

OraQuick® HCV Rapid Antibody Test

# Implementation Guide



**OraQuick**® Rapid  
Antibody  
Test  
**HCV**



OraSure Technologies

## Table of Contents

	Section
Executive Summary .....	1
CDC Guideline Recommendations .....	2
Obtaining a CLIA Waived Certification .....	3
HCV Testing Counseling Protocol .....	4
Hepatitis C Assessment Form .....	5
OraQuick® HCV Rapid Antibody Test Procedure .....	6
State-Specific Testing Guidelines .....	7
Quality Assurance Guidelines <i>(Includes Appendices A-H)</i> .....	8
Support Documents and Forms .....	9
Product Documentation .....	10
<i>(Package Insert, Visual Reference Package Insert, Kit Control Package Insert)</i>	





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## 1. Executive Summary



# Implementation Guide for Establishing a Rapid HCV Testing Program Using the OraQuick® HCV Rapid Antibody Test

## Executive Summary

### Purpose

This document and compendium of materials have been compiled to provide guidance and support for sites seeking to establish programs using the OraQuick® HCV Rapid Antibody Test to detect antibodies to the hepatitis C virus (anti-HCV) with fingerstick and/or venipuncture whole blood specimens.

*In November 2011, the OraQuick® HCV test became the first rapid HCV test to be waived under the Clinical Laboratory Improvement Amendment (CLIA) regulations for use with fingerstick and venipuncture whole blood specimens. This guide focuses on the use of the test for the CLIA-waived fingerstick whole blood samples.*

### Background

In June 2010, OraQuick® HCV Rapid Antibody Test became the first rapid HCV point-of-care test to be approved by the FDA. In February 2011, OraQuick® became the first rapid HCV test to be FDA-approved for fingerstick whole blood specimens. As of April 2012, OraQuick® HCV Rapid Antibody Test is the *only* HCV point-of-care test that is FDA-approved and CLIA-waived.

Since the launch of OraQuick® in June 2010, OraSure has been a leader in distributing thousands of tests in the United States, helping people learn their HCV antibody status in as little as 20 minutes, helping to link HCV+ patients to care.

To help ensure the quality of testing with the OraQuick® HCV Rapid Antibody Test, the FDA approved the test kit with specific restrictions for its sale. These restrictions apply to the waived test kit use on either venipuncture and/or fingerstick whole blood specimens only and by purchasing the test, the customer agrees to follow these restrictions.

The kit purchaser must:

- Be qualified to conduct this testing, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate) 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.
- Not use the kit to screen blood or tissue donors.

The materials in this implementation guide are provided to assist testing sites in meeting the requirements necessary to administer the test and maintain a quality program.

### **Summary**

The three basic steps that sites needed to take to prepare for successful implementation of rapid HCV testing are:

Step 1: Enroll in CLIA

Step 2: Follow counseling guidelines

Step 3: Ensure high-quality testing and counseling

#### *Step 1 – Enroll in CLIA*

The first step in implementing a rapid HCV testing program is to enroll in CLIA. The US Congress established quality standards for all medical testing procedures when it passed the Clinical Laboratory Improvement Amendments, CLIA, in 1988. This action applies to any test that uses specimens derived from humans for the purpose of diagnosing, preventing, or treating disease. This includes all HCV tests.

OraQuick® HCV Rapid Antibody Test is a CLIA-waived test. CLIA-waived tests are the least complicated of all medical tests that are available only to licensed professionals or testing sites. To be “CLIA-waived,” a test must be simple to perform and interpret, accurate, and present no reasonable risk of harm to either the person being tested or the person performing the test. Like other medical tests, CLIA-waived tests require quality assurance measures for performing the test and counseling patients. CLIA-waived tests are not available directly to consumers.

Clinics and other facilities interested in using the OraQuick® HCV Rapid Antibody Test need to enroll in the CLIA program, pay a user fee, and be prepared to follow the specific test instructions described in detail in the Package Insert for the OraQuick® HCV Rapid Antibody test.

In addition to CLIA, some States have specific regulatory requirements for HCV testing. It is important to contact your State agency for information on State requirements.

Information on “How to Apply for a CLIA Certificate of Waiver” with data on State agencies is included in this guide. 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>. To find your State agency contact, refer to the information provided in section 3 of this guide or at the following Internet address <https://www.cms.gov/CLIA/downloads/CLIA.SA.pdf>.

### *Step 2 – Follow Counseling Guidelines*

While obtaining CLIA certification allows you to test, the delivery of high-quality counseling will support your testing efforts and help link people to follow-up testing and evaluation. Any medical testing counseling must be done in a professional manner that respects the dignity of the person taking the test, as well as his or her medical and legal rights. Counselors must be fully trained to provide the best service for your clients.

HCV counseling provides information about hepatitis C, the HCV test, as well as counseling clients about HCV prevention. The exact information to be provided must be individualized for each person both before and after he or she takes the HCV test. Counseling after the test will depend on whether the test result is reactive or non-reactive.

HCV counselors should be trained to provide specific information to people who will be tested with the rapid HCV antibody test. Counselors should:

- Describe the rapid test
- Tell each person that his or her test results will be available during the same visit the test is taken
- Discuss the ways HCV is transmitted and how to prevent it
- Explain the meaning of a negative rapid HCV test result using words and descriptions that the person receiving the counseling can understand
- Explain the meaning of a reactive rapid HCV test result using words and descriptions that the person receiving the counseling can understand
- Explain that a reactive HCV test result is a presumptive positive and requires supplemental testing
- Tell each person where to obtain more information
- Begin the linkage to care by offering each person a list of facilities or programs that provide other HCV services, including supplemental testing and linkages to care.

Regardless of whether a person's test is reactive or non-reactive, he or she should be given HCV prevention counseling. The goal is to keep each HCV-infected person from spreading the infection to other people and to help keep each person who does not have HCV from becoming infected. Prevention counseling should include the following:

- Focus on HCV risk reduction
- Include an in-depth, personalized risk assessment
- Acknowledge and provide support for positive steps already taken
- Clarify critical rather than general misconceptions about HCV risk
- Negotiate a concrete, achievable behavior-change step that will reduce HCV risk
- Seek flexibility in the counseling technique and process, avoiding a "one-size-fits-all" approach.

Excerpts of core education and counseling messages presented by the Hepatitis C Program, Division of Disease Control, New York City Department of Health and Mental Hygiene has been including in this manual as an example.\*

### *Step 3 – Ensure High Quality Testing and Counseling*

The third and final step in implementing a rapid HCV testing program is to ensure that your program meets specific criteria for high-quality testing and counseling. This begins by making certain that all personnel (operators) fully understand the test procedure; they have received the appropriate training; and are deemed proficient to administer the test. You can do this in several ways.

1. Set up comprehensive training for all operators on HCV testing, counseling and linkage to care. This training should incorporate site-specific policies around quality assurance criteria, testing procedure and care recommendations.
2. Conduct quality-control tests with each operator of the rapid HCV antibody test. Quality control testing should be incorporated into initial training and then conducted minimally according to the manufacturer's recommendations but also meeting state and CLIA regulations. Kits for this quality-control test are available from OraSure Technologies. For new operators, establish proficiency test interpretation with the OraQuick® HCV Visual Reference Panel.
3. Develop an ongoing quality assurance program. This will allow you to drive continuous quality improvement through monitoring and critiquing your testers and counselors in their approach with the test and test subjects. Role-playing exercises are an excellent way to evaluate and refine counseling skills.
4. For your reference, included in this implementation guide are "Quality Assurance Guidelines for Testing Using the OraQuick® HCV Rapid Antibody Test" – an excellent resource for establishing a quality program. This document is a revised version of the "Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test" originally issued by the CDC in August, 2003.

\* Hepatitis C-A Practical Guide for Incorporating Hepatitis C Services into Existing Program, New York City Department of Health and Mental Hygiene, Hepatitis C Program, Division of Disease Control, 2003.  
[http://www.pdfdownload.org/pdf2html/view\\_online.php?url=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fdoh%2Fdownloads%2Fpdf%2Fcd%2Fcdhepc\\_hcvtechmanual.pdf](http://www.pdfdownload.org/pdf2html/view_online.php?url=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fdoh%2Fdownloads%2Fpdf%2Fcd%2Fcdhepc_hcvtechmanual.pdf)



5. The OraQuick® HCV Rapid Antibody Test Procedure provides the specifics on administering the test and should be used to support your training efforts.

### **Additional Materials**

For your reference, additional materials are included in this implementation guide to support establishing a program using the OraQuick® HCV Rapid Antibody Test. These materials include additional sample forms (new and from existing programs) for use in establishing your quality assurance program and additional reference materials.

### **Additional Resources**

- CDC Hepatitis C Information for Health Professionals (<http://www.cdc.gov/hepatitis/hcv/Management.htm>)
- American Association for the Study of Liver Disease (AASLD) Practical Guidelines for Hepatitis C Virus (HCV) (<http://www.aasld.org/practiceguidelines/Pages/NewUpdatedGuidelines.aspx>)
- Chronic Liver Disease Foundation (<http://www.chronicliverdisease.org>)
- American Liver Foundation (<http://www.liverfoundation.org>)
- AIDS Education and Training Centers (<http://www.aidseduc.org>)
- Health Resources and Services Administration (HRSA), *A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV* (<http://hab.hrsa.org/deliverhivaidscafe/files/hepccoinspectguide2011.pdf>)
- [Customercare@orasure.com](mailto:Customercare@orasure.com) – for current OraQuick® HCV customer training and support tools.



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## 2. CDC Guideline Recommendations



 **OraQuick**® Rapid  
Antibody  
Test  
**HCV**

## **CDC Guidelines – Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease- MMWR 47(RR19);1-39**

On October 16, 1998, the CDC released recommendations on HCV testing in the U.S. as an expansion of their previous recommendations to provide broader guidelines for a) preventing transmission of HCV; b) identifying, counseling, and testing persons at risk for HCV infection; and c) providing appropriate medical evaluation and management of HCV-infected persons. The report is intended to serve as a resource for health-care professionals, public health officials, and organizations involved in the development, delivery, and evaluation of prevention and clinical services.\*

For your reference, we've included excerpts of these guidelines and excerpts of the AASLD guidelines to review.

### **Introduction§**

The hepatitis C virus (HCV) is a major public health problem and a leading cause of chronic liver disease. An estimated 180 million people are infected worldwide. In the United States (U.S.), the prevalence of HCV infection between the years 1999 and 2002 was 1.6%, equating to about 4.1 million persons positive for antibody to hepatitis C (anti-HCV), 80% of whom are estimated to be viremic. Hepatitis C is the principal cause of death from liver disease and the leading indication for liver transplantation in the U.S. Some calculations suggest that mortality related to HCV infection (death from liver failure or hepatocellular carcinoma) will continue to increase over the next two decades.

HCV is transmitted primarily through large or repeated direct percutaneous exposures to blood. In the United States, the relative importance of the two most common exposures associated with transmission of HCV, blood transfusion and injecting-drug use, has changed over time. Blood transfusion, which accounted for a substantial proportion of HCV infections acquired greater than 10 years ago, rarely accounts for recently acquired infections. Since 1994, risk for transfusion-transmitted HCV infection has been so low that CDC's sentinel counties viral hepatitis surveillance system has been unable to detect any transfusion-associated cases of acute hepatitis C, although the risk is not zero. In contrast, injecting-drug use consistently has accounted for a substantial proportion of HCV infections and currently accounts for 60% of HCV transmission in the United States. A high proportion of infections continues to be associated with injecting-drug use, but for reasons that are unclear, the dramatic decline in incidence of acute hepatitis C since 1989 correlates with a decrease in cases among injecting-drug users.\*

\*CDC. Guidelines-Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, MMWR 37 (RR19); 1-39, 1998.

§ Ghany, M. *et al.* AASLD Practice Guidelines, Diagnosis, Management, and Treatment of Hepatitis C-An Update *Hepatology*, April, 2009; pp. 1335-1374.

### **Prevalence of HCV Infection in Selected Populations in the United States\***

The greatest variation in prevalence of HCV infection occurs among persons with different risk factors for infection. Highest prevalence of infection is found among those with large or repeated direct percutaneous exposures to blood (e.g., injecting-drug users, persons with hemophilia who were treated with clotting factor concentrates produced before 1987, and recipients of transfusions from HCV-positive donors).

Moderate prevalence is found among those with frequent but smaller direct percutaneous exposures (e.g., long-term hemodialysis patients). Lower prevalence is found among those with inapparent percutaneous or mucosal exposures (e.g., persons with evidence of high-risk sexual practices) or among those with small, sporadic percutaneous exposures (e.g., health-care workers).

In perinatal populations, the average rate of HCV infection among infants born to HCV-positive, HIV-negative women is 5%-6% (range: 0%-25%), based on detection of anti-HCV and HCV RNA, respectively. The average infection rate for infants born to women coinfecting with HCV and HIV is higher -- 14% (range: 5%-36%) and 17%.

### **Screening and Diagnostic Tests\***

Tests that are currently approved by the U.S. Food and Drug Administration (FDA) for diagnosis of HCV infection include those that measure anti-HCV (See FDA site at: <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/default.htm>). These tests detect anti-HCV in greater than or equal to 97% of infected patients, but do not distinguish between acute, chronic, or resolved infection. The positive predictive value of enzyme immunoassay (EIA) have been established with the signal-to-cutoff ratios of 95% positive predictive value.<sup>§</sup> Supplemental testing with a more specific assay (i.e., recombinant immunoblot assay (RIBA™) or a nucleic acid test (NAT) of a specimen with a positive EIA. This more specific, supplemental testing is necessary, particularly in populations with a lower prevalence of disease, to identify and exclude false positive screening test results. However, currently, the majority of laboratories report positive anti-HCV results based on a positive screening assay alone.

Supplemental test results might be reported as positive, negative, or indeterminate. An anti-HCV-positive person is defined as one whose serologic results are EIA-test-positive and supplemental-test-positive. Persons with a negative EIA test result or a positive EIA and a negative supplemental test result are considered uninfected, unless other evidence exists to indicate HCV infection (e.g., abnormal ALT levels in immunocompromised persons or persons with no other etiology for their liver disease). Indeterminate

\*CDC. Guidelines-Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, MMWR 37 (RR19); 1-39, 1998.

§CDC. Signal-to-Cut-Off Ratios for Commercially Available Assays, <http://cdc.gov/hepatitis/HCV/labtesting.htm>, accessed, 1/11/12.

supplemental test results have been observed in recently infected persons who are in the process of seroconversion, as well as in persons chronically infected with HCV. Indeterminate anti-HCV results also might indicate a false-positive result, particularly in those persons at low risk for HCV infection.

At least six different genotypes and greater than 90 subtypes of HCV exist. Approximately 70% of HCV-infected persons in the United States are infected with genotype 1, with frequency of subtype 1a predominating over subtype 1b. Different nucleic acid detection methods are available commercially to group isolates of HCV, based on genotypes and subtypes. Evidence is limited regarding differences in clinical features, disease outcome, or progression to cirrhosis or hepatocellular carcinoma (HCC) among persons with different genotypes. However, differences do exist in responses to antiviral therapy according to HCV genotype. Rates of response in patients infected with genotype 1 are substantially lower than in patients with other genotypes, and treatment regimens might differ on the basis of genotype. Thus, genotyping might be warranted among persons with chronic hepatitis C who are being considered for antiviral therapy.\*

### **Clinical Features and Natural History\***

#### **Acute HCV Infection**

Persons with acute HCV infection typically are either asymptomatic or have a mild clinical illness; 60%-70% have no discernible symptoms; 20%-30% might have jaundice; and 10%-20% might have nonspecific symptoms (e.g., anorexia, malaise, or abdominal pain). Clinical illness in patients with acute hepatitis C who seek medical care is similar to that of other types of viral hepatitis, and serologic testing is necessary to determine the etiology of hepatitis in an individual patient. In less than or equal to 20% of these patients, onset of symptoms might precede anti-HCV seroconversion. Average time period from exposure to symptom onset is 6-7 weeks, whereas average time period from exposure to seroconversion is 8-9 weeks. Anti-HCV can be detected in 80% of patients within 15 weeks after exposure, in greater than or equal to 90% within 5 months after exposure, and in greater than or equal to 97% by 6 months after exposure. Rarely, seroconversion might be delayed until 9 months after exposure or not produced with some immunosuppressed or immunoincompetent individuals.<sup>§</sup>

The course of acute hepatitis C is variable, although elevations in serum ALT levels, often in a fluctuating pattern, are its most characteristic feature. Normalization of ALT levels might occur and suggests full recovery, but this is frequently followed by ALT elevations that indicate progression to chronic disease. Fulminant hepatic failure following acute hepatitis C is rare.

\*CDC. Guidelines-Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, MMWR 37 (RR19); 1-39, 1998.

§The Foundation for Better Health Care (FBHC). Hepatitis C, <http://fbhc.org/patients/modules/hepatitisc.cfm>, accessed 3/27/12.

### **Chronic HCV Infection**

After acute infection, 15%-25% of persons appear to resolve their infection without sequelae as defined by sustained absence of HCV RNA in serum and normalization of ALT levels. Chronic HCV infection develops in most persons (75%-85%), with persistent or fluctuating ALT elevations indicating active liver disease developing in 60%-70% of chronically infected persons. In the remaining 30%-40% of chronically infected persons, ALT levels are normal. No clinical or epidemiologic features among patients with acute infection have been found to be predictive of either persistent infection or chronic liver disease. Moreover, various ALT patterns have been observed in these patients during follow-up, and patients might have prolonged periods (greater than or equal to 12 months) of normal ALT activity even though they have histologic-confirmed chronic hepatitis. Thus, a single ALT determination cannot be used to exclude ongoing hepatic injury, and long-term follow-up of patients with HCV infection is required to determine their clinical outcome or prognosis.

The course of chronic liver disease is usually insidious, progressing at a slow rate without symptoms or physical signs in the majority of patients during the first two or more decades after infection. Frequently, chronic hepatitis C is not recognized until asymptomatic persons are identified as HCV-positive during blood-donor screening, or elevated ALT levels are detected during routine physical examinations. Most studies have reported that cirrhosis develops in 10%-20% of persons with chronic hepatitis C over a period of 20-30 years, and HCC in 1%-5%, with striking geographic variations in rates of this disease. However, when cirrhosis is established, the rate of development of HCC might be as high as 1%-4%/year.

### **Prevention and Control Recommendations**

Reducing the burden of HCV infection and HCV-related disease in the United States requires implementation of primary prevention activities that reduce risks for contracting HCV infection and secondary prevention activities that reduce risks for liver and other chronic diseases in HCV-infected persons. In addition, surveillance and evaluation activities are required to determine the effectiveness of prevention programs in reducing incidence of disease, identifying persons infected with HCV, providing appropriate medical follow-up, and promoting healthy lifestyles and behaviors.

Primary prevention activities can reduce or eliminate potential risk for HCV transmission from a) blood, blood components, and plasma derivatives; b) such high-risk activities as injecting-drug use and sex with multiple partners; and c) percutaneous exposures to blood in health care and other (i.e., tattooing and body piercing) settings. Immunization against HCV is not available; therefore, identifying persons at risk but not infected with HCV provides opportunity for counseling on how to reduce their risk for becoming infected.

Elements of a comprehensive strategy to prevent and control hepatitis C virus (HCV) infection and HCV-related disease

- Primary prevention activities include
  - screening and testing of blood, plasma, organ, tissue, and semen donors
  - virus inactivation of plasma-derived products;
  - risk-reduction counseling and services; and
  - implementation and maintenance of infection-control practices.
- Secondary prevention activities include
  - identification, counseling, and testing of persons at risk, and
  - medical management of infected persons.
- Professional and public education.
- Surveillance and research to monitor disease trends and the effectiveness of prevention activities and to develop improved prevention methods.

*Secondary prevention activities can reduce risks for chronic disease by identifying HCV-infected persons through diagnostic testing and by providing appropriate medical management and antiviral therapy. Because of the number of persons with chronic HCV infection, identification of these persons must be a major focus of current prevention programs. Identification of persons at risk for HCV infection provides opportunity for testing to determine their infection status, medical evaluation to determine their disease status if infected, and antiviral therapy, if appropriate. Identification also provides infected persons opportunity to obtain information concerning how they can prevent further harm to their liver and prevent transmitting HCV to others.*

Factors for consideration when making decisions regarding development and implementation of preventive services for a particular disease include the public health importance of the disease, the availability of appropriate diagnostic tests, and the effectiveness of available preventive and therapeutic interventions. However, identification of persons at risk for HCV infection must take into account not only the benefits but also the limitations and drawbacks associated with such efforts. Hepatitis C is a disease of major public health importance, and suitable and accurate diagnostic tests as well as behavioral and therapeutic interventions are available. Counseling and testing can prevent disease transmission and progression through reducing high-risk practices (e.g., injecting-drug use and alcohol intake). However, the degree to which persons will change their high-risk practices based on knowing their test results is not known, and possible adverse consequences of testing exist, including disclosure of test results to others that might result in disrupted personal relationships and possible discriminatory action (e.g., loss of employment, insurance, and educational opportunities). Antiviral treatment is also available, and treatment guidelines have been developed. Such treatment is beneficial for many patients, although sustained response rates and mode of delivery in clinical settings are currently less than ideal.

Persons at risk for HCV infection who receive health-care services in the public and private sectors should have access to counseling and testing. Facilities that provide counseling and testing should include services or referrals for medical evaluation and management of persons identified as infected with HCV. Priorities for implementing new counseling and testing programs should be based on providing access to persons who are most likely to be infected or who practice high-risk behaviors.

### **Primary Prevention Recommendations**

Testing should be offered routinely to persons most likely to be infected with HCV who might require medical management, and testing should be accompanied by appropriate counseling and medical follow-up. In addition, anyone who wishes to know or is concerned regarding their HCV-infection status should be provided the opportunity for counseling, testing, and appropriate follow-up. The determination of which persons at risk to recommend for routine testing is based on various considerations, including a known epidemiologic relationship between a risk factor and acquiring HCV infection, prevalence of risk behavior or characteristic in the population, prevalence of infection among those with a risk behavior or characteristic, and the need for persons with a recognized exposure to be evaluated for infection.

Persons who should be tested routinely for hepatitis C virus (HCV) infection based on their risk for infection

- Persons who ever injected illegal drugs, including those who injected once or a few times many years ago and do not consider themselves as drug users.
- Persons with selected medical conditions, including
  - persons who received clotting factor concentrates produced before 1987;
  - persons who were ever on chronic (long-term) hemodialysis; and
  - persons with persistently abnormal alanine aminotransferase levels.
- Prior recipients of transfusions or organ transplants, including
  - persons who were notified that they received blood from a donor who later tested positive for HCV infection;
  - persons who received a transfusion of blood or blood components before July 1992; and
  - persons who received an organ transplant before July 1992.
- Persons with HIV infection.

