



OraQuick® HCV Product Training

U.S. Only

- Fingerstick Whole Blood
- Venous Whole Blood

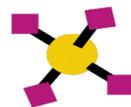
OraQuick[®] Rapid HCV Antibody Test

- Test with Ease and Convenience
 - The only FDA-approved rapid HCV test for use with:
 - Fingertick whole blood
 - Venipuncture whole blood
 - Results in just 20 minutes
 - Clinical performance with >99% accuracy



OraQuick® HCV Clinical Features Operating Principle

▲ Anti-Human Antibody

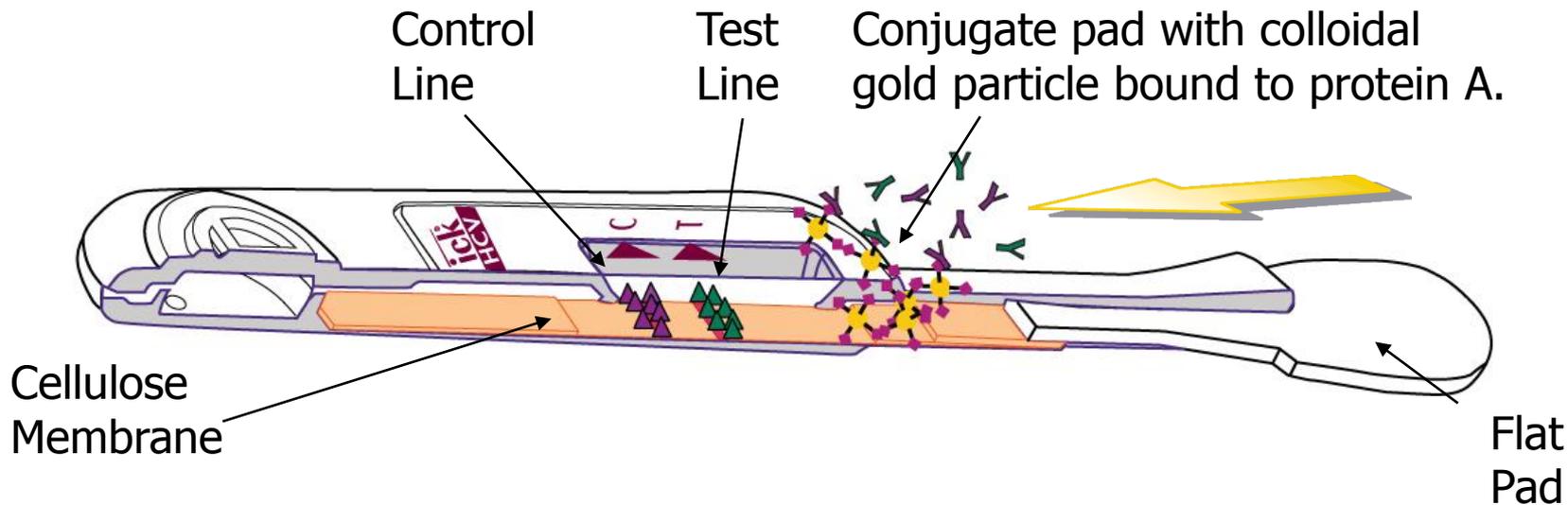


Colloidal Gold
Conjugated
to Protein A

Y Human Antibodies

▲ HCV Antigen

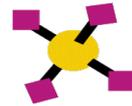
Y HCV Antibodies



Using a lateral flow process, a sample specimen is wicked up by the flat pad of the device and transferred to the cellulose membrane. Human antibodies and HCV antibodies (if present) bind to the colloidal gold particles.

