Hepatitis C Rapid Testing: Quality Assurance (QA) Manual

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Virginia Department of Health, Office of Epidemiology, Division of Disease Prevention

VDH VIRGINIA DEPARTMENT OF HEALTH

Revision History

Version	Date	Description of Changes
1.0	05/23/2017	Original document
1.1	02/20/2018	VDH staffing updates and Client Self-Assessment - added
1.2	03/14/2018	VDH staffing updates and removal of Test Assessment
1.3	06/07/2018	Addition of Test Assessment and Epi-1
1.4	02/11/2019	Staff Contact Information, and whole document formatting
1.5	06/03/2019	Staff Contact Information
1.6	02/05/2020	Training and Technical Assistance
1.7	05/2020	Updated testing recommendations
1.8	10/23/2020	Updated testing recommendations
1.9	08/25/2022	Staff Contact Information

Contents

Goals of the Viral Hepatitis Testing Program

- Increase the number of individuals who are aware of their hepatitis C virus (HCV) status.
- Minimize the public health burden of infection with HCV.
- Provide counseling to decrease behaviors associated with transmission of HCV and other infectious diseases.
- Link clients with reactive test results to appropriate HCV medical care.

Intended Use

OraSure Technologies, Inc. manufactures the OraQuick® HCV Rapid Antibody Test. The test detects hepatitis C virus antibodies (anti-HCV) in fingerstick and venous whole blood. The Food and Drug Administration approved the test as a Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waived, point of care test for HCV antibodies. Waived tests are simple and accurate when performed by personnel trained to follow the manufacturer's instructions. This manual outlines standards, procedures, and quality assurance (QA) measures for performing the OraQuick® HCV Rapid Antibody Test for agencies that are conducting screening through the Virginia Department of Health (VDH) Viral Hepatitis Testing Program. Follow the manufacturer's instructions throughout the testing process. The OraQuick® HCV Rapid Antibody Test has not been validated for use on anyone under age 15, anyone who is pregnant, and is not approved for self-administration, and therefore should not be provided to clients for at-home testing.

Contact Information

Nicole Barron, MS Viral Hepatitis Program Coordinator nicole.barron@vdh.virginia.gov (804) 864-7350	**Alyson Scullin, MPH** Viral Hepatitis Testing Coordinator alyson.scullin@vdh.virginia.gov (804) 864-7992	**Emily Schreer** Viral Hepatitis & Harm Reduction Project Administrator emily.schreer@vdh.virginia.gov (804) 864-7593

Reporting Requirements and Relevant State Laws

All tests conducted must be documented on the Rapid Hepatitis C Test Assessment Form which should be submitted to DDP on a monthly basis (by the 10th of the following month) to the confidential fax line (804) 371-2895.

As of 2016, a positive HCV Ab result obtained through a rapid test is considered a probable chronic hepatitis C case and is reportable within three days of the positive test result. The Confidential Morbidity Report, the "Epi-1", must be submitted for each positive result. Below are the related laws.

A. HBV and HCV is reportable by state law (Sections 32.1-36 and 32.1-37 of the *Code of Virginia* and 12 VAC 5-90-80 and 12 VAC 5-90-90 of the Board of Health *Regulations for Diseases Reporting and Control* - http://www.vdh.virginia.gov/surveillance-and-

investigation/commonwealth-of-virginiastate-board-of-health/).

a. § 32.1-37. Reports by persons other than physicians.
    i. The person in charge of any medical care facility shall immediately make or cause to be made a report of a disease required by the Board to be reported when such information is available to that person and that person has reason to believe that no physician has reported such disease as provided in § 32.1-36. Such report shall be made to the local health director according to the provisions of the Board.
    ii. The person in charge of any residential or day program, service or facility licensed or operated by any agency of the Commonwealth, school or summer camp as defined in § 35.1-1 shall immediately make or cause to be made a report of an outbreak of disease as defined by the Board. Such report shall be made by rapid means to the local health director or to the Commissioner.
    iii. The person in charge of any medical care facility, residential or day program, service or facility licensed or operated by any agency of the Commonwealth, school, or summer camp as defined in § 35.1-1 may also voluntarily report additional information, including individual cases of communicable diseases, at the request of the Department of Health for special surveillance or other epidemiological studies.

B. HIV and HBV Infected Healthcare Workers and Occupational Exposure, Year 1993 SB 829 §32.1-45.1. Deemed consent to testing and release of test results related to infection with HIV or hepatitis B or C viruses. http://www.vdh.virginia.gov/epidemiology/documents/pdf/regs.pdf (Section II, Article 3, pp. A8-A10)

C. Reporting of Hepatitis C, §32.1-36 Reports by physicians and laboratory directors. http://www.vdh.virginia.gov/epidemiology/documents/pdf/regs.pdf (Section II, Article 1, pp. A1-A2). All information collected from clients is used for surveillance and investigation and is reported to the Virginia Department of Health (VDH).

