

B001- B130

P102 - P107

S111 - S114

Cytology

H102 through H115 and T140

H-Histopathology

H001 – H061

I-Immunohistochemistry

I003 through I165

M-Molecular-PCR

M001 through M322

N-Necropsy

N001 through N118

S-Serology

V013, V150

S101-127

V-Virology

V001-V096

Master Lists (Table of Contents for each SOP manual)

3.0 Director's Quality Policy Statement

The Arizona Veterinary Diagnostic Laboratory (AzVDL) is an AAVLD accredited laboratory. A current accreditation certificate is prominently displayed and maintained in the front office, Rm. 120. AzVDL maintains a quality system that meets or exceeds the standards of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) Requirements for an Accredited Veterinary Medical Diagnostic Laboratory.

AzVDL is committed to excellence in diagnostic service and animal disease surveillance provided to the veterinarians and animal owners of the State of Arizona. Our qualified laboratory staff is committed to conduct all tests, evaluations and reports in a reliable manner, in accordance with established policies and procedures. We will strive to improve the quality of our services at reasonable cost and to constantly satisfy the expectations of our customers and relevant agencies.

Measurable objectives include:

- Providing timely and accurate diagnostic results as requested by our clients
- Providing appropriate training for faculty and staff when possible
- Maintaining compliance with the quality standards established in this manual.

AzVDL conducts all measurements under conditions and by using techniques that are conducive to a high degree of reliability and follows good laboratory practices. It is our policy to provide the highest quality services attainable to clients and field staff through continuous improvement of the quality system.

The senior management of AzVDL also undertakes to ensure that all activities comply with the AAVLD Requirements and are conducted in accordance with University documented procedures as described in the UA Policies and Procedures.

Signed: GAB (Signature on File)
Dr. Gregory Bradley

Title: Director

Date: June 12, 2015

4.0 The Arizona Veterinary Diagnostic Laboratory

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(520) 626-8696 Fax
cals.arizona.edu/vdl

4.1 Organization of AzVDL

4.1.1 The Arizona Veterinary Diagnostic Laboratory (AzVDL) is a state and fee funded laboratory; a part of the Arizona Agricultural Experiment Station under the College of Agriculture and Life Sciences of the University of Arizona in Tucson, Arizona. The University of Arizona is a legally responsible entity. The Laboratory Director reports to the Dean of the College of Agriculture and Life Sciences.

4.1.2 The laboratory operates according to the terms of this Quality Manual and the AAVLD Requirements, whether work is conducted in the permanent facility, at sites away from the permanent facility, or in temporary quarters.

4.1.3 AzVDL has a clearly defined organizational system and structure. Refer to the Organizational Chart in Appendix A of this manual for the organization structure and personnel. The job responsibilities and authorities for all personnel are found in the job descriptions which are maintained at the laboratory as well as at the University of Arizona website: http://www.hr.arizona.edu/cs_jobdesc_search (Accessed June 2015)

4.1.4 a) AzVDL management has the responsibility and authority for supervising and administering the quality system. The Quality Assurance Manager may identify the occurrence of departures from protocol, via quality system inspections (SOP Q005 *Internal Audits*), and has the authority to initiate actions to prevent or minimize non-conformances as needed (SOPs Q006 *Non-Conformance and Corrective Actions* and Q007 *Preventive Actions*).

b) AzVDL management and personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. Potential conflicts of interest are governed by university policies as stated in the UA Conflict of Interest and Commitment Policy and by the regulations of the State of Arizona. AzVDL management and staff do not engage in any outside activities that would compromise their ability to generate quality and legally defensible data.

c) The laboratory protects confidential information and the proprietary rights of its clients during the analysis period and when issuing hard copy or electronic reports according to SOP A012 *Client Confidentiality*. AzVDL maintains all material and information it obtains in the course of its professional consultations in the strictest confidence, to the extent allowed by state laws. No material relating to any client consultation will be disclosed except as required under such laws, absent consent of the client to disclosure. To assist it in these efforts, AzVDL expects all its clients to cooperate fully and to provide AzVDL with assistance in any proceedings or other actions that may be necessary to maintain confidentiality.

d) Management has policy and procedures as established in SOP *Q016 Code of Ethics* to ensure that employees do not engage in any activities that might diminish the confidence in its competence, impartiality, judgment or operational integrity.

e) The AzVDL technical staff report to a Section Head. The Section Heads report to the Laboratory Director, who in turn reports to the Dean for the College of Agriculture and Life Sciences. Refer to the organizational chart in section 6.0 for organization structure and the relationship between management, quality management and technical staff.

f) Section heads are responsible for ensuring that their section members are competent and have received all required training prior to allowing them to work on client specimens. Section Heads are responsible for the review of data including quality control results. Refer to AzVDL job descriptions for a more detailed description of job duties and responsibilities for each position in the laboratory.

