

**Rapid HIV Testing Workbook and
Implementation Guidelines for
Limited Testing Sites in New York State**

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Establishing a Quality Assurance Program

See Appendix A: "Clinical Laboratory Evaluation Program"

I. Introduction

Even though rapid tests are relatively simple to use, things can go wrong. To help find and prevent problems, the basic elements of a Quality Assurance (QA) program must be in place before offering testing. This workbook outlines the basic elements of a QA program. Each site needs to decide which rapid test product to use and how to fit the various QA elements of that product into its own workflow and system of operation. These guidelines are intended to assist providers who wish to implement rapid HIV testing under a limited service laboratory status, in developing policies, processes and procedures to ensure high quality HIV testing services. Sample tools are provided to demonstrate documentation and tracking requirements.

Resources are needed to establish and maintain a QA program, no matter how simple the test is. Someone must oversee the program and ensure the necessary staff and supplies are available. Each organization must:

- ▶ Identify a Laboratory Director.
- ▶ Complete and submit an application to become a Limited Service Laboratory.
- ▶ Assign a designee(s) for program oversight to ensure compliance with established policies and procedures based upon the New York State Public Health Law and other regulatory requirements.
- ▶ Identify the person(s) responsible for conducting the rapid testing program.
- ▶ Develop policies and procedures and make them available to all staff involved in rapid testing:

Rapid HIV testing will require modification to current counseling protocols. Organizations will need to consider the logistics of how information about the test should be given, identify when the informed consent will be obtained, prior to collecting a specimen for testing, and determine how the elements of prevention counseling will change using rapid tests.

Procedures should be established for setting up the work space, labeling testing devices, completing reporting forms and identifying each person's specimens tested to ensure specimens do not get mixed up during the testing process.

- ▶ Obtain inventory of supplies (product information) to conduct HIV counseling and testing, up to and including disposal of medical waste.
 - ▶ Verify the testing process and develop an implementation plan for how rapid testing is integrated into existing services. This plan should address possible program concerns such as:
 - Client flow and demand for services.
 - Review of program operations and the appointment schedule, taking into consideration the 2005 Guidance for HIV counseling and testing and rapid test procedures.
 - The need for flexibility in appointments to accommodate the amount of time necessary to deal with preliminary positive results and the collection of confirmatory specimens.
 - The possibility of needing staff backup to assist at a clinic that

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| | <p>may have an increase in demand for services.</p> <ul style="list-style-type: none"> - The need to prepare clients prior to conducting an HIV testing. Clients should be informed ahead of time of the available testing options (e.g., post a sign, have a client information sheet/pamphlet available, share information upon making the appointment, show a video in the waiting area). <ul style="list-style-type: none"> ▶ Ensure staff are properly oriented, trained, perform procedures correctly and attend annual updates. ▶ Create mechanisms for communication so that those who conduct testing and oversee programs are informed about QA issues. ▶ Develop a method to detect and resolve problems that occur at any point in the testing process, especially those that may affect the accuracy of test results. ▶ Create a remedial action plan and make it available to all staff who conduct testing. ▶ Develop and implement mechanisms to ensure confirmatory testing when needed. ▶ Ensure OSHA regulations are followed for employee, client and community safety. |
| <p><i>See Appendix B: "Biohazard Safety/ Universal Precautions"</i></p> | <p style="text-align: center;">II. Personnel Issues</p> <p>Having qualified, trained staff to manage and perform rapid testing, along with the various QA activities, is one of the most important factors for ensuring accurate and reliable results. Key aspects include:</p> <ul style="list-style-type: none"> ▶ Qualifications ▶ Training ▶ Competency Assessment (i.e., ability to perform rapid testing) |
| <p>Qualifications</p> | <p>Current rapid tests are simple tests classified as waived, and therefore free of many requirements of the Clinical Laboratory Improvement Act (CLIA). A waived test must be conducted in compliance with the manufacturers' product insert instructions. There are no specific federal or state educational requirements concerning who can perform a waived test. It is recommended that the individual have a high school education or its equivalent and that the following qualities be considered when selecting personnel to perform rapid testing:</p> <ul style="list-style-type: none"> ▶ <u>Sincerity and Commitment</u> - A dedication to perform HIV testing according to defined procedures. ▶ <u>Literacy</u> - The ability to read instructions and record results is critical. ▶ <u>Organizational Skills</u> - If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be even more critical. ▶ <u>Decision-Making Skills</u> - Rapid testing personnel should be able to interpret results and recognize and handle problems that might come up. ▶ <u>Communication Skills</u> - If the person performing the rapid test is also the person who shares results or other information with the person being tested, being able to communicate clearly is important. |
| <p>Training</p> | <p>Training is crucial to ensuring quality rapid testing. Staff should be fully trained on how to perform their assigned tasks and responsibilities. Job orientation and training should be documented for each staff member. Using checklists is one way to handle this documentation. The key components to include in training associated with HIV counseling and rapid testing are:</p> |

