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

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OraQuick® Rapid Antibody Test HCV

- **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.[1]**

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 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.[2] HCV is primarily transmitted by contact with contaminated blood, blood products, or through other close personal contact.[3] 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.

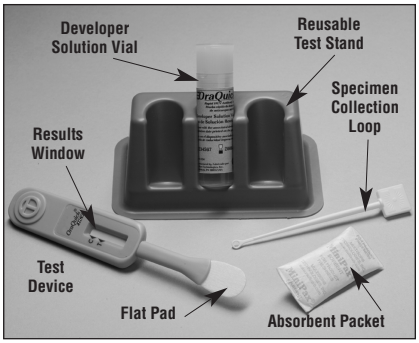
A fingerstick whole blood specimen or venipuncture whole blood specimen is collected using a specimen loop and transferred into the developer solution vial, followed by the insertion of the device. The developer solution facilitates the capillary flow of the specimen into the device and onto the assay 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.[1]**
- **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"[1] and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis".[4]

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.

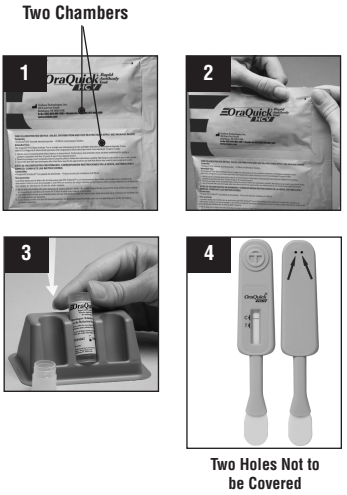
STORAGE INSTRUCTIONS

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.



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

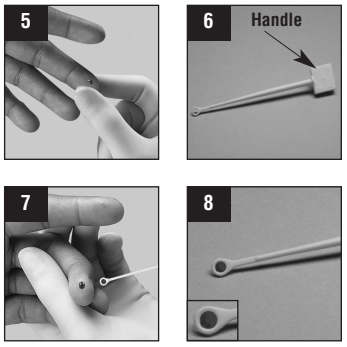
The OraQuick® HCV Rapid Antibody Test can be used for testing fingerstick whole blood specimens and venipuncture whole blood specimens. Refer to the specific testing procedure below.

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

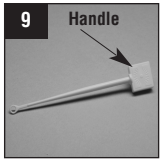
1. Using standard venous phlebotomy procedures collect a whole blood specimen using a tube containing any of the following anticoagulants: EDTA, sodium heparin, lithium heparin, or sodium citrate. **Other anticoagulants have not been tested and may cause an inaccurate result.** If the specimens are not 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.
2. 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.

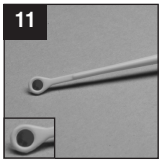
STEP 2: MIX

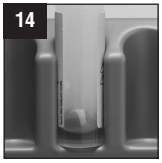
1. Immediately insert the blood-filled end of the Loop all the way into the Developer Vial (*see picture 12*). Use the Loop to stir the blood sample in the Developer Solution (*see picture 13*). Remove the used Loop from the Solution and discard in a biohazard waste container.
2. Verify that the Solution 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.

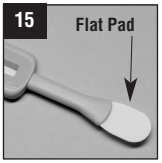
STEP 3: TEST

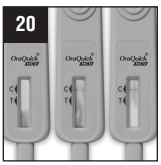
1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture 15*). Verify that an Absorbent Packet is included with the Device (*see picture 16*). If no Absorbent Packet is present, or if the Absorbent Packet is damaged, discard the Device and obtain a new Pouch for testing.
2. Insert 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*).
3. 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*).
4. 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.
5. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.











GENERAL TEST CLEAN-UP

1. Dispose of the used test materials and gloves in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.[5]

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.[6]

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).

LIMITATIONS OF THE TEST

1. The OraQuick® HCV Rapid Antibody Test must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. 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.
3. Reading test results earlier than 20 minutes or later than 40 minutes may yield inaccurate test results.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.[7] 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§	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	Non-Reactive	Invalid	Total	Reactive	Non-Reactive	Invalid	Total
		n (%)	n (%)	n (%)	(n)	n (%)	n (%)	n (%)	(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.[7] 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§	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§	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				
	OraQuick® HCV Rapid Antibody Test		FDA anti-HCV EIA		Difference (OraQuick® - 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
Average		**59.2**		**62.7**	**- 3.6 (-5.9 to -1.2)**

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[8]. 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 (%)
Autoimmune Diseases			
Myasthenia Gravis	4	4 (100)	0 (0)
Rheumatoid Arthritis	10	10 (100)	0 (0)
Systemic Lupus Erythematosus (SLE)	10	10 (100)	0 (0)
Other Medical Conditions			
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)
Total Samples Tested	**405**	**405**	**0**

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 Ethylenediaminetetracetic 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.

	Intended Users		Trained Laboratorians	
Sample Type	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

LOT	Batch Code	IVD	*In Vitro* 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		

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015 USA
(800) ORASURE (800-672-7873)
(610) 882-1820
www.orasure.com

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