Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test

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Introduction and Background

Purpose	This document provides guidance on quality assurance (QA) practices for sites using or planning to use the OraQuick® Rapid HIV-1 Antibody Test to detect antibodies to the human immunodeficiency virus (HIV).
Background	The OraQuick Rapid HIV-1 Antibody Test is the first rapid HIV point-of-care (i.e., testing and results are available in one visit) test approved by the U.S. Food and Drug Administration (FDA). It is also the first test for HIV that the FDA has waived under the Clinical Laboratory Improvement Amendment regulations (CLIA). The OraQuick test uses whole blood obtained from puncture of a finger. Results are available within 20 to 60 minutes.[1] Positive results with the OraQuick rapid test are preliminary, however, and must be followed up with an acceptable confirmatory test. Although the OraQuick test device is simple to use and can provide reliable results when the manufacturer's directions are followed, mistakes can occur at any point in the testing process. To reduce mistakes and to ensure that the FDA restrictions for sale of the test are followed (see Appendix A for information on the FDA sales restrictions), a site must have a QA program in place before offering OraQuick testing. The guidelines in this document outline the basic parts of a QA program.
How these guidelines were developed	These guidelines were developed after many discussions on quality assurance for rapid HIV testing within the Centers for Disease Control and Prevention (CDC) and culminated from the discussions at a meeting of experts convened by the CDC at the end of January 2003. This working group included individuals from Federal agencies—CDC, FDA, U.S. Department of Defense (DOD), and the Centers for Medicare & Medicaid Services (CMS)—as well as individuals outside the Federal government with expertise in rapid point-of-care testing, QA, HIV prevention programs, and private and public health laboratories.
How to use these guidelines	This document outlines the basic processes and procedures that should be in place before a site offers rapid HIV testing. It describes steps that can be taken to identify and prevent errors in the testing process. Because the OraQuick test will be used in many different settings, each site needs to decide how to fit the various QA elements into its own workflow and system of operation. For example, following these guidelines in a large clinic or hospital environment where on-site laboratory support is available may be quite different from using them in a small voluntary counseling and testing site or outreach setting with few staff and resources. These guidelines are intended to assist a range of providers in developing policies, processes and procedures to ensure high quality HIV testing services.
How this document is organized	This document includes text and appendices that provide basic information that staff in sites offering OraQuick testing should know. It includes information on: ▪ The basics of a QA program for testing using the OraQuick test. ▪ An overview of government rules that apply to using this test. ▪ Examples of forms/checklists that can be used to keep track of QA outcomes.

Basic Elements of a Quality Assurance Program

What is quality assurance?

Quality assurance (QA) refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Quality assurance is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. Quality assurance activities should be in place during the entire testing process; this means from the time a person asks to be tested using the rapid HIV test to providing the test result.

How does quality assurance differ from quality control?

As described above, QA is an overall program of activities throughout the entire testing process. Quality control (QC) is one part of the QA program. See page 11 for details on quality control testing for the OraQuick test. Here are definitions for both terms[2]:

Term	Definition and activities performed
Quality assurance	Planned and organized activities to help ensure that certain requirements for quality will be met
Quality control	Operational techniques or tasks that are in place to find and correct problems that might occur

Basic elements of a QA program for OraQuick Rapid HIV-1 Antibody testing

Even though the OraQuick test is simple to use, things can go wrong. To help find and prevent problems, the basic elements of a QA program should be in place before offering testing. These basic elements are the building blocks of a QA program and are listed below. More detail on these five elements is provided in this document.