OraQuick® HCV Clinical Features Operating Principle

▲ Anti-Human Antibody

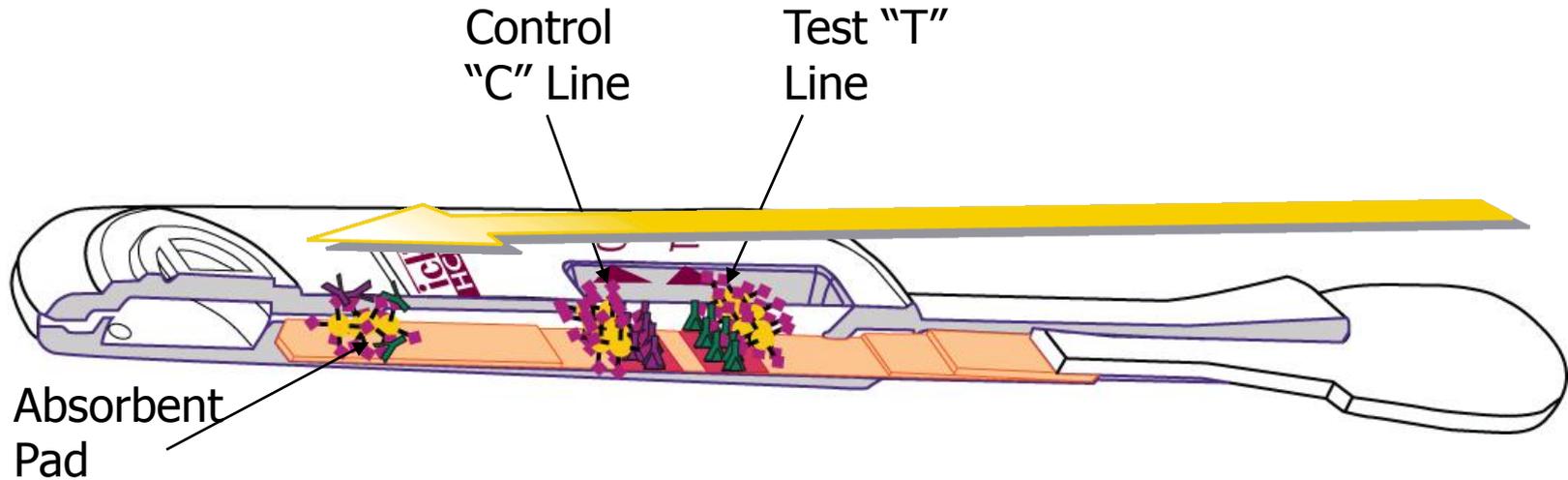


Colloidal Gold
Conjugated
to Protein A

Y Human Antibodies

▲ HCV Antigen

Y HCV Antibodies



Colloidal gold particles containing HCV antibodies bind to the HCV antigen "T" line forming a visible red band. Colloidal gold particles containing Human antibodies bind to the Anti-Human Antibodies "C" line forming a visible red band. Any remaining colloidal gold particles are captured and retained by the absorbent pad.

OraQuick® HCV Clinical Features Product Training



Intended Use

- The OraQuick[®] Rapid HCV Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Hepatitis C Virus (anti-HCV) in fingerstick whole blood and venipuncture whole blood specimens (EDTA, sodium heparin, lithium heparin and sodium citrate) from individuals 15 years or older.
- For *in vitro* diagnostic use.

OraQuick® Rapid HCV Antibody Test Kit



- Single-use testing device with built-in procedural control
- Single-use test developer solution vial
- Reusable test stand
- Disposable single-use specimen collection loop

Additional Materials Required



- Timer or Watch
- Biohazard Waste Container
- Disposable, Absorbent Workspace Cover

Additional Required Phlebotomy

Materials (Whole Blood):

- Disposable Gloves
- Sterile Lancet
- Phlebotomy materials
- Centrifuge
- Antiseptic Wipe
- Sterile Gauze Pads

Prior to Testing

- **Remember to observe “Universal Precautions” at all times.**
- **Read the package insert instructions *first*.**
- Gather testing materials.
- Allow the test to come to operating temperature.
- Set up workspace cover and reusable Test Stand on a flat level surface.
- Put on disposable gloves if working with blood specimens.

General Test Preparation



- Open two chambers of Divided Pouch by tearing at the notches.
- Leave the Test Device in the Pouch.
- Remove the Developer Vial. Gently rock the cap back and forth to remove.
- Slide the Vial into the top of one of the slots of the Stand. Make sure it is seated in the stand.



Specimen and Test Performance

- Fingertstick whole blood
- Venous whole blood

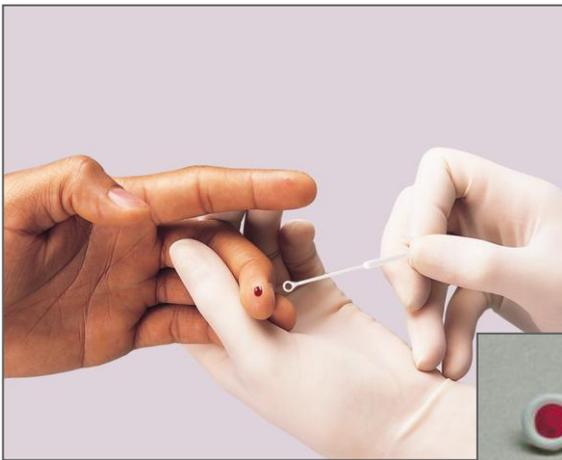
Fingerstick—Specimen Collection



- Remove test device from Pouch. **DO NOT** touch the Flat Pad.
- Make sure an Absorbent Packet is present. If no Absorbent Packet is present, discard Device; obtain a new Pouch for testing.
- Label device with subject's ID information. **DO NOT** block holes on back of device.

