

Before performing 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, Hepatitis C Virus, and other Bloodborne Pathogens in Health-Care Settings.

Handle specimens and materials contacting specimens as if capable of transmitting infectious agents. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container. Oral fluid is not considered potentially infectious unless it contains blood.

Warnings, Restrictions, Precautions and Limitations of the Test are not included in this abbreviated Step-By-Step Instruction Guide.

Intended Use

The OraQuick[®] HCV Rapid Antibody Test is a single-use, qualitative immunoassay to detect antibodies to the Hepatitis C Virus (HCV) in oral fluid, fingerstick and venous whole blood, serum and plasma specimens. The OraQuick[®] HCV Test may be used to provide presumptive evidence of HCV infection in individuals with signs and symptoms of Hepatitis and in individuals at risk for Hepatitis C infection.

WARNING: Not intended for use in screening blood, plasma, or tissue donors.

STORAGE INSTRUCTIONS:

- Store unused OraQuick[®] HCV Tests unopened at 2°-30°C.
- Do not open the pouch until you are ready to perform a test.
- Bring all components to operating temperature (15°-37°C) before opening.

Materials Provided in the Kit:

- Package Insert (full instructions for use)
- Reusable Test Stands
- Specimen Collection Loops

The divided pouch contains:

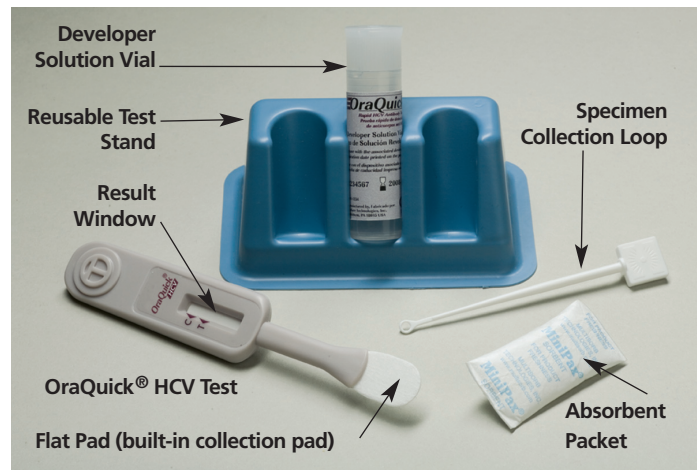
- OraQuick[®] HCV Test: Single-use test device with built-in sample collection pad (Flat Pad)
- OraQuick[®] HCV Developer Solution Vial

Materials Needed but Not Provided:

- Timer or watch capable of timing 20 to 40 minutes
- Biohazard waste container

Additional items required for fingerstick and venipuncture whole blood collection, serum and plasma specimens:

- Antiseptic wipe
- Sterile gauze pads
- Latex, vinyl or nitrile disposable gloves (optional for oral fluid testing)
- Sterile lancet for fingerstick or venipuncture supplies to collect whole blood, plasma or serum
- Centrifuge to process a serum or plasma specimen



General Test Preparation

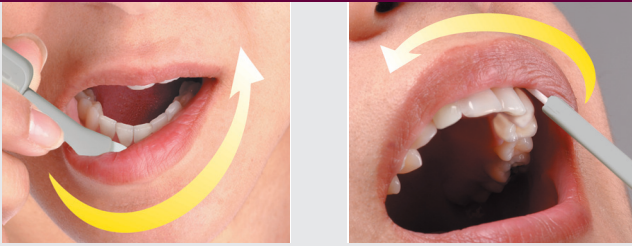
1. Allow all components to come to operating temperature (15°-37°C).
2. Place the reusable Test Stand on your work space. Use only the Stand provided with the OraQuick[®] HCV Kit. Set up your timer for 20 to 40 minutes but **DO NOT** start.
3. Do not open the pouch until you are ready to perform a test. Check the pouch for damage or holes. Discard the pouch if it is damaged.
4. After opening the pouch, check for an absorbent packet. If it is not present or appears damaged, discard the pouch and open a new one.
5. Hold the Vial firmly in your hand. Remove the cap by rocking it back and forth while pulling it off. Set the cap aside. Slide the Vial into the top of one of the slots in the Stand.
6. **DO NOT** cover the 2 holes on the back of the test with labels or other materials. Blocking the holes may cause an invalid result.



The OraQuick[®] HCV Test is approved for use with multiple specimens. The procedure for using oral fluid is illustrated below. The procedures for fingerstick whole blood, venous whole blood, plasma or serum are presented on the next page. Instructions for reading results are on the back page of this brochure.