1. Organization of the QA program
2. Testing personnel
3. Process control
   a. Before testing
   b. During testing
   c. After testing
4. Documents and records
5. Troubleshooting

Organization of the QA program

Establishing a QA program

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

- Identify the person(s) responsible for managing the QA program (this could be a senior staff member, outside consultant or a network of individuals who oversee different aspects of the QA program).
- Write procedures (step-by-step instructions) and make them available to all staff involved in testing (see the list of recommended procedures below).
- Verify the testing process (see below).
- Ensure staff know how to perform processes and procedures (see the section on personnel who conduct testing on page 6).
- Create mechanisms for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate.
- Develop and implement mechanisms to ensure the site meets all applicable Federal, State, and other regulatory requirements. Each site offering testing must have a CLIA Certificate of Waiver if they are performing only the OraQuick test or the OraQuick test and other waived tests, or be included under an organization with a CLIA exception for limited public health or mobile testing. Each site must also meet Federal requirements for biohazard safety, as well as applicable State rules. See Appendix A for more information on regulatory requirements.

Verifying the testing process

Before offering the test to clients or patients, each site should make sure (verify) that the testing process works as planned. This verification should be completed before testing is offered. Verification includes ensuring that staff have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected (e.g., make sure the test gives accurate results for a referenced panel of non-reactive, weakly reactive and reactive specimens), and the logistics for providing confirmatory testing (if a person tests positive, he or she still has to have a test to confirm the finding) and biohazardous waste handling are in place.

Organization of the QA program (continued)

Providing written procedures

It is strongly recommended that step-by-step, written instructions be made available to all staff performing testing. This will help to ensure that personnel know how to perform specific tasks and testing success is not left to chance. Testing personnel must follow instructions provided by the manufacturer. Additional procedures, as listed below, should be provided along with the manufacturer's instructions. Text from the current OraQuick package insert may be used for some of the items denoted by an asterisk (*) in the list below. Written instructions should describe how to:

- Train new employees, assess their ability to do the testing and document training.
- Provide information to persons being tested before testing.*
- Use gloves and other personal protective equipment.
- Safely dispose of biohazardous waste, including used lancets.
- Maintain sufficient supplies and unexpired test and control kits, follow the manufacturer's instructions for storage, and check performance of new test kit lots and shipments with external controls as explained on page 10.
- Maintain and document the temperature of the room and refrigerator where the tests and controls are stored and testing is performed.
- Perform quality control testing and take action (e.g., contact the manufacturer) if controls don't work.
- Collect the OraQuick specimen. *
- Perform steps in the test procedure. *
- Report results.
- Refer specimens or persons being tested for confirmatory testing and manage confirmatory test results.
- Record test and quality control results.
- Conduct external quality assessment (see description on page 15)
- Review records and store and destroy them when they are outdated (how long test result records are kept as part of a medical record may be subject to State or other requirements).
- Troubleshoot and take corrective action when things go wrong.

Testing Personnel

Overview

Having qualified, trained staff to perform and supervise OraQuick testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- Qualifications
- Training
- Competency assessment (i.e., how well they are doing their job)

Personnel qualifications

Since the OraQuick test is waived under CLIA, there are no specific Federal requirements on who can perform the test. Each site should find out if there are State or other requirements for personnel that they must meet. Beyond any regulatory requirements, it is recommended that certain qualities be considered when selecting personnel to perform the OraQuick test. The following list of qualities resulted from practical considerations and expert opinion:

- *Sincerity and commitment* – A dedication to performing testing according to defined procedures.
- *Literacy* – The ability to read instructions and record results is critical.
- *Organizational skills* – The need for this quality will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
- *Decision-making skills* – Testing personnel should be able to interpret results and be able to recognize and handle problems that might come up.
- *Communication skills* – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.

Components of training

Training is crucial to ensuring quality testing.[3] Training is also required to be able to purchase the OraQuick test kit (see Appendix A for details on the FDA sales restrictions). Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member; using training checklists is one way to handle this documentation (see Appendix B for an example of a training checklist). The key components to include in a training program are

- How to perform the test, including procedures performed before, during and after testing.
- How testing is integrated into the overall counseling and testing program.
- The importance of QA and the elements of the site's QA program.
- The use and importance of Universal (or Standard) Precautions/biohazard safety.