NOTE: Test Device must be inserted into Vial within 60 minutes of sample introduction.

Fingerstick—Specimen Collection



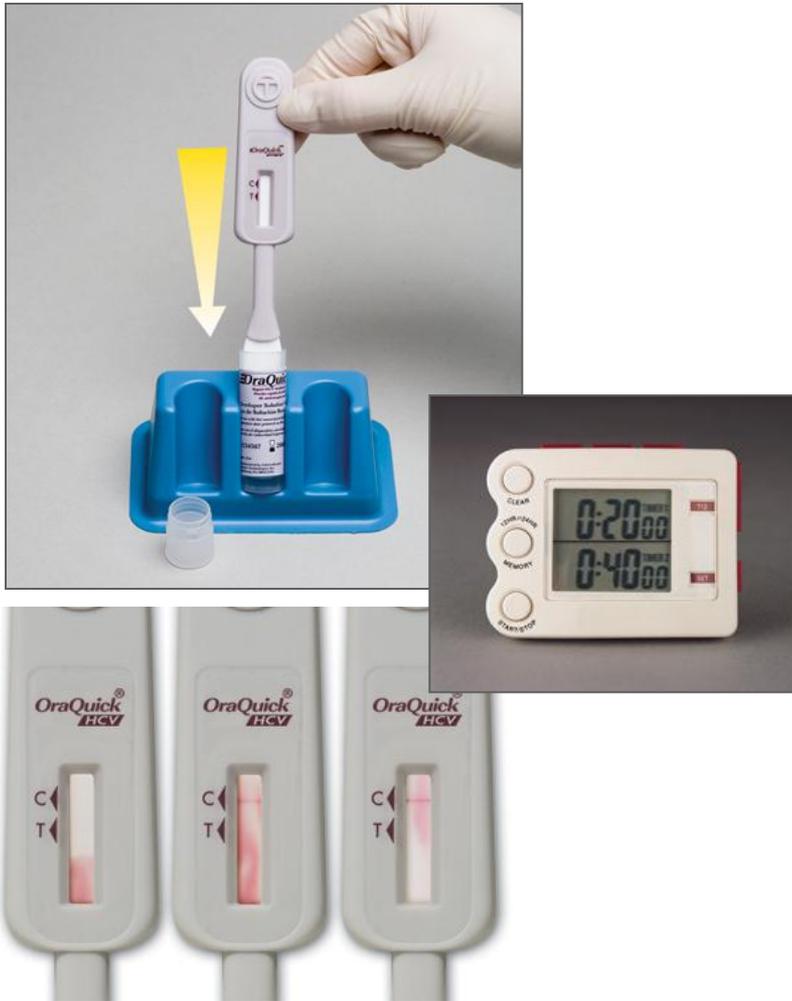
- Use an antiseptic wipe; clean finger of person being tested. **Dry completely.**
- Using sterile lancet, puncture skin off center of finger pad.
- **WIPE** first droplet with gauze. Hold the hand downward for new droplet. Gently apply pressure to express if needed.
- With new Specimen Collection Loop, touch to droplet.
- *Make sure Loop is completely filled with blood.*

Fingerstick—Mixing Specimen



- Insert blood-filled end of Loop into the vial. **Be careful not to touch the sides of the vial.**
- Use Loop to stir sample in Vial. Dispose of used Loop in biohazard waste container.
- Check Solution to make sure it appears pink in color.

