



# **OraQuick<sup>®</sup>**

*Rapid HCV Antibody Test*

*Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne pathogens in Health-Care Settings.<sup>1</sup>*

## **STEP-BY-STEP INSTRUCTIONS**

**FOR ORAQUICK<sup>®</sup> RAPID HCV ANTIBODY TEST**

**FOR INVESTIGATIONAL USE**



## ■ PROPOSED INTENDED USE STATEMENT:

The OraSure Technologies, Inc. OraQuick® Rapid HCV Antibody Test is a single-use, Anti-HCV assay. It is an immunoassay for the qualitative detection of immunoglobulin G (IgG) antibodies to hepatitis C virus (anti-HCV) in oral fluid, finger-stick whole blood, venipuncture whole blood, serum and plasma specimens (EDTA, heparin and sodium citrate) from persons 10 years or older. The OraSure Technologies, Inc. anti-HCV assay 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 and symptoms of hepatitis and in persons at risk for hepatitis C infection.

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

The effectiveness of OraSure Technologies, Inc. Anti-HCV Assay for use in screening blood, plasma, or tissue donors has not been established.

## THE FOLLOWING ITEMS ARE NEEDED TO DO THE TEST:

### ■ THE ORAQUICK® RAPID HCV ANTIBODY TEST CONSISTS OF A DIVIDED POUCH CONTAINING THE FOLLOWING:

- Test Device (including an absorbent packet)
- Developer Solution Vial (containing 0.75 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 MASTER SHIPPING CARTON:

- Reusable Test Stand
- Specimen Collection Loop
- Package Insert

### ■ MATERIALS REQUIRED BUT NOT PROVIDED:

- Timer or Watch capable of timing 20 to 40 minutes
- Biohazard Waste Container
- Clean, Disposable, Absorbent Workspace Cover

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

- Antiseptic Wipe
- Latex, Vinyl or Nitrile Disposable Gloves (Optional for Oral Fluid Testing)
- Sterile Lancet to Obtain a Fingerstick Whole Blood Specimen, or Materials Required to Obtain a Venipuncture Whole Blood, Serum or Plasma Specimen
- Sterile Gauze Pads
- Centrifuge to Process a Serum or Plasma Specimen

**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 waste container.<sup>1</sup> Oral fluid is not considered potentially infectious unless it contains blood.<sup>2</sup>

<sup>1</sup> See "Universal Precautions," CDC, MMWR, 1988; 37(24):377-388. <sup>2</sup> CDC, MMWR, 2001; 50(RR-11):1-42.

For answers to questions regarding the OraQuick® Rapid HCV Antibody Test contact your Principle Investigator:

## Set Up Your Work Space

- Gather the materials you will need.
- Allow the test kit to come to operating temperature (15°– 37°C; 59°– 99°F) before use.
- Cover your workspace with a clean, disposable, absorbent workspace cover.
- Set an OraQuick® Reusable Test Stand (“Stand”) up on your workspace cover. Use only the Stand provided.
- Put on your disposable gloves if you are planning to perform the test using a blood specimen. Use of gloves is optional for oral fluid testing.

## General Test Preparation



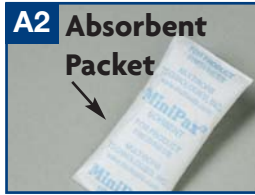
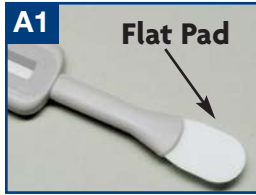
Two Chambers



**NOTE: DO NOT** cover the two holes in the back of the Device with labels or other materials. Doing so may cause an Invalid result.

- Open the two chambers of the OraQuick® Divided Pouch (“Pouch”) by tearing at the notches on the top of each side of the Pouch (*see picture a and b*).
- To prevent contamination, leave the Test Device (“Device”) in the Pouch until you are ready to use it.
- Remove the Developer Solution Vial (“Vial”) from the Pouch.
- Hold the Vial firmly in your hand.
- Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off.
- Set the cap on your workspace cover.
- Slide the Vial into the top of one of the slots in the Stand (*see picture c*).
- **DO NOT** force the Vial into the stand from the front of the slot as splashing may occur.
- Make sure the Vial is pushed all the way to the bottom of the slot in the stand (*see picture c*).

