Rapid Hepatitis C Testing Program Implementation Guide

To be used in conjunction with the
Hepatitis 09 Service Manual

Background

Hepatitis is a liver disease that results from infection with the hepatitis C virus (HCV). It can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness. Hepatitis C typically spreads when blood from someone infected with HCV enters the body of someone who is not infected. Before 1992, when widespread blood supply screening began in the United States, HCV was commonly spread through blood transfusions and organ transplants. Today, most people become infected with HCV by sharing needles or other equipment to inject drugs.

Hepatitis C can be either "acute" or "chronic." Acute HCV infection is a short-term illness that occurs within the first six months after someone gets exposed to the HCV. For most people, acute infection leads to chronic infection. Chronic HCV is a severe disease than can result in long-term health problems or even death. Approximately 75%–85% of people infected with HCV develop chronic infections.

Most people do not know they are infected because they do not look or feel sick. An estimated 2.4 million persons in the United States have chronic HCV infection. In 2020, an estimated 57,500 cases of acute HCV infections were reported in the United States.[1] In Florida, there are an estimated 151,000 persons living with HCV infection, with an average of over 25,247 chronic HCV cases per year reported from 2013 to 2020 and about 614 acute HCV cases per year reported over the same period. [2]

Overview: OraQuick rapid HCV antibody test

The Florida Department of Health (the Department) purchases the OraQuick HCV rapid antibody test for the screening program. The OraQuick HCV rapid antibody test is a single-use immunoassay for qualitatively detecting antibodies to HCV in fingerstick whole blood specimens and venipuncture whole blood specimens from individuals 15 years or older. In conjunction with other laboratory results and clinical information, the OraQuick HCV rapid antibody test results can provide evidence of infection with HCV in persons with signs or symptoms of hepatitis and persons at risk for HCV infection. The OraQuick HCV test is not a diagnostic test and cannot determine the stage of HCV infection.

Site Requirements

The following information gives a broad overview of requirements for sites wishing to offer rapid HCV testing within Florida. Sites are responsible for ensuring all state and federal requirements are met before initiating a rapid testing program.

Communication between the HIV/AIDS Section, Viral Hepatitis and Outbreak Response Section (VHORS), county health departments (CHDs), and rapid testing venues is essential to proper compliance.

Clinical Laboratory Improvement Amendments (CLIA) Requirements

The CLIA of 1988 established quality standards for laboratory testing performed on human specimens, such as blood, body fluid, and tissue, for diagnosis, prevention, or treatment of disease or health assessment. Federal law requires that all laboratories performing testing, no matter what type, must obtain a CLIA certificate and number. More information on CLIA laws and regulations can be found at STATUTE-102-Pg2903.pdf (govinfo.gov)

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[1] Division of Viral Hepatitis, Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD and TB Prevention, *Viral Hepatitis Surveillance Report United States, 2019,* 2021 National Progress Report on Viral Hepatitis from CDC | CDC

[2] Data Source: Merlin

There is an important distinction between traditional HCV testing and rapid testing. Sites that conduct standard HCV testing obtain specimens and send them to a laboratory where testing occurs. Sites conducting rapid HCV testing are considered clinical laboratories and held to laboratory standards. Rapid test sites must possess a CLIA waiver that designates the facility as authorized to perform waived rapid HCV testing.

Before initiating a rapid testing program, sites must be issued a CLIA waiver and number from the U.S. Centers for Medicare and Medicaid Services (CMS). A CLIA Certificate of Waiver allows these sites to perform FDA-approved waived rapid tests. Applications are available from the Florida Agency for Health Care Administration (AHCA).

Sites needing rapid HCV testing at multiple locations must ensure all sites are under a current CLIA waiver. All rapid testing sites must adhere to the same standards of a waived testing venue. For special events and on a limited basis, sites may offer rapid testing at places not on the CLIA waiver.