Fingerstick—Test Performance



- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

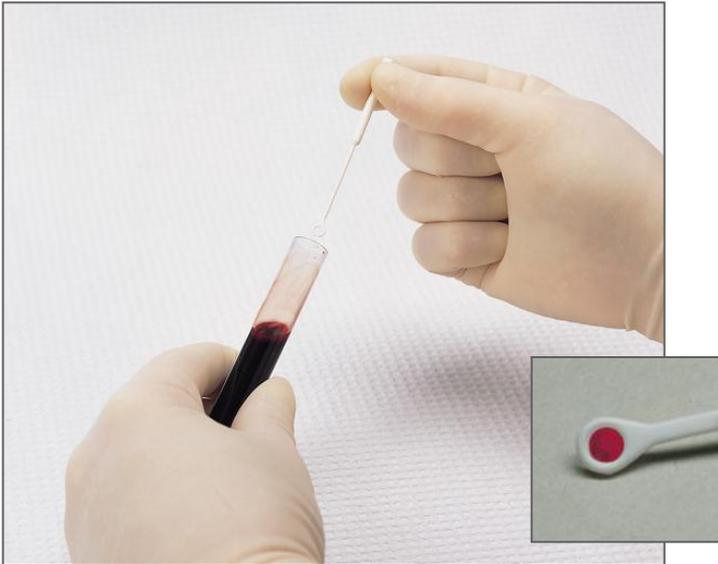
Whole Blood—Specimen Collection



- Remove test device from Pouch. **DO NOT** touch the Flat Pad.
- Make sure an Absorbent Packet is present. If no Absorbent Packet is present, discard Device; obtain a new Pouch for testing.
- Label device with subject's ID information. **DO NOT** block holes on back of device.

NOTE: Test Device must be inserted into Vial within 60 minutes of sample introduction.

Whole Blood—Specimen Collection



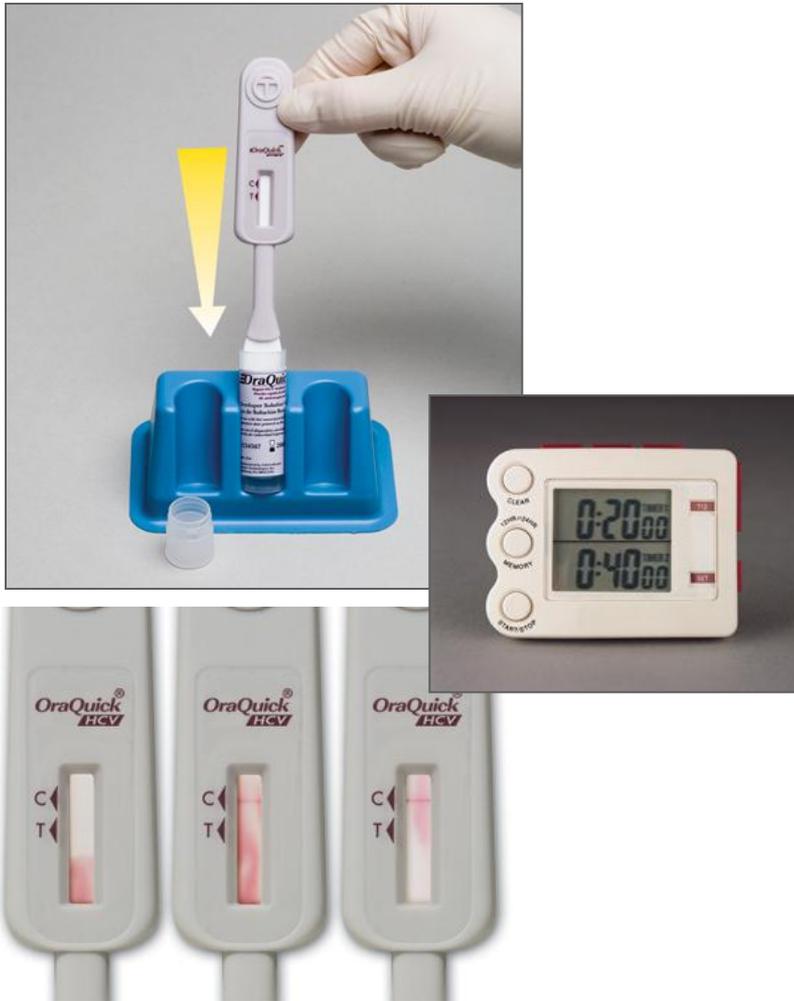
- Using standard phlebotomy procedures, collect whole blood sample with an EDTA, sodium heparin, lithium heparin, or sodium citrate test tube.
- Mix blood tube by inversion.
- With new Specimen Collection Loop, dip Loop into test tube.
- Visually inspect the Loop to make sure that it is completely filled with a specimen.

Whole Blood—Mixing Specimen



- Insert blood-filled end of Loop into the Vial. **Be careful not to touch the sides of the Vial.**
- Use Loop to stir sample in Vial. Dispose of used Loop in biohazard waste container.
- Check Solution to make sure it appears pink in color if using whole blood.

