## **HIV Test Site Registration Protocol**

- 1. Must review relevant statutes, administrative rules, and model protocols as seen below.
  - a. Florida Administrative Codes: Rule 64D-2.006 for initial registration process.
  - b. Florida Statues Section 381.004 for HIV test site for rules & regulations.
  - c. IOP 360-07-17 "Minimum Standards for HIV Counselors"
  - d. IOP 360-09-17 "Provision of HIV Testing and Linkage"
  - e. Model Protocol for Non-health care settings (if applicable)
  - f. Model Protocol for Health care settings (if applicable)
- 2. If the site wishes to receive in-kind support (e.g., HIV test kits and supplies), the site must complete a Memorandum of Agreement with the Florida Department of Health in the county in which the site intends to operate.
- 3. Must undergo initial inspection and have the mandatory specifications as seen below.
  - Site Certification
  - Private testing room
  - Separate waiting area
  - Counselors' 500/501 Certificates
  - $\circ \quad \ \ {\rm Linkage\ protocol\ for\ HIV} + {\rm clients}$
  - Doctor to sign off on application
  - o Condoms

- Testing Log
- Double locked storage of files
- Non-opening secured windows
- Contact info: (email, phone, etc.)
- o MOA, upon request
- Policies & procedure manual
- 4. Must successfully complete the Quality Improvement/Technical Assistance Checklist by setting up an appointment with the Area Early Intervention Consultant at least once a year.

Additional Requirements for Rapid HIV Testing Sites

- 5. Must develop and adhere to a detailed Quality Assurance Plan as followed by the Center for Disease Control Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests.
- 6. Must be issued a Federally Clinical Laboratory Improvement Amendment (CLIA) Waiver and number from the U.S. Centers for Medicare and Medicaid Services prior to initiating the rapid testing program.
- 7. Must have established a written exposure control plan designed to eliminate or minimize employee exposures to occupational risks as part of OSHA requirements.
- 8. Must undergo initial inspection and have the mandatory specifications as seen below.
  - Biohazardous Control Plan
  - Approved confirmatory test methods
  - HEP B vaccine available to employees
  - Alternate exit for clients
  - Personal protective equipment

- Seropositivity rate of 1% or better for non-health care settings
- Rapid Testing Log
- Refrigeration unit for controls
- Thermometer regulated environment
- o Proper Kit Storage area
- 9. Must complete the DH Form 1781 "Application for Registration and Reregistration for HIV Testing Programs" and return it electronically to the HIV/AIDS Section at Derrick.Traylor@flhealth.gov.