

**Rapid HIV-1 Antibody Test – Guidance Document**

**Section I – Designation of a Laboratory Director**

The regulations to the Commonwealth's Clinical Laboratory Act define the Laboratory Director as the individual responsible for the overall performance of the laboratory. They further require that the director hold a doctoral degree with experience acceptable to the Department. In many organizations, the Medical Director serves as the Laboratory Director.

**Section II – Designation of Laboratory Supervisors**

The regulations to the Commonwealth's Clinical Laboratory Act define two types of Laboratory Supervisors, General and Technical. The General Supervisor is responsible for the daily oversight of the laboratory while the Technical Supervisor is responsible for the technical performance of the laboratory. Both require a relevant bachelor's degree and experience acceptable to the Department. One person may perform both functions.

**Section III – Training, Evaluation, Monitoring**

All personnel must be trained and their competency evaluated prior to performing patient testing. If this training has occurred prior to receipt of this protocol, document it as accurately as possible. This training may be performed by a manufacturer's representative and must include a thorough discussion of the test kit package insert with particular attention to any critical steps.

Personnel competency must be re-evaluated within six months of initial training. Competency must be monitored annually thereafter. An example of an acceptable performance documentation log is enclosed. This document is to be retained in your facility.

**Section IV – Procedure Manual**

The laboratory must have a written description of all of its activities, including test requisition and reporting, specimen collection and handling, each step involved in the actual test, quality controls and corrective actions (that is, what to do when anything goes wrong). The manufacturer's package insert is an excellent place to start. Make sure that the manual contains the *current* insert (check the dates) and add those activities that are specific to the individual laboratory.

### **Section V – Quality Control**

In addition to following the manufacturer's requirements, the facility must include a positive and a negative control each day of testing until it obtains its first confirmed positive patient result and both the quality control and positive patient results have been reviewed and approved by the technical supervisor. Control frequency can then be reduced to once each week of testing. The facility must document all quality control results, supervisory reviews and the steps taken if results are "out-of –control."

### **SECTION VI – Quality Assurance Review**

One of the laboratory licensure requirements is participation in an approved proficiency testing program. The facility must enroll in an approved proficiency testing program each year.

### **Section VII – Testing Personnel**

Testing personnel shall be determined by the director to be fully qualified for all assigned technical duties.

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