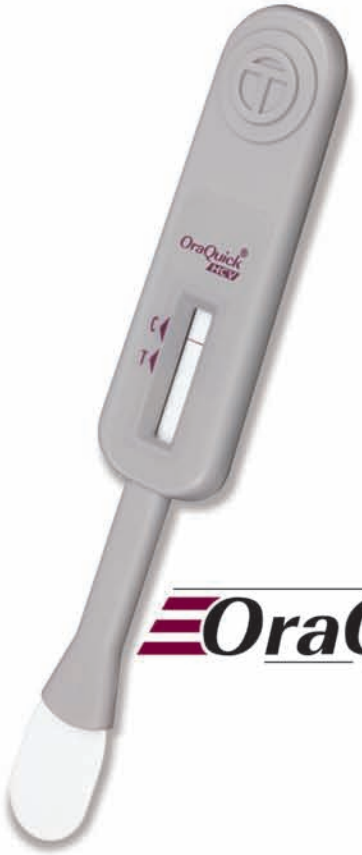
9. Support Documents and Forms



OraQuick® Rapid Antibody Test HCV

Support Documents and Forms

Checklist for Conducting Rapid HCV Tests

General Test Preparation

- ❑ Conditions for testing verified (temperature and lighting)
- ❑ Clock or timer made available
- ❑ Expiration date verified on Pouch
- ❑ Clean, disposable absorbent workspace cover
- ❑ Manufacturer's Stand used
- ❑ Stand is on flat level surface
- ❑ Test Device left in pouch until needed (not contaminated)
- ❑ Absorbent Packet included in Pouch
- ❑ Vial slid into Stand
- ❑ Vial is completely seated in Stand
- ❑ Two holes in back of Test Device not covered

Sample Collection and Test Procedures - Fingerstick Whole Blood Collection

- ❑ Disposable gloves worn
- ❑ Client finger cleaned with antiseptic wipe
- ❑ Finger allowed to dry thoroughly
- ❑ Second drop of blood collected
- ❑ Loop was completely filled with blood
- ❑ Loop stirred into Developer Solution
- ❑ Solution turned pink
- ❑ Pad on the Test Device touched the bottom of the vial
- ❑ Results Window faced forward
- ❑ Timer used
- ❑ Results read between 20 and 40 minutes after Test Device inserted into the vial
- ❑ Test Device read while in Developer Solution Vial
- ❑ Test results properly recorded

Checklist for Conducting Rapid HCV Tests

Sample Collection and Test Procedures - Venipuncture Whole Blood Collection

- ❑ Specimen collection conducted with an EDTA, lithium heparin, sodium heparin or sodium citrate test tube
- ❑ Loop was completely filled with blood
- ❑ Loop stirred into Developer Solution
- ❑ Solution turned pink
- ❑ Pad on the Testing Device touched the bottom of the vial
- ❑ Results Window faced forward
- ❑ Timer used
- ❑ Results read between 20 and 40 minutes after Testing Device inserted into the vial
- ❑ Test Device read while in Developer Solution Vial

Quality Control (To be conducted as per manufacturer's guidelines)

- ❑ Kit Controls run; Date and Time_____
- ❑ Kit Controls verify Control Test Results match the expected results
- ❑ Good lighting used with Controls
- ❑ Test viewed good lighting conditions
- ❑ Clinic room temperature checked and recorded

Comments:_____

_____

_____

HCV Positive Enhanced Risk Assessment Tool

1. Did you receive a blood transfusion or solid organ transplant (heart, lung, liver, pancreas, kidney) before July 1992?	❑ No	❑ Yes
2. Did you receive clotting factor concentrates produced before 1987?	❑ No	❑ Yes
3. Have you ever received hemodialysis?	❑ No	❑ Yes
4. Have you had blood tests that showed a liver problem?	❑ No	❑ Yes
5. Have you had a needlestick injury working in a health care setting?	❑ No	❑ Yes
6. Did your mother have hepatitis C when you were born?	❑ No	❑ Yes
7. Have you shared a toothbrush, razor, or any other item that might have blood on it (visible or not) with a person who has hepatitis C?	❑ No	❑ Yes
8. Have you or any of your sex partner(s) injected illegal drugs, even if it was only one time many years ago?	❑ No	❑ Yes
9. Have you ever been told by a medical provider that you have HIV infection?	❑ No	❑ Yes

