



## **AAVLD Accreditation Program**

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### **What is Laboratory Accreditation?**

Accreditation is a voluntary, third party-reviewed process by a certifying body providing formal recognition of laboratory competence and quality. As part of accreditation, a laboratory's quality management system is thoroughly evaluated on a regular basis to ensure continued management and technical competence and compliance with appropriate laboratory quality management system standards. The accreditation process is followed by ongoing maintenance of the QMS by the laboratory, as well as surveillance audits performed by a certifying body. The desired outcomes of this process are assurance of credible laboratory results for clients, and the expectation of continual improvement of the accredited laboratory's processes.

### **What is a Quality Management System?**

A Quality-Management System (QMS) is a combination of organizational structure, resources, people, documents and activities designed to ensure a consistent product and services that meet the needs of an organization's clients. Worldwide, the most widely adopted QMS program is the ISO 9000 family developed by the International Organization for Standardization (ISO). A related QMS program stems from ISO 17025, which is tailored for testing laboratories, including veterinary diagnostic laboratories. Laboratory accreditation, although voluntary in the USA, serves as an attractive credential, especially for clients reaching international markets, and demonstrates intent to manage quality through practices deemed acceptable by the ISO. Laboratory quality management systems based upon ISO standards require fundamental activities such as: Control of documents; Control of records; Control of supplies; Control and validation of tests; Control of measuring equipment; Competency of personnel; Internal audits; Control of non-conforming work; Measurement of client satisfaction; Corrective and preventive actions; and Continual improvement.

### **What is the basis of the AAVLD Accreditation Requirements?**

The AAVLD Accreditation Requirements are based upon the ISO 9000 family, specifically ISO/IEC 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories". Although the ISO 9000 family focuses on quality management requirements that are general for the manufacturing and service industries, ISO/IEC 17025 is more specific to testing laboratories and is an ISO standard accepted internationally by the World Organization for Animal Health (OIE) and the Food and Agricultural Organization of the United Nations (FAO) for veterinary diagnostic laboratories. The AAVLD Requirements for accreditation align very closely with [ISO/IEC 17025:2005 White Paper](#) and are accepted by the USDA and FDA for participation in national laboratory networks for disease surveillance.

### **What is the AAVLD Accreditation Program Scope?**

The AAVLD Accreditation Program is a comprehensive laboratory inspection and accreditation program encompassing all laboratory disciplines. It is conducted as a peer-review process, inspections being performed by experienced working professionals also trained in auditing techniques specific to the [AAVLD Accreditation Requirements](#).

Laboratory inspections and accreditation are restricted to publically funded, full-service laboratories, full service being defined as offering necropsy, histopathology, bacteriology, and virology or equivalent services on site. Accreditation certificates are issued for a maximum of 5 years, after which re-assessment is required.

### **What are the benefits of AAVLD accreditation?**

AAVLD Accreditation does not certify a product or service, rather it attests that a laboratory adheres to documented processes and quality controls in conformance with ISO-based international standards. Conformance to standards inherently contributes to higher quality, safety, reliability, and consistency of services. This increases a laboratory's marketability, customer satisfaction, and acquisition of new customers. The increased credibility associated with AAVLD Accreditation leads to advantages such as:

- Decreased operating expenses from retesting.
- Enhanced management control through management review participation.
- Reduced product liability risk resulting from robust QMS.
- Increased customer satisfaction as a result of customer-focused QMS.
- Increased marketability from the commitment to meeting internationally accepted quality standards.
- Participation in funded national and international programs for foreign animal disease detection, animal/zoonotic/and emerging disease surveillance, and export testing.
- Expanding customer ability to reach international markets.
- Ability to provide documentary evidence (records) of the whole laboratory test process.

### **What is the AAVLD Accreditation Process?**

The laboratory accreditation process in general includes:

1. Application submission
2. Assessment of application
3. On-site assessment of laboratory QMS
4. Laboratory demonstrates compliance
5. AAVLD issues certificate of compliance

The more detailed process incorporates the following:

1. Assignment of assessment team and lead assessor by AAVLD Accreditation Committee (AC)
2. Assessment team reviews laboratory application materials and if compliant schedules on-site assessment with laboratory director
3. Assessment team performs site visit and drafts site visit report
4. Site visit report is presented by assessment team to full Accreditation Committee for determination of laboratory compliance and final drafting of site visit report; possible outcomes are accredited, provisionally accredited, or not accredited

5. If the decision is to accredit or provisionally accredit the laboratory, the AC communicates the laboratory's compliance status to the laboratory director along with a request for a laboratory response to non-conformances, with documentary evidence, in the site visit report
6. Laboratory prepares a response to the site visit report and sends to AC for review;
7. Accreditation assessment complete OR continued follow-up of laboratory response requested for further assessment.

**Who do I contact for more details about the AAVLD Accreditation Program?**

More information regarding the AAVLD Accreditation Program is available on line at [www.aavld.org](http://www.aavld.org) in the drop-down menu under the "Accreditation" tab. The details of the AAVLD Accreditation process are available in Accreditation Committee Standard Operating Procedures posted on-line for AAVLD membership at the same URL.