



Hepatitis C Rapid Testing Program Implementation Guidelines

October 2013

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VIRAL HEPATITIS SECTION

HEPATITIS C VIRUS (HCV) RAPID TESTING PROGRAM

INTRODUCTION

The OraQuick[®] HCV Rapid Test is the only rapid testing technology currently available for HCV screening. There are currently four specimen collection methods available: whole blood, plasma, serum and finger stick whole blood. The finger stick collection method is the only waived HCV screening technology available. This is a screening test used to detect HCV antibodies (anti-HCV), similar to the enzyme immunoassay (EIA) or the recombinant immunoblot assay (RIBA). This is only a screening test. It is not a diagnostic test. This test cannot determine the stage of HCV infection (i.e., active, chronic infection or a previous HCV infection).

PROGRAM REQUIREMENTS

Program Enrollment, Eligibility and Responsibilities

Programs seeking enrollment in the NYSDOH HCV Rapid Testing Program must complete and submit an on-line application. The application can be found on the NYSDOH Health Commerce System (HCS) web site at: <https://commerce.health.state.ny.us> Applications will be reviewed and approved by the NYSDOH AIDS Institute's Viral Hepatitis Section. Programs must have an HCS account in order to access the application. If the HCV screening program staff does not have an HCS account, contact your HCS account administrator/coordinator to apply for one. In the event that the agency does not have an HCS account administrator/coordinator, contact the Viral Hepatitis Section. It will take 3-4 weeks to process a new account.

See Appendix 1: Steps to Accessing the HCV Rapid Testing Program Online Application

All programs participating in the NYSDOH HCV Screening Program must demonstrate linkages to care to ensure referrals for diagnostic testing for those with a reactive rapid test result. A written memorandum of understanding (MOU)- specific to HCV services- must be developed with a health care provider who at a minimum can perform HCV diagnostic testing (HCV PCR testing), or if performing HCV PCR testing on-site, linkages to a medical provider who can provide medical evaluation and treatment for patients with confirmed infection. Programs must also have a mechanism (e.g., follow-up phone call, etc) in place to track all referrals. MOUs should include at a minimum the following information:

- Roles and responsibilities of the referring agency
- Roles and responsibilities of the agency accepting the referral
- Mechanism for tracking all referrals.

See Appendix 2: Sample MOU

Programs requesting rapid test kits through this program must have no other source of reimbursement for the test kits, including AIDS Institute (AI) contracts that support the purchase of HCV rapid test kits. If you are unsure whether the purchase of HCV rapid test kits and/or controls is a fundable service on your AI contract, or whether the use of AI contract funds to purchase the test kits is limited to specific target populations (e.g., MSM, women, etc.), please contact your AI contract manager.

Billing for HCV Rapid Testing

Programs may not bill a client's health insurance, including Medicaid, for a HCV screening test conducted using test kits received through this program. Therefore, test kits should only be used for clients who are: 1) uninsured or whose insurance does not reimburse for HCV screening; 2) accessing services on a sliding fee scale; or, 3) during events where billing processes are not feasible (e.g., outreach events).

Sites Visits by the New York State Department of Health

The Viral Hepatitis Section staff will conduct on-site visits at each testing program at least every two years to monitor compliance with program requirements, and to provide technical assistance to facilitate successful program implementation and ensure quality service delivery.

See Appendix 3: HCV Rapid Testing Site Visit Check List

Clinical Laboratory Evaluation Program (CLEP) Requirements

Sites Registered as a Limited Service Laboratory

Programs currently performing other waived tests, such as HIV rapid testing, and registered with the New York State Department of Health (NYSDOH) Wadsworth Center Clinical Laboratory Evaluation Program (CLEP) as a Limited Service Laboratory, must complete and submit a *Limited Services Laboratory Registration - Notification to Add and/or Delete Test Procedures, (DOH-4236e)*

See Appendix 4: Limited Services Laboratory Registration - Notification to Add and/or Delete Test Procedures, (DOH-4236e)

Sites Not Registered as a Limited Service Laboratory

Non-clinical providers must register their testing site(s) with NYSDOH CLEP as a Limited Service Laboratory to offer HCV rapid testing. This registration requires completion and submission of an application with a \$200.00 application fee. All Limited Service Laboratories

must designate a licensed health care practitioner who will function as site director and provide technical and clinical oversight of testing.

Note: Only individuals currently certified by NYS as laboratory directors, or individuals authorized by law to order and use laboratory tests in their practices, are eligible to be designated as directors of Limited Service Laboratories. [The Limited Testing Permit Application and Instructions](#) may be obtained by calling 518-485-5378 or, on-line at <http://www.wadsworth.org/labcert/clep/clep.html>

Authorization for Testing

Tests performed by Limited Service Laboratories must be ordered by a physician or other health care provider, such as a nurse practitioner or physician assistant, who is legally authorized (by NYS professional practice law) to use the results of clinical laboratory tests in the practice of his or her profession. A nurse (RN or LPN) or a MSW counselor may not authorize testing. Agencies may want to consider developing a standing order as part of their testing procedures.

Reporting Requirements of Reactive Test Results

Unlike positive anti-HCV EIA test results, reactive HCV rapid antibody test results are not reportable to the local health department.

STAFF TRAINING

All program staff performing HCV rapid testing must be fully trained before implementing HCV rapid testing. Training must be documented for each staff member in the personnel record by the supervisor. Before staff are permitted to perform a HCV rapid test on their own, their ability to conduct and interpret the test and controls must be demonstrated and documented. This assessment of proficiency must be carried out by the supervisor at periodic intervals and it must be documented.

In addition, all staff must be knowledgeable of HCV and be able to effectively deliver appropriate HCV counseling messages based on the rapid test result and the clients' risk behaviors.

All staff participating in the HCV rapid testing program must be trained in the following:

- Overview of hepatitis C, including appropriate counseling messages
- Conducting and interpreting the HCV Rapid Antibody Test and Controls
- Specimen collection
- Disposal of biohazardous materials

General HCV Training

An introductory training on hepatitis C, including appropriate counseling messages and an overview of the NYSDOH HCV rapid testing program is provided by the Viral Hepatitis Section. Trainings must be arranged between the testing program and the section. HCV rapid testing may not start until this training has occurred unless other arrangements have been approved by the Viral Hepatitis Section. To arrange for this training, send an email to hepatabc@health.state.ny.us or call 518-486-6806.

Training on HCV Rapid Test Device

Training on the test device can be arranged by contacting the rapid test manufacturer. Call the Viral Hepatitis Section for the name and number of the representative for your region.

Additional Training

Additional training on HIV, STD and viral hepatitis is available through the NYSDOH AIDS Institute HIV/STI/Hepatitis Regional Training Centers - <http://www.health.ny.gov/diseases/aids/training/nonclinical.htm> .

QUALITY CONTROL PLAN

Any program using the HCV rapid test must have a Quality Control (QC) Plan. This plan must include the elements listed below. QC plans will be reviewed by the Clinical Laboratory Evaluation Program (CLEP) and the AI when they perform periodic site visits.

Check Inventory and Test Kits Lots

Staff must ensure the site is appropriately stocked with the materials needed to conduct testing. An adequate supply of unexpired test kits, controls and testing medical supplies must be available and monitored by the program manager. Since test kits and controls have a defined shelf life, the oldest should be used first. Test and/or control kits must not be used beyond their expiration dates.

Kit and Controls Storage

Kit Storage

Store unused OraQuick® HCV Rapid Antibody Tests unopened at 2°-30°C (36°-86°F). Do not open the Divided Pouch until you are ready to perform a test. If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°-37°C, 59°-99°F) before opening.

Control Storage

Store the OraQuick® HCV Rapid Antibody Test Kit Controls at 2°-8°C (36°-46°F). Do not use Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2°-8°C (36°-46°F) after use. Once opened, Kit Controls should be discarded after eight weeks.

The staff conducting the external controls must ensure testing device and developer solution, once removed from the refrigerator, have come to room temperature between 59 and 99 degrees Fahrenheit before opening and using.

Temperature Monitoring and Maintenance

Staff must check temperature daily in test kit storage room, control kit storage room, and testing area. A thermometer must be kept in the storage room where the test and control kits are stored, and staff must record the storage temperatures in the Storage Temperature Logs. Kit storage temperatures should be 2°-30°C (36°-86°F). Control storage temperatures should be 2° - 8° C (36°-46°F).

A thermometer must also be kept in the testing area. Each time a test or a control is conducted, the room temperature shall be recorded in the Testing Area Temperature Log. Testing area temperatures should be 15°-37°C (59°-99°F).

All of the above logs must be kept in one binder with dividers to keep them readily available. The program supervisor shall review the logs, note and sign that the logs were reviewed once a week.

See Appendix 5: Temperature Logs

Corrective action for temperatures that go above and below the range will include adjustment to the environmental condition (heat/air conditioner). If storage temperature falls out of range, an external control will be performed on the supply to ensure product quality. Action will be documented and reviewed by supervisor.

Testing Area Readiness

Tests should be conducted in an area/room which is environmentally stable, well-lit, has a flat stable surface (counter top/table) and offers privacy to the client. A supervisor must conduct periodic direct observation of testing activities and ensure corrective action be taken, if necessary.

Performing Quality Controls

Quality Control (QC) is performed with a negative and positive test as required by manufacturer. Each new tester will run a control as part of training, when a new test kit lot is opened, when a new shipment comes in, if the temperature of the storage area falls outside of the

temperature range, and/or if the test area falls outside of the temperature range. In addition, control tests must be done at periodic intervals as dictated by the program. If either the negative or positive controls do not provide expected results, a supervisor must be notified. Staff must review the process for conducting the control with a new control kit to rule out cross contamination. If corrective action does not resolve the problem, testing with the kits will cease and the company will be contacted. Significant problems should be immediately reported to the appropriate supervisory personnel/laboratory director.

Control records must include the date and time of control testing, lot numbers and expiration date of the test kit, lot number and expiration date of the controls, control results and corrective action taken if control results are unacceptable. Control records must be kept in the logbook and in the order in which they were completed so they can be easily compared with the test records. This will assist in finding answers if there are questions about testing performed within a specific time frame.

Kit controls must be run according to the manufacturer's protocol.

See Appendix 6: OraQuick® HCV Rapid Antibody Test Kit Controls Laboratory Procedure

ESTABLISHING POLICIES AND PROCEDURES

Program policies and procedures for HCV rapid testing must address confidentiality, staff training and proficiency, quality control, HCV counseling, record keeping, laboratory quality assurance activities and appropriate referrals and referral tracking to HCV diagnostic testing, care, treatment and other supportive services.

