

Information on the 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://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/index.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 obtain a federal Clinical Laboratory Improvement Amendment (CLIA) certificate. Laboratories that only do "waived" testing are issued a Certificate of Waiver by the CLIA program. Applications for the federal Certificate of Waiver must be submitted 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.

Effective July 1, 2009, state law changed to no longer require labs doing only waived testing and NOT using a microscopy to obtain a State of Florida Certificate of Exemption.

A CLIA fee of \$150.00 is assessed by the federal Centers for Medicare and Medicaid Services (CMS). You will be billed directly by CMS for the CLIA fee. CLIA fees should not be sent to the State of Florida.

The CLIA Certificate of Waiver must be renewed every two (2) years.

APPLICATION PROCESS

Rapid test sites in Florida will deal primarily with the Initial Application (CMS-116).

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 I. GENERAL INFORMATION

For the initial application, check "initial application".

Do not use a post office box or mail drop address for your number and street address. The facility address **MUST** be the physical address of your facility.

The Director indicates the Lab Director for your facility. For waived testing, this person can be your agency's Executive Director

Section II. TYPE OF CERTIFICATE REQUESTED

Check the Certificate of Waiver box and complete sections I – VI and IX – X

Section III. TYPE OF LABORATORY

Choose the category that best describes your facility

Section IV. HOURS OF LABORATORY TESTING

Provide only the times when actual testing is provided in your facility.

Section V. MULTIPLE SITES

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.

Most sites testing with the Department of Health would qualify for a multiple site exemption based on #2 in the application. Please review the section carefully and determine if your agency falls into this category.

Section VI. WAIVED TESTING

List the type and name of test you will be using (i.e., "rapid HIV test, Clearview Complete/OraQuick ADVANCE/Uni-Gold).

Indicate the estimated total annual test volume for your agency.

Section IX. TYPE OF CONTROL

Select the option that best describes your agency.

Section X. DIRECTOR OF ADDITIONAL LABORATORIES

Complete this section if the director listed in Section I is also the director of any other facilities offering waived or non-waived testing.

RENEWAL PROCESS

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.

FAILURE TO PAY OR RENEW YOUR CLIA WAIVER WILL RESULT IN YOUR 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.

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/foiwaived.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.

You must also notify AHCA and CMS for the following changes (always provide the CLIA ID number):

- Change in name of the laboratory.
- Change in address, whether street address or mailing address
- Change in telephone or fax number
- Change in Ownership
- Change in Tax ID
- Reinstatement if there is no gap in service (please call our office if you are unsure if there is a gap)
- Change in accreditation organization
- Voluntary closure/termination

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.