## ORAL FLUID – Specimen Collection and Testing Procedure



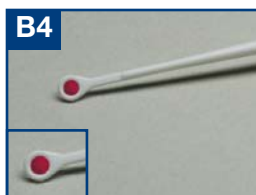
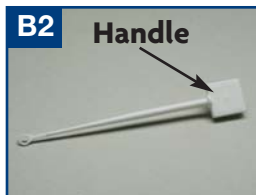
### ■ STEP 1 – COLLECT

- Have the person being tested remove the Device from its Pouch.
- DO NOT allow the person to touch the Flat Pad (see picture A1).
- Check to make sure that an Absorbent Packet is included with the Device (see picture A2). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Direct the person to place the Flat Pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad (see picture A3 and A4). **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. NOTE: Both sides of the Flat Pad may be used during this procedure.

### ■ STEP 2 – TEST

- Instruct the person being tested to insert the Flat Pad of the Device all the way into the Vial (see picture A5). 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 A6).
- Start timing the test (see picture A7). **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 (see picture A8).
- Read the results after 20 minutes but not more than 40 minutes in a well lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections at the back of these instructions.

## FINGERSTICK - WHOLE BLOOD – Specimen Collection and Testing Procedure



**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 specimen.



### STEP 1 – COLLECT

- Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
- 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 this 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*).

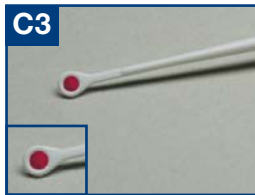
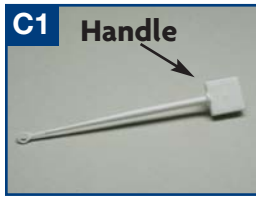
### STEP 2 – MIX

- Immediately insert the blood-filled end of the Loop all the way into the Vial (*see picture B5*).
- Use the Loop to stir the blood specimen in the Developer Solution (“Solution”) (*see picture B6*).
- 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 B7*). 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 specimen.

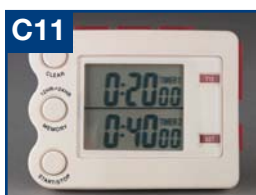
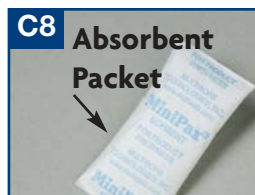
### STEP 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture B8*).
- Check to make sure that an Absorbent Packet is included with the Device (*see picture B9*). 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 specimen (*see picture B10*). 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 B11*).
- Start timing the test (*see picture B12*). **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 (*see picture B13*).
- Read the results after 20 minutes but not more than 40 minutes in a well lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections at the back of these instructions.

## VENIPUNCTURE - WHOLE BLOOD – Specimen Collection and Testing Procedure



**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 specimen.



### STEP 1 – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood specimen using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium and 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°– 30°C (35°– 86°F) for up to 24 hours.
- 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 C1*).
- Put the "rounded" end of the Loop into the tube of blood (*see picture C2*). Make sure the Loop is completely filled with blood (*see picture C3*).

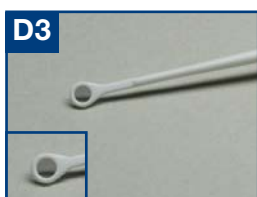
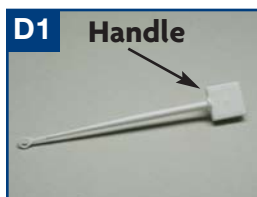
### STEP 2 – MIX

- Immediately insert the blood-filled end of the Loop all the way into the Vial (*see picture C4*).
- Use the Loop to stir the blood specimen in the Developer Solution ("Solution") (*see picture C5*).
- 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 C6*). 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 specimen.

### STEP 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture C7*).
- Check to make sure that an Absorbent Packet is included with the Device (*see picture C8*). 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 specimen (*see picture C9*). 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 C10*).
- Start timing the test (*see picture C11*). **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 (*see picture C12*).
- Read the results after 20 minutes but not more than 40 minutes in a well lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections at the back of these instructions.