Persons who should be tested routinely for HCV-infection based on a recognized exposure

- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood.
- Children born to HCV-positive women.





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### 3. Obtaining a CLIA-Waived Certification



**OraQuick**® Rapid  
Antibody  
Test  
**HCV**

*How to apply for a*



# CLIA Certificate of Waiver

## Clinical Laboratory Improvement Amendments (CLIA) Background

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. The Centers for Medicare and Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of proficiency testing (PT) providers, accrediting organizations and exempt states. The FDA is responsible for test categorization.

# Completing the application form

## Section 1 - General Information

- > The CLIA application form (CMS-116) can be obtained at the CMS website:  
[www.cms.gov/cmsforms/downloads/cms116.pdf](http://www.cms.gov/cmsforms/downloads/cms116.pdf).

You must have Adobe Acrobat Reader installed on your computer in order to view and print this document. A link on the CMS site has been provided for obtaining the free viewing software if it is not already installed on your computer system.

### Name of Director

- > This person should be identified as the principle party responsible for overseeing testing programs, ensuring that facility personnel administering testing are fully trained, and documentation is maintained to the meet CLIA standards. States deemed as "State Licensure" or "Exempt" may require additional accreditation within their individual states to qualify (e.g. medical director with licensed medical degree, etc.). Refer to state listing for the states that may apply.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
Form Approved  
OMB No. 0938-0581

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)  
APPLICATION FOR CERTIFICATION**

**I. GENERAL INFORMATION**

Initial Application       Survey  
 Change in Certification Type  
 Other Changes (Specify)

CLIA IDENTIFICATION NUMBER  
**Leave Blank for New Applications**  
D

(If an initial application leave blank, a number will be assigned)

FACILITY NAME  
**The Family Health Center of PA**

FEDERAL TAX IDENTIFICATION NUMBER  
**12-3456789**

EMAIL ADDRESS

TELEPHONE NO. (Include area code)      FAX NO. (Include area code)  
**(610)345-6789**      **(610)345-6788**

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite  
if applicable.) Fee Coupon/Certificate will be mailed to this Address unless  
mailing address is specified

MAILING/BILLING ADDRESS (If different from street address)  
**The Family Health Center of PA  
Attn: Accounts Payable**

NUMBER, STREET (No P.O. Boxes)  
**123 East First Street - Suite 100**

NUMBER, STREET  
**123 East First Street - Suite 100**

CITY      STATE      ZIP CODE      CITY      STATE      ZIP CODE  
**Reading      PA      12345      Reading      PA      12346**

NAME OF DIRECTOR (Last, First, Middle Initial)  
**Taylor, John, S.**

FOR OFFICE USE ONLY  
Date Received \_\_\_\_\_

**II. TYPE OF CERTIFICATE REQUESTED (Check only one)**

Certificate of Waiver (Complete Sections I – VI and IX – X)

## Section 2 - Type of Certificate

### Certificate of

- > Check box indicated.

**II. TYPE OF CERTIFICATE REQUESTED (Check only one)**

Certificate of Waiver (Complete Sections I – VI and IX – X)

Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)

Certificate of Compliance (Complete Sections I – X)

Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

The Joint Commission       AOA       AABB  
 CAP       COLA       ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

**NOTE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.

### Section 3 - Type of Laboratory

#### Facility Identification

- > This should be checked off from the description that best describes the type of facility and services provided.

**III. TYPE OF LABORATORY** (Check the one most descriptive of facility type)

<input type="checkbox"/> 01 Ambulance	<input type="checkbox"/> 11 Health Main. Organization	<input type="checkbox"/> 22 Practitioner Other (Specify)
<input type="checkbox"/> 02 Ambulatory Surgery Center	<input type="checkbox"/> 12 Home Health Agency	
<input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility	<input type="checkbox"/> 13 Hospice	<input type="checkbox"/> 23 Prison
<input type="checkbox"/> 04 Assisted Living Facility	<input type="checkbox"/> 14 Hospital	<input type="checkbox"/> 24 Public Health Laboratories
<input type="checkbox"/> 05 Blood Bank	<input type="checkbox"/> 15 Independent	<input type="checkbox"/> 25 Rural Health Clinic
<input checked="" type="checkbox"/> 06 Community Clinic	<input type="checkbox"/> 16 Industrial	<input type="checkbox"/> 26 School/Student Health Service
<input type="checkbox"/> 07 Comp. Outpatient Rehab Facility	<input type="checkbox"/> 17 Insurance	<input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility
<input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility	<input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded	<input type="checkbox"/> 28 Tissue Bank/Repositories
<input type="checkbox"/> 09 Federally Qualified Health Center	<input type="checkbox"/> 19 Mobile Laboratory	<input type="checkbox"/> 29 Other (Specify)
<input type="checkbox"/> 10 Health Fair	<input type="checkbox"/> 20 Pharmacy	
	<input type="checkbox"/> 21 Physician Office	

Is this a shared lab?  Yes  No

**IV. HOURS OF LABORATORY TESTING** (List times during which laboratory testing is performed in HH:MM format)

### Section 4 - Hours of Laboratory Testing

#### Hours of Operation

- > Indicate when testing services will be available at the test site. This may or may not mirror site location's operating hours.

**IV. HOURS OF LABORATORY TESTING** (List times during which laboratory testing is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:		9:00	9:00	9:00	9:00	9:00	8:00
TO:		5:00	5:00	5:00	5:00	5:00	3:30

(For multiple sites, attach the additional information using the same format.)

**V. MULTIPLE SITES** (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?  
 No. If no, go to section VI.  Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

- Is this a laboratory that has temporary testing sites?  
 Yes  No

### Section 5 - Multiple Sites

#### Multiple Locations

- > Most applications will respond "NO" to this question. Check off as indicated if applicable and immediately go to Section 6.

For applications that have multiple location sites, contact your local CMS office to ensure that the regulatory exceptions for this provision are met prior to completing this form. Additionally, Section 5 will require that each location's testing hours are identified.

**V. MULTIPLE SITES** (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?  
 No. If no, go to section VI.  Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

- Is this a laboratory that has temporary testing sites?  
 Yes  No
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?  
 Yes  No  
 If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?  
 Yes  No  
 If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here  and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION	TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)

Form CMS-116 (10/10) 2

**Section 6 - Waived Testing**

**Annual Test Volume**

- > This number represents the total estimate number of tests that will be performed at the testing facility annually. Under CLIA Application of Waiver submission, the fee charged for a two-year certificate is \$150.00, regardless of the volume of CLIA waived tests conducted within a facility. Whereas, CLIA Certificates for Moderate Complexity and High Complexity are fee rendered by this number indicated as well as the type of testing performed as identified under Section 7.

In the next three sections, indicate testing performed and annual test volume.

**VI. WAIVED TESTING**  
 Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.  
 e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed 1,500

Check if no waived tests are performed

**VII. PPM TESTING**  
 Identify the PPM testing performed.

**Skip Section 7 & 8  
 IF YOU ARE ONLY CONDUCTING WAIVED TESTING**

**Section 9 - Type of Control**

**Facility Overseer**

- > Indicate which code closely identifies with your organization. This would be understood by how you are identified currently with the IRS for tax filing purposes.

**IX. TYPE OF CONTROL**

<b>VOLUNTARY NONPROFIT</b> <input type="checkbox"/> 01 Religious Affiliation <input checked="" type="checkbox"/> 02 Private Nonprofit <input type="checkbox"/> 03 Other Nonprofit  _____ (Specify)	<b>FOR PROFIT</b> <input type="checkbox"/> 04 Proprietary	<b>GOVERNMENT</b> <input type="checkbox"/> 05 City <input type="checkbox"/> 06 County <input type="checkbox"/> 07 State <input type="checkbox"/> 08 Federal <input type="checkbox"/> 09 Other Government  _____ (Specify)
--	--	---

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

**Section 10 - Director Affiliation with Other Laboratories**

**Other Affiliations**

- > Many identified Directors may have affiliations with other facilities and/or programs within each state. This section must be completed if the Director identified for this application has been registered to other site locations and/or organizations.

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY
41D1234567	Eastern Pennsylvania Health Center

ATTENTION: BE CAREFUL WITH THIS SECTION

## Section 10 - Director Affiliation with Other Laboratories

### Contractual Obligation

- > The Laboratory Director must sign and complete the application. By signing this application, the Director agrees to permit the Secretary, or any Federal officer or employee designated by the Secretary to inspect the laboratory, operations and all records at any reasonable time to determine applicants eligibility or continued eligibility for a CLIA certificate and continued compliance with CLIA requirements are met.

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION	
<p>Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.</p> <p>Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.</p>	
SIGNATURE OF OWNER/DIRECTOR OF LABORATORY <i>(Sign in ink)</i>	DATE
<b>John S. Taylor</b>	<b>03/02/2011</b>
Form CMS-116 (10/10) <span style="float: right;">4</span>	

## Mail

### Completed Application

- > Once the application is completed, it should be mailed directly to the local CMS office in your state. No check or money order should be sent at this time. The application is then entered into a national database. Within the next two (2) weeks, a bill with a detachable coupon will be mailed to the attention of the Director. Fees for a Certificate of Waiver for two years will be \$150.00. Detach the coupon and send along with payment to the address provided. Be sure to reference the assigned CLIA certificate number on your check should the coupon be lost or separated from payment.

# CLIA Certificate of Waiver

- > Processing for a new certificate may take up to two months, however calling your local office may or may not yield information on the progress of your application. Your CLIA certificate number is established on your original invoice. Only once your payment is credited with your application approval may you begin testing within your facility. The CLIA certificate will arrive approximately two (2) weeks following credited payment.

## Renewal

- > Anticipate ten months prior to renewal date of your CLIA Certificate, a coupon voucher to arrive directed to the listed Director of the facility. Payment should be made by expected due date. Any changes from the original application should also be indicated. Once payment is received a renewal Certificate will be sent one month prior to the expiration date.

**For additional information, contact your local CMS office.**

## State Survey Agencies (CLIA Contact List)

	CLIA State Licensure Exempt		CLIA State Licensure Exempt		CLIA State Licensure Exempt
<b>REGION I - Boston</b>					
CLIA LABORATORY PROGRAM DEPARTMENT OF PUBLIC HEALTH P. O. Box 340308 410 Capitol Avenue, MS#12 HSR Hartford, CT 06134-0308 (860) 509-7400 FAX: (860) 509-7543 Contact: John J. Murphy	•				
BUREAU OF HEALTH CARE SAFETY AND QUALITY MASS. DEPT. OF PUBLIC HEALTH CLINICAL LABORATORY PROGRAM 99 Chauncy Street, 11th Floor Boston, MA 02111 (617) 753-8438 or 8439 FAX: (617) 753-8240 Contact: Roberta Teixeira	•				
DIVISION OF FACILITIES REGULATION RI DEPARTMENT OF HEALTH 3 Capitol Hill, Room 306 Providence, RI 02908 (401) 222-4526 FAX: (401) 222-3999 Contact: Nancy Hines	•				
CLIA PROGRAM DIVISION OF LICENSING & REGULATORY SERVICES 41 Anthony Avenue, Station #11 Augusta, ME 04333-0011 (207) 287-9339 FAX: (207) 287-9304 Contact: Dale Payne	•				
HEALTH FACILITIES ADMINISTRATION DEPARTMENT OF HEALTH & HUMAN SERVICES 129 Pleasant Street Concord, NH 03301 (603) 271-4832 FAX: (603) 271-4968 Contact: Rodney Bascom	•				
CLIA LABORATORY PROGRAM VERMONT DEPARTMENT OF HEALTH 108 Cherry Street Burlington, VT 05401 (802) 652-4145 FAX: (802) 865-7701 Contact: Carol Drawbaugh	•				
<b>REGION II - New York</b>					
CLINICAL LABORATORY IMPROVEMENT SVC STATE OF NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES P. O. Box 361 Trenton, NJ 08625-0361 (609) 292-0016 FAX: (609) 292-0424 Contact: Marilou Mallada	•				
		<b>For Physician Office Laboratories in New York:</b> STATE OF NEW YORK DEPARTMENT OF HEALTH PHYSICIAN OFFICE LABORATORY EVALUATION PROGRAM Empire State Plaza P. O. Box 509 Albany, NY 12201-0509 (518) 485-5352 Contacts: Dr. Michael P. Ryan		•	VIRGINIA DEPARTMENT OF HEALTH OFFICE OF LICENSURE AND CERTIFICATION 9600 Mayland Drive, Suite 401 Richmond, VA 23233 (804) 367-2107 FAX: (804) 527-4504 Contact: Sarah Pendergrass
		<b>For All Other Laboratory Facility Types in New York:</b> CLINICAL LABORATORY EVALUATION PROGRAM Empire State Plaza P. O. Box 509 Albany, NY 12201-0509 (518) 485-5378 Contacts: Stephanie Shulman		•	WEST VIRGINIA DEPARTMENT OF HEALTH OFFICE OF LABORATORY SERVICES 167 11th Avenue South Charleston, WV 25303-1137 (304) 558-3530, extension 2103 FAX: (304) 558-2006 Contact: Jerry Gross
		COMMONWEALTH OF PUERTO RICO PUERTO RICO HEALTH DEPARTMENT OFFICE OF CERTIFICATION & LICENSURE FORMER-RUIZ SOLER HOSPITAL Road No. 2 Bayamon PR 00619 (787) 782-0120 Ext. 2222 FAX: (787) 781-2088 Contact: Julia Colón		•	<b>REGION IV - Atlanta</b>
		<b>REGION III - Philadelphia</b>	•		ALABAMA DEPARTMENT OF PUBLIC HEALTH DIVISION OF HEALTH CARE FACILITIES CLIA PROGRAM, P.O. Box 303017 Montgomery, AL 36130-3017 (334) 206-5120 Contact: Faye Allen
		DELAWARE STATE PUBLIC HEALTH LABORATORY 30 Sunnyside Road Smyrna, DE 19977 (302) 223-1392 FAX: (302) 653-2877 Contact: Donna Phillips-DiMaria		•	STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION LABORATORY LICENSING UNIT 2727 Mahan Drive, Mail Stop 32 Tallahassee, FL 32308 (850) 412-4500 FAX: (850) 410-1511 Contact: Karen Rivera
		DC DEPARTMENT OF HEALTH Health Regulations and Licensing Administration Health Facilities Division - Laboratory Services 899 North Capitol Street, NE-2nd Floor Washington, DC 20002 (202) 727-1740 FAX: (202) 442-9431 Contact: Semret Tesfaye		•	DEPARTMENT OF COMMUNITY HEALTH HEALTHCARE FACILITY REGULATION DIVISION DIAGNOSTIC SERVICES UNIT 2 Peachtree Street, N.W., Suite 31-447 Atlanta, GA 30303-3142 (404) 657-5447 FAX: (404) 657-5442 Contact: Sheela E. Puthumana
		MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENNE OFFICE OF HEALTH CARE - LABS Bland Bryant Building Spring Grove Hospital Center 55 Wade Avenue Catonsville, MD 21228 (410) 402-8025 FAX: (410) 402-8213		•	KENTUCKY CLIA PROGRAM Office of Inspector General 275 E Main Street 5E-A Frankfort, KY 40601 (502) 564-7963 Contact: Connie Barker, Ext. 3280
		PENNSYLVANIA DEPARTMENT OF HEALTH BUREAU OF LABORATORIES 110 Pickering Way Exton, PA 19341-0500 (610) 280-3464 Ext. 3233 FAX: (610) 594-9763 Contact: Melissa Seale		•	LICENSURE AND CERTIFICATION MISSISSIPPI DEPARTMENT OF PUBLIC HEALTH P. O. Box 1700 Jackson, MS 39215-1700 (601) 364-1115 Contact: Theresa Irwin

CLIA  
State  
Licensure  
Exempt

• NORTH CAROLINA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES  
DIVISION OF FACILITY SERVICES/  
CLIA CERTIFICATION  
2713 Mail Service Center  
Raleigh, NC 27699-2713  
(919) 855-4620  
FAX: (919) 733-0176  
Contact: Azzie Conley

• SOUTH CAROLINA DEPARTMENT OF HEALTH  
& ENVIRONMENTAL CONTROL  
BUREAU OF CERTIFICATION/ HEALTH  
REGULATION  
2600 Bull Street  
Columbia, SC 29201  
(803) 545-4291  
FAX: (803) 545-4563  
Contact: Lakeisha N. Wright

• TENNESSEE HEALTH CARE FACILITIES  
227 French Landing, Suite 501  
Heritage Place Metro Center  
Nashville, TN 37243  
(615) 741-7023  
FAX: (615) 532-2700  
Contact: Sandra Bogard

**REGION V - Chicago**

• ILLINOIS DEPARTMENT OF PUBLIC HEALTH  
DIVISION OF HEALTH CARE FACILITIES  
& PROGRAMS  
525 W Jefferson Street  
Fourth Floor  
Springfield, IL 62761  
(217) 782-2343  
FAX: (217) 782-0382  
Contact: Juan Garcis, Supervisor

• INDIANA STATE DEPARTMENT OF HEALTH  
DIVISION OF ACUTE CARE SERVICES  
2 North Meridian Street, Room 4A  
Indianapolis, IN 46204  
(317) 233-7502  
FAX: (317) 233-7157  
Contact: Lorraine Switzer

• MICHIGAN DEPARTMENT OF COMMUNITY  
LABORATORY IMPROVEMENT SECTION  
611 W. Ottawa Street, First Floor  
Lansing, MI 48909  
(517) 241-2648  
FAX: (517) 241-3354

• MINNESOTA DEPARTMENT OF HEALTH  
LICENSING & CERTIFICATION CLIA PROGRAM  
85 East 7th Place  
P. O. Box 64900  
St. Paul, MN 55164-0900  
(651) 215-8420  
FAX: (651) 215-9697  
Contacts: Bridget Woitas

• OHIO DEPARTMENT OF HEALTH  
LABORATORY CLIA LABORATORY PROGRAM  
246 N. High Street, 3rd Floor  
Columbus, OH 43215  
(614) 644-1845  
FAX: (614) 387-2762  
Contact: Drema Phelps

• DEPARTMENT OF HEALTH SERVICES  
DIVISION OF QUALITY ASSURANCE  
CLINICAL LABORATORY SECTION  
1 W. Wilson Street, Room 1151  
Madison, WI 53701-2969  
(608) 261-0653  
FAX: (608) 264-9847  
Contact: Barbara Saar

**REGION VI - Dallas**

• HEALTH FACILITY SERVICES Slot H9  
ARKANSAS DEPARTMENT OF HEALTH  
AND HUMAN SERVICES  
5800 West 10th Street, Suite 400  
Little Rock, AR 72204-9916  
(501) 661-2201  
Contact: Liz Davis

• DEPARTMENT OF HEALTH & HOSPITALS  
HEALTH STANDARDS SECTION  
500 Laurel Street, Suite 100  
Baton Rouge, LA 70801  
(225) 342-9324  
Contact: Staci Glueck

• HEALTH FACILITY LICENSING  
AND CERTIFICATION BUREAU  
Bank of the West Building  
5301 Central Avenue NW, Suite 400  
Albuquerque, NM 87108  
(505) 222-8646  
Fax: (505) 841-5834  
Contact: Julie Aragon

• OKLAHOMA STATE DEPARTMENT OF HEALTH  
PROTECTIVE HEALTH SERVICES  
MEDICAL FACILITIES  
1000 NE 10th Street  
Oklahoma City, OK 73117-1299  
(405) 271-6576  
Contact: Dean Bay

• TEXAS DEPARTMENT OF STATE  
HEALTH SERVICES  
ATTN: Charles Peck  
P. O. Box 149347  
Austin, TX 78714-9347  
(512) 834-6792

**REGION VII - Kansas City**

• IOWA CLIA LABORATORY PROGRAM  
STATE HYGIENIC LABORATORY  
Research Park  
The University of Iowa  
Iowa City, IA 52242  
(319) 335-4500  
FAX: (319) 335 4174  
Contact: Nancy Grove, Sr. Laboratory Consultant

• KANSAS DEPARTMENT OF HEALTH  
& ENVIRONMENT  
LABORATORY CERTIFICATION  
Building 740  
Forbes Field  
Topeka, KS 66620-0001  
(785) 296-3811  
Contact: Ruby Brower

• MISSOURI DEPARTMENT OF HEALTH AND  
SENIOR SERVICES  
CLIA Section  
P. O. Box 570  
Jefferson City, MO 65102  
(573) 751-6318  
Contact: William Nugent

• NEBRASKA STATE HEALTH & HUMAN SERVICES  
LICENSURE UNIT-DIVISION OF PUBLIC HEALTH  
Office of Acute Care Facilities  
P. O. Box 94986  
Lincoln, NE 68509-4986  
(402) 471-3484  
Contact: Joann Erickson

**REGION VIII - Denver**

• COLORADO DEPARTMENT OF PUBLIC HEALTH  
& ENVIRONMENT  
LABORATORY SERVICES DIVISION  
8100 Lowry Blvd.  
Denver, CO 80230-6928  
(303) 692-3681  
FAX: (303) 344-9965  
Contact: Jeff Groff

• MONTANA CLIA PROGRAM - DIVISION  
OF QUALITY ASSURANCE - DEPARTMENT  
OF PUBLIC HEALTH & HUMAN SERVICES  
2401 Colonial Drive, 2nd Floor  
P. O. Box 202953  
Helena, MT 59620-2953  
(406) 444-1451  
FAX: (406) 444-3456  
Contact: Ed Adams

• HEALTH RESOURCES SECTION  
NORTH DAKOTA DEPARTMENT OF HEALTH  
STATE CAPITAL  
600 East Boulevard Avenue/DEPT 301  
Bismarck, ND 58505-0200  
(701) 328-2352  
FAX: (701) 328-1890  
Contact: Bridget Weidner

• SOUTH DAKOTA DEPARTMENT OF HEALTH  
OFFICE OF HEALTH CARE FACILITIES  
LICENSURE AND CERTIFICATION  
615 E. 4th Street  
Pierre, SD 57501-1700  
(605) 773-3694  
FAX: (605) 773-6667  
Contact: Connie Richards

• UNIFIED STATE LABORATORIES-PUBLIC HEALTH  
BUREAU OF LABORATORY IMPROVEMENT  
4431 South 2700 West  
Taylorsville, UT 84119  
(801) 965-2531  
FAX: (801) 965-2544  
Contact: Jan Case

• OFFICE OF HEALTHCARE  
LICENSING AND SURVEYS  
400 Qwest Building  
6101 North Yellowstone Road  
Cheyenne, WY 82002  
(307) 777-7123  
FAX: (307) 777-7127  
Contact: Russ Forney