g) Section Heads are familiar with the testing performed in their area to adequately supervise the analysts and trainees performing those tests. The Section Head shall authorize the analyst to conduct the tasks and tests and to operate specific equipment.

h) Section Heads enforce the quality and safety policies within their sections. It is their responsibility that all requirements of the quality system are strictly followed. Section Heads are also responsible for providing the resources needed to ensure the required quality of laboratory operations.

i) The Laboratory Director has overall responsibility for the technical operations within the laboratory and supervises the Section Heads. The Laboratory Director has responsibility and authority for:

1. Enforcing the quality and safety policies within the laboratory;
2. Facilitating resolution of conflicting issues involving two or more sections within the laboratory;
3. Approving departures from documented policies and procedures; and
4. Ensuring compliance with the laboratory quality management system and the AAVLD Requirements.

The Quality Manager reports to the Laboratory Director. The Quality Manager has responsibility and authority for:

1. Ensuring that the quality system is implemented and followed at all times;
2. Ensuring compliance with the laboratory quality management system and the AAVLD Requirements;
3. Stopping work for reasons of doubtful quality;
4. Working directly with Section Heads and other employees concerning quality assurance;
5. Reviewing and approving quality policies and procedures, as well as technical and administrative procedures to ensure that quality assurance and safety principles are included;
6. Issuing revisions of the Quality Manual and quality procedures as necessary; and

7. Establishing the schedule for internal auditing, selecting the employees to perform the internal audits, and providing training and direction for each audit team member during the course of the audit process.

j) Deputies for key managerial personnel:

1. In the absence of the Quality Manager, the deputy is the Laboratory Director, or an employee designated by the Laboratory Director.
2. In the absence of any Laboratory Section Head, the deputy is the employee designated by the Section Head for that absence. In the event that the Section Head has not designated a deputy, the Laboratory Director or an employee assigned by him is the deputy Section Head.
3. In the absence of the Laboratory Director, the deputy is the Section Head assigned by the Laboratory Director.
4. Deputies for technical staff are not specifically nominated since each position has at least one competent and authorized backup staff member.

4.2 *Quality System*

4.2.1 The quality system of AzVDL has been established to formalize the quality practices employed to meet the scope, mission, and quality objectives of this laboratory as set forth in this Quality Assurance Manual. Documentation used in the quality system is controlled in accordance with SOP *Q004 Document Control* and is communicated to, available to, understood by and implemented by AzVDL staff.

4.2.2 The AzVDL quality policy and objectives are stated in the Directors Quality Policy Statement Section 3.0 of this manual.

4.2.3 Elements of the quality system, those developed by the laboratory and those taken from outside sources, are formally documented. The structure of the quality system documentation is outlined in Section 2.0 of this manual.

4.2.4 The roles and responsibilities of the Laboratory Director, Section Heads, and the Quality Manager are provided in Sections 4.1.4 of this manual.

4.3 *Document Control*

4.3.1 Controlled copies of quality system documents (this Quality Manual, system procedures referenced in this manual, and laboratory procedures) used at AzVDL are available to all laboratory personnel and are controlled as described in SOP *Q004 Document Control*.

4.3.2 All documents produced by personnel as part of the quality system are reviewed and approved by the Laboratory Director or his designee prior to use and once approved are distributed as outlined in SOP *Q004 Document Control*. Electronic versions of approved SOPs are placed on the server in an electronic folder titled 'QA'. The files located in this folder are read-only and accessible by all AzVDL personnel. The quality manager(s) and network administrator have read / write access to this folder and are responsible for maintaining the Master List of quality system documents and posting new procedures to the server.

Authorized copies of quality documents pertinent to AzVDL operations are available electronically to all AzVDL employees in the 'QA' folder on the server. AzVDL employees are not permitted to print personal copies of any AzVDL standard operating procedure, but forms may be printed as needed. An authorized printed version of a document may be requested by any employee. In response to a request for a printed copy of an AzVDL procedure, an authorized copy is generated and made available to the employee following the procedures in *SOP Q004 Document Control*.

- 1) One hard copy of each document will be stamped in red with **Original**, and placed in the Quality Manual notebook in the Quality Assurance office.
- 2) At least one other hard copy will be stamped in blue **Authorized Copy**, and placed in the SOP notebook in the appropriate laboratory or office(s).
- 3) Hard copies of procedures may be printed out for short-term use only (for example, a training session) and stamped in green **Uncontrolled Copy**.

Non-official printed copies of any AzVDL procedure are invalid and must be immediately removed and destroyed according to the policies in *SOP Q004 Document Control*. Copies with a version number different from the current electronic version are obsolete and should be immediately archived or destroyed. One copy of each obsolete document will be stamped and archived. All others will be destroyed.

