

## CLIA Waiver Application – Where to Send

### Where to send your CLIA Waiver application

CLIA Program

DHR – Office of Regulatory Services

Diagnostic Services Unit

2 Peachtree Street, NW

Suite 33-250

Atlanta, GA 30303-3142

### Fee

There is a biennial certificate fee of about \$150, but send no money with your application. CLIA will send you a bill.

### If you have multiple sites

According to the regulations, with some exceptions, each site where rapid HIV testing is conducted requires its own certificate of waiver.

- One exception is a lab that is mobile.
- Another is Federal, State, or local government laboratory engaged in limited public health testing.\*

Theresa Snelling of the Office of Regulatory Services translated this for us: as a government lab engaged in limited public health testing, the HIV EIS program falls within this exception. In other words, HIV EIS workers in a single Community Service Board (CSB) may operate labs in multiple sites within the CSB.

### If you have questions about the form

Please contact Winona Holloway at [winonaholloway@hughes.net](mailto:winonaholloway@hughes.net) if you have questions about the form.

*\* Source: Clinical Laboratory Improvement Amendments: How to Obtain a CLIA Certificate - - pdf released by the Department of Health & Human Services, referencing "final CLIA Quality Systems laboratory regulations" published by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) on January 24, 2003. These became effective April 24, 2003.*