CLIA  
State  
Licensure  
Exempt

**REGION IX - San Francisco**

• ARIZONA DEPARTMENT OF HEALTH  
SERVICES  
DIVISION OF PUBLIC HEALTH SERVICES  
Office of Laboratory Services  
250 N. 17th Avenue  
Phoenix, AZ 85007  
(602) 364-0741  
FAX: (602) 364-0759  
Contact: Odalys Hinds

• DEPARTMENT OF PUBLIC HEALTH  
DIVISION OF LABORATORY SERVICES  
LABORATORY FIELD SERVICES  
320 West 4th Street, Suite 890  
Los Angeles, CA 90013-2398  
(213) 620-6160  
FAX: (213) 620-6565  
Contact: Donna McCallum, Examiner III

• HAWAII DEPARTMENT OF HEALTH  
CLIA Program  
601 Kamokila Blvd., Room 395  
Kapolei, HI 96707  
(808) 692-7420  
FAX: (808) 692-7447  
Contact: Susan O. Naka

• **FOR LABS IN AMERICAN SAMOA (64), CONTACT  
THE HAWAII STATE AGENCY (12) FOR LABS IN  
SAIPAN (66) AND GUAM (65), CONTACT REGIONAL  
OFFICE IX, SAN FRANCISCO**

• STATE OF NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES  
HEALTH DIVISION  
BUREAU OF HEALTH CARE QUALITY & COMPLIANCE  
727 Fairview Dr., Ste E  
Carson City, NV 89701-5493  
(775) 684-1060  
FAX: (775) 684-1073  
Contact: Vicki Estes, MT (ASCP)

**REGION X - Seattle**

• OFF. OF LABORATORY QUALITY ASSURANCE  
DEPARTMENT OF HEALTH  
1610 NE 150TH Street  
Shoreline, WA 98155-9701  
(206) 418-5418  
FAX: (206) 418-5505  
Contact: Susan Walker

• OREGON HEALTH AUTHORITY  
OREGON STATE PUBLIC HEALTH DIVISION  
LABORATORY COMPLIANCE SECTION (LCS)  
3150 NW 229th Avenue, Suite 100  
Hillsboro, OR 97124-6536  
(503) 693-4121  
FAX: (503) 693-5602  
Contact: Rita A. Youell

• LABORATORY IMPROVEMENT SECTION  
BUREAU OF LABORATORIES  
2220 Old Penitentiary Road  
Boise, ID 83712-8299  
(208) 334-2235 x245  
FAX: (208) 334-4067  
Contact: David Eisentrager

• ALASKA CLIA PROGRAM  
ALASKA STATE PUBLIC HEALTH LABORATORY  
5455 Dr. Martin Luther King Jr. Avenue  
Anchorage, AK 99507  
(907) 334-2583  
FAX: (907) 334-2161  
Contact: Doris Thompson

CLIA  
State  
Licensure  
Exempt



# CLIA Important Information

## State Licensure or Exemption

- > Prior to the introduction of the Clinical Laboratory Improvement Amendments of 1988, numerous states had already adopted quality procedures and protocols by which laboratories operating within the state had to maintain. Many of these already established guidelines were deemed more stringent than the new protocols established under the new federal law (42 CFR Part 493). Petitions were heard and granted that allow for states with already existing protocols that proved to be “equal to or more stringent” may apply for a CLIA “Exemption”. To date, New York and Washington are the only two states operating under exemption whereas there are 17 states that have “State Licensure” in addition to CLIA. The previous chart assists in identifying these. Under State Licensure however, additional guidelines may be required in order to perform CLIA waived testing within the given state. These may include Proficiency Testing, Training Requirements, Quality Assurance Programs and Testing Procedures, Record Keeping Requirements, etc. For any application within these states, contact your local office to determine what additional steps and filings may be required to perform CLIA waived testing.

## Additions or Changes to Issued Certificates

- > During the two-year certificate period, information supplied on the original certificate application may change (e.g., lab director, add-on site location, etc). It is important that this information be communicated in a prompt manner to the local State Reporting office. The local states maintain the database for each issued certificate within the state. For questions concerning changes to the current certificate status, it is best to contact your local CMS office for clarification. Most often a simple letter is all that is required. This will be kept on file at the state office. A new certificate **will not** be issued reflecting these changes. Only upon renewal application will the changed information be indicated.

## Facility Inspections

- > The local state offices of CMS inspect facilities from time to time to monitor and ensure that each is operating under the CLIA guidelines. While these inspections are not punitive in nature, inspectors will check to see that Manufacturers’ Guidelines are followed within each facility. Additionally, reported complaints in the field will prompt a mandatory inspection of any facility. A report will be written for both random and mandated inspections that will advise any inconsistencies and recommendations to bring a facility up to compliance. Timelines for compliance adherence will be established. What can this mean potentially to a CLIA waived testing site? If a second follow-up inspection reveals that conformance has not been established, the local CMS office can cease CLIA testing operations for a given time to that facility or site until conformance has been satisfactorily met. Similarly, if additional complaints are filed against the facility, CLIA certification can be permanently revoked and punitive action can take place dependent on the nature of the complaint.



Linking people to care

## 4. HCV Testing Counseling Protocol



## HCV Testing and Counseling

*“The most effective means to prevent HCV infection and its consequences is to integrate HCV prevention activities into existing services, such as those for the prevention and treatment of human immunodeficiency virus (HIV), sexually transmitted diseases (STDs), and substance abuse.”*

- CDC National Hepatitis C Prevention Strategy

Awareness of HCV as an important public health issue is growing, but agencies, medical providers, community-based organizations, and others who work with those at risk or infected with HCV must address several key issues:\*

- prevention of HCV infection;
- identification of people infected with HCV;
- preventing transmission to others;
- capacity for care and treatment;
- provision of support for people living with HCV; and
- education for staff and people at risk.

The following are general guidelines for presenting counseling to your clients who may be at risk of hepatitis C infection.

### I. Pre-Test Counseling§

The counselor must be professional and respectful toward the client and recognize that issues of sex and drug use behaviors may be sensitive and difficult for the client to discuss.

To establish initial rapport with the client, the counselor will need to convey positive regard, genuine concern and an empathic response toward the client. This connection will help build trust and will set the tone for the rest of the session. The client should be helped to feel comfortable with the clinic procedures, understand the role of the counselor, and be clear about the content and purpose of the session. If the client is clear about the expectations and the process, the counselor has reduced the client's anxiety and increased the client's ability to focus on the session. This clear delineation of the session serves to model for the client a rational and responsible approach to addressing the challenging issues of behavior change. It is important that the counselor conduct the session, to the extent possible, as described to the client. If the counselor must deviate from what he/she has indicated will occur in the session, this change should be explained to the client.

\* Hepatitis C-A Practical Guide for Incorporating Hepatitis C Services into Existing Program, New York City Department of Health and Mental Hygiene, Hepatitis C Program, Division of Disease Control, 2003.  
[http://www.pdfdownload.org/pdf2html/view\\_online.php?url=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fdoh%2Fdownloads%2Fpdf%2Fcd%2Fcdhepc\\_hcvtechmanual.pdf](http://www.pdfdownload.org/pdf2html/view_online.php?url=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fdoh%2Fdownloads%2Fpdf%2Fcd%2Fcdhepc_hcvtechmanual.pdf)

§ Adapted from Respect – 2 Study launched by the Centers for Disease Control and Prevention in February 1999. More information on the Respect – 2 counseling protocols can be found at:  
<http://www.cdc.gov/hiv/projects/respect-2/counseling.htm>

The counselor should convey confidence in being able to understand the client's risk behavior and in the client's ability to initiate a risk reduction process. Also, the counselor should communicate an appropriate sense of urgency and concern relative to the client's HCV/HIV/STD risks. The counselor should establish the collaborative nature of the session and the mutual commitment of both counselor and client to earnestly address risk reduction issues.

The client is more likely to retain information you discuss with them if he/she has an information handout to refer to during the session and to take home. Reading level and language should be considered when selecting these materials. You may want to offer the CDC's "*Hepatitis C General Information*" pamphlet or other materials that your State Department of Health may have available.

- 1) Explain the purpose of the session–
- 2) Present general HCV information; for example:\*

Hepatitis C is one of several viruses that cause viral hepatitis (an inflammation of the liver). Hepatitis C is spread mostly by human blood-to-blood exposure and 70-85% of persons infected with hepatitis C carry the virus for the rest of their lives. Somewhere around 30% of those infected with HCV will clear the virus naturally. Most people infected with hepatitis C do not know they are infected, have no symptoms, and lead normal lives though they will have some mild damage to their liver over time but not enough to make them sick. About 25% of those infected will develop more severe damage called cirrhosis or scarring of the liver and some of those may progress onto liver failure. Being infected with HCV makes a person 20 times more likely to get liver cancer than those with out chronic viral hepatitis. There is no vaccine for hepatitis C at this time though there are some treatment options available and much research with a promise of more potential choices on the horizon.

HCV is spread primarily by human blood to blood contact as when a person's blood comes into direct contact with an open or bleeding area on another person, or by a contaminated blood transfusion or tissue/organ transplant, or needle. The most common way to get HCV is caused by sharing contaminated injection drug use equipment, even one (1) time.

\* Text adapted from: PreAlaska Native Medical Center (ANMC), Transfusion LookBack Project: Recruitment of Pre-July 1992 Transfusion Recipients for Hepatitis C (HCV) Screening.

- 3) Help the client determine the need for testing. When possible use open-ended questions.\*

*Hepatitis is primarily spread through blood-to-blood contact.*

- "Can you tell me about any experiences where you came in contact with someone's blood?"
- "Were you ever tested in the past for Hepatitis C? What were the reason/s? When were you last tested? Where? Do you know the test result?"
- *Injecting drugs with other people is a major way hepatitis is spread. I can happen when people use each others equipment, either intentionally or by accident.*  
"Have you ever used a needle to inject drugs? Can you tell me about how often you have ever used any injecting equipment that someone else may have used?"
- "Were you ever successful in donating blood in the past? Anytime after 1992?"  
Determine if the client wants testing and what is the reason for coming here today.
- "Thank you for coming in today to listen to the information we have to offer and to take the test. This is a positive step in taking charge of your health."

**Reason for testing:** To find out if you are infected with HCV.

**Examples follow:**

- Test purpose--"To determine if you are infected with HCV."
- What the test can tell you --"This is a test for HCV infection--it can tell you if you are infected with HCV but it does not mean you have liver disease or predict if you will be ill. The majority of persons with chronic HCV will not develop severe liver disease."
- HCV diagnosis--Emphasize: "A positive antibody test does not mean that you still have hepatitis C virus in your blood--remember that up to 30% of those infected clear the virus with their body's own defense system. If you are antibody positive, we will need to test for virus to see if it is still present."

- 4) Explain the benefits of testing. If positive - "By testing and knowing you have HCV, there are things you can do to protect your health and get treatment for hepatitis C. By knowing, you can reduce the risk of spreading the infection to others."\*

"By testing and knowing you don't have HCV, there are things you can do to ensure you stay healthy and reduce the risk of exposure and infection."

- 5) Inform the client that all test results will be confidential.

- 6) Describe the testing procedure. Explain what will happen if they decide to take the test.

- "A small fingerstick blood sample will be taken. The results will be available in 20 minutes."

\* Text adapted from: PreAlaska Native Medical Center (ANMC), Transfusion LookBack Project: Recruitment of Pre-July 1992 Transfusion Recipients for Hepatitis C (HCV) Screening.

- 7) Ask the client if they want to proceed with the test and what plans they have for dealing with results.

**Examples follow:**

- “What other questions do you have about testing? What would you like to do about taking the test?”
- Assess with the client how they will react to and/or use the test results. Any HCV antibody test result can have a significant psychological impact on both the individual tested and those who are close to them. These or similar questions can help:
  - “What are your expectations about the test result?”
  - “How do you think you will react? What will you do if you feel this way?”
  - “What would a presumptive positive test mean for you?”
  - “What plans have you made to tell anyone that you've had an HCV test?”

**II. Post-Test Counseling<sup>§</sup>**

Disclosure Session

**If the HCV test result is non-reactive (negative):**

- Discuss with client what the result means, including information about the window period;
- Reinforce existing behaviors that reduce risk of transmission;
- Discuss safer injection practices, if appropriate; and,
- Provide referral to support services for further counseling, including information on how to reduce the risk of acquiring HCV in the future.

**If the HCV test results is reactive (presumptive positive):**

- Discuss with client what the result means; the presence and exposure, but not proof of acute, chronic, resolved or potential lab error;
- Discuss recommendation to seek further testing from a physician to determine health status including the necessity of supplemental testing nucleic acid testing (NAT);
- Discuss how to reduce the risk of transmission to others;
- Discuss the differences between an HIV positive and an HCV positive test result;
- Discuss disclosure of test result to needle-sharing partners; and,
- If applicable, discuss co-infection issues;
- Co-create a risk reduction plan.

\* Hepatitis C Harm Reduction Project. Hepatitis C Counseling, 2003.

## **Negotiate Risk Reduction Plan**

The risk reduction plan is a fundamental component of the prevention counseling session. The counselor should assist the client in identifying a behavior that corresponds to their risk and that they are invested in changing. It is essential that the plan match the client's skills and abilities with their motivation to change a specific behavior. The counselor should challenge the patient to go beyond what they have previously attempted in terms of risk reduction. The plan must be specific in that it describes the who, what, where, when and how of the risk reduction process. It must be concrete in that it details the successive actions required of the patient to implement and complete the risk reduction plan. Finally, it must be incremental in that it is directed at a single aspect of the risk behavior or one particular factor/issue that contributes to that risk behavior.

The counselor should avoid supporting risk reduction plans that involve unreasonable or radical changes in the client's life. The client may experience a "flight to health" characterized by the belief that therapy is no longer needed as a result of the clinic experience, the anxiety from the testing process, or the quality of the counseling interaction. Global risk reduction messages such as "always wear condoms," "remain monogamous," or "abstain from sex" do not meet the criteria for an appropriate risk reduction plan.

The counselor should ensure that the client agrees with the plan and is committed to its implementation. The client should be asked to critique the plan and identify problems with the plan. The counselor may even quiz the client on the plan or provide plausible examples of obstacles the client may encounter in initiating the plan. These obstacles should be problem-solved with the client and may require revising the plan. The process of developing a plan represents the client's movement toward risk reduction.

## **Identify Sources of Support and Provide Additional Referrals**

This component of the session is intended to identify or develop for the client peer and community support for HCV risk reduction, as well as to provide referral to professional services directed at addressing specific issues the client may have identified. The priority of this component of the session is to identify a specific friend, partner or relative with whom the client will discuss their risk reduction plan and report to regarding the implementation and completion of the plan. This step is critical because in the rapid test scenario there is no second session for the counselor to review with the client and their experience in implementing the plan.

The process of the client checking in with someone about the plan is important because it gives enhanced meaning to the plan and increases the client's personal expectations about completing the plan. The client must trust this person and feel comfortable with their ability to keep the client's confidence. It is reasonable that the trusted person be the same person with whom the patient is trying to initiate the behavior change plan.



## 5. Hepatitis C Assessment Form





# SAMPLE

## Hepatitis C Assessment Form

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ County: \_\_\_\_\_  
Phone: \_\_\_\_\_ DOB (mm/dd/yyyy): \_\_\_\_\_ Age: \_\_\_\_\_  
Gender:  M  F  MTF  FTM  Other Ethnicity:  Hispanic  Non-Hispanic  
Race:  W  B  Asian/PI  American Indian/Alaskan Native  other  unknown

### Test and vaccination history (check all that apply)

1. Have you ever been told that you tested positive for hepatitis?  Yes  No  unknown
2. Have you ever received the hepatitis A?  Yes  No  unknown  
If yes, how many doses?  1  2  unknown
3. Have you ever received the hepatitis B?  Yes  No  unknown  
If yes, how many doses?  1  2  3  unknown
4. Have you ever received the combination hepatitis A/B (Twinrix) vaccine?  Yes  No  unknown  
If yes, how many doses?  1  2  3  4  unknown

### Risk Exposures (CDC, defined high risk groups for HCV infection)

1. Have you ever injected drugs, even once?  Yes  No  unknown  
If yes, have you ever shared needles with others?  Yes  No  unknown
2. Have you ever snorted drugs?  Yes  No  unknown
3. Have you ever received a blood transfusion or organ transplant?  Yes  No  unknown
4. Have you ever received clotting factor(s) made before 1987?  Yes  No  unknown
5. Have you ever been on demodialysis (kidney machine)?  Yes  No  unknown
6. Have you ever been told by any physician that you have liver disease or abnormal liver enzymes?  
 yes  no  unknown
7. Have you ever been notified that you received blood, blood components or organs from a donor who later tested positive for hepatitis C?  yes  no  unknown

### Other risk factors (check all that apply)

- |   |  |
|---|--|
| <input type="checkbox"/> History of incarceration (prison/jail)         | <input type="checkbox"/> Multiple tattoos or body piercing not done in a professional shop |
| <input type="checkbox"/> Household contact of a person with hepatitis C | <input type="checkbox"/> Long term sexual partner of a person with hepatitis C             |
| <input type="checkbox"/> Born to a mother with hepatitis C              | <input type="checkbox"/> Multiple sexual partners  |
| <input type="checkbox"/> Sex for money or drugs                         | <input type="checkbox"/> Diagnosis of sexually transmitted diseases                        |

Interviewer's name: \_\_\_\_\_ Date: \_\_\_\_\_ County: \_\_\_\_\_

Clinic site:  HIV/AIDS  Family Planning  STD



## 6. OraQuick® HCV Rapid Antibody Test Procedure



**OraQuick**® Rapid  
Antibody  
Test  
**HCV**

# OraQuick® HCV Rapid Antibody Test Procedure With Fingerstick and Venipuncture Whole Blood Specimens

## I. Summary & Principle of the Test

The standard laboratory HCV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EIA) and supplemental testing using RIBA™ or Nucleic Acid Testing (NAT). Results are typically reported within hours to weeks, making these standard screening and supplemental tests inadequate to meet the need for rapid HCV diagnosis. The OraQuick® HCV Rapid Antibody Test is a point-of-care test to aid in the diagnosis of infection with hepatitis C. This Rapid HCV test provides results with greater than 98% accuracy in as little as 20 minutes from a fingerstick whole blood or venipuncture whole blood sample.

Using a rapid HCV test increases the number of HCV-infected persons who may be diagnosed. The American Association for the Study of Liver Disease (AASLD) estimates that nearly eighty percent of the estimated 4,100,000 HCV-infected persons in the United States are viremic.\* Three out of four HCV-infected individuals do not know they are infected. As a result, they cannot benefit from early intervention with effective new treatment therapy. Rapid HCV testing addresses this issue by providing results during the initial visit and enabling immediate counseling and prevention of spreading the virus to others. This is particularly important for injection drug users who are the leading source of HCV infection and transmit infection through sharing of needles and other injection equipment often due to limited access to sterile injection equipment. Additionally, rapid HCV testing is instrumental in the decision to monitor health care workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 600,000 to 1,000,000 “needlestick injuries” occur each year.

The OraQuick® HCV Rapid Antibody Test utilizes a proprietary lateral flow immunoassay procedure. The device plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results. The assay test strip, which can be viewed through the test device result window, contains synthetic peptides and recombinant proteins from the core, NS3, and NS4 regions of the HCV genome (test) and a goat anti-human IgG (procedural control) immobilized onto a nitrocellulose membrane at the Test (T) and the Control (C) Zone, respectively.

\* Ghany, M. *et al.* AASLD Practice Guidelines, Diagnosis, Management, and Treatment of Hepatitis C-An Update *Hepatology*, April, 2009; pp. 1335-1374.

A fingerstick whole blood specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it re-hydrates the protein-A gold colorimetric reagent contained in the device. As specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HCV in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen. Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HCV.

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen.

## **II. Specimen**

Oral fluid or whole blood obtained by fingerstick procedure (see **Fingerstick Blood Collection procedure**)

## **III. Materials**

- A. Materials required but not supplied with kit
  - 1. Timer/ Stop Watch (20-40 min)
  - 2. Clean, disposable, absorbent workspace cover
  - 3. Biohazard disposal container
- B. Additional materials required for fingerstick specimens
  - 1. Lancet
  - 2. Sterile gauze pad
  - 3. Antiseptic wipe
  - 4. Latex, vinyl or nitrile disposable glove
- C. Materials supplied in kit
  - 1. Test device: A single use
  - 2. Absorbent Packet
  - 3. Developer solution vial
  - 4. Reusable Test Stand
  - 5. Specimen Collection Loops
  - 6. Package insert
- D. Storage

Store unused OraQuick® HCV Rapid Antibody Tests unopened at 2°-30°C (36-86° F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature 15°-37°C (59-99° F) before opening.

#### IV. Safety

- A. Handle specimens and materials contacting specimens as if capable of transmitting infectious agents.
- B. Do not drink, eat, or smoke in areas where specimens are being handled.
- C. Wear a lab coat, eye protection and disposable gloves while handling blood specimens. Change gloves and wash hands thoroughly after performing each test.
- D. Dispose of gloves in a biohazard waste container after use.
- E. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container.
- F. Lancets should be placed in a puncture-resistant container prior to disposal.
- G. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants.
- H. A solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination.
- I. **NOTE: Do not autoclave solutions that contain bleach.** For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings".<sup>5</sup>
- J. Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant.

#### V. General Test Preparation

- A. Set up your Workspace
  - 1. Gather the materials you will need for a fingerstick whole blood collection.
  - 2. This test should be performed at operating temperature 15°-37°C (59°-99°F). If the Divided Pouch containing the Test Device and Developer Solution Vial is not at operating temperature, allow time for the Pouch to come to operating temperature before removing the contents from its wrapper.
  - 3. Review specimen collection instructions.
  - 4. For new operators, refer to the OraQuick® HCV Visual Reference Panel instructions prior to testing any specimens.
  - 5. Refer to the *External Quality Control* section of the OraQuick® HCV Rapid Antibody Test package insert to determine when Kit Controls should be run.
  - 6. Cover your workspace with a clean, disposable, absorbent workspace cover.
  - 7. Place the Reusable Test Stand on a flat, level surface. Use only the stand provided.

