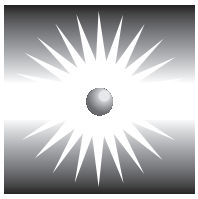
Linking people to care

8. Quality Assurance Guidelines

(Includes Appendices A-G)

OraQuick® Rapid Antibody Test HCV

Quality Assurance Guidelines for Testing Using the OraQuick® HCV Rapid Antibody Test



OraSure Technologies, Inc.

This document has been modified by OraSure Technologies from its original document "Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test" authored by the CDC and other individuals found on Internet site: http://wwwn.cdc.gov/cliac/pdf/Addenda/clia0903/C-GuidlinesOraQk.pdf.

The edits contained in these Quality Assurance Guidelines reflect suggested changes for purposes of establishing a Quality Assurance Program with the OraQuick® HCV Rapid Antibody Test. These changes have been provided as a guide in an effort to maintain the integrity and intent of the original document. These edits do not necessarily express the views of the original authors.

Item# HCV0068 (rev. 01/12)

Introduction and Background

Purpose

This document provides guidance on quality assurance (QA) practices for sites using or planning to use the OraQuick® HCV Rapid Antibody Test to detect antibodies to the hepatitis C virus (HCV).

Background

The OraQuick® HCV Rapid Antibody Test is the first rapid HCV 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 HCV that the FDA has waived under the Clinical Laboratory Improvement Amendment regulations (CLIA).
The OraQuick® test uses whole blood obtained from the puncture of a finger and whole blood obtained from a vein. Results are available within 20 to 40 minutes.[1]
Reactive results with the OraQuick® HCV rapid test are presumed to be positive for HCV infection and should undergo appropriate clinical follow-up according to CDC recommendations for supplemental testing. Although the OraQuick® HCV 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

Guidelines for HIV were originally 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. The original 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.

This guideline has been edited by OraSure Technologies and reviewed by the NY TA Center Rapid HCV Test Working Group in an effort to reflect the changes from the original QA program established for HIV testing for adaptation with the OraQuick® HCV Rapid Antibody Test. These revisions do not necessarily express the opinions of the original discussion panel.

How to use these guidelines

This document outlines the basic processes and procedures that should be in place before a site offers rapid HCV testing. It describes steps that can be taken to identify and prevent errors in the testing process. Because the OraQuick® HCV 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 HCV 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® HCV Rapid Antibody 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 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 12-13 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® HCV Rapid Antibody Test

Even though the OraQuick® HCV 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 section 8, page 7).
- 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® HCV test. 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 the 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 reference panel of non-reactive, low reactive and limit of detection specimens), and the logistics for providing supplemental testing (if a person's test is reactive, he or she should undergo appropriate clinical follow-up with supplemental testing) and biohazardous waste handling procedures 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® HCV Rapid Antibody Test 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.
- Discuss Hepatitis C Virus information to persons being tested before testing.*
- Use gloves and other personal protective equipment when performing a fingerstick or venipuncture whole blood test. (Refer to the CDC Guidelines for the Management of Occupational Exposures to HBV, HCV, HIV and Recommendations for Postexposure Prophylaxis).
- Maintain sufficient supplies and unexpired test and control kits (for new operators, the OraQuick® HCV Visual Reference Panel must be made available), follow the manufacturer's instructions for storage, and check performance of new test kit lots and shipments with external controls as explained on section 8, page 12.
- Maintain and document the temperature of the room and refrigerator where the tests, visual reference panel, 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® HCV specimen.*
- Perform steps in the test procedure.*
- Report results.
- Refer specimens or persons being tested for appropriate clinical follow-up for supplemental testing.
- Record test and quality control results.
- Conduct external quality assessment (see description on section 8, page 12).
- 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).

*Refer to the OraQuick® HCV Rapid Antibody Test package insert for complete instructions.

Testing Personnel

Overview

Having qualified, trained staff to perform and supervise OraQuick® HCV 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® HCV 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® HCV 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® HCV 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® HCV test 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.
- Identify correctly all the devices provided within the OraQuick® HCV Visual Reference Panel.
- Practice performing the test with a positive HCV and a negative control.
- Practice performing the fingerstick 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.

