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 360-07-23 "Minimum Standards for HIV Counselors"
 - d. IOP 360-09-23 "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 each 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
 - Linkage protocol for HIV + clients
 - Doctor to sign off on application
 - Condoms

- Testing Log
- Double locked storage of files
- o Non-opening secured windows
- Contact info: (email, phone, etc.)
- 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 Federal 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.
 - o 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
- Refrigeration unit for controls
- o Thermometer regulated environment
- Proper Kit Storage area
- 9. Must complete the DH Form 1781 "Application for Registration and Reregistration for HIV Testing Programs" and return it electronically along with a copy of the signed MOA, CLIA certificate of waiver, biohazard certificate and certificates of completion for each counselor for the 500/501 training, to your local Early Intervention Consultant located at your County Health Department. The EIC will forward all items to Central Office for final approval.

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