Hepatitis C Virus (HCV) Rapid Testing Protocol

WISCONSIN DEPARTMENT of HEALTH SERVICES

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Table of Contents

Introduction and Background

Intended audience for this protocol

This protocol is intended for agencies funded by the Wisconsin Department of Health Services (DHS), Division of Public Health, Bureau of Communicable Diseases, Communicable Diseases Harm Reduction Section, Hepatitis C Program, to provide rapid hepatitis C testing services. These agencies include local and Tribal health departments (LTHDs), community-based organizations (CBOs), and harm reduction sites. Agencies are funded through General Purpose Revenue (GPR).

Purpose of this protocol

This protocol provides an overview of the Wisconsin Rapid Hepatitis C Testing Program and identifies guidelines of contracted agencies that provide services related to counseling, testing, referral, data collection, and record keeping. Rapid hepatitis C testing sites are required to adhere to this protocol, in addition to the terms and conditions of contractual agreements and memoranda of understanding (MOUs) with the Division of Public Health (DPH).

Purpose of a rapid HCV testing program

The Wisconsin Hepatitis C Program coordinates a statewide program with hepatitis C virus (HCV) rapid testing sites to provide the following critical services:

- Accessible rapid HCV counseling, testing, and referral services for individuals at increased risk for hepatitis C.
- Hepatitis C testing at no cost to people who are otherwise unable to afford testing.
- Client-centered counseling designed to reduce risk of acquiring or transmitting HCV.
- Appropriate referrals for HCV medical services, social and emotional support, harm reduction interventions, other communicable disease testing and vaccination, and resources to meet daily living needs.

Philosophy of service

Rapid HCV testing services should be provided in a manner consistent with community and consumer norms and values. The quality of services (for example, accessibility of services, provision of services that are culturally and gender responsive) and the ability to provide services to people and groups at increased or disproportionate risk for hepatitis C is more important than the number of tests conducted. Services should be provided in a collaborative, cooperative manner among local agencies in a community.

HCV: biology, testing & treatment recommendations

HCV disease

Hepatitis C is a liver infection caused by the hepatitis C virus (HCV), which is a ribonucleic acid (RNA) virus in the Flavivirus family. Disease caused by HCV can be acute or short-term, or it can become chronic, prolonged, or lifelong. Chronic hepatitis C can lead to cirrhosis, liver failure, or cancer.

Most people with new HCV infections do not experience symptoms or report mild symptoms that do not result in a health care visit. If people have symptoms, they may include:

- Fatigue.
- Abdominal pain.
- Poor appetite.
- Jaundice.
- Fever.
- Dark urine.
- Clay-colored stool.
- Nausea or vomiting.
- Joint pain.

Transmission

HCV is transmitted through exposure to HCV-infected blood. HCV can survive outside the body and on surfaces for up to three weeks at room temperature. Examples of common methods of HCV transmission include:

- Sharing syringes or other equipment used to prepare or inject drugs (sometimes referred to as “works”), or by other means such as sharing pipes when lips are cracked or bleeding or sharing snorting equipment (straws).
- Occupational exposures, such as a needlestick injury in a health care setting.
- Of children born to an HCV-positive parent, 6% will acquire HCV.
- Receipt of blood, blood products, or organs from a donor with HCV. (Before 1992, when HCV blood screening became available, this was a common method of transmission).

Although less common, HCV can be spread through:

- Sharing personal care items that have the blood of a person with HCV on them (for example, toothbrushes, razors, nail clippers).

- Sexual contact with a person who has HCV, with increased risk for male-male sexual contact (MMSC).
- Tattoos and body piercings done somewhere other than a licensed tattoo facility or with nonsterile instruments.

Epidemiology of HCV in the U.S. and Wisconsin

In the U.S., an estimated 2.4 million people have a chronic HCV infection. However, it is estimated that only half of these people are aware of their diagnosis. In Wisconsin, as many as 47,000 adults are living with HCV. However, only approximately half of these people have received testing and are aware of their HCV status. Most HCV case reports in Wisconsin are among baby boomers (born between 1945 and 1965) and younger people who inject drugs. For more information on the epidemiology of HCV in the U.S. and Wisconsin, see Centers for Disease Control and Prevention (CDC) Viral Hepatitis or the Wisconsin Hepatitis C Virus Surveillance Annual Review.

Testing recommendations

In 2020, the CDC updated their testing guidelines to the following:

- Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older.
- Hepatitis C screening for **all pregnant people during each pregnancy**.

One-time hepatitis C testing regardless of age or setting prevalence among people with recognized conditions or exposures:

- People living with HIV.
- People who ever injected drugs and shared syringes or other drug preparation equipment, including those who injected once or a few times many years ago.
- Prior recipients of transfusions or organ transplants before 1992.

Routine periodic testing for people with ongoing exposures, like injection drug use and sharing syringes or other drug preparation equipment, while these exposures persist.

Populations of focus for HCV rapid testing services

The Wisconsin HCV Rapid Testing Program is designed to serve people with a higher chance of acquiring HCV, particularly those people without a health care provider.

Populations of focus for HCV testing are:

- People who currently or have ever injected drugs (PWID).
- People who use drugs or have ever used drugs (PWUD).
- People whose sex partners are living with HCV **or** who have a history of drug use.
- People who currently or have ever had male-male sexual contact (MMSC).

- People living with HIV (PLWH).
- Any adult 18 or older.

Any person who requests HCV testing should receive it, regardless of disclosure of exposure behaviors, because many people may be reluctant to disclose stigmatizing exposures to their health care providers or at outreach testing sites.