For more information about the CLIA waiver application process, visit the CMS CLIA website at: How to Apply for a CLIA Certificate, Including International Laboratories | CMS

Occupational Safety and Health Administration (OSHA) Requirements
All sites that collect blood samples for traditional and rapid testing must meet the OSHA standards for blood-borne pathogens. Providers must establish a written Exposure Control Plan to eliminate or minimize employee exposure to occupational risks. Providers must provide employees with personal protective equipment (PPE) at no cost. Examples of PPE are latex or vinyl gloves, eye protectors, and lab coats. If a problem arises with an article of PPE, the provider must repair or replace it at no cost to the employee.

The Exposure Control Plan must be readily accessible to all employees who may encounter occupational exposure. Providers must provide hand-washing facilities, which are readily accessible to all employees. If hand washing facilities are not feasible, the provider must provide an appropriate antiseptic hand cleanser or antiseptic towelettes. Activities prohibited in work areas with a reasonable likelihood of occupational exposure include eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses. Food and drink cannot be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or other potentially infectious materials are present.

Following a report of an exposure incident, the employer shall immediately make a confidential medical evaluation and follow up with the exposed employee. The employer must ensure that all medical evaluations and procedures, including the hepatitis B vaccination series, post-exposure evaluation, and follow up, including prophylaxis, are made available at no cost to employees. Providers must contain and dispose of biohazardous waste under applicable regulations and develop a plan to ensure proper biohazardous waste and sharps disposal.

Information regarding OSHA standards can be found at: Law and Regulations | Occupational Safety and Health Administration (osha.gov)

Biomedical Waste Disposal
The definition of biomedical waste is any solid or liquid contaminated with body fluid, body tissue, or blood products. Providers creating, transporting, or storing biomedical waste must observe universal precautions and adhere to applicable OSHA standards. Providers that generate, transport, store, or treat biomedical waste must comply with Florida Administrative Code Chapter 64E-16.

The provision of rapid HCV testing generates biomedical waste, usually in the form of products contaminated with blood. These include used lancets (sharps), gauze pads, gloves, test devices, developer solution vials, specimen collection loops, and absorbent workspace covers.

Using external kit controls also generates biomedical waste. All biomedical waste disposals will follow current OSHA and Florida regulations.

Florida requires providers that generate and transport biomedical waste to register with the Department of Health. All registered sites must pay the applicable fees unless:

- The provider generates less than 25 pounds of biomedical waste every 30 days
- The provider transports less than 25 pounds of biomedical waste per trip

All sites that generate biomedical waste must have:

- Storage permits
- A closed location in a sanitary area
- A scale to measure the amount of waste generated
- Emergency equipment to manage the waste in the event of a spill
- An annual inspection of the mode of transport of the biomedical waste

Site inspections by the Department of Health will include:

- Verification of a valid biomedical waste permit
- Easy access to sharps containers (if applicable) and red biohazard bags
- Storage
- Waste pick-up and transport receipts dating up to three years
- A review of the organization's Biomedical Waste protocol
- Proper labeling of the sharp containers and red biohazard bags
- Easily accessible spill kits

Florida Department of Health Standards

Sites wishing to offer rapid HCV testing must follow all applicable Florida rules and regulations on HCV testing. Any location in violation of or out of compliance with the Department, state of Florida, or Federal CLIA requirements, policies, guidelines, or procedures will not be allowed to continue operating a rapid HCV testing program until all aspects of the program are compliant.

Sites must follow the manufacturer's instructions on the operation and restrictions of the rapid HCV test.

Sites must complete a risk assessment on all clients receiving a rapid HCV test. If an approved testing site is not using CTLS, all assessments are required to be submitted monthly to the VHORS data team.

Clients with a reactive rapid test result will be provided a confirmatory blood test and evaluation for treatment if found to be positive.

Providers offering rapid HCV testing must develop and adhere to a detailed Quality Assurance Plan.

CHDs wishing to participate in Florida's rapid HCV screening program should contact the HCV Testing Team within the VHOR Section.