Whole Blood—Test Performance



- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

Test Reading & Interpretation

- Non-reactive result
- Reactive result
- Invalid

Reading a Non-Reactive Test

A test is **NON-REACTIVE** if:

- A line appears in the “C” zone and no line appears in the “T” zone.



Interpreting a **Non-Reactive** Test



A **Non-Reactive** test result means that HCV antibodies were not detected in the specimen.

Patient is presumed not to be infected with HCV.

Reading a Reactive Test

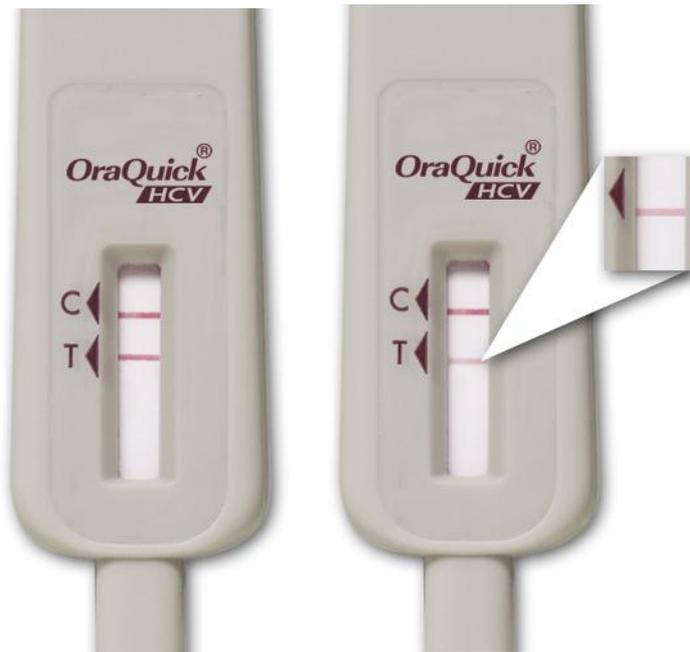


A test is REACTIVE if:

- A line appears in the “C” zone **and** a line appears in the “T” zone. Lines may vary in intensity

NOTE: The test is reactive if any line appears in the “T” zone **and** in the “C” zone, no matter how faint.

Interpreting a Reactive Test

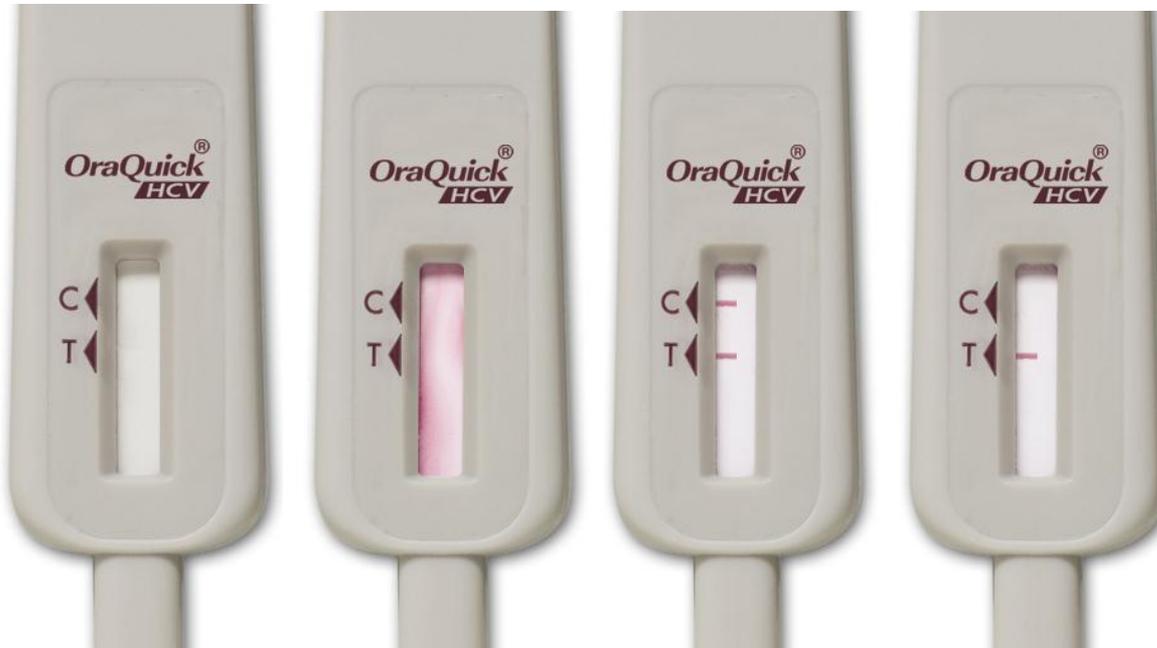


A **Reactive** test result means that HCV antibodies have been detected in the specimen.