Clinic Name/Site Location: _____

Name/ID Number: _____ Date: _____

Counselor/Tester: _____ Date: _____

Comments:_____

_____

_____

OraQuick® HCV Rapid Antibody Test
Client Test Result Log

Clinic Name: ____________________

Testing Location: ____________________

Client ID/Name	Counselor Code/Initials	Test Dates mm/dd/yy	Test # Performed	Lot #/Exp. Date of Test	Time Test Performed	Testing Room Temperature	Time Test Interpreted	Testing Room Temperature	Test Result	Date Client Received Result	Result & Type of Supplemental Serum or Plasma	Date Client Received Test Suppl Result	How Result Received by: Phone (PH) or Result in Person (IP)
			☐ First ☐ Second		____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	Non-Reactive Reactive Invalid (*circle one*)		☐ Serum ☐ Plasma ☐ Positive ☐ Negative		PH IP (*circle one*)
			☐ First ☐ Second		____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	Non-Reactive Reactive Invalid (*circle one*)		☐ Serum ☐ Plasma ☐ Positive ☐ Negative		PH IP (*circle one*)
			☐ First ☐ Second		____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	Non-Reactive Reactive Invalid (*circle one*)		☐ Serum ☐ Plasma ☐ Positive ☐ Negative		PH IP (*circle one*)
			☐ First ☐ Second		____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	Non-Reactive Reactive Invalid (*circle one*)		☐ Serum ☐ Plasma ☐ Positive ☐ Negative		PH IP (*circle one*)
			☐ First ☐ Second		____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	Non-Reactive Reactive Invalid (*circle one*)		☐ Serum ☐ Plasma ☐ Positive ☐ Negative		PH IP (*circle one*)
			☐ First ☐ Second		____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	____ a.m. ____ p.m. (*circle one*)	____ °C ____ °F (*circle one*)	Non-Reactive Reactive Invalid (*circle one*)		☐ Serum ☐ Plasma ☐ Positive ☐ Negative		PH IP (*circle one*)

OraQuick® HCV Rapid Antibody Test
Client Test Result Log

Clinic Name: _____

Testing Location: _____

Client ID/Name	Counselor Code/Initials	Test Dates mm/dd/yy	Test # Performed	Lot #/Exp. Date of Test	Time Test Performed	Testing Room Temperature	Time Test Interpreted	Testing Room Temperature	Test Result	Date Client Received Result	Result & Type of Supplemental Serum or Plasma	Date Client Received Test Suppl Result	How Result Received by: Phone (PH) or Result in Person (IP)
Virginia Hall #12345678	#938-LB	09/05/11	[X] First [ ] Second	#1234567 12/23/12	8:45 a.m. / p.m. (circle one)	72.6 °F (circle one)	9:08 a.m. / p.m. (circle one)	72.6 °F (circle one)	Non-Reactive / Reactive / Invalid (circle one)	9/5/11	[ ] Serum [ ] Plasma [ ] Positive [ ] Negative	N/A	PH IP (circle one)
Mark Dewitt #12345679	#938-LB	09/05/11	[X] First [ ] Second	#1234567 12/23/12	9:42 a.m. / p.m. (circle one)	72.4 °F (circle one)	10:10 a.m. / p.m. (circle one)	72.0 °F (circle one)	Non-Reactive / Reactive / Invalid (circle one)	Positive 9/5/11	[ ] Serum [X] Plasma [X] Positive [ ] Negative	9/16/03	PH IP (circle one)
Theresa Howard #12345680	#938-LB	09/05/11	[X] First [ ] Second	#1234567 12/23/12	11:55 a.m. / p.m. (circle one)	72.0 °F (circle one)	12:17 a.m. / p.m. (circle one)	72.0 °F (circle one)	Non-Reactive / Reactive / Invalid (circle one)	Invalid N/A	[ ] Serum [ ] Plasma [ ] Positive [ ] Negative		PH IP (circle one)
Theresa Howard #12345680	#938-LB	09/05/11	[ ] First [X] Second Repeat Test	#1234567 12/23/12	12:30 a.m. / p.m. (circle one)	72.1 °F (circle one)	12:50 a.m. / p.m. (circle one)	72.2 °F (circle one)	Non-Reactive / Reactive / Invalid (circle one)	9/5/11	[ ] Serum [ ] Plasma [ ] Positive [ ] Negative	N/A	PH IP (circle one)
			[ ] First [ ] Second		____ a.m. / p.m. (circle one)	____ °C / ____ °F (circle one)	____ a.m. / p.m. (circle one)	____ °C / ____ °F (circle one)	Non-Reactive / Reactive / Invalid (circle one)		[ ] Serum [ ] Plasma [ ] Positive [ ] Negative		PH IP (circle one)
			[ ] First [ ] Second		____ a.m. / p.m. (circle one)	____ °C / ____ °F (circle one)	____ a.m. / p.m. (circle one)	____ °C / ____ °F (circle one)	Non-Reactive / Reactive / Invalid (circle one)		[ ] Serum [ ] Plasma [ ] Positive [ ] Negative		PH IP (circle one)