Informed Consent

In order for a counselor to administer the test to a client, the client must first give consent. Discuss the difference between rapid and conventional testing, the difference between a screening and confirmatory test, and the follow-up procedures for both a negative and a reactive result. Ask the client if they have any questions or concerns about the test. Each site will follow their own procedure for obtaining a client's signature on the consent form they have in place. To release test results to anyone other than the client or VDH, the client must sign an authorization to release information.

Conflicts of Interest

Agencies should not test persons who are employed by the agency providing testing. If the client to be tested is a friend or associate of the test counselor, and either the client or the test counselor is uncomfortable with the situation, the test counselor must immediately locate another capable staff member to provide the client services. The counselor should verify that the client is comfortable with the test counselor performing the counseling and knowing the test result. Test counselors should not provide testing to their co-workers; agencies should assist their staff in locating another test site for services.

OSHA Requirements

All sites that collect blood samples for traditional and/or rapid testing must meet the OSHA standards for blood-borne pathogens. Information regarding OSHA standards can be found at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS

Clinical Laboratory Improvement Amendments (CLIA) Requirements

Rapid test sites must possess a valid CLIA waiver, which designates the facility as authorized to perform waived rapid HCV testing.

Health Insurance Portability and Accountability Act (HIPAA) Requirements

Agencies contracting with VDH to provide rapid HCV tests must agree to ensure security and confidentiality of client identifying information contained on the testing log and/or client assessment forms as required by law. Submit the client testing logs and/or assessment forms to VDH via the fax number identified in this manual, or mailed in a secure envelope. Patient identifying information can include name, date of birth, phone number, address, medical record number, and test result.

Counseling Messages

A. Reactive Results: The OraQuick® HCV Rapid Antibody Test is a preliminary screening test. A positive result indicates that HCV antibodies may be present. The client should presume they are infected with HCV until he/she receives a confirmatory test result.
B. Non-Reactive Result: A non-reactive result means that HCV antibodies were not detected in the specimen. The test result is interpreted as negative for HCV antibodies. However, this does not preclude possible infection with HCV. For clients with risk factor(s) for HCV, a repeat test might be indicated in 6 months. In immunocompromised clients (e.g. HIV positive with a low CD4 count) who are at risk for HCV infection or who have symptoms of liver disease, the risk of false negative result on the antibody test might indicate the need for HCV PCR testing to determine the presence or absence of the virus.
C. Invalid Results: An invalid test cannot be interpreted. Repeat the test with a new pouch and a new specimen.
D. A Guide to Comprehensive Hepatitis C Counseling and Testing is available at: https://www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtestingpc.pdf

Training and Technical Assistance

If a testing entity receives HCV rapid tests that are paid for and supported by VDH, the entity must be trained directly by a representative from OraSure Technologies and/or VDH staff. The training consists of an overview of the etiology and epidemiology of hepatitis C, VDH reporting requirements, and a practical component. The practical component ensures that each participant gains hands-on experience running the test and interpreting the results. The in-person training ensures that each attendee has the correct and most up-to-date information, and can demonstrate the ability to conduct a test and interpret the result to the manufacture's standard. A one-time training for any staff who will conduct HCV rapid testing is required prior to conducting a test on a client. VDH will support on-going technical assistance, as needed, or as requested by the testing entity. To schedule training or technical assistance, please contact the Viral Hepatitis Testing Coordinator.

Determining Eligibility for Persons Who May Benefit from Hepatitis C Testing

In accordance with the Centers of Disease Control and Prevention (CDC) (CDC, 2020), the World Health Organization (WHO) (WHO, 2017), and the U.S. Preventative Services Task Force (USPSTF) (U.S. Preventive Services Task Force, 2020) testing recommendations, VDH funds rapid HCV testing for clients with at least one of the following criteria:

One-time testing
Adults aged 18 - 79
Clients who could benefit from a HCV test
Persons who inject drugs (PWID or IDU) or have ever injected drugs
Persons who have HIV infection
Persons with liver disease of unknown etiology (i.e. elevated ALT/AST)
Persons engaging in intranasal cocaine use and other non-injecting illegal drug use
Men who have sex with men (MSM)
Persons who engage in transactional sex work for money or drugs
Persons who were ever on long-term hemodialysis
Persons who received a transfusion or an organ transplant before July 1992, or clotting factor concentrates produced before 1987
Persons with a history of tattooing or body piercing if the procedure was done where infection control practices are substandard
Persons with a long-term steady sexual partner who is HCV-positive
Persons who have been or are currently incarcerated
Pregnant person during each pregnancy except in settings where prevalence is less than 0.1%
Testing based on recognized exposure
Healthcare, emergency medical and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
Children birthed from an HCV-infected person (to avoid detecting maternal antibody, these children should not be tested before age 18 months)