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| <p><i>See Appendix C: "Subpart 58-8 (HIV Testing)"</i></p> <p>Competency Assessment</p> <p><i>See Sample #1: Observation Checklist</i></p> <p><i>See Appendix E: "Proficiency Testing"</i></p> <p>Process Control</p> <p>Before Testing</p> <p><i>See Sample #2: "Rapid Testing Checklist for Clinic Room Set-Up"</i></p> | <ul style="list-style-type: none"> ▶ HIV counseling and testing skills ▶ NYS Public Health Law - confidentiality, HIV reporting and partner notification ▶ Laboratory regulations, Part 58-8 ▶ How to perform the test (including procedures performed before, during and after testing) ▶ How testing is integrated into the overall counseling and testing program ▶ QA program elements and documentation ▶ OSHA guidelines (i.e., exposure control plan of universal precautions, bio-hazard safety) <p>Before an employee is permitted to perform a rapid test on their own, his/her ability to conduct the test should be demonstrated and documented. This assessment should also be carried out at periodic intervals after training, such as every six months or as determined by the testing site and it must be documented. This assessment can be carried out in many ways, but, regardless of the method, every task for which a staff member is responsible should be evaluated and performance documented. A supervisor should perform the assessment using a combination of methods to determine competency. Direct observation using a "check list" is one form of assessment. Additional information is available on external assessments, such as a proficiency test.</p> <h3>III. Conducting HIV Rapid Testing</h3> <p>Rapid HIV tests allow for a very different approach to specimen collection and HIV testing. Counselors or other designated staff can assume responsibility for both specimen collection and for the testing that was previously conducted in a licensed laboratory. The method of administering the test is dictated by the manufacturer's instructions. The activities and techniques that are carried out to ensure that the testing procedures are performed correctly, that the environment is suitable, and that test kits work as expected to produce accurate and reliable results, is called process control.</p> <p>✔ Check inventory and test kits lots, per established protocol.</p> <p>Ensure clinics are appropriately stocked with material needed to conduct testing. Procedures should be in place to ensure that an adequate supply of unexpired test kits, controls and testing medical supplies are available. Test kits and controls have a defined shelf life. Use the oldest first. Never use test or control kits beyond their expiration dates. It is helpful to use a log sheet to document when test and control kits are received, their lot numbers and expiration dates.</p> <p>Once quality control kit vials are opened, they are stable for a certain number of days dictated by the manufacturer. Therefore, record the date that the control is opened and discard unused opened controls after the stated time period.</p> <p>✔ Check storage and room temperatures daily.</p> <p>Procedures for storage of the supplies, setting up the testing area and conducting a test must be developed. Test kits and quality control kits must be stored in an environment within the temperature control ranges specified by the manufacturer. Test kits can be stored refrigerated or non refrigerated as long as they remain in the environmental range dictated by the manufacturer. If test kits are refrigerated, devices are usually brought to room temperature before opening. Control kits <u>must be</u> refrigerated at 2° to 8° C (35° to 46° F). Control kits are also brought to room temperature before use. Please see Manufacturers' product inserts for product specific details.</p> <p>To ensure these temperature ranges are maintained, monitor and document temperatures of</p> |
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| <p><i>See Sample #3: “Temperature Log”</i></p> | <p>the storage areas each day testing is performed. If the temperature falls outside of the specified range, take action as needed to adjust the temperature. To monitor the temperatures, place thermometers in the storage areas (e.g., in the refrigerator and on the shelf in the room where kits are stored). Check and record temperatures on a log sheet each day testing is performed. An example of a temperature log is provided in this manual.</p> <p>The environment in the area where the test will be performed must be within a certain temperature range. Temperatures of the testing site must be recorded prior to conducting a test. The kind of heating system utilized and whether there is an air-conditioning system present that is operational and used during clinic hours are important considerations. If the test must be performed at a temperature area below ranged dictated by the manufacturer, an external control must be run to ensure the test operates correctly. If testing is carried out in the field, monitor the temperature of the test and control kits in their portable storage containers and check the temperature where testing will be performed and processed. If there are doubts about the testing area temperature or whether test kits have stayed within the appropriate temperature range, run a positive and negative external control as described in the quality control section.</p> <ul style="list-style-type: none"> ✓ Perform external quality control according to manufacturer’s instructions prior to conducting testing. ✓ Establish test area readiness. Before performing the test, ensure that there is an adequate level of lighting. If fluorescent lighting is used, the lamps should be covered with light diffusers. In addition, blinds/curtains should be adjusted appropriately. |
| <p><i>See Page 5 “Quality Control”</i></p> | <p>The workspace to perform the test must include availability of a flat surface. Hand washing facilities must be in close proximity to the counseling area or hand sanitizer must be used if there is no sink (soap/water) available.</p> <ul style="list-style-type: none"> ✓ Provide HIV information, subject information sheet and conduct the informed consent according to the NYS Public Health Law. ✓ Follow biohazard safety precautions according to OSHA standards. ✓ Collect specimen as per manufacturers requirement (blood/oral fluid) ✓ Perform the test as per manufacturer’s instructions. |
| <p><i>During Testing</i></p> | <ul style="list-style-type: none"> ✓ Read and record the test result on a Lab Result Slip. ✓ Report the result to client; ensure client understands meaning of result. ✓ Document results in client chart and on master log. |
| <p><i>Refer to product information</i></p> <p><i>See Sample# 6: “Lab Result”</i></p> | <ul style="list-style-type: none"> ✓ Clean up testing area and dispose of biohazardous waste. ✓ Collect, process and transport confirmatory test specimens if rapid test reactive. ✓ Manage confirmatory testing and results, when indicated. |
| <p><i>After Testing</i></p> | <ul style="list-style-type: none"> ✓ Follow up with client and provide appropriate referrals as discussed in the counseling session. <p>There are two types of quality control (QC) for the rapid tests. Internal controls are built in</p> |