OraQuick® HCV Product Information Training

Clinic Name/Site Location: _____

Name: _____ Date: _____

Score: _____ Trainer/Tester: _____

Select the best response for statements 1 through 6:

1. The complete storage temperature range of the OraQuick® HCV Test Kit is

(a) 2–8˚C; 36–46˚F
(b) 2–30˚C; 36–86˚F
(c) comfortable room temperature - 15˚–37˚C; 59˚–99˚F

2. The complete storage temperature range of the OraQuick® HCV Visual Reference Panel is

(a) 15–30˚C; 59–86˚F
(b) 2–30˚C; 36–86˚F
(c) comfortable room temperature - 15˚–37˚C; 59˚–99˚F

3. The complete storage temperature range of the OraQuick® HCV Kit Controls is

(a) 2–8˚C; 36–46˚F
(b) 2–30˚C; 36–86˚F
(c) comfortable room temperature - 15˚–37˚C; 59˚–99˚F

4. The acceptable temperature range for performing OraQuick® HCV Test is

(a) 2–8˚C; 36–46˚F
(b) 2–37˚C; 35–99˚F
(c) comfortable room temperature - 15˚–37˚C; 59˚–99˚F

5. According to the manufacturer's instructions, the acceptable time to read the OraQuick® HCV Test Device result is

(a) 10 to 30 minutes
(b) 20 to 40 minutes
(c) 20 to 80 minutes
(d) 10 to 60 minutes

6. The three possible OraQuick® HCV Test Device result outcomes are

(a) reactive, non-reactive, borderline
(b) reactive, non-reactive, inconclusive
(c) reactive, non-reactive, weakly reactive
(d) reactive, non-reactive, invalid

7. The blood-filled Specimen Collection Loop

(a) should be rapidly dipped in the Developer Solution Vial and discarded
(b) should be stirred in the Developer Solution Vial and then discarded
(c) can be left in the Developer Solution Vial for up to 10 minutes and discarded
(d) should be stirred in the Developer Solution Vial and then saved until the test is complete

Select True or False for Statements 7 – 16:

8. **When conducting an OraQuick® HCV Test Control, if the positive and/or negative control does not give the correct result(s), clients can still be tested with the OraQuick® HCV Kits.**

   True False

9. **If the absorbent packet is not present when opening the OraQuick® HCV pouch, the pouch contents should be allowed to remain open for 5 – 10 minutes before using.**

   True False

10. **The 2 holes in the back of the OraQuick® HCV Test Device must be covered after placing the device into the Developer Solution Vial.**

    True False

11. **The built-in procedural control in the OraQuick® HCV Test Device is intended to confirm that the patient sample has moved past the Test (T) area.**

    True False

12. **The Developer Solution Vial must turn pink after adding the fingerstick whole blood sample.**

    True False

13. **The OraQuick® HCV Test Device should not be removed from the Developer Solution Vial before reading the Test result.**

    True False

14. **The first drop of blood from a fingerstick can be use to perform the OraQuick® HCV test.**

    True False

15. **An OraQuick® HCV reactive test result is interpreted as positive test for the presence of HCV antibodies.**

    True False

16. **OraQuick® HCV is currently CLIA-waiver approved for use in the U.S. with fingerstick whole blood specimens *only*.**

    True False

OraQuick® HCV Product Information Training Answer Key

1) **B.** Storage conditions for the OraQuick® HCV Test Kits is 2–30˚C; 36–86˚F.

2) **A.** Storage conditions for the OraQuick® HCV Visual Reference Panel is 15–30˚C; 59–86˚F.

3) **A.** Storage conditions for the OraQuick® HCV Kit Controls is 2–8˚C; 35–46˚F.

4) **C.** Acceptable temperature range for performing the OraQuick® HCV Test Device is a comfortable room temperature of 15˚–37˚C; 59˚–99˚F.

5) **B.** Acceptable times to read the OraQuick® HCV Test Device is 20 minutes to 40 minutes. **DO NOT** attempt to read the test result after the 40 minute test development.

6) **D.** The three possible OraQuick® HCV Test result outcomes is (R) Reactive, (NR) Non-Reactive and (INV) Invalid. An Invalid test result cannot be interpreted and is an indication that there was a problem running the test, either related to the specimen or the Device. A repeat test should be performed with a new Pouch and new sample.

