

Appendix 8: General Criteria for Independent Laboratories

General Criteria for Independent Laboratories

Organization and Management - The laboratory shall be legally identifiable and shall have the following attributes:

- Managerial staff with the authority and resources to accomplish the task;
- Adequate facilities, equipment, and staff to complete the work in a quality and timely manner;
- Demonstrated experience or capability using the technology necessary for testing of the test kit under evaluation;
- A technical manager who has overall responsibility for the technical operations. Whenever possible, the test kit evaluation will be supervised by a person familiar with the required test methods and procedures and the objectives of the assessment;
- Documented policies and procedures to ensure the protection of clients' confidential information and proprietary rights;
- Where appropriate, participation in inter-laboratory comparisons and proficiency testing programs;
- A quality control manager (however named) who has responsibility for the quality control system;
- Compliance with Good Laboratory Practices (GLP) of the USFDA, USEPA, or other government mandated practices, if applicable.

Quality Control System - The laboratory shall have an established quality control system appropriate for the range of testing activities it undertakes. The quality control system shall be documented and operational in day-to-day operations. A quality control manual shall be maintained under the direction of the quality control manager. The manual shall contain the following elements:

- A quality control policy statement;
- Organization and management structure of the laboratory;
- Relations between management, technical operations, support services, and quality control system;
- Job descriptions of the staff;
- Arrangements for ensuring laboratory review of all new proposals to ensure the laboratory has the appropriate resources before commencing work;
- Procedures for handling calibrations;
- References to procedures for calibration, verification, and maintenance of equipment, and documentation of same;
- References to verification practices including inter-laboratory comparisons, proficiency testing, use of reference materials, and internal quality control schemes;
- Procedures for audit and review; and
- Procedures for taking corrective action.

Personnel - The independent laboratory shall have sufficient personnel having the necessary education, training, technical knowledge, and experience to conduct the testing protocol. Records on the relevant qualifications, training, skills, and experience of the technical personnel shall be maintained by the laboratory.

Facilities - The laboratory shall have facilities suitable to conduct the testing protocol. The environment in which the testing activities are undertaken must not be such as to put into question or invalidate the results. The laboratory shall provide facilities for the monitoring, control, and recording of environmental conditions as appropriate.

Equipment and Documentation - Equipment shall be properly maintained and maintenance records shall be documented. Records shall be maintained on each item of equipment and reference material significant to the calibrations or tests performed.

Calibrations - The laboratory shall have an established program for the calibration of its measuring, test equipment, and analytical standard