Test Kits

Materials provided in the test kits:

- Package insert (full instructions for use)
- Reusable test stands
- Specimen collection loops
- OraQuick® HCV Rapid Antibody Test single-use test device with built-in sample collection pad (flat pad)
- OraQuick® HCV Rapid Antibody developer solution vial
- Absorbent packet

Materials needed but not provided with the test kits:

- Timer
- Biohazard waste container
- Sharps container
- Disposable, absorbent workplace cover
- Disposable gloves
- Antiseptic wipes
- Sterile gauze pads
- Band-Aids
- Sterile 5mm lancet to collect a fingerstick specimen
- OraQuick® HCV Visual Reference Panel
- OraQuick® HCV Rapid Antibody Test Kit Controls

Monitoring Shipments

The OraQuick® HCV Rapid Antibody test has a manufacturer shelf life of 18 months, and should have a shelf life ranging from 12-15 months when received by a testing site. Tests arriving in new shipments should be verified to have a shelf life of at least 12 months when they are received. If the expiration date is within 12 months, notify the testing coordinator.

Monitoring Temperatures

Temperature logs should be maintained for the refrigerator where the controls are stored, and for the ambient room temperature where kits are stored and used for testing. Refer to the Appendices for instructions and logs for monitoring temperatures. If a temperature is observed to be out-of- range for any time during the monitoring period, corrective action must be taken and documented immediately.

Storage

A. Test Cassettes: Store unused tests unopened at 2°–30°C (36°-86°F). Maintain proper temperature at all times, including during transport.
B. Controls: Store controls at 2° – 8°C (36°-46°F). Maintain temperature at all times, including during transport. Following use, recap and store the vials in their original box. Once opened, discard controls after eight weeks.
C. Visual Reference Panels: Store the panels at 15°–30°C (59°-86°F). Maintain temperature at all times, including during transport. After use, reseal and store the devices in their original pouch.

Quality Control Testing

Quality control (QC) testing gives confidence that your results are accurate and reliable. Incorrect QC results alert the user to potential problems such as reagent/test kit deterioration, equipment failure, adverse environmental conditions, or human error.

Types of Controls

Internal Controls

Also referred to as built-in or procedural controls, evaluate whether:

- The test is working as it should,
- Enough sample is added,
- The sample is moving through the test strip correctly, and/or
- The electronic functions of the instrument are working correctly.

The test devices have a built-in control that demonstrates assay validity. A reddish-purple line should appear next to the triangle labeled “C” for control on all valid tests, whether the sample is reactive or non-reactive. The presence of this line indicates that the test is running correctly. If this line is missing, the test was not run correctly or failed to function correctly. The test is invalid and the test should be repeated using a new cassette.

External Controls

External Controls evaluate whether:

- The entire testing process is performed correctly, and
- The control results are in the expected ranges or values as found in the manufacturer’s instructions.

The control package includes:

- Package Insert
- Positive Control – a purple-capped vial containing 0.2 ml of inactivated human plasma that is positive for antibodies to HCV
- Negative Control – a white-capped vial containing 0.2 ml of human plasma that is negative for

antibodies to HCV

- Sufficient volume for 25 tests

Running Controls

A. Run controls under the following circumstances:
    1. With each new tester, prior to testing client specimens;
    2. Before using a new test kit lot;
    3. When a new shipment of test kits is received;
    4. If the temperature of the test kit storage area falls outside of 2°-30°C (36°-86°F);
    5. If the temperature of the testing area falls outside of 15°-37°C (59°-99°F);
    6. When setting up a new test site of any kind, including a new room in the same building, a change in lighting, or an entirely new venue;
    7. Whenever there is a reason to suspect the kits are not functioning properly, such as two invalid test results in a row or an excessive number of unexpected results; and
    8. At regular intervals determined by testing facility or contract agency. Each agency performing HCV rapid testing is responsible for including quality control procedures in their QA policies to ensure the performance of the device under their specific locations and conditions of use.
B. Verify that the "Use By" date on the outside of the test pouch is still in date. Check the pouch for damage or holes; discard the pouch and contents if damaged.
C. Allow all refrigerated components to come to testing temperature, about 5-10 minutes, before opening.
D. Remove and label a test device and developer vial from one pouch as 'positive,' and the other as 'negative.'
E. NOTE: Do not touch the flat pad of the devices and do not block the holes on the back of the devices.
F. Visually inspect the controls. They should be clear to straw-colored. Do not use a control that appears cloudy or discolored.
G. Insert the round end of a new specimen collection loop into the negative control vial.
H. Immerse the loop into the developer solution vial, being careful not to touch the side of the vial. Stir the contents using the loop. Discard the loop in a biohazard waste container.
I. With the result window facing the tester, insert the flat pad of the test device labeled negative into the corresponding developer vial until the pad touches the bottom of the vial.
J. Repeat for the positive control, using a new loop. *Start the timer.*
K. Pink fluid should travel up the result window, and should fade as the test develops.
L. NOTE: Do not move or remove the device while the test is running.
M. Read results in 20-40 minutes under adequate lighting.