7) **B.** The blood-filled Specimen Collection Loop should be gently stirred in the Developer Solution Vial and then immediately discarded in a bio-hazard waste container.

8) **False.** If the kit controls DO NOT produce the expected outcome of a reactive and non-reactive result prior to testing a patient sample, re-run the controls. If the test devices still do not produce a reactive and non-reactive result, contact OraSure Technologies. DO NOT conduct any patient testing.

9) **False.** An absorbent packet is included in each Device Pouch to ensure that moisture levels are maintained and do not compromise the Test Device performance. The absence of an absorbent packet means that the Test Device may have been compromised during storage. Immediately discard package, device and developer vial and open a new pouch to proceed.

10) **False.** The two holes at the back of the OraQuick® HCV Test Device are part of the design of the lateral flow system. Blocking these holes with labels and or other materials will interfere with the test development.

11) **True.** The built-in procedural control on the OraQuick® Test Device is designed to verify that the chemistry of the test has flowed past the "T" or Test Line of the Device and that a sample was added to the Developer Vial Solution.

12) **True.** If the blood-filled loop has been properly introduced to the Developer Solution Vial, the solution will turn a shade of pink indicating sample has been mixed.

13) **True.** The OraQuick® HCV Test Device should not be removed from the Developer Solution Vial until the test result has been read, interpreted and documented.

14) **False.** The first droplet of blood should be wiped away from the finger. Typically, the first droplet will contain tissue sample as well as blood. This may interfere with the test performance. Apply the loop to the second droplet for a clean sample.

15) **True.** An OraQuick® HCV Reactive test results is reported as a POSITIVE. OraQuick® HCV Rapid Antibody Test is a qualitative immunoassay test. A positive test result indicates that the presence of HCV antibodies have been detected. The patient should undergo appropriate clinical follow-up for supplemental testing.

16) **False.** The OraQuick® HCV Rapid Antibody Test is CLIA-waived approved in fingerstick **AND** venipuncture whole blood.

OraQuick® HCV Rapid Test Result Panel Training

Clinic Name/Site Location: _____

Name: _____ Date: _____

Score: _____ Trainer/Tester: _____

1

Result:_____

2

Result:_____

3

Result:_____

4

Result:_____

5

Result:_____

6

Result:_____

7

Result:_____

8

Result:_____

9

Result:_____

10

Result:_____

Write the Result on the line below each Test Device: Non-Reactive (**NR**); Reactive (**R**); Invalid (**INV**)

OraQuick® HCV Test Result Panel Training Answer Key

OraQuick® Rapid Test Result Panel Training - Answer Key

1) **NR**. Test line appears only in the "C" designated area, indicating no detection of HCV antibodies are present at the time the test was conducted. Patient is presumed not to be infected with HCV.

2) **R**. Test lines appear in the "C" and "T" designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the "T" line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.

3) **INV**. No test lines appear in the "T" or "C" designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new specimen.

4) **R**. Test lines appear in the "C" and "T" designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the "T" line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.

5) **INV**. No test lines appear in the "C" designated area and only a partial line appears in the "T" designated area. This result means there was a problem running the test, either related to the specimen or to the Device. No interpretation can be made. Repeat the test with a new Pouch and a new sample.

6) **R**. Test lines appear in the "C" and "T" designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the "T" line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.

7) **INV**. No test lines appear in the "T" or "C" designated areas. The test result window has not cleared revealing the test result rendering it impossible to read or interpret. This result means there was a problem running the test, either related to the specimen or to the Device. No interpretation can be made. Repeat the test with a new Pouch and a new sample.

8) **INV**. Partial test lines appear inside the "T" and "C" designated areas. While on appearance, it would seem that a POSITIVE could be interpreted, the partial development of the test lines are not fully developed within the designated areas. No interpretation can be made. Repeat the test with a new Pouch and a new sample.

9) **NR**. Test line appears only in the "C" designated area, indicating no detection of HCV antibodies are present at the time the test was conducted. Patient is presumed not to be infected with HCV.

10) **R**. Test lines appear in the "C" and "T" designated areas, indicating that the presence of HCV antibodies have been detected in the specimen. The patient is presumed to be infected with HCV. The strength of the "T" line has no direct correlation to a quantitative interpretation of the HCV virus. A reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, according to CDC recommendations for supplemental testing.

Proficiency Testing Panel Results

Specimen Proficiency Panel Interpretation:

For each specimen, indicate the result with a checkmark for either REACTIVE, NON-REACTIVE, or INVALID.

