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Rapid HIV Testing Recommended Guidelines
Massachusetts Department of Public Health
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The development of rapid testing technology to detect HIV infection has created new opportunities for Massachusetts clinical providers and community-based organizations currently offering HIV counseling and testing to increase testing options available to clients. The Clinical Laboratory Program and the Office of HIV/AIDS of the Massachusetts Department of Public Health (MDPH) have collaborated to develop an advisory on the use of rapid HIV testing in the Commonwealth. The implementation of rapid HIV testing services is a complex process that requires adherence to HIV testing laws and regulations and a commitment to conducting quality control and safety procedures in each testing setting. This advisory explains the regulatory and legal requirements, and programmatic recommendations for conducting rapid HIV tests in Massachusetts.

Certifications and Licensure

The Massachusetts Department of Public Health (MDPH) **recommends** that all agencies and organizations within the Commonwealth of Massachusetts currently offering or seeking to offer rapid HIV tests determine their Clinical Laboratory Improvement Amendments (CLIA) certificate and state licensing status. All such agencies and organizations must complete necessary application forms. In addition, they should review laws and regulations governing HIV testing. Massachusetts General Laws, ch. 111, s. 70f, requires written informed consent prior to HIV testing, independent of the type of HIV test utilized. 105 Code of Massachusetts Regulations 180.000: Rules and Regulations Relating to the Operation, Approval and Licensing of Laboratories Special Requirements – Viral Serology [105 C.M.R 180.300] applies to all sites that conduct any type of HIV testing.

To provide rapid HIV testing in Massachusetts, the following documents **must** be filed with the MDPH Clinical Laboratory Program:

A current CLIA Certificate of Waiver, Compliance or Accreditation

(see <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf> for application);

and one of the following:

A Massachusetts Clinical Laboratory License/Approval, with sub-specialty to perform clinical laboratory testing in Viral/HIV Serology;

or a

A HIV Special Projects Waiver Application; requires response in writing to the Special Project Requirements for Implementation of waived Rapid HIV Tests. The Special Projects Waiver Application is reviewed in consideration of the individualized setting/site.

Completing and signing the above documents affirms a commitment to provide rapid HIV testing and acknowledgement of the Massachusetts Department of Public Health recommendations that all sites offering rapid HIV tests establish written protocols that address the components identified below (1-7).

MDPH is available to provide technical assistance for each level of testing implementation. Please see the contacts below for information. Additionally, the Clinical Laboratory Program of the Division of Health Care Quality will provide ongoing site-based reviews.

CONTACTS:

Clinical Laboratory Program: Roberta Teixeira at 617.753.8438, roberta.teixeira@state.ma.us

Office of HIV/AIDS: Thera Meehan at 617.624.5300, thera.meehan@state.ma.us

Recommended Guidelines for Rapid HIV Testing in Massachusetts

1. Informed Consent and Confidentiality

Protocols to protect client confidentiality should be written and adhered to in accordance with M.G.L. ch. 111, s. 70F and 105 C.M.R. 180.300 (B) & (C). Policies should define the steps that are in place to maintain confidentiality and privacy throughout the entire testing process: written consent, test performance, disclosure of test results, and storage of records. A specific identifier must be maintained for each specimen tested; however, it does not need to contain the patient name.

2. Test Procedures

- a. *Specimen collection and preparation.* Providers should develop written protocols that define: 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 control results do not fall within acceptable limits. Protocols for specimen collection and preparation for running patient tests using OraQuick ADVANCE® and/or UniGold™ Recombigen® are available by request from the Office of HIV/AIDS or the manufacturers of the test technologies.
- b. *Follow-up Testing.* All reactive rapid test results require confirmation through submission of a serum specimen. Regardless of the licensed clinical laboratory identified for submission, the specimen should be flagged as confirmatory and have additional supplemental/confirmatory tests performed, regardless of any enzyme immunosorbent assay (EIA) result. Protocols for all funded programs should include policies and procedures to address receipt of rapid results and confirmatory testing follow-up if the rapid test is reactive.
- c. *Reagents.* Providers should store and dispose of all reagents properly. Reagents cannot be used beyond their expiration dates. A documentation system should be maintained for lot numbers, date of receipt, record of storage temperatures, expiration date, and dates in use. Manufacturer directions should be followed regarding the expiration date of opened reagents. Reagents from kits with different lot numbers should not be used interchangeably.