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| <p>Quality Control</p> <p>Internal Controls</p> <p><i>See Page 6: “Trouble-shooting”</i></p> <p>External Controls</p> | <p>to each testing device to verify that the specimen is adequate and the solution flowed through the devices as intended. External controls are known reactive and non-reactive reagents (control specimens). They are available from the manufacturer to sites purchasing the rapid HIV product and are used to evaluate the accuracy of the test in detecting HIV antibodies and to verify that the person conducting the test is performing it correctly.</p> <p>Some devices include a built-in (internal) control. When a complete single line develops in the “C” location on the device, the client’s specimen has been correctly loaded and traveled through the test strip, indicating a valid test. Additional information is provided in the test kit package insert. Not every device includes an internal control and this varies according to the product. If the internal control does not produce the expected result, the test is not valid, <u>can not be reported to the client</u>, and must be repeated. If a second invalid result occurs, external controls must be evaluated, as described below, before repeating the test a third time. The organization must develop a remedial action plan for staff conducting HIV rapid testing to follow in the event of an invalid test result.</p> <p>To verify that the test device is accurately detecting HIV-1 or HIV 2 antibodies, external positive and negative controls must be tested from time to time. Control kits are ordered separately from the test kit. Control kits contain 2 or 3 vials of an HIV antibody-negative (non-reactive) and positive (HIV 1 and/or 2 reactive) human plasma reagent. How often controls are run to verify the accuracy of the test will depend upon the number of tests carried out by the site, how often new test kit shipments or lot numbers are received by a site, changes in how the tests are stored and in testing area temperatures and how often staff who conduct the testing change.</p> <p>Manufacturers have established guidelines for the minimum number of times to run controls. This is described in the test kit instructions, which specifies running controls for each product. Most controls are run under the following circumstances:</p> <ul style="list-style-type: none"> ▶ By each new employee prior to performing testing on patients; ▶ When opening a new test kit lot (a test kit lot is defined as the boxes of test devices that contain either 25 or 100 tests that have the same lot number labeled on the outside of the boxes); ▶ Whenever a new shipment of test kits is received (even if it is the same kit lot number in current use); ▶ If the temperature of the test storage area falls outside of dictated range; ▶ If the temperature of the testing area falls outside of dictated range; and, ▶ At periodic intervals as dictated by the user facility. <p>In addition to the specific circumstances listed, testing sites should determine the optimal frequency for running controls based upon their testing volume. When external controls provide incorrect results, none of the tests that were run since the last time control results were correct can be considered valid. This means that everyone who was tested since the last time controls ran correctly will need to be called back and retested (unless a confirmatory test was ordered).</p> <p>Sites testing large numbers of persons should plan to run controls more often than facilities that conduct fewer tests. Each site needs to decide how often to run controls based on its own situation and testing practices. Instructions for other waived tests recommend running external controls each time a new box of 25 tests is opened. It is recommended for facilities that test 25 or more clients a day to run controls every day. Low volume sites, such as those testing fewer than 25 subjects per month, should run external controls every two to four weeks at a minimum. Controls should be run more often if new lots or shipments are opened or if storage or testing temperatures fluctuate. Control results must be documented and logs maintained to prove QA practices are followed.</p> <p>Each site should have a method to detect and resolve problems that occur at any point in the</p> |
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| <p><i>See Sample #4: “Control Results Log”</i></p> <p><i>Trouble-shooting</i></p> | <p>testing process, especially those that may affect the accuracy of test results. Significant problems should be immediately reported to the appropriate supervisory personnel/laboratory director.</p> <p>Written procedures should be available to all testing personnel for the following:</p> <ul style="list-style-type: none"> ▶ When to discontinue testing (e.g., when the external control results are unacceptable as described in the package insert). ▶ How to take corrective action, or an action taken in response to a problem (e.g., contacting the supervisor when the external control results are unacceptable). ▶ How to document problems and action taken (e.g., a logbook where problems and corrective actions taken can be recorded). ▶ How to verify that the corrective actions taken addressed the problem. <p>IV. Rapid Tests Results and Confirmatory Testing</p> <p>Test sites must follow the manufacturer’s instructions for performing the test and reading the test results. Results can only be one of the following:</p> <ul style="list-style-type: none"> ▶ Nonreactive (negative) ▶ Reactive (preliminary positive) ▶ Invalid (the test result can not be interpreted) <p>Whenever a rapid test result is reactive (preliminary positive), a confirmatory test by a licensed laboratory must be performed to confirm that the person being tested is infected with HIV. Therefore, each site must have established procedures for confirmatory testing when there is a rapid reactive result. Specimens should be collected on-site, the site must have procedures describing how to collect, label, process, store and document specimen transfer; transport the confirmatory test specimens to the site(s) where they will be tested; and obtain the confirmatory results to give to the clients. It should be indicated on the specimen transfer log that the specimen is from an individual who had a reactive rapid test result.</p> <p>The standard testing algorithm protocol is followed for confirmatory testing, with the following exceptions:</p> <ol style="list-style-type: none"> 1. All rapid reactive (preliminary positive) results <u>must be</u> followed up with either a Western blot or immunofluorescent assay (IFA) for confirmation. 2. Confirmatory testing can be done on blood (plasma, serum or dried blood spots) or oral fluid specimens. Urine testing should not be performed due to its lower sensitivity (i.e., ability to detect positive results). Confirmatory testing using blood is preferred. 3. With blood specimens, enzyme immunoassay (EIA) screening tests prior to the Western blot or IFA confirmatory test are optional. If an EIA is performed, even if it is non-reactive, the specimen <u>must</u> proceed to Western blot or IFA testing (reactive EIA specimens will automatically be tested by Western blot or IFA). For oral fluid testing, both EIA and Western blot testing should be performed to confirm results. <p>Most confirmatory test results will be positive; however, some may be negative or indeterminate. If the confirmatory test result is negative, in order to determine whether or not the preliminary positive result was a false positive, specimen mix-up needs to be ruled out. If the Western blot or IFA test is negative, it is recommended that:</p> |
| <p><i>Confirmatory Testing</i></p> <p><i>See Sample #5: “Specimen Transfer Log”</i></p> | |