B. General Test Preparation

1. Using the notched corners, tear the top of each end of the Divided Pouch containing the Test Device and Developer Solution Vial. To prevent contamination, leave the Test Device in the Divided Pouch until needed.
2. Remove the Developer Solution Vial from the Divided Pouch. Firmly holding the Developer Solution Vial, carefully uncap the vial by gently rocking the cap back and forth. Set the cap on your workspace cover. Slide the uncapped Developer Solution Vial into the top of the slot in the angled Reusable Test Stand, making sure the vial is completely seated in the stand.
3. DO NOT force the vial into the stand from the front of the slot, as splashing may occur.
4. DO NOT touch the Flat Pad.
5. Check to see if an Absorbent Packet is present. If no Absorbent Packet is present, discard the Test Device and obtain a new Divided Pouch for testing

C. Testing Procedure - Fingertick Whole Blood

1. If tests are performed on more than one client at one time label the Developer Vial either with the sticker or sharpie pen appropriately. NOTE: **DO NOT cover the two holes on back of the Device with labels or other materials. Doing so may cause an Invalid result.**
2. Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
3. Pick up an unused Specimen Collection Loop by the thick 'handle' end. Touch the round end of an unused Specimen Collection Loop to the drop of blood. Visually inspect the Loop to make sure that it is completely filled with blood. NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.
4. Immediately immerse the blood-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard the used loop in a biohazard waste container.
5. Examine the solution in the Developer Solution Vial to ensure that it appears pink, indicating that the blood specimen was properly introduced. If the developer solution is not pink after adding the specimen, discard the Developer Solution Vial as infectious waste, open a new Divided Pouch, and collect a new specimen.

6. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Solution Vial containing the specimen. **Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial.**
7. **DO NOT** cover the two holes in the back of the Test Device after placing it into the Developer Solution. Doing so may cause an invalid result.
8. Start timing the test. **DO NOT** remove the Test Device from the Developer Solution Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops. Read the results at 20 minutes but not more than 40 minutes in a fully lighted area.
9. Read the results: Note whether there is a band opposite the "C" and/or "T" area.
10. After recording the results, dispose of the used Developer Solution Vial and the Test Device in a biohazard waste container.
11. Follow CDC guidelines to inform the test subject of the test result and its interpretation.

E. Reading the Test

1. Sample of a **Non-Reactive** (negative) Result: (see Fig. 1 below)
  - Only the control (C) area shows a line.
  - No line is present in the test (T) area.
  - Test result interpreted as **NEGATIVE HCV Antibodies**. Patient is presumed not to be infected with HCV.



Fig. 1

2. Sample of a **Reactive** (positive) Result: (see Fig. 2 below)
- Lines appear in both the control (C) and the test (T) areas.
  - Test result interpreted as **Reactive For HCV Antibodies**. Patient is presumed to be infected with HCV.
  - Individuals with a reactive result should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.



Fig. 2

3. Sample of **Invalid** Result: (see Fig. 3 below)
- **No line** is present in the area adjacent to either the "C" or "T" triangle.
  - A line appears opposite the "T" triangle but not the "C" triangle.
  - A red background in the result window makes it difficult to read the results after 20 minutes.
  - A line appears, but not opposite the "C" (or "T") triangle - misalignment.
  - An **Invalid** test result means that there was a problem running the test either related to the specimen or to the Device. An **Invalid** result cannot be interpreted. Repeat the test with a new Pouch and a new specimen. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.



Fig. 3



## VI. Quality Control

### A. Controls

Positive and negative controls (human plasma-based reagents) are supplied with the kit. These kit controls verify that the test is working properly. These are negative for Hepatitis B and HIV-1 and HIV-2 antibodies.

### B. Frequency of Controls

1. Commercial positive and negative controls should be run under the following circumstances:
  - Each new operator prior to performing testing on patient specimens
  - When opening a new test kit lot
  - Whenever a new shipment of test kits is received
  - If the temperature of the test kit 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.

### C. Use

Store the OraQuick® HCV Test Kit Controls at 2-8°C (35-46°F). Do not use controls past the expiration date printed on the outer carton. Open kit control vials only when you are performing tests. Recap and store the vials in their original container at 2-8°C (35-46°F) after use. Opened vials expire 8 weeks after they are put in use. Do not use controls if the reagent appears visually cloudy or discolored.

### D. Expected Values

1. Positive control: both the control region and test region will show a line. (see Fig. 2)
2. Negative control: only the control region will turn color, the test region will **not** show a line. (see Fig. 1)

### E. Quality Control Records

Quality Control (QC) information is to be recorded on the appropriate QC Log Sheet (see section 8, appendix D). The information required includes name of test, site performed, date, time and person performing the test, lot numbers of all reagents, expiration dates of all reagents, expected results and observed results.

### F. Corrective Action

1. If the controls fail to yield the expected results, **DO NOT** perform any patient testing until performance issues are resolved and expected results are obtained and recorded.
2. Document the corrective action taken.

(See the **CDC Quality Assurance Guidelines**)

## **VII. Test Limitations**

- A. The OraQuick® HCV Rapid Antibody Test must be used in accordance with the instructions in the package insert of the device to obtain an accurate result.
- B. The clinical performance of this device was established based on an operator's ability to read visual intensities at the "T" line at all levels including very weak bands representing low antibody levels.
- C. Reading test results earlier than 20 minutes or later than 40 minutes may yield inaccurate results.
- D. This test is approved for use with fingerstick whole blood specimens and venipuncture whole blood specimens only. Use of other types of specimens, or venipuncture whole blood specimens collected using a tube containing anticoagulants other than EDTA, lithium heparin, sodium heparin, or sodium citrate may yield inaccurate results.
- E. Clinical data has not been collected to demonstrate the performance of the OraQuick® HCV Rapid Antibody Test in individuals under 15 years of age or for pregnant women.
- F. A Reactive result using the OraQuick® HCV Rapid Antibody Test suggests the presence of HCV antibodies in the specimen, and the intensity of the test line does not necessarily correlate with the HCV antibody titer in the specimen. The OraQuick® HCV Rapid Test is intended as an aid in the diagnosis of HCV infection.
- G. A non-reactive result does not exclude the possibility of exposure to HCV or infection HCV. An antibody response to recent exposure may take several months to reach detectable levels.
- H. A person who has HCV antibodies is presumed to be infected with the virus. Additional testing and medical evaluation is required to diagnose current HCV infection and to evaluate the need for treatment.



## 7. State-Specific Testing Guidelines



**OraQuick**® Rapid Antibody Test  
**HCV**

# A Quick Reference Listing for Clinicians and Health care Professionals to State HCV Testing Requirements

- > This Quick Reference Listing for clinicians and health care professionals is a summary of relevant state HCV testing requirements. Please refer to your individual state link for updates that may have occurred since this listing as of March 1, 2012.

State	Can Perform Non-Medical Personnel Use CLIA-waived Tests?	Notes/Recommended Resources
Alabama	Yes	No restrictions. Non-medical personanel may perform CLIA-waived tests under the supervision of a clinician within a clinical laboratory license by and registered within the state. <a href="http://www.adph.org">http://www.adph.org</a>
Alaska	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.hss.state.ak.us/dph/labs/cli/default.htm">http://www.hss.state.ak.us/dph/labs/cli/default.htm</a>
Arizona	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.azdhs.gov/lab/license/cliapps.htm">http://www.azdhs.gov/lab/license/cliapps.htm</a>
Arkansas	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.healthy.arkansas.gov/programsServices/hsLicensingRegulation/HealthFacilityServices/Pages/default.aspx">http://www.healthy.arkansas.gov/programsServices/hsLicensingRegulation/HealthFacilityServices/Pages/default.aspx</a>
California	Yes	Restrictions. For Public Health, follow the California Implementation Guide for HCV testing. The Department of Health will require training by the Office of AIDS prior to conducting HCV testing. <a href="http://www.dhcs.ca.gov/provgovpart/Pages/ClinicalLabProviderApplicationPackage.aspx">http://www.dhcs.ca.gov/provgovpart/Pages/ClinicalLabProviderApplicationPackage.aspx</a>
Colorado	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.cdphe.state.co.us/lr/pages/cert/clinical.htm">http://www.cdphe.state.co.us/lr/pages/cert/clinical.htm</a>
Connecticut	Yes	No restrictions. Non-Medical personnel may perform CLIA-waived tests under the supervision of a licensed physician of record (e.g. at a health fair or community based-organization). The clinician does not need to be on site but must provide guidance on what tests to perform and what to do in case of an emergency, etc.) <a href="http://www.ct.gov/dph/site/default.asp">http://www.ct.gov/dph/site/default.asp</a>

<b>State</b>	<b>Can Perform Non-Medical Personnel Use CLIA-waived Tests?</b>	<b>Notes/Recommended Resources</b>
<b>Delaware</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://dhss.delaware.gov/dhss/dph/lab/clia.html">http://dhss.delaware.gov/dhss/dph/lab/clia.html</a>
<b>District of Columbia</b>	Yes	No restrictions. Non-medical personnel may perform CLIA-waived tests under the supervision of a clinician within a clinical laboratory license by and registered within the state. <a href="http://www.dchealth.dc.gov/doh/site/default.asp">http://www.dchealth.dc.gov/doh/site/default.asp</a>
<b>Florida</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/index.shtml">http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/index.shtml</a>
<b>Georgia</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://health.state.ga.us/">http://health.state.ga.us/</a>
<b>Hawaii</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://hawaii.gov/health">http://hawaii.gov/health</a>
<b>Idaho</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://healthandwelfare.idaho.gov/Health/Labs/CertificationClinicalLabsMammographyXRray/tabid/186/Default.aspx">http://healthandwelfare.idaho.gov/Health/Labs/CertificationClinicalLabsMammographyXRray/tabid/186/Default.aspx</a>
<b>Illinois</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.ilga.gov/commission/jcar/admincode/077/07700450sections.html">http://www.ilga.gov/commission/jcar/admincode/077/07700450sections.html</a>
<b>Indiana</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.in.gov/isdh/20129.htm">http://www.in.gov/isdh/20129.htm</a>
<b>Iowa</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.idph.state.ia.us/">http://www.idph.state.ia.us/</a>
<b>Kansas</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.kdheks.gov/lipo/clia_survey_and_cert.htm">http://www.kdheks.gov/lipo/clia_survey_and_cert.htm</a>

State	Can Perform Non-Medical Personnel Use CLIA-waived Tests?	Notes/Recommended Resources
Kentucky	Yes	No restrictions. Follow federal law guidelines. <a href="http://chfs.ky.gov/dms/ilab.htm">http://chfs.ky.gov/dms/ilab.htm</a>
Louisiana	Yes	No restrictions. Follow federal law guidelines. <a href="http://new.dhh.louisiana.gov/index.cfm/newsroom/category/19">http://new.dhh.louisiana.gov/index.cfm/newsroom/category/19</a>
Maine	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.maine.gov/sos/cec/rules/10/144/144c256.doc">www.maine.gov/sos/cec/rules/10/144/144c256.doc</a>
Maryland	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.dhmh.maryland.gov/ohcq/Labs/sitePages/Licensure.aspx">http://www.dhmh.maryland.gov/ohcq/Labs/sitePages/Licensure.aspx</a>
Massachusetts	Yes	No restrictions. Follow federal law guidelines. <b>NOTE:</b> Physician offices laboratories with 3 or more physicians require a State Licensure in addition to a CLIA-waiver. <a href="http://www.mass.gov/eohhs/gov/departments/dph/programs/clinical-lab.html">http://www.mass.gov/eohhs/gov/departments/dph/programs/clinical-lab.html</a>
Michigan	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.michigan.gov/lara/0,4601,7-154-27417_27655_31191---,00.html">http://www.michigan.gov/lara/0,4601,7-154-27417_27655_31191---,00.html</a>
Minnesota	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&amp;dDocName=dhs16_144353&amp;RevisionSelectionMethod=LatestReleased">http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&amp;dDocName=dhs16_144353&amp;RevisionSelectionMethod=LatestReleased</a>
Mississippi	Yes	No restrictions. Follow federal law guidelines. <a href="http://new.dhh.louisiana.gov/index.cfm/page/287">http://new.dhh.louisiana.gov/index.cfm/page/287</a>
Missouri	Yes	No restrictions. Follow federal law guidelines. <a href="http://health.mo.gov/lab/certifications.php">http://health.mo.gov/lab/certifications.php</a>
Montana	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.dphhs.mt.gov/">http://www.dphhs.mt.gov/</a>

State	Can Perform Non-Medical Personnel Use CLIA-waived Tests?	Notes/Recommended Resources
Nebraska	Yes	No restrictions. Follow federal law guidelines. <a href="http://dhhs.ne.gov/publichealth/Pages/crl_hcddlabs_labs_labs.aspx">http://dhhs.ne.gov/publichealth/Pages/crl_hcddlabs_labs_labs.aspx</a>
Nevada	Yes	Non-medical personanel may perform CLIA-waived tests under the supervision of a clinician within a clinical laboratory license by and registered within the state. <a href="http://health.nv.gov/HCQC_Medical.htm">http://health.nv.gov/HCQC_Medical.htm</a>
New Hampshire	Yes	Restrictions. Non-medical personnel performing lab test in health centers and other settings other than a physician's office must have at least an Associates Degree in lab sciences. The health centers register with the State. They can also apply for a waiver to the Associates Degree requirement by demonstrating that the non-medical personnel have comparable adequate training. <a href="http://www.dhhs.nh.gov/oos/bhfa/contact.htm">http://www.dhhs.nh.gov/oos/bhfa/contact.htm</a>
New Jersey	Yes	Restrictions. In addition to a CLIA certificate, labs must obtain a NJ clinical laboratory license if they perform additional waived tests outside the original 8 permitted (e.g. urinalysis, fecal occult blood, non-automated erythrocyte sedimentation rate, etc.). Test is not waived under New Jersey's rules for the operation of clinical laboratories at N.J.A.C 8:44. <a href="http://web.doh.state.nj.us/apps2/forms/index.aspx">http://web.doh.state.nj.us/apps2/forms/index.aspx</a>
New Mexico	Yes	No restrictions. Follow federal law guidelines. <a href="http://dhi.health.state.nm.us/clia/index.php">http://dhi.health.state.nm.us/clia/index.php</a>
New York	Yes	Restrictions. To perform a CLIA-waived test, sites must register with the State as Limited Service Lab. Requirements include a Clinical Laboratory Evaluation Program (CLEP). <a href="http://www.wadsworth.org/labcert/clep/Administrative/apps.htm">http://www.wadsworth.org/labcert/clep/Administrative/apps.htm</a>
North Carolina	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.ncdhhs.gov/dhsr/ahc/clia/cliafaq.html">http://www.ncdhhs.gov/dhsr/ahc/clia/cliafaq.html</a>

State	Can Perform Non-Medical Personnel Use CLIA-waived Tests?	Notes/Recommended Resources
North Dakota	Yes	Restrictions. Only the original 6 CLIA-waived tests may be performed unless certificate was obtained prior to 1991. To perform CLIA-waived tests, non-medical personnel must have a Bachelor's degree, participate in continuing education, and be registered with a licensed clinical lab. <a href="http://www.ndhealth.gov/hf/ndclia.htm">http://www.ndhealth.gov/hf/ndclia.htm</a>
Ohio	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.odh.ohio.gov/odhPrograms/dspc/labcert/labcert1.aspx">http://www.odh.ohio.gov/odhPrograms/dspc/labcert/labcert1.aspx</a>
Oklahoma	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.ok.gov/health/Protective_Health/Medical_Facilities_Service/Facility_Services_Division/index.html">http://www.ok.gov/health/Protective_Health/Medical_Facilities_Service/Facility_Services_Division/index.html</a>
Oregon	Yes	No restrictions. Follow federal law guidelines. <a href="http://public.health.oregon.gov/LaboratoryServices/ClinicalLaboratoryRegulation/Pages/index.aspx">http://public.health.oregon.gov/LaboratoryServices/ClinicalLaboratoryRegulation/Pages/index.aspx</a>
Pennsylvania	Yes	Restrictions. Non-medical personnel may perform CLIA-waived tests under the supervision of a doctorate-level clinician within a clinic or site registered by the State or under the supervision, within that clinic, of a BS-level staff person with 6 years of lab supervision experience. <a href="http://www.portal.health.state.pa.us/portal/server.pt/community/department_of_health_home/17457">http://www.portal.health.state.pa.us/portal/server.pt/community/department_of_health_home/17457</a>
Rhode Island	Yes	No restrictions. Follow federal law guidelines. <b>NOTE:</b> Sites promoting public health fairs may require a Blood Testing Screening Permit in addition to a CLIA certificate. Contact Nancy Hines at 401-222-4526 to assess additional requirements. <a href="http://www.health.ri.gov/programs/laboratory/">http://www.health.ri.gov/programs/laboratory/</a>
South Carolina	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.scdhec.gov/health/cert/clia_fa_q.htm">http://www.scdhec.gov/health/cert/clia_fa_q.htm</a>
South Dakota	Yes	No restrictions. Follow federal law guidelines. <a href="http://legis.state.sd.us/rules/DisplayRule.aspx?Rule=44:67:04:11">http://legis.state.sd.us/rules/DisplayRule.aspx?Rule=44:67:04:11</a>



<b>State</b>	<b>Can Perform Non-Medical Personnel Use CLIA-waived Tests?</b>	<b>Notes/Recommended Resources</b>
<b>Tennessee</b>	Yes	Restrictions. The Laboratory Board reviews each test to determine whether it may be performed by non-medical personnel. A list of which tests are exempted is available on the TN DOH website. HIV and STD testing for public health screening purposes and is overseen by the State Health Dept. CBOs may apply for a CLIA waiver and, after a site visit to ensure staff are trained be designated by the health dept. to do HIV/STD rapid testing. For non-medical personnel to administer HCV tests in a public health setting, the Health Dept. would have to ask the Lab Board for an exemption. Board meets in January, April, July and October. <a href="http://health.state.tn.us/HCF/federal.htm">http://health.state.tn.us/HCF/federal.htm</a>
<b>Texas</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.dshs.state.tx.us/hfp/apps.shtm">http://www.dshs.state.tx.us/hfp/apps.shtm</a>
<b>Utah</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://health.utah.gov/lab/labimp/labcert/clialabcert.html">http://health.utah.gov/lab/labimp/labcert/clialabcert.html</a>
<b>Vermont</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.dlp.vermont.gov/other/other">http://www.dlp.vermont.gov/other/other</a>
<b>Virginia</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.vdh.state.va.us/OLC/AcuteCare/clia.htm">http://www.vdh.state.va.us/OLC/AcuteCare/clia.htm</a>
<b>Washington</b>	Yes	Non-medical personanel may perform CLIA-waived tests under the supervision of a clinician within a clinical laboratory license by and registered within the state. <a href="http://www.doh.wa.gov/hsqa/fsl/lqa_home.htm">http://www.doh.wa.gov/hsqa/fsl/lqa_home.htm</a>
<b>West Virginia</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.wvdhhr.org/labservices/compliance/clia/index.cfm">http://www.wvdhhr.org/labservices/compliance/clia/index.cfm</a>
<b>Wisconsin</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.dhs.wisconsin.gov/rl_dsl/publications/09-040.htm">http://www.dhs.wisconsin.gov/rl_dsl/publications/09-040.htm</a>
<b>Wyoming</b>	Yes	No restrictions. Follow federal law guidelines. <a href="http://www.health.wyo.gov/ohls/CLIA.html">http://www.health.wyo.gov/ohls/CLIA.html</a>



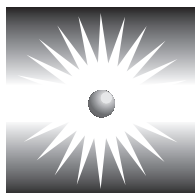
## 8. Quality Assurance Guidelines

*(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/cia0903/C-GuidelinesOraQk.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.*

# Introduction and Background

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**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).

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**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.<sup>1</sup> 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.

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**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.

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**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
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## Basic Elements of a Quality Assurance Program

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### 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.

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### 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<sup>2</sup>:

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

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### 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

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### 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.

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### 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.

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## Organization of the QA program (continued)

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### 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).

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



## Testing Personnel

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### 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.
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### Components of training

Training is crucial to ensuring quality testing.<sup>3</sup> 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.
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## Testing Personnel (continued)

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<b>Training method</b>	<p>Experience with training to perform the OraQuick® HCV test shows that a training method should optimally include the following activities:</p> <ul style="list-style-type: none"><li>• Read the instructions for performing the test.</li><li>• Watch someone perform the test or view a video of someone performing the test.</li><li>• Identify correctly all the devices provided within the OraQuick® HCV Visual Reference Panel.</li><li>• Practice performing the test with a positive HCV and a negative control.</li><li>• Practice performing the fingerstick collection procedure.*</li><li>• Review the procedures and forms on how to document testing.</li></ul>
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<b>Competency assessment</b>	<p>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.</p>
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<b>Assessing performance of tasks done before testing</b>	<p>To assess the task performance before testing, staff should be observed as they:</p> <ul style="list-style-type: none"><li>• Check and record the temperatures of the testing and storage areas.</li><li>• Set up the testing area, label the device and prepare control and test results log sheets.</li><li>• Run the external controls and record results.</li></ul>
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\*Refer to the OraQuick® HCV Rapid Antibody Test package insert for complete instructions.

## Testing Personnel (continued)

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### 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.

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### 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
<ul style="list-style-type: none"> <li>• Check storage and room temperatures daily</li> <li>• Check inventory and test kit lots as needed</li> <li>• Receive request for testing</li> <li>• Discuss the Hepatitis C Virus</li> <li>• Set up test area, label test device</li> <li>• Perform external quality control according to the manufacturer’s and the site’s instructions</li> </ul>	<ul style="list-style-type: none"> <li>• Follow biohazard safety precautions</li> <li>• Collect the fingerstick or venipuncture specimen</li> <li>• Perform the test</li> <li>• Interpret test results</li> </ul>	<ul style="list-style-type: none"> <li>• Clean up and dispose of biohazardous waste</li> <li>• Report results to client</li> <li>• Document results</li> <li>• Provide information for clinical follow-up (linkage to supplemental testing and evaluation)</li> <li>• Participate in external quality assessment (periodically)</li> </ul>

## Before Testing

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### 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.

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### 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.

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### 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.

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### 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.

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# 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)<sup>4</sup> 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)

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### **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

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### 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.

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### Fingerstick whole blood collection

Follow the written procedure for fingerstick specimen collection.

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### Venipuncture whole blood collection

Refer to the Clinical and Laboratory Standards Institute (CLSI) procedure for venipuncture specimen collection.

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## During Testing (continued)

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**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 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 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.<sup>1,6,7,8</sup>

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## After Testing

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### 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.

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## After Testing (continued)

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### **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.\*

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\*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)

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### **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

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### 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.

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## Troubleshooting

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**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.

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**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.

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## 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

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### 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

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### **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)

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### **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.

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### **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>.

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## Government Regulations (continued)

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### 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

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#### **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.