Tracking Quality Control

Documenting and tracking QC results can show whether a test is being performed correctly and if the test is working correctly. A periodic review of QC records can show whether the QC results are changing over time. This information can help identify problems that may be affecting client testing and need to be addressed.

Actions for Unexpected QC Results

A. If controls do not give the expected results, client results should not be reported until the problem is identified and corrected.
    1. Check to see if the manufacturer's instructions were followed correctly.
    2. Look for possible sources of error such as outdated reagents or test devices.
    3. Check to see if reagents were stored correctly.
    4. Make sure controls or reagents were not cross-contaminated by accidentally switching caps.
    5. Follow the troubleshooting steps in the manufacturer's instructions or site-specific procedure.
    6. For additional assistance, contact the manufacturer, technical representative, and/or the person(s) who directs or supervises the testing.

B. Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test client sample(s) and report the final acceptable results.

Visual Reference Panel

New testers shall be able to interpret all devices provided within the OraQuick® HCV Visual Reference Panel correctly prior to performing the test for the first time.

A. The reference panel is intended to assist new testers in becoming proficient at reading specimens with antibody levels near the lower limit of the detection range of the device.
B. The reference panel includes HCV rapid antibody test devices that have been manufactured to demonstrate reaction strengths of 'weakly reactive,' 'reactive,' and 'non-reactive.'
C. Failure to detect weak reactions on the reference panel indicates the possible inability of the tester to identify specimen reactions that are weak, and could result in false negative results.
D. Color blindness may affect the ability to interpret test results.
E. When a staff person conducts client testing and counseling using the HCV rapid test for the first time, he or she shall be observed by a testing coordinator or trained staff and the observation shall be documented. New staff shall be observed for testing proficiency at six months following their performance of the initial training, and annually thereafter.
F. The reference panel should be viewed and interpreted in the same area as the testing and result interpretation occurs.
G. Verify the expiration date on the foil pouch. If the pouch is opened for the first time, document the opened date and the 15-day "open pouch" expiration date on the space

provided on the pouch label. Once opened, discard the panel after 15 days.

H. The pouch contains three devices; refer to the package insert for additional information on interpreting the panel.
I. After use, return the devices to the original pouch, reseal, and store them at 15°–30°C (59°-86°F).
J. Failure to interpret results at low reaction strengths could result in false negative results. If a tester is unable to accurately interpret all three devices in the reference panel, they are not competent to perform the rapid antibody test.

Performing the OraQuick® HCV Rapid Antibody Test:

General Test Preparation

A. Do not interchange test devices and developer solution vials from kits with different lot numbers.
B. Verify that the "Use By" date on the outside of the test pouch is still in date. Check the pouch for damage or holes; discard the pouch and contents if damaged.
C. If refrigerated, allow all components to come to testing temperature, about 5-10 minutes, before opening.
D. Place the disposable, absorbent cover and reusable test stand on a flat, level work space; use only stands provided with the OraQuick test kits.
E. Do not open the pouch or remove the device until you are ready to perform a test. Open the pouch by tearing the notches. Verify that there is an absorbent packet in the pouch; if not, discard the pouch and open a new one.
F. Remove and label the device and developer vial with the client's information and time of sample collection if the test will not be run immediately, or if it is part of a batch. NOTE: Do not touch the flat pad of the devices. Do not block the holes on the back of the devices.
G. Remove the cap from the developer vial by holding it firmly, while rocking the cap back and forth and pulling it off gently. Set the cap aside. NOTE: If any liquid in the developer vial spills, obtain a new pouch and device; an insufficient amount of fluid will result in an invalid test result.
H. Seat the vial securely into the top of one of the slots in the stand.