Invalid and obsolete documents are removed from accessible locations. One copy is stamped **Obsolete** and placed in the file cabinet in the Quality Assurance Office and the others are destroyed. Obsolete documents are maintained in the quality assurance office for a minimum of 5 years after removing from service. Electronic copies of obsolete documents are held in separate folders.

- 4.3.3** Document changes are proposed by the laboratory Section Heads or other laboratory staff member, reviewed and approved following the policy and procedures in *Q004 Document Control*.

The specific changes that result in a new version are clearly identified in the revised document and noted on the associated document revision form.

Hand amendments to printed copies of AzVDL documents are not permitted. Amendments to approved documents need to be submitted for revision following procedures outlined in *SOP Q004 Document Control*. Printed AzVDL documents amended by hand are invalid and should be destroyed immediately.

The procedures used to identify and revise documents in the laboratory's computer system are found in *SOP Q004 Document Control*.

- 4.3.4** All AzVDL quality system documents are uniquely identified and cross-referenced as described in *Q004 Document Control*.

4.4 *Review of Request, Tender or Contract*

4.4.1 The policy and procedures set forth in SOP *A001 Contract Review* and SOP *A003 Processing of Submissions* provide guidance for the review of proposed work to ensure the laboratory is capable of fulfilling the test request.

4.4.2 This review process also applies to test requests that are performed by referral laboratories. Refer to SOP *A004 Referral Laboratory Services*. Form *A003 AzVDL Submission Form* serves as the client contract and notifies client that a referral laboratory may be used. This form becomes a permanent part of the case record.

4.5 *Subcontracting of Test Services*

4.5.1 It is the policy of AzVDL not to subcontract test services covered under the scope of accreditation. In extenuating circumstances such as equipment malfunction or personnel shortages, tests may be referred to outside laboratories.

4.6 *Purchasing Supplies and Services*

4.6.1 Services and supplies are purchased as described in SOP *A015 Purchasing Supplies and Services*. Each laboratory section has policy and procedures in place for the selection, evaluation, use, handling and storage of materials and reagents that affect the quality of test results.

All items received are visually inspected to ensure compliance with the order specifications. Verifications of the quality of consumable materials is performed by the receiving laboratory. All supplies are stored as specified in the related method procedures or in accordance to manufacturer specifications.

4.7 *Complaints*

4.7.1 AzVDL has policy and procedures, described in SOP *A014 Complaints*, for the resolution of complaints received from clients or other parties. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

4.8 *Non-conformance of Tests and Test Results*

4.8.1 AzVDL has a policy and procedures, which are described in SOP *Q006 Non-Conformance and Corrective Actions* to ensure the detection and correction of any condition that may adversely affect the reliability of test results. The quality manager has the authority to stop any non-conforming testing work and to reinitiate work following appropriate corrective actions. The Laboratory Director will notify any clients who have received test results that are questionable or incorrect.

4.8.2 In the event a non-conformance compromises the quality of test results, AzVDL will immediately implement the corrective action procedures given in Section 4.9.

4.9 *Corrective and Preventive Actions*

4.9.1 Corrective actions are initiated when there are significant testing discrepancies, non-conforming testing work, proficiency testing problems, departures from quality system policies and procedures, internal or external audit findings, deviations from

client requirements, client complaints, or other related problems in accordance with SOP Q006 *Non-conformance & Corrective Action*.

a) The responsibility for the management of corrective actions is as follows:

1. AzVDL staff will initiate corrective action requests for any problem within their job responsibilities, including testing discrepancies and quality control problems;
2. Section Heads will initiate corrective action requests for any planned or unplanned deviations from laboratory policies and procedures;
3. Technical and quality management will initiate corrective action requests for other issues;
4. After evaluating the situation initiated by the corrective action request, the Quality Manager is authorized to conduct a detailed internal audit in the appropriate area.
5. Final disposition of a corrective action request requires the approval of the quality manager and Director or Section Head.

b) All problems require an investigation to determine the root cause of problems detailed in the corrective action request. This root cause analysis is done according to SOP Q006 *Non-conformance & Corrective Action*.

c) Selection of the required corrective action takes into account the impact of the problems and non-conformances and the probability of their reoccurrence.

d) Changes to operational procedures are done following procedures in SOP Q004 *Document Control*

e) Once implemented, corrective actions are monitored to ensure effectiveness.

f) When a serious issue or risk to the quality of test results or integrity of the quality system has been the subject of corrective actions an internal audit will be initiated in accordance with Section 4.11 of this manual.

4.9.2 Procedures for the improvement of the laboratory's quality system and identification of actions to prevent potential problems are addressed in SOP Q007 *Preventive Actions*.

4.10 *Records Management*

AzVDL has established policy and procedures for management of records generated at the laboratory in SOP Q013 *Records Management*. This SOP includes a description of the records generated and applies to records of all types of media used at the laboratory.

4.10.1 General records management

4.10.1.1 The policy and procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposal of records generated in the laboratory can be found in SOP *Q013 Records Management*. Laboratory records may be paper copy or electronic copy and include: all raw, derived and reported data and results.