3. Quality Control Procedures

- a. *Test Procedures.* Providers should develop procedures that outline the specific steps required to perform the test correctly; how to interpret both patient test results and internal/external control results; actions to be taken when results are not acceptable; and, documentation of required data. Protocols for running patient tests using OraQuick ADVANCE® and/or UniGold™ Recombigen® are available by request from the Office of HIV/AIDS or the manufacturers of the test technologies.
- b. *Controls.*
 - i. *Internal Quality Controls.* Under 105CMR.030.D4, “each qualitative method must be tested with a positive and negative control on each day of testing”. The OraQuick ADVANCE® and UniGold™ Recombigen® test devices are manufactured with a built-in internal quality control.
 - ii. *External Quality Controls.* External controls must be run as dictated by the manufacturer guidelines and the user facility, in accordance with the Massachusetts Department of Public Health guidance. Both positive and negative controls should be run on each day of testing.

Guidance on when to run external controls may be found on pages 5-6 of these recommended guidelines.

- iii. *Documentation.* Providers should document that controls have been run; noting the date, type of external control, control test results, control lot number, and control expiration date.
- c. *Outside Review.* The Clinical Laboratory Program of the Division of Health Care Quality at 99 Chauncy Street, Boston will provide ongoing site-based reviews.

4. Safety

- a. *Storage and Disposal.* Providers should develop storage and disposal procedures for all infectious or physically dangerous medical waste, including blood stained materials in accordance with the following State and Federal regulations:
 - i. Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VII [105 C.M.R. 480.000]
 - ii. OSHA Blood Borne Pathogen Regulations [29 C.F.R. 1910.1030]
- b. *Sanitization of Physical Space.* Providers should develop procedures to disinfect the testing area appropriately on each day of testing.
- c. *Protective Equipment.* Providers should acquire, store and utilize appropriate personal protective equipment for collecting specimens or performing tests. This equipment includes safety goggles, gloves, absorbent workspace covers, splash guards, sharps disposal container, biohazard waste container, and any other apparatus required at the individual site.
- d. *Specimen Collection.* Providers should develop training and procedures to indicate blood and oral fluid collection is done in an aseptic manner so as to protect both the patient and the testing personnel. Training for proper capillary blood collection techniques should be documented.

5. Program Components

- a. *Counseling.* In addition to assessing the patient's readiness and capacity to test, the following should be explained to patients prior to obtaining informed consent and a specimen for HIV testing:
 - 1. The purpose of the test and voluntary nature of the procedure
 - 2. The seroconversion period
 - 3. Confidentiality of test results
 - 4. What the test results may mean
 - 5. What will happen if the tests result is positive and how the patient may be linked to HIV treatment and care.

Please note that for providers funded by the MDPH Office of HIV/AIDS, pre-test counseling requirements differ depending on the testing strategy employed by the program. Providers funded to conduct targeted HIV Counseling, Testing, and Referral (CTR) services should consistently adhere to all elements of pre-test and post-test counseling protocols. Routine screening providers are not required to provide pre-test counseling or risk assessment services, but are required to provide post-test counseling for all patients testing HIV positive. For more information on routine HIV screening, please visit the MDPH Office of HIV/AIDS website at www.mass.gov/dph/aids.

- b. *Integration of Rapid Tests.* All providers who receive funding from the MDPH Office of HIV/AIDS to provide HIV Counseling, Testing & Referral services must integrate rapid HIV tests into the established program as funding allows.
- c. *Referrals to Care and Support Services.* Providers should develop referral and linkage processes. These should include links to case management services, primary health care, follow-up confirmatory testing, HIV Partner Services, needle exchange and other services. A Resource Guide is available at www.mass.gov/dph/aids.