Sample Collection

A. Using an antiseptic wipe, clean the client's finger. Allow to air dry or wipe dry with a sterile gauze pad.
B. Using a sterile safety lancet, puncture finger just off the center of the finger pad.
C. Hold the finger downward. Apply gentle pressure beside the point of puncture. Avoid squeezing the finger to make it bleed.
D. Wipe away first drop of blood with a sterile gauze pad and allow a new drop of blood to form.
E. Touch an unused specimen collection loop to droplet of blood. Make sure that the loop fills completely.
F. If the loop is dropped or contacts any other surface, discard it in a biohazard waste container and use a new loop to collect another drop

Performing the Test

A. Place sample in developer vial:
    1. Insert the blood-filled loop into the developer solution vial, being careful not to touch the side of the vial.
    2. Stir the contents using the loop. Discard the loop in a biohazard waste container.
    3. Verify that the solution appears pink in color. If the solution is not pink, discard all test materials and start over using a new pouch and new blood sample.
    4. The sample can be left in the vial for up to 60 minutes before the test device must be inserted into the solution. Recap the vial if the test device will not be inserted immediately after the sample is added to the solution.
B. With the result window facing toward you, insert the flat pad of the device into the developer vial containing the blood sample until the pad touches the bottom of the vial.
C. Start the timer. Record the time on the Test Result Log (Appendix C).

Interpretation of Results

Read the results between 20 and 40 minutes, using adequate lighting.

Non-Reactive Test (Image A)
Non-Reactive Test A line appears next to the triangle labeled “C”, but no line appears next to the triangle labeled “T”.
Reactive Test (Image B)
A line appears next to the triangle labeled “C” and a second line appears next to the triangle labeled “T.” **NOTE:** The intensity of the line has no correlation to the amount of HCV antibody present in the specimen.
Invalid Result (Image C)
No reddish-purple lines appear next to the triangle labeled “C” If a red background in the results window makes it difficult to read the results after 20 minutes. If any of the lines that appear are not next to the triangle area. If the lines do not extend completely across the result window: If the results are invalid, repeat the test using a new test device, developer solution vial, and specimen. If the results are still invalid after repeating the test, discontinue testing and contact the VDH contract monitor or Orasure Technologies Customer Care (800-ORASURE).

A. Non-Reactive Test

B. Reactive Test

C. Invalid Test

Prevention Counseling

Pre-test and post-test counseling is a critical component of the hepatitis screening and referral process.

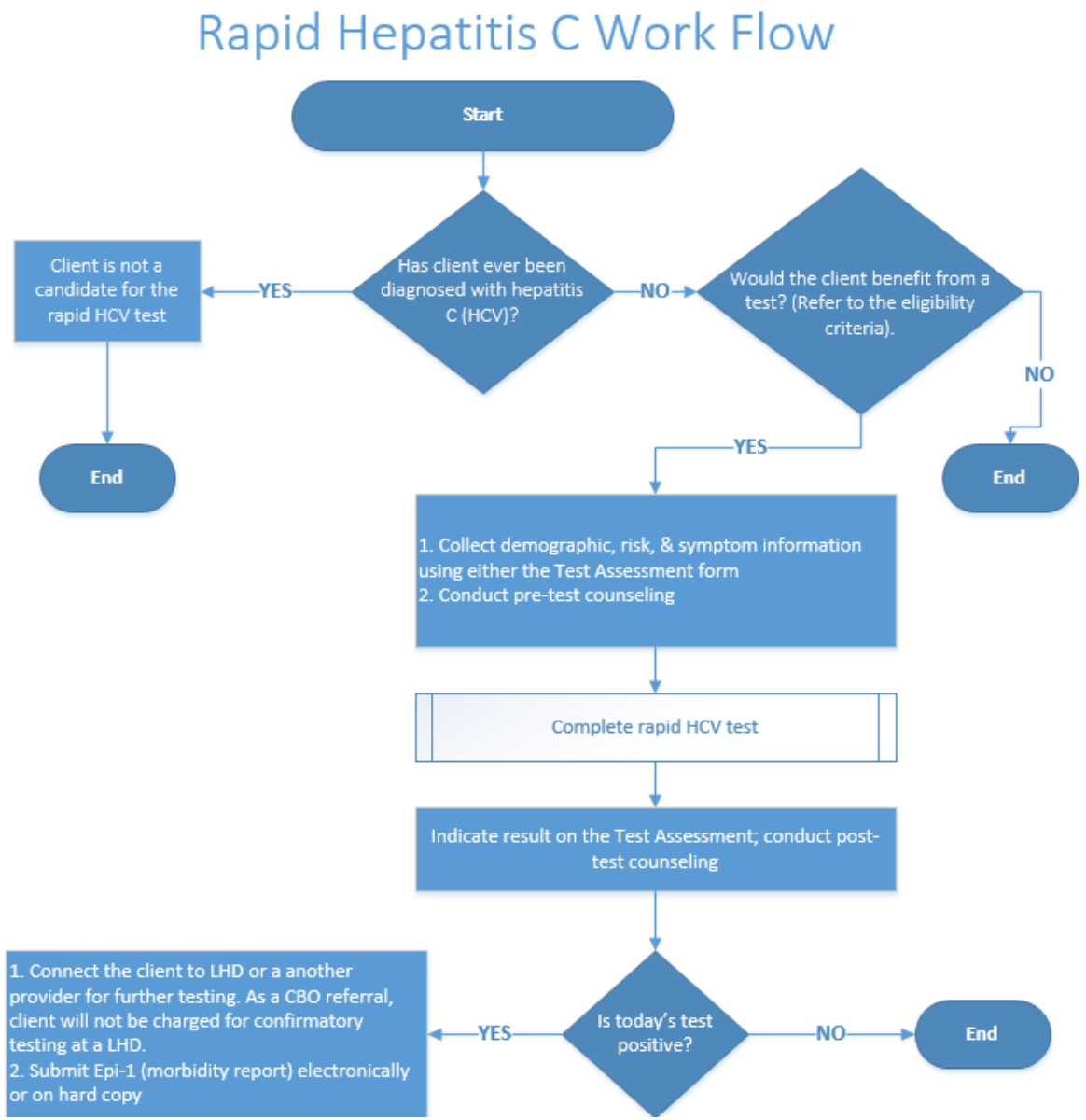
A. Pre-test counseling should include, but is not limited to:
    1. Basic information about viral hepatitis (hepatitis A, B, and C), including transmission and prevention information
    2. Assess whether or not client would benefit from testing
    3. Education regarding potential test results and what they mean
    4. Obligations to report, in the event of a positive test result
    5. Education regarding HIV and other sexually transmitted infections (STI)