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| <p><i>See Page 8: “Discrepancies”</i></p> | <ul style="list-style-type: none"> ▶ For blood specimens, a confirmatory test should be repeated with a new specimen in to rule out specimen mix-up. ▶ For oral fluid specimens, a repeat confirmatory test with a blood specimen should be done, since the oral fluid test is less sensitive than the blood test, with early infection. ▶ Occasionally, confirmatory test results are indeterminate. If the Western blot is indeterminate or an IFA is indeterminate, it is recommended that: <ul style="list-style-type: none"> ○ For blood specimens, the person should be advised to return for repeat testing in one month. ○ For oral fluid specimens, the Western blot or IFA test should be repeated using a blood specimen. <p>Confirmatory testing should follow established procedures describing how to match the client’s confirmatory test results with their rapid test result; assist in identifying potential discrepancies; and ensure that testing was performed according to standard testing protocols as described above.</p> <p>Rapid test results should be documented on a Lab Result Slip. Reporting of the test result to the person tested, and instructions on how to obtain any additional specimens needed should be outlined in agency protocols. In addition, test results should be recorded and logged each day of testing. Logs should include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid, identification of the person who performed the test, whether confirmatory testing was completed, including the type of specimen sent for confirmation (e.g., oral fluid, blood) and the confirmatory test results when they are available. If more than one person is conducting testing, there should be a mechanism to chronologically link the test record log sheets to detect problems, such as invalid results occurring repeatedly with the same kit lot number.</p> |
| <p><i>See Sample #6: “Rapid HIV Antibody Test Result”</i></p> | <p>Procedures should describe how to handle result discrepancies when the rapid test result was reactive and the confirmatory test negative or indeterminate. If the laboratory providing confirmatory testing performed an EIA test only and reported a non-reactive or negative result, the testing site should contact the confirmatory testing laboratory and request a Western blot test or IFA test. If the original specimen is not available, a new specimen will need to be collected from the person in question to be used for confirmatory testing. Additional steps should be outlined to ensure specimen mix-up has not occurred and how to resolve a potential specimen mix-up and retest, as needed.</p> |
| <p><i>See Sample #7: “Test Results Log”</i></p> | <p>External assessment, or an evaluation of the testing process by a source outside the testing site, can evaluate how testing is being performed and whether it is being performed reliably. It can also help to identify existing or potential problems. Moreover, information gathered can provide an educational tool to improve performance. Some form of external assessment is highly recommended. It is not required by federal (CLIA) or State (CLEP) regulations since the test is waived and the test kit manufacturer does not specifically require it.</p> |
| <p>Discrepancies</p> | <p>Every reactive rapid test is externally assessed by a second, confirmatory test. However, if there is a low prevalence of HIV infection in the population being tested, these assessments may be infrequent and will not provide an external check for the majority of the results (i.e., those that are non-reactive).</p> <p>Other ways to assess performance may be needed. Some external assessment mechanisms include:</p> <ul style="list-style-type: none"> ▶ Comparing the rapid reactive results with the confirmatory test results. ▶ Arranging for someone outside the organization to observe testing. ▶ Participating in a proficiency testing or external evaluation program. |

