The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Quality
Clinical Laboratory Program
99 Chauncy Street, 2nd Floor, Boston, MA 02111
(617) 753-8439/8438 (617) 753-8240 - Fax

RAPID (WAIVED) HIV TESTS
SPECIAL PROJECTS WAIVER PROVISION OF THE CLINICAL LABORATORY LICENSURE REGULATIONS
SPECIAL PROJECT REQUIREMENTS

Facilities wishing to perform Waived HIV Testing must be licensed and/or approved by the Department of Public Health to perform clinical laboratory testing in the sub-specialty area of "Viral/HIV" Serology. The requirements that must be met are located in the Code of Massachusetts Regulations (CMR), *105 CMR 180.000: The Operation, Approval and Licensing of Clinical Laboratories*. These regulations also allow the Department to "consider proposals for special projects for the innovative delivery of clinical laboratory services." Under this provision, the Department will consider granting an HIV Special Projects Waiver to facilities that meet the requirements noted below. The Clinical Laboratory Program will work in conjunction with the HIV/AIDS Bureau in reviewing and approving the HIV Special Projects Waiver applications. Applicants must respond to each item below (1-8) in writing with the "Waived" HIV Special Project Waiver application.

1. CLIA CERTIFICATE
    a. Testing facility must have a current CLIA certificate that covers the testing to be performed by the facility. All Federal CLIA requirements must be followed [42 CFR 493.000].

2. PERSONNEL
    a. Personnel performing the waived HIV test must have received training specific to this special request approval. The training needs to be inclusive from specimen collection through to test reporting [must include but not limited to: technical procedure, regulatory reporting requirements, quality control requirements]. The training needs to be documented and each testing person must demonstrate competency before reporting any tests.
    b. Ongoing competency must be demonstrated and documented annually thereafter.
    c. All training and competency evaluations must be documented.

3. PROCEDURES
    a. Procedures must be established that include: specimen collection and preparation; materials and equipment required; steps to follow to perform the test; limitations of the procedure; cautions to be observed which may affect the test results; safety precautions to protect patients and testing personnel; quality control procedures to be followed; and, a

plan for remedial or corrective action to be followed in the event that quality controls results do not fall within acceptable limits.

b. Policies need to define the steps that are in place to maintain confidentiality throughout the entire process - consent form, test performance, release of test results, and storage of records. A specific identifier must be maintained for each specimen tested; however, it does not need to be the patient name. [see MGL c. 111 s. 70F].

c. All "non-negative/reactive" results require follow-up testing. The facility must re-examine every "non negative/reactive" patient specimen and conduct confirmatory testing (different from the first and having greater specificity) or collect a follow-up specimen and arrange for a confirmatory test to be conducted.

4. REAGENTS

a. All reagents must be properly stored and cannot be used beyond their expiration dates. All information including lot numbers, date of receipt, record of storage temperatures, expiration date, etc. must be documented. Manufacturer's directions must be followed regarding the expiration date of "opened" reagents.

b. Reagents from kits with different lot numbers cannot be used interchangeably.

5. QUALITY CONTROL

a. All testing must be conducted in a manner to assure proper performance and quality results. Procedures need to include the specific steps required to perform the test correctly; how to interpret both patient and internal/procedural control results; actions to be taken when results are not acceptable; documentation of required data, etc.

b. The internal/procedural control that is part of each test strip ensures adequate migration of the test developer solution and this reading must be recorded for each patient.

c. An external positive and negative control must be run each day of testing at each testing location. Results must be documented. Remedial/corrective action must be taken if results fall outside of the acceptable range and these actions must be documented.

d. Manufacturer's directions must be followed.

6. RECORDS

a. All test/reagent data must be documented. This data includes but is not limited to: record of reagent storage temperatures; date and time of specimen collection; time Testing Device was inserted into the Developer; time result was read; temperature in the room when the test was performed; test result; quality control results; who performed the test, etc.

b. Records must indicate that confirmatory testing was performed on all "non-negative/reactive" patient specimens.

c. All records must be maintained for four (4) years.

7. SAFETY
    a. All infectious or physically dangerous medical waste, including blood stained materials, must be stored and disposed of in accordance with State and Federal regulations.
        1. OSHA Blood Borne Pathogen Guidelines
        2. Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VII [105 CMR 480.000]
    b. Testing areas must be appropriately disinfected on each day of testing.
    c. Personnel must be provided with and wear/use appropriate personal protective equipment when collecting specimens or performing testing.
    d. The blood collection procedure must be done in an aseptic manner so as to protect both the patient and the testing personnel. Appropriate training on proper capillary blood collection techniques must be given to each professional doing testing.

8. PROGRAM COMPONENTS FROM THE HIV/AIDS BUREAU.
    a. Pre- and Post-Test Counseling
    Copies of pre-test and post-test counseling protocols. Protocols should have same type of information recommended for those tested with standard tests and should include principles for addressing the rapid availability of results as well as confirmatory testing follow-up if the rapid test is reactive.

    b. Integration of Rapid Tests
    If your agency/facility currently receives funding from the HIV/AIDS Bureau to conduct an HIV Counseling and Testing program, please describe how HIV rapid testing will be integrated into the existing program, and how choice of test will be maintained.

    c. Referrals and Linkages to Care/Support Services
    Description of referral and linkage processes. This should include links to case management services, primary health care, follow-up testing if not available on-site, needle exchange and other services.

Facilities applying for a "Waived" HIV Special Projects Waiver must complete the application and submit the required documentation [see attached sheet] to:

Clinical Laboratory Program
99 Chauncy Street, 2nd Floor
Boston, MA 02111

REQUIRED DOCUMENTS

☐ **Application for Clinical Laboratory Improvement Amendments of 1998 [CLIA] Certificate** - complete, sign, date and return

download CMS 116 form from website: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf

OR

Copy of your current CLIA Certificate

☐ **"WAIVED" HIV Special Projects Waiver Application**- complete, sign, date and return

download from website

☐ **Training Program**

- Copy of training program / material
- Ongoing competency protocol
- Training records for current testing personnel

☐ **Procedures**

- 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

Failure to provide this information in a timely manner will result in a delay in the processing of information required for the issuance of a Massachusetts Clinical Laboratory Special Waiver Approval.