Treatment

Acute HCV infection may clear naturally without treatment. Chronic HCV can be cured with treatment. Since 2011, treatments known as direct-acting antivirals (DAAs), have become available and have been shown to cure more than 95% of HCV-infected people with 8–12 weeks of oral therapy. A complete list of FDA-approved HCV medications can be found on Hepatitis C Online, a free educational website by the University of Washington National Hepatitis Center.

Testing staff should share information on these HCV treatments with clients and help refer them to a health care provider. **Treatment does not require a referral to a specialist; any prescribing provider can prescribe hepatitis C medications. The client also does not need to abstain from drug use to be treated for hepatitis C.** Providers can access guidance from HCVGuidelines.org, an online resource created through a partnership between the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA). There is also a hepatitis C treatment locator on the Wisconsin Hepatitis C Program website.

Program Requirements

Agency requirements

To align with best practices and state and federal standards, agencies should agree to meet the following requirements:

Laws and Wisconsin HCV program protocols

- Adhere to HCV-related statues, including around confidentiality and reporting (Wis. Admin Code §252.12).
- Provide testing and related services, regardless of ability or willingness to pay.
- Participate in trainings sponsored by the Wisconsin HCV Program.
- CLIA Waiver and OSHA Requirements as described in following sections.

Testing

- Offer confidential (name-associated) testing to all clients seeking testing.
- Confirm reactive rapid test results by submitting a blood sample to the WSLH for laboratory testing.

Referrals

- Coordinate services with other local agencies and health services to facilitate referrals related to HCV testing and prevention, general health, and daily living needs for all clients.
- Coordinate services with other local agencies and health services to facilitate referrals for clients who test positive for HCV to access medical care, case management or linkage to care, and other prevention services.

Procedures

- Develop a workflow and a written process for how clients obtain their test results.
- Monitor quality of services through observation of testing sessions, client satisfaction surveys, creating community advisory boards, or other means, within agency limits.
- Establish agency policies and procedures regarding the development and delivery of HCV testing services in a manner consistent with all core requirements, program protocols, and Wisconsin statutes.
- Provide culturally competent services, recruit and retain staff members with lived experience, and involve a diverse group of individuals in the planning, design, and implementation of services.

CLIA and OSHA requirements

Prior to establishing HCV testing services within an agency, that agency **must** submit and complete all forms and trainings associated with CLIA and OSHA requirements.

CLIA requirements

The rapid tests used by the Wisconsin HCV Program are classified as "waived" by the FDA when used with whole blood samples. CLIA requires that all sites offering these tests have laboratory certification allowing them to conduct waived testing. Sites should hold a CLIA Certificate of Waiver or Provider Performed Microscopy Procedure (PPMP) certificate and must have it readily available upon request. For more information on CLIA and how to apply for a certificate, view the federal Centers for Medicare & Medicaid Services website at www.cms.gov/clia. Staff in the Clinical Laboratory Section of the DHS Division of Quality Assurance is also available to answer questions. The CLIA application should be mailed, faxed, or emailed to:

Wisconsin Department of Health Services
Division of Quality Assurance Clinical
Laboratory Section
201 E. Washington Ave.
Madison, WI 53703

Phone: 608-261-0654
Fax: 608-283-7462
Email: dhsdqaclia@wisconsin.gov

When submitting the application, please add the email address for the person who is completing the application and identify the State of Wisconsin License Number (for example, MD, RN, Certified Social Worker) for the person who will be the laboratory director.

OSHA requirements

All sites should adhere to the Occupational Safety and Health Administration (OSHA) *Occupational Exposure to Bloodborne Pathogen* standard. OSHA published this standard to protect workers against health hazards related to bloodborne pathogens. Under the OSHA standard, an employer must develop and implement a worksite exposure control plan that describes detailed steps to protect employees. Since the external controls used with rapid tests are derived from plasma, all sites must develop an exposure control plan and implement the bloodborne pathogen controls standard. Resources for developing and implementing a bloodborne pathogen control plan and additional infection control information are available at DHS' Healthcare-Associated Infections: Resources for Health Professionals webpage.

Also available is a copy of a form entitled *Determination of Exposure to Blood/Body Fluids* (Form WKC-8165). This form must be completed by a health care provider to certify that a staff person has been significantly exposed to the blood or body fluids of a client. This form may also be used for the purpose of Worker's Compensation. **Form WKC-8165 is available**

for purchase from the Bureau of Document Services by calling 608-243-2441, emailing doadocumentsalesinformation@wisconsin.gov, or at https://docsales.wi.gov.

Staff should be trained annually in bloodborne pathogen control ("universal precautions") through their employer. Staff who conduct rapid testing with whole blood must be trained and competent in finger-stick collection of whole blood specimens. It is the responsibility of the agency to assure that staff are proficient and are using universal precautions. To comply with OSHA standards, the agency should document training of staff in bloodborne pathogen control and finger-stick specimen collection. All relevant training and results of any competency assessment should be documented in the personnel file.

Staff training requirements

Wisconsin HCV program trainings

Testing staff should attend the following trainings in sequential order:

HCV basic facts

- Hepatitis C: Basic Facts online training can be accessed at any time during the year. Staff should register for the training online. They will be approved to complete the online modules at their own pace.

HCV rapid testing training

- The OraQuick® HCV Rapid Testing Training includes training on how to perform a rapid test and effectively deliver HCV test results. **Submit certificate of completion to** DHSDPHHCVPrevention@dhs.wisconsin.gov **yearly.**

- In-person rapid hepatitis C training is provided by either the viral hepatitis prevention coordinator or hepatitis C disease intervention specialist. This training covers materials in the HCV Rapid Testing Training and the Blood Draw Training. It is also an opportunity for staff to ask questions, discuss scenarios, and share knowledge. **This training should be completed by all new staff. Email** DHSDPHHCVPrevention@dhs.wisconsin.gov **for scheduling.**

Blood draw training

- The Wisconsin HIV Program has partnered with Midstate Technical College to provide a free blood draw training to testing center staff. If staff do not complete this training, they must complete another blood draw training prior to working with clients. This other training must be based through a certified organization, and it cannot be a peer-based training. Register for training online.