V. Documentation

Conducting HIV rapid testing requires the development of new forms, tracking logs and documentation systems to fulfill the requirements of a laboratory status. Policies and procedures describing the rapid test records are required, in regard to how and when they are reviewed, stored and destroyed.

Having periodic supervisory review of these records is recommended and ensures staff are following established protocols. Laboratory records should be retained for a period of two (2) years to demonstrate compliance. These records should include permit and CLIA documentation, staff training documentation, HIV test result logs and specimen transfer logs for confirmatory tests, temperature logs, and external control result logs.

Temperature logs should include a daily record of the refrigerator temperature in which controls are stored, the temperature where test kits are stored and the temperature of the testing area. Thermometers should be placed in each location. Laboratory grade thermometers can be purchased from medical or laboratory supply houses and are recommended. Their accuracy should be checked periodically (e.g., every six months) by comparison with another thermometer.

External control records should include the date and time of control testing, lot result logs number and expiration of the test kit, lot number and expiration date of the controls, control results and corrective action taken if control results are unacceptable. Control records should be kept in the order in which they were completed so they can be easily compared with the test records. This will help find answers if there are questions about testing performed within a specific time frame.

VI. Additional Information

For additional information related to HIV rapid testing, refer to the New York State Department of Health website at:

<http://www.health.state.ny.us>

For addition information related to specific HIV rapid test products please refer to the manufacturer websites.

*See
Appendix F:
“How to Access
Information Via
the Web on Rapid
Testing for HIV”*

Sample Documentation

The following attachments are being shared as “examples” of required documentation needed to maintain a limited service laboratory status. Agencies applying to the New York State Department of Health, Clinical Laboratory Evaluation Program (CLEP) are not mandated to use these forms and can develop their own systems to monitor and record quality assurance practices. Documentation of the quality assurance procedures conducted by the laboratory must be available for presentation during a CLEP site visit. Failure to do so will result in a deficiency statement and could lead to the removal of an agencies laboratory permit.

