



Linking People to Care

Step-by-Step Instructions For OraQuick® HCV Rapid Antibody Test



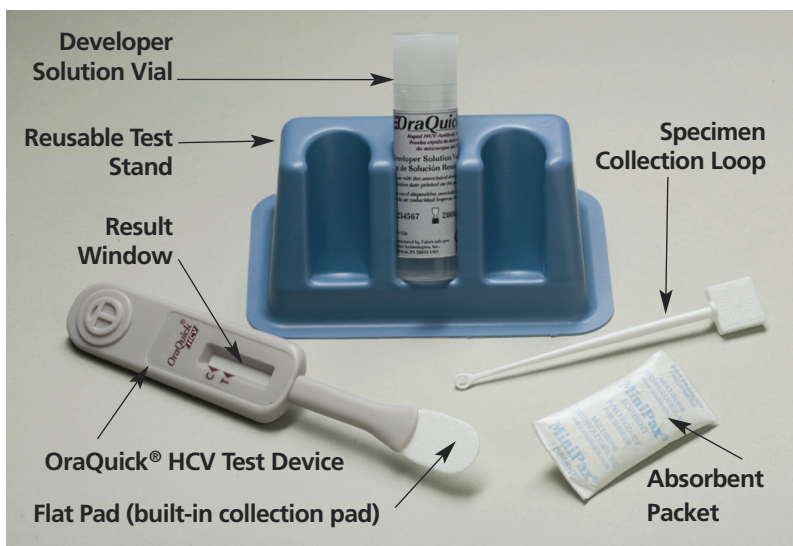
Complexity: WAIVED for fingerstick whole blood and venipuncture whole blood.

A Certificate of CLIA 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 modifications to the Test instructions, will result in the Test no longer meeting the requirement for Waived Classification and will be subject to all applicable CLIA requirements.

- These instructions are only a Reference Guide. For complete information including Restrictions, Precautions, and Limitations of the Test, refer to the OraQuick® HCV Rapid Antibody Test Package Insert.
- Read these instructions completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results.
- 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, and other Bloodborne Pathogens in Health-Care Settings.^{1,2}

OraQuick® Rapid Antibody Test
HCV



INTENDED USE:

The OraQuick® HCV Rapid Antibody Tests 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 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.

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.

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.

NOTE: Handle all blood 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 container.¹

¹ See "Universal Precautions," CDC, MMWR, 1988; 37(24):377-388. ² "Guideline for Isolation Precautions," CDC, HICPAC, 2007; 12-93.

FOR *IN VITRO* DIAGNOSTIC USE

THE FOLLOWING ITEMS ARE NEED TO DO THE TEST:

The OraQuick® HCV Rapid Antibody Test Consists of a Divided Pouch Containing the Following:

- Single-Use Test Device (including an absorbent packet)
- Developer Solution Vial (containing .750 mL)

NOTE: The pouch is divided into two chambers. One chamber holds the Test Device while the other chamber holds the Developer Solution Vial.

Materials Provided in the Kit:

- Reusable Test Stands
- Package Insert
- Specimen Collection Loops

Materials Required But Not Provided:

- Timer or watch capable of timing 20 to 40 Minutes
- Materials required for venipuncture whole blood specimen collection
- OraQuick® HCV Visual Reference Panel
- Biohazard waste container
- Sterile lancet to obtain a fingerstick whole blood specimen
- OraQuick® HCV Rapid Antibody Test Kit Controls

EXTERNAL QUALITY CONTROL

OraQuick® HCV Rapid Antibody Test Kit Controls are available separately for use only with OraQuick® HCV Rapid Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform and test and interpret the results. Refer to the Kit Control Package Insert for complete instructions.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit,
- 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.

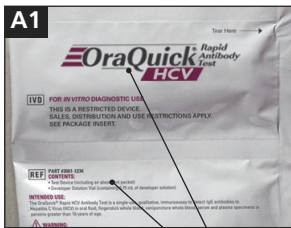
Test Procedure for Kit Controls

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 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 *Testing Procedure* for additional instruction.