Assay Lot #: _____

				To be completed by study monitor:	
Specimen A:	❑ REACTIVE	❑ NON-REACTIVE	❑ INVALID	❑ CORRECT	❑ INCORRECT
Specimen B:	❑ REACTIVE	❑ NON-REACTIVE	❑ INVALID	❑ CORRECT	❑ INCORRECT
Specimen C:	❑ REACTIVE	❑ NON-REACTIVE	❑ INVALID	❑ CORRECT	❑ INCORRECT
Specimen D:	❑ REACTIVE	❑ NON-REACTIVE	❑ INVALID	❑ CORRECT	❑ INCORRECT
Specimen E:	❑ REACTIVE	❑ NON-REACTIVE	❑ INVALID	❑ CORRECT	❑ INCORRECT

Clinic Name/Site Location: _____

Name: _____ Date: _____

Score: _____ Trainer/Tester: _____

Comments: _____

_____

_____

Investigational and Remedial Action on Unacceptable Proficiency Testing

Date of Investigation: _____ Clinic Name/Site Location: _____

Prepared by: _____

Client Sample: ☐ Yes ☐ No	Control Sample: ☐ Yes ☐ No
Date of Testing:	Time of Testing:
Lot # of Test Device:	Exp. Date of Test Device:
Unacceptable (Reported) Result:	
Acceptable Result Range:	
Day of Testing - Quality Control Results Reviewed: ☐ Yes ☐ Acceptable ☐ Not Acceptable Indicate Corrective Action:	
Clerical/Transcription Review: ☐ Acceptable ☐ Not Acceptable Indicate Corrective Action:	
Was Patient Reported Results Affected? ☐ No, (*skip to next section*) ☐ Yes Indicate Corrective Action:	
Classification of Problem: ☐ Clerical ☐ Technical ☐ Methodology ☐ Problem with Client ☐ Training Issue ☐ No Explanation	
Conclusions:	
Corrective Actions/System Change(s) To Prevent Recurrence:	
Supervisor:	Date:
Lab Director:	Date:

Upon Completion - This Record Must be Maintained According to Local Regulations

Clinic Communication and Complaint Log

Clinic Name/Site Location:		
Date Reported:	Time:	Initiated By:
Source of Communication/Complaint:		
Date of Occurrence:	Time:	
Narrative of Event (If necessary):		
Immediate Corrective Action Taken:		
Does the written procedure cover how to deal with this event? ☐ Yes ☐ No ☐ Not Applicable ***If No** – Procedure must be updated within fifteen days from date of event.		
If Yes – Was the written procedure followed? ☐ Yes ☐ No	If No – Why not? Explain Below	
Follow-up Activities Required? ☐ Yes ☐ No	If Yes-Indicate what and date to be completed below	
Form Completed by:	Date:	
Signature	Date:	

Upon Completion - This Record Must be Maintained According to Local Regulations

Clinic Communication and Complaint Log

Clinic Name/Site Location:
Schnectady Women's Health Clinic - Schnectady, New York

Date Reported:	Time:	Initiated By:
9/5/11	9:50 a.m.	Josephine Parker

Source of Communication/Complaint:
Kathy DeWitt's (#1234581) Rapid HCV Screening Test revealed a "Positive" test result. Client verbally provided Informed Consent but refuses clinical follow-up and supplemental testing.

Date of Occurrence:	Time:
9/5/11	9:00 a.m.

Narrative of Event (If necessary):
Explained to Ms. DeWitt's the importance of clinical follow-up appointments and the need to perform supplemental testing for the detection of viremia as well as including importance of receiving future medical care and treatment. Reviewed availability of local programs and further counseling information. Re-emphasized the issues of protection from potential exposure to partner.

Immediate Corrective Action Taken:

Does the written procedure cover how to deal with this event? ☒ Yes ☐ No ☐ Not Applicable
***If No** – Procedure must be updated within fifteen days from date of event.

If Yes – Was the written procedure followed?	If No – Why not? Explain Below
☒ Yes ☐ No	
Follow-up Activities Required?	If Yes-Indicate what and date to be completed below
☐ Yes ☒ No	

Form Completed by:	Date:
Josephine Parker	9/5/11
Signature	Date:
Diane Lancer - Supervisor	9/5/11

Upon Completion - This Record Must be Maintained According to Local Regulations

OraSure Technologies

220 East First Street
Bethlehem, PA 18015
1-800-ORASURE (672-7873)
www.OraSure.com

Item#HCV0068 (rev. 04/12)