The Commonwealth of Massachusetts

Department of Public Health

Clinical Laboratory Program

67 Forest Street, Marlborough, MA 01752

(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 |