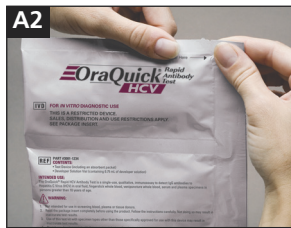
SET UP YOUR WORKSPACE

- Gather the materials you will need.
- Allow the test kit to come to operating temperature (15°–37°C; 59°–99°F) before use.
- Refer to the External Quality Control section above to determine when the Kit Controls should be run.
- Set an OraQuick® HCV Reusable Test Stand (“Stand”) on your workspace. Use only the Stand provided.
- Disposable gloves are needed when performing the test.

GENERAL TEST PREPARATION



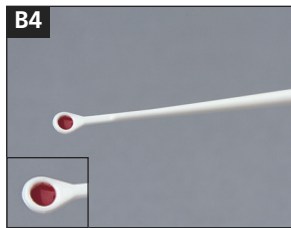
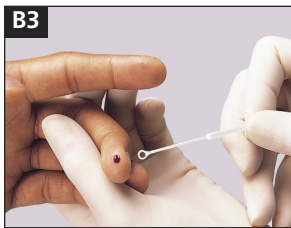
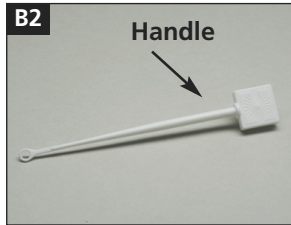
Two Chambers



- If you are a new operator, you **MUST** be able to interpret all devices provided in the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.
- Allow all components to come to operating temperature (15°–37°C, 59°–99°F).
- Place the reusable Test Stand on your workspace. Use only the Stand provided with the OraQuick® HCV Rapid Antibody Kit. Set up your timer for 20 to 40 minutes but **DO NOT** start.
- 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 (see picture A1).
- 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 (see picture A2).
- Hold the Developer Solution 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 tops of one of the slots in the Stand (see picture A3).
- Leave the OraQuick® HCV Test Device in the pouch until testing is started. Refer to Step 3 in the *Testing Procedure* section.
- **DO NOT** cover the 2 holes on the back of the OraQuick® HCV Test Device with labels or other materials. Blocking the holes may cause an invalid result.

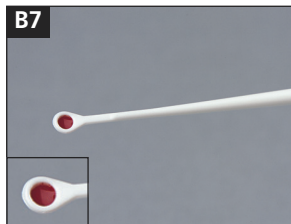
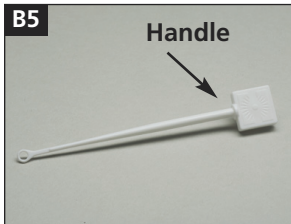


SPECIMEN COLLECTION PROCEDURE – FINGERSTICK WHOLE BLOOD



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.

VENIPUNCTURE WHOLE 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.

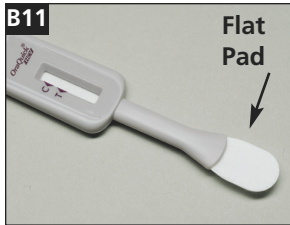
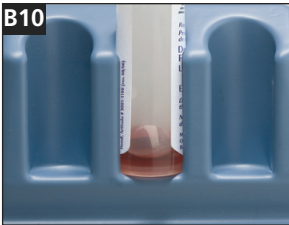
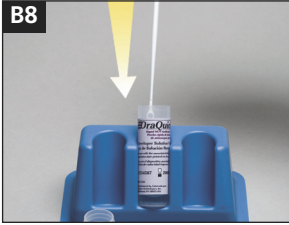
Step 1A – COLLECT

- 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. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (see *picture B1*).
- Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
- Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see *picture B2*).
- Put the "rounded" end of the Loop on the drop of blood (see *picture B3*). Make sure that the Loop is completely filled with blood (see *picture B4*).