*Refer to the OraQuick® HCV Rapid Antibody Test package insert for complete instructions.

Testing Personnel (continued)

Assessing performance of tasks during testing

To assess staff's ability to perform the test and interpret results:

- Observe the staff member performing the fingerstick, 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 supplemental testing or from other commercial sources.
- Appraise the individual's ability to interpret results. This should include the OraQuick® HCV Visual Reference Panel and might also include using previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive and invalid results.

Assessing performance of tasks after testing

To assess task performance after testing:

- Review test records and quality control results documentation.
- Observe verbal reporting of results to a test subject (if trainee's responsibility).
- Observe venous blood and/or fingerstick whole blood specimen collection and handling for supplemental testing. If the frequency of OraQuick® reactive results is low, the trainee should be observed collecting fingerstick blood and/or venipuncture whole blood from a staff volunteer and demonstrate next steps for appropriate clinical follow-up.
- 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 • Discuss the Hepatitis C Virus • 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 fingerstick or venipuncture specimen • Perform the test • Interpret test results	• Clean up and dispose of biohazardous waste • Report results to client • Document results • Provide information for clinical follow-up (linkage to supplemental testing and evaluation) • Participate in external quality assessment (periodically)

Before Testing

Overview

As shown in the previous table, there are a number of steps that must be followed before testing the fingerstick or venipuncture whole blood sample for HCV. 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.

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° to 30° C (36° to 86° F). If test kits are refrigerated, the pouch containing the test device and developer solution must be brought to operating temperature (15° to 37° C or 59° to 99° F) before opening. Control kits must be refrigerated at 2° to 8° C (35° to 46° F). To ensure these temperature ranges are maintained, monitor and document temperatures of the storage area 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° to 37° C (59° to 99°F). If the test must be performed at a temperature below 15°C / 59°F or above 37°C / 99°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 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 the control vials are opened, they are stable for 8 weeks. Therefore, record on the vial the date it is opened and discard unused opened controls after 8 weeks. As described in the package insert and in the section on quality control below run the positive HCV, 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

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 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 persons being tested before collecting the specimen. These components include the developer solution vial, test device, and documents for recording results. Using preprinted labels improve 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 may cause an invalid result.*

Providing information to test subjects

Refer to your local Department of Health for information you may provide to each person getting tested prior to performing the OraQuick® HCV rapid test. Each site may provide additional information. For further details, see the CDC website http://www.cdc.gov/hepatitis/HCV/PatientEduHCV.htm#cdc, the *Sexually Transmitted Diseases Treatment Guidelines 2010*, MMWR 2010;59(RR-12)[4] and applicable State or local rules.

Quality control

There are two types of quality control (QC) for the OraQuick® HCV 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 added to the solution and flowed through the device as intended.
External controls	Known reactive and non-reactive specimens (controls) are available from the manufacturer to sites purchasing the OraQuick® HCV Rapid Antibody Test. They are used to evaluate the accuracy of the test in detecting antibody to HCV and to check if the person conducting the test performs it correctly.

Before Testing (continued)

External quality control

To verify that the test device is accurately detecting HCV 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® HCV Rapid Antibody Test Kit Controls. This control kit must be ordered separately from the test kit. It includes one vial each of an HCV antibody-negative (non-reactive), and an HCV antibody-positive (reactive for HCV antibodies) 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 temperature, and how often staff who conduct the testing change. An example of a log for control testing results is available in Appendix D.

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°-30°C (36°-86°F),
- If the temperature of the testing area falls outside of 15°-37°C (59°-99°F),
- At periodic intervals as dictated by the user facility.

Before Testing (continued)

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 supplemental testing 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 tests recommend running external controls each time a new box of 25 tests is opened. The CDC's original guidelines recommend 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 observing specimen collection (fingerstick or venipuncture whole blood), performing the test, interpreting the internal control and client/patient test results, and following biohazard safety guidelines when applicable.
Fingerstick whole blood collection	Follow the written procedure for fingerstick specimen collection.
Venipuncture whole blood collection	Refer to the Clinical and Laboratory Standards Institute (CLSI) procedure for venipuncture specimen collection.