4.10.1.2 Records are stored and retained in a suitable environment that allows retrievability, prevents damage or deterioration and prevents loss. Records are retained by the laboratory for 5 years, except for validation records which are kept for 7 years after the associated test has been retired from use. Following the retention period all records are destroyed.

4.10.1.3 Records shall be held secure and in confidence following the policy set forth in SOPs *A012 Client Confidentiality* and *Q013 Records Management*.

4.10.1.4 Computer records are protected as described in SOP *A024 Computer Security* and backed-up according to SOP *A026 Data Backup*.

4.10.2 Technical records management

4.10.2.1 The quality manager is the custodian of all quality records, including internal and external audits, management reviews, corrective actions, preventive actions, training files, proficiency test results, and other related records. The Section Head of each laboratory section is responsible for the completed technical records (laboratory notebooks, worksheets, reports, electronic data stored on computers, etc.) generated by the employees in their section.

4.10.2.2 Records shall be recorded at the time of their creation. Data shall be permanent and legible, and identifiable to the specific test for which it was gathered.

4.10.2.3 Corrections to hard copy record errors are made using a single-line strike through, writing the correct information alongside, and initialing and dating each correction. For changes to the database, similar measures shall be taken to avoid loss or change of original data. Any changes to data on paper records, such as laboratory worksheets, must be accompanied by the initials of the employee making the change, and the date of the change.

4.11 *Internal Audits*

4.11.1 Internal audits of all policies and procedures in the laboratory's quality system are conducted to ensure compliance with the quality system according to the schedule published by the quality manager and according to the procedures described in SOP *Q005 Internal Audits*.

4.11.2 The quality manager or trained and qualified designees, who are independent of the activity being audited, conduct internal audits. When an audit casts doubt on the effectiveness of operations or correctness of laboratory results timely corrective action shall be taken. Should the audits show that client results have been

compromised; the Laboratory Director shall immediately notify the affected clients in writing.

- 4.11.3** All audit findings are recorded along with any related corrective actions resulting from audit findings. Follow-up monitoring and other activities are taken to ensure corrective actions have been effective.

4.12 *Management Reviews*

- 4.12.1** The Laboratory Director and select members of the laboratory review all aspects of the quality system and test related activities according to the schedule and procedure defined in SOP Q008 *Management Review*. This procedure outlines all the topics that are to be addressed. The goal of the management review is to determine if the laboratory's quality system is suitable and effective in meeting the quality objectives of the laboratory.

- 4.12.2** All findings from management reviews are recorded on Management Review forms and related corrective actions are recorded on corrective action requests as described in SOP Q006 *Non Conformance and Corrective Action*.

- 4.12.3** Management reviews ensure the effectiveness of the Quality System and the introduction of necessary changes and improvements in the quality system.

5.0 **Technical Requirements**

5.1 *General*

- 5.1.1** Management has developed the technical requirements of its quality system recognizing that the factors in the following sections are critical in determining the correctness and reliability of tests and it has addressed these factors with policies and procedures to reduce the uncertainty of the tests performed.

5.2 *Personnel*

- 5.2.1** The Section Heads are responsible for ensuring that all team members are competent and have received all required training prior to allowing them to work on client specimens.

The laboratory uses personnel who are permanently employed or are under contract. When part-time or temporary employees are used their work shall be compliant with the laboratory's quality system, and shall be subject to all policies and procedures for training and demonstration of competency.

- 5.2.2** Laboratory personnel are responsible for completing all required training in testing procedures prior to testing. Training records are maintained by and stored in the QA department.

For each position appearing on the organizational chart, the University of Arizona has an associated job description. The job responsibilities and authorities for personnel are contained in their training files, which are on file at the laboratory

The process of defining individual training needs and providing that training is described in SOP *Q003 Personnel Training*. The demonstration of competence of the staff is an ongoing activity and is monitored through the use of QC control samples and proficiency testing. The data used to demonstrate analyst competency is kept in that person's training records. The analyst's Section Head shall clearly authorize the analyst to conduct the tasks and tests and to operate specific equipment.

5.2.3 Participation in inter-laboratory proficiency testing programs serves as a tool for qualifying laboratory personnel and aids management in authorizing personnel to perform particular laboratory tasks. In addition, the laboratory has established an internal quality control program to monitor test and analyst performance. *Q011 Ensuring Quality of Tests* describes this system.

5.2.4 It is the policy of AzVDL to encourage and facilitate continuing education opportunities for all staff. A written record of attendance at meetings, training session, conferences and such are maintained in the employee's training file.