Confidentiality requirements

Client confidentiality is essential to successful HCV testing services. Strict client confidentiality must be maintained to protect the client and to preserve the integrity of testing services. Client confidentiality is not limited to just protecting the client's name, but

also applies to other information that could identify a client, such as where they reside, their age, race or ethnicity, or social connections.

- Client information should be kept confidential in locked file cabinets—ideally, in a locked room. Use secure shredder bins to dispose of documents with confidential information.
- When conducting outreach/field-based testing, client testing forms and records should be transported in portable, locked file containers. Ensure this information is securely stored in the vehicle, like in a locked trunk, and is not visible. All files should be returned to the agency at the end of the testing event. This should be done in a way that addresses staff safety and record security (for example, testing staff return files to agency while working in pairs). Files should not be left in vehicles or staff homes overnight.
- Counseling at all agencies should be provided in a private, comfortable, and non-threatening environment that fosters open discussion and ensures confidentiality.
- Access to test results and client records must be limited to those with a legitimate need to access these documents (for example, testing staff, supervisory oversight staff).
- Agencies must provide all testing and program support staff with copies of the Wisconsin HCV Rapid Testing Protocol and agency policies around client confidentiality. In addition, agencies must require all testing and program support staff to sign confidentiality agreements at time of hire, which should be kept in their personnel files.
- Agencies should periodically review confidentiality policies and monitor agency procedures to ensure client confidentiality is maintained.

Reporting requirements

The purpose of disease reporting and surveillance is to identify patterns and trends of infection across Wisconsin; identify priority populations and reduce the number of new cases; inform people with hepatitis C about treatment options and preventing liver damage; educate people about transmission and how to reduce transmission rates; and better understand the epidemiology of HCV infection and the burden of disease.

Wisconsin statutes Wis. Admin Code § DHS 145.15 and Wis. Stat. § 252.11(7)(b) require that people who test reactive on confidential, name-associated lab based HCV tests must be reported to the local health department or the HCV Program within 72 hours of the result. **Tests reportable to Wisconsin DHS and local and Tribal health departments include reactive HCV antibody tests; positive HCV RNA tests; and negative RNA tests.** If testing is done through WSLH, those results are automatically reported to DHS and the LTHDs.

If staff need to report a case by using the *Wisconsin Acute and Communicable Disease Case Report* form (F-44151) they can **send the completed form via electronic fax to 608-261-**

4976. This is a secure fax in a locked room. Be sure to fax with a fax cover letter. **Electronic faxing is strongly preferred over mail**. If an agency cannot fax the form, they can mail it in an envelope marked "Confidential" to:

Wisconsin Department of Health Services
Bureau of Communicable Diseases
Hepatitis C Program
201 E. Washington Ave.
Madison, WI 53703

If there are questions about reporting requirements, they can be emailed to DHSDPHHCVPrevention@dhs.wisconsin.gov. **Do not include any confidential or personally identifiable information in emails.**

Record keeping and review requirements

A file should be established for each client tested. The file should retain copies of all Wisconsin HCV Rapid Testing Program documents used as part of the HCV testing process. These forms will include Rapid HCV Testing Form, a copy of test results received from WSLH, if applicable, and other forms that the agency deems necessary for the client record. Sites are expected to retain their agency's testing, temperature, and inventory logs for one year. **Email DHSDPHHCVPrevention@dhs.wisconsin.gov for access to the Rapid HCV Testing Form.**

How long to keep records

One year
For Rapid Testing only. Logs with personally identifiable information should be shredded:

- Temperature Logs (Appendix A)
- Inventory Logs (Appendix B)
- Instructions for Testing and Testing Log (Appendices C and D)
- Rapid HCV Testing Form

Three years

- Individual employee records documenting training, vaccination, post-exposure evaluation, and follow-up **to be kept for the duration of employment, plus three years.**
- Sharps injury log.

The quality assurance staff at your agency should review all testing documentation at least once a month to assure that testing practices meet the requirements indicated in the manufacturer's package insert and this protocol. QA staff should also review whether the number of test kits left in inventory is consistent with the number of tests used as documented on the testing log. The hepatitis prevention coordinator will review all logs related to rapid testing annually.

HCV Test Technology and Procedures

Hepatitis C testing

Testing is the only way to identify HCV infection. There are two types of tests used in the diagnosis of HCV infection: screening tests that detect HCV antibodies, and confirmatory tests that detect HCV RNA. The CDC-recommended testing sequence consists of an initial HCV antibody test. A positive or reactive HCV antibody test is followed by an HCV RNA test.

Types of tests

The following are the most common HCV antibody tests. The name and type of test may vary by laboratory or laboratory system.

Screening test—detects hepatitis C antibody

Tests that detect hepatitis C antibodies are screening tests for HCV infection. Hepatitis C antibody tests indicate infection at some point in time; they do not differentiate between resolved infection and current infection.

- **Enzyme Immunoassay (EIA):** The EIA test is a laboratory-conducted assay. In the U.S., it is the most commonly used test for initial HCV antibody testing.
- **Point-of-Care Rapid Immunoassays (HCV Rapid Antibody Tests)**: The OraQuick® HCV Rapid Antibody Test (OraSure Technologies Incorporated) is FDA-approved for detecting HCV antibodies in finger stick and venipuncture whole blood. The test provides an accurate result in 20 minutes. In Wisconsin, this test is used by syringe service providers and local and Tribal health departments.