Sample 1: Checklist for the Rapid Antibody Test Procedure: OraQuick HIV rapid test

Sample 2: Rapid Testing Checklist for Clinic Room Set-Up

Sample 3: Temperature Log

Sample 4: Control Results Log

Sample5: Specimen Transfer Log

Sample 6: Rapid HIV Antibody Test Result (Lap Slip)

Sample 7: Test Results Log

Sample #1:
Checklist for the OraQuick Rapid HIV Antibody Test

Instructions: Fill in dates when the employee observes and performs each objective or procedural step, as applicable. If the employee will not be trained to perform a specific task, enter N/A for Not Applicable. The employee should initial/date when he/she has completed each step and the supervisor should initial/date when he/she agrees that the employee met the objective or performed the specific task competently. This form should remain in the employee's personnel records.

Employee Name: _____ Date: _____

| Objective/ Procedural Step | Date Observed | Date Performed | Employee's Initials/ Date | Supervisor's Initials/ Date |
|--|------------------|-------------------|---------------------------------|-----------------------------------|
| Read OraQuick procedure | | | | |
| Read procedure manuals and other materials i.e. Biohazard Exposure Control Plan | | | | |
| Able to determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space) | | | | |
| Practiced test with negative and positive external controls | | | | |
| Provides the "Subject Information" brochure appropriately | | | | |
| Labels test device components and appropriate paperwork according to policy | | | | |
| Collects finger-stick/oral fluid specimen, according to instructions | | | | |
| Insert test device, time test, read result correctly | | | | |
| Disposes of lancet and other biohazardous waste appropriately /cleans area | | | | |
| Records results on report form/log sheet | | | | |
| Reports test result to the person being tested | | | | |
| When needed, collects specimen for confirmatory testing | | | | |
| Sends confirmatory test specimen to referral laboratory and document submission appropriately | | | | |
| Able to track receipt of referral laboratory results and record results | | | | |
| Able to evaluate a new OraQuick test kit lot number and record results in QC log | | | | |
| Records internal and external quality control (QC) results in QC log | | | | |
| Explains what to do if QC results show a problem or the test does not work properly | | | | |

Sample #2:
Rapid Testing Checklist for Clinic Room Set-Up

Inventory Needed in Preparation for Rapid Testing

Testing Supplies: According to Product Insert

- Product Kits (device pouch)
- _____
- _____
- Thermometer
- Timer
- Barrier (provide a clean testing area)

For Blood testing

- Alcohol Pads, Gauze, Band-Aids

For disposal of Biohazardous waste

- Sharps Container
- Biohazard Bag

For infection control

- Gloves
- Hand Sanitizer (if no sink is available)
- Antiseptic Wipes

For transport only

- Cooler

Paperwork:

- Data (CTS) forms (if applicable)
- Client Information Sheets
- Informed Consent Forms
- Test Result Log
- Clinic Schedule
- Client Note Form
- Lab Result Form
- Appointment Card (for confirmatory testing)
- Referral information and other pamphlets
- Labels
- Specimen Track Logs
- Temperature Logs

Additional Testing Supplies:

- Needles
- Vacutainer Holders
- Tourniquet
- Blood Tubes
- OraSure Kits
- Laboratory Mailers (to send specimens for confirmation)

Sample #3: Temperature Log

Thermometer Location: _____

Acceptable Temperature Range*: _____ to _____

| Month: _____ Year: _____ | | | | | |
|--------------------------|-------------|----------|-----|-------------|----------|
| Day | Temperature | Initials | Day | Temperature | Initials |
| 1 | | | 17 | | |
| 2 | | | 18 | | |
| 3 | | | 19 | | |
| 4 | | | 20 | | |
| 5 | | | 21 | | |
| 6 | | | 22 | | |
| 7 | | | 23 | | |
| 8 | | | 24 | | |
| 9 | | | 25 | | |
| 10 | | | 26 | | |
| 11 | | | 27 | | |
| 12 | | | 28 | | |
| 13 | | | 29 | | |
| 14 | | | 30 | | |
| 15 | | | 31 | | |
| 16 | | | | | |

* The acceptable range for test kit storage can be found on your product insert Note: Periodically (e.g., every 6 months) check thermometer performance and document.