Testing Personnel (continued)

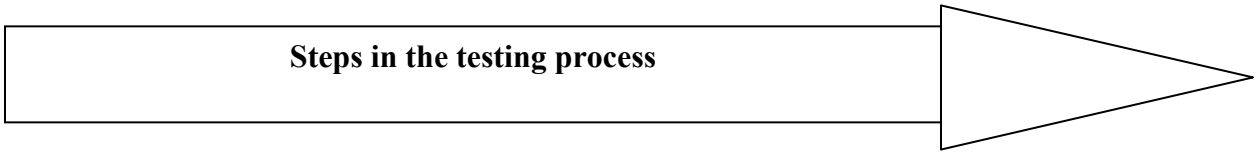
Training method	Experience with training to perform the OraQuick test (CDC unpublished data) shows that a training method should optimally include the following activities: ▪ Read the instructions for performing the test. ▪ Watch someone perform the test or view a video of someone performing the test. ▪ Practice performing the test with positive and negative control materials. ▪ Practice performing the finger-stick collection procedure. ▪ Review the procedures and forms on how to document testing.
Competency assessment	Before a trainee is permitted to perform testing alone for the first time, his or 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 other interval as determined by the testing site. 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. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency. Examples of these methods are presented below.
Assessing performance of tasks done before testing	To assess the task performance before testing, staff should be observed as they: ▪ Check and record the temperatures of the testing and storage areas. ▪ Set up the testing area, label the device and prepare control and test results log sheets. ▪ Run the external controls and record results.
Assessing performance of tasks done during testing	To assess staff's ability to perform the test and interpret results ▪ Observe the staff member performing the finger-stick, collecting the blood on a test loop and placing it into the testing vial. ▪ Observe how the test is performed on a client/patient. If such observation will interfere with actual client-provider interactions, observe test performance on a volunteer. ▪ Evaluate the use of Universal or Standard Precautions and procedures for biohazard and sharps (e.g., lancets, needles) waste disposal. ▪ Review results obtained on a panel of referenced specimens that show a range of results, such as five specimens that include non-reactive, weakly reactive and reactive results. Control materials supplied by the manufacturer may be used as a source of specimens in the panel. In addition, specimens may be obtained from laboratories performing confirmatory testing or from other commercial sources. ▪ Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive and invalid results.

Testing Personnel (continued)

Assessing performance of tasks done after testing	To assess task performance after testing: ▪ Review test records and quality control results documentation. ▪ Observe oral reporting of results to a test subject (if trainee's responsibility). ▪ Observe venous blood and/or oral fluid specimen collection and handling for confirmatory testing. If the frequency of OraQuick reactive results is low, the trainee should be observed collecting blood and/or oral fluid from a staff volunteer and demonstrate how it is processed for confirmatory testing. ▪ Verify that confidentiality is maintained.

Process Control

What is process control?	Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.
Steps in the testing process	Steps in the testing process follow the path of workflow beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown in the table below. Detailed descriptions about each of the steps listed in this table are provided in the remainder of this document.



Before testing	During testing	After testing
▪ Check storage and room temperatures daily ▪ Check inventory and test kit lots, as needed ▪ Receive request for testing ▪ Provide HIV/AIDS information to the test subject ▪ Set up test area, label test device ▪ Perform external quality control according to the manufacturer's and the site's instructions	▪ Follow biohazard safety precautions ▪ Collect the finger-stick specimen ▪ Perform the test ▪ Interpret test results	▪ Clean up and dispose of biohazardous waste ▪ Report results to client ▪ Document results ▪ Collect, process and transport confirmatory test specimens ▪ Manage confirmatory test results ▪ Participate in external quality assessment (periodically)

Before Testing

Overview	As shown in the table above, there are a number of steps that must be followed before testing the blood sample for HIV. These activities are in place to ensure that the conditions in which the tests are stored and performed are suitable, the test area and the test subject are prepared, and the test is working appropriately.