The patient is presumed to be infected with HCV.

Individuals with a reactive result should undergo appropriate clinical follow-up according to CDC recommendations for supplemental testing.

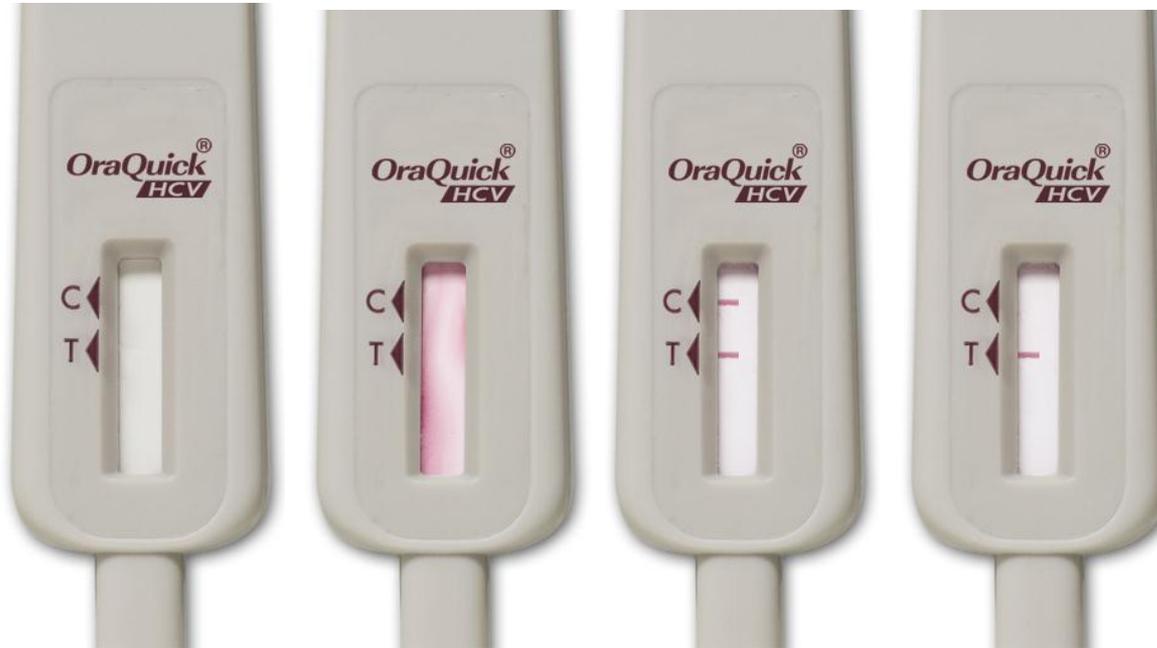
Reading an Invalid Test



A test is INVALID if:

- No line appears in the “C” zone, **or**
- A pink background in the result window makes it difficult to read the result during the 20 to 40 minute read times, **or**
- If any of the lines are **partially developed** on one side of the “C” or “T” zones

Interpreting an **Invalid** Test

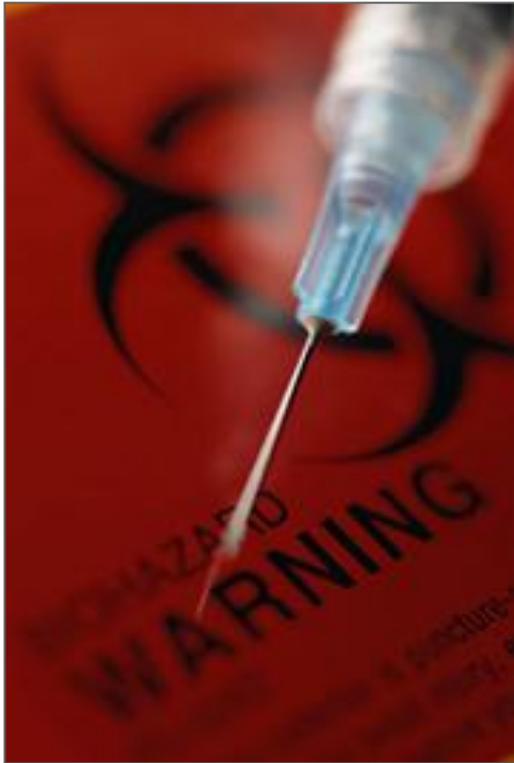


An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Device.