Corrective Action:

| Date | Action Taken | Initials |
|------|--------------|----------|
| | | |
| | | |
| | | |

Reviewer's Name: _____ Date: _____

Sample #4 Control Results Log

| Date | Time | Test Kit Lot # | Test Kit Exp. Date* | New Lot # Shipment? | Control Kit Lot # | Control Kit Exp. Date* | Date Controls Opened | Negative Control Result | Positive Control Result | Results Acceptable? | Performed By | Reviewer & Date |
|------|------|----------------|---------------------|---------------------|-------------------|------------------------|----------------------|-------------------------|-------------------------|---------------------|--------------|-----------------|
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* Exp. = Expiration

Corrective Action (use reverse side if needed)

| Date | Action Taken | Initials | Reviewer/Date |
|------|--------------|----------|---------------|
| | | | |
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Sample #6:

“Name and Address of Agency which Holds the Limited Service Laboratory Permit”

Rapid HIV Antibody Test Result

Client Name: _____ **Collection Date:** ___/___/___

Counselor Initials: _____

Clients Date of Birth: ___/___/___ **Race:** _____ **Gender:** _____

Name of Authorizing Physician _____

The HIV-1 antibody result from the **Rapid HIV Antibody Test** is:

| Non-Reactive (Negative) | Reactive (Preliminary Positive) |
|------------------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> |

Name of Product used: _____

Lot # /Expiration Date: _____

Type of Specimen:

Rapid test, finger stick with whole blood

Rapid test, Oral Fluid

Other: _____

Meaning of the test result:

A **non-reactive (negative)** test result means that no antibodies to HIV-1 have been detected. HIV antibodies may be absent during the “window period” of infection. Follow-up testing may be necessary if indicated by risk factors.

A **reactive (preliminary positive)** test result suggests that antibodies to HIV-1 or HIV-2 may be present in the specimen obtained from a rapid test. A second specimen will have to be sent to a comprehensive laboratory for a Western Blot test prior to confirmation of the reactive test result. Precautions should be taken to avoid the chance of spreading HIV.

Questions: If you have any questions about the rapid test result, please contact the Authorizing Physician.

Confidentiality and Disclosure:

This information has been disclosed to you from confidential records that are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law.

Appendices

- Appendix A: Clinical Laboratory Evaluation Program
- Appendix B: Biohazard Safety/Universal Precautions
- Appendix C: Subpart 58-8: Human Immunodeficiency Virus (HIV) Testing
- Appendix D: Food and Drug Administration (FDA) Sales Restrictions
- Appendix E: Proficiency Testing
- Appendix F: How to Access Information Via the Web on Rapid Testing for HIV

Appendix A

(Insert “Clinical Laboratory Evaluation Program”)

Appendix B

Biohazard Safety/Universal Precautions

All specimens, and materials containing specimens, must be handled as if they are capable of transmitting an infectious organism. Sites must ensure that the Occupational Safety and Health Administration (OSHA) Precautions for blood borne pathogens are met. Also, according to Universal (standard) Precautions, all human blood should be treated as if it is known to be infectious for HIV, hepatitis B and other blood borne pathogens. Sites must have available, and follow procedures for, biohazard safety including instructions for gloves, hand washing, sharps and biohazardous waste disposal, spill containment and disinfection. A different pair of gloves should be worn for collecting a specimen from each person being tested. Used gloves should be handled as biohazardous waste. For further details on these precautions, see the OraQuick package insert, OSHA regulations and guidelines on Universal and Standard Precautions.

Employers with employees who have potential for an occupational exposure to blood or other potentially infectious materials must meet OSHA standards for blood borne pathogens. Individuals collecting blood specimens or performing HIV rapid testing, are exposed to blood or other potentially infectious materials resulting from the performance of their duties. Therefore, sites offering testing with blood must meet OSHA standards that include, but are not limited to, the following requirements:

- ▶ Written exposure control plan.
- ▶ Personal protective equipment (e.g., gloves).
- ▶ Hepatitis B vaccine and vaccination series to all employees who have occupational exposure.
- ▶ Training for all employees with occupational exposure.
- ▶ Post-exposure evaluation and follow-up for all employees who have had an exposure incident.
- ▶ Containment and disposal of bio-hazardous waste (including blood and items contaminated with blood or other potentially infectious materials) that follows all federal, State and local regulations.

Individuals that administer OraQuick should follow universal precautions and all regulations for disposal of bio-hazardous materials. Agencies should keep a log of all occupational exposure injuries. In addition, agencies should review their current liability insurance and obtain advice from their legal counsel for specific issues. State laws and regulations related to liability for blood borne pathogen exposure and occupational safety should be carefully reviewed. Agencies should seek legal counsel for specific issues.