5.3 *Accommodation and Environmental Conditions*

5.3.1 The laboratory is located on the West Campus Agricultural Center, and is accommodated in rooms and laboratories totaling approximately 14,500 square feet (12,500 in the main building and 2,000 square feet in the Necropsy Building). It has designated areas for office functions, administration, client receiving and specimen processing, laboratories, a conference room and library, and maintenance and storage rooms. General safety rules and chemical handling processes are described in the University of Arizona [Biosafety Reference Guide](#) (Accessed June 2015) and the online University of Arizona Laboratory [Chemical Safety Manual](#) (Accessed June 2015) which outlines University of Arizona policies. Fume hoods and biological safety cabinets (BSC) are located throughout the laboratory to facilitate quality and safety requirements. It is the responsibility of all personnel to report any malfunctioning fume hood or BSC to their Section Head. Management personnel arrange for repair of any malfunctioning fume hood/biological safety cabinet and, in the interim, move all work routinely performed in the fume hood/biological safety cabinet to the closest or most appropriate available alternative.

5.3.2 Environmental temperatures in the laboratory, including but not limited to, refrigerators, freezers, ovens, and incubators are monitored as described in SOP *F005 Facility Monitoring* and *F024 Thermometer Calibration and Recording*.

5.3.3 All staff is responsible for maintaining a clean work area. A clean workspace helps to facilitate the laboratory operations and serves to protect the health and safety of the staff. Safe collection, storage, and disposal practices are followed as described in the University of Arizona Laboratory Chemical Safety Manual and associated SOPs.

5.3.4 Access to all areas of the laboratory is controlled. AzVDL has a locked door policy as established by the Laboratory Worker Safety Agreement. SOP *F018 Laboratory Security and Access Policy* addresses access control policy and procedures in more detail.

5.4 Test Methods

5.4.1 General

5.4.1.1 Analytical work is accomplished using methodology validated for use by documentation of internal performance using known reference standards for the specific purpose. The methods include those endorsed or published by a reputable technical organization, published in a peer-reviewed journal with sufficient documentation to establish diagnostic performance and interpretation of results, , internal or inter-laboratory comparison to accepted methodology or protocol, and methods mandated by legal requirements. If a client requests use of methodology other than that described in Laboratory Standard Operating Procedures, this request will be considered in light of the Section Heads' or Diagnosticians' judgment regarding the methodology as described in SOP *A003 Acceptance of Submissions*.

5.4.1.2 No method is used to obtain data for routine samples until its applicability has been established and it has been approved following procedures described in *Q004 Document Control*. The competence of each technical staff member to use those methods is demonstrated and documented as described in SOP *Q003 Personnel Training* prior to performing the test.

5.4.1.3 All tests are controlled following procedures in *Q004 Document Control*.

5.4.1.4 Testing is conducted using written Laboratory Standard Operating Procedures as described in SOP *Q002 Instruction for Writing SOPs*. These procedures address specimen preparation, analysis, and quality control, general work instructions, as well as data recording and reporting. These same procedures address the use of laboratory equipment and instrumentation. Copies of technical procedures are kept up to date and are distributed to the staff as specified in SOP *Q004 Document Control*.

5.4.1.5 The laboratory develops test methods, takes test methods from authoritative sources, and adapts or modifies test methods from the refereed scientific literature or from other AAVLD and federally accredited laboratories. When using test methods prepared by national and international standards-setting bodies, the laboratory has a system to receive updates in a timely manner. Test version updates are received from NVSL by mail, email or fax. Updated manuals of methods published by national and international organizations are purchased as they are available. Section Heads are responsible for cross-checking SOPs with the manuals.

5.4.2 Selection of methods

5.4.2.1 The methodology to be used in testing is available to the client by request.

5.4.2.2 The laboratory has an established training program for technical staff. Documentation associated with initial demonstration and ongoing proficiency for test performed is maintained in the employee's personnel file. The laboratory maintains an internal quality control program, SOP *Q011 Ensuring Quality of Tests*, to assess proficiency for test performed.

5.4.2.3 Test methods used by the laboratory incorporate quality control and traceability into procedures. References, safety considerations, special conditions, acceptance criteria, sample identification and equipment specifics as appropriate are included in the SOP. Quality Control results are reviewed prior to releasing final test results.

5.4.2.4 Test methods contain enough information for the experienced technician to properly perform all tests within established control limits. Standard Operating Procedures are written following SOP *Q002 Instructions for Writing SOPs* and using *Q002 SOP Template* as the standard format.

5.4.2.5 It is the policy of AzVDL to use test methods prepared by national and international standards setting bodies and other external technical organizations. When it is necessary to use laboratory developed or non-standard tests these will be validated before incorporation into routine diagnostic activities.

5.4.3 *Validation of test methods*

5.4.3.1 Validation of test procedures follows the principals established in the OIE [Manual of Standards for Diagnostic Tests and Vaccines](#). (Accessed June 2015)

5.4.3.2 All Validation data, including original observations, calculations, equipment monitoring and calibration records and archived procedures used to formulate performance characteristics are retained for 7 years after the assay has been retired from use.