Before Testing (continued)

Temperature control: test kits and control kits	Test kits and controls must be stored in an environment within the temperature ranges specified by the manufacturer. Store test kits at 2^{o} to 27^{o} C (35^{o} to 80^{o} F). If test kits are refrigerated, the pouch containing the test device and developer solution must be brought to room temperature (15^{o} to 27^{o} C or 59^{o} to 80^{o} F) before opening. Control kits must be refrigerated at 2^{o} to 8^{o} C (35^{o} to 46^{o} F). To ensure these temperature ranges are maintained, monitor and document temperatures of 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 temperature log is provided in Appendix C.
Temperature control: testing area	The temperature in the area where the test will be performed must be within the range of 15^{o} to 27^{o} C (59^{o} to 80^{o} F). If the test must be performed at a temperature below 15^{o}C/59^{o}F or above 27^{o}C/80^{o}F, run external controls that have been stored within the proper temperature range to find out if the test can be performed at another temperature (see the section below on external controls). 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 if it appears to be outside the specified range. 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 below.
Checking inventory and test kits	Procedures should be in place to ensure that an adequate supply of unexpired test kits, controls, and supplies is 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. Also, once control vials are opened, they are stable for 21 days. Therefore, record on the vial the date it is opened and discard unused opened controls after 21 days. As described in the package insert and in the section on quality control below, run the positive and negative controls with new lots and new shipments of test kits before using them for testing, to verify that they work as expected.

Before Testing (continued)

Setting up the testing area and labeling the test device

Before testing, the testing area should be prepared according to the specific site procedure, which should include directions for setting up the workspace listed in the test kit instructions, as well as instructions for how to label testing devices and complete report forms, including the method for identifying each person to be tested to ensure specimens are not mixed up during the testing process. Labeling is especially important when more than one test is being performed at the same time. Label components of the test with the name or identifying number of the person being tested before collecting the specimen. These components include the developer solution vial, test device, and documents for recording results. Using preprinted labels improves the efficiency of performing this task.

Note: *Do not place a label over the two holes on the back of the test device as this can cause an invalid result*.

Providing information to test subjects

OraSure Technologies, Inc., provides a "Subject Information" pamphlet that must be given to each person getting tested prior to performing the HIV rapid test. Each site may provide additional information. For further details, see the CDC website http://www.cdc.gov/hiv/pubs/rt-counseling.htm, the *Revised Guidelines for HIV Counseling, Testing, and Referral*, MMWR Recommendations and Reports, RR-19, vol. 50, November 9, 2001[4] and applicable State or local rules.

Quality control

There are two types of quality control (QC) for the OraQuick test. These are described in the table below.

Type of quality control	Description of activity
Internal controls	A control is built in to each testing device to verify that the specimen was adequate and the solution flowed through the device as intended.
External controls	Known reactive and non-reactive specimens (controls) are available from the manufacturer to sites purchasing the OraSure Rapid HIV Test. They are used to evaluate the accuracy of the test in detecting antibody to HIV and to check if the person conducting the test performs it correctly.

External quality control

To verify that the test device is accurately detecting HIV-1 antibodies, external positive and negative controls must be tested from time to time. The test kit manufacturer provides external controls in the form of the OraQuick Rapid HIV-1 Antibody Test Kit Controls. This control kit must be ordered separately from the test kit. It includes one vial each of an HIV antibody-negative (non-reactive) and positive (reactive) human plasma control. How often controls are run to verify the accuracy of the test will depend on 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 testing area temperatures, and how often staff who conduct the testing change. An example of a log for control testing results is available in Appendix D.

