

Rapid HIV Testing Systems: Regulatory Compliance

Organizations considering use of a waived rapid HIV-1 antibody test must be aware of the need to comply with both state and federal (Clinical Laboratory Improvement Amendments, or CLIA) laboratory regulations. To assist you in complying with these regulations, the Bureau of Laboratories has developed the following guidance document.

For federal compliance, the laboratory must apply for and obtain a CLIA Certificate of Waiver. This requires the completion of the federal application (CMS 116) and the payment of a \$150 fee every two years. The laboratory must comply with all manufacturer's requirements and instructions.

For state compliance, the laboratory must apply for and obtain a state laboratory license for a level two physician's office or clinic laboratory. (If the laboratory performs testing for other agencies or is part of a hospital, other regulations may apply. Please call for additional information.) This requires the completion of the Commonwealth application, and payment of a one time \$25 registration fee. The laboratory must comply with all Commonwealth requirements for quality assurance. These requirements are detailed in the following guidance document.

To obtain and hold the necessary permit, the laboratory must:

1. Complete the applications and file them with this office.
2. Designate a laboratory director – Guidance Document Section I
3. Designate a general and a technical supervisor – Section II
4. Document training & periodic competency evaluation of personnel. – Section III
5. Develop a procedure manual. – Section IV
6. Develop and adhere to a satisfactory quality control program – Section V
7. Enroll and participate successfully in an approved proficiency testing program – Section VI
8. Notify the Bureau in advance of any changes, including:
 - a) Director
 - b) Supervisor
 - c) Location
 - d) Testing menu or kit used

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