IT CANNOT BE INTERPRETED.

Repeat test with a new Pouch and a fingerstick or venipuncture whole blood, sample.

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.

Quality Control

- Positive and Negative Kit Controls provide:
 - Quality Control to:
 - Assure test performance
 - Provide for user proficiency
- Positive Controls
 - Are calibrated specifically to a very low assay reactivity level (challenge line)
 - Low assay performance reaffirms assay functionality (assay chemistry)
 - Provide better training tool for user proficiency



Test Kit—Kit Controls

Positive Controls

- Purple-capped vial—inactivated human plasma positive for antibodies to HCV.

Negative Control

- White-capped vial—human plasma negative for antibodies to HCV.

Sufficient volume for a minimum of 25 tests.

Test Kit—Kit Controls

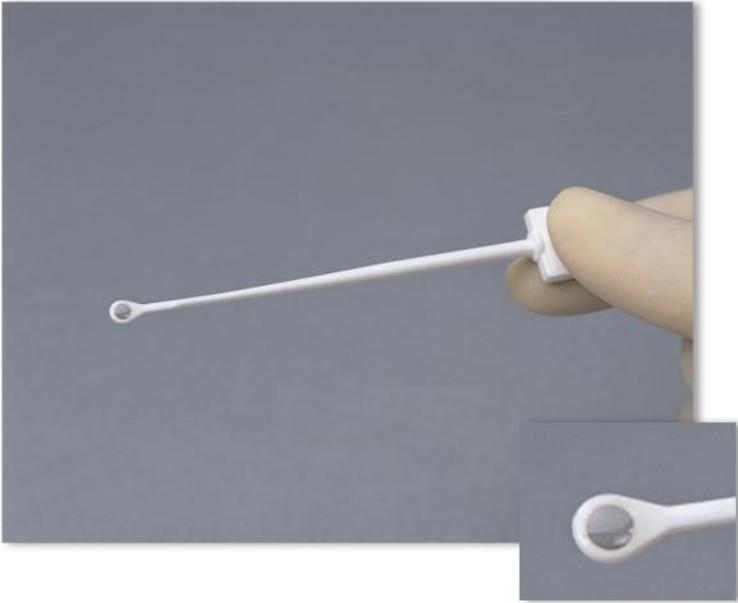
Run one positive HCV control (+), and one negative control (-) for:

- Each new operator
- Each new lot of test kits
- Each new shipment of test kits
- Test kit storage temperature falls outside 2-27°C; 35-80°F
- Testing area temperature falls outside of 15-37°C; 59-99°F
- At periodic intervals dictated by user facility

Performing Kit Controls

- Getting Started
 - Remember to observe “Universal Precautions” at all times.
 - Follow directions for setting up workspace.
 - Label devices for Negative and Positive Controls.
DO NOT block holes on back of device.
DO NOT touch Flat Pad of device.

Performing Kit Controls



- Open a Kit Control vial.
- Insert round end of a new Specimen Collection Loop into the reagent vial.
- Remember to use separate unused Loop for each control reagent.