Before Testing (continued)

Run external controls according to the manufacturer's instructions	The manufacturer has set guidelines for the minimum number of times to run the negative and positive controls. This is described in the test kit instructions, which specifies running controls under the following circumstances: ▪ By each new operator 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 2^{o}-27^{o} C (35^{o}-80^{o}F), ▪ If the temperature of the testing area falls outside of 15^{o}-27^{o}C (59^{o}-80^{o}F), and ▪ At periodic intervals as dictated by the user facility.
Frequency of running external controls on the basis of test volume	In addition to the specific circumstances listed in the manufacturer's instructions, testing sites should determine the optimal frequency for running controls on the basis of their test 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). Sites testing large numbers of persons, and especially those that offer anonymous testing, 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 some other waived tests recommend running external controls each time a new box of 25 tests is opened. Facilities that test 25 or more subjects a day should 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.

During Testing

Overview	This phase of the testing process involves running the test and interpreting the results. Activities during testing include collecting the specimen, performing the test, interpreting the internal control and client/patient test results, and following biohazard safety guidelines.
Collecting the OraQuick specimen	Follow the written procedure for finger-stick specimen collection. Further information on collecting blood by skin puncture can be found in *Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture.*[5]

During Testing (continued)

Performing the test and interpreting results	Follow the manufacturer's instructions for performing the test and interpreting the results. Results can be one of the following: ▪ *Nonreactive* (negative) ▪ *Reactive* (preliminary positive) ▪ *Invalid* (the test result is inconclusive and cannot be interpreted; see below for information on handling invalid results)
Evaluating internal control results	Each OraQuick device includes a built-in (internal) control. When an appropriate line develops at the center of the "C" location on the device, the patient'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. These controls are included in every device, and control results are evaluated with every test. If the internal control does not produce the expected result, the test result for the patient is not valid, cannot be reported, and the test must be repeated. If a second invalid result occurs, external controls should be evaluated as described below before repeating the test a third time.
Running external controls to troubleshoot invalid results	CDC experience (unpublished data) has shown that external controls should be run to help find out if repeated invalid test results are due to the test device, test performance, or the patient specimen. If the same test kit lot yields repeated invalid results, the test kit may have gone bad. It is important to run the positive and negative controls whenever two consecutive invalid test results are obtained on a person being tested.
Biohazard safety/Universal (Standard) Precautions	All specimens and materials contacting specimens must be handled as if they are capable of transmitting an infectious organism. As described in Appendix A, each site must ensure that the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standards are met, that is persons doing the testing must know how to safely handle potentially infectious specimens. Also, according to Universal (Standard) Precautions, all human blood should be treated as if known to be infectious for HIV, hepatitis B virus, and other bloodborne pathogens. Sites must have available and follow procedures for biohazard safety to include instructions for the use of 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. [1, 6, 7, 8]

After Testing

Overview	Quality assurance extends to those activities completed following the performance of the test. Each site should have established procedures for: ▪ Reporting and recording results, ▪ Referring specimens (or test subjects, if specimens are not collected on-site) for confirmatory testing, ▪ Managing confirmatory test results, and ▪ Conducting external quality assessment.
Reporting results	Reporting procedures should describe how results are provided to the person being tested (verbal and/or written results) and how results are documented in the person's chart and in the test result logs. Some States have laws and regulations that include certain reporting criteria for HIV testing results. Check with your State agency for more information on these requirements. See Appendix A for State agency contact information and Appendix E for an example of a test result log.
Referral for confirmatory testing	Whenever the OraQuick test result is reactive (preliminary positive), a confirmatory test must be performed to confirm that the person being tested is infected with HIV. Therefore, each site must have established procedures for referral of either test specimens or persons being tested for confirmatory testing when OraQuick results are reactive. If specimens are collected on-site, the site must establish 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 client/patients. It should be indicated on the specimen transfer sheet that the specimen is from an individual who had a reactive OraQuick rapid test result. See the Appendix F for an example of a specimen transfer sheet. Collecting confirmatory specimens on-site may improve follow-up, since some clients may not go elsewhere for the testing or to obtain results. However, if the site is not able to collect confirmatory test specimens, a procedure must be in place for referring persons to another site to obtain this testing.