Specimen Collection and Testing Procedures

All clients determined to be at-risk for HCV and/or exhibiting symptoms of HCV infection should be informed that rapid HCV testing technology is used for HCV screening, not diagnosis. A second test is required to diagnose active infection. The waived rapid testing specimen collection method available is fingerstick or venipuncture whole blood, serum or plasma.

Who Should be Tested for HCV

The OraQuick® HCV rapid antibody test is currently FDA approved for use on persons at risk for HCV and/or exhibiting symptoms of HCV infection. HCV screening is recommended for anyone at increased risk for HCV infection, including:

- Persons born from 1945 through 1965
- Persons who have ever injected illegal drugs, including those who injected only once many years ago
- Recipients of clotting factor concentrates made before 1987
- Recipients of blood transfusions or solid organ transplants before July 1992

- Patients who have ever received long-term hemodialysis treatment
- Persons with known exposures to HCV, such as
 - health care workers after needlesticks involving HCV-positive blood
 - recipients of blood or organs from a donor who later tested HCV-positive
- All persons with HIV infection
- Patients with signs or symptoms of liver disease (e.g., abnormal liver enzyme tests)
- Children born to HCV-positive mothers (to avoid detecting maternal antibody, these children should not be tested before age 18 months)
- Persons who snort drugs
- Persons who have received a tattoo or body piercing from an unlicensed tattoo artist or piercer.

The OraQuick[®] HCV rapid antibody test is NOT FDA approved for use on persons under the age of 15 and pregnant women.

Additional information on who should be screened for HCV can be found on the NYSDOH Hepatitis Web Site at: www.ny.health.gov/hepatitis or at the CDC Viral Hepatitis web site at: www.cdc.gov/hepatitis

Performing the HCV Rapid Test

Step by step instructions on how to perform the OraQuick[®] HCV Rapid Antibody Test are outlined in the OraSure HCV Rapid Antibody Test Product insert.

See Appendix 7: Step-by-Step Instructions for OraQuick[®] HCV Rapid Antibody Test
See Appendix 8: Hepatitis C Rapid Testing Algorithm

Interpreting HCV Rapid Test Results

HCV rapid test results may be non-reactive, reactive or invalid. All test results (non-reactive and reactive) must be recorded on a lab results form and given to the client (Appendix 9). The test result will determine the counseling messages and next steps. A full explanation of the counseling messages can be found in Appendix 10.

A. HCV Rapid Non-reactive Test Results

When the result is non-reactive, the individual is considered to be HCV negative and no additional testing is necessary at that time. However, if the client was recently exposed, he/she may be in the window period. If this is the case, repeat testing in six months is recommended. Education and counseling information on risk reduction and any necessary referrals should be given prior to the client leaving the testing site.

B. HCV Rapid Reactive Test Results

A reactive test results means that HCV antibodies have been detected in the specimen. The client is presumed to be infected with HCV. Clients with a reactive rapid test result are required to have HCV diagnostic testing (i.e., HCV RNA by PCR-Quantitative) performed by referral or on-site to confirm active infection (i.e., chronic HCV). Referrals may be given to the client's own private provider if available, or to the provider identified

by the screening program. Clients must be given the name and phone number of that provider and an appointment date before leaving the testing site. In addition to the test results, clients must receive HCV counseling messages as outlined in Appendix 10.

C. Invalid Rapid Test Results

Invalid results are not a result. It means the test did not work properly. Repeat the test with a new test device and specimen. Contact OraSure Technologies' Customer Service at 1- 800-ORASURE (800-672-7873), if you are unable to get a valid test result upon repeat testing.

See Appendix 9: Rapid HCV Antibody Test Result Form

See Appendix 10: Counseling Messages HCV Rapid Test Results

HCV DIAGNOSTIC TESTING - CONFIRMING HCV INFECTION

Because the HCV rapid test is a screening test detecting HCV antibodies, it cannot determine if someone is actively infected (acute or chronic) with HCV. In order to determine if someone is actively infected with HCV, HCV diagnostic testing (i.e., HCV RNA by PCR) must be performed. HCV diagnostic testing requires a blood draw and special handling of the specimen before it is shipped to a commercial lab for processing. HCV diagnostic testing can be conducted on-site by the testing program or by referral to a site identified by the program.

HCV Diagnostic Testing – By referral

Agencies providing HCV diagnostic testing through referral must have written MOU/ linkage agreements with a provider that can perform HCV diagnostic testing for clients with reactive screening results. All referral appointments must be tracked to ensure follow through by the client (See Appendix 2). The costs associated with HCV diagnostic testing performed by referral will not be covered by the NYSDOH.

HCV Diagnostic Testing - On-Site

HCV diagnostic testing will be paid for by the NYSDOH AIDS Institute, Viral Hepatitis Section for providers willing and able to offer the service on-site. Any site conducting on-site HCV diagnostic testing must first be approved by the NYSDOH AIDS Institute, Viral Hepatitis Section. Approval for on-site HCV diagnostic testing requires submission of the following:

1. A written protocol that outlines:
 - Process for training staff and ensuring ongoing proficiency in specimen collection and handling.
 - Roles and expectations of the provider ordering the test, including but not limited to responsibility for reporting all positive HCV diagnostic test results according to NYS Public Health Law – Communicable Disease Reporting.

2. A written MOU/linkage agreement with a health care provider that can provide follow-up HCV medical care and treatment evaluation for clients with a detectable HCV PCR test result.

Note: Programs considering the on-site PCR testing option should review their current professional liability insurance to determine whether the policy provides coverage for claims resulting from the performance—or non-performance—of phlebotomy services.

Once approved, training (excluding phlebotomy) will be provided on-site by Quest Diagnostics. All supplies needed to collect the specimen will be provided free of charge by Quest Diagnostics.

Each test site will receive its own account with Quest Diagnostics. This account number will be located on a pre-printed lab requisition, supplied by Quest Diagnostics, and must accompany each specimen. The account number ensures that results are returned to the appropriate testing site and routes all invoices to the NYSDOH. Because the cost of testing is covered by NYSDOH, test sites can not charge the clients and/or their health insurance for this service.

Clients with a detectable HCV PCR test result must be referred to a health care provider for follow-up HCV medical care and treatment evaluation. All referral appointments must be tracked to ensure follow through by the client.

See Appendix 11: Steps for Conducting On-site HCV PCR Testing

REFERRALS AND REFERRAL TRACKING

All HCV screening programs must have written linkage agreements with referral providers (i.e., those performing HCV diagnostic testing or those performing further medical care and evaluation). All referral appointments must be tracked to ensure follow through by the client. Linkage agreements/MOU should include specific language on the process for tracking referrals to ensure efficient tracking of all referrals (See Appendix 2).

Programs must obtain a signed release of information form from clients so that they may obtain all necessary information from the referral provider.

OCCUPATIONAL SAFETY – BLOOD BORNE PATHOGEN EXPOSURE

All specimens, and materials containing specimens, must be handled as if they are capable of transmitting an infectious organism. Programs must ensure that the Occupational Safety and Health Administration (OSHA) Precautions for blood borne pathogens are met. This includes the following requirements:

- Written exposure control plan
- Personal protective equipment (e.g., gloves)

- Hepatitis B vaccine and vaccination series to all employees who have occupational exposure
- Training for all employees with occupational exposure
- Post-exposure evaluation and follow-up for all employees who have had an exposure incident
- Containment and disposal of bio-hazardous waste (including blood and items contaminated with blood or other potentially infectious materials) that follows all federal, state and local regulations.

Individuals that administer the OraQuick® HCV Rapid Test should follow universal precautions and all regulations for disposal of bio-hazardous materials. Agencies should keep a log of all occupational exposure injuries. In addition, agencies should review their current liability insurance and obtain advice from their legal counsel for specific issues. State laws and regulations related to liability for blood borne pathogen exposure and occupational safety should be carefully reviewed.

For more information, see the blood borne pathogen section of the OSHA web site:

www.osha.gov/SLTC/bloodbornepathogens/index.html

DATA COLLECTION AND REPORTING

Both Aggregate Hepatitis C Rapid Testing Data - (*Appendix 12-A*) and Client Level Testing Data - (*Appendices 12-B and 12-C*) must be collected and submitted to the AIDS Institute Viral Hepatitis Section no later than 30 days after the end of each month.

Submitting Data – Health Commerce System

Aggregate and client level data can be submitted on-line via the NYSDOH Health Commerce System (HCS): <https://commerce.health.state.ny.us>. The person entering the data must have an account on the HCS and access to the HCV Rapid Testing application on the HCS.

Steps to entering HCV rapid testing program data on the HCS:

1. Log into the Health Commerce System web site: <https://commerce.health.state.ny.us>.
2. Click on “Hepatitis C Rapid Testing” (left hand side of the page)
3. Log into Hepatitis Rapid Testing
4. Click - “Hepatitis C Rapid Test Kit Order Form”
5. You will now see a list of all previous orders
6. At the top of the page you will also see:
 - a. Aggregate Data Form
 - b. Client level Data Form
7. Enter data accordingly
 - a. All required fields (*) must be entered or the data cannot be submitted.

See Appendix 12-D: Steps to entering HCV rapid testing program data on the HCS

Submitting Data – AIDS Institute Reporting System – AIRS

Programs with existing access to the AIDS Institute Reporting System (AIRS) have the option to enter HCV rapid testing data into AIRS using the HCV rapid testing module. The Viral Hepatitis Section will provide the agency with the program structure and mapping file(s) to enable appropriate AIRS data reporting. It is important that the AIRS system be maintained in the most recent version and that any patches or mapping files received be uploaded as soon as possible.

AIRS video tutorials, training information, implementation strategies, and contact information can be found on the AIRSNY Website- <http://www.airсны.org/>

See Appendix 12E: Steps to entering HCV rapid testing program data into AIRS

PROMOTIONAL MATERIALS

To promote HCV screening, HCV testing palm cards are currently available free of charge to all programs performing HCV screening. The palm cards provide a space for agencies to list the locations where free HCV testing is being conducted.

See Appendix 13: Hepatitis C Testing Palm Card Order Form

TECHNICAL ASSISTANCE

The AIDS Institute Viral Hepatitis Section is available to provide technical assistance and guidance on implementation of the HCV rapid test. For technical assistance please call 518-486-6806 or send an email to hepatabc@health.state.ny.us.

HCV RAPID TEST KIT APPLICATION AND ORDER FORM (TEST KITS AND CONTROLS)

The HCV Rapid Test Program Application and Order Form can be found on the NYSDOH Health Commerce System (HCS). <https://commerce.health.state.ny.us>

To access the HCV rapid testing application and order form, you must first request access to the **HCV Rapid Testing Program Application** on the HCS. To request access you must:

1. Log onto HCS.
2. Click the link name '**Applications**' on the top of the internet browser.
3. Then, click letter '**H**' on the alphabetical list on the top of the internet browser.
4. You will see a list of applications related to letter '**H**' on the screen. Find the application named '**Hepatitis C Rapid Testing**'. Click that link and it will lead you to the Request Access Form.
5. Please enter the reason for access to this application. Then, click '**Send**' button
6. It will take about 1-2 days to process the request.
7. If your request is approved, you will see the approval message in your email box.

