

Information on the State of Florida Clinical Laboratory License and Federal Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendment (CLIA) Certification (waived testing)

This is not meant to be an exhaustive list or instruction manual, but rather a list of some helpful tips to be used in conjunction with the instructions and information found on the Florida Agency for Health Care Administration website at:

http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/clinical.shtml, and the CMS CLIA website at: <http://www.cms.hhs.gov/CLIA/>

Registered HIV test sites in Florida wishing to conduct waived rapid HIV testing must complete all of the necessary applications and forward those, along with a check for \$100.00 (fee due every two years) payable to the Agency for Health Care Administration. Mail all forms and correspondence to:

Laboratory Unit
Agency for Health Care Administration
Bureau of Health Facility Regulation
2727 Mahan Drive, Mail Stop #32
Tallahassee, FL 32308

AHCA suggests that all applications and necessary forms and documentation be sent via traceable mail to avoid the possibility of applications being misplaced.

Please note that the \$100.00 fee due to AHCA is in addition to the CLIA fee (\$150.00) assessed by CMS. You will be billed directly by CMS for the CLIA fee.

APPLICATION PROCESS

Rapid test sites in Florida will deal primarily with one of three applications: the Initial Application, the Renewal Application, or the Reactivation After Expiration.

If there has been a change in ownership as defined in Florida law, your agency must submit a Change of Ownership application 60 days prior to the effective date of the change.

Change in Ownership means an event in which the licensee changes to a different legal entity or in which 45 percent or more of the ownership, voting shares, or controlling interest in a corporation whose shares are not publicly traded on a recognized stock exchange is transferred or assigned, including the final transfer or assignment or multiple transfers or assignments over a 2-year period that cumulatively total 45 percent or greater. A change solely in the management company or board of directors is not a change of ownership. [see section 408.803(5), Florida Statutes]

Please carefully read all instructions prior to filling out the application and be sure that all required documents, attachments, and items listed in the checklist (attached to application) are completed in full.

Only complete the sections required for sites conducting **waived** testing.

INITIAL APPLICATION

Section 4. OWNERSHIP/CONTROL

DO NOT put N/A or similar in the section where this information is requested. The “owner” is the same name as listed on your agency’s Federal Tax Identification form. You must submit proof of your federal tax identification number with your initial lab application. A copy of your Federal Tax Identification form is an example of proof.

Section 5.a. Laboratory Director

This name must match throughout the application. This individual must also sign the application. If these names do not match, or this individual does not sign the application, it will be returned as incomplete.

Section 10

The application must be signed and notarized or it will be returned as incomplete. Remember, the “Laboratory Director” as identified in the application must also be the individual who signs the application.

Section 11

If you wish to conduct rapid HIV testing at sites other than your primary site (listed in Section 1) list them in this section. Please remember, **all sites must be approved by Bureau of HIV/AIDS Counseling and Testing staff** prior to beginning rapid testing.

Declaration of Proposed Test Menu...

List the type and name of test you will be using. In column 1, this would be “rapid HIV test.” In column 2, the Instrument/Test Kit would be the name of the test device (OraQuick ADVANCE, UniGold or Clearview).

RENEWAL APPLICATION

When you receive your renewal notice, begin the process immediately. Renewal applications take a minimum of 60 days to complete once received by AHCA, which means it must be completed and returned at least 60 days prior to the date of expiration. The renewal application is available on the AHCA website and must be completed in its entirety. Incomplete applications will be returned for additional information.

AHCA will send all sites a renewal notice via certified mail to the physical (street) address of the site as listed in the initial application, approximately 120 days prior to the expiration of the State Laboratory License.**

CMS will generate a bill approximately six months prior to the expiration of the CLIA Certificate of Waiver, which will be sent directly to the site. The new Certificate should be received within 2-4 weeks of the new effective date.**

****THESE ARE NOT NOTIFICATIONS OR PAYMENT OF THE SAME LICENSURE.
THESE ARE TWO DIFFERENT THINGS.****

**FAILURE TO PAY OR RENEW EITHER YOUR CLIA WAIVER OR STATE LAB
LICENSE WILL RESULT IN YOUR LICENSE AND/OR CLIA WAIVER EXPIRING AND
MAY LEAD TO FINES.**

Sites are not allowed to continue to offer rapid HIV testing until all licenses and waivers are in compliance with state and federal statutes. Disregarding this statement may result in fines and/or criminal prosecution.

REACTIVATION AFTER EXPIRATION

If you received the Statement of Deficiencies form (CMS 2567) in the mail with a certified letter regarding the expiration of your lab license, complete and return your plan of correction on this form along with the fee and forms required.

Sites are not allowed to continue to offer rapid HIV testing until all licenses and waivers are in compliance with state and federal statutes. Disregarding this statement may result in fines and/or criminal prosecution.

The agency provides links to information that is helpful to waived laboratories when completing applications as well as a list of frequently omitted items from waived applications at the following website:

http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/foiwaved.shtml

ADDITIONAL INFORMATION

The responsibilities of the Clinical Laboratory Licensing Unit of the Agency for Healthcare Administration are covered in Chapter 408, Part II and Chapter 483, Part I F.S. and 59A-7, Florida Administrative Code.

AHCA has sixty (60) days from the receipt of your **completed** application in which to issue your State of Florida Clinical Laboratory License. If your application is returned to you for completion or additional information, the 60-day period begins on the date the agency receives your completed application.

Applications must be accompanied by the appropriate licensing fee to be accepted. If the fee, or proof of transfer of funds in the case of state agencies, does not accompany the application, the application will be returned.

If you have any question on the completion of your applications, please contact Tom Bendle in the Bureau of HIV/AIDS at (850) 245-4424. Do not contact AHCA Clinical Lab Licensing Unit until you have contacted Tom Bendle.

It is your responsibility to complete the applications and all required paperwork and attachments in their entirety.