5.4.4 *Control of data*

5.4.4.1 Guidelines for each quantitative method are developed to establish quality control acceptance criteria by validation of the test. All data relating to test results are secure, retrievable, and approved for use by specified, qualified personnel.

5.4.4.2 All manual data calculations and data transfers are subject to systematic review as described in SOP *Q005 Internal Audits*. Discrepancies will initiate a corrective action.

5.4.4.3 The laboratory uses computers and automated equipment for the acquisition, processing, recording, reporting, storage, and retrieval of test data.

a) Standard software within its designed application is used whenever possible. When customized computer software is used it will be documented and validated for its intended use. The laboratory has established change control procedures to document system changes and establish an audit trail. These procedures are described in SOP *Q004 Document Control*.

b) The protection and security of data that is recorded, processed, stored, reported, or retrieved via computers is addressed in SOPs *Q013 Records Management, A024 Computer Security, A026 Data Back-Up and A031 Workstation Backup*.

c) All computers and automated equipment are maintained properly under normal environmental operating conditions.

5.5 *Equipment*

- 5.5.1** The requirements for the selection, use, and maintenance of laboratory equipment and instrumentation are found in *SOP F010 Laboratory Equipment*.
- 5.5.2** Equipment used for diagnostic activities operates within specifications relevant to the procedures concerned, and are qualified by calibration data to indicate their calibration status as required by *SOP F010 Laboratory Equipment*. Calibrations are performed by qualified individuals, at intervals defined by established schedules. No equipment is used until it is in a safe and reliable operational state and then only by personnel who have been trained and qualified as operators.
- 5.5.3** The Section Heads ensure the competence level of their team members in the operation of any laboratory equipment as described in *SOP Q003 Personnel Training*. Instructions for use and maintenance of equipment, including relevant manufacturer provided manuals, are available to laboratory personnel. It is the responsibility of each employee to read, understand and document their training for the procedures and safe utilization of the equipment they use.
- 5.5.4** Each piece of equipment used for activities significant to test results is uniquely identified by manufacturer's information, serial number, or UA A-tag. This information is used to associate the equipment with a particular test.
- 5.5.5** Maintenance records of all equipment are kept as specified by *SOP F010 Laboratory Equipment*.
- 5.5.6** Each section is responsible for following established equipment calibration and maintenance procedures and generating the associated records in compliance with *SOP F010 Laboratory Equipment*.
- 5.5.7** Intermediate checks used to maintain confidence in the calibration status of equipment will be described in the AzVDL Standard Operating Procedures. These checks serve to safeguard the equipment to ensure the acceptance of data.
- 5.5.8** Equipment that gives suspect results or is not functioning is removed from service and labeled "out of service" following the procedures in *SOP F010 Laboratory Equipment*.
- 5.5.9** Equipment requiring calibration is labeled to indicate the status of calibration and the due date of the next calibration.
- 5.5.10** Equipment sent outside the control of the laboratory for repair is validated prior to being placed back into service and records maintained as stated in *SOP F010 Laboratory Equipment*.
- 5.5.11** Computers and automated test equipment employed, whose performance has a bearing on any results supplied to clients will follow *SOP A024 Computer Security* to meet the requirements of section 5.4.4.3 of this manual.
- 5.5.12** Test equipment, computers and software will be safeguarded from adjustments that would invalidate test results.

5.6 *Measurement Traceability*

5.6.1 Wherever possible, AzVDL uses reference standards traceable to NIST International System of Units (weights/masses, thermometers, metal analysis standards, etc).

5.6.2 Where traceability to SI units is not possible: reference standards used to provide confidence in results will conform to the guidelines set forth in *F009 Reference Standards and Materials*:

a) Using the best available means, or

b) By mutual consent agreed upon by all parties concerned.

c) AzVDL participates in proficiency testing through the Department of Agriculture Sponsored Programs in conjunction with National Veterinary Services Laboratories (NVSL)

5.6.3 The laboratory handles and stores reference standards and materials used in conjunction with testing activities according to *F009 Reference Standards and Materials*.

5.6.4 Where possible, biological reference materials are traceable to accepted international standards. Where traceability to standard reference materials is not possible and/or not relevant, other methods are used to establish confidence in the results, e.g. participation in proficiency testing programs, use of reference materials (certified if available), testing by another technical procedure, or ratio-type measurements.

5.6.5 Checks needed to maintain confidence in the calibration status of the reference standards and materials used are performed as described in *SOP F009 Reference Standards and Materials* and the laboratory standard operating procedures.

5.7 *Specimens*

5.7.1 The responsibility for specimens suitable for testing ultimately lies with the client. Guidelines for acceptable specimens for submission are available and may be provided to the client by AzVDL. In cases where AzVDL is directly responsible for sample collection, the laboratory has procedures in place to ensure that they are both appropriate to the test and suitable for testing. This applies to AzVDL only when the laboratory is directly responsible for sample collection.