---

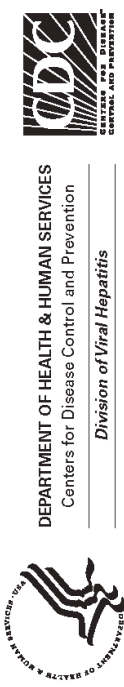
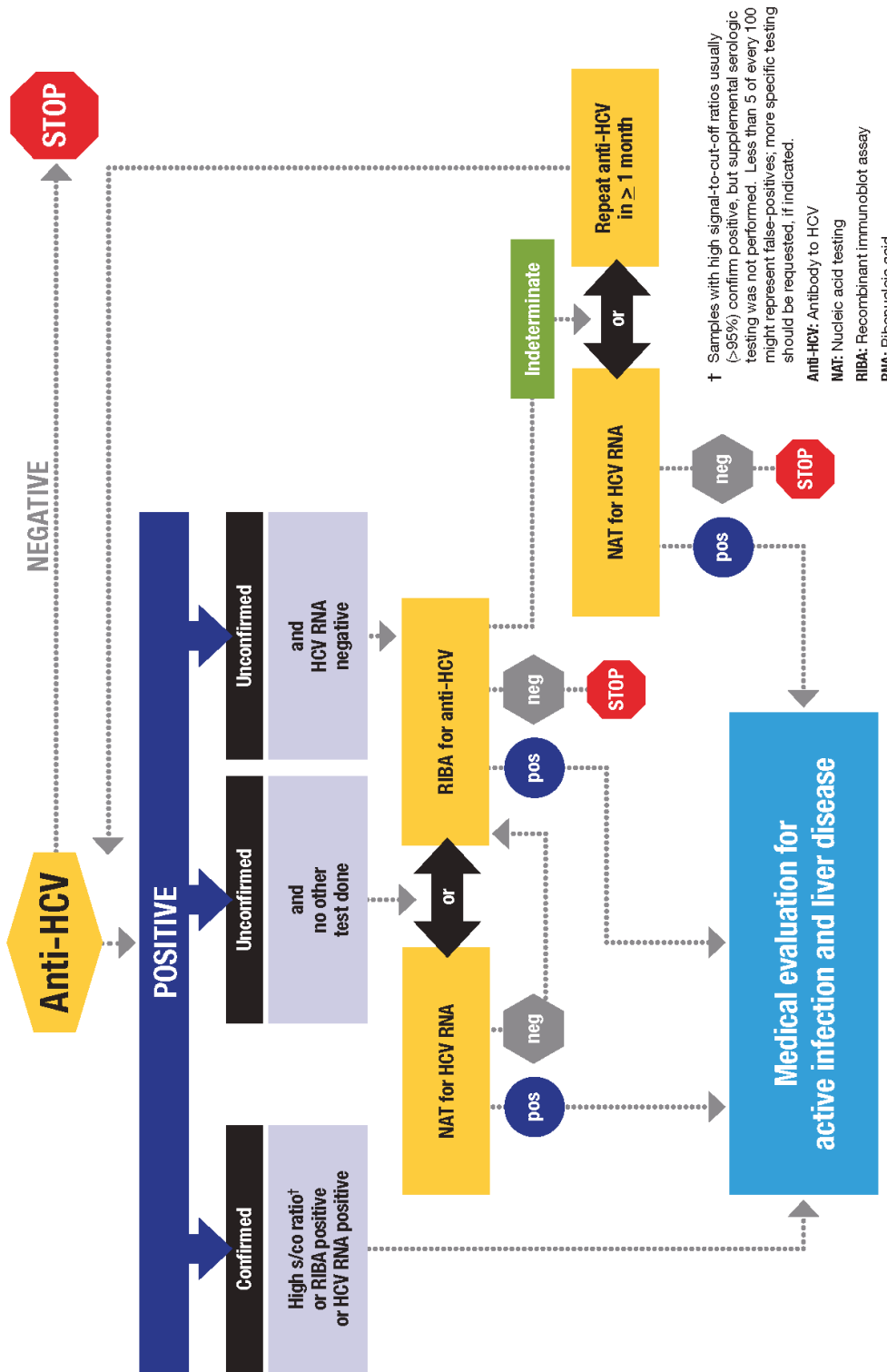
#### **Evaluation reports**

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

# Hepatitis C Virus (HCV) Infection Testing for Diagnosis



www.cdc.gov/hepatitis



Linking people to care

## 9. Support Documents and Forms



**Support Documents and Forms**

Checklist for Conducting Rapid HCV Tests ..... 9-2

HCV Positive Enhance Risk Assessment Tool ..... 9-4

Client Test Result Log ..... 9-5

Product Information Training ..... 9-7

Proficiency Testing Panel Results ..... 9-12

Investigational and Remedial Action on Unacceptable Proficiency Testing ..... 9-13

Clinic Communication and Complaint Log ..... 9-14

# Checklist for Conducting Rapid HCV Tests

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## General Test Preparation

- Conditions for testing verified (temperature and lighting)
- Clock or timer made available
- Expiration date verified on Pouch
- Clean, disposable absorbent workspace cover
- Manufacturer's Stand used
- Stand is on flat level surface
- Test Device left in pouch until needed (not contaminated)
- Absorbent Packet included in Pouch
- Vial slid into Stand
- Vial is completely seated in Stand
- Two holes in back of Test Device not covered

## Sample Collection and Test Procedures - Fingerstick Whole Blood Collection

- Disposable gloves worn
- Client finger cleaned with antiseptic wipe
- Finger allowed to dry thoroughly
- Second drop of blood collected
- Loop was completely filled with blood
- Loop stirred into Developer Solution
- Solution turned pink
- Pad on the Test Device touched the bottom of the vial
- Results Window faced forward
- Timer used
- Results read between 20 and 40 minutes after Test Device inserted into the vial
- Test Device read while in Developer Solution Vial
- Test results properly recorded

# Checklist for Conducting Rapid HCV Tests

---

## Sample Collection and Test Procedures - Venipuncture Whole Blood Collection

- Specimen collection conducted with an EDTA, lithium heparin, sodium heparin or sodium citrate test tube
- Loop was completely filled with blood
- Loop stirred into Developer Solution
- Solution turned pink
- Pad on the Testing Device touched the bottom of the vial
- Results Window faced forward
- Timer used
- Results read between 20 and 40 minutes after Testing Device inserted into the vial
- Test Device read while in Developer Solution Vial

## Quality Control (To be conducted as per manufacturer's guidelines)

- Kit Controls run; Date and Time\_\_\_\_\_
- Kit Controls verify Control Test Results match the expected results
- Good lighting used with Controls
- Test viewed good lighting conditions
- Clinic room temperature checked and recorded

**Comments:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

# HCV Positive Enhanced Risk Assessment Tool

---

1. Did you receive a blood transfusion or solid organ transplant (heart, lung, liver, pancreas, kidney) before July 1992?  No  Yes
2. Did you receive clotting factor concentrates produced before 1987?  No  Yes
3. Have you ever received hemodialysis?  No  Yes
4. Have you had blood tests that showed a liver problem?  No  Yes
5. Have you had a needlestick injury working in a health care setting?  No  Yes
6. Did your mother have hepatitis C when you were born?  No  Yes
7. Have you shared a toothbrush, razor, or any other item that might have blood on it (visible or not) with a person who has hepatitis C?  No  Yes
8. Have you or any of your sex partner(s) injected illegal drugs, even if it was only one time many years ago?  No  Yes
9. Have you ever been told by a medical provider that you have HIV infection?  No  Yes

Clinic Name/Site Location: \_\_\_\_\_

Name/ID Number: \_\_\_\_\_ Date: \_\_\_\_\_

Counselor/Tester: \_\_\_\_\_ Date: \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## OraQuick® HCV Rapid Antibody Test Client Test Result Log

Clinic Name: \_\_\_\_\_

Testing Location: \_\_\_\_\_

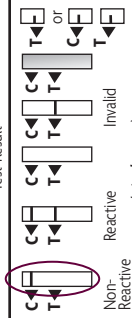
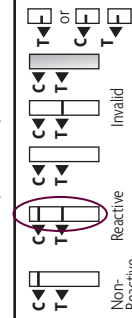
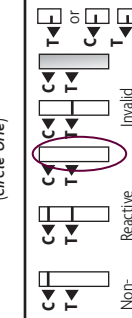
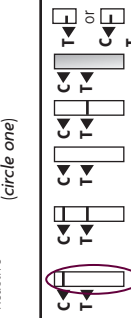
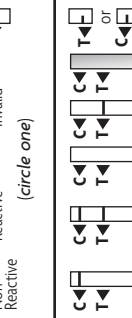
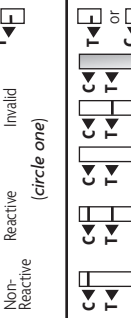
Client ID/Name	Counselor Code/Initials	Test Dates mm/dd/yy	Test # Performed	Lot #/Exp. Date of Test	Time Test Performed	Testing Room Temperature	Time Test Interpreted	Testing Room Temperature	Test Result	Date Client Received Result	Result & Type of Supplemental Serum or Plasma	Date Client Received Test/Suppl Result	How Result Received by: Phone (PH) or Result in Person (IP)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	C T Non-Reactive Reactive Invalid (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	C T Non-Reactive Reactive Invalid (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	C T Non-Reactive Reactive Invalid (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	C T Non-Reactive Reactive Invalid (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	C T Non-Reactive Reactive Invalid (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	____ a.m. ____ p.m. (circle one)	____ °C ____ °F (circle one)	C T Non-Reactive Reactive Invalid (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)



# OraQuick® HCV Rapid Antibody Test Client Test Result Log

Clinic Name: \_\_\_\_\_

Testing Location: \_\_\_\_\_

Client ID/Name	Counselor Code/Initials	Test Dates mm/dd/yy	Test # Performed	Lot #/Exp. Date of Test	Time Test Performed	Testing Room Temperature	Time Test Interpreted	Testing Room Temperature	Test Result	Date Client Received Result	Result & Type of Supplemental Serum or Plasma	Date Client Received Test/Suppl Result	How Result Received by: Phone (PH) or Result in Person (IP)
Virginia Hall #12345678	#938-LB	09/05/11	<input checked="" type="checkbox"/> First <input type="checkbox"/> Second	#1234567 12/23/12	8:45 a.m. (circle one)	72.6 °F (circle one)	9:08 a.m. (circle one)	72.6 °F (circle one)	 Reactive (circle one)	9/5/11	<input checked="" type="checkbox"/> Serum <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative	N/A	PH IP (circle one)
Mark Dewitt #12345679	#938-LB	09/05/11	<input checked="" type="checkbox"/> First <input type="checkbox"/> Second	#1234567 12/23/12	9:42 a.m. (circle one)	72.4 °F (circle one)	10:10 a.m. (circle one)	72.0 °F (circle one)	 Reactive (circle one)	Positive 9/5/11	<input type="checkbox"/> Serum <input checked="" type="checkbox"/> Plasma <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative	9/16/03	PH IP (circle one)
Theresa Howard #12345680	#938-LB	09/05/11	<input checked="" type="checkbox"/> First <input type="checkbox"/> Second	#1234567 12/23/12	11:55 a.m. (circle one)	72.0 °F (circle one)	12:17 a.m. (circle one)	72.0 °F (circle one)	 Reactive (circle one)	Invalid N/A	<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
Theresa Howard #12345680	#938-LB	09/05/11	<input type="checkbox"/> First <input checked="" type="checkbox"/> Second Repeat Test	#1234567 12/23/12	12:30 a.m. (circle one)	72.1 °F (circle one)	12:50 a.m. (circle one)	72.2 °F (circle one)	 Reactive (circle one)	9/5/11	<input checked="" type="checkbox"/> Serum <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative	N/A	PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		a.m. p.m. (circle one)	°C °F (circle one)	a.m. p.m. (circle one)	°C °F (circle one)	 Reactive (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)
			<input type="checkbox"/> First <input type="checkbox"/> Second		a.m. p.m. (circle one)	°C °F (circle one)	a.m. p.m. (circle one)	°C °F (circle one)	 Reactive (circle one)		<input type="checkbox"/> Serum <input type="checkbox"/> Plasma <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PH IP (circle one)

# OraQuick® HCV Product Information Training

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Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

Select the best response for statements 1 through 6:

- 1. The complete storage temperature range of the OraQuick® HCV Test Kit is**
  - (a) 2–8°C; 36–46°F
  - (b) 2–30°C; 36–86°F
  - (c) comfortable room temperature - 15°–37°C; 59°–99°F
  
- 2. The complete storage temperature range of the OraQuick® HCV Visual Reference Panel is**
  - (a) 15–30°C; 59–86°F
  - (b) 2–30°C; 36–86°F
  - (c) comfortable room temperature - 15°–37°C; 59°–99°F
  
- 3. The complete storage temperature range of the OraQuick® HCV Kit Controls is**
  - (a) 2–8°C; 36–46°F
  - (b) 2–30°C; 36–86°F
  - (c) comfortable room temperature - 15°–37°C; 59°–99°F
  
- 4. The acceptable temperature range for performing OraQuick® HCV Test is**
  - (a) 2–8°C; 36–46°F
  - (b) 2–37°C; 35–99°F
  - (c) comfortable room temperature - 15°–37°C; 59°–99°F
  
- 5. According to the manufacturer’s instructions, the acceptable time to read the OraQuick® HCV Test Device result is**
  - (a) 10 to 30 minutes
  - (b) 20 to 40 minutes
  - (c) 20 to 80 minutes
  - (d) 10 to 60 minutes
  
- 6. The three possible OraQuick® HCV Test Device result outcomes are**
  - (a) reactive, non-reactive, borderline
  - (b) reactive, non-reactive, inconclusive
  - (c) reactive, non-reactive, weakly reactive
  - (d) reactive, non-reactive, invalid
  
- 7. The blood-filled Specimen Collection Loop**
  - (a) should be rapidly dipped in the Developer Solution Vial and discarded
  - (b) should be stirred in the Developer Solution Vial and then discarded
  - (c) can be left in the Developer Solution Vial for up to 10 minutes and discarded
  - (d) should be stirred in the Developer Solution Vial and then saved until the test is complete

Select True or False for Statements 7 – 16:

**8. When conducting an OraQuick® HCV Test Control, if the positive and/or negative control does not give the correct result(s), clients can still be tested with the OraQuick® HCV Kits.**

True                      False

**9. If the absorbent packet is not present when opening the OraQuick® HCV pouch, the pouch contents should be allowed to remain open for 5 – 10 minutes before using.**

True                      False

**10. The 2 holes in the back of the OraQuick® HCV Test Device must be covered after placing the device into the Developer Solution Vial.**

True                      False

**11. The built-in procedural control in the OraQuick® HCV Test Device is intended to confirm that the patient sample has moved past the Test (T) area.**

True                      False

**12. The Developer Solution Vial must turn pink after adding the fingerstick whole blood sample.**

True                      False

**13. The OraQuick® HCV Test Device should not be removed from the Developer Solution Vial before reading the Test result.**

True                      False

**14. The first drop of blood from a fingerstick can be use to perform the OraQuick® HCV test.**

True                      False

**15. An OraQuick® HCV reactive test result is interpreted as positive test for the presence of HCV antibodies.**

True                      False

**16. OraQuick® HCV is currently CLIA-waiver approved for use in the U.S. with fingerstick whole blood specimens *only*.**

True                      False

# OraQuick® HCV Product Information Training Answer Key

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- 1) **B.** Storage conditions for the OraQuick® HCV Test Kits is 2–30°C; 36–86°F.
- 2) **A.** Storage conditions for the OraQuick® HCV Visual Reference Panel is 15–30°C; 59–86°F.
- 3) **A.** Storage conditions for the OraQuick® HCV Kit Controls is 2–8°C; 35–46°F.
- 4) **C.** Acceptable temperature range for performing the OraQuick® HCV Test Device is a comfortable room temperature of 15°–37°C; 59°–99°F.
- 5) **B.** Acceptable times to read the OraQuick® HCV Test Device is 20 minutes to 40 minutes. **DO NOT** attempt to read the test result after the 40 minute test development.
- 6) **D.** The three possible OraQuick® HCV Test result outcomes is (R) Reactive, (NR) Non-Reactive and (INV) Invalid. An Invalid test result cannot be interpreted and is an indication that there was a problem running the test, either related to the specimen or the Device. A repeat test should be performed with a new Pouch and new sample.
- 7) **B.** The blood-filled Specimen Collection Loop should be gently stirred in the Developer Solution Vial and then immediately discarded in a bio-hazard waste container.
- 8) **False.** If the kit controls DO NOT produce the expected outcome of a reactive and non-reactive result prior to testing a patient sample, re-run the controls. If the test devices still do not produce a reactive and non-reactive result, contact OraSure Technologies. DO NOT conduct any patient testing.
- 9) **False.** An absorbent packet is included in each Device Pouch to ensure that moisture levels are maintained and do not compromise the Test Device performance. The absence of an absorbent packet means that the Test Device may have been compromised during storage. Immediately discard package, device and developer vial and open a new pouch to proceed.
- 10) **False.** The two holes at the back of the OraQuick® HCV Test Device are part of the design of the lateral flow system. Blocking these holes with labels and or other materials will interfere with the test development.
- 11) **True.** The built-in procedural control on the OraQuick® Test Device is designed to verify that the chemistry of the test has flowed past the “T” or Test Line of the Device and that a sample was added to the Developer Vial Solution.
- 12) **True.** If the blood-filled loop has been properly introduced to the Developer Solution Vial, the solution will turn a shade of pink indicating sample has been mixed.
- 13) **True.** The OraQuick® HCV Test Device should not be removed from the Developer Solution Vial until the test result has been read, interpreted and documented.
- 14) **False.** The first droplet of blood should be wiped away from the finger. Typically, the first droplet will contain tissue sample as well as blood. This may interfere with the test performance. Apply the loop to the second droplet for a clean sample.
- 15) **True.** An OraQuick® HCV Reactive test results is reported as a POSITIVE. OraQuick® HCV Rapid Antibody Test is a qualitative immunoassay test. A positive test result indicates that the presence of HCV antibodies have been detected. The patient should undergo appropriate clinical follow-up for supplemental testing.
- 16) **False.** The OraQuick® HCV Rapid Antibody Test is CLIA-waived approved in fingerstick **AND** venipuncture whole blood.

# OraQuick® HCV Rapid Test Result Panel Training

Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



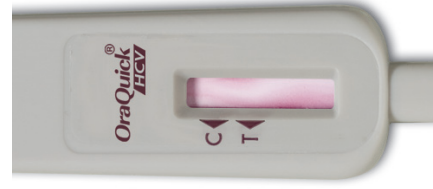
Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_



Result: \_\_\_\_\_

Write the Result on the line below each Test Device: Non-Reactive (NR); Reactive (R); Invalid (INV)

# OraQuick® HCV Test Result Panel Training Answer Key

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## OraQuick® Rapid Test Result Panel Training - Answer Key

- 1) **NR.** Test line appears only in the “C” designated area, indicating no detection of HCV antibodies are present at the time the test was conducted. Patient is presumed not to be infected with HCV.
- 2) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.
- 3) **INV.** No test lines appear in the “T” or “C” designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new specimen.
- 4) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.
- 5) **INV.** No test lines appear in the “C” designated area and only a partial line appears in the “T” designated area. This result means there was a problem running the test, either related to the specimen or to the Device. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 6) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.
- 7) **INV.** No test lines appear in the “T” or “C” designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 8) **INV.** Partial test lines appear inside the “T” and “C” designated areas. While on appearance, it would seem that a POSITIVE could be interpreted, the partial development of the test lines are not fully developed within the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.
- 9) **NR.** Test line appears only in the “C” designated area, indicating no detection of HCV antibodies are present at the time the test was conducted. Patient is presumed not to be infected with HCV.
- 10) **R.** Test lines appear in the “C” and “T” designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the “T” line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.

# Proficiency Testing Panel Results

## Specimen Proficiency Panel Interpretation:

For each specimen, indicate the result with a checkmark for either REACTIVE, NON-REACTIVE, or INVALID.

Assay Lot #: \_\_\_\_\_

Specimen A:  REACTIVE  NON-REACTIVE  INVALID

Specimen B:  REACTIVE  NON-REACTIVE  INVALID

Specimen C:  REACTIVE  NON-REACTIVE  INVALID

Specimen D:  REACTIVE  NON-REACTIVE  INVALID

Specimen E:  REACTIVE  NON-REACTIVE  INVALID

To be completed by study monitor:

<input type="checkbox"/> CORRECT	<input type="checkbox"/> INCORRECT
<input type="checkbox"/> CORRECT	<input type="checkbox"/> INCORRECT
<input type="checkbox"/> CORRECT	<input type="checkbox"/> INCORRECT
<input type="checkbox"/> CORRECT	<input type="checkbox"/> INCORRECT
<input type="checkbox"/> CORRECT	<input type="checkbox"/> INCORRECT

Clinic Name/Site Location: \_\_\_\_\_

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Score: \_\_\_\_\_ Trainer/Tester: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

# Investigational and Remedial Action on Unacceptable Proficiency Testing

Date of Investigation: \_\_\_\_\_ Clinic Name/Site Location: \_\_\_\_\_

Prepared by: \_\_\_\_\_

Client Sample: <input type="checkbox"/> Yes <input type="checkbox"/> No	Control Sample: <input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Testing:	Time of Testing:
Lot # of Test Device:	Exp. Date of Test Device:
Unacceptable (Reported) Result:	
Acceptable Result Range:	
Day of Testing - Quality Control Results Reviewed: <input type="checkbox"/> Yes <input type="checkbox"/> Acceptable <input type="checkbox"/> Not Acceptable Indicate Corrective Action:	
Clerical/Transcription Review: <input type="checkbox"/> Acceptable <input type="checkbox"/> Not Acceptable Indicate Corrective Action:	
Was Patient Reported Results Affected? <input type="checkbox"/> No, ( <i>skip to next section</i> ) <input type="checkbox"/> Yes Indicate Corrective Action:	
Classification of Problem: <input type="checkbox"/> Clerical <input type="checkbox"/> Technical <input type="checkbox"/> Methodology <input type="checkbox"/> Problem with Client  <input type="checkbox"/> Training Issue <input type="checkbox"/> No Explanation	
Conclusions:	
Corrective Actions/System Change(s) To Prevent Recurrence:	
Supervisor:	Date:
Lab Director:	Date:

Upon Completion - This Record Must be Maintained According to Local Regulations



## Clinic Communication and Complaint Log

Clinic Name/Site Location:		
Date Reported:	Time:	Initiated By:
Source of Communication/Complaint:		
Date of Occurrence:	Time:	
Narrative of Event (If necessary):		
Immediate Corrective Action Taken:		
Does the written procedure cover how to deal with this event? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable		
<b>*If No – Procedure must be updated within fifteen days from date of event.</b>		
<b>If Yes – Was the written procedure followed?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>If No – Why not? Explain Below</b>	
<b>Follow-up Activities Required?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>If Yes-Indicate what and date to be completed below</b>	
Form Completed by:		Date:
Signature		Date:

Upon Completion - This Record Must be Maintained According to Local Regulations

## Clinic Communication and Complaint Log

Clinic Name/Site Location: <b>Schnectady Women's Health Clinic - Schnectady, New York</b>		
Date Reported: <b>9/5/11</b>	Time: <b>9:50 a.m.</b>	Initiated By: <b>Josephine Parker</b>
Source of Communication/Complaint: <b>Kathy DeWitt's (#1234581) Rapid HCV Screening Test revealed a "Positive" test result. Client verbally provided Informed Consent but refuses clinical follow-up and supplemental testing.</b>		
Date of Occurrence: <b>9/5/11</b>	Time: <b>9:00 a.m.</b>	
Narrative of Event (If necessary): <b>Explained to Ms. DeWitt's the importance of clinical follow-up appointments and the need to perform supplemental testing for the detection of viremia as well as including importance of receiving future medical care and treatment. Reviewed availability of local programs and further counseling information. Re-emphasized the issues of protection from potential exposure to partner.</b>		
Immediate Corrective Action Taken:		
Does the written procedure cover how to deal with this event? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <b>*If No – Procedure must be updated within fifteen days from date of event.</b>		
If Yes – Was the written procedure followed?  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No – Why not? Explain Below	
Follow-up Activities Required?  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If Yes-Indicate what and date to be completed below	
Form Completed by: <b>Josephine Parker</b>		Date: <b>9/5/11</b>
Signature  <i>Diane Rancer - Supervisor</i>		Date: <b>9/5/11</b>

Upon Completion - This Record Must be Maintained According to Local Regulations



Linking people to care

## 10. Product Documentation



**OraQuick**® Rapid Antibody Test  
**HCV**



OraSure Technologies, Inc.

