

Rapid HIV Testing Site Guidelines

The following information is designed to give a broad overview of basic site requirements needed to implement rapid HIV testing in the state of Florida.

Federal Regulations

- Each site must obtain a Federal CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver. To obtain a Federal Certificate of Waiver, complete Form CMS-116, found at the following CMS Internet address: www.cms.hhs.gov/CLIA
- Each site must adhere to the manufacturer's instructions when performing the test. This includes providing the additional materials essential to administering a rapid HIV test that are not included with the test kit. These materials may include, but may not be limited to:
 - A 20-40 minute timer
 - Sterile lancets
 - Antiseptic wipes
 - Clean disposable workspace cover
 - Sterile gauze pads
 - Refrigeration unit on site for controls
 - Thermometer in refrigeration unit to monitor temperature
 - Climate control for testing sites
 - Thermometer in testing facility and test kit storage area to monitor room temperature
 - Good lighting
 - Level workspace
- Each site may be subject to announced/unannounced inspections by representatives of the Department of Health and Human Services

Occupational Safety and Health Administration

Sites offering rapid HIV testing must meet the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) standards for blood-borne pathogens. Each site must:

- Provide training on occupational exposure to bloodborne pathogens for all employees
- Have a written exposure control plan
- Provide personnel with protective equipment, such as gloves and laboratory coats
- Make the hepatitis B vaccination series available to all employees who have the potential for occupational exposure
- Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident
- Contain and dispose of biohazardous waste in accordance with all applicable regulations
- Develop a plan to ensure proper biohazardous waste and sharps disposal

Florida Guidelines

Each site offering rapid HIV testing in Florida:

- Must obtain a state laboratory license. To obtain a laboratory license in Florida, complete Form 3000-4, found on the Florida Agency for Health Care Administration (AHCA) website at: http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/clinical.shtml
- Must obtain informed consent prior to HIV testing, following procedures found in Florida statute
- Must develop and adhere to a detailed Quality Assurance Plan
- Should provide linkages to appropriate services
- Should follow all applicable Department of Health guidelines with regards to rapid HIV testing

It is each site's responsibility to ensure the client has access to confirmatory testing. The Department of Health strongly recommends that each rapid test site be equipped to provide confirmatory testing. If a situation arises where that is not feasible, it is the site's responsibility to ensure the client receives a confirmatory test at a more convenient time or location.