5.7.1.1 AzVDL has procedures for the collection, processing if indicated, and preservation of specimens. Collection and related procedures are available at the location where collection is undertaken.

5.7.1.2 The laboratory has procedures for recording relevant data and operations relating to specimen collecting. Records include the collection procedure used, identification of collector, environmental conditions (if relevant) and diagrams or other equivalent means to identify the collection location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

Note: While AzVDL 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 standard.

5.8 *Handling Specimens*

- 5.8.1** There are policy and procedures for the handling of specimens submitted by clients to ensure specimen integrity. Each laboratory has a specimen handling SOP for tests performed in that section. The receiving area handles specimens as described in SOP *A002 Receiving Submissions*, *A003 Processing of Submissions* and *A003-F15 Acceptable Specimen Conditions Table*. Any specimen sent to referral laboratories will be processed according to SOP *A006 Dangerous Goods Shipping*. These procedures describe proper transportation, receipt, handling, protection, retention, and/or disposal of specimens.
- 5.8.2** AzVDL has a system for uniquely identifying specimens that is retained throughout the life of the specimen and derived samples in the laboratory and is linked to the test report. Refer to SOP *A003 Processing of Submissions*.
- 5.8.3** Submissions are evaluated upon receipt at the laboratory and any abnormalities or departures from normal or specified conditions are recorded as described in SOP *A003 Acceptance of Submissions* and *A003-F15 Acceptable Specimen Conditions Table*. A specimen not meeting relevant test method specification is considered not viable for testing.
- 5.8.4** If a specimen is of doubtful quality, AzVDL will consult the client for advice, and maintain a record of the discussion. Refer to SOP *A003 Processing of Submissions*.

5.9 *Assuring the Quality of Test Results*

- 5.9.1** The laboratory monitors the validity (accuracy and precision) of test results by the inclusion of appropriate internal or external quality control measures on all tests done in AzVDL. When practical, retesting of specimens and replicate tests using the same or different methods will be performed as described in SOP *Q011 Ensuring Quality of Test Results*. The laboratory also participates in proficiency testing programs when available.

5.10 *Reporting Test Results*

- 5.10.1** Results of tests performed by the laboratory are provided to clients via test reports generated in the database, as specified in SOP *A011 Reporting Test Results*. Each test report contains all information required by the client to whom the report is sent.
- 5.10.2** The format of the test report and information included in each test report is described in SOP *A011 Reporting Test Results*. Formats for test results are designed to accommodate each type of test carried out by AzVDL and to minimize the possibility of misunderstanding or misuse of results.

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- 5.10.3** The laboratory provides opinions and interpretations of reported data by qualified faculty. The basis upon which opinions and interpretations have been made are recorded and maintained as part of the case record.
- 5.10.4** Results of tests performed by referral laboratories are clearly identified on test reports as such.
- 5.10.5** The issuance of reports by facsimile or other electronic means conforms to the requirements of *SOP A011 Reporting Test Results* and the confidentiality policy described in 4.1.4c of this document and *SOP A012 Client Confidentiality*.
- 5.10.6** *SOP A011 Reporting Test Results* describes the policy and procedures for issuing interim test reports, final test reports, the requirements for submitting amendments or addendums to test reports and the reissuing of test reports.

7.0 Terms 7.0 Terms and Definitions

Common Abbreviations

AAVLD – American Association of Veterinary Laboratory Diagnosticians
AGFD – Arizona Game & Fish Department
APHIS – Animal and Plant Health Inspection Service (USDA agency)
ATCC – American Type Culture Collection
AzVDL – Arizona Veterinary Diagnostic Laboratory
DHS – Department of Homeland Security
FAD – Foreign Animal Disease
FAO – Food and Agriculture Organization, Rome
GLP – Good Laboratory Practice
ISO – International Organization for Standardization, Geneva ISO/IEC International Organization for Standardization / International Electrotechnical Commission, Geneva
ISO/IEC 17025:1999 - General requirements for the competence of testing and calibration laboratories.
NAHLN – National Animal Health Laboratory Network
NIST – National Institute of Standards and Technology
NVSL – National Veterinary Service Laboratory, New York (part of Veterinary Services, APHIS, USDA)
OIE – Standard Office International des Epizooties – Quality System Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases
OSHA – Occupational Safety & Health Association
QA – quality assurance
QC – quality control
QM – quality manual
QS – quality system
SOP – standard operating procedure
UA – University of Arizona
VSM – Department of Veterinary Science & Microbiology

Glossary of Terms

Accreditation – Formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests.

Accuracy – The closeness of agreement between a test result and the accepted reference value.