B. Post-test counseling should include, but is not limited to:
    1. Education about test results
    2. Recommendations for follow up testing, if applicable
    3. Strategies for reducing risk of transmission and of liver damage
    4. Provision/referral for hepatitis A virus (HAV)/hepatitis B virus (HBV) vaccination, if indicated
    5. Referral for HIV and STI testing, if indicated
    6. Referral for drug treatment if client is currently injecting drugs
    7. Referral for follow-up testing and medical management

Ordering Information

To order test kits and/or controls, contact the Viral Hepatitis Testing Coordinator, Nicole.Barron@vdh.virginia.gov. Please order only the amount of testing supplies you will use before they expire. Notify VDH of any inventory expiring within 45 days, which will not be used by the expiration date.

Appendix A: Testing Workflow



Appendix B: External Control Log

The purpose of the External Control Log is to document performance of external positive and negative control tests.

Agency: _____ Site: _____ CLIA#: _____ Month/Year: _____/_____

Date	Site	Initials	QC Code	Test Kit		Control Kit			Non-reactive Control			Positive Control			Result Acceptable? *	
				Lot #	Exp. date	Lot #	Closed vial exp	Open vial exp	Start time/ temp	End time/ temp	Result (circle one)	Start time/ temp	End time/ temp	Result (circle one)		
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: ° °	: ° °	R N I	: ° °	: ° °	R N I	Yes	No

Initial Review:

_____ _____/_____/_____
Signature Date

Final Review:

_____ _____/_____/_____
Signature Date

Appendix B: External Control Log – Continued

Instructions

Code (reason for running external controls)

1. New setting
2. New operator
3. New test kit lot
4. New test kit shipment
5. Environmental change-temperature outside range in storage area
6. Environmental change-temperature outside range in test area
7. Environmental change-low lighting
8. Scheduled, periodic test
9. Other (document reason on back of form)

Closed vial expiration: expiration date printed on
control unit package by manufacturer
Open vial expiration: eight weeks from the date vials are opened. This date should be written on the
packaging when first opened and recorded above when used. Control unit may not be used if either open or closed expiration date has passed.

Result Codes:

R- Reactive
N - Non- reactive
I- Invalid

Acceptable Control Results

Both non-reactive and reactive control units must
yield correct results. If either yields an incorrect result, result of external quality control procedure is unacceptable in this case. **DO NOT conduct client tests until problem is resolved.** Document problem and corrective action taken on back of this form

Appendix C: HCV OraQuick® Test Result Log

Client Id	Client Name	Room Temp	Specimen Collection		Pouch Lot #	Pouch Expiration Date	Test Wait Time* (in minutes)	Results:***	Initials	Report Time**	Review Initials/date
			Date	Time							

*Test Wait Time= Time from starting test to reading test results (in minutes); **Report Time=Time that the test result is reported to the client;
***N=non-reactive, R=reactive, I=Invalid