Quality Assurance

All programs participating in the rapid HCV testing program must have a quality assurance (QA) program. The QA program should include:

Inventory Control

Staff must ensure that all programs are stocked with the necessary inventory to conduct testing successfully. Including materials provided (test kits, controls, and visual reference panels) along with

other items needed that are not supplied by the HIV/AIDS or VHOR sections. Including lancets, antiseptic wipes, gloves, adhesive bandages, workspace towels, timers, and other materials necessary but not mentioned here.

Test kits and controls have a specified expiration date. Staff must monitor the expiration dates of supplies and ensure that those products close to the expiration date get used first. Sites with kits in danger of expiring before use should first attempt to use them or offer them to another approved provider to use before their expiration. Sites allowing test kits to expire may be required to reimburse the program for the lost kits. Test kits and controls **MAY NOT** be used beyond their expiration date.

Test Kit Orders and Supplies
Approved sites are provided an electronic ordering form for OraQuick HCV test kits and controls. The forms are submitted electronically to a dedicated email account accessible by the HIV and HCV testing teams. The forms are submitted by clicking on the "submit form" button on the bottom left side of the document. If sites cannot submit electronically, the form may be saved and attached to an email to the VHOR Section or submitted by fax to (850) 922-4202. Each box contains 25 individual rapid HCV tests. Sites may order test kits as needed but may be limited by the availability of tests purchased by the Department. Sites may contact the manufacturer to purchase additional kits at their own expense.

Screening Policies and Procedures
Policies and procedures for rapid HCV screening may vary by area but should contain at least the following:

Who Should be Screened:
The following recommendations for HCV screening augment those issued by the Centers for Disease Control and Prevention (CDC) in 2012. The recommendations issued by CDC in 1998 remain in effect. CDC recommends:

- Universal HCV screening:
    - HCV screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is < 0.1%
    - HCV screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is < 0.1%
- One-time HCV testing regardless of age or setting prevalence among persons with recognized risk factors or exposures:
    - Persons with HIV
    - Persons who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
    - Persons with selected medical conditions, including persons who ever received maintenance hemodialysis and persons with persistently abnormal ALT levels
    - Prior recipients of transfusions or organ transplants, including persons who received clotting factor concentrates produced before 1987, persons who received a transfusion of blood or blood components before July 1992, persons who received an organ transplant before July 1992, and persons who were notified that they received blood from a donor who later tested positive for HCV infection
    - Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood
    - Children born to mothers with HCV infection
- Routine periodic testing for persons with ongoing risk factors, while risk factors persist:
    - Persons who currently inject drugs and share needles, syringes, or other drug preparation equipment
    - Persons with selected medical conditions, including persons who ever received maintenance hemodialysis

- Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks

These guidelines can be found online at: CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020 | MMWR

Who Should Not Be Screened
Persons who have previously tested positive should not be screened with a rapid test. Persons previously treated and cured of HCV should not be screened with a rapid HCV test. Those persons will always have antibodies of HCV in their blood, so their rapid HCV test will always be reactive. A rapid HCV test cannot be used to confirm infection but must be provided with a confirmatory blood test to establish an active HCV infection.

Risk Assessment
Approved sites are supplied with risk assessment forms that must be entered into the Counseling, Testing, and Linkage System (CTLS) database for each client receiving a rapid HCV test. Paper copies of the forms completed during outreach contain client-level data and must be treated accordingly. The rapid HCV program's success depends upon all information being accurately filled in for each client.

The number of HCV rapid tests entered into the CTLS database by any site should closely equal the number of tests supplied over a given period (with exceptions for controls). The ongoing evaluation of the project depends on all forms being accurately filled in for each client. The data must be entered into the CTLS database no more than 10 days following the end of the month (i.e., return forms for tests conducted in April no later than May 10th). Risk assessment forms may be completed by hand for outreach events and entered into CTLS afterward. (See Appendix)

The HCV Testing Team leader will monitor orders to ensure a corresponding number of tests have been entered into the CTLS database. This monitoring will occur monthly. The VHOR Section will contact sites that are not entering data into the CTLS database. Locations that fall behind in form submission by more than 60 days or cannot account for the tests received will not receive any additional tests until the discrepancy is resolved and will not continue to participate in the screening program.