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:

- *Non-reactive* (negative)
- *Reactive* (presumptive positive)
- *Invalid* (the test 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 with a new specimen, developer solution vial, and test device. If a second invalid result occurs, external controls should be evaluated and OraSure Technologies contacted at 1-800-672-7873.

Running external controls to troubleshoot invalid results

CDC experience with other test devices (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 been compromised. 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 much 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 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 and hepatitis C virus, and other bloodborne pathogens. Sites must have available and follow procedures for biohazard safety including 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® HCV Rapid Antibody Test 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 supplemental testing if arrangements at testing site apply.
- Managing supplemental 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 HCV testing results. Check with your State agency for more information on these requirements. See Appendix E for an example of a test result log.

Referral for supplemental testing

Whenever the OraQuick® test result is reactive (presumptive positive), a patient should undergo appropriate clinical follow-up according to the CDC recommendations for supplemental testing. Therefore, each site must have established procedures for referral of either test specimens or persons being tested for clinical follow-up or supplemental testing when OraQuick® HCV 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 supplemental test specimens to the site(s) where they will be tested; and obtain the supplemental 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® HCV rapid test result. See Appendix F for an example of a specimen transfer sheet. Collecting supplemental specimens on-site may improve follow-up, since some clients may not go elsewhere for testing or to obtain results. However, if the site is not able to collect supplemental test specimens, a procedure must be in place for referring persons to another site for clinical follow-up to obtain this testing.

After Testing (continued)

Supplemental testing protocols

For supplemental testing, the current standard testing algorithm should be followed (see description on section 8, page 32-33):

- All OraQuick® reactive (presumptive positive) results should follow the CDC's guidelines for clinical follow-up evaluation and supplemental testing.
- Supplemental testing is performed on plasma or serum specimens.

Follow up testing for negative supplemental result

Most supplemental test results will be positive; however, some may be negative or indeterminate. CDC's guidance suggests that if the supplemental test result is negative, specimen mix-up needs to be ruled out versus a false positive OraQuick® HCV result.

Follow up testing for indeterminate supplemental results

Occasionally, supplemental test results are indeterminate by RIBA. A subsequent quantitative NAT should be performed to determine the presence of viremia. If the NAT result is negative, another specimen should be collected for repeat anti-HCV testing (>1 month) or for HCV RNA testing.*

*Refer to CDC Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus, MMWR 52(RR03);1-16, Feb. 7, 2003 for more information.

After Testing (continued)

Managing supplemental results

OraQuick® HCV testing sites that refer specimens for supplemental testing should have established procedures describing how to:

- Match the client's/patient's supplemental test results with their OraQuick® HCV 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.

Handling result discrepancies

Procedures should describe how to handle result discrepancies when the OraQuick® HCV result was reactive and the supplemental test indeterminate. If the laboratory providing supplemental testing performed a RIBA® test only and reported an indeterminate result, the OraQuick® testing site should contact the supplemental testing laboratory and request a quantitative PCR. If the original specimen is not available, a new specimen will need to be collected from the person in question to be used for supplemental 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® HCV test is externally assessed by a second, supplemental test. However, if there is a lower prevalence of HCV infection in the population being tested, these assessments may be rare and will not provide an external check for the majority of the results, i.e., those that are non-reactive. Other ways to assess performance may be needed. Some external assessment mechanisms include:

- Comparing the OraQuick® HCV reactive result with the supplemental test results.
- Arranging for someone outside the organization to observe testing.
- Participating in 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® HCV 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 supplemental testing was requested or where the patient was referred for supplemental testing, including the type of specimen sent for supplemental (e.g., serum or plasma), and the supplemental 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 the 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® HCV Rapid Antibody Test package insert. OraSure Technologies, Inc., Bethlehem, PA 18015, 2011.