Audit – To carry out a systematic and independent examination to determine whether the quality activities and their results comply with the established documentation; to confirm whether these activities are appropriate for achieving the objectives proposed and whether they have been implemented effectively.

internal audits – are performed by staff who do not have direct responsibility for the areas audited, or by the quality manager.

external audits – are performed by official bodies for the accreditation of testing laboratories or by international bodies.

Analytical method – Defines the technical procedure for determining one or more specific characteristics of a product or material.

Analytical report – Document which contains the results of the analyses and any other information relating to the test.

Calibration – A set of operations that establish under traceable conditions the relationship between values indicated by a measuring instrument or measuring system for an established reference material and the corresponding value of a candidate reference material.

Certification – Procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements.

Corrective action – Action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

Equipment – Equipment is considered to be all apparatus necessary for carrying out analytical processes, but which do not provide quantitative results for these, such as autoclaves, ovens, laminar flow and gas extraction hoods.

Evaluation – Constant process of comparison of the results obtained from activities carried out by the evaluating group, which are used to measure selectively the efficiency, efficacy and congruence of the administrative programs of the laboratory for preventive purposes.

Instruments – Apparatus used in the various analytical methods and which provide quantitative results, e.g. spectrophotometer, gas chromatograph, liquid chromatograph.

National measurements standard – Authorized standard for obtaining, setting or comparing the value of other standards of the same magnitude, which serves as a basis for setting the values of all standards of the given magnitude.

Norm or written standard – Document stating the accepted rules for carrying out a specific test.

Precision – The closeness of agreement between test results obtained under stipulated conditions.

Preventive action – A proactive process to identify improvement opportunities, and potential sources of non-conformance.

Quality – Series of characteristics of an element which make it capable of satisfying explicit and implicit requirements.

Quality assurance – Series of planned, routine activities which a control laboratory carries out with the aim of offering adequate confidence that a product or service complies with the specified quality requirements.

Quality control – Series of operating methods and activities which are used to satisfy compliance with the established quality requirements.

Quality manual – Document which establishes the quality policies and describes the quality system of an organization.

Quality policy – Guidelines and general objectives of an organization concerning quality which are expressed formally by the senior management and supported by the authorities of the country.

Quality system – Organizational structure, including resources, responsibilities and established procedures to ensure that products, processes or service comply satisfactorily with their intended purpose, directed to achieving quality.

Reference material – A material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to test materials.

Reference standard – A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. Generally, this refers to national traceable standards such as those from the National Institute of Standards and Technology (NIST).

Sample – Material derived from a specimen and used for testing purposes.

Specimen – Material submitted for testing.

Standard operating procedure (SOP) – Written description of all operations, including the diagnostic tests to be carried out for the production of a result meeting certain specifications.

Test – Technical operation which involves the determination of one or several characteristics of a given product, process or service, according to a specified procedure.

Traceability – The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Validation – Action of proving that a procedure, process, system, equipment or method used in manufacturing or controlling a product works as expected and achieves the intended result.

Verification – A series of operations to check that a piece of equipment, an apparatus, or an instrument functions within the permissible limits.

Working standard or reference – Also called secondary standard. A reference material whose value is fixed by comparison with a primary standard of reference material. In the vast majority of cases, reference materials such as a National Standard and laboratory standard are secondary standards.

Computer Terms

Computer System – Refers to a personal computer, or workstation, with an operating system and networking and printing capabilities. This would also include a monitor, keyboard, mouse and any additional peripherals that would be needed for a specific purpose.

Data – Units of information stored on some type of magnetic media that can be called into a computer program for use.

Backup – A copy of a file, directory, or volume placed on a separate storage device for the purpose of retrieval in case the original is accidentally erased, damaged or destroyed. This separate media would include CDs, Zip disks, hard drives of workstations and other media as designated by IT systems personnel. Any copies of files should not be considered a backup unless they reside on separate media.

Disk Drive – A physical unit of storage on which data is read from, written to, and deleted from. This is considered the primary storage device for a computer system.

Desktop or Laptop – A networked computer found in the office or laboratory of AzVDL personnel.

File Server – A computer that provides mass file and program storage capabilities for networked computer systems with control access to sharable resources. A server usually has more computing ability than a computer system or workstation. It may or may not include a separate disk array for added disk drive space. System security is the main reason for the network operating system and server and it should be considered the most important aspect of the server. Depending on the network operating system, purpose, and abilities of the server, it may also be used as a computer system.

8.0 References

Note: Critical references described in this quality manual are maintained on file in the Quality Control Office and are accessible to all laboratory staff and management.

8.1 *Critical References*

8.1.1 Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, American Association of Veterinary Laboratory Diagnosticians (AAVLD) current version.

8.1.2 [Quality Management in Veterinary Testing Laboratories, Chap 1.1.4 in OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals \(Accessed June 2015\)](#)



**THE UNIVERSITY
OF ARIZONA**
Arizona Veterinary Diagnostic Laboratory
Organizational Chart
April 2015