To access the HCV Rapid Testing Program Order Form:

1. Log onto HCS again with your HCS ID and password. If you log on successfully, you will see the application name '**Hepatitis C Rapid Testing**' under the '**My Applications**' on the left side of your internet browser. If the application name does not appear under the '**My Applications**' tab, close the internet browser and wait approximately 30 minutes for HCS to update the settings in your HCS profile. Try again.
2. Click the application link name '**Hepatitis C Rapid Testing**' and it will bring you to the initial web page of this application.
3. Click on the link '**Hepatitis C Rapid Testing Information**' for more information about this program. If you are ready, you can click the link '**Hepatitis C Rapid Test Kit Order Form**' to order the test kits.
4. Use your HCS ID as user name in order to log on to the ordering application. You will now see the order form. Complete all required fields with asterisk (*).
5. Click '**Submit**' button after you fill in all the information. Your order will then be processed.

Listing of Appendices

- Appendix 1:** Steps to Accessing the HCV Rapid Testing Program Online Application
- Appendix 2:** Sample MOU
- Appendix 3:** HCV Rapid Testing Site Visit Check List
- Appendix 4:** Limited Services Laboratory Registration - Notification to Add and/or Delete Test Procedures, (DOH-4236e)
- Appendix 5:** Temperature Logs
- Appendix 6:** OraQuick® HCV Rapid Antibody Test Kit Controls Laboratory Procedure
- Appendix 7:** Step-by-Step Instructions for OraQuick® HCV Rapid Antibody Test
- Appendix 8:** Hepatitis C Rapid Testing Algorithm
- Appendix 9:** Rapid HCV Antibody Test Result form
- Appendix 10:** Counseling Messages HCV Rapid Test Results
- Appendix 11:** Steps for Conducting On-site HCV PCR Testing
- Appendix 12:** Data Forms
 - 12a: Aggregate Hepatitis C Rapid Testing Data
 - 12b: Client Level Data-Master Log On-site PCR
 - 12c: Client Level Data-Master Log Off-site PCR
 - 12d: Steps to entering HCV rapid testing program data on the HCS
 - 12e: Steps to entering HCV rapid testing program data into AIRS
- Appendix 13:** Hepatitis C Testing Palm Card Order Form

Steps to Access the Hepatitis C Rapid Testing Order Form/Application

- 1) You must have an account to access the Health Commerce System (HCS). If you do not, contact the HCS account administrator/coordinator in your office to apply for one. It will take 3-4 weeks to process a new account. If you do not have an HCS Coordinator, contact the Viral Hepatitis Section for assistance.
- 2) After log on to the HCS, click the **'Applications'** link at the top of the internet browser.



- 3) Click the letter **'H'** on the alphabetical list at the top of the internet browser.



- 4) You will see a list of applications related to the letter 'H' on the screen. Find the application named **'Hepatitis C Rapid Testing'**. Click that link and it will lead you to the **Request Access Form**.



- 5) Enter the reason for accessing this application then click the **'send'** button.

NEW YORK STATE DEPARTMENT OF HEALTH
Health Provider Network
Request for Access to the Hepatitis C Rapid Testing

Date: 02/24/2012
Time: 02:06:58 PM

[Click Here to go BACK to Previous Page](#)

Although you have a valid HPN user account, access to this area must be approved by the New York State Department of Health. Please complete the form and click on the SEND button below.
Note: All fields are required.
If requesting access for another person or group, please e-mail or call: Jonathan Chan 518-473-8459

Name: Jonathan Chan
E-mail: jwc05@health.state.ny.us [Add/Correct My E-Mail/Phone](#)
Address:
Organization: NYSDOH AIDS Institute
Phone Number: 518-473-8459

Please enter the reason access is being requested:

Press to submit your request or to clear form.

- 6) It will take about 1-2 days to process the request.

- 7) When your request is approved, you will receive an approval email.



Access to HEPC Rapid Test Materials Order Recording Syus

03/12/2012 03:35 PM

You have been given new permissions for the application named
Hepatitis C Rapid Testing

You are now authorized to access data for
All Hospital PFI's As A Group

with permission(s):
All Permissions For This Application

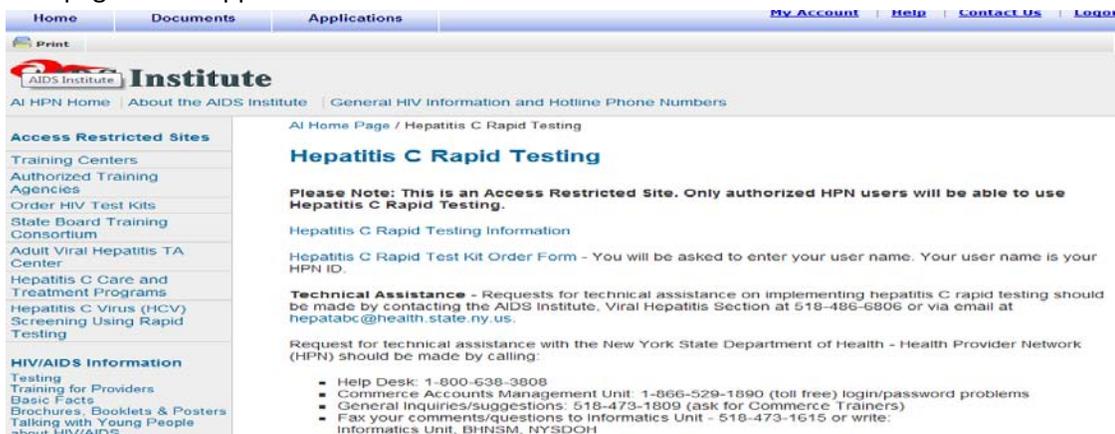
Please be aware that this application is for your use only and cannot
be shared with any other persons. If you have any questions
regarding use of the application or your responsibilities under
this access, please contact

Jonathan W. Chan at jwc05@health.state.ny.us

- 8) Once your request has been approved, log on to the HCS with your HCS ID and password. If you log on successfully, you will see the application named **'Hepatitis C Rapid Testing'** under the **'My Applications'** tab on the left side of your internet browser. If the application does not show under the **'My Applications'** tab, close the internet browser and wait about 30 minutes for HCS to update the settings in your HCS profile.



- 9) Click the application link named **'Hepatitis C Rapid Testing'** and it will bring you to the initial web page of this application.



- 10) Click on the link 'Hepatitis C Rapid Testing Information' for more information about this program. Click the 'Hepatitis C Rapid Test Kit Order Form' link to order test kits and controls.
- 11) Use the HPN/HCS ID as your user name in order to log on to the ordering application.

- 12) Complete all required fields marked with an asterisk and click 'submit'.

Note: The initial test order serves as the application to the HCV Rapid Testing Program. The Viral Hepatitis Section will approve orders once program eligibility has been verified (e.g. MOU submitted, attestation of staff training, etc.). Please see the **Hepatitis C Rapid Testing Program Implementation Guidelines** for a comprehensive description of program eligibility and enrollment requirements.

AGENCY LETTERHEAD

Memorandum of Understanding
Between

TESTING AGENCY NAME AND ADDRESS
And
REFERRAL AGENCY NAME AND ADDRESS

PURPOSE OF LINKAGE AGREEMENT: *The purpose of this linkage agreement is to acknowledge the collaborative relationship that exists between, and outline the cooperative efforts of, the above named agencies to coordinate and integrate services and care for individuals who are infected with the hepatitis C virus (HCV) or have reactive/ positive rapid HCV test results. Staff of both agencies will document services provided and conduct follow-up as necessary, provided appropriate confidentiality releases are obtained.*

UNDER THE TERMS OF THIS AGREEMENT, TESTING AGENCY AGREES TO:

1. Refer clients who have a reactive/positive rapid hepatitis C antibody test to REFERRAL AGENCY for HCV diagnostic testing (HCV RNA by PCR).
2. Contact REFERRAL AGENCY to coordinate appointments for clients with a reactive /positive hepatitis C rapid antibody test result.
3. Obtain client's signed consent agreement to release confidential information in order to provide REFERRAL AGENCY with a copy of the referred client's HCV rapid reactive test result.

UNDER THE TERMS OF THIS AGREEMENT, REFERRAL AGENCY AGREES TO:

1. Accept referrals to conduct HCV diagnostic testing for clients with reactive/positive rapid hepatitis C antibody test from TESTING AGENCY.
2. Contact TESTING AGENCY to verify client's receipt of HCV diagnostic testing.
3. Provide HCV medical evaluation and linkage to specialized HCV care based on HCV diagnostic test result and as needed and appropriate.

GENERAL TERMS

Both agencies agree to secure appropriate authorization for Release of Information from clients prior to sharing client-identifying information.

Neither party will hold the other financially responsible for services provided as a result of the agreement.

This agreement will remain in effect until terminated by one or both parties via a written 30 day notice.

Responsibility for coordination of this agreement shall be the parties signed below or his/her designee.

TESTING AGENCY SIGNATURE/TITLE

DATE

REFERRAL AGENCY SIGNATURE/TITLE

DATE

HCV RAPID TESTING
SITE VISIT CHECK LIST

Agency Name: _____

DOH Reviewer: _____ Date of Review: _____

Overall Program	Yes	No	Comment
Program has a valid CLIA Permit #: _____ Expiration date: _____			
Authorizing health care provider			
Designated Lab Director and Program Manager			
Written Policies and Procedures are current			
QC Log Maintained			
Documentation logs for current and past years include Temperature Log/Storage/refrigerator/testing site			
Logs maintained according to policy			
Tracking of test results and test outcomes			
Thermometer available			
Timer available			
Disinfectant solution available			
Inventory Control System – Test Kits/supplies			
Refrigerator available and working properly for controls			
Documentation complete and has supervisor signature			
Testing supplies available and not expired			
Medical waste – if applicable			

Personnel – job descriptions and roles are identified

Personnel	Yes	No	Comment
Job descriptions and roles are identified			
Program has proper oversight for activities			

Communications	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Identified Chain of Command			
Regular staff meetings are held (minutes are maintained)			
System in place for schedule and planning for site coverage, and appropriate staffing.			
Other means of communication to staff with documentation -- explain			

Staff Training and Competency	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Evidence of orientation and training (annual)			
Staff have performance reviews (annually) there is a system to track			
Observations conducted twice a year			
Proficiency testing competence established through observation of performing external controls			
Records are reviewed			
Findings of reviews and observations are incorporated into performance evaluations			

Client Files	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Records maintained according to policy			
Client records are kept locked when not in use and double-locked when office is closed, policy on mobile testing and client files			
Record retention policies are followed			

Referral for HCV Diagnostic Testing	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Written linkage agreements are in place for HCV diagnostic testing			
Tracking of referrals is conducted and documented			

Data	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Data is submitted and timely			

Miscellaneous	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Culturally/linguistically appropriate services			
Confidentiality			
Educational materials are available			

Blood borne Pathogen	<u>Yes</u>	<u>No</u>	<u>Comment</u>
Management of Blood borne Pathogens is appropriate			
PPE is available			
Exposure control plan is updated and available			

Comments:

How is testing conducted?