6. Records

- a. *Test/Reagent Data.* Providers should document all test/reagent data. These data should include but are not limited to: lot number, record of reagent storage temperatures; date and time of specimen collection; time test was initiated; time result was read; temperature in the room when the test was performed; test result; quality control results; who performed the test, test kit storage logs and confirmatory result logs. Sample temperature logs and external control logs are available through the Office of HIV/AIDS.
- b. *Confirmatory Testing.* Providers should indicate in records that confirmatory serum testing was performed on all reactive patient specimens. Protocols for all funded programs should include policies and procedures to address receipt of rapid results and confirmatory testing follow-up if the rapid test is reactive.
- c. *Unconfirmed Reactive Results.* Providers must consult with MDPH on appropriate state and federal guidelines for the reporting of unconfirmed reactive results. Current CDC guidelines state that if confirmatory testing yields either negative or indeterminate results, follow-up testing should be performed on a blood specimen collected 4 weeks after the initial reactive HIV rapid test result. (www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm)
- d. *Maintenance.* Providers should maintain all records for at least four (4) years, or according to CLIA certificate (whichever is longer).

7. Personnel

- a. *Qualifications.* Providers should identify and document qualifications and training needs of personnel performing rapid HIV testing. Training should be inclusive from specimen collection to test reporting (including, but not limited to, technical procedures, quality control requirements, competency testing).
- b. *Proficiency.* Providers should demonstrate and document ongoing competency via proficiency testing enrollment and practice on an annual basis. Documentation and proficiency reports will be examined by Clinical Laboratory Program staff during on-site reviews and licensure renewals. Quality assurance and training measures must be established for staff who fail competency and proficiency procedures.
- c. *Training Requirements.* Providers funded by the MDPH Office of HIV/AIDS to perform rapid HIV testing as a scope of service within their funded contract are required to participate in the MDPH rapid HIV testing certification training. Full competency in visual and practice panels are required for certification.

MDPH Office of HIV/AIDS
Rapid HIV Testing- Guidelines for Running External Controls using
UniGold™ Recombigen® HIV-1 Antibody Test and/or
OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

When to run External Controls

- 1. External controls must be run at periodic intervals as dictated by the Massachusetts HIV Special Projects Waiver Standards document: daily for HIV negative controls and HIV-1 positive controls.**
 - The Massachusetts Department of Public Health has mandated that negative and HIV-1 positive external controls be run each day prior to performing UniGold™ Recombigen® testing on patient samples.

- 2. Each new operator must first successfully run the rapid HIV test using the external controls before they are allowed to test patient specimens.**
 - Each new operator must first successfully run UniGold™ Recombigen® using the external controls before they are allowed to test patient specimens. If more than one operator is present, they may run controls as a group and agree on the interpretation of the test results.

- 3. External controls must be run each time a new lot number is opened. Use only one lot number at a time.**

- 4. External controls must be run on all new shipments that are received, even if it is the same lot number that is currently in use. If the shipment contains more than one lot number, the external controls must be run on each lot number.**
 - If the shipment contains a new lot number and will not be used right away for patient testing, the external controls must be run when the shipment has been received and again prior to testing patient samples.
 - If the shipment contains a new lot number and will be used right away for patient testing, the external controls do not have to be re-run prior to testing patient samples.

- 5. External controls must be run when the temperature of the test storage area falls below or above the storage temperature range as recommended by the manufacturer of the rapid HIV test (2°C – 27°C or 35°F - 80.6°F).**

- 6. External controls must be run when the temperature of the testing area falls below or above the operating temperature range as recommended by the manufacturer of the rapid HIV test (2°C – 27°C or 35°F - 80.6°F).**

- 7. External controls must be run in duplicate if two consecutive invalid test results are received on a patient specimen.**

- 8. If operator tests at more than one site, external controls must be successfully run at the additional site before the operator can begin testing at that site.**

Considerations when Interpreting Results from External Controls

If the external quality controls produce the expected result (the HIV-1 positive control is positive and the negative control is negative), continue with patient testing.

UniGold™ Recombigen® HIV-1 Antibody Test

If the external quality controls do not produce the expected result, repeat the external controls in duplicate as required by the manufacturer (two simultaneous runs of negative controls and two simultaneous runs HIV-1 positive controls). If the external controls still do not produce the expected results, DO NOT proceed with patient testing and contact Trinity Biotech Customer Service (800-325-3424) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab Institute (617-983-6372).

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

If the external quality controls do not produce the expected result, repeat the external controls. If the external controls still do not produce the expected results, DO NOT proceed with patient testing and contact OraSure Technologies Customer Service (800-869-3538) and notify Arthur Kazianis, HIV Laboratory Supervisor at the State Lab Institute (617-983-6372).