Appendix D: Refrigerator Temperature Log

Acceptable Range: 36° – 46º F

Location:_____ Month/Year:_____

Date	Time	Temperature	Corrective Action/Comments	Initials

Initial Review: _____ Date:____/____/____

Final Review:_____ Date:____/____/____

Appendix E: Ambient Temperature Log (Storage Area)

Acceptable Range: 36° – 86°F

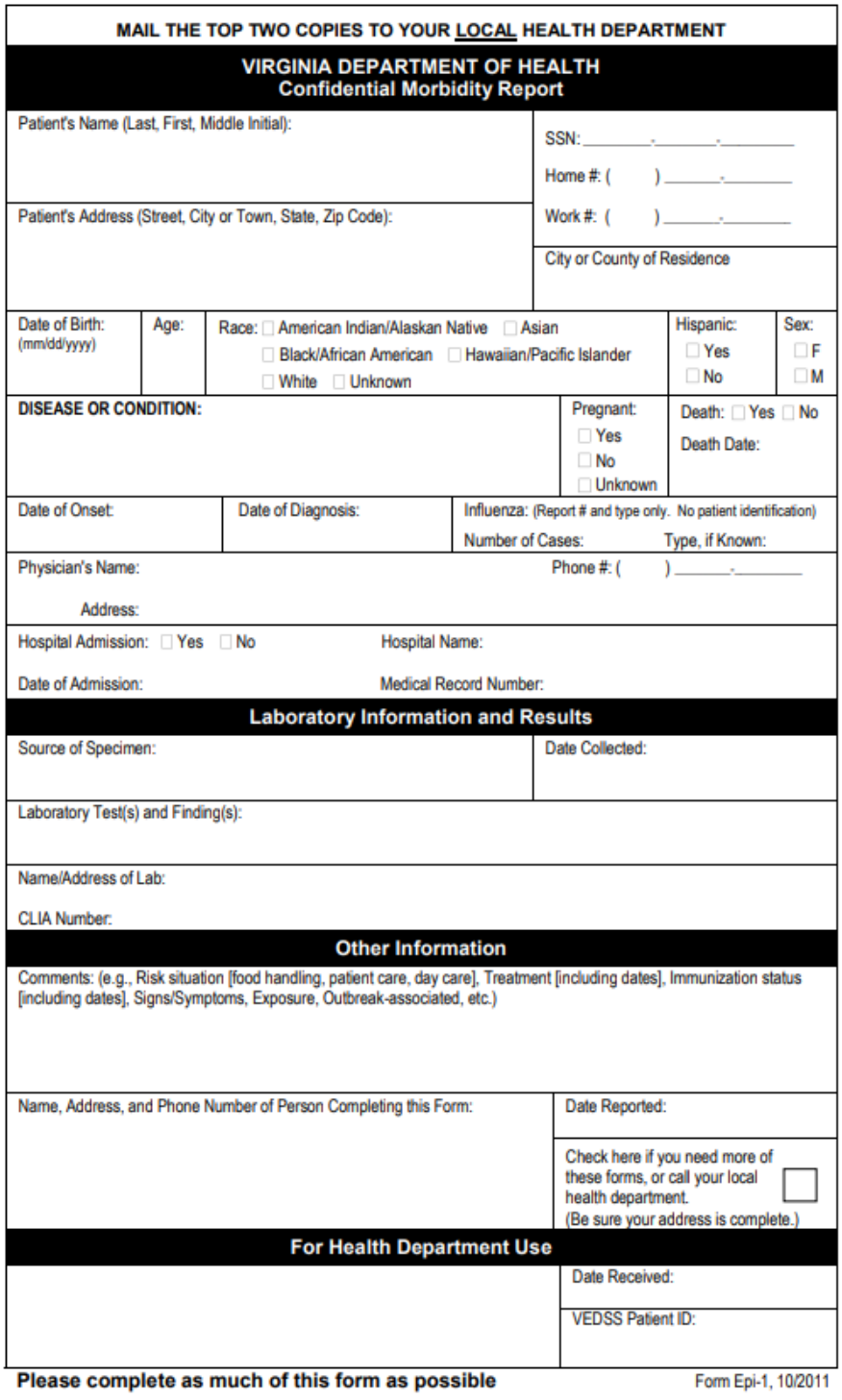
Location:_____ Month/Year:_____

Date	Time	Temperature	Corrective Action/Comments	Initials

Appendix F: Rapid Hepatitis C Test Assessment

Please contact the Hepatitis Prevention Team to discuss the assessment and data collection needs of your program. A test assessment form will be provided to you directly from the Hepatitis Testing Coordinator.