Reactive antibody test

If the HCV antibody test is positive (reactive), HCV antibody is detected. The presence of HCV antibody indicates one of the following:

- Current HCV infection.
- Past HCV infection that has resolved.
- False positivity.

Further testing needs to be done to identify if there is current HCV infection.

Nonreactive antibody test

If the HCV antibody test is negative (non-reactive), there is no HCV antibody detected. No further testing needs to be done.

For people newly exposed to HCV, testing for HCV RNA is recommended ***2–3 weeks after their last exposure****. Follow-up testing for HCV antibody is recommended* ***3–6 months after their last exposure****. For people with compromised immune systems, an HCV antibody test may not work and testing for HCV RNA should be considered.*

Confirmatory test—detects hepatitis C RNA

A positive (reactive) HCV antibody test should be followed by testing for HCV RNA. Tests that detect HCV RNA are called confirmatory tests and are the **only tests available that determine if someone has a current HCV infection**.

Types of tests

There are several different names for tests that detect HCV RNA, including polymerase chain reaction (PCR) test, nucleic acid test (NAT), and the nucleic acid amplification test (NAAT). The name and type of test may vary by laboratory or laboratory system. In addition, the results produced by these tests might be qualitative, quantitative, or genotype results.

Positive (detected) confirmatory test

If the test indicates that HCV RNA was detected or the viral load is higher than the reported reference range, then there is a current HCV infection, and the patient should be linked to care. To interpret laboratory results, always read the reference range on that laboratory report and determine if the reported results for that patient fall outside the reference range (indicating a positive or reactive result) or fall within the reference range (indicating a normal or negative result).

Negative (undetected) confirmatory test

If the test indicates that HCV RNA was not detected or viral load is less than detectable level (less than 15 IU/mL or less than 10 IU/mL depending on test type), there is no current HCV infection. This may be a past case of HCV that resolved itself or the patient may have had a false positive HCV antibody test.

OraSure HCV rapid test

Introduction

The OraSure Technologies OraQuick® HCV Rapid Antibody Test is the first FDA-approved, CLIA-waived, rapid HCV test.

The OraQuick® HCV test is FDA-approved for detecting HCV antibodies in fingerstick and venipuncture whole blood. It enables providers to deliver an accurate antibody result in 20 minutes with greater than 98% accuracy, regardless of HCV genotype status. OraSure

provides an online training and package insert PDF with complete information on the OraQuick test. This training must be completed, and the PDF should be read and referenced frequently by staff performing rapid HCV testing.

Conditions for testing

The following conditions must be present to use OraQuick® HCV Rapid Antibody Test and can also be found in the PDF provided by OraSure:

- Sufficient lighting to perform the test and read the result safely and accurately.
- A level, clean surface where testing can be performed.
- Storage temperature of the test kit between **36° and 86° F.**
- The temperature during testing must be between **59° and 99° F.**
- Space that ensures confidentiality for both testing and counseling. Ideally, the test is set up in an area apart from the client and where no other individuals can read the result.

Obtaining rapid tests, devices, and controls

Agencies should email DHSDPHHCVPrevention@dhs.wisconsin.gov to obtain rapid tests and external quality controls. Agencies should order tests and controls at least two weeks before current inventories run out. Agency staff should maintain sufficient inventory of both tests and controls so that rapid testing services are not interrupted.

If an agency cannot use all their tests prior to the expiration date, the lead staff person should email DHSDPHHCVPrevention@dhs.wisconsin.gov to find out whether another site can use the tests prior to expiration so that these tests are not wasted. Shipments with the earliest expiration dates should be used first. Tests should be kept in a secure area, and inventory should be reviewed to assure that the number of remaining tests is consistent with the number of tests that have been used.

Confirmatory testing of blood specimens with the Wisconsin State Lab of Hygiene (WSLH)

All agencies approved for rapid HCV testing must also be equipped to perform confirmatory blood draws and submit specimens to the WSLH. This includes purchasing a centrifuge or identifying a centrifuge site that will be used to spin blood specimens. Example centrifuge: LW Scientific E8 Variable Centrifuge, Pulmolab.com. If an agency conducts rapid testing and blood sample collection in a mobile setting, they must also use a cooler with thermometer for storing blood samples, lab slips for each blood sample, and specimen label stickers.

Testing at the WSLH is supported financially by the state's basic agreement. Local and Tribal health departments (LTHDs) and organizations providing HCV counseling, testing, and referral services are not charged for this lab-based testing.

All clients who receive a reactive result should have a blood specimen collected and sent to the laboratory to confirm their HCV status. WSLH sends results to sites in 3–7 days, depending on agency location and how long it takes for specimens to reach WSLH. Post-test counseling appointments should be scheduled accordingly. The WSLH will maintain a record of all test results, and a copy of results will be sent via mail or secure fax to the testing site. WSLH results are also directly uploaded to the state's reportable conditions database, called the Wisconsin Electronic Disease Surveillance System (WEDSS). Testing sites only need to send their HCV Rapid Testing forms to the Hepatitis C Program. The results of any confirmatory testing done by WSLH are automatically entered into WEDSS.

The WSLH will test the specimen using an HCV antibody test and, if positive, reflex it to a confirmatory PCR. See "Types of Tests" above for details on what each test result indicates.

Questions related to confirmatory testing and results

Questions related to shipping and processing of specimens, including use of a centrifuge to spin down samples, should be directed to WSLH Customer Service at 800-862-1013. All calls or questions related to interpretation of test results should be directed to DHSDPHHCVPrevention@dhs.wisconsin.gov.