For more information, see the blood borne pathogen section of the OSHA web site:

www.osha.gov/SLTC/bloodbornepathogens/index.html

For a model exposure control plan, see the directives section of the OSHA web site:

www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1574

(Insert “Subpart 58-8: HIV Testing”)

Appendix D

Food and Drug Administration (FDA) Sales Restrictions

To help ensure the quality of testing with the OraQuick test, the FDA approved the test kit with specific restrictions for its sale. These restrictions apply to the sales of waived test kits. By purchasing the test, the customer agrees to follow these restrictions, outlined below. For the specific FDA language, refer to the OraQuick package insert.

The kit purchaser must:

1. Be a clinical laboratory, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate and NYS DOH certification that is required by the Clinical Lab Evaluation Program (CLEP)
2. Have an established quality assurance program.
3. Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
4. Provide information to persons being tested by giving each a copy of the manufacturer's "Subject Information" pamphlet prior to specimen collection and appropriate information when providing the test results.
5. Not use the kit to screen blood or tissue donors.

Each site must:

1. Have a valid CLIA certificate of waiver, certificate of compliance or certificate of accreditation.
2. Follow the manufacturer's instructions for performing the test.
3. Permit announced or unannounced inspections by representatives of the CLEP program under certain circumstances.
4. Perform only waived tests if registered as a Limited Testing Site.

Appendix E

Proficiency Testing

External Assessment: Proficiency Testing and Other Mailed Evaluation Programs

Agencies may voluntarily participate in a proficiency testing program approved by New York State or the Centers for Medicare & Medicaid Services, even though such participation is not required by CLIA for waived tests. Participating in proficiency testing or an external evaluation program is a relatively easy way to obtain an external assessment of the quality of waived testing. There are several programs in which a site may choose to enroll. Test samples will be received by mail on a periodic basis, usually two to three times per year. These samples include a combination of several (typically five) HIV antibody positive and negative specimens with results known to the program provider, but not to the participants. The participants test the samples as if they were client/patient specimens and send results back to the program provider.

In proficiency testing programs, the results from the individual participant sites are compared to the expected values. Each site receives a graded individualized report and summary report showing their performance and the performance of all the participants. In some evaluation programs, such as the Model Performance Evaluation Program (MPEP) offered by the Centers for Disease Control and Prevention (CDC), individual participant results are not graded; instead a summary report is provided with a compilation of results from all participants and a commentary on overall performance.

For more information, refer to the following Internet sites:

CLIA Approved sites: <http://www.cms.gov/clia/ptlist.pdf>

CDC MPEP sites: <http://www.phppo.cdc.gov/mpep/enrollment.asp>

Appendix F

Additional information available on CLIA Waived Rapid Tests:

Rapid HIV test technology is evolving and it is expected that there will be a number of tests to choose from in the future. What rapid HIV test product an agency uses is based on a variety of issues such as cost, ease of use, and population served. Currently there are two CLIA waived products available in New York State.

OraQuick® Rapid HIV Antibody Test

OraQuick® is currently being distributed by two companies, OraSure Technologies and Abbott. Product information may be obtained directly from:

- OraSure Technologies, Inc. at: 1-800-869-3538 or via the internet at: <http://www.orasure.com>; or from
- Abbott Laboratories at: 1-800-323-9100 or <http://www.abbott.com>

The Centers for Disease Control and Prevention (CDC) offers "Frequently Asked Questions: OraQuick® Rapid HIV-1 Antibody Test: at: <http://www.cdc.gov/hiv/pubs/rt-faq.htm>

Uni-Gold Recombigen HIV Antibody Test

Uni-Gold HIV antibody test is distributed by Trinity Biotech. Product information may be obtained directly from:

- <http://www.trinitybiotech.com/EN/index.asp> or
- <http://www.trinitybiotech.com/EN/HIV-ComplimentaryProductApplication.pdf>

There other rapid tests for HIV that can be used in New York State.

Some rapid HIV tests are designated as moderately complex by CLIA, and due to its complexity must be performed in a traditional clinical laboratory. This entails fulfilling requirements that are likely beyond the means of non-clinical providers, unless they have an affiliation or partnership with a clinical provider.

More information on rapid tests for HIV can be found at the CDCP web site.

The Centers for Disease Control and Prevention (CDC) offers several documents that are accessible via the Internet. "General and Laboratory Consideration: Rapid HIV Tests Currently Available in the United States" can be found at: <http://www.cdc.gov/hiv/pubs/rt-lab.htm>

Rapid test technology updates and information regarding new product approval can be found on the FDA website at: <http://www.fda.gov/>