Appendix G: Confidential Morbidity Report



MAIL THE TOP TWO COPIES TO YOUR LOCAL HEALTH DEPARTMENT

VIRGINIA DEPARTMENT OF HEALTH
Confidential Morbidity Report

Patient's Name (Last, First, Middle Initial):

SSN: ___-___-___

Home #: ( ) ___-___

Work #: ( ) ___-___

Patient's Address (Street, City or Town, State, Zip Code):

City or County of Residence

Date of Birth: (mm/dd/yyyy) | Age: | Race: ☐ American Indian/Alaskan Native ☐ Asian ☐ Black/African American ☐ Hawaiian/Pacific Islander ☐ White ☐ Unknown | Hispanic: ☐ Yes ☐ No | Sex: ☐ F ☐ M

DISEASE OR CONDITION:

Pregnant: ☐ Yes ☐ No ☐ Unknown

Death: ☐ Yes ☐ No

Death Date:

Date of Onset: | Date of Diagnosis: | Influenza: (Report # and type only. No patient identification) Number of Cases: Type, if Known:

Physician's Name: Phone #: ( ) ___-___

Address:

Hospital Admission: ☐ Yes ☐ No Hospital Name:

Date of Admission: Medical Record Number:

Laboratory Information and Results

Source of Specimen: | Date Collected:

Laboratory Test(s) and Finding(s):

Name/Address of Lab:

CLIA Number:

Other Information

Comments: (e.g., Risk situation [food handling, patient care, day care], Treatment [including dates], Immunization status [including dates], Signs/Symptoms, Exposure, Outbreak-associated, etc.)

Name, Address, and Phone Number of Person Completing this Form: | Date Reported:

Check here if you need more of these forms, or call your local health department. (Be sure your address is complete.) ☐

For Health Department Use

Date Received:

VEDSS Patient ID:

Please complete as much of this form as possible Form Epi-1, 10/2011

Available online: http://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/

Appendix H: Recommendations for Releasing Negative Results

Recommendations for Responding to Clients' Requests for Negative HCV Test Results

1. Follow your agency's standard procedures for responding to clients' requests for their medical records.
2. Written proof of HCV test results should include the client's name, date of test, and an explanation of what the test results mean.
3. Review appropriate use of test results documentation with the client.
4. The format of documentation provided to clients should reduce its use for unintended purposes by requiring original signatures in blue ink, use of watermarks, letterhead or other mechanisms that discourage photocopying.
5. The HCV rapid hepatitis test client self-assessment is a data collection tool and should not be provided to clients as proof of HCV test results due to the following:
    a. These forms contain confidential information (such as risk behavior) that is not needed to document HCV test results.
    b. These forms do not provide an explanation of what a negative test result means.

If you have questions on this issue, please contact the Viral Hepatitis Testing Coordinator at (804) 864-7992 or via email at Alyson.scullin@vdh.virginia.gov OR the Viral Hepatitis Epidemiologist at (804) 864-7350 or via email at Nicole.barron@vdh.virginia.gov. A sample template for use can be found on the following page (see Appendix I).

Appendix I: Negative HCV Result Form Template

Print Client Name: _____ **Date of HCV Test:**_____

Your Hepatitis C Virus (HCV) test result was negative. A negative test result means:

1) You are not infected with HCV, the virus that causes hepatitis C.

2) A negative test today does NOT mean you cannot get HCV in the future.

3) You may have been recently infected with HCV and the test is not able to detect it yet. It takes about 6 months for this test to detect if you are infected.

4) For a person who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended.

If you have questions or want more information on hepatitis, HIV/AIDS, or other sexually transmitted diseases, contact the Virginia Disease Prevention Hotline at 1-800-533-4148 or hiv-stdhotline@vdh.virginia.gov.

My signature means I understand this form is provided to me at my request and that I may be required to complete additional medical records release forms.

Client Signature: Date:

Print Agency Name: [Your Agency Name Here]

Staff Person Providing Result:_____

Staff Person Signature:_____Date:

Valid only if signatures are original and form is on agency letterhead.

[Agency Address]
[Agency Phone Number]
[Agency Website]

References

CDC. (2017, April). Hepatitis C FAQs for Health Professionals. *Retrieved from Centers for Disease Control and Prevention - Viral Hepatitis: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#c1*

U.S. Preventive Services Task Force. (2020, March). Hepatitis C: Screening. *Retrieved from U.S. Preventive Services Task Force : www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-c-screening*

WHO. (2017, February). Guidelines on Hepatitis B and C Testing. World Health Organization. *Retrieved from World Health Organization: https://www.who.int/publications/i/item/9789241549981*