Specimen collection and submission to the WSLH

Supplies for confirmatory HCV tests are available from WSLH at no charge and can be ordered by calling WSLH Clinical Orders at 800-862-1088. Sites can use this link to send a specimen to the WSLH. For sites that conduct a high volume of tests, all test components can be ordered in bulk from the WSLH. Email DHSDPHHCVPrevention@dhs.wisconsin.gov for questions about ordering rapid tests and controls. See Appendix E for the Blood Sample Guidelines for hepatitis C Tests by the Wisconsin State Lab of Hygiene.

External Controls

Use of external quality controls

The Wisconsin HCV Program supplies each testing site with external quality controls that verify whether the tests are working properly, or the staff person is properly performing the test. Staff should run tests on samples that are manufactured to create a specific result.

The external controls must be refrigerated at temperatures between **36° and 46° F.** The controls must be warmed prior to use. Take the controls out of the refrigerator 15 minutes before you run the controls.

When controls are run, these tests should be documented on the testing log. External controls do not need to be run in different outreach locations provided the testing temperature conditions have been met.

External controls should be run:

- When a staff person has been newly trained to use OraQuick rapid HCV tests prior to testing clients.
- When opening a new lot of test kits.
- Whenever a new shipment of test kits is received by the agency.
- If the temperature of the test storage area falls outside of **36° to 86° F.**
- If the temperature of the testing area falls outside of **59° to 99° F.**

Controls have a designated expiration date. They can be used repeatedly but must be disposed of by the expiration date. Controls must be disposed of in a biohazard waste container.

If the results of the control are not as expected, staff must assess all possible reasons for the failure of the controls (see Appendix F). If you have not determined the reason(s) for the failure, run the controls again using a new box of tests. If the controls fail again, open a new set of controls, and run them. If the controls fail a fourth time, discontinue testing, and email DHSDPHHCVPrevention@dhs.wisconsin.gov for further guidance. **When controls fail, all results prior to the last control run are suspect.**

Shelf-Life of test and control kits

Sites will have approximately one year to use tests once received, based on the one-year expiration date. However, **please be advised to confirm the expiration date on both the testing box and on each individual test.** Whichever expiration date is shortest is the one that

should be referenced and used first. Additionally, **external quality controls have a designated expiration date on the outside of the box**.

Ensuring proper temperatures for tests and controls

Tests must be stored between 36° and 86° Fahrenheit. If tests were stored in the refrigerator, they must be warmed to room temperature prior to use.

External controls must be stored in a refrigerator between 36° and 46° F. They must also be warmed to room temperature prior to use.

Staff should place a thermometer in the storage areas for the tests and controls to assure that the materials are kept at the proper temperature. Ideally the thermometer should identify the high and low temperatures from the last reading. Agency staff should document storage temperatures on a log each day that testing is performed. See the sample temperature log on page 34.

The location where tests are performed must be within the temperature range of 59°–86° F. Staff must use a thermometer to determine whether the temperature is within the specified range, particularly in outreach venues. If the temperature is out of this range, staff should not conduct any tests.

Refer to Appendices F and G and follow the instructions for what to do if either a rapid test is invalid or external quality controls fail.

Quality assurance

Written quality assurance policies and procedures should be developed, shared with all testing staff, and routinely implemented. Quality assurance measures should ensure services and materials are accessible and appropriate to the clients' culture, language, gender, sexual orientation, age, developmental level, and exposure activities, such as injection drug use. Checklists detailing required and recommended quality assurance activities, along with staff QA requirements, can be found in Appendix H. **Review these checklists carefully; the required activities must be completed at each site in the timeframes specified.** The Wisconsin viral hepatitis prevention coordinator may conduct an annual review of individual agencies' quality assurance policies and procedures.

Lead QA staff

Each agency may designate a staff person responsible for assuring the quality of their agency's rapid testing. This person will be responsible for assuring that:

- Storage and site temperatures are monitored and documented.
- The site testing log is completed accurately.
- Testing devices and controls are used prior to expiration.

- The agency has sufficient, supplies, tests, and controls to provide efficient services to clients.
- Staff are trained and follow protocol.

The staff member responsible for quality assurance will be the first person notified by other testing staff when invalid test results appear, or external quality controls fail. This person will work with site staff to determine the error source and notify additional personnel, as needed. Larger agencies may have a hierarchy of administrative staff who oversee quality assurance of testing. Each agency should develop communication mechanisms to assure staff are made aware of testing problems and solutions.

When problems arise, the lead QA staff or designated administrative staff should email DHSDPHHCVPrevention@dhs.wisconsin.gov for technical assistance and problem solving. It may be necessary to contact the test manufacturer to report defective devices or controls.

The lead QA staff person is additionally responsible for ensuring staff have proper training in rapid testing procedures and should observe new staff through every step.

Use of external quality controls

Using external quality controls on a consistent basis is important to maintain quality testing. Each new box of HCV rapid tests should be QA'd prior to use and QA'd if ever out of temperature range. Please find additional information on how to run OraQuick® HCV Rapid Antibody Test controls in the OraQuick online training.

Documentation

To assure that conditions and key elements of the testing process are in place for quality testing, each site is required to complete several logs. Examples of each log can be found in Appendices A–D. Each log is described below.

1. **Testing Log**: Each time a test is run on a client specimen **or** an external control, the information regarding the test must be documented on a testing log. This documentation should occur at the same time the test is conducted. Staff should *not* wait to document tests on the log at a later time (for example, waiting until back in the office after an outreach event), since it increases the potential for error.

   For each test, the following must be documented:

   - Date of the test.
   - Test ID number and code or initials or positive or negative control.
   - Initials of staff performing test.
   - Current temperature of testing area.
   - When the test was started.
   - When the test was read.

- Whether the internal control on the test device was valid.
- Whether the result was reactive or nonreactive.
- Whether a client specimen was sent for confirmatory testing.
- Confirmatory test result.
- Comments (for example, why external controls were run, troubleshooting for invalid results, whether client received confirmatory results, venue where test was done).

