

The Commonwealth of Massachusetts

Department of Public Health
Clinical Laboratory Program
99 Chauncy Street, Boston MA 02111
(617) 753-8438/8439 (617) 983-6740 - Fax

WAIVED HIV SPECIAL PROJECTS WAIVER APPLICATION

I. APPLICATION INFORMATION

Name: _____

Address: _____
Street City State Zip code

Telephone: _____ Contact Person: _____

EMAIL: _____

CLIA #: _____ Certificate Type: _____

II. SCREENING PROGRAM INFORMATION

A.. Facility or company which will provide final disposal of the holder's special medical waste:

Name: _____

Address: _____
Street City State Zip code

Telephone: _____

B.) Licensed laboratory where specimens will be sent semi-annually to verify test accuracy:

Name: _____

Address: _____
Street City State Zip code

Telephone: _____ Contact Person: _____

C.) Licensed laboratory where specimens will be sent for confirmatory testing (if required):

Name: _____

Address: _____
Street City State Zip code

Telephone: _____ Contact Person: _____

III. TESTING LOCATION(S)

A.) Address (street, city) of Permanent Testing Location

Schedule of Operation

Days of Week

Time (Hours)

B.) Address of Off-Site Testing Locations

Schedule of Operation

Days of Week

Time (Hours)

C.) Personnel

Laboratory Director

Program Contact Person

Signature of Authorized Individual

Title:

Date:

Telephone:

**DEPARTMENT OF PUBLIC HEALTH
CLINICAL LABORATORY PROGRAM**

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“WAIVED” HIV SPECIAL PROJECTS WAIVER APPLICATION

Waived HIV Special Projects Waiver - Required Documentation

- CLIA application - completed and signed [if facility does not already have a certificate]
website: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>
- “WAIVED” HIV Special Projects Waiver Application
- Training Program
 - Copy of training program / material
 - Ongoing competency protocol
 - Training records for current testing personnel
 - Documentation of enrollment in an approved proficiency testing program
- Enrollment in HIV proficiency testing
- Procedures [include copies of forms/log sheets/test report]
 - HIV(waived) step by step testing procedure
 - Confidentiality procedures
 - Quality control procedure
 - Confirmatory process - include copy of agreement with reference laboratory if confirmatory testing is not provided on-site
 - Patient and testing personnel safety protocols
- Counseling, Referrals and Test Integration
 - Copies of pre and post test protocols
 - Description of referral process
 - Description of rapid test integration