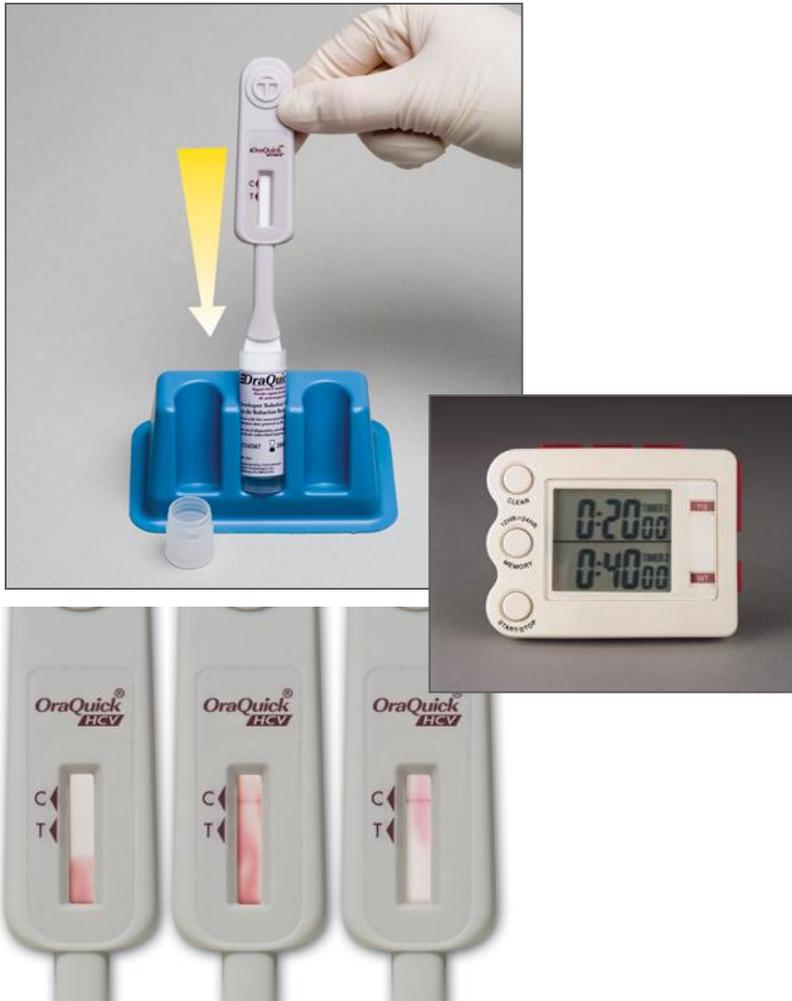
NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears cloudy or discolored.

Performing Kit Controls



- Immerse Loop into Developer Solution Vial.
- DO NOT touch side of Vial.
- Use the Loop to stir contents.
- Discard Loop in a biohazard waste container.

Performing Kit Controls



- Retrieve correct labeled device.
- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

Performing Kit Controls

Example of a
Non-Reactive Result
(Negative)



Example of a
Reactive Result
(Positive)

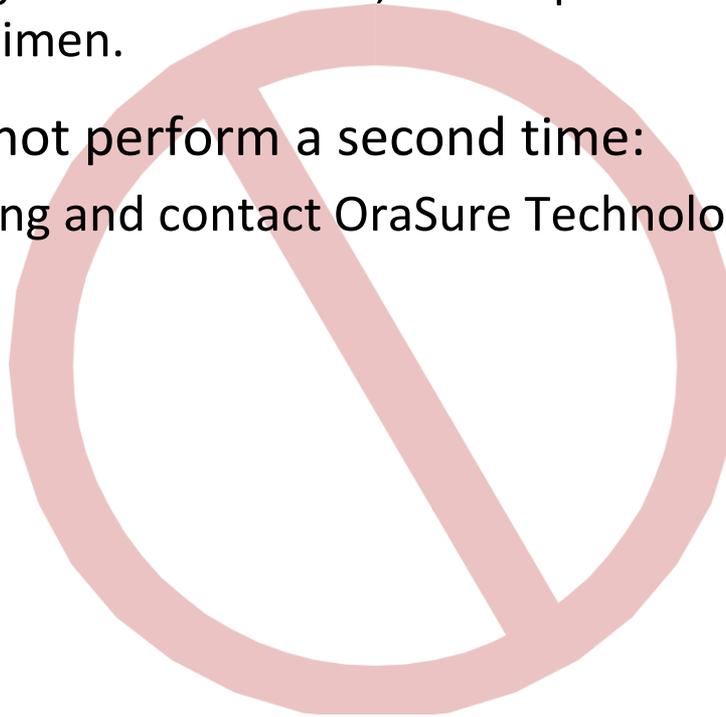


Expected Results:

- Negative Control will produce a Non-Reactive test result. A line should be present at the “C” zone in result window.
- Positive Controls will produce a Reactive test result specifically manufactured to produce a faint (*Challenge Test*) “T” line. Lines should appear at “C” and “T” zones in result window.

Kit Control Failure

- If test result does not perform as expected:
 - Repeat test using new Test Device, Developer Solution Vial, and Control Specimen.
- If test result does not perform a second time:
 - Discontinue testing and contact OraSure Technologies Customer Care.



Universal Precautions

Handling of Potentially Infectious Human Samples

- Before handling any specimens, please refer to your facility's procedures on universal precautions.
- Universal guidelines stress that all patients should be assumed to be infectious for blood-borne diseases such as HIV and hepatitis B.
- Barriers are used for protection against occupational exposure to blood and certain body fluids.
 - These barriers consist of:
 - Personal protective equipment (PPE)
 - Engineering controls
 - Work practice controls

OraQuick® HCV Interpretation Quiz



A



B



C



D



E