Step 1. Collect Oral Fluid

Swab completely around the lower and upper gum **ONE TIME**.
DO NOT swab the roof of the mouth, cheeks or tongue.



Collection Tips

- Do not eat, drink or chew gum for at least 15 minutes prior to testing.
- Wait at least 30 minutes prior to testing after use of oral care products.
- Remove the OraQuick[®] HCV Test from the pouch. **DO NOT** touch the Flat Pad.

Step 2. Perform the Test

Insert Device into buffer.



Start the timer.



Pink fluid travels through the Result Window.



- **DO NOT** move while test is running.
- **DO NOT** remove the device from the Developer Solution while the test is running.

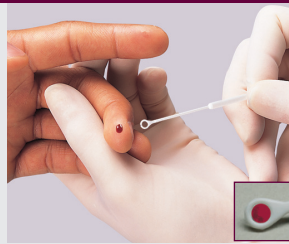
Step 1a. Options for Blood Collection

A. Fingertick Whole Blood

Cleanse finger.
 Air dry. Puncture
 with sterile lancet.



Wipe away first drop of
 blood with a sterile gauze pad.
 Fill the Collection Loop.



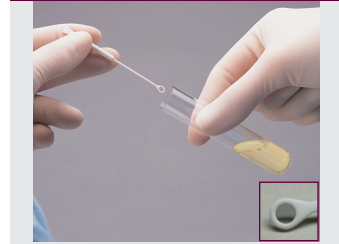
B. Venous Whole Blood

Collect blood using standard
 phlebotomy procedures.
 Fill the Collection Loop.



C. Plasma or Serum

Collect blood using standard
 phlebotomy procedures.
 Fill the Collection Loop.



Collection Tips

- Hold the finger downward and apply gentle pressure beside the point of puncture. Avoid squeezing the finger to make it bleed.
- If the Loop is dropped or contacts any other surface, discard it. Use a new Loop to collect the blood.

For use with EDTA, sodium/lithium heparin and sodium citrate.

- Whole blood may be stored at 15°-30°C or up to 3 days or at 2°-8°C for up to 7 days.
- Invert the tube several times to mix.

For use with EDTA, sodium/lithium heparin and sodium citrate or serum (SST).

- Specimens stored frozen at -20°C may have up to 3 freeze-thaw cycles.
- Serum/plasma may be stored at 15°-30°C for up to 3 days or at 2°-8°C for up to 7 days.
- Centrifuge at 1000-1300 x g for approximately 5 minutes.

Step 1b. Mix

- Immediately insert the Loop into the Developer Solution. Mix with Loop. Discard the used Loop in a biohazard waste container.

Insert the Loop and mix.



Step 2. Perform the Test

Insert Device into buffer.



Start the timer.




Pink fluid travels through the Result Window.












- **DO NOT** move while test is running.
- **DO NOT** remove the device from the Developer Solution while the test is running.

Step 3. Read Results Between 20 and 40 Minutes

Non-Reactive: Line in C Zone Only




Line in C Zone No HCV antibodies detected.	Interpretation of Results.
	<ul style="list-style-type: none"> A non-reactive test means that HCV antibodies were NOT detected in the sample. The patient is presumed not to be infected with HCV.

Reactive: Lines in C and T Zones

Examples of positive results. Lines in C Zone in each test.	Interpretation of Results.						
<table border="0"> <tr> <td data-bbox="89 716 287 983">Line in T Zone</td> <td data-bbox="287 716 486 983">Line in T Zone</td> <td data-bbox="486 716 686 983">Faint Line in T Zone</td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table>	Line in T Zone	Line in T Zone	Faint Line in T Zone				<ul style="list-style-type: none"> A reactive test means that HCV antibodies were detected in the sample. The patient is presumed to be infected with HCV. Follow appropriate guidelines for supplemental testing.
Line in T Zone	Line in T Zone	Faint Line in T Zone					
							

Invalid: No Lines in C Zone or Partially Developed Lines

The result cannot be interpreted. Repeat the test with a new Device and new Specimen.

No Line in C Zone	Red background obscures results	Partial Line on one side of C or T Zones	Interpretation of Results.
			<ul style="list-style-type: none"> An invalid test means that there was a problem with the test or sample. The result cannot be interpreted.

General Test Clean-Up

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

Order Information	Description
	Box of 25 tests Box of 100 tests Controls



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Made in the USA

Please refer to the Package Insert for complete information and instructions on the proper use of the OraQuick® HCV Rapid Antibody Test.
©2009, 2010 OraSure Technologies, Inc. U.S. Patent #7,192,555, #7,541,194 and various international and U.S. patents pending. OraQuick® is a registered trademark of OraSure Technologies, Inc.
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