After Testing (continued)

Confirmatory testing protocols	For confirmatory testing, the current standard testing algorithm should be followed, with the following exceptions: ▪ All OraQuick reactive (preliminary positive) results must be followed up with either a Western blot or immunofluorescent assay (IFA) for confirmation. ▪ 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). ▪ 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 must 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.
Follow up testing for negative confirmatory result	Most confirmatory test results will be positive; however, some may be negative or indeterminate. If the confirmatory test result is negative, specimen mix-up needs to be ruled out versus a false positive OraQuick result. If the Western blot or IFA test is negative, it is recommended that: ▪ For blood specimens, a confirmatory test should be repeated with a new specimen 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.
Follow up testing for indeterminate results	Occasionally, confirmatory test results are indeterminate. If the Western blot or IFA is indeterminate, it is recommended that: ▪ For blood specimens, the person should be advised to return for repeat testing in one month. See *CDC's Revised Guidelines for HIV Counseling, Testing and Referral* found at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm. ▪ For oral fluid specimens, the Western blot or IFA test should be repeated using a blood specimen.
Managing confirmatory results	OraQuick testing sites that refer specimens for confirmatory testing should have established procedures describing how to: ▪ Match the client's/patient's confirmatory test results with their OraQuick results to find potential discrepancies and to ensure that testing was performed according to the protocol described above, ▪ Report the test result to the person being tested, and ▪ Obtain any additional specimens needed to resolve potential specimen mix-up and for retesting, as needed.

After Testing (continued)

Handling result discrepancies	Procedures should describe how to handle result discrepancies when the OraQuick 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 OraQuick 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.
External assessment	External assessment, or an evaluation of the testing process by a source outside the testing site, can look at 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, but it is not required by Federal (CLIA) regulations since the test is waived and the test kit manufacturer does not specifically require it.
Methods for external assessment	Every reactive OraQuick test is externally assessed by a second, confirmatory test. However, if there is a low prevalence of HIV infection in the population being testied, these assessments may be rare and will not provide an external check for the majority of the results, i.e., those that are nonreactive. Other ways to assess performance may be needed. Some external assessment mechanisms include: ▪ Comparing the OraQuick 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 (for more information on these programs, see Appendix G).

Documents and Records

Overview	One of the hallmarks of a QA program is comprehensive documentation. Sites using the OraQuick test should have policies and procedures describing what QA records are required and how and when they are reviewed, stored and destroyed. Having a supervisor review records periodically is recommended. State regulations or other governmental or accrediting agencies may require facilities to have specific record retention policies. QA records include the following: ▪ Training documentation (Appendix B) ▪ Temperature logs (Appendix C) ▪ External control result logs (Appendix D) ▪ Test result logs (Appendix E) ▪ Specimen transfer logs (Appendix F)
Temperature 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) are recommended and their accuracy checked periodically (e.g., every six months) by comparison with another thermometer.
External control result logs	External control records should include the date and time of control testing, lot 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.
Test result logs	Test result records 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 requested, 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.

Troubleshooting

Overview	Each site should have 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. Significant problems should be immediately reported to the appropriate supervisory personnel.
Procedures	Procedures should be available to all testing personnel for the following: ▪ 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, such as contacting the manufacturer when the external control results are unacceptable and following the advice provided. ▪ How to document problems and actions taken, such as a logbook where problems and corrective actions taken can be recorded. ▪ How to verify the corrective actions taken addressed the problem.

References

1. OraQuick Rapid HIV-1 Antibody Test package insert. OraSure Technologies, Inc., Bethlehem, PA 18015, 2003.
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3. NCCLS document GP21-A.Training verification for laboratory personnel, Approved guideline. NCCLS, Wayne, PA, 1995.
4. CDC. CDC revised guidelines for HIV counseling, testing, and referral. MMWR Recommendations and Reports. 2001;RR-19:50.
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6. Occupational Safety and Health Administration regulations, 29CFR Part 1910. Available from http://www.osha.gov/SLTC/bloodbornepathogens/index.html
7. CDC. Perspectives in disease prevention and health promotion update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37(24):377-88.
8. Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. Infect Control Hosp Epidemiology 1996;17:53-80, and Am J Infect Control 1996;24:24-52.

