



Memorandum

TO: All Contractors Implementing HIV Rapid Testing

FROM: HIV/STD Comprehensive Services Branch

DATE: January 10, 2007

SUBJECT: Applying for a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver

requirement

Prior to implementing HIV rapid testing, all agencies must have a current CLIA Certificate of Compliance or Waiver.

background

Passed by Congress in 1998, the CLIA program governs human diagnostic testing. According to this federal law, all laboratories performing testing require the CLIA Certificate of Compliance.

the process

While the HIV Rapid test is usually performed outside of a laboratory setting, agencies possessing a current CLIA certificate of Compliance may already be licensed to perform the HIV Rapid Test in outreach settings. To determine if your agency's Certificate of Compliance is sufficient:

1. Contact the local CLIA office to ensure the agency's current Certificate of Compliance covers the HIV rapid test performed in outreach settings,
2. Contact the agency medical director to ensure he/she is agreeable to providing medical oversight to the HIV rapid testing program

Agencies that do not have an on-site laboratory, do not possess a CLIA Certificate of Compliance, or cannot meet the requirements outlined above, must have a CLIA Certificate of Waiver. Agencies seeking to apply for a waiver need to:

1. Complete an application and other required forms
2. Pay the certificate fee every two years
3. Follow manufacturer's instructions, including but not limited to
 - a. Observe storage and handling requirements for test system components,
 - b. Adhere to expiration dates of the test system and reagents,
 - c. Train testing personnel in the performance of the test,
 - d. Send specimens for confirmatory tests when required

Note: agencies should address these issues in quality assurance plans
4. Permit inspections by a CMS agent, such as a surveyor from the State Agency

obtaining a CLIA waiver

Download a CLIA application at: <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>

Agencies applying for waivers complete sections I thru VI and VIII thru X, following the instructions attached to the form. *Below are some additional instructions for certain sections:*

Section III – Type of Laboratory

Health departments check box #2 – Community Clinic

Community-Based Organizations check box #27 – Other, and write in Community-Based Organization

Section IV – Hours of Laboratory Testing

Write in times you perform HIV rapid testing for *all* sites, venues and locations.

Section V - Multiple Sites

Question One: Are you applying for the multiple site exception?

If your agency had more than one physical plant, facility or location, check yes, and write in the total number of locations in the blank. If your agency has only one formal location, check no. Do NOT consider testing at outreach locations, including drug treatment centers, bars, parks, health fairs, and the like as multiple sites.

Question Two: Indicate which of the following regulatory exceptions applies to your facilities operations. Only agencies that maintain more than one physical office complete this question. Check yes under the question “is this a not-for-profit or federal, state, or local government”, then write in the addresses of other agency physical plants in the table. Remember: Outreach testing sites that are not regular offices for the agency do NOT belong in this table.

After completing the entire application, complete the forms “Listing of Tests Performed in the Facility” and the CMS-1513 “Disclosure of Ownership and Control Interest Statement”. Not all local offices require these two forms. You can fax the completed application and accompanying forms to the local office. For local fax numbers and answers to additional questions, please contact your local CLIA office:

Austin	(512)834-6650	San Antonio	(210)534-8857 x2923
Arlington	(817)264-4500	Tyler	(903)533-5379
Houston	(713)767-3340		

You will receive your CLIA waiver number once your completed application is entered into the system. A fee coupon will be mailed in 2-3 weeks. Follow the instructions for payment of the \$150.00 fee and you should receive your CLIA certificate in about 30 days.

If you have any questions about the information contained in this bulletin, please contact your field operations consultant or regional representative.