Florida Department of Health, HIV/AIDS Section
Rapid HIV Testing Site Guidelines

The following information is designed to give a broad overview of requirements for sites wishing to offer rapid HIV testing within the state of Florida. Sites are responsible for ensuring that all state and federal requirements are met prior to initiating a rapid testing program. Communication between the HIV/AIDS Section, county health departments (CHD) and rapid testing venues is essential to ensure proper compliance.

For more information, please visit www.preventhivflorida.org

Rapid Test Site Application Procedures

Part I: Florida Department of Health Standards

Sites wishing to become a rapid HIV test site must meet certain state and federal requirements. A general listing of applicable Florida statutes and rules pertaining to HIV testing can be found at Florida Statutes.

All sites wishing to implement rapid HIV testing must contact the regional Early Intervention Consultant (EIC) at their local CHD. The local EIC will assist in the development of a Memorandum of Understanding between their site and the local CHD with the completion and submission of the DH1781 *Application for Registration and Reregistration of HIV Testing Site Programs*, completion of rapid testing trainings, ordering rapid testing supplies, and ensure compliance with the quality assurance and technical assistance guidelines. Registered HIV test sites approved to provide rapid testing will receive free HIV testing supplies and lab processing support.

Non-health care sites applying for rapid test site registration must demonstrate a **successful** history of conventional HIV testing for one year, must be in compliance with all state and federal policies, procedures and guidelines, and must have a positivity rate of at least 1 percent for newly-identified positives.

All CHD programs conducting HIV testing in compliance with all federal and state policies, procedures and guidelines, may conduct rapid HIV testing.

Clients with a reactive rapid test result must be offered an approved confirmatory HIV test (preferably by blood draw), which will be processed at a clinical laboratory. Clients with a reactive rapid test result should be linked to care for an initial medical evaluation and possible treatment initiation before a confirmatory test result is received. When a client is confirmed positive, sites must ensure the client has been linked to a local case manager and provider. Clients with a rapid negative HIV test result indicating high-risk behaviors should be referred to a local Pre-Exposure Prophylaxis provider.

Providers offering rapid HIV testing must develop and adhere to a detailed Quality Assurance Plan. A copy of the Centers for Disease Control and Prevention Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988 can be found here. In addition to this tool, the HIV/AIDS Section has

developed a sample quality assurance manual and quality assurance logs designed specifically for approved rapid test sites. These are available through the EIC.

Only confidential rapid testing is supported by the HIV/AIDS Section. The HIV/AIDS Section does not support anonymous rapid HIV testing.

Sites that want to perform 4th generation rapid HIV tests (for example, Alere Determine) **MUST** confirm all reactive results with a blood specimen. Sites confirming with OraSure will not be considered for 4th generation rapid testing.

All counselors conducting rapid HIV testing must satisfactorily complete the Florida Department of Health (Department) approved training on the rapid test device that they will be using. No other training may substitute for this required training. Only training conducted by or approved by the HIV/AIDS Section, HIV Testing Team Leader or their designee will meet this requirement. All counselors must begin rapid testing within 30 days of training.

Any site found to be in violation of or out of compliance with the Department, State of Florida, or Federal Clinical Laboratory Improvement Amendment (CLIA) requirements, policies, guidelines, or procedures will not be allowed to continue to operate a rapid HIV testing program until all aspects of the program are brought into compliance. Violations identified and reported will be investigated by the regional EIC and/or Central Office staff. Once the investigation is complete, the EIC will report the findings to the Central Office HIV Testing Team Lead for corrective action or site termination.

Part II: CLIA Requirements

Prior to initiating a rapid testing program, sites must be issued a CLIA waiver and number from the U.S. Centers for Medicare and Medicaid Services (CMS). A CLIA Certificate of Waiver allows these sites to perform FDA-approved waived rapid tests. Applications are available from, and must be submitted to, the Florida Agency for Health Care Administration.

Sites that need rapid HIV testing at multiple locations must ensure all satellite locations are listed on the CLIA waiver and are registered with the HIV/AIDS Section.

Federal law requires that all laboratories performing testing, no matter what type, must obtain a CLIA certificate and number.

For more information about the CLIA waiver application process, visit CMS CLIA website.

Part III: Occupational Safety and Health Administration (OSHA) Requirements

All sites that collect blood samples for traditional and/or rapid testing must meet the OSHA standards for blood-borne pathogens. Providers must establish a written exposure control plan designed to eliminate or minimize employee exposures to occupational risks. Providers must provide personal protective equipment (PPE) to employees at no cost. Examples of PPE are

latex or vinyl gloves, eye protectors, and lab coats. If a problem arises with an article of PPE, the provider must repair or replace it at no cost to the employee.

The plan must be readily accessible to all employees who may encounter occupational exposure. Providers must provide hand-washing facilities, which are readily accessible to all employees. If hand-washing facilities are not feasible, the provider must provide either an appropriate antiseptic hand cleanser or antiseptic towelettes. Activities prohibited in work areas where there is a reasonable likelihood of occupational exposure include eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses. Food and drinks must not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or other potentially infectious materials are present.

Following a report of an exposure incident, the employer shall immediately make available, at no cost to employee, a confidential medical evaluation and follow up. The employer must ensure that all medical evaluations and procedures including prophylaxis, the hepatitis B vaccination series, and post-exposure evaluation are included. Providers must contain and dispose of biohazardous waste in accordance with applicable regulations and develop a plan to ensure proper biohazardous waste and sharps disposal. Information regarding OSHA standards can be found at: Blood-borne Pathogens Standards.

Part IV: Biomedical Waste Disposal

The definition of biomedical waste is any solid or liquid that has been contaminated with body fluid, body tissue, or blood products. Providers that generate, transport, store, or treat biomedical waste must comply with Florida Administrative Code Chapter 64E-16. Providers that generate, transport, or store biomedical waste must observe universal precautions at all times and adhere to OSHA standards as applicable. All sites meeting such criteria are required to have a biohazard permit or waiver from the local CHD's Environmental Health program.

Provision of rapid HIV testing generates biomedical waste, usually in the form of products contaminated with blood or oral mucosal fluid. These products would include used lancets (sharps), gauze pads, gloves, test devices, developer solution vials, specimen collection loops, and used absorbent workspace covers. Using external kit controls also generates biomedical waste, as will rapid testing via oral fluid samples which may have unseen amounts of blood in the sample. Biomedical waste from oral fluid rapid testing includes test devices, collection loops, and developer solutions vials. All biomedical waste should be disposed of in accordance with OSHA and/or Florida regulations. Information and requirements for application may be found at: Florida Health, Biomedical Waste Program.

Resources

Florida Department of Health Prevention Helpline - (800) FLA-AIDS
Regional Early Intervention Consultant Contact Info - http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/_documents/Counseling_testing/ctl-eic-map%20-05-05-17-dlt.pptx

County Health Department Listing - http://www.floridahealth.gov/programs-and-services/county-health-departments/find-a-county-health-department/index.html

Minimum Standards for HIV Counselors, Trainers, and Early Intervention Consultants - http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/_documents/Counseling_testing/iop-360-07-17-final-3-30-17-rbedits.pdf