In addition, the lot numbers and expiration dates of both the tests and external quality controls must be documented at the top of the log.

All tests and controls must be logged chronologically, so that the log provides an accurate history of testing at that location. **A new log should be started every time a new lot of tests or external controls are used**.

2. **Inventory Log**: Each time a shipment of tests or external quality controls is received by the agency, it should be documented on the log. The log should indicate when the item was received, the lot number, and the expiration date. The log should also indicate the date of first use with each box. Items with the earliest expiration dates should be used first.

3. **Storage Temperature Logs**: Staff must document storage temperatures of both test kits and the controls on each day tests are performed. The sample temperature log in Appendix A specifies a column for the high and low temperatures since the last reading as indicated on a min or max thermometer. If the temperature falls out of the specified range, staff must document what corrective action was taken.

   When temperatures fall out of the required range for storing test kits, staff should run a set of external quality controls. If the expected results are obtained, the tests may be used. If either the tests are invalid or the expected results are not obtained, the tests should be disposed.

   When temperatures fall out of the required range for storing external control kits, staff should use that set of controls to run a positive and negative control on test devices that have been stored properly. If the expected results are obtained, the controls may be used. If not, the controls should be disposed. This process should be done for each set of controls exposed to the out-of-range temperatures.

   Whenever a site has an invalid result, this test should still be logged on the testing log. Staff should run through the steps outlined in Appendix F and G. If a rapid test is still resulting as invalid after these steps, email DHSDPHHCVPrevention@dhs.wisconsin.gov regarding the invalid result, possible reasons for it, and whether a repeat test yielded a valid result. Similarly, whenever a site has a discordant or false-positive result (a reactive rapid, but negative confirmatory test), staff should email DHSDPHHCVPrevention@dhs.wisconsin.gov.

Testing Session

Pre-test counseling components

Here is a list of key components for each HCV testing session. Each of these components should take place at some point within a testing session. Appendices I and J provide an overview of the overall client engagement process and the rapid testing algorithm.

Test decision counseling

To assist the client in making the decision to receive an HCV test, the following topics should be discussed:

- Potential benefits of or concerns with testing.
- The window period of the test.
- Choosing a confirmatory blood draw over a rapid test if client states they have ever had hepatitis C.
- Anticipated feelings about possible test results.
- Discussion of action steps post-test, whether the test result is reactive or not.
- Benefits and limitations of available testing methods (laboratory-based testing or rapid testing).

Confidential testing and consent

Confidential testing uses the client's name on the rapid HCV testing form and lab result (if applicable), the same as all other medical services provided in health care settings. The client's name will be printed on the test result and becomes part of the client's confidential record. Confidential testing makes it easier to locate clients who have a reactive test result but don't return for their confirmatory results and conduct follow-up on referrals to HCV-related services. It eliminates the need for re-testing when a person is linked to HCV care, streamlining their care process. Confidential testing also means that the client will receive a test result with their name. This is particularly beneficial for clients who want to share their HCV status with their partners.

When testing someone confidentially the client should know:

- They can decline the rapid HCV test, and it will not affect their access to other resources or services at the site.
- The benefits and limitations of the rapid test, when results will be available (20 minutes post testing), and what the results mean.

- The process and/or referrals for confirmatory blood draw testing, the wait time for obtaining confirmatory results, and how the client will receive those results.
- Results for both rapid and confirmatory testing are reportable to your local and Tribal health department (LTHD), like many other communicable diseases.
- If the rapid test is reactive, public health nurses (PHN) at LTHDs will contact the client, likely by phone, to share test results and discuss insurance, assist in care acquisition, and recommend vaccines, as the client desires.
- Hepatitis C is a curable disease, and staff can help clients navigate options for treatment, payment, insurance options, and connections to social support services.

Deferring testing

Testing staff have the authority to defer testing for any client. Explain the deferral reason to the client at a level appropriate for the situation. If testing staff are concerned that client's mood, behavior, or intoxication status would endanger staff safety, defer in a way that takes judgement off the client. Examples of phrases to use when deferring testing are: "I'm sorry, we're out of tests today" or "We aren't able to offer testing today because of…". Deferral should be based on a determination that testing the individual is not in their best interest. Reasons to defer include: a client is unable to consent (mental illness, intoxication, under the influence of drugs, cognitive problems, not 18 years or older); has been coerced to seek testing; or has expressed intent to harm themselves or others.

Staff and clients can also make the decision to defer testing because a client stated they have had hepatitis C in the past. **If they have a history of past infection, a rapid test will always result as reactive.** It will not tell the client if they have a current HCV infection, or if their infection cleared. **Staff can perform a confirmatory blood draw instead of a rapid test in this situation.** If not trained to perform blood draws, staff can refer clients to their local health department, primary care provider, federally qualified health center, or community-based organization instead of conducting a rapid test.

Rapid HCV testing form

The rapid HCV testing form collects demographic and possible exposure information that can be used to guide your counseling session with the client. The testing form must be sent via secure fax to 608-261-4976. Email DHSDPHHCVPrevention@dhs.wisconsin.gov to access this form.

Prevention and exposure counseling

HCV prevention counseling provides a critical opportunity to assist the client in identifying whether they are at risk for HCV, and to develop a plan to reduce or eliminate those exposures. HCV prevention counseling should be offered to all clients and should be done confidentially with as much privacy as possible. The focus of client-centered counseling is to develop personalized prevention goals and strategies with the client rather than simply providing information. Agency staff should engage in prevention counseling using the evidence-based practice of motivational interviewing. These strategies are intended to equip

clients with the services they view most impactful to their current health care needs. If any staff members are interested in completing motivational interviewing training, email DHSDPHHCVPrevention@dhs.wisconsin.gov.