## OraQuick® HCV Rapid Antibody Test Customer Letter

Dear Customer,

Thank you for deciding to use the OraQuick® HCV Rapid Antibody Test. The sale, distribution, and use of this product is restricted as described in the product insert. By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the following restrictions on the sale, distribution, and use of the device:

- 1. Sale of the OraQuick® HCV Rapid Antibody Test is restricted to healthcare professionals:**
  - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met;
  - where there is assurance that operators will receive and use the instructional materials.
- 2. This assay has not been FDA approved for use in patient populations without signs, symptoms, or not at risk for hepatitis C infection.**
- 3. Not for use in screening whole blood, plasma, or tissue donors. Performance characteristics have not been established for testing a pediatric population less than 15 years of age or for pregnant women.**

**READER PROFICIENCY:** All new operators **MUST** be able to correctly interpret all devices provided within the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test. The clinical performance of this device was established based on an operator's ability to read visual intensities at the "T" line at all levels including very weak bands representing low antibody levels.

The package insert for the OraQuick® HCV Rapid Antibody Test contains warnings and precautions, restrictions on the sale, distribution, and use of the device, and information about how the device works, how to use the device, interpretation of the results, and limitations of the OraQuick® HCV Rapid Antibody Test and the meaning of a reactive or non-reactive result with the OraQuick® HCV Rapid Antibody Test, as well as general information about Hepatitis C Virus. You should review all of these materials yourself.

If you have any questions, please call us toll-free at 1-800-ORASURE (1-800-672-7873) or 1-800-869-3538 and ask for customer service.

Sincerely,  
OraSure Technologies' Customer Service

### References

1. CLSI Document GP2-A5, Laboratory Documents: Development and Control
2. CLSI Document GP27-A2, Using Proficiency Testing (PT) to Improve the Clinical Laboratory
3. CLSI Document POCT4-A2, Point-of-Care In Vitro Diagnostic (IVD) Testing



- If you are a new operator, before proceeding you **MUST** be able to correctly interpret the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test device.
- Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.
- Read this package insert completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results.
- Before performing the testing, all operators **MUST** read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>

### **COMPLEXITY: WAIVED**

For fingerstick whole blood and venipuncture whole blood.

A CLIA Certificate of Waiver is required to perform the test in a waived setting. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at [www.cms.hhs.gov/CLIA](http://www.cms.hhs.gov/CLIA) or from your state health department.

Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification and will be subject to all applicable CLIA requirements.

### **RESTRICTIONS**

- **Sale of the OraQuick® HCV Rapid Antibody Test is restricted to healthcare professionals:**
  - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met;
  - where there is assurance that operators will receive and use the instructional materials.
- **This assay has not been FDA approved for use in patient populations without signs, symptoms, or not at risk for hepatitis C infection.**
- **Not for use in screening whole blood, plasma, or tissue donors. Performance characteristics have not been established for testing a pediatric population less than 15 years of age or for pregnant women.**

### **NAME AND INTENDED USE**

The OraQuick® HCV Rapid Antibody Test is a single-use immunoassay for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in fingerstick whole blood specimens and venipuncture whole blood specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate) from individuals 15 years or older. The OraQuick® HCV Rapid Antibody Test results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HCV (state of infection or associated disease not determined) in persons with signs or symptoms of hepatitis and in persons at risk for hepatitis C infection.

**Warning: This assay has not been FDA approved for use in patient populations without signs, symptoms, or not at risk for hepatitis C infection.**

**Not for use in screening whole blood, plasma, or tissue donors. Performance characteristics have not been established for testing a pediatric population less than 15 years of age or for pregnant women.**

### **SUMMARY AND EXPLANATION OF THE TEST**

Hepatitis C virus is a single-stranded ribonucleic acid RNA virus responsible for most, if not all non-A, non-B hepatitis.<sup>2</sup> HCV is primarily transmitted by contact with contaminated blood, blood products, or through other close personal contact.<sup>3</sup> The presence of antibodies to HCV indicates that the individual may be currently infected and capable of transmitting the virus.

The OraQuick® HCV Rapid Antibody Test utilizes an indirect lateral flow immunoassay method to detect antibodies to both structural and non-structural HCV proteins. The device utilizes synthetic peptides and recombinant antigens from the core, NS3, and NS4 regions of the HCV genome, that are immobilized as a single test line on the assay strip. Antibodies reacting with these peptides and antigens are visualized by colloidal gold labeled with protein A generating a visible line in the test zone for a reactive sample.

## PRINCIPLES OF THE TEST

The OraQuick® HCV Rapid Antibody Test is a manually performed, visually read immunoassay for the qualitative detection of HCV antibodies in human fingerstick and venipuncture whole blood. The OraQuick® HCV Rapid Antibody Test is comprised of both a single-use test device and vial containing a pre-measured amount of a buffered developer solution. The test consists of a sealed pouch with two separate compartments for each component. The OraQuick® HCV Rapid Antibody Test utilizes a proprietary lateral flow immunoassay procedure.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides and recombinant proteins from the core, NS3, and NS4 regions of the HCV genome (test) and a goat anti-human IgG (procedural control) immobilized onto a nitrocellulose membrane at the Test (T) and the Control (C) Zone, respectively.

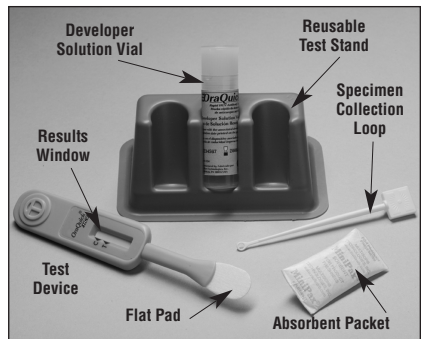
A fingerstick whole blood specimen or venipuncture whole blood specimen is collected using a specimen loop and transferred into the developer solution vial, followed by the insertion of the device. The developer solution facilitates the capillary flow of the specimen into the device and onto the assay strip. As the specimen flows through the device, antibodies from the specimen are bound to the protein A gold colorimetric reagent present on the assay strip. If the specimen contains anti-HCV antibodies, the resulting labeled complexes contain HCV antibody and bind to immobilized HCV antigens at the HCV Test Zone (T Zone) resulting in a reddish-purple line. If the specimen does not contain anti-HCV antibodies, the labeled complexes do not bind at the HCV Test Zone and no line is observed in the T Zone. The intensity of the line color is not directly proportional to the amount of HCV antibody present in the specimen. The remaining labeled complexes are transported to the Control Zone (C Zone) binding to a goat anti-human antibody fragment. The presence of IgG antibodies in the sample (regardless of their specificity) results in a reddish-purple line at the C Zone. This procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the device. A reddish-purple line will appear at the C Zone during the performance of all valid tests; whether or not the sample is positive or negative for HCV antibodies (refer to the *Test Result and Interpretation of Test Result* section in this package insert).

The test results are interpreted after 20 minutes, but not more than 40 minutes following the introduction of the device into the developer solution vial. No precision pipetting, pre-dilutions, or specialized instrumentation are required to perform the OraQuick® HCV Rapid Antibody Test.

## MATERIALS PROVIDED

**OraQuick® HCV Rapid Antibody Test Kits are available in the following packaging configurations:**

Components of Kit Catalog Number	25 Count Kit 1001-0181	100 Count Kit 1001-0180
Divided Pouch, Each containing: Test Device (1) Absorbent Packet (1) Developer Solution Vial (1) (each vial contains 0.750 mL of a buffered saline solution with an antimicrobial agent)	25	100
Reusable Test Stands	5	10
Specimen Collection Loops	25	100
Package Insert	1	1



## MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

### OraQuick® HCV Rapid Antibody Test Kit Controls 1001-0182

Package contains:

- HCV Positive Control (1 vial, purple cap, 0.2 mL),
- HCV Negative Control (1 vial, white cap, 0.2 mL), and
- Package Insert

### OraQuick® HCV Visual Reference Panel 1001-0343

**Package Contains:**

- HCV Limit of Detection (1 device)
- HCV Low Reactive (1 device)
- HCV Non-Reactive (1 device)

## MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 20 to 40 minutes

Biohazard waste container

Materials required for venipuncture whole blood specimen collection

Sterile lancet to obtain a fingerstick whole blood specimen

## WARNINGS

### For *in vitro* Diagnostic Use

- This package insert must be read completely before using the product.
- Follow the instructions carefully when performing the OraQuick® HCV Rapid Antibody Test, failure to do so may cause an inaccurate test result.
- All new operators that have not previously demonstrated proficiency in the use of this device **MUST** be able to correctly interpret all devices provided within the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.
- Before proceeding with testing, all operators **MUST** read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>
- This kit has been approved for use with fingerstick whole blood and venipuncture whole blood specimens only. Use of this test kit with specimen types other than those specifically approved for this device may cause inaccurate test results.
- This test is not intended to be used to monitor individuals who are undergoing treatment.
- This test should be performed at temperatures in the range of 15°-37°C (59°-99°F). If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°-37°C, 59°-99°F) before performing testing.
- Do not use if the test kit is exposed to temperatures outside of the recommended storage temperature (2°-30°C, 36°-86°F), or if tested outside of the operating temperature (15°-37°C, 59°-99°F).

## PRECAUTIONS

### Safety Precautions

- Handle specimens and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
- For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings" and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis".<sup>4</sup>

### Device Handling Precautions

- Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (*see Safety Precautions*). **Do not reuse any of these test components.**
- Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
- Inspect the Divided Pouch. If the Divided Pouch has been damaged, discard the Divided Pouch and its contents and select a new Divided Pouch for testing.
- Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
- If any of the liquid in the Developer Vial spills, obtain a new pouched device. An insufficient volume of solution will result in an invalid test result.
- Avoid extreme temperature variations when operating and interpreting the OraQuick® HCV Rapid Antibody Test.
- Condensation on the read window may cause an inability to interpret test results. If unable to interpret the test results, repeat testing with a new device.
- Avoid microbial contamination and exercise care in handling the kit components.
- To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the specimen into the Developer Solution.
- Adequate lighting is required to read a test result.
- Color blindness may affect the ability to interpret test results.

## STORAGE INSTRUCTIONS

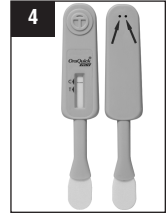
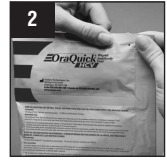
Store unused OraQuick® HCV Rapid Antibody Tests unopened at 2°-30°C (36°-86°F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°-37°C, 59°-99°F) before opening.

## DIRECTIONS FOR USE

### GENERAL TEST PREPARATION

1. If you are a new operator, before proceeding you **MUST** be able to correctly interpret the OraQuick® HCV Visual Reference Panel to use the OraQuick® HCV Rapid Antibody Test.
2. Follow *Safety Precautions* section in this package insert.
3. Gather the materials you will need.
4. Allow the OraQuick® HCV Rapid Antibody Tests to come to operating temperature (15°-37°C; 59°-99°F) before use.
5. Refer to the *External Quality Control* section in this package insert to determine when the Kit Controls should be run.
6. Set an OraQuick® reusable Test Stand at your workspace, using only the stand provided.
7. Open the two chambers of the OraQuick® Divided Pouch by tearing at the top notches located on each side of the Pouch (see pictures 1 and 2).
8. Remove the Developer Solution Vial from the Pouch. Hold the Developer Vial firmly in your hand. Remove the cap from the Developer Vial by gently rocking the cap back and forth while pulling it off. Set the cap aside. Slide the vial into the top of the slots in the reusable Test Stand. (see picture 3).
9. Leave the Test Device in the Pouch until you are ready to use it to prevent contamination.

### Two Chambers



**Two Holes Not to be Covered**

**NOTE: DO NOT cover the two holes in the back of the Device with labels or other materials, as it may cause an invalid test result (see picture 4).**

### SPECIMEN COLLECTION AND TESTING PROCEDURE

The OraQuick® HCV Rapid Antibody Test can be used for testing fingerstick whole blood specimens and venipuncture whole blood specimens. Refer to the specific testing procedure below.

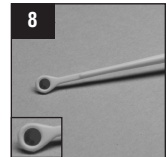
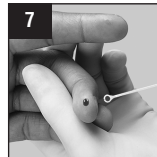
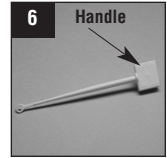
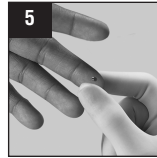
#### FINGERSTICK WHOLE BLOOD AND VENIPUNCTURE WHOLE BLOOD PROCEDURE

##### STEP 1: COLLECT

##### STEP 1A: FINGERSTICK WHOLE BLOOD

1. Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to air dry. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward and apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (see picture 5). Wipe away the first drop of blood with a sterile gauze pad and allow a new drop of blood to form.
2. Obtain an unused Specimen Collection Loop by the handle (see picture 6). Place the rounded end of the Loop on the drop of blood (see picture 7) and verify that the Loop is completely filled with blood (see picture 8).

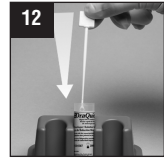
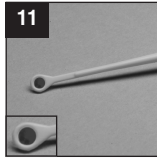
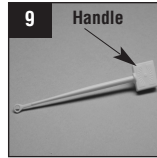
**NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Obtain a new Loop for the collection of the blood specimen.





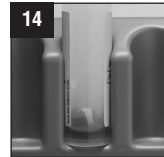
### STEP 1B: VENIPUNCTURE WHOLE BLOOD

- Using standard venous phlebotomy procedures collect a whole blood specimen using a tube containing any of the following anticoagulants: EDTA, sodium heparin, lithium heparin, or sodium citrate. **Other anticoagulants have not been tested and may cause an inaccurate result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 2°-8°C (36°-46°F) for up to 7 days or at 15°-30°C (59°-86°F) for up to 3 days.
- Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous specimen. Obtain an unused Specimen Collection Loop by the handle (see picture 9). Insert the rounded end of the Loop into the tube of blood (see picture 10), and verify that the Loop is completely filled with blood (see picture 11).  
**NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Use a new Loop for the collection of the blood specimen.



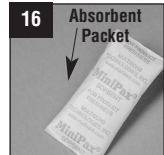
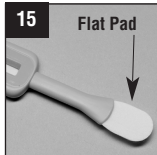
### STEP 2: MIX

- Immediately insert the blood-filled end of the Loop all the way into the Developer Vial (see picture 12). Use the Loop to stir the blood sample in the Developer Solution (see picture 13). Remove the used Loop from the Solution and discard in a biohazard waste container.
- Verify that the Solution is pink in color, indicating that the blood was thoroughly mixed into the Solution (see picture 14). If the Solution is not pink, discard all test materials in a biohazard waste container. Start the test over using a new Pouch and a new blood sample.  
**NOTE:** To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the specimen into the Developer Solution.



### STEP 3: TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture 15). Verify that an Absorbent Packet is included with the Device (see picture 16). If no Absorbent Packet is present, or if the Absorbent Packet is damaged, discard the Device and obtain a new Pouch for testing.
- Insert the Flat Pad of the Device all the way into the Developer Vial containing the blood sample (see picture 17), and verify that the Flat Pad touches the bottom of the Developer Vial. The Result Window on the Device should be facing towards you (see picture 18).
- Start timing the test (see picture 19). **DO NOT** remove the Device from the Developer Vial while the test is running. A pink color will migrate up the Result Window, and will gradually disappear as the test develops (see picture 20).
- Read the result in a fully lighted area after 20 minutes, but no more than 40 minutes.  
**NOTE: DO NOT** read the result before 20 minutes.
- Refer to the *Test Result and Interpretation of Test Result* section in this package insert.



### GENERAL TEST CLEAN-UP

- Dispose of the used test materials and gloves in a biohazard waste container.
- When using gloves, change your gloves between each test to prevent contamination.
- Use a freshly prepared 10% solution of bleach to clean up any spills.<sup>5</sup>

## QUALITY CONTROL

### Built-in Control Features

The OraQuick® HCV Rapid Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control Zone (C Zone) of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Device. The Control line will appear on all valid tests, whether or not the sample is reactive or non-reactive for anti-HCV (Refer to *Test Result and Interpretation of Test Result* section in this package insert).

### External Quality Control

OraQuick® HCV Rapid Antibody Test Kit Controls are available separately for use only with the OraQuick® HCV Rapid Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test Zone (T Zone). The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the T Zone). Refer to *Test Result and Interpretation of Test Result* section in this package insert. Use of kit control reagents manufactured by any other source may not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test. If the external controls do not produce expected results, patient testing should not be performed. Contact OraSure Technologies' Customer Service if the Kit Control reagents do not produce the expected results.

Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

### Run the External Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit 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), and
- At periodic intervals as dictated by the user facility.

### Test Procedure for External Controls:

1. Open a Kit Control Vial containing the control reagent.
2. Insert the rounded end of an unused Specimen Collection Loop into the vial of the control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Vial and discard the used Loop in a biohazard waste container.
4. Follow Step 3 of the *Test Procedure* for additional instructions.

Refer to the OraQuick® HCV Rapid Antibody Test Kit Controls package insert for full instructions on the use of these reagents. It is the responsibility of each laboratory using the OraQuick® HCV Rapid Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

### Qualification for New Operators

The OraQuick® HCV Visual Reference Panel is available separately for use with the OraQuick® HCV Rapid Antibody Test. The OraQuick® HCV Visual Reference Panel includes potential test results including non-reactive, weakly reactive and the limit of detection of the test device. **New operators MUST be able to correctly interpret all devices in the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.** Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.

## TEST RESULT AND INTERPRETATION OF TEST RESULT

Refer to the Result Window on the Test Device.

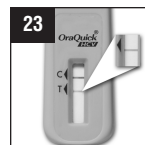
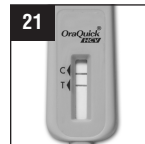
### REACTIVE

A test is **Reactive** if:

a line appears in the C Zone and a line appears in the T Zone. Lines may vary in intensity. The test is reactive regardless of how faint these lines appear (see pictures 21, 22 and 23).

A **Reactive** test result means that HCV antibodies have been detected in the specimen. Patient is presumed to be infected with HCV.

Individuals with a reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.<sup>6</sup>



## NON-REACTIVE

A test is **Non-Reactive** if:

- a line appears in the C Zone and NO line appears in the T Zone (see picture 24).

A **Non-Reactive** test result means that HCV antibodies were not detected in the specimen. Patient is presumed not to be infected with HCV.

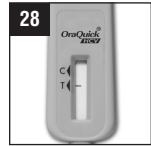
## INVALID

A test is **Invalid** if:

- NO** line appears in the C Zone (see picture 25), or
- a pink background obscures the results during the 20 to 40 minute read times (see picture 26), or
- any partial line on one side of the C or T Zones (see pictures 27 and 28).

An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Device. **An Invalid result cannot be interpreted.** Repeat the test with a new Pouch and a new specimen. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.

To report a device problem, contact OraSure Technologies Customer Service (1-800-orasure) and/or FDA ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).



## LIMITATIONS OF THE TEST

- The OraQuick® HCV Rapid Antibody Test must be used in accordance with the instructions in this package insert to obtain an accurate result.
- The clinical performance of this device was established based on an operator's ability to read visual intensities at the "T" line at all levels including very weak bands representing low antibody levels.
- Reading test results earlier than 20 minutes or later than 40 minutes may yield inaccurate test results.
- This test is approved for use with fingerstick whole blood specimens and venipuncture whole blood specimens only. Use of other types of specimens, or venipuncture whole blood specimens collected using a tube containing anticoagulants other than EDTA, lithium heparin, sodium heparin, or sodium citrate may yield inaccurate results.
- Clinical data has not been collected to demonstrate the performance of the OraQuick® HCV Rapid Antibody Test in individuals under 15 years of age or for pregnant women.
- A reactive result using the OraQuick® HCV Rapid Antibody Test suggests the presence of HCV antibodies in the specimen, and the intensity of the test line does not necessarily correlate with the HCV antibody titer in the specimen. The OraQuick® HCV Rapid Antibody Test is intended as an aid in the diagnosis of HCV infection.
- A non-reactive result does not exclude the possibility of exposure to HCV or infection with HCV. An antibody response to recent exposure may take several months to reach detectable levels.
- A person who has HCV antibodies is presumed to be infected with the virus. Additional testing and medical evaluation is required to determine the state or associated disease.

## EXPECTED RESULTS FOR THE INTENDED USE POPULATION

### Venous Whole Blood

Of the 1207 specimens tested in two OraQuick® HCV Rapid Antibody Test clinical studies of venipuncture whole blood, 88.2% (1064/1207) were from subjects at risk for hepatitis C infection but were asymptomatic and reported no current signs or symptoms of hepatitis, and 11.8% (142/1207) were from subjects with current signs or symptoms of hepatitis. One (1/1207) pregnant subject was enrolled without signs or symptoms of hepatitis or risk factors for hepatitis C infection. The 1207 individuals were enrolled from the following collection locations:

- 50.3% from Miami, FL
- 24.7% from Ft. Lauderdale, FL
- 13.6% from Fall River, MA
- 10.7% from Allentown, PA
- 0.7% from College Park, MD, San Francisco, CA, Dallas, TX, and Philadelphia, PA.

The OraQuick® HCV Rapid Antibody Test was reactive in 36.7% (443/1207) of subjects tested. There were no invalid OraQuick® HCV Rapid Antibody Test results reported for the 1207 specimens tested (0/1207, 95% CI: 0.0%, 0.3%). Of the 1207 individuals tested, 33.1% (400/1207) were also self-reported HIV positive. The table below summarizes the distribution of OraQuick® HCV Rapid Antibody Test reactive, non-reactive, and invalid results for the 1207 specimens tested.

