Getting a CLIA Waiver for Rapid HCV Testing

**If your agency is NOT already doing rapid HIV testing, skip to page 2**

If your agency **is** already doing rapid HIV testing, simply apply for an amendment to your CLIA Waiver. Use the CLIA Waiver form to apply for an amendment:

* There are only 2 parts of the form you need to fill out - I. and VI.
* Then on page 4, you need the signature of your medical director or owner.

Part I:

* Check **Closure/Other Changes** and write: **Additional Test**
* Write in the effective date
* Be *sure* you enter the correct CLIA number.
* The only other information you may need to provide in this section is information that has changed since your original application.
* For example, has your address changed ?

Part VI:

* Insert: **Rapid HCV Antibody Test.  Currently doing Rapid HIV Testing.**
* Update the estimated number of waived tests (HIV *and* HCV) you will perform in a year.

On the last page include the signature of the Medical Director, owner or director (in ink).

Mail your amendment to:

Department of Community Health

Healthcare Facility Regulation Division

Diagnostic Services Unit / CLIA

2 Peachtree Street, NW

Suite 31-447

Atlanta, Georgia 30303-3142

Note: this office has undergone turnover and can be slow to respond. Once you have submitted your application, it is not necessary to wait until you receive a response to begin HCV testing.

**If your agency is NOT already doing rapid HIV testing**

Fill out an application – see [www.hiveis.com](http://www.hiveis.com) FORMS for a CLIA Waiver Application

Fill out sections:

1. General Information
2. Type of Certificate Requested (check Certificate of Waiver)
3. Type of Laboratory (check Other: Substance Use Treatment Provider)
4. Hours of Laboratory Testing (Hours of operation/when testing will available)
5. Multiple Sites
6. Number of tests you anticipate conducting each year
7. Skip
8. Type of Control
9. Skip unless your agency director serves as director of other providers separately certified for waived testing
10. Individuals Involved in Laboratory Testing – A. Waived \_\_\_\_ (no. of staff trained to do testing)
11. Signed by Medical Director, owner, or director (in ink).

**Send your CLIA Waiver application to:**

Department of Community Health Contact: Tiffany Clegg, CLIA Program Assistant

Healthcare Facility Regulation Division Phone: 404.657.5558

Diagnostic Services Unit / CLIA

2 Peachtree Street, NW

Suite 31-447

Atlanta, Georgia 30303-3142

**Fee - Send No Money with Application**

Your new waiver will be in effect for 2 years; there is a biennial fee of $150.

Please send no money with your application. CLIA will send you a bill.

**If Your Agency Has Multiple Sites**

As government labs engaged in limited public health testing, HIV EIS counselors working for a single Community Service Board (CSB) may operate labs at multiple sites within the CSB.

**Renewing Your CLIA Waiver**

Do not send money to 2 Peachtree. Once you are in the system, you should receive a renewal fee coupon every 2 years. Your coupon should arrive by U.S. mail about 6 months prior to the expiration date.

**If Your Waiver is About to Expire**

You may send a check for $150 without a coupon.

Make the check out to CLIA Laboratory Program

Enter your CLIA ID # on the check.

Mail to: CLIA Laboratory Program, P.O. Box 70948, Charlotte, NC 28272-0948