Exposure assessment

Exposure assessment is an essential component of HCV prevention counseling because it provides the basis for helping the client create a harm reduction plan. An exposure assessment can begin with a review of information provided on the testing form.

You may begin to assess the client's prevention, social, and clinical needs by asking open-ended questions on the following topics:

- Reason for visit and other relevant concerns.
- History of HCV testing and results.
- Knowledge of HCV.
- Exposure activities, awareness of exposures, and steps taken to reduce exposure.
- Desire and readiness to alter activities that are likely to expose them to HCV.
- Resources and support systems.
- Benefits of developing a tailored HCV testing plan based on exposure.
- Receptiveness to available services and referrals.

Listen for and address the following information **if it is disclosed by the client**:

- Sex with a partner known to have HCV.
- Syringe-sharing history and other drug use activities.
- Sex in exchange for drugs or money.
- HIV and STI history.
- History of sexual assault.
- Use of alcohol or other drugs in connection with sex.

Based on the assessment, staff should meet the client where they are to develop a realistic, incremental plan to reduce their exposure for HCV. Providing support and affirming all behavioral changes that the client has already made should be provided in tandem with any individualized harm reduction activities pursued.

While pre-test HCV prevention counseling is a high priority, it should never be a barrier to clients who want to know their status.

Additional recommendations

CDC promotes additional recommendations for people accessing HCV testing. Staff should recommend the following during prevention counseling:

- **HIV testing:** CDC recommends that everyone between the ages of 13 and 64 get tested for HIV at least once as part of routine health care. For people with certain exposure factors, CDC recommends getting tested at least once a year. CDC Recommendations for HIV Testing
- **STI testing:** Anyone who is sexually active with multiple partners or partners who have had an STI should receive regular STI testing.
  CDC Recommendations for STI Testing
- **Hepatitis A & B vaccination:** Assess whether people have been vaccinated for Hepatitis A and B, provide information on exposures to and effects of Hepatitis A and B, identify the benefits of being vaccinated, and have referral systems in place for vaccination. CDC Recommendations for Hepatitis A & Hepatitis B Vaccination
- **Harm Reduction:** Wisconsin DHS has many resources for people who are interested in obtaining Narcan to prevent opioid overdose, Medication Assisted Treatment (MAT), or practices for safer drug use.

Conducting a rapid test

Following pre-test counseling and client consent, testing staff will conduct a rapid HCV test using a whole blood sample from a fingerstick. Protocols for safe storage, testing, and handling of specimens are available through the OraQuick Rapid HCV Test Training and **must be followed for every test.** The results of the rapid test will determine if confirmatory testing is needed and will inform each post-test counseling session.

Post-Test counseling session

The post-test counseling session occurs when staff provide HCV test results to the client. This session may happen the same day as the pre-test session for rapid tests, and 7–10 days after the initial session for laboratory-based test results. The purpose of this session is to:

- Notify the client of their test result(s).
- Assess need for repeat testing.
- Provide referrals, as needed.
- Reinforce the existing plan for reducing exposures to HCV, as appropriate.

Post-test counseling and referral for rapid results

What is discussed during the post-test counseling session depends on whether the rapid test was reactive or nonreactive.

Nonreactive rapid test results

The following information should be covered when counseling someone with a nonreactive result:

- Interpret the result and discuss possible need for re-testing: A nonreactive result is interpreted as negative unless the client has engaged in exposure behavior within the last month. **If the client engaged in exposure behavior during this time, staff should recommend retesting three to six months after their last exposure and/or developing a testing schedule based on their exposure behavior.**
- Assess need for referrals: Staff should assess any need for additional client services, like substance use disorder treatment, financial assistance, domestic violence services, housing, STI testing and treatment, hepatitis vaccination, and other testing in accordance with CDC guidelines.

Reactive rapid test results

The following information should be covered when counseling someone with a reactive result:

- Interpret the result and assess client understanding of the result*:* By hearing the word "positive" instead of "reactive," clients may believe they have HCV, regardless of how the staff person describes the screening result. To more accurately convey that this result is an initial screen and requires confirmatory testing, staff should explain the result in the following manner:
  - "Your rapid test was reactive. We need to do a confirmatory test to find out whether you have current HCV infection."
  - "Your reactive rapid test result shows that we need to do another test to check whether you are HCV-positive."
  - "Your rapid test result indicated that you may have HCV. We need you to have another test done to confirm whether you have hepatitis C."

Staff should provide the client with written documentation of their result. If results are discordant, for example a client states that they've had reactive tests before and their rapid test today is nonreactive, staff should encourage confirmatory testing.

- Explain confirmatory testing: A blood sample for confirmatory laboratory testing should be obtained immediately following a reactive rapid test. Confirmatory results should be available from the WSLH in three to seven days. If staff cannot complete the blood draw on site or the client does not want to receive confirmatory test at that time, refer to a site that can offer confirmatory testing or schedule a time for follow-up.
- Obtain commitment from client to return for confirmatory result: Staff should set an appointment with the client in one week to receive the confirmatory test result. Staff should verify that the client is willing to have the agency contact them regarding the result if the client does not return.

All confirmatory results should be provided in person to facilitate linkage to further services and to offer emotional support. If it is impossible for the client to return for the confirmatory

result, staff should make a strong effort to obtain contact information to follow up with the client at another site or by phone.

- Encourage the client to take precautions to avoid potentially transmitting HCV to others: Staff should support the client in using harm reduction behaviors to avoid potentially passing HCV to others. This includes examining the client's exposure factors while waiting for the test result and developing a plan with the client for modifying this behavior.
- Assess need for referrals: The client may need emotional support during this waiting period. Staff should offer to support the client by phone or in person. In addition, the client may need referrals to social support or harm reduction services. Staff should educate clients that HCV is curable with 8–12 weeks of treatment.