Age Range	Gender	OraQuick® HCV Rapid Antibody Test Results in High Risk Individuals							
		No signs or symptoms				Signs or symptoms			
		Reactive	Non-Reactive	Invalid	Total	Reactive	Non-Reactive	Invalid	Total
		n (%)	n (%)	n (%)	(n)	n (%)	n (%)	n (%)	(n)
0-9	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
	M	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
10-19	F	0 (0.0)	11 (1.0)	0 (0.0)	11	1 (0.7)	1 (0.7)	0 (0.0)	2
	M	0 (0.0)	14 (1.3)	0 (0.0)	14	0 (0.0)	1 (0.7)	0 (0.0)	1
20-29	F	11 (1.0)	29 (2.7)	0 (0.0)	40	1 (0.7)	9 (6.3)	0 (0.0)	10
	M	7 (0.7)	50 (4.7)	0 (0.0)	57	1 (0.7)	3 (2.1)	0 (0.0)	4
30-39	F	15 (1.4)	44 (4.1)	0 (0.0)	59	4 (2.8)	18 (12.7)	0 (0.0)	22
	M	23 (2.2)	56 (5.3)	0 (0.0)	79	4 (2.8)	4 (2.8)	0 (0.0)	8
40-49	F	53 (5.0)	97 (9.1)	0 (0.0)	150	7 (4.9)	8 (5.6)	0 (0.0)	15
	M	82 (7.7)	191 (18.0)	0 (0.0)	273	6 (4.2)	8 (5.6)	0 (0.0)	14
50-59	F	41 (3.9)	38 (3.6)	0 (0.0)	79	3 (2.1)	5 (3.5)	0 (0.0)	8
	M	137 (12.9)	117 (11.0)	0 (0.0)	254	23 (16.2)	9 (6.3)	0 (0.0)	32
60-69	F	6 (0.6)	5 (0.5)	0 (0.0)	11	1 (0.7)	9 (6.3)	0 (0.0)	10
	M	13 (1.2)	19 (1.8)	0 (0.0)	32	2 (1.4)	5 (3.5)	0 (0.0)	7
70-79	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	4 (2.8)	0 (0.0)	4
	M	1 (0.1)	4 (0.4)	0 (0.0)	5	1 (0.7)	2 (1.4)	0 (0.0)	3
80-89	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	1 (0.7)	0 (0.0)	1
	M	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	1 (0.7)	0 (0.0)	1
90-100	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
	M	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
Total (N)*		389 (36.6)	675 (63.4)	0 (0.0)	1064	54 (38.0)	88 (62.0)	0 (0.0)	142

\* Does not include one pregnant woman enrolled without signs or symptoms of hepatitis or at risk for hepatitis C infection.

## PERFORMANCE CHARACTERISTICS

### Venous Whole Blood Clinical Performance

Two multi-center prospective studies were conducted to evaluate the clinical performance of the OraQuick® HCV Rapid Antibody Test in subjects with signs or symptoms of hepatitis and subjects at risk for hepatitis C infection. These risk factors included past or present intravenous drug use, having received a blood transfusion or organ transplant prior to 1992, evidence of high-risk sexual behavior, being born to an HCV positive mother, having been on long-term hemodialysis, history of incarceration, and positive for HIV. Clinical performance was evaluated in venipuncture whole blood specimens from subjects prospectively enrolled at 8 geographically dispersed centers within the United States.

The population tested was African American (43.0%), Caucasian (37.7%), Hispanic/Latino (17.1%), as well as a small proportion of other ethnic groups (2.2%). The mean age was 45 years (age range: 15 to 84 years). Of the 1207 subject specimens tested, 436 were HCV infected, 762 were negative, and 9 specimens had the status of "Unable to Determine". HCV status was determined for each subject by EIA, with supplemental RIBA® and PCR assays as required. The table below summarizes the distribution of OraQuick® HCV Rapid Antibody Test reactive, non-reactive, and invalid results in subjects with HCV infected status per the reference laboratory testing algorithm.

OraQuick® HCV Rapid Antibody Test Results	Subject HCV Infected Status		
	Positive	Negative	Unable to Determine Infected Status
Positive	435	0	8
Negative	1	762	1
Invalid	0	0	0

### Positive and Negative Agreement Calculations

Percent positive and percent negative agreement between the OraQuick® HCV Rapid Antibody Test and HCV status were calculated overall for the population (n=1207), as well as for subjects with signs or symptoms of hepatitis and subjects at risk for hepatitis C infection.

$$\text{Percent Positive Agreement} = \frac{\text{Number of OraQuick® HCV Rapid Antibody Test Reactive Results}}{\text{Total number of HCV Infected status}} \times 100$$

$$\text{Percent Negative Agreement} = \frac{\text{Number of OraQuick® HCV Rapid Antibody Test Non-Reactive Results}}{\text{Total number of HCV Not Infected status}} \times 100$$

For the purposes of calculating percent agreement, OraQuick® HCV Rapid Antibody Test reactive results for samples whose HCV status was "Unable to Determine" following EIA with supplemental RIBA® and PCR testing were considered "HCV Not Infected", and OraQuick® HCV Rapid Antibody Test non-reactive results for samples whose HCV status was "Unable to Determine" following EIA with supplemental RIBA® and PCR testing were considered "HCV Infected".

### Positive and Negative Agreement

The percent positive and negative agreement between the OraQuick® HCV Rapid Antibody Test and the subject HCV Infected Status was calculated for the per protocol population (n=1207). Percent positive and negative agreement was also calculated for individuals with signs or symptoms of hepatitis (n=142), and for individuals at risk for hepatitis C infection (n=1064). Percent positive and negative agreement according to risk factors for HCV infection was also calculated. The risks for HCV were ranked on a clinical evaluation of the likelihood of acquiring hepatitis C, with the most common given higher rankings.<sup>7</sup> Each subject was assigned only one risk (the highest). Results with the 95% confidence intervals are summarized in the following table.

Study Subjects	Total	Positive Percent Agreement	95% Exact Confidence Interval	Negative Percent Agreement	95% Exact Confidence Interval
Overall	1207	99.5%* (435 / 437)	98.4, 99.9	99.0%* (762 / 770)	98.0, 99.6
Overall with signs or symptoms	142	100.0% (54 / 54)	93.4, 100.0	100.0% (88 / 88)	95.9, 100.0
Overall without signs or symptoms	1064	99.5%* (381 / 383)	98.1, 99.9	98.8%* (673 / 681)	97.7, 99.5
IVDU	456	99.3% (291 / 293)	97.6, 99.9	98.2% (160 / 163)	94.7, 99.6
Dialysis	6	100.0% (1 / 1)	2.5, 100.0	100.0% (5 / 5)	47.8, 100.0
Transfusion/ Transplant	63	100.0% (16 / 16)	79.4, 100.0	100.0% (47 / 47)	92.5, 100.0
High Risk sex	461	100.0% (58 / 58)	93.8, 100.0	98.8% (398 / 403)	97.1, 99.6
HCV positive mother	2	100.0% (1 / 1)	2.5, 100.0	100.0% (1 / 1)	2.5, 100.0
Prior history of incarceration	56	100.0% (11 / 11)	71.5, 100.0	100.0% (45 / 45)	92.1, 100.0
HIV positive <sup>§</sup>	17	100.0% (2 / 2)	15.8, 100.0	100.0% (15 / 15)	78.2, 100.0
None specified	3	100.0% (1 / 1)	2.5, 100.0	100.0% (2 / 2)	15.8, 100.0

\*Includes subjects with "unable to determine" status.

§Does not include 377 additional HIV positive subjects enrolled but included in higher ranked risk categories, and 6 HIV positive subjects enrolled with signs or symptoms of hepatitis.

**Results of Supplemental Testing of Specimens Reactive in The OraQuick® HCV Rapid Antibody Test**

The table below shows the results obtained when subjects reactive in the OraQuick® HCV Rapid Antibody Test were tested by recombinant immunoblot assay (RIBA®).

Number of OraQuick® Reactive Results	RIBA® Results		
	Positive	Indeterminate	Negative
443	418	25*	0

\*Seventeen (17) of the RIBA® indeterminate results were positive for HCV RNA when tested by PCR.

Of the subjects reactive in the OraQuick® HCV Rapid Antibody Test 94.4% (418/443) were positive by RIBA®. Seventeen (17) of the RIBA® indeterminate results were positive for HCV RNA when tested by PCR.

**EXPECTED RESULTS FOR THE INTENDED USE POPULATION**

**Fingerstick Whole Blood**

Of the 1670 fingerstick whole blood specimens tested in an OraQuick® HCV Rapid Antibody clinical study, 78.7% (1315/1670) were from subjects at risk for hepatitis C infection but were asymptomatic and reported no current signs or symptoms of hepatitis, and 21.3% (355/1670) were from subjects with current signs or symptoms of hepatitis. The 1670 individuals were enrolled from the following collection locations:

- 29.9% from Ft. Lauderdale, FL
- 15.2% from Miami, FL
- 9.8% from Allentown, PA
- 3.1% from Lebanon, NH
- 20.5% from New Bedford, MA
- 12.2% from Lexington, KY
- 9.3% from Baltimore, MD

A total of 1660 specimen results were included in the study analysis, as ten (10) OraQuick® results were excluded due to results read outside of the 20-40 minute read window. The OraQuick® HCV Rapid Antibody Test was reactive in 43.5% (722/1660) of subjects. Of the 1670 individuals tested, 26.6% (445/1670) were also self-reported HIV positive. The table below summarizes the distribution of OraQuick® HCV Rapid Antibody Test reactive, non-reactive, and invalid results for the 1660 subjects included in the analysis.

Age Range	Gender	OraQuick® HCV Rapid Antibody Test Results in High Risk Individuals - Fingerstick Whole Blood							
		No signs or symptoms				Signs or symptoms			
		Reactive n (%)	Non-Reactive n (%)	Invalid n (%)	Total (n)	Reactive n (%)	Non-Reactive n (%)	Invalid n (%)	Total (n)
0-10	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
	M	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
11-19	F	3 (0.2)	8 (0.6)	0 (0.0)	11	0 (0.0)	6 (1.7)	0 (0.0)	6
	M	0 (0.0)	11 (0.8)	0 (0.0)	11	1 (0.2)	2 (0.6)	0 (0.0)	3
20-29	F	29 (2.2)	86 (6.6)	0 (0.0)	115	9 (2.5)	11 (3.1)	0 (0.0)	20
	M	25 (1.9)	73 (5.6)	0 (0.0)	98	5 (1.4)	9 (2.5)	0 (0.0)	14
30-39	F	31 (2.4)	65 (5.0)	0 (0.0)	96	9 (2.5)	13 (3.7)	0 (0.0)	22
	M	50 (3.8)	80 (6.1)	0 (0.0)	130	16 (4.5)	20 (5.6)	0 (0.0)	36
40-49	F	63 (4.8)	102 (7.8)	0 (0.0)	165	23 (6.5)	27 (7.6)	0 (0.0)	50
	M	109 (8.4)	184 (14.1)	0 (0.0)	293	46 (13.0)	28 (7.9)	0 (0.0)	74
50-59	F	48 (3.7)	46 (3.5)	0 (0.0)	94	18 (5.1)	13 (3.7)	0 (0.0)	31
	M	134 (10.3)	106 (8.1)	0 (0.0)	240	64 (18.0)	24 (6.8)	0 (0.0)	88
60-69	F	8 (0.6)	4 (0.3)	0 (0.0)	12	3 (0.8)	1 (0.3)	0 (0.0)	4
	M	21 (1.6)	18 (1.4)	0 (0.0)	39	7 (2.0)	0 (0.0)	0 (0.0)	7
70-79	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
	M	0 (0.0)	1 (0.1)	0 (0.0)	1	0 (0.0)	0 (0.0)	0 (0.0)	0
80-89	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
	M	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
90-100	F	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
	M	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0
Total (N)*		521 (40.0)	784 (60.0)	0 (0.0)	1305	201 (56.6)	154 (43.4)	0 (0.0)	355

\* Excludes 10 subjects with OraQuick® results read out of the 20-40 minute read window.

## PERFORMANCE CHARACTERISTICS

### Fingerstick Whole Blood Clinical Performance

A multi-center prospective study was conducted to evaluate the clinical performance of the OraQuick® HCV Rapid Antibody Test in fingerstick whole blood specimens from subjects with signs or symptoms of hepatitis and subjects at risk for hepatitis C infection. These risk factors included past or present intravenous drug use, having received a blood transfusion or organ transplant prior to 1992, evidence of high-risk sexual behavior, being born to an HCV positive mother, having been on long-term hemodialysis, history of incarceration, and positive for HIV. Clinical performance was evaluated in fingerstick whole blood specimens from subjects prospectively enrolled at 8 geographically dispersed centers within the United States. The population tested was Caucasian (53.1%), African American (40.6%), as well as a small proportion of other ethnic groups (6.3%). The mean age was 42.8 years (age range: 14 to 77 years). Of the 1660 subject specimens in the analysis population, 719 were HCV infected, 926 were negative, and 15 specimens had the status of "Unable to Determine". HCV status was determined for each subject by EIA, with supplemental RIBA® and PCR assays as required. The table below summarizes the distribution of OraQuick® HCV Rapid Antibody Test reactive, non-reactive, and invalid results in subjects with HCV infected status per the reference laboratory testing algorithm.

OraQuick® HCV Rapid Antibody Test Results	Subject HCV Infected Status		
	Positive	Negative	Unable to Determine Infected Status
Positive	708	3	11
Negative	11*	923	4
Invalid	0	0	0

\*Six (6) of the eleven (11) were negative for HCV RNA by PCR.

### Positive and Negative Agreement Calculations

Percent positive and negative agreement between the OraQuick® HCV Rapid Antibody Test and HCV status were calculated overall for the analysis population (n=1660), as well as for subjects with signs or symptoms of hepatitis and subjects at risk for hepatitis C infection.

$$\text{Percent Positive Agreement} = \frac{\text{Number of OraQuick® HCV Rapid Antibody Test Reactive Results}}{\text{Total number of HCV Infected status}} \times 100$$

$$\text{Percent Negative Agreement} = \frac{\text{Number of OraQuick® HCV Rapid Antibody Test Non-Reactive Results}}{\text{Total number of HCV Not Infected status}} \times 100$$

For the purposes of calculating percent agreement, subjects reactive by the OraQuick® HCV Rapid Antibody Test whose HCV status was "Unable to Determine" were considered "HCV Not Infected", non-reactive subjects by OraQuick® HCV Rapid Test whose HCV status was "Unable to Determine" were considered "HCV Infected".

### Positive and Negative Agreement

The percent positive and negative agreement between the OraQuick® HCV Rapid Antibody Test and the subject HCV Infected Status was calculated for the analysis population (n=1660). Percent positive and negative agreement was also calculated for individuals with signs or symptoms of hepatitis, and for individuals at risk for hepatitis C infection. In addition, the percent positive and negative agreement according to risk factors for HCV infection was also calculated. The risks for HCV were ranked on a clinical evaluation of the likelihood of acquiring hepatitis C, with the most common given higher rankings.<sup>7</sup> Each subject was assigned only one risk (the highest ranking). Results with the 95% confidence intervals are summarized in the following tables.

### Percent Positive Agreement and Percent Negative Agreement According to Risk

Study Subjects	Total	Positive Percent Agreement	95% Exact Confidence Interval	Negative Percent Agreement	95% Exact Confidence Interval
Overall	1660	97.9%* (708 / 723)	96.6, 98.8	98.5%* (923 / 937)	97.5, 99.2
Overall with signs or symptoms	355	99.0% (197 / 199)	96.4, 99.9	97.4% (152 / 156)	93.6, 99.3
Overall without signs or symptoms	1305	97.5%* (511 / 524)	95.8, 98.7	98.7%* (771 / 781)	97.7, 99.4
IVDU	661	98.2% (428 / 436)	96.4, 99.2	97.3% (219 / 225)	94.3, 99.0
Dialysis	11	100.0% (2 / 2)	15.8, 100.0	100.0% (9 / 9)	66.4, 100.0
Transfusion/ Transplant	48	92.3% (12 / 13)	64.0, 99.8	97.1% (34 / 35)	85.1, 99.9
High Risk sex	502	96.5% (55 / 57)	87.9, 99.6	99.6% (443 / 445)	98.4, 99.9
HCV positive mother	5	No subjects met criteria	No subjects met criteria	100.0% (5 / 5)	47.8, 100.0
Prior history of incarceration	67	86.7% (13 / 15)	59.5, 98.3	98.1% (51 / 52)	89.7, 100.0
HIV positive <sup>§</sup>	11	100.0% (1 / 1)	2.5, 100.0	100.0% (10 / 10)	69.2, 100.0

\*Includes subjects with "unable to determine" status.

§Does not include 314 additional HIV positive subjects enrolled but included in higher ranked risk categories, and 120 HIV positive subjects enrolled with signs or symptoms of hepatitis.

### Results of Supplemental Testing of Specimens Reactive in the OraQuick® HCV Rapid Antibody Test

The table below shows the results obtained when subjects reactive in the OraQuick® HCV Rapid Antibody Test were tested by recombinant immunoblot assay (RIBA®).

Number of OraQuick® Reactive Results	RIBA® Results		
	Positive	Indeterminate	Negative
722 <sup>§</sup>	690	29*	2

\*Eighteen (18) of the RIBA® indeterminate results were positive for HCV RNA when tested by PCR.

§ One (1) subject reactive by OraQuick® did not have RIBA® or PCR completed.

Of the subjects reactive in the OraQuick® HCV Rapid Antibody Test 95.6% (690/722) were positive by RIBA®. Eighteen (18) of the RIBA® indeterminate results were positive for HCV RNA when tested by PCR.



## REACTIVITY WITH HCV SEROCONVERSION PANELS

Eighteen panels containing sequential plasma specimens from individuals undergoing seroconversion as a result of HCV infection were evaluated with the OraQuick® HCV Rapid Antibody Test and compared with an FDA approved anti-HCV EIA test. The OraQuick® HCV Rapid Antibody Test and the reference anti-HCV assay results are summarized in the following table. The sensitivity of the OraQuick® HCV Rapid Antibody Test to detect seroconversion was similar to that of the comparator EIA. The OraQuick® HCV Rapid Antibody Test detected anti-HCV antibodies earlier than EIA in 9 of the 18 seroconversion panels (50%) and by an overall average of 3.6 days (95% CI = 1.2 to 5.9).

Seroconversion Panel	Days to Evidence of HCV Infection				Difference (OraQuick® - EIA)
	OraQuick® HCV Rapid Antibody Test		FDA anti-HCV EIA		
	Last Non-Reactive	First Reactive	Last Non-Reactive	First Reactive	
HCV 6213	35	37	30	37	0
HCV 6214	18	23	23	25	-2
HCV 6227	46	74	46	74	0
HCV 9041	31	62	31	62	0
HCV 9046	0	69	0	69	0
HCV 9047	21	28	21	28	0
PHV 901	65	97	65	97	0
PHV 905	7	11	11	18	-7
PHV 907	7	13	13	18	-5
PHV 910 (M)	0	4	0	4	0
PHV 911 (M)	0	11	0	11	0
PHV 914	9	12	19	24	-12
PHV 916 (M)	7	9	9	23	-14
PHV 917 (M)	22	85	22	85	0
PHV 920	7	13	7	16	-3
PHV 921	0	4	4	14	-10
RP 006	388	461	461	469	-8
RP 038	47	52	52	55	-3
<b>Average</b>		<b>59.2</b>		<b>62.7</b>	<b>- 3.6 (-5.9 to -1.2)</b>

## REACTIVITY WITH HCV SPECIMENS FROM VARIOUS GENOTYPES AND SUBTYPES

The ability of the OraQuick® HCV Rapid Antibody Test to detect infection derived from various genotypes and subtypes was assessed using two commercially available Worldwide HCV Performance panels. Thirty-two HCV-positive plasma specimens derived from multiple geographies, representing six genotypes (1, 2, 3, 4, 5, and 6) and multiple sub-types were tested. All specimens were reactive with the OraQuick® HCV Rapid Antibody Test. Three HCV-negative samples were included in the panel and all were non-reactive with the OraQuick® HCV Rapid Antibody Test.

## INTERFERING SUBSTANCES

The OraQuick® HCV Rapid Antibody Test was evaluated with the following interfering substances present in whole blood, samples in order to assess their potential effect on the assay performance as per CLSI guidelines EP7-A2<sup>8</sup>. Testing was completed on ten HCV-negative whole blood, samples and ten HCV-positive spiked matched whole blood samples. All matched samples were spiked according to one of the following conditions as per the table below:

Interfering Substances	Concentration
Bilirubin	10 mg/dL
Hemoglobin	500 mg/dL
Lipid (Triolein)	3500 mg/dL
Protein	12 g/dL

None of these interfering substances had any impact on the OraQuick® HCV Rapid Antibody Test assay performance at the concentrations evaluated.

## MEDICAL CONDITIONS UNRELATED TO HCV INFECTION

The performance of the OraQuick® HCV Rapid Antibody Test was evaluated with commercially available HCV negative plasma and serum specimens derived from medical conditions unrelated to HCV infection. Results are summarized in the table below.

Medical Condition		Non-Reactive (%)	Reactive (%)
<b>Autoimmune Diseases</b>			
Myasthenia Gravis	4	4 (100)	0 (0)
Rheumatoid Arthritis	10	10 (100)	0 (0)
Systemic Lupus Erythematosus (SLE)	10	10 (100)	0 (0)
<b>Other Medical Conditions</b>			
Influenza Vaccination	10	10 (100)	0 (0)
Hepatitis A Virus (HAV)	59	59 (100)	0 (0)
Hepatitis B Virus (HBV)	58	58 (100)	0 (0)
Hepatitis D Virus (HDV)	2	2 (100)	0 (0)
Hepatitis E Virus (HEV)	8	8 (100)	0 (0)
Epstein-Barr Virus (EBV)	10	10 (100)	0 (0)
Cytomegalovirus (CMV)	10	10 (100)	0 (0)
Herpes Simplex Virus (HSV)	10	10 (100)	0 (0)
Parvovirus B19	10	10 (100)	0 (0)
Rubella	10	10 (100)	0 (0)
Syphilis	10	10 (100)	0 (0)
Toxoplasmosis	10	10 (100)	0 (0)
Human Immunodeficiency Virus (HIV-1/2)	154	154 (100)	0 (0)
Heterophilic antibodies	10	10 (100)	0 (0)
Multiparous Female	10	10 (100)	0 (0)
<b>Total Samples Tested</b>	<b>405</b>	<b>405</b>	<b>0</b>

None of the medical conditions tested produced false positive results in the OraQuick® HCV Rapid Antibody Test. Performance characteristics in scleroderma, Sjögren's Syndrome and Human T-Cell Lymphotropic Virus (HTLV I/II) have not been established.