2. NCCLS document HSI-A. A quality system model for health care, Approved guideline. NCCLS, Wayne, PA, 2002.

3. NCCLS document GP21A. Training verification for laboratory personnel, Approved guideline. NCCLS, Wayne, PA, 1995.

4. CDC. Sexually Transmitted Diseases Treatment Guidelines 2010, MMWR 2010;59(RR-12).

5. NCCLS document H4-A4. Procedures and devices for the collection of diagnostic blood specimens by skin puncture. Approved guideline. NCCLS, Wayne, PA, 1999.

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. CDC. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. HICPAP 2007; 12-93.

9. 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® HCV Rapid Antibody Test

Overview

This appendix includes several items to facilitate conducting testing and performing quality assurance using OraQuick® HCV Rapid 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® HCV Rapid 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

H. CDC HCV testing algorithm recommendation

Appendix A
Government Regulations

Food and Drug Administration (FDA) sales restrictions

To help ensure the quality of testing with the OraQuick® HCV test, the FDA approved the test kit with specific restrictions for its sale. These restrictions apply to 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® HCV Rapid Antibody Test 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 with information on the hepatitis C virus 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® HCV 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® HCV test are extensive. The CLIA requirements for sites wishing to offer testing using the OraQuick® HCV test are listed below and can be found at http://www.cdc.gov/clia/regs/toc.aspx. 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® HCV 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 https://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf. This form asks for information on the facility type (select from a list), hours of operation, estimated annual number of 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 https://www.cms.gov/CLIA/Downloads/CLIA.SA.pdf. 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 may have specific regulatory requirements for HCV testing. Contact your State agency for information on State requirements. State agency contacts are list at https://www.cms.gov/CLIA/Downloads/CLIA.SA.pdf.

Government Regulations (continued)

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 Administrations (OSHA) standards for bloodborne pathogens. Individuals collecting blood specimens or performing the OraQuick® HCV test have exposure to blood or other potentially infectious materials resulting from the performance of their duties. Therefore, sites offering the OraQuick® HCV 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® HCV Rapid Antibody Test

Employee: _____

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. See below as an example of a site conducting only fingerstick whole blood testing). The trainee should initial when they feel the objective/procedure has been mastered and the trainer when they think 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® HCV test procedure				
Read Biohazard Exposure Control Plan				
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level workspace)				
Correctly identified test devices in the OraQuick® HCV Visual Reference Panel				
Practice test with negative and positive HCV external controls				
Present the client with information on the hepatitis C virus				
Label test device components and appropriate paperwork				
Collect fingerstick specimen, put loop into vial and mix correctly				
Insert test device into vial				
Time test, read result				
Dispose of lancet and/or other biohazardous waste materials appropriately				
Record results on report form and log sheet				
Record internal and external quality control (QC) results in QC log				
Evaluate a new OraQuick® HCV test kit lot number and record results in QC log				
Report test result interpretation to the person being tested (one negative and one presumptive positive)				
Refer person or collect specimen for supplemental testing				
Send supplemental test specimen to laboratory and document submission				
Receive supplemental 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° to 30°C or 36° to 86°F; the acceptable range for the visual reference panel is 15° to 30°C or 59° to 86°F; and the acceptable range for control kit storage is 2° to 8°C or 35° to 46°F; the acceptable range for the testing area is 15° to 37°C or 59° to 99°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 #, Shipment?	Control Kit Lot #	Control Kit. Exp. Date	Date Controls Opened	Negative Control Result	HCV Positive Control Result	Results Acceptable	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 #	Test Kit Exp. Date.	Actual Test Incubation Time	Result N=non-reactive R=reactive I=invalid	Tester Initials	Result and Time Reported to Subject	Supplemental Testing					Reviewed by and Date
								Tracking #	Specimen Type (Serum or Plasma)	Result	Date Result Received	Date Result Given to Test Subject	