CHD sites that wish to also enter the testing information into HMS must do so locally. A local field for hepatitis rapid testing will need to be created if this is not already done in each area. Risk assessment data must be entered into the CTLS database even if the information is entered into HMS locally.

Results
Non-reactive: When the results are non-reactive, the clients are considered HCV-negative unless they have had a recent exposure. If there has been a recent exposure, the client should retest again in six months. Clients should receive education and counseling on risk reduction and any necessary referrals.

Reactive: When the result is reactive, HCV antibodies are detected in the specimen and the client could be infected with HCV. Once infected with HCV but cleared of the virus, clients may still trigger a reactive rapid test; therefore, reactive tests require further diagnostic testing to confirm an infection. Clients with reactive results should also receive education and counseling and be linked to care for further evaluation and treatment. A supplemental hepatitis questionnaire should be completed for each reactive test.

Confirmatory Testing
The OraQuick rapid HCV antibody test is a screening test designed to detect HCV antibodies. The test does not determine if someone is actively infected with HCV, either acute or chronic. To determine if an individual is HCV infected, additional diagnostic testing is required. Further testing requires that blood specimens get submitted to a diagnostic lab for processing. Participating sites will collect blood

specimens from clients with reactive rapid tests. Providers collecting confirmatory specimens for further testing will submit the sample to the state lab. Sites unable to collect specimens for confirmatory testing MUST link the client to an appropriate provider for additional testing.

All participating sites are STRONGLY encouraged to draw blood immediately for all reactive rapid HCV tests and submit that specimen to the state lab for further testing.

Form DH 1847 must be used to submit specimens. Staff must follow local CHD procedures for submitting lab specimens and use proper codes to ensure the health department does not get charged for the labs.

CHDs should request and include Medicaid and Medicare eligibility numbers on the form.

In-House Confirmatory
Counties can access testing services via state lab testing sites contingent upon available funding. Form DH 1847 must be used to submit specimens.

If the form is completed manually, please ensure that all writing is legible.

If the CHD is conducting a confirmatory test, staff should ensure that clients are provided with a copy of all confirmatory test results to take with them to their medical appointment.

Linkage to Confirmatory Testing
Those sites that cannot conduct confirmatory testing for rapid reactive results must link clients to a provider who can perform the confirmatory testing. Local agencies should establish a memorandum of understanding (MOU) with a provider who can perform the test. Local staff should track linkage appointments to ensure the client keeps their designated appointments with the provider.

Linkage to Care
Clients with confirmed results will be linked to a health care provider for further evaluation, care, and treatment. Linkage is defined as an individual under the supervision of a health care provider (physician, physician's assistant, nurse practitioner) scheduled to receive medical care for HCV infection, usually within a specific time, and the post-referral verification that the individual accessed medical services referred to care. Linkage to medical care is the outcome of the referral and ensures that the client has seamless access to medical care.

Staff should track referral appointments to ensure the client attends their medical appointments. Programs should have written linkage agreements or MOUs with providers. These should include specific language on the process for tracking referrals. Programs must also get a signed release of information from clients to receive all necessary information from health care providers. Entities conducting a confirmatory test should ensure that clients have a copy of all confirmatory test results to take with them to their medical appointment.

Sites should develop a comprehensive linkage process that includes identifying the individual who will follow up on client appointments to confirm attendance by the client. Depending on the availability of staff within the approved testing sites, this could include the county's HIV linkage to care specialists (especially for those who are co-infected), DIS, and funded hepatitis staff.

Technical Assistance
The Bureau of Communicable Diseases and the VHOR Section remain committed to the Department's mission of protecting, promoting, and improving the health of all people in Florida. The rapid HCV screening program is an exciting program that brings the Department closer to fulfilling its mission.