Appendix: Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test

Overview

This appendix includes several items to facilitate conducting testing and performing quality assurance using the OraQuick Rapid HIV-1 Antibody test. The forms provided are examples and templates that can be adapted for local use, adding or deleting fields, as needed. The appendix includes the following:

A. Government regulations

B. Example training checklist for the OraQuick Rapid HIV-1 Antibody Test

C. Example of a temperature log

D. Example log of quality control results

E. Example log of test results

F. Example specimen transfer log

G. External assessment: proficiency testing and other mailed evaluation programs

Appendix A
Government Regulations

Food and Drug Administration (FDA) sales restrictions

To help ensure the quality of testing with the OraQuick test, the FDA approved the test kit it with specific restrictions for its sale. These restrictions apply to the waived test kit. By purchasing the test, the customer agrees to follow these restrictions. The restrictions are outlined below (for the specific FDA language, refer to the OraQuick package insert). The kit purchaser must:

- Be a clinical laboratory, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate – see below for details) and any state or other certification that is required.
- Have an established quality assurance program.
- Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
- 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.
- Not use the kit to screen blood or tissue donors.

Clinical Laboratory Improvement Amendment (CLIA) regulations

The OraQuick test is a waived test under Federal regulations—the regulations for the Clinical Laboratory Improvement Amendments of 1988 (CLIA regulations). As a waived test, Federal requirements for the OraQuick test are minimal. The CLIA requirements for sites wishing to offer testing using the OraQuick test are listed below and can be found at http://www.phppo.cdc.gov/clia/regs/toc.asp. Each site must:

- Have a valid CLIA certificate of waiver, certificate of compliance or certificate of accreditation.
- Follow the manufacturer's instructions for performing the test, and
- Permit announced or unannounced inspections by representatives of the Centers for Medicare & Medicaid Services (CMS) under certain circumstances (see §493.35(d) in the regulations at the Web site listed above).
- Perform only waived tests if holding a certificate of waiver.

Government Regulations (continued)

How to obtain a CLIA certificate	All sites planning to offer only the OraQuick test that are not already CLIA certified, must obtain a Certificate of Waiver or be included under a multiple site exception, such as limited public health testing or mobile testing. To obtain a Certificate of Waiver, complete Form CMS-116, found at the following CMS Internet address: http://www.cms.gov/clia/cliaapp.asp. This form asks for information on the facility type (select from a list), hours of operation, estimated annual number of waived tests to be performed, the type of control (nonprofit, for profit or government control) and the total number of individuals involved in performing testing. The facility owner or laboratory director must sign the form. Mail the completed form to the State agency in which your site is located. To find your State agency contact, refer to the information provided at the following Internet address http://www.cms.gov/clia/ssa-map.asp. After the completed form is processed by the State agency, a fee of $150 will be assessed for a Certificate of Waiver. The certificate is valid for two years.
State regulations	In addition to CLIA, some States have specific regulatory requirements for HIV testing. Contact your State agency for information on State requirements. State agency contacts are listed at http://www.cms.gov/clia/ssa-map.asp.
Occupational safety and health regulations	Employers with employees who have an occupational exposure to blood or other potentially infectious materials must meet the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for bloodborne pathogens. Individuals collecting blood specimens or performing the OraQuick test have exposure to blood or other potentially infectious materials resulting from the performance of their duties. Therefore, sites offering the OraQuick test must meet OSHA standards that include, but are not limited to, the following requirements: ▪ Have a written Exposure Control Plan. ▪ Provide personal protective equipment, such as gloves. ▪ Make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure. ▪ Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident. ▪ Provide training for all employees with occupational exposure. ▪ Contain and dispose of biohazard waste following applicable regulations (includes blood and items contaminated with blood or other potentially infectious materials). Refer to state and local regulations regarding disposal of biohazardous materials. **NOTE**: This is an overview of OSHA requirements and is not a complete list. For specific information, visit the OSHA Web site at http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