*ID = Identification

Appendix F
Example Specimen Transfer Log for Supplemental Testing

**[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 Suppl. Test Result Received	Suppl. Test Result

*ID = Identification

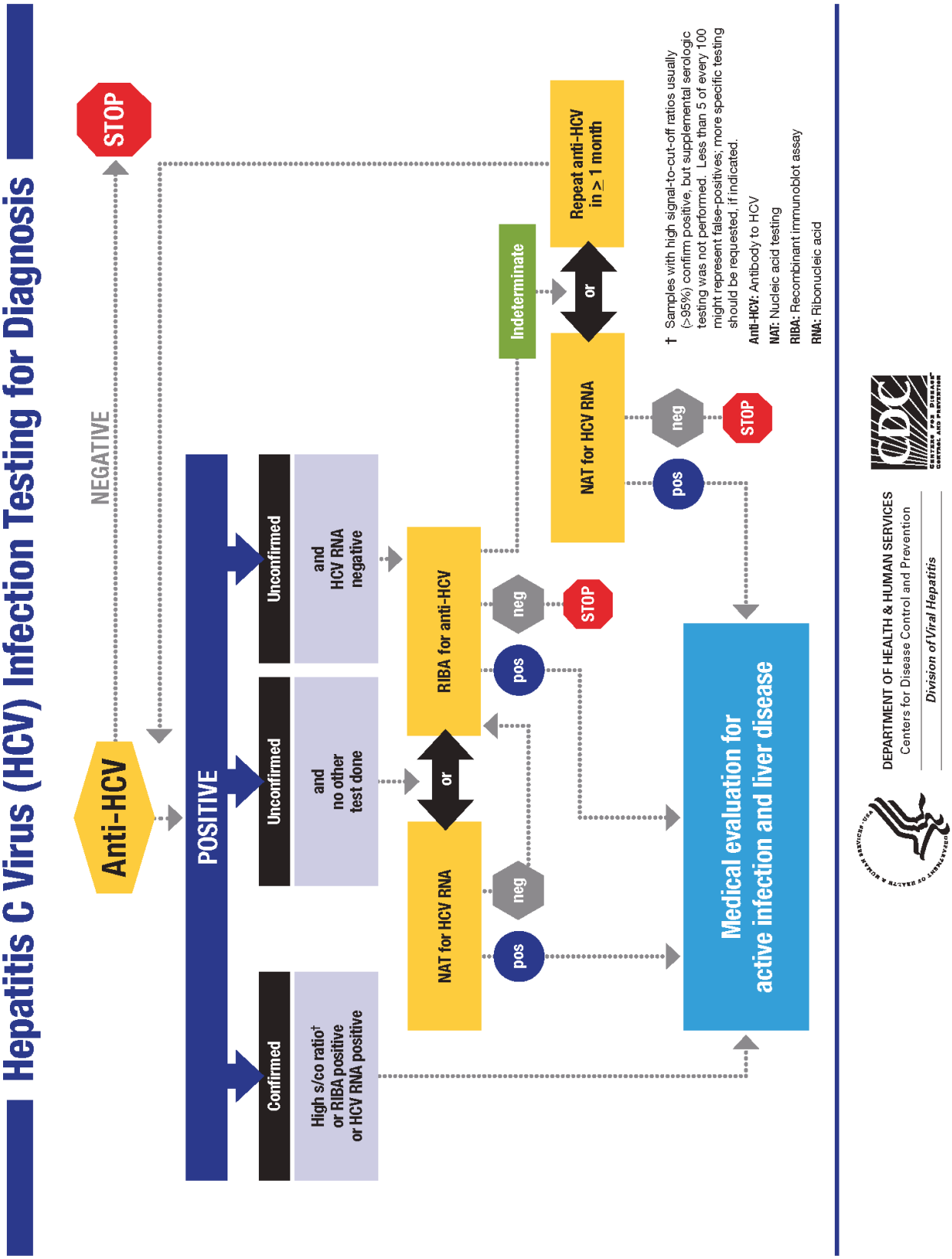
†Lab Req = Laboratory Requisition

(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 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) HCV 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, 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.

Appendix H
CDC HCV Supplemental Testing Guide



OraSure Technologies

220 East First Street
Bethlehem, PA 18015
1-800-ORASURE (672-7873)
www.OraSure.com

Item#HCV0068 (rev. 04/12)