Technical assistance with this screening program is available through the bureau's HIV Testing Team and the VHOR Section. Please contact the HCV Rapid Testing Team Lead by email at hsd.hepatitis@flhealth.gov

Headquarters-Specific Protocols

Site Recruitment and Selection:
Since the test is almost identical to the OraQuick ADVANCE rapid HIV antibody test, HIV or other staff members with rapid HIV testing experience may be called on to implement rapid HCV testing in their areas. CHD hepatitis staff is a logical first choice for program implementation, especially in those counties that receive funding for hepatitis prevention and control programs. However, the bureau recognizes limitations that may otherwise make this impractical.

Once a site is identified, the HIV testing and VHOR staff members will contact staff at the local CHD for further discussion regarding implementation. Local staff members will discuss how tests can be used (i.e., for injection drug users in outpatient drug treatment centers) and confirm any preliminary positive results and the linkage to care protocols and assurances.

1. Division of Viral Hepatitis, Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD and TB Prevention, *Viral Hepatitis Surveillance Report United States, 2019.*
2. HepVu, Emory University's Rollins School of Public Health in partnership with Gilead Sciences, Inc.

Hepatitis C Virus Rapid Test Risk Assessment

All risk assessments must be completed in full on all clients who are tested with a rapid screening test.
PLEASE PRINT LEGIBLY

Today's Date: _____County: _____ ☐ CHD ☐ CBO Site #:_____

Clinic/Site (check one): ☐CHD ☐Family Planning ☐Hep 09 ☐STD ☐HIV ☐Jail ☐Outreach ☐Other

DO NOT TEST if client has tested positive for hepatitis C. Complete confirmatory blood test for accurate results.

Last Name: _____ **First Name**: _____

Address: _____

City: _____ **State**: _____ **Zip**: _____ **County**: _____

Phone: _____ **Date of Birth (mm/dd/yyyy)**: _____ **Age**: _____ **Gender**: ☐Male ☐Female

Race: ☐White ☐Black ☐American Indian/Alaskan Native ☐Asian/Pacific Islander ☐Other ☐Unknown ☐Refused

Ethnicity: ☐Hispanic or Latino ☐Non-Hispanic or Latino ☐Unknown ☐ Refused to answer

Do you have any of the following symptoms?

☐ Abdominal Pain ☐ Vomiting ☐ Jaundice (yellowing of eyes or skin) ☐ Loss of appetite
☐ Fever ☐ Nausea ☐ Headache ☐ Diarrhea ☐ Refused to answer

History (Check all that apply)

1. Have you ever received a hepatitis vaccine for the following? ☐Hepatitis A? ☐Hepatitis B? ☐No ☐Unknown
2. Have you ever had ☐Hepatitis A? ☐Hepatitis B? ☐No ☐Unknown
3. Have you ever been told that you tested positive for hepatitis C? ☐Yes **(DO NOT TEST)** ☐No ☐Unknown
4. Have you ever received a transfusion of blood or blood components before July 1992? ☐Yes ☐No ☐Unknown
5. Have you ever been employed in the medical/dental field involving direct contact with blood? ☐Yes ☐No Unknown
6. Have you had an invasive procedure in the last year? ☐Yes ☐No ☐Unknown
7. Refused to answer ☐

Risks (Check all that apply)

☐ Born 1945–1965
☐ Body piercing (in the past year)
☐ Tattoos (in the past year)
☐ Incarcerated in a jail (in the past year)
☐ Incarcerated in a prison (in the past year)
☐ Household contact of a person with hepatitis C
☐ Refused to answer
☐ Injected drugs (in the past year)
☐ Needle stick injury
☐ Snorting drugs
☐ Multiple sexual partners (in the past year) _2-5 __>5___Unknown
☐ Unknown sexual partners Sexually transmitted disease
☐ Sexually transmitted disease
☐ Long term sexual partner with hepatitis C
☐ Shared needles for any reason (in the past year)

Rapid Test Information

- Rapid Test Kit Lot Number: _____
- Rapid Test Kit Expiration Date: _____
- Time Test Began: _____
- Time Test Read: _____

Test Results: ☐Reactive ☐Non-Reactive

Results Given? ☐Yes ☐No ☐Refused Test

Linked to Care: ☐Yes ☐No

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