Appendix B
Example Training Checklist for the OraQuick Rapid HIV-1 Antibody Test

Employee: *Name*_____

Instructions: Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable.) The trainee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	**Date Observed**	**Date Performed**	**Trainee's initial and date**	**Trainer's initial and date**
Read OraQuick procedure	N/A			
Read Biohazard Exposure Control Plan	N/A			
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space)				
Practice test with negative and positive external controls				
Give person getting tested the "Subject Information" brochure				
Label test device components and appropriate paperwork				
Collect finger-stick specimen, put loop into vial and mix correctly				
Insert test device, time test, read result				
Dispose of lancet and other biohazardous waste appropriately				
Record results on report form and log sheet				
Record internal and external quality control (QC) results in QC log				
Evaluate a new OraQuick test kit lot number and record results in QC log				
Report test result to the person being tested (one negative and one preliminary positive)				
Refer person or collect specimen for confirmatory testing				
Send confirmatory test specimen to referral laboratory and document submission				
Receive referral laboratory results and record results				
Explain what to do if QC results show a problem				

Appendix C
Example Temperature Log

Thermometer location _____

Acceptable temperature range* _____

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 is 2^{o} to 27^{o} C or 35^{o} to 80^{o} F; the acceptable range for control kit storage is 2^{o} to 8^{o}C or 35^{o} to 46^{o} F; the acceptable range for the testing area is 15^{o} to 27^{o} C or 59^{o} to 80^{o} F.
NOTE: Periodically (e.g., every six months) check thermometer performance and document**.**

Corrective Action

Date	Action Taken	Initials

Reviewed by and date _____

Appendix D
Example Log of Control Results

Date	Time	Test Kit Lot #	Test Kit Exp. Date*	New Lot #, ship-ment ?	Control Kit Lot #	Control Kit Exp. Date	Date controls opened	Negative Control Result	Positive Control Result	Results Accept-able?	Performed by	Reviewed by and Date

*Exp. = Expiration

Corrective Action (use reverse side, if needed)

Date	Action Taken	Initials	Reviewed by and date

Appendix E
Example Log of Test Results

Test Subject ID*	Date and Time Specimen Collected	Kit Lot Number	Kit Expiration Date	Actual Test Incubation Time	Test result N=non-reactive R=reactive I=invalid	Tester	Result and Time Reported to Subject	Confirmatory Testing					Reviewed by and Date
								Track-ing #	Specimen type (blood or oral fluid)	Result	Date result received	Date result given to test subject	

*ID = Identification

Appendix F
Example Specimen Transfer Log

**[Put Referring Facility Name,
Address and Phone Number here]**

Date:_____

Referral Laboratory _____

Specimen Tracking Number	Test Subject ID*	OraQuick Test Result	Date Specimen Collected	Time Specimen Collected	Collected by	Referral Lab Req† Completed (✓)	Date Conf Result Received	Confirm Test Result

*ID = Identification
†Lab Req = Laboratory Requisition
(NOTE: If you use more than one referral laboratory, add a column to record each one.)

Appendix G
External Assessment: Proficiency Testing and Other Mailed Evaluation Programs

Background and overview	Some States may require participation in a State or Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing program, even though this program 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.
Evaluation reports	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	For more information, refer to the following Internet sites: ▪ The CDC MPEP for rapid HIV testing can accommodate a limited number of additional sites. For more information and to enroll on-line go to the following Web sites: http://www.phppo.cdc.gov/mpep/default.asp, http://www.phppo.cdc.gov/mpep/enrollment.asp. There is currently no fee to enroll in the MPEP program. ▪ For a list of CLIA approved proficiency testing programs (several of which include HIV testing) go to http://www.cms.gov/clia/ptlist.pdf. This list includes contact information for each program and the tests offered. These programs charge an enrollment fee.