## PLASMA, OR SERUM – Specimen Collection and Testing Procedure



**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 plasma specimen.



### STEP 1 – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood specimen using a tube containing whole blood EDTA (lavender top), sodium and lithium heparin (green top), sodium citrate (light blue top) or serum (red top or SST). **Other test tube types have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the specimen may be stored as whole blood for up to 24 hours at 2°–30°C (35°–86°F).
- Centrifuge the tube of blood (1000-1300 x g), for approximately 10 minutes, (no refrigeration required) to separate the cells from the plasma.
- Carefully uncap the tube by gently rocking the stopper towards you so that it vents away from you.
- Pick up an unused Specimen Collection Loop (“Loop”) by the thick “handle” end (see picture D1).
- Put the “rounded end” of the Loop into the tube of plasma or serum (see picture D2).
- Make sure that the Loop is completely filled with specimen (see picture D3).

### STEP 2 – MIX

- Immediately insert the specimen-filled end of the Loop all the way into the Vial (see picture D4).
- Use the Loop to stir the specimen in the Developer Solution (“Solution”) (see picture D5).
- Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.

### STEP 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture D6).
- Check to make sure that an Absorbent Packet is included with the Device (see picture D7). 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 specimen (see picture D8). 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 D9).
- Start timing the test (see picture D10). **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 (see picture D11).
- Read the results after 20 minutes but not more than 40 minutes in a well lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections at the back of these instructions.

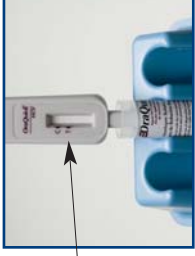
## General Test Clean Up

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

**ADEQUATE  
LIGHTING  
REQUIRED**

## Reading Test Result

Look at the Result Window of the Test Device



Read results after 20 minutes but not more than 40 minutes.

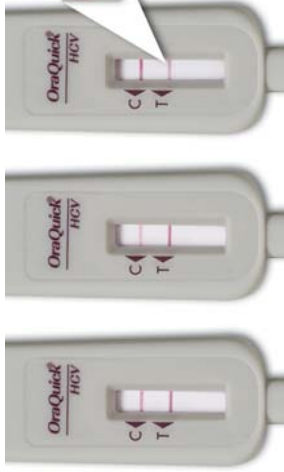
### Non-Reactive



#### Test is **NON-REACTIVE** if:

- A single pink or reddish-purple line across the device window appears next to the triangle labeled "C" **and** NO line appears next to the triangle labeled "T".

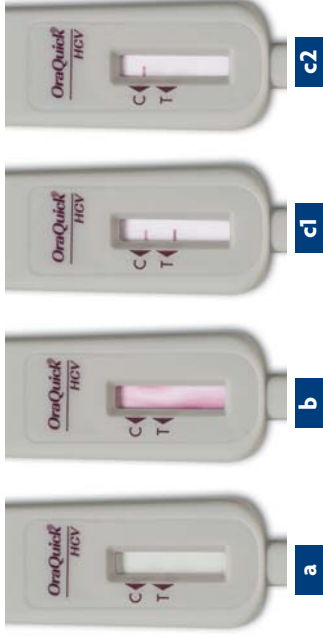
### Reactive



#### Test is **REACTIVE** if:

- A single pink or reddish-purple line appears next to the triangle labeled "C" **and** a pink or reddish-purple line across the device window appears next to the triangle labeled "T". One of these lines may be darker than the other. **NOTE:** The test is **REACTIVE** if **any** pink or reddish-purple line across the device window appears next to the "T" triangle **and** next to the "C" triangle, no matter how faint these lines are.

### Invalid



#### Test is **INVALID** if:

- NO** pink or reddish-purple line across the device window appears next to the triangle labeled "C" (see *Diagram a*), or
- A red background in the Results Window makes it difficult to read the result **after 20 minutes** (*Diagram b*), or
- Any partial line on one side of the test window next to the triangle labeled "C" or "T" (see *Diagram c1 and c2*).

## Interpretation of Test Result

- A **Non-Reactive** test result means that HCV antibodies were not detected in the specimen. The test result is interpreted as **NEGATIVE for HCV antibodies**.
- A **Reactive** test result means that HCV antibodies have been detected in the specimen. The test result is interpreted as **REACTIVE for HCV antibodies**.
- 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 oral fluid, fingerstick or venipuncture whole blood, plasma or serum specimen. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.



OraSure Technologies, Inc.  
diagnostic solutions for the new millennium

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L3001-XXXX (rev. 11/07)