Scheduling a post-test appointment

Agency staff should provide clients with an appointment to return for their result as needed. Clients who receive a rapid HCV test will receive their result on the same day. All clients who have a laboratory test should have an appointment scheduled to obtain their result 7–10 days after their initial visit. The staff member should assess potential barriers to returning for test results and develop both a plan to overcome barriers and locate the client in the event of a missed appointment. It is important to obtain contact information, such as a phone number, from the client to help with follow-up.

Other HCV test scenarios

Providing test results to clients

Confirming client identity over the phone is difficult. Providers and clients should identify a secure and confidential method for delivering results acceptable to both people. This could include physical mail, phone calls, email, or text messages. Agencies should also follow their own guidelines for HIPAA-compliant communication regarding secure messaging systems and electronic medical records.

Failure to return for results

There are many reasons why people do not return for their confirmatory HCV test result. The individual may have simply forgotten, the testing site hours may be inconvenient or incompatible with their schedule, or they may have decided they are not ready to know their result. A client may assume that if there was a problem someone from the site would call them.

If a client tests positive for HCV and agency staff are unable to locate them, PHNs will attempt to locate them to provide the test result and offer them health education and services.

Previously positive clients seeking testing

In some circumstances, clients who already know they are living with HCV will seek out a rapid HCV test from a testing site. There are various reasons this may happen. The client might not share with the agency staff prior to testing that they already know their status. This is an important opportunity to educate the client on HCV and assist the client with getting reconnected to care services, as needed. If a client shares their status before a rapid test, staff can encourage a blood draw over a rapid test so that client can get confirmatory results instead of requiring both a rapid test and a blood draw.

Testing of children and adolescents

Testing sites should only use rapid HCV tests for people who are 18 years old or older. Parents of children and adolescents aged 18 and younger should be encouraged to have HCV testing performed by the child's pediatrician or regular primary care provider.

Hepatitis C prevention messages

These prevention messages should be shared with all clients, and can be shared at any point during the testing session:

- Currently there is no vaccine for HCV. Recommend that people get vaccinated against other forms of hepatitis—hepatitis A virus (HAV) and hepatitis B virus (HBV). Questions about vaccines and immunizations should be directed to the Wisconsin Immunization Program at 608-267-9959.
- Avoid sharing or reusing syringes, or other equipment to prepare or inject drugs, steroids, hormones, or anything else.
- Do not use personal items that may have come in contact with the blood of another person, such as toothbrushes, razors, nail clippers, syringes, blood testing equipment.
- Only get tattoos or body piercings from licensed tattoo facilities. Avoid getting homemade tattoos or tattoos in jail or prison.
- Any blood spills—including dried blood, which can still be infectious—should be cleaned using a dilution of one part household bleach to 10 parts of water. Gloves should be worn when cleaning up blood spills.

Referrals

Summary

Direct-acting antivirals (DAAs) have been used to treat and cure HCV infections for over a decade, making HCV treatment even easier with an 8–12-week medication regimen. Therefore, linking clients to medical services is a critical component of HCV Rapid Testing services: the sooner clients access HCV care services, the better it is for their long-term health. While the referral process outline below is comprehensive, staff should ask each client what they need as a part of their individualized harm reduction plan.

Stages of the referral process

After assessing a client's needs, making a referral is a two-step process:

1. Linking the client to the referral source.
2. Conducting referral follow-up.

Agency staff should offer to assist clients who test positive for HCV with scheduling a medical appointment, linkage to care services and/or case management if available, or other appropriate appointments. Agency staff also should encourage the client to return for another appointment for additional counseling, referral follow-up, and assessment of any barriers to accessing HCV care services.

Counseling associated with referrals

Agency staff should assess the client's readiness to accept a referral and link them to an appropriate agency or resource. Some clients will prefer to access referrals on their own. Other clients will want to be directly linked to the referral agency.

When discussing referral possibilities:

- Clearly describe the extent of agency services.
- Cite benefits to the referral, being realistic about what the agency can provide.
- Discuss and problem-solve possible barriers to accessing the referral source (for example, transportation, childcare, agency hours).
- Discuss referral follow-up and develop a plan to determine outcomes—including client satisfaction.

Referral lists

Agencies are encouraged to develop and maintain referral lists—complete with telephone numbers, emails, websites, and the names of contact people—for people with positive results.

Referrals for people testing positive for HCV should include:

- Medical care and treatment, including confirmatory blood draws.
- Disease prevention and education services.
- Linkage to care and/or case management services (if available).
- Prevention and/or harm reduction planning.
- Reproductive health.
- Legal support services.
- Support groups and mental health resources.

Referrals for people with unknown status and people testing negative should include:

- HIV & STI testing, along with Hepatitis A & B vaccinations.
- Syringe Access Programs.
- Substance use disorder treatment and support.
- Crisis intervention phone lines and centers.
- Housing, food, domestic violence, and other social support services.

Referral lists should contain the following:

- Name and location(s) of provider or agency.
- Range of services provided.
- Contact name(s), phone number(s), email(s), and website.
- Cultural competency information (for example, do they have bilingual staff).
- Costs and acceptable payments.
- Eligibility.
- Directions, transportation information.

Referral lists should be provided to each staff conducting rapid testing and updated annually or as needed. Efforts should be made to establish connections with agencies before including them on any referral lists.

Referral to HCV care

Advances in medical treatment have significantly improved health outcomes for people living with HCV, impacted public health and transmission rates, and enhanced the roles and responsibilities of public HCV testing sites.

All agencies are encouraged to develop and maintain protocols to link clients to a medical provider. Linkages to HCV medical care should be maintained for people who are insured and those who may be