Are there any training or technical assistance needs?

What challenges do you have carrying out this testing program?

NEW YORK STATE DEPARTMENT OF HEALTH
 WADSWORTH CENTER
 CLINICAL LABORATORY EVALUATION PROGRAM
 EMPIRE STATE PLAZA, P.O. BOX 509
 ALBANY, NEW YORK 12201-0509
 Telephone: (518) 402-4253 Fax: (518) 449-6902
 E-mail: clepltd@health.state.ny.us
 Web: http://www.wadsworth.org/labcert/limited/

**LIMITED SERVICE
 LABORATORY REGISTRATION
 Notification to Add and/or Delete
 Test Procedure(s)**

LABORATORY INFORMATION:

Laboratory PFI Number:	Laboratory Name:		
	Street Address:		
	City:	State:	ZIP Code:

LABORATORY TESTING INFORMATION:

Article 5, Title V, Section 3 of the New York State Public Health Law states that Limited Service Laboratories may only provide the tests listed on the registration issued by the Department. Therefore, Limited Service Laboratories may not begin patient testing until written confirmation is received from this Program. **(*NOTE: For laboratories wishing to offer lead, rapid HCV and/or rapid HIV testing using a kit, device or procedure, which has been designated by the Food and Drug Administration as Waived for purposes of CLIA '88, you must submit a written protocol with this form. Non-DOT breath alcohol testing must be performed using an FDA approved IVD Over-The-Counter device.)**

1.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
2.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
3.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
4.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
5.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
6.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
7.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
8.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
9.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete
10.	Test Procedure Name:		Request:	<input type="checkbox"/> Add <input type="checkbox"/> Delete

CERTIFICATION: By signing this form, I hereby certify that the information given is true and correct. I attest that I have reviewed a copy of the most current Limited Service Laboratory Registration application on file with the Department for this laboratory, and will comply with the requirements of Section 579 of the Public Health Law. I also assume responsibility for any laboratory testing performed at secondary testing sites covered under this CLIA Number and Limited Service Laboratory Registration. **NOTE: All signatures must be original. SIGNATURE STAMPS WILL NOT BE ACCEPTED.**

Date	Signature, Laboratory Director	Name, Laboratory Director (Print)

ORAUQUICK® HCV Rapid Antibody TEST AREA Temperature Log

Test Area location:

Acceptable Temperature Range for Storage: 15° - 37°C (59° - 99°F)

Day/Date	January	February	March	April	May	June	July	August	September	October	November	December
	Temp	Temp	Temp	Temp	Temp	Temp	Temp	Temp	Temp	Temp	Temp	Temp
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Instructions: Minimum and Maximum temperatures must be taken in the storage area on a daily basis. If temperatures are out of the designated range, inform the supervisor and await further instruction.

ORAQUICK® HCV Rapid Antibody TEST STORAGE Temperature Log

Device Storage location:

Acceptable Temperature Range for Storage: 2° - 30°C (36° - 86°F)

Day/Date	January Temp	February Temp	March Temp	April Temp	May Temp	June Temp	July Temp	August Temp	September Temp	October Temp	November Temp	December Temp
1												
2												
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Instructions: Minimum and Maximum temperatures must be taken in the storage area on a daily basis. If temperatures are out of the designated range, inform the supervisor and await further instruction.

ORAQUICK® HCV Rapid Antibody CONTROL STORAGE Temperature Log
 Acceptable Temperature Range for Storage: 2° - 8°C (36° - 46°F)

Day/Date	January Temp	February Temp	March Temp	April Temp	May Temp	June Temp	July Temp	August Temp	September Temp	October Temp	November Temp	December Temp
1												
2												
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Instructions: Temperatures must be taken in the storage area on a daily basis. Thermometer Probe may be used for temperature reading in the refrigerator. If temperatures are out of the designated range, inform the supervisor and await further instruction.



This package insert and the OraQuick® HCV Rapid Antibody Test package insert must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result. Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.¹

NAME AND INTENDED USE

The OraQuick® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°-30°C (36°-86°F),
- If the temperature of the testing area falls outside of 15°-37°C (59°-99°F), and
- At periodic intervals as dictated by the user facility.

It is the responsibility of each laboratory using the OraQuick® HCV Rapid Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The OraQuick® HCV Rapid Antibody Test Kit Controls are human plasma-based reagents. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test (T) Zone. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the Test (T) Zone). Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert. Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

MATERIALS PROVIDED

OraQuick® HCV Rapid Antibody Test Kit Controls

Each Kit Control box contains a package insert and two vials (one HCV Positive Control and one HCV Negative Control) as described below:

HCV Positive Control

One purple-capped vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HCV, diluted in a defibrinated pool of normal human plasma. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and HIV-1/2 antibody.

HCV Negative Control

One white-capped vial containing 0.2 mL of defibrinated pool of normal human plasma negative for antibodies to HCV. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and HIV-1/2 antibody.

MATERIALS REQUIRED AND PROVIDED in the OraQuick® HCV Rapid Antibody Test Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial
Reusable Test Stands
Specimen Collection Loops
OraQuick® HCV Rapid Antibody Test Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 20 to 40 minutes
Latex, vinyl, or nitrile disposable gloves
Biohazard waste container

WARNINGS

For *in vitro* Diagnostic Use

- **This package insert must be read completely before using the product.**
- **Follow the instructions carefully when performing the OraQuick® HCV Rapid Antibody Test, failure to do so may cause an inaccurate test result.**
- **Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.¹**

PRECAUTIONS

Safety Precautions

- Handle Kit Controls and materials in contact with Kit Controls as if capable of transmitting infectious agents.
- Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container.
- Wear disposable gloves while handling and testing the Kit Controls. Dispose of used gloves in a biohazard waste container.
- Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

STORAGE INSTRUCTIONS

Store the OraQuick® HCV Rapid Antibody Test Kit Controls at 2°-8°C (36°-46°F). Do not use Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2°-8°C (36°-46°F) after use. Once opened, Kit Controls should be discarded after eight weeks.

DIRECTIONS FOR USE

General Test Preparation

Perform procedures according to the *General Test Preparation* section of the OraQuick® HCV Rapid Antibody Test package insert.

TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the rounded end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Vial and discard the used loop in a biohazard waste container.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Vial containing the specimen. **Be sure that the Result Window is facing towards you and the flat pad touches the bottom of the Developer Vial.**
5. Leave the Test Device in the Developer Solution Vial and start a timer. Do not remove the Test Device from the vial until you have read the results. Read the results in a fully lighted area after 20 minutes, but no more than 40 minutes. Read the results as described in the *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test Kit Package Insert.
6. Dispose of the used test materials in a biohazard waste container.
7. Reseal the Kit Control reagent vials and store them in the original container at 2°-8°C (36°-46°F).

EXPECTED RESULTS

HCV Negative Control

The HCV Negative Control will produce a Non-Reactive test result. A single line should be present in the Result Window in the (C) Zone and NO line should be present in the (T) Zone. This indicates a Non-Reactive test result.

HCV Positive Control

The HCV Positive Control will produce a Reactive test result and has been manufactured to produce a line at the Test (T) Zone. A line should be present in the Result Window in the (C) Zone and a line should appear in the (T) Zone. This indicates a Reactive test result. The lines will not necessarily be the same intensity.

NOTE: If the test result for either the HCV Negative Control or the HCV Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen. If the test result for any of the controls is not as expected upon repeat testing, discontinue testing and contact OraSure Technologies' Customer Service.

LIMITATIONS

The OraQuick® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test.

BIBLIOGRAPHY

1. CDC. Universal Precautions For Prevention Of Transmission Of Human Immunodeficiency Virus, Hepatitis B Virus, And Other Bloodborne Pathogens In Health-Care Settings. *MMWR* 1988; 37(24):377-388.



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(610) 882-1820
www.orasure.com



Linking People to Care

Step-by-Step Instructions For OraQuick® HCV Rapid Antibody Test



Complexity: WAIVED for fingerstick whole blood and venipuncture whole blood.

A Certificate of CLIA Waiver is required to perform the test in a waived setting. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA or from your state health department.

Failure to follow the instructions, or modifications to the Test instructions, will result in the Test no longer meeting the requirement for Waived Classification and will be subject to all applicable CLIA requirements.

- These instructions are only a Reference Guide. For complete information including Restrictions, Precautions, and Limitations of the Test, refer to the OraQuick® HCV Rapid Antibody Test Package Insert.
- Read these instructions completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results.
- Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.^{1,2}

OraQuick® Rapid Antibody Test
HCV



INTENDED USE:

The OraQuick® HCV Rapid Antibody Tests 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 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.

WARNING: This assay has not been FDA approved for use in patient populations without signs, symptoms, or not at risk for hepatitis C infection.

Not for use in screening whole blood, plasma, or tissue donors. Performance characteristics have not been established for testing a pediatric population less than 15 years of age or for pregnant women.

If you are a new operator, before proceeding you **MUST** be able to correctly interpret the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.

Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® HCV Rapid Antibody Test and may result in false negative results.

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 container.¹

¹ See "Universal Precautions," CDC, MMWR, 1988; 37(24):377-388. ² "Guideline for Isolation Precautions," CDC, HICPAC, 2007; 12-93.

FOR IN VITRO DIAGNOSTIC USE

THE FOLLOWING ITEMS ARE NEED TO DO THE TEST:

The OraQuick® HCV Rapid Antibody Test Consists of a Divided Pouch Containing the Following:

- Single-Use Test Device (including an absorbent packet)
- Developer Solution Vial (containing .750 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 Kit:

- Reusable Test Stands
- Package Insert
- Specimen Collection Loops

Materials Required But Not Provided:

- Timer or watch capable of timing 20 to 40 Minutes
- Materials required for venipuncture whole blood specimen collection
- OraQuick® HCV Visual Reference Panel
- Biohazard waste container
- Sterile lancet to obtain a fingerstick whole blood specimen
- OraQuick® HCV Rapid Antibody Test Kit Controls

EXTERNAL QUALITY CONTROL

OraQuick® HCV Rapid Antibody Test Kit Controls are available separately for use only with OraQuick® HCV Rapid Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform and test and interpret the results. Refer to the Kit Control Package Insert for complete instructions.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit, lot
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°–30°C (36°–86°F),
- If the temperature of the testing area falls outside of 15°–37°C (59°–99°F),
- At periodic intervals as dictated by the user facility.