## SAMPLE STABILITY

The OraQuick® HCV Rapid Antibody Test was evaluated with whole blood stored at various storage conditions over numerous days. Results are summarized in the table below.

Specimen Type	Days at Storage Condition	
	2°-8°C (36°-46°F)	15°-30°C (59°-86°F)
Whole Blood	7	3

Storing whole blood for up to 7 days refrigerated or 3 days incubated at 15°-30°C (59°-86°F) did not impact the performance of the OraQuick® HCV Rapid Antibody Test.

## SPECIMEN TYPES

The OraQuick® HCV Rapid Antibody Test was evaluated with whole blood samples collected in various types of anticoagulants including Ethylenediaminetetraacetic Acid (EDTA), sodium heparin, lithium heparin, and sodium citrate. Testing was performed with twenty anti-HCV negative whole blood samples and twenty anti-HCV-spiked positive whole blood samples. All samples produced acceptable assay performance. The recommended anticoagulant types for use with the OraQuick® HCV Rapid Antibody Test in whole blood are vacutainers containing EDTA, sodium heparin, lithium heparin, sodium citrate.

## LIMIT OF DETECTION

The limit of detection (LoD), defined as the EIA signal to cutoff ratio which yielded reactive results 95% of the time in the OraQuick® Rapid HCV Antibody Test device, was calculated for each of three (3) lots separately and for three (3) lots combined. The LoD for venous whole blood and fingerstick whole blood was calculated to be 0.75 and 0.89 s/co, respectively, using an FDA approved EIA. This means that the OraQuick® HCV Rapid Antibody Test may provide a positive result where the comparator EIA is equivocal. Since the assay is visually read, the LoD may vary depending on the user.

## REPRODUCIBILITY

The reproducibility of the OraQuick® HCV Rapid Antibody Test was tested at 3 sites using 3 lots of test devices twice a day for 5 days with 9 operators (3 per site). Three whole blood panel member types (negative, limit of detection (LoD), and low positive) were tested in 5 unique test kit types. Each test kit consisted of eight (8) blinded panel members that had various combinations of the 3 panel members in a randomized sequence. Panel members were blinded per operator, run, and device lot to ensure that the results of the panel member types were unpredictable to the operator. LoD specimen was determined to be a 0.75 s/co by an FDA approved EIA. Overall concordance across operators, sites, and device lots was 98.9% (95% CI 97.9-99.5%) for the negative specimen, 98.7% (95% CI 97.6-99.4%) for the specimen at the limit of detection and 99.7% (95% CI 99.0-100.0%) for the low positive specimen.

## CLIA WAIVER STUDY

The performance of the OraQuick® HCV Rapid Antibody Test was evaluated when used by operators who had no laboratory experience and were representative of users at CLIA waived testing sites (intended users). A prospective study was conducted over two months at four (4) geographically diverse sites located in Arizona, New York, Texas and Vermont. The 13 operators who participated in the study were not given any training on the use of the test. There were 707 subjects tested with the OraQuick® HCV Rapid Antibody Test and with the comparator method. Both venipuncture whole blood and fingerstick whole blood were tested with the OraQuick® HCV Rapid Antibody Test by different operators. HCV status (comparator method) for each subject was determined by EIA, with supplemental RIBA® and PCR assays as required. The result of the OraQuick® HCV Rapid Antibody Test was compared to the HCV status of the subject. The positive percent agreement and the negative percent agreement between the OraQuick® HCV Rapid Antibody Test results and the comparator method (HCV status) for each specimen type is presented in the table below. There were no invalid results observed in the study.

**Positive Percent Agreement and Negative Percent Agreement of the OraQuick® HCV Rapid Antibody Test with HCV Status**

Specimen Type	Total No. of Subjects	Positive Percent Agreement	95% Exact Confidence Interval	Negative Percent Agreement	95% Exact Confidence Interval
Fingerstick Whole Blood	665**	97.0%* (129/133)	92.5%, 99.2%	98.9%* (526/532)	97.6%, 99.6%
Venipuncture Whole Blood	703**	97.8%* (134/137)	93.7%, 99.5%	98.9%* (560/566)	97.7%, 99.6%

\*Includes subjects with an HCV status of "unable to determine"

\*\*Forty-two fingerstick samples and four venous samples were excluded due to protocol deviations

Percent of invalid results for fingerstick whole blood was 0% (0/665) with 95% CI: 0.0% to 0.6%

Percent of invalid results for venipuncture whole blood was 0% (0/703) with 95% CI: 0.0% to 0.5%

Additionally, a study was conducted to determine whether operators not trained in the use of the test could detect weakly reactive results with the same accuracy as trained laboratorians. A randomly coded panel consisting of two weakly reactive samples and one negative sample, prepared in whole blood, was tested with the OraQuick® HCV Rapid Antibody Test at four (4) intended use sites (90 measurements in total per sample) and at one (1) trained user site (30 measurements in total per sample). There were nine (9) intended users and three (3) trained operators participating in the study. The intended users completed the panel testing over five (5) consecutive days integrated into their daily work flow at the site. One weakly reactive sample was at the limit of detection (LoD) and the other weakly reactive sample was approximately at 1.5 times the LoD.

The table below shows performance of the test with samples near the cutoff of the assay, both in the hands of intended users (across all sites) and trained laboratorians.

Sample Type	Intended Users		Trained Laboratorians	
	Percent Detection	95% Confidence Interval	Percent Detection	95% Confidence Interval
Weakly Reactive 1 (LoD)	97.8% (87/89)	92.2%, 99.4%	96.6% (28/29)	82.8%, 99.4%
Weakly Reactive 2	98.9% (89/90)	94.0%, 99.8%	100% (30/30)	88.7%, 100%
Negative	98.9% (88/89)	93.9%, 99.8%	96.7% (29/30)	83.3%, 99.4%





Three (3) samples were excluded from the analysis due to protocol deviation.

Using risk analysis as a guide, analytical flex studies were conducted. The studies demonstrated that the test is insensitive to stresses of environmental conditions and potential user errors.

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## EXPLANATION OF SYMBOLS

<b>LOT</b>	Batch Code	<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device
<b>REF</b>	Catalog Number	<b>KIT CTRLS</b>	Kit Controls
	Caution, Consult Accompanying Documents		Manufacturer
<b>CONTENTS</b>	Contents	<b>PN</b>	Part Number
<b>CONTROL -</b>	Control Negative		Temperature Limitation
<b>CONTROL +</b>	Control Positive		Use By
<b>DEV SOL VIAL</b>	Developer Solution Vial		



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## Kit Controls

**This package insert and the OraQuick® HCV Rapid Antibody Test package insert must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result. Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>**

### NAME AND INTENDED USE

The OraQuick® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test.

### Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit 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), and
- At periodic intervals as dictated by the user facility.

It is the responsibility of each laboratory using the OraQuick® HCV Rapid Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

### SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The OraQuick® HCV Rapid Antibody Test Kit Controls are human plasma-based reagents. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test (T) Zone. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the Test (T) Zone). Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert. Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

### MATERIALS PROVIDED

#### OraQuick® HCV Rapid Antibody Test Kit Controls

Each Kit Control box contains a package insert and two vials (one HCV Positive Control and one HCV Negative Control) as described below:

### **HCV Positive Control**

One purple-capped vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HCV, diluted in a defibrinated pool of normal human plasma. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and HIV-1/2 antibody.

### **HCV Negative Control**

One white-capped vial containing 0.2 mL of defibrinated pool of normal human plasma negative for antibodies to HCV. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and HIV-1/2 antibody.

### **MATERIALS REQUIRED AND PROVIDED in the OraQuick® HCV Rapid Antibody Test Kit**

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial  
Reusable Test Stands  
Specimen Collection Loops  
OraQuick® HCV Rapid Antibody Test Package Insert

### **MATERIALS REQUIRED BUT NOT PROVIDED**

Timer or watch capable of timing 20 to 40 minutes  
Latex, vinyl, or nitrile disposable gloves  
Biohazard waste container

### **WARNINGS**

#### **For *in vitro* Diagnostic Use**

- **This package insert must be read completely before using the product.**
- **Follow the instructions carefully when performing the OraQuick® HCV Rapid Antibody Test, failure to do so may cause an inaccurate test result.**
- **Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>**

### **PRECAUTIONS**

#### **Safety Precautions**

- Handle Kit Controls and materials in contact with Kit Controls as if capable of transmitting infectious agents.
- Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container.
- Wear disposable gloves while handling and testing the Kit Controls. Dispose of used gloves in a biohazard waste container.
- Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

### **STORAGE INSTRUCTIONS**

Store the OraQuick® HCV Rapid Antibody Test Kit Controls at 2°-8°C (36°-46°F). Do not use Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2°-8°C (36°-46°F) after use. Once opened, Kit Controls should be discarded after eight weeks.

## DIRECTIONS FOR USE

### General Test Preparation

Perform procedures according to the *General Test Preparation* section of the OraQuick® HCV Rapid Antibody Test package insert.

### TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the rounded end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Vial and discard the used loop in a biohazard waste container.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Vial containing the specimen. **Be sure that the Result Window is facing towards you and the flat pad touches the bottom of the Developer Vial.**
5. Leave the Test Device in the Developer Solution Vial and start a timer. Do not remove the Test Device from the vial until you have read the results. Read the results in a fully lighted area after 20 minutes, but no more than 40 minutes. Read the results as described in the *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test Kit Package Insert.
6. Dispose of the used test materials in a biohazard waste container.
7. Reseal the Kit Control reagent vials and store them in the original container at 2°-8°C (36°-46°F).

### EXPECTED RESULTS

#### HCV Negative Control

The HCV Negative Control will produce a Non-Reactive test result. A single line should be present in the Result Window in the (C) Zone and NO line should be present in the (T) Zone. This indicates a Non-Reactive test result.

#### HCV Positive Control

The HCV Positive Control will produce a Reactive test result and has been manufactured to produce a line at the Test (T) Zone. A line should be present in the Result Window in the (C) Zone and a line should appear in the (T) Zone. This indicates a Reactive test result. The lines will not necessarily be the same intensity.

**NOTE: If the test result for either the HCV Negative Control or the HCV Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen. If the test result for any of the controls is not as expected upon repeat testing, discontinue testing and contact OraSure Technologies' Customer Service.**

### LIMITATIONS














The OraQuick® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test.



## BIBLIOGRAPHY

1. CDC. 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):377-388.

### EXPLANATION OF SYMBOLS

 LOT	Batch Code	 IVD	<i>In Vitro</i> Diagnostic Medical Device
 REF	Catalog Number	 KIT CTRLS	Kit Controls
	Caution, Consult Accompanying Documents		Manufacturer
 CONTENTS	Contents	 PN	Part Number
 CONTROL -	Control Negative		Temperature Limitation
 CONTROL +	Control Positive		Use By
 DEV SOL VIAL	Developer Solution Vial		



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## VISUAL REFERENCE PANEL

All new operators **MUST** be able to correctly interpret all devices provided within the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.

Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.

**This package insert and the OraQuick® HCV Rapid Antibody Test package insert must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result.**

### NAME AND INTENDED USE

The OraQuick® HCV Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antibody levels near the limit of detection of the device. The OraQuick® HCV Visual Reference Panel is comprised of OraQuick® HCV Rapid Antibody Test devices that have been designed to represent reading intensities of limit of detection, low reactive, and non-reactive test results. The limit of detection test device is indicative of specimens with antibody levels at the limit of detection of the device.

It is the responsibility of each laboratory using the OraQuick® HCV Rapid Antibody Test to establish an adequate quality assurance program to ensure proficiency of new operators in their ability to interpret test results. The clinical performance of this device was established based on an operator's ability to read visual intensities at the "T" line at all levels including very weak lines representing low antibody levels.

### SUMMARY AND EXPLANATION OF THE HCV VISUAL REFERENCE PANEL

The OraQuick® HCV Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low reactive, and non-reactive test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antibody levels near the limit of detection of the device. The HCV Limit of Detection Device has a very faint reddish-purple line at the Test (T) Zone. The HCV Low Reactive Device has a reddish-purple line at the Test (T) Zone. The HCV Non-Reactive Device does not have a reddish-purple line at the Test (T) Zone. Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.

***This panel is to be used to assist new operators with becoming proficient at reading and interpreting OraQuick® HCV Rapid Antibody Test results at or near the limit of detection of the device. The OraQuick® HCV Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® HCV Rapid Antibody Test devices. Any line at the T Zone is considered to be a reactive result regardless of how faint the line appears.***

## MATERIALS PROVIDED

### OraQuick® HCV Visual Reference Panel

The Foil pouch contains a package insert and three devices (one HCV Limit of Detection Device, one HCV Low Reactive Device and one HCV Non-Reactive Device) as described below:

### HCV Limit of Detection Device

One OraQuick® HCV Rapid Antibody Test device that has been manufactured at a predetermined reactivity level to produce a reactive test result.

### HCV Low Reactive Device

One OraQuick® HCV Rapid Antibody Test device that has been manufactured at a predetermined reactivity level to produce a reactive test result.

### HCV Non-Reactive Device

One OraQuick® HCV Rapid Antibody Test device that has been manufactured to produce a non-reactive test result.

## MATERIALS REQUIRED AND PROVIDED in the OraQuick® HCV Visual Reference Panel

- Foil Pouch containing three predetermined OraQuick® HCV Rapid Antibody Test devices representing limit of detection, low reactive, and non-reactive test results
- OraQuick® HCV Visual Reference Panel Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Latex, vinyl, or nitrile disposable gloves

## WARNINGS

- **This package insert must be read completely before using the product.**
- **Adequate lighting is required for reading and interpreting the OraQuick® HCV Visual Reference Panel and the OraQuick® HCV Rapid Antibody Test.**
- **Follow the Test Result and Interpretation of Test Result section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.**
- **The OraQuick® HCV Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® HCV Rapid Antibody Test devices. Any line at the T Zone is considered to be a reactive result regardless of how faint the line appears.**
- **Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>**

## PRECAUTIONS

### Safety Precautions

- Dispose of all OraQuick® HCV Visual Reference Panel devices in a waste container according to the expiration date printed on the foil pouch.
- Use of Visual Reference Panels manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

## STORAGE INSTRUCTIONS

Store the OraQuick® HCV Visual Reference Panel at 15-30°C (59-86°F). Do not use the OraQuick® HCV Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the OraQuick® HCV Visual Reference Panel pouch only when qualifying new operators in interpreting test results. Reseal and store the devices in their original foil pouch at 15-30°C (59-86°F) after use.

**The OraQuick® HCV Visual Reference Panel may be used for up to 15 days after opening.**

**NOTE: Document the date the pouch was opened and the 15 day open pouch expiration date on the space provided on the foil pouch label.**

## DIRECTIONS FOR USE

### Test Procedure

**Note: The OraQuick® HCV Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the OraQuick® HCV Rapid Antibody Test occurs.**

1. Open the foil pouch containing the OraQuick® HCV Visual Reference Panel.
2. Document the date the pouch was opened on the space provided on the foil pouch label.
3. Calculate the 15 day open pouch expiration date and document it on the space provided on the foil pouch label.
4. Pull out the three devices contained within the foil pouch.
5. Follow the *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.
6. Store the OraQuick® HCV Visual Reference Panel Devices in the original re-sealable foil pouch at 15-30°C (59-86°F).

## EXPECTED RESULTS

### HCV Limit of Detection Device

The OraQuick® HCV Limit of Detection Device has been manufactured to have a very faint line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a reactive test result. The C Zone and the T zone lines will not be the same intensity.

### HCV Low Reactive Device

The OraQuick® HCV Low Reactive Device has been manufactured to have a line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a reactive test result. The C Zone and the T Zone lines will not be the same intensity.

### HCV Non-Reactive Device

The OraQuick® HCV Non-Reactive Device has been manufactured to have a line at the Control (C) Zone. A single line should be present in the Result Window in the C Zone and NO line should be present in the T Zone. This indicates a non-reactive test result.

**NOTE: If a new operator is unable to interpret all devices provided as part of the OraQuick® HCV Visual Reference Panel, they are not considered to be proficient at reading and interpreting the OraQuick® HCV Rapid Antibody Test. Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.**










## LIMITATIONS

The OraQuick® HCV Visual Reference Panel is for use only with the OraQuick® HCV Rapid Antibody Test.

## BIBLIOGRAPHY

1. CDC. 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):377-388.

## EXPLANATION OF SYMBOLS

 Batch Code	 <i>In Vitro</i> Diagnostic Medical Device
 Catalog Number	 Manufacturer
 Caution, Consult Accompanying Documents	 Temperature Limitation
 Developer Solution Vial	 Use By
 Part Number	



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## VISUAL REFERENCE PANEL

All new operators **MUST** be able to correctly interpret all devices provided within the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.

Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.

**This package insert and the OraQuick® HCV Rapid Antibody Test package insert must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result.**

### NAME AND INTENDED USE

The OraQuick® HCV Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antibody levels near the limit of detection of the device. The OraQuick® HCV Visual Reference Panel is comprised of OraQuick® HCV Rapid Antibody Test devices that have been designed to represent reading intensities of limit of detection, low reactive, and non-reactive test results. The limit of detection test device is indicative of specimens with antibody levels at the limit of detection of the device.

It is the responsibility of each laboratory using the OraQuick® HCV Rapid Antibody Test to establish an adequate quality assurance program to ensure proficiency of new operators in their ability to interpret test results. The clinical performance of this device was established based on an operator's ability to read visual intensities at the "T" line at all levels including very weak lines representing low antibody levels.

### SUMMARY AND EXPLANATION OF THE HCV VISUAL REFERENCE PANEL

The OraQuick® HCV Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low reactive, and non-reactive test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antibody levels near the limit of detection of the device. The HCV Limit of Detection Device has a very faint reddish-purple line at the Test (T) Zone. The HCV Low Reactive Device has a reddish-purple line at the Test (T) Zone. The HCV Non-Reactive Device does not have a reddish-purple line at the Test (T) Zone. Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.

***This panel is to be used to assist new operators with becoming proficient at reading and interpreting OraQuick® HCV Rapid Antibody Test results at or near the limit of detection of the device. The OraQuick® HCV Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® HCV Rapid Antibody Test devices. Any line at the T Zone is considered to be a reactive result regardless of how faint the line appears.***

### MATERIALS PROVIDED

#### OraQuick® HCV Visual Reference Panel

The Foil pouch contains a package insert and three devices (one HCV Limit of Detection Device, one HCV Low Reactive Device and one HCV Non-Reactive Device) as described below:

### **HCV Limit of Detection Device**

One OraQuick® HCV Rapid Antibody Test device that has been manufactured at a predetermined reactivity level to produce a reactive test result.

### **HCV Low Reactive Device**

One OraQuick® HCV Rapid Antibody Test device that has been manufactured at a predetermined reactivity level to produce a reactive test result.

### **HCV Non-Reactive Device**

One OraQuick® HCV Rapid Antibody Test device that has been manufactured to produce a non-reactive test result.

### **MATERIALS REQUIRED AND PROVIDED in the OraQuick® HCV Visual Reference Panel**

- Foil Pouch containing three predetermined OraQuick® HCV Rapid Antibody Test devices representing limit of detection, low reactive, and non-reactive test results
- OraQuick® HCV Visual Reference Panel Package Insert

### **MATERIALS REQUIRED BUT NOT PROVIDED**

- Latex, vinyl, or nitrile disposable gloves

### **WARNINGS**

- **This package insert must be read completely before using the product.**
- **Adequate lighting is required for reading and interpreting the OraQuick® HCV Visual Reference Panel and the OraQuick® HCV Rapid Antibody Test.**
- **Follow the Test Result and Interpretation of Test Result section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.**
- **The OraQuick® HCV Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® HCV Rapid Antibody Test devices. Any line at the T Zone is considered to be a reactive result regardless of how faint the line appears.**
- **Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>**

### **PRECAUTIONS**

#### **Safety Precautions**

- Dispose of all OraQuick® HCV Visual Reference Panel devices in a waste container according to the expiration date printed on the foil pouch.
- Use of Visual Reference Panels manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

### **STORAGE INSTRUCTIONS**

Store the OraQuick® HCV Visual Reference Panel at 15-30°C (59-86°F). Do not use the OraQuick® HCV Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the OraQuick® HCV Visual Reference Panel

pouch only when qualifying new operators in interpreting test results. Reseal and store the devices in their original foil pouch at 15-30°C (59-86°F) after use.

**The OraQuick® HCV Visual Reference Panel may be used for up to 15 days after opening.**

**NOTE: Document the date the pouch was opened and the 15 day open pouch expiration date on the space provided on the foil pouch label.**

## **DIRECTIONS FOR USE**

### **Test Procedure**

**Note: The OraQuick® HCV Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the OraQuick® HCV Rapid Antibody Test occurs.**

1. Open the foil pouch containing the OraQuick® HCV Visual Reference Panel.
2. Document the date the pouch was opened on the space provided on the foil pouch label.
3. Calculate the 15 day open pouch expiration date and document it on the space provided on the foil pouch label.
4. Pull out the three devices contained within the foil pouch.
5. Follow the *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.
6. Store the OraQuick® HCV Visual Reference Panel Devices in the original re-sealable foil pouch at 15-30°C (59-86°F).

## **EXPECTED RESULTS**

### **HCV Limit of Detection Device**

The OraQuick® HCV Limit of Detection Device has been manufactured to have a very faint line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a reactive test result. The C Zone and the T zone lines will not be the same intensity.

### **HCV Low Reactive Device**

The OraQuick® HCV Low Reactive Device has been manufactured to have a line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a reactive test result. The C Zone and the T Zone lines will not be the same intensity.

### **HCV Non-Reactive Device**

The OraQuick® HCV Non-Reactive Device has been manufactured to have a line at the Control (C) Zone. A single line should be present in the Result Window in the C Zone and NO line should be present in the T Zone. This indicates a non-reactive test result.

**NOTE: If a new operator is unable to interpret all devices provided as part of the OraQuick® HCV Visual Reference Panel, they are not considered to be proficient at reading and interpreting the OraQuick® HCV Rapid Antibody Test. Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.**

## **LIMITATIONS**














The OraQuick® HCV Visual Reference Panel is for use only with the OraQuick® HCV Rapid Antibody Test.



## BIBLIOGRAPHY

1. CDC. 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):377-388.

### EXPLANATION OF SYMBOLS

 Batch Code	 <i>In Vitro</i> Diagnostic Medical Device
 Catalog Number	 Kit Controls
 Caution, Consult Accompanying Documents	 Manufacturer
 Contents	 Part Number
 Control Negative	 Temperature Limitation
 Control Positive	 Use By
 Developer Solution Vial	



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