Step 1B – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium/lithium heparin (green top), or sodium citrate (light blue top). **Other anticoagulants have not been tested and may give an incorrect 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.
- Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see *picture B5*).
- Put the "rounded" end of the Loop into the tube of blood (see *picture B6*). Make sure the Loop is completely filled with blood (see *picture B7*).

TESTING PROCEDURE



Step 2 – MIX

- Immediately insert the blood-filled end of the Loop all the way into the Vial (see *picture B8*).
- Use the Loop to stir the blood sample in the Developer Solution (“Solution”) (see *picture B9*).
- Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.
- Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (see *picture B10*). If the Solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.

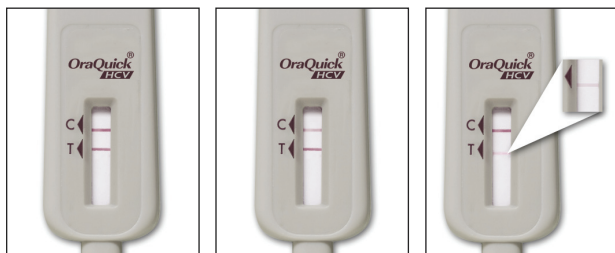
Step 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see *picture B11*).
- Check to make sure that an Absorbent Packet is included with the Device (see *picture B12*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see *picture B13*). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see *picture B14*).
- Start timing the test (see *picture B15*). **DO NOT** remove the Device from the 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.
- Wait 20 minutes.
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Test Result and Interpretation* section in these instructions.

TEST RESULT AND INTERPRETATION – Refer to the Result Window on the Test Device

CAUTION: Adequate lighting required. Color blindness may affect the ability to interpret Test results.

REACTIVE: Lines in C and T Zones



Line in T Zone

Line in T Zone

Faint Line
in T Zone

Test is Reactive if:

- A line appears in the C Zone and a line appears in the T Zone. Lines may vary in intensity. Two lines must be present for a “reactive” result.
- **The test is reactive regardless of how faint these lines appear.**
- A Reactive test result means that HCV antibodies have been detected in the specimen. Patient is presumed to be infected with HCV.
- Follow appropriate guidelines for supplemental testing.

NON-REACTIVE: Lines in C Zone Only



Line in C Zone
No HCV antibodies detected.

Test is Non-Reactive if:

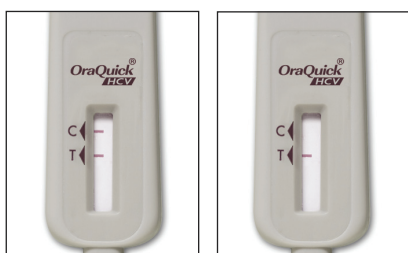
- A line appears in the C Zone and NO line appears in the T Zone.
- A Non-Reactive test result means that HCV antibodies were not detected in the specimen.
- Patient is presumed not to be infected with HCV.

INVALID: No Lines in C Zone or Partially Developed Lines



No Line in
C Zone

Red background
obscures results



Partial Line on one side
of C or T Zones

Test is Invalid if:

- No line appears in the C Zone, or
- A pink background obscures the results during the 20-40 minute read time, or
- Any partial line appears on one side of the C or T Zones.
- An Invalid test result means that there was a problem running the test either related to the Specimen or to the Test 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.

For answers to questions or technical assistance regarding the OraQuick® HCV Rapid Antibody Test, call: 1-800-ORASURE (800-672-7873) or visit our web site: www.orasure.com

GENERAL TEST CLEAN UP

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

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Order Information	Description	Reimbursement Information	CPT Code
	Box of 25 tests Box of 100 tests Controls OraQuick® HCV Visual Reference Panel		86803



OraSure Technologies

220 East First Street
Bethlehem, PA 18015 USA
phone: 800.ORASURE
web: www.orasure.com
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.
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