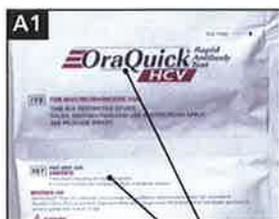
Test Procedure for Kit Controls

1. Open a Kit Control vial containing the control reagent.
2. Insert the rounded end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
3. Immediately immerse the control-reagent filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Vial and discard the used loop in a biohazard waste container.
4. Follow Step 3 *Testing Procedure* for additional instruction.

SET UP YOUR WORKSPACE

- Gather the materials you will need.
- Allow the test kit to come to operating temperature (15°–37°C; 59°–99°F) before use.
- Refer to the External Quality Control section above to determine when the Kit Controls should be run.
- Set an OraQuick® HCV Reusable Test Stand (“Stand”) on your workspace. Use only the Stand provided.
- Disposable gloves are needed when performing the test.

GENERAL TEST PREPARATION

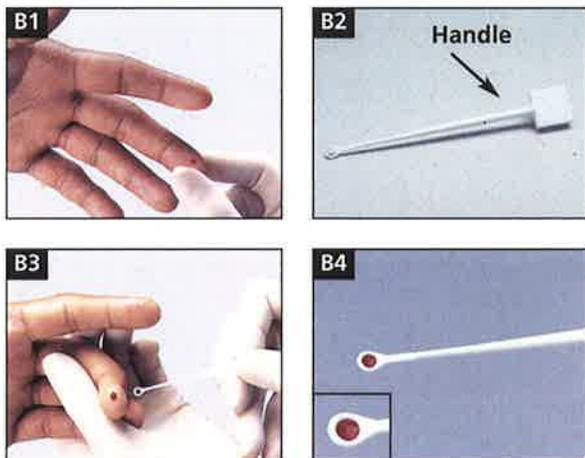


Two Chambers



- If you are a new operator, you **MUST** be able to interpret all devices provided in the OraQuick® HCV Visual Reference Panel prior to using the Oraquick® HCV Rapid Antibody Test.
- Allow all components to come to operating temperature (15°–37°C, 59°–99°F).
- Place the reusable Test Stand on your workspace. Use only the Stand provided with the OraQuick® HCV Rapid Antibody Kit. Set up your timer for 20 to 40 minutes but **DO NOT** start.
- Do not open the pouch until you are ready to perform a test. Check the pouch for damage or holes. Discard the pouch if it is damaged (see picture A1).
- After opening the pouch, check for an absorbent packet. If it is not present or appears damaged, discard the pouch and open a new one (see picture A2).
- Hold the Developer Solution Vial firmly in your hand. Remove the cap by rocking it back and forth while pulling it off. Set the cap aside. Slide the Vial into the tops of one of the slots in the Stand (see picture A3).
- Leave the OraQuick® HCV Test Device in the pouch until testing is started. Refer to Step 3 in the *Testing Procedure* section.
- **DO NOT** cover the 2 holes on the back of the OraQuick® HCV Test Device with labels or other materials. Blocking the holes may cause an invalid result.

SPECIMEN COLLECTION PROCEDURE – FINGERSTICK WHOLE BLOOD

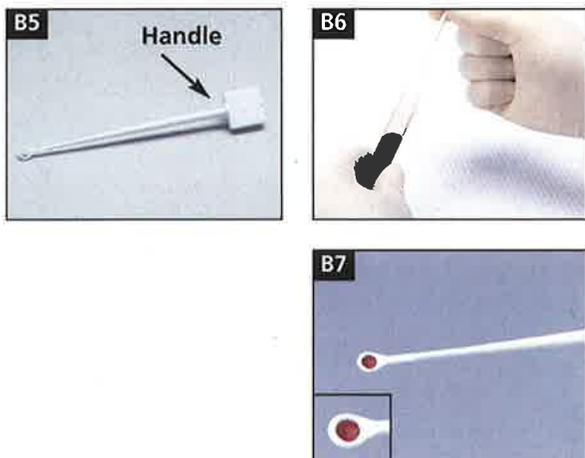


NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

Step 1A – COLLECT

- Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to air dry.
- 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 the 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*).

VENIPUNCTURE WHOLE BLOOD

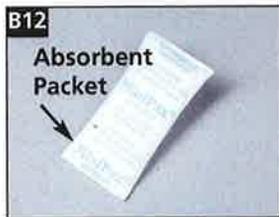
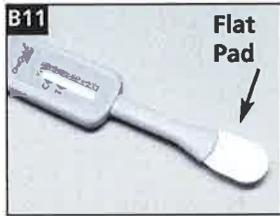
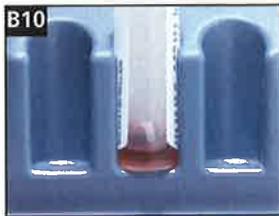


NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

Step 1B – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium/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°– 8°C (36°– 46°F) for up to 7 days or at 15°– 30°C (59°– 86°F) for up to 7 days.
- 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 B5*).
- Put the "rounded" end of the Loop into the tube of blood (see *picture B6*). Make sure the Loop is completely filled with blood (see *picture B7*).

TESTING PROCEDURE



Step 2 – MIX

- Immediately insert the blood-filled end of the Loop all the way into the Vial (see picture B8).
- Use the Loop to stir the blood sample in the Developer Solution ("Solution") (see picture B9).
- 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 B10). 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 sample.

Step 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture B11).
- Check to make sure that an Absorbent Packet is included with the Device (see picture B12). 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 sample (see picture B13). 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 B14).
- Start timing the test (see picture B15). **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.
- Wait 20 minutes.
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Test Result and Interpretation* section in these instructions.

TEST RESULT AND INTERPRETATION – Refer to the Result Window on the Test Device

CAUTION: Adequate lighting required. Color blindness may affect the ability to interpret Test results.

REACTIVE: Lines in C and T Zones



Line in T Zone

Line in T Zone

Faint Line
in T Zone

Test is Reactive if:

- A line appears in the C Zone and a line appears in the T Zone. Lines may vary in intensity. Two lines must be present for a “reactive” result.
- **The test is reactive regardless of how faint these lines appear.**
- A Reactive test result means that HCV antibodies have been detected in the specimen. Patient is presumed to be infected with HCV.
- Follow appropriate guidelines for supplemental testing.

NON-REACTIVE: Lines in C Zone Only



Line in C Zone
No HCV antibodies detected.

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.

INVALID: No Lines in C Zone or Partially Developed Lines



No Line in
C Zone

Red background
obscures results



Partial Line on one side
of C or T Zones

Test is Invalid if:

- No line appears in the C Zone, or
- A pink background obscures the results during the 20-40 minute read time, or
- Any partial line appears on one side of the C or T Zones.
- An Invalid test result means that there was a problem running the test either related to the Specimen or to the Test Device.
- An Invalid result cannot be interpreted. Repeat the test with a new Pouch and a new Specimen.
- Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.

For answers to questions or technical assistance regarding the OraQuick® HCV Rapid Antibody Test, call: 1-800-ORASURE (800-672-7873) or visit our web site: www.orasure.com

GENERAL TEST CLEAN UP

- Dispose of the used test materials in a biohazard waste container.
- 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.

For answers to questions or technical assistance regarding the
OraQuick® HCV Rapid Antibody Test, call: 1-800-ORASURE (800-672-7873)
or visit our web site: www.orasure.com

Order Information	Description	Reimbursement Information	CPT Code
	Box of 25 tests		86803
	Box of 100 tests		
	Controls		
	OraQuick® HCV Visual Reference Panel		



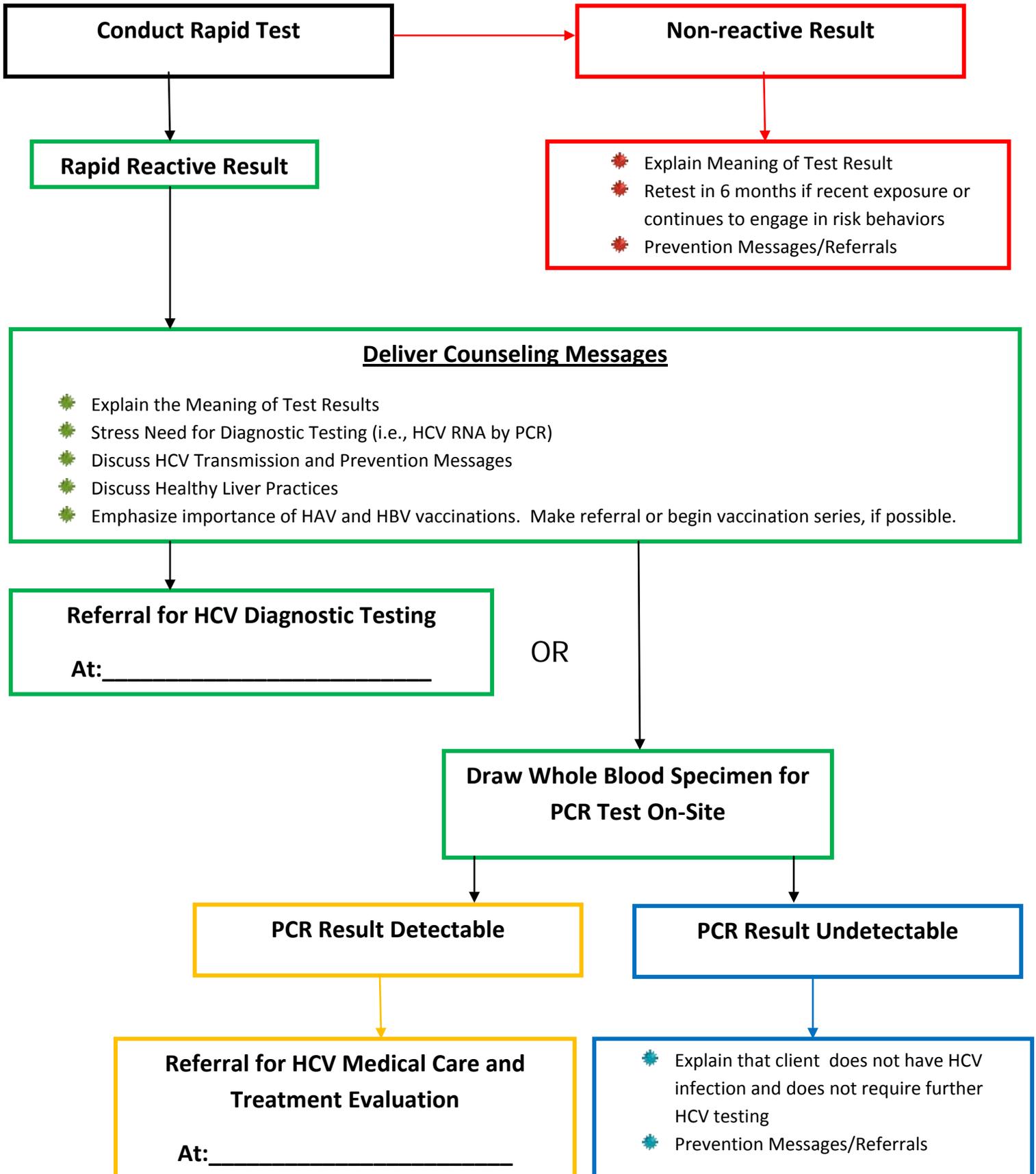
OraSure Technologies

220 East First Street
Bethlehem, PA 18015 USA
phone: 800.ORASURE
web: www.orasure.com

Made in the USA

Please refer to the package insert for complete information and instructions on the proper use of the OraQuick® HCV Rapid Antibody test
©2009, 2011 OraSure Technologies, Inc. U.S. Patent #7,192,555, #7,541,194 and various international and U.S. patents pending. OraQuick® is a registered trademark of OraSure Technologies, Inc
Item# 3001-1529 rev. 11/11

Hepatitis C Rapid Testing Algorithm



“Name and Address of Agency which Holds the Limited Test Site Permit”

Rapid HCV Antibody Test Result

Client Name: _____ **Collection Date:** __/__/__

Counselor Initials: _____

Client’s Date of Birth: __/__/__ **Race:** _____ **Gender:** _____

Name of Authorizing Physician: _____

The HCV antibody result from the **Rapid HCV Antibody Test** is:

Non-Reactive	Reactive
<input type="checkbox"/>	<input type="checkbox"/>

Type of Specimen: **Rapid test, fingerstick with whole blood**
 Rapid test, venipuncture with whole blood

Meaning of Test Result:

A **non-reactive** test result means that no antibodies to hepatitis C have been found in your blood. Hepatitis C antibodies may be absent if your exposure to the virus was recent. If it was a recent exposure, repeat testing is necessary. Remember that a non-reactive test result does not mean you cannot become infected with hepatitis C in the future.

A **reactive** test result means that hepatitis C antibodies have been found in your blood. This means you were exposed to the hepatitis C virus at some time. This test does not mean you currently have hepatitis C. To tell if you have hepatitis C, a second test to detect the **hepatitis C virus** must be done. This test is called a **HCV PCR test**. **It is important to keep your appointment for this second test (HCV PCR) so that you know whether you are currently infected.**

You have a referral for HCV PCR Testing at:

Location: _____

Counseling Messages HCV Rapid Test Results

For a non-reactive screening result:

- Explain that the result of the screening was negative and what that means.
- Discuss that if the client had a recent exposure (6 months) they maybe in the window period and that repeat screening is recommended in 6 months. Schedule an appointment for repeat testing if necessary.
- Reassess the client's knowledge and awareness regarding HCV.
- Emphasize that in order to avoid contracting HCV the client must sustain behavior changes, including:
 - Avoiding sharing any injection drug equipment, tattooing equipment, razors, toothbrushes, straws for intranasal drug use, and any other implements that might hold blood;
 - Following standard precautions in occupations that involve possible exposure to blood; and
 - Using a condom or other barrier when having sex.
- Emphasize the importance of HAV and HBV vaccination and make a referral or begin the series immediately if possible.
- Be certain not to allow a client to walk away from the counseling session with the idea that a negative screening result grants immunity for future risk-taking behaviors.
- Provide educational materials on HCV prevention and risk reduction.

For a reactive result:

- Explain that the result of the screening was reactive and the meaning of the result.
- Explain that the result is just a screening test for hepatitis C antibodies only. Additional testing is required to confirm the diagnosis of chronic hepatitis C. Emphasize the importance of keeping the appointment for diagnostic testing.
- Using the results of the needs assessment that you conducted while the screening was being performed, help the client understand the likelihood that he/she is truly infected.
- Explain that a small number of people who were infected with HCV clear the virus; about 85% who become infected do not clear the virus.
- Explain that HCV progresses slowly and many people living with HCV experience only mild symptoms for many years. Provide a basic overview of treatment options and explain that getting treatment is an individualized decision made between the patient and provider.
- Discuss healthy liver practices. Stress the importance of stopping or reducing alcohol intake. This may be the most important thing you can do to promote wellness.

- Emphasize the importance of HAV and HBV vaccinations and make a referral or begin the series immediately if possible.
- Encourage the client to actively develop a support system consisting of support services providers, friends, relatives, and peers.
- Explain the importance of minimizing risk behaviors to avoid transmitting HCV infection to others.
 - Avoiding sharing any injection drug equipment, tattooing equipment, razors, toothbrushes, straws for intranasal drug use, and any other implements that might hold blood;
 - Using a condom or other barrier when having sex.
- Discuss the importance of notifying sexual and needle sharing partners and encourage screening of each.

For an Invalid Test Result:

- Explain that this is not a true test result and that the test did not work properly.
- Offer to repeat the test using a new testing device and specimen.

Counseling Messages for a Detectable HCV PCR Test

A detectable HCV PCR test means that the client is currently infected with hepatitis C.

Prognosis:

- Most people have no symptoms and stay healthy for a long time, but slowly progressing disease can lead to serious liver damage over time. Can also infect others.
- Having a medical provider who is monitoring liver damage is very important.

Treatment:

- New treatments can cure hep C with fewer side effects and a shorter treatment length.
- Not everyone will need treatment. See a medical provider to monitor your condition even if you feel well and are not ready for treatment.

Prevent further damage to the liver:

- Abstain from/limit alcohol.
- Get vaccinated for hep A and B.
- Eat nutritious food, low in fat and sugar and no iron supplements.
- Drink lots of water, get moderate exercise and lots of rest
- Talk with people who care about you and ask for support. Consider joining an HCV support group in person or online.

Prevent transmission to others:

- Avoid sharing needles, syringes, cookers, water, cotton & other drug equipment.
- Practice safe injection, tattooing & piercing practices.
- Practice safer sex (condoms, dental dams). Avoid practices that lead to blood exposure.
- Hep C is not spread by casual contact, i.e. eating, drinking, hugging.

Referral:

- Discuss notification of contacts and offer screening to drug-sharing partners or sexual partners.
- Refer to medical provider for additional care and treatment evaluation.
- Refer to substance use or harm reduction program if indicated. Discuss ESAP and needle exchange.
- Refer to hep C support group, if available.
- Notify client that detectable PCR results are reported to the local health department.

Counseling Messages for an Undetectable PCR Test

An undetectable PCR result means that the client is not currently infected with hep C.

- The client was either previously exposed and cleared the infection, or received hep C treatment in the past.
- The client is not immune to hep C and can be re-infected .

If risky behavior is continuing:

Provide Hep C Risk & Harm Reduction

- Explain the importance of minimizing risk behaviors, such as sharing needles, syringes, cookers, water, cotton & other drug equipment. Explore alternatives to injection.
- Refer for drug treatment.
- Discuss safe injection, tattooing & piercing practices.
- Provide information on syringe exchange & ESAP.
- Discuss safer sex practices (condoms, dental dams). Avoid practices that lead to blood exposure.
- Encourage repeat testing in 6 months.

HCV(PCR)

Specimen Preparation

- Prep patient for venipuncture
- Write patient name on the tube label
- Put the test requisition label on the tubes
- Draw 2 Plasma Prep Tubes (PPT)
- After collection, gently invert back and forth 5 times
- Centrifuge immediately for 15 minutes
- Put tube in a specimen bag with the lab req form in the separate pouch.
- Secure zip lock seal
- Refrigerate until pick-up
- Specimen can be stored refrigerated for up to 3 days

**New York State Department of Health
Aggregate Hepatitis C Rapid Testing Data Form**

Agency Name: _____ Month ____/____
mm yy

Total Number of HCV Rapid Tests Conducted: _____

*Total Number of HCV Rapid Reactive Test Results: _____ Total Number of HCV Rapid Non-reactive Test Results: _____

Total Number of Clients who Received their Test Results: _____

Please list the number for each category in the space provided.

Gender: Male _____ Female _____ Transgender _____ Refused _____

Age: <19 _____ 20-29 _____ 30-39 _____
40-49 _____ 50 and over _____ Refused _____

Race: White _____ African American _____ Asian _____ American Indian _____
Native Hawaiian/Pacific Islander _____ More Than One Race _____ Other _____ Refused _____

Ethnicity (separate from Race): Hispanic/Latino(a) _____ Non-Hispanic/Latino(a) _____ Refused _____

Primary Risk Factors (Must have at least one):

IDU _____ Born between 1945- 1965(baby boomer) _____ Blood transfusion/transplant before 1992 _____

Clotting factor before 1987 _____ Long term dialysis _____ Snorting Drugs _____ Refused _____

Tattoo (unlicensed setting) _____ Body piercing (unlicensed setting) _____ Occupational exposure _____

Additional Risk Factors: MSM(HIV+) _____ Sex with HCV infected person _____

Household contact _____ Sex with multiple partners _____

Testing Method: Finger stick _____ Whole blood _____ Plasma _____ Serum _____

Other Testing Conducted:

HIV _____ TB _____ STD _____ Hepatitis A _____ Hepatitis B _____

Hepatitis C Rapid Testing Master Log for On-site PCR Testing Sites - Instructions

Client ID	Use a unique identifier. Must begin with first three letters of agency name.
Date of Test	Enter the date of the test in MM/DD/YYYY format
Gender	Enter the client's gender; M =Male; F =Female; T =Transgender; R =Refused to provide
Date of Birth	Enter the client's date of birth in MM/DD/YYYY format. If client refuses to provide date, enter 01/01/1900 .
Ethnicity	Enter the client's ethnicity; H =Hispanic or Latino; NH =Not Hispanic or Latino; R =Refused to provide
Race	Enter the client's race; AA =African American; W =White; AS =Asian; AI =American Indian; PI =Native Hawaiian/Pacific Islander; MR =More than one race; O =Other; R =Refused to provide
Primary Risk Factor - Select one -the highest risk.	1 =IDU; 3 =Blood transfusion/organ transplant before 1992; 4 =Clotting factor prior to 1987; 6 =Occupational exposure; 9 =Long term dialysis; 10 =Tattoo; 11 =Body piercing; 12 = Born between 1945-65; 14 =Snorting drugs; R =Refused to provide
Additional Risk Factors	2 =Sex with multiple partners; 5 =Household contact; 7 =Sex with an HCV infected person; 8 =MSM
Test Technology	F =Finger stick; WB =Whole blood; P =Plasma; S =Serum
Test Result	Enter test result; RN =Rapid negative; RR =Rapid reactive. If RN-Rapid Negative, skip to Other Testing.
PCR Test Done	Indicate whether the client received a PCR test. Y =Yes; NO-R =Refused; NO-U =Unable to obtain specimen. If NO, skip to Other Testing
HCV PCR Testing Results	Enter the HCV PCR test result as D =Detectable/+ ; U =Undetectable/-
Returned for HCV PCR Test Results	Indicate whether the client returned and received his/her HCV PCR test result. Y =Yes; N = No; P =Pending if the client is scheduled to come in at a later date. For providers reporting data in the HCS, update status via e-mail to hepatabc@health.state.ny.us . AIRS users should update status in AIRS. If NO or Pending, or PCR test is undetectable, skip to Other Testing.
Medical Referral Provided	Indicate if a referral for follow-up medical evaluation and care was provided. Y =Yes; NO-R = Client refused referral. If NO, skip to Other Testing .
Medical Referral Kept	Indicate if referral was reached. Y =Yes; N =No; P =Pending if referral appointment has not occurred at the time of data reporting. For providers reporting data in the HCS, update status via e-mail to hepatabc@health.state.ny.us . AIRS users should update status in the AIRS system.
Other Testing	Indicate if other testing was conducted during the same visit. Y =Yes; N =No

Hepatitis C Rapid Testing Master Log - Instructions

Client ID	Use a unique identifier. Must begin with first three letters of agency name.
Date of Test	Enter the date of the test in MM/DD/YYYY format
Gender	Enter the client's gender; M =Male; F =Female; T =Transgender R = Refused to provide
Date of Birth	Enter the client's date of birth in MM/DD/YYYY format. If client refuses to provide date, enter 01/01/1900 .
Ethnicity	Enter the client's ethnicity; H =Hispanic or Latino; NH =Not Hispanic or Latino; R =Refused to provide
Race	Enter the client's race; AA =African American; W =White; AS =Asian; AI =American Indian; PI =Native Hawaiian/Pacific Islander; MR =More than one race; O =Other; R =Refused to provide
Primary Risk Factor - Select one -the highest risk.	1 =IDU; 3 =Blood transfusion/organ transplant before 1992; 4 =Clotting factor prior to 1987; 6 =Occupational exposure; 9 =Long term dialysis; 10 =Tattoo; 11 =Body piercing; 12 =Born between 1945-65; 14 =Snorting drugs; R =Refused to provide
Other Risk Factors-Select one	2 =Sex with multiple partners; 5 =Household contact; 7 =Sex with an HCV infected person; 8 =MSM;
Test Technology	F =Finger stick; WB =Whole blood; P =Plasma; S =Serum
Test Result	Enter test result; RN =Rapid negative; RR =Rapid reactive. If RN-Rapid negative, skip to Other Testing
Referral Made for HCV PCR Testing	Indicate if a referral for HCV diagnostic testing was provided. Y =Yes; NO-R = client refused a PCR test. If NO , skip to Other Testing .
Referral Kept for HCV PCR Testing	Indicate if referral was reached. Y =Yes; N =No; P =Pending. Select Pending if referral appointment has not occurred at the time of data reporting. For providers reporting data in the HCS, update status via e-mail to hepatabc@health.state.ny.us . AIRS users should update status in AIRS.
Other Testing	Indicate if other testing was conducted during the same visit. Y =Yes; N =No

HCV Rapid Testing Program

Steps to Enter HCV Rapid Testing Program DATA

1. Log into the Health Commerce System web site
2. Click on “Hepatitis C Rapid Testing” (left hand side of the page)
3. Log into Hepatitis Rapid Testing
4. Click - “Hepatitis C Rapid Test Kit Order Form”
5. You will now see a list of all previous orders
6. At the top of the page you will also see:
 - a. Aggregate Data Form
 - b. Client level Data Form
7. Enter data accordingly
 - a. All required fields (*) must be entered or the data cannot be submitted.

NOTE: You must have access to both the HCS and the Hepatitis C Rapid Testing Application to enter data

HCS Portal - Windows Internet Explorer

https://commerce.health.state.ny.us/hcsportal/hcs_home.portal?_nfpb=true&_windowLabel=hcs_MyApplications&hcs_MyApplications_actionOverride=%2Fgov%2Fnyhealth%2Fapps%2Fhcs

File Edit View Favorites Tools Help

HCS Portal

Home Documents Applications My Account Help Contact Us Logout

Print

AIDS Institute

Today's Date: 08/06/2012
 Welcome [Log Off](#) [Recent Orders](#) [Aggregate Data Form](#) [Client Level Data Form](#) [AI Home](#)

PREVIOUS HCV RAPID TEST KIT ORDERS

Count	Order Date	Order ID	Name	Address	City	State	Zip	Contact Person	Status
1	05/02/2012	3810931	Upper Hudson Planned Parenthood	855 Central Ave	Albany	NY	12206		Delivered

INFORMATION SYSTEMS OFFICE Corning Tower Room 270 Albany, NY 12237 Phone:(518) 473-8459

Done Local intranet 150% 11:48 AM

AIRS Module for HCV Rapid Testing

Agency Setup – Add a New Program

Agency Setup

+ Add Edit Remove... Save Cancel Print... Help

Programs Setup

Code	Program Name
FWAB0	Free Test Kits
FWAB7	HCV Care
FWACJ	HCV Testing Program
FWABQ	HCV-HIV Coinfection Program
FWAA4	Harlem Education
FWAB9	Health Homes

Status: Active Inactive System Generated Code: FWACJ

Name: HCV Testing Program

Type:

This program requires enrollment

Include this program on "SER Unit Referral Report [All Referrals]" report

Include this program in the "HCV Rapid Testing" screen

Eligibility & Funding

Effective Date: // View Eligibility and Funding History...

Current Eligibility Type: 04 Other

Current Funding Type: 15 State

CTR / Planning File Information

CTS/CTR Funding Source:

CTR Risk Factor Local Recall Period:

Service Categories Operated by this Program

Not Entered

View Planning Data for the Program & Service Category...

Status: Active.

Name: HCV Testing Program.

Make sure to check “Include this program in the “HCV Rapid Testing” screen. This will allow you to select this program when entering a rapid test.

Current Eligibility Type: 04 “Other”.

Current Funding Type: 15 “State”.

CTR/Planning File Information: Not required.

Service Categories Operated by this Program: You do not need to add service categories to the program; the HCV Rapid Test screen does not generate any encounters or services in AIRS. The AIDS Institute will not send any planning file mappings for this program. However, you may add a service category if you wish to track services for your own purposes.

Entering a New Test

The screenshot shows the 'Client Information and Services' window for client 'Abner, Doubleday'. The main form is titled 'HCV Rapid Testing' and contains the following sections:

- Intake Information:** Includes a table for 'HCV Rapid Testing' with columns for Date, Program, Testing Method, and Result.
- Test Date:** A date input field with slashes (//).
- Program:** A text input field.
- Worker:** A text input field.
- Site:** A text input field.
- Identified Risks Factors...:** A section titled 'Select all that apply - at least one selection is required' with two columns of checkboxes:
 - Column 1: Blood transfusion / organ transplant prior to 1992, Clotting factor concentrate produced prior to 1987, Long term hemodialysis, Injection drug use (ever), Sex with multiple partners, MSM.
 - Column 2: Sex with HCV infected person, Household contact of hepatitis C infected person, Occupational exposure, Tattoo, Body piercing, Birth Cohort (Born between 1945 and 1965), Unknown (no Identified Risk Factors).
- Technology:** A radio button group with 'Rapid' selected. A note says '(Predefined for the Test)'.
- Testing Method:** A radio button group with 'Finger Stick', 'Whole Blood', 'Serum', 'Oral Fluid', and 'Plasma' options.
- Results:** Radio buttons for 'Reactive (Positive)' and 'Non-Reactive (Negative)'. The 'Non-Reactive (Negative)' option is selected.
- Provided...:** Radio buttons for 'Yes' and 'No'. The 'No' option is selected. There are input fields for 'If Yes, Date' and 'If No, Reason'.
- Referrals:** A dropdown menu currently showing 'Not Entered'.
- Other Testing Conducted:** A section with a 'Refused' checkbox and checkboxes for 'Hepatitis A', 'Hepatitis B', 'HIV', 'TB', and 'STD'.

On the left side, there is a navigation tree with categories like 'Intake Information', 'Enrollments / Assignments', 'Historical Information', 'Hepatitis', 'Assessments', and 'Services'. The 'Services' category is expanded, showing 'Counseling Testing and Referrals...'. Below the navigation tree, a status box displays client details: Status: Active 12/05/2012 12:00 AM, Intake: 12/05/2012, Agency ID#: ABBASEBALL, Full Name: Doubleday B Abner (Male), DOB: 12/05/1998 Current Age: 14, Contact By: *Not Allowed*, Social Security Number: n/a, Case Number: n/a.

Test Date: Date test is conducted.

Program: “HCV Testing Program”. Even though “Program” is an optional field on the screen, you are still required to enter it.

Worker: Enter worker/staff person performing test. This field is required.

Site: Enter site where test was conducted (e.g., SEP, mobile van, street outreach, clinic, etc).

Identified Risk Factors: Select all risk factors that apply at the time of the test. Birth Cohort will be automatically selected based on the client’s date of birth from the Intake. At least one selection is required.

Technology: Predefined as “Rapid”.

Testing Method: Select specimen collection method/type. Most likely will be “Fingerstick”.

Results: Enter test result. If result is invalid, client must be retested. Invalid results are not a test result.

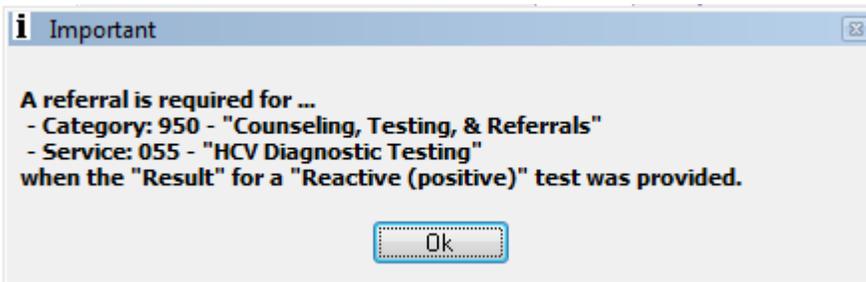
Provided: Enter whether or not the client received the test result. If you select “Yes”, you are required to enter a date. If you select “No”, you are required to enter a reason from the pick list.

Referrals: See section below.

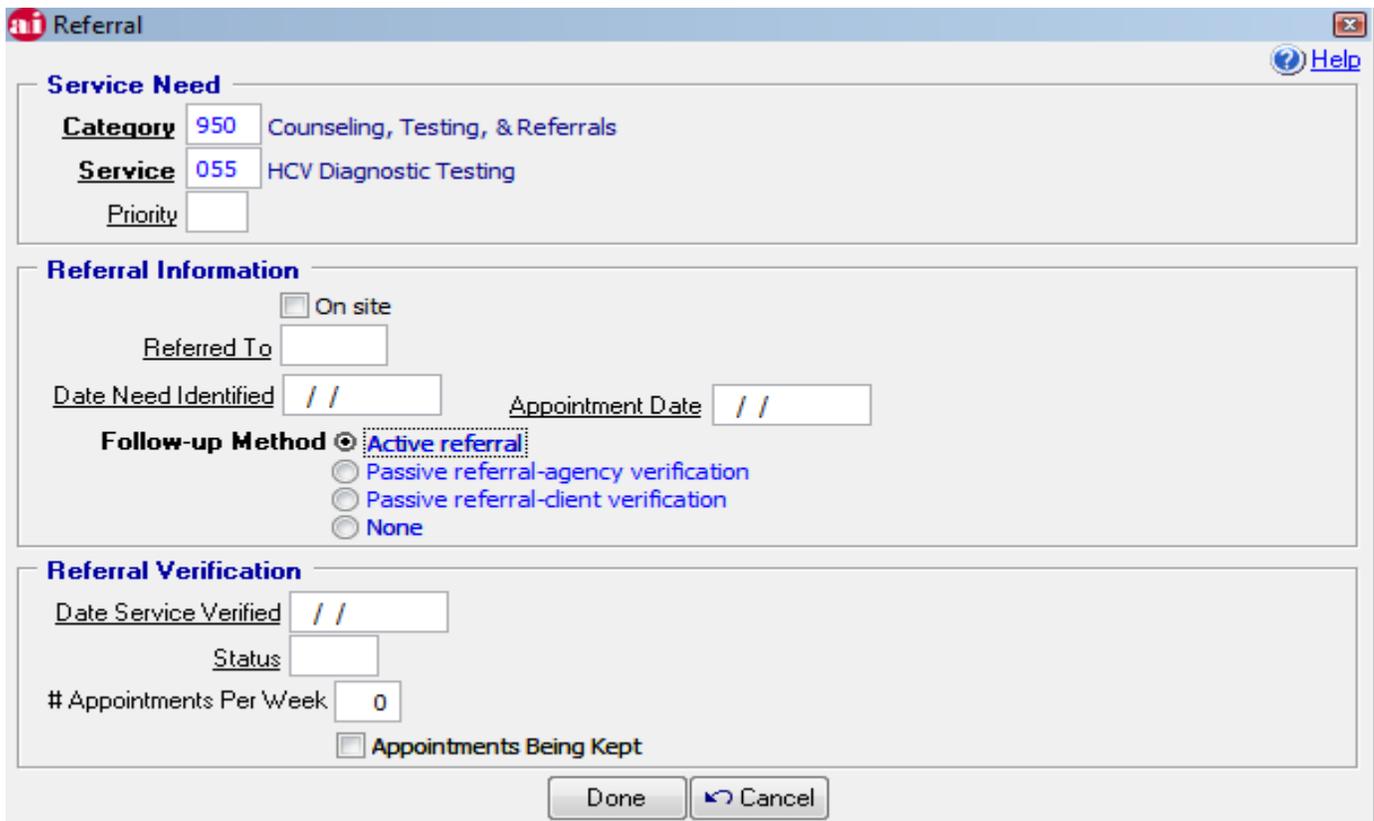
Other Testing Conducted: These fields are optional. Indicate any other tests that may have been conducted at the same time as the HCV rapid test. If client refused other testing, check “Refused”. If these services are not available at your site, do not make any selection.

Referral for HCV PCR Testing (Off Site or On Site)

You may enter any referral category and service using the referral screen. However, if the HCV Rapid test result was “Reactive” and the test results were provided, then you are required to enter a referral for **Category 950 “Counseling, Testing, & Referrals” – Service 055 “HCV Diagnostic Testing”**. If you do not, you will get the following error message:



Service Need: Enter Category 950 “Counseling, Testing, & Referrals” and Service 055 “HCV Diagnostic testing”, as required when the result of a positive/reactive test was provided to the client.



Referral Information: If you are conducting on site HCV PCR testing, check the on site box. Do not check the box if you are referring the client to another agency for diagnostic testing.

Referred To: If conducting PCR testing on site, choose your agency name from the drop down box. If referring the client off site, choose the name of the referral agency. If your agency name or the referral agency name is not included on the drop down list, add the name(s) through the referral library.

Date Need Identified: Not required.

Appointment Date: Not required.

Follow-up Method: This is a required field in AIRS. Choose “Active Referral”.

Referral Verification: If conducting PCR testing on site, enter the date that you draw the blood specimen for PCR Testing. If referring off site for PCR testing, enter the date that you verify whether or not the client attended the off site appointment. You may also use the main referral tracking screen to enter a referral verification date.

Status: If conducting PCR testing on site, choose =01 “Client Received Service”. If referring off site for PCR testing, select the appropriate response from the drop down box.

of Appointments Per Week and Appointments Being Kept can be left blank.

Entering HCV PCR Test Results (for sites conducting on site PCR testing only)

The screenshot displays the 'Client Information and Services' window for a client named Abner, Doubleday. The interface includes a navigation menu on the left with categories like Intake Information, Enrollments / Assignments, and Historical Information. The 'Laboratory & Psychological Test Information' section is active, showing a table of test results:

Date	Type	Description	Result	Count	%
02/19/2013	HC	Hepatitis C Test	Positive/Detectable	0	0
02/12/2013	HC	Hepatitis C Test	Positive/Detectable	0	0

Below the table, there are input fields for Test Type (HC), Test (03), Test Result (01), Range, Count (0.00), Percentage (0), and Test Date (02/19/2013). A checkbox for 'Not Medically Indicated [NMI]' is present. The bottom left corner shows client details: Status: Active 12/05/2012 12:00 AM, Intake: 12/05/2012, Agency ID#: ABBASEBALL, Full Name: Doubleday B Abner (Male), DOB: 12/05/1998, Current Age: 14, Contact By: *Not Allowed*, Social Security Number: n/a, Case Number: n/a.

HCV PCR test results are entered in the Historical Information/Laboratory & Psychological Test Information Screen.

Test Type: Choose HC “Hepatitis C Test”. This is a required field.

Test: Choose 03 “HCV RNA”. This is a required field.

Test Result: Choose “Positive/Detectable” or “Negative/Undetectable”. This is a required field.

Range: Not required

Count: This is a required field in the AIRS system. You may enter a count if one is available. If not, you must check “No Count/Not Applicable”.

Percentage: Not required.

Provided by: Not required.

Test Date: Enter the date of the blood draw for HCV PCR testing. This is a required field.

Result Date: Enter the date that the HCV PCR test results were received.

Program: Not Required.

Detectable HCV PCR Test (for sites conducting on site PCR testing only)

The screenshot displays the AIRS from NYSDOH AIDS Institute [ver 8.9.368] interface. The main window is titled "Client Information and Services" and shows the "HCV Rapid Testing" form for client "Abner, Doubleday".

Client Information:

- Status: Active 12/05/2012 12:00 AM
- Intake: 12/05/2012
- Agency ID#: ABBASEBALL
- Full Name: Doubleday B Abner (Male)
- DOB: 12/05/1998 Current Age: 14
- Contact By: *Not Allowed*
- Social Security Number: n/a
- Case Number: n/a

HCV Rapid Testing Table:

Date	Program	Testing Method	Result
02/19/2013	HCV Testing Program	Finger Stick	Positive/Reac.

Form Fields:

- Test Date: 02/19/2013
- Program: FWACJ HCV Testing Program
- Worker: FWABV weir, beth
- Site: FWAAC SITE 2

Identified Risks Factors...

Select all that apply - at least one selection is required

- Blood transfusion / organ transplant prior to 1992
- Clotting Factor concentrate produced prior to 1987
- Long term hemodialysis
- Injection drug use (ever)
- Sex with multiple partners
- MSM
- Sex with HCV infected person
- Household contact of hepatitis C infected person
- Occupational exposure
- Tattoo
- Body piercing
- Birth Cohort (Born between 1945 and 1965)
- Unknown (no Identified Risk Factors)

Technology (Predefined for the Test) Rapid Finger Stick Whole Blood Serum Oral Fluid Plasma

Results

- Reactive (Positive)
- Non-Reactive (Negative)

Provided...

- Yes If Yes, Date: 02/21/2013
- No If No, Reason: []

Referrals

- Other Medical/Health to Dr. Jones

Other Testing Conducted Refused

- Hepatitis A
- Hepatitis B
- HIV
- TB
- STD

When a HCV PCR test is Positive/Detectable, you must enter a referral for follow-up HCV medical care and treatment evaluation. This is done by adding a new referral through the HCV Rapid Testing Screen. In the HCV Rapid Testing screen, select the appropriate test date which represents the Positive/Reactive test. Click 'Edit', then right click in the 'Referrals' box to add a new referral.

Referral

Service Need

Category: 100 Medical/Health

Service: 999 Other Medical/Health

Priority: []

Referral Information

On site

Referred To: FWAAR Dr. Jones 15 Main Street, Gansevoort, NY 12831

Date Need Identified: // Appointment Date: //

Follow-up Method

Active referral

Passive referral-agency verification

Passive referral-client verification

None

Referral Verification

Date Service Verified: 02/21/2013

Status: +01 Client Received Service

Appointments Per Week: 0

Appointments Being Kept

Done Cancel

Category: Enter 100 “Medical/Health”.

Service: Enter 999 “Other Medical/Health”. The next version of AIRS will be updated to include the service “HCV Medical Evaluation, Treatment”.

Referral Information: Complete Referral Information as described in the **Referral** section.

Referral Verification: Enter the date that you verify whether or not the client attended the medical evaluation/treatment appointment.

**New York State Department of Health
AIDS Institute**

Special Order Form: Hepatitis C Testing Palm Cards – ENGLISH ONLY



Title	Code	Quantity (circle 1 per card)			
Hepatitis C – Get Tested Palm Card - English	1873	25	50	100	250
Hepatitis C – Get Tested Palm Card - Spanish	1874	25	50	100	250

Ordering Instructions:

1. Please circle only one quantity per item.
2. Complete the address label below. Be sure to print clearly. All orders must include a street address.
3. Fax orders to (518) 474-2749 or mail orders to:

AIDS Institute
New York State Department of Health
Corning Tower, Room 429
Albany, New York 12237-0684

Contact Information:

Name:		
Street:		
City:	State:	Zip Code:
Phone Number:	Fax Number:	
Email Address:		

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