OraQuick® HCV Rapid Antibody Test Training

Kentucky Department of Public Health
February 20, 2020
Training Content Outline

• Hepatitis C: Past, Present and Future

• OraQuick® HCV Rapid Antibody Test Device Training

• Kit Controls and Visual Reference Panel
Viral Hepatitis

- **A**: Vaccine
- **B**: No Vaccine
- **C**: Acute and Chronic

**Acute**: Fever, fatigue, nausea, abdominal pain, jaundice, etc.

**Supportive Care**: Treatable
Incubation period: 14-180 days (average: 45 days)

- Symptoms:
  - Loss of appetite
  - Fever
  - Fatigue
  - Nausea
  - Vomiting
  - Abdominal pain
  - Joint pain
  - Jaundice
  - Gray-colored bowel movements

*Approximately 20-30% of people experience symptoms
Known Risk Factors for HCV Exposure

CERTAIN MEDICAL CONDITIONS
- Unexplained chronic liver disease and hepatitis, including increased alanine aminotransferase (ALT) levels
- HIV Infection

PRIOR BEHAVIORS
- Injection drug use, even once
- Intranasal illicit drug use

KNOWN EXPOSURES
- Receiving a blood transfusion or organ transplant prior to 1992
- Receiving clotting factor prior to 1987
- Long term hemodialysis
- Children born to a mother who has HCV
- Needle stick injury (Healthcare Workers)
- Incarceration or work in a jail or prison
- Had unprotected sex with a person with hepatitis C
- Shared toothbrushes, razors and similar toiletries with a person who has hepatitis C
- Have unregulated tattoos or body piercings
- Military veterans (especially Vietnam veterans)

The Challenge: A Silent Epidemic

HCV can remain asymptomatic for many years, contributing to low diagnosis rates.

- 75% of people with HCV don’t know they are infected.
- 62–68% of people with chronic HCV infection don’t receive follow-up HCV care.

~5.2 million people in the U.S. have been exposed to or are infected with HCV.

~3.2 million people have chronic HCV infection.

~2.4 million undiagnosed HCV cases.

A GAP EXISTS IN DIAGNOSIS

Deaths Due to HCV Infections Now Exceed Those Due to HIV Infections


The presence of the anti-HCV antibody shows a person has been exposed to or is infected with the hepatitis C virus.

The distinction between acute and chronic viral hepatitis C is very important.

- **Acute** illness is defined as the presence of hepatitis for less than 6 months.

- **Chronic** illness is defined as the presence of hepatitis for greater than 6 months.

HCV Liver Disease Progression

For every 100 people infected with HCV there are...

- Up to 85 will develop chronic infection
- Up to 70 will develop chronic liver disease
- Up to 20 will develop cirrhosis that progresses for 20-30 yrs.
- Up to 5 will die from the consequences of chronic infection

Hepatocellular Carcinoma
~1 - 4% will develop HCC annually
1% - 5% will die of HCC
The incidence of HCC has tripled over the past 20 years

Chronic hepatitis

Cirrhosis

Decompensated Cirrhosis
HCV infection is leading cause of liver transplant (40% of all transplants)

* Direct all-cause costs: Medical and Pharmacy

OraQuick® HCV Rapid Antibody Test Device Training
OraQuick® Rapid HCV Antibody Test

• Test with Ease and Convenience
  – The only FDA-approved rapid HCV test for use with:
    • Fingerstick whole blood
    • Venipuncture whole blood
  – ACCURATE – Reliable results with >98% accuracy
  – SIMPLE – 3-easy steps; CLIA-waived
  – FAST – Test and result delivery in 20 minutes for immediate linkage to care.

• The **only FDA-approved, point-of-care test** for HCV antibodies that meets all current HCV guidelines and recommendations
Summary of Clinical Performance

- Serostatus analysis ≥ 98% agreement with known HCV-positive and HCV-negative subjects.

<table>
<thead>
<tr>
<th></th>
<th>Positive % agreement (with confirmed HCV-positive subjects)</th>
<th>Negative % agreement (with confirmed HCV-negative subjects)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VENIPUNCTURE</td>
<td>N=1207</td>
<td>n=762/770</td>
</tr>
<tr>
<td></td>
<td>n=435/437</td>
<td>99.5%*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>98.4, 99.9</td>
</tr>
<tr>
<td>FINGERSTICK</td>
<td>N=1660</td>
<td>n=923/937</td>
</tr>
<tr>
<td></td>
<td>n=708/723</td>
<td>97.9%*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>96.6, 98.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n=923/937</td>
</tr>
<tr>
<td></td>
<td></td>
<td>98.5%*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>97.5, 99.2</td>
</tr>
</tbody>
</table>

^Multiple clinical studies were conducted to determine positive and negative agreement of the OraQuick® HCV Rapid Antibody Test. Confirmation was performed by a licensed RIBA®. Indeterminate RIBA results were tested by PCR.

*Includes subjects with "unable to determine" status.
Summary of Clinical Performance

- On average, OraQuick® HCV Rapid Antibody Test detects seroconversion **UP TO 6 DAYS EARLIER** when compared to laboratory-based FDA-approved EIA’s

<table>
<thead>
<tr>
<th>Days to Evidence of HCV Infection</th>
<th>OraQuick® HCV Rapid Antibody Test Time to Detection</th>
<th>FDA-Approved anti-HCV EIA Time to Detection</th>
<th>Difference (OraQuick-EIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>59.2</td>
<td>62.7</td>
<td>-3.6 (-5.9 to -1.2)</td>
</tr>
</tbody>
</table>

See package insert performance characteristics for additional data
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.

- For *in vitro* diagnostic use.

- Complexity: CLIA-waived for Fingerstick Whole Blood and Venipuncture Whole Blood.
Prior to Testing

• Remember to observe “Universal Precautions” at all times.
• Read the package insert first.
• Gather testing materials required but not provided (see package insert detail page 3).
• Allow the test to come to operating temperature.
• Set up workspace cover and reusable Test Stand on a flat level surface.
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.

• 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

• FOR COMPLETE INFORMATION REFER TO THE CDC WEBSITE AT: http://www.cdc.gov/HAI/prevent/prevention.html
# Test Kit – Available Packaging

<table>
<thead>
<tr>
<th>Kit Size</th>
<th>25 Count</th>
<th>100 Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item No.</strong></td>
<td>1001-0181</td>
<td>1001-0180</td>
</tr>
<tr>
<td>Test Devices</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>Reusable Test Stand</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Specimen Collection Loops</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>Package Insert</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Storage Requirements**: 2-30°C (36-86°F)
- **Operating Requirements**: 15-37°C (59-99°F)
- **Test Sample Type**: Fingerstick or Venipuncture Whole Blood
- **CLIA Complexity**: CLIA-waived
- **Test Type**: Qualitative Immunoassay
- **CPT Code**: 86803; G0472 (Medicare HCPCS)
Additional Materials Required, But Not Provided

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

Additional Required Phlebotomy Materials (Whole Blood):
- Disposable Gloves
- Sterile Lancet
- Phlebotomy materials
- Antiseptic Wipe
- Sterile Gauze Pads
need to insert video. also need to figure out how we would do this for a pdf
Ray Ahmed, 7/13/2015
OraQuick® HCV Rapid Antibody Test

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

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 Rapid Antibody Test

Simple, 3-step procedure

1) Collect
2) Mix
3) Read

Whole blood finger stick procedure only shown. Refer to package insert for complete instructions and for the whole blood venipuncture procedure.
General Test Preparation

• Check expiration date on the OraQuick® HCV pouch

• 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 Collection

- Remove test device from Pouch. **DO NOT** touch the Flat Pad.

- 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.

- Make sure an Absorbent Packet is present. If no Absorbent Packet is present, discard Device; obtain a new Pouch for testing.
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 Procedure

- 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

- 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 Procedure

• 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.
A 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.
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.

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

An Invalid result cannot be interpreted. Repeat the test with a new pouch and new specimen. Contact OraSure Technologies’ Customer Service if you are unable to get a valid test result upon repeat testing.
Additional Materials Required

**OraQuick® HCV Rapid Antibody Test**

Kit Controls #1001-0182

- HCV Positive Control Vial (0.2 mL)
- HCV Negative Control Vial (0.2 mL)

**OraQuick® Visual Reference Panel**

#1001-0343

- HCV Non- Reactive (1 device)
- HCV Low Reactive (1 device)
- HCV Limit of Detection (1 device)
**Kit Controls**

**External Kit Controls**

- 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

*It is important that test operators read the OraQuick® HCV Rapid Antibody Test Kit, Kit Control and Visual Reference Panel Package Inserts prior to performing the test procedure. This training is not intended to replace this requirement.*
OraQuick® Rapid HCV Antibody Test Kit Controls

Positive Control
• 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 to perform 25 tests.
#1001-0182 OraQuick® HCV Rapid Antibody Test Kit Controls

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive HCV Control Vial (Purple Cap)</td>
<td>(1) 0.2mL</td>
</tr>
<tr>
<td>Negative Control Vial (White Cap)</td>
<td>(1) 0.2mL</td>
</tr>
<tr>
<td>Package Insert</td>
<td>1</td>
</tr>
<tr>
<td>Storage Requirements</td>
<td>2-8°C (36-46°F)</td>
</tr>
<tr>
<td>Shelf-Life</td>
<td>1 Year from Date of Manufacture or 8 weeks after initial opening of packaging</td>
</tr>
</tbody>
</table>

Note: Kit Controls do not have to be brought to operating temperature prior to performing quality control testing.
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 2-30°C; 36-86°F
- Testing area temperature falls outside of 15-37°C; 59-99°F
- At periodic intervals dictated by user facility
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.
Visual Reference Panel

• **Visual Reference Panel provides:**
  - Operator education tool:
    • Assure test operators can interpret various line intensities of the OraQuick® HCV Device
    • Provide better training tool for user proficiency
  - Each Kit Includes:
    - 1 Negative Device
    - 1 Low Reactive Device
      • Calibrated specifically to a very low assay reactivity level (challenge line)
    - 1 Limit of Detection Device
      • Calibrated specifically to the lowest detection range (0.75 signal to cutoff)

*It is important that test operators read the OraQuick® HCV Rapid Antibody Test Kit, Kit Control and Visual Reference Panel Package Inserts prior to performing the test procedure. This training is not intended to replace this requirement.*
#1001-0343 OraQuick® HCV Visual Reference Panel

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Reactive Result</td>
<td>(1) device</td>
</tr>
<tr>
<td>Low Reactive Result</td>
<td>(1) device</td>
</tr>
<tr>
<td>Limit of Detection Result</td>
<td>(1) device</td>
</tr>
<tr>
<td>Package Insert</td>
<td>1</td>
</tr>
<tr>
<td>Storage Requirements</td>
<td>15-30°C (59-86°F)</td>
</tr>
<tr>
<td>Shelf-Life</td>
<td>5 Months from Date of Manufacture</td>
</tr>
</tbody>
</table>

**NOTE:** The OraQuick® HCV Visual Reference Panel is intentionally manufactured to be hard to read. The inability to read at low intensities can result in false negative interpretation.

Correct interpretation is an important QA Step
Summary
Key Points

• The benefits of the OraQuick HCV Rapid Antibody Test:

  – **ACCURATE** – reliable results with >98% accuracy, as good or better than any lab-based assay
  – **SIMPLE** – 3 simple steps, CLIA waived, can be done by nearly anyone in any setting
  – **FAST** – test and result delivery in 20 minutes for immediate linkage to care, less than 2 minutes of hands on time

  – The *only FDA-approved, point-of-care test* for HCV antibodies that meets all current HCV guidelines and recommendations.

  – Patients receive results while speaking to their HCP face-to-face.

  – Early detection is important. The earlier HCV is detected, the better the patient’s prognosis.
Summary of Today’s Discussion

Integrate HCV Testing Daily

• **Step 1:** Identify birth cohort and patients at-risk for HCV

• **Step 2:** Test patients with **OraQuick® Rapid Antibody Test** at the point of care

• **Step 3:** If your patients are HCV-positive, order a confirmatory test

• **Step 4:** Refer your patient to a specialist for treatment

*Option for 1:1 support with a Hep C Community Educator.*
Thank You! We appreciate your time and engagement

Please keep the following resources in mind to assist you in implementing the OraQuick® HCV Rapid Antibody Test

- OraQuick® HCV Customer Care
  1- 800-OraSure (673-7873)

- www.TestHepC.com
CDC Recommended Supplemental Testing Algorithms for HCV

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

- HCV antibody

  - Nonreactive
    - No HCV antibody detected
      - STOP
  - Reactive
    - Not Detected
      - No current HCV infection
        - Additional testing as appropriate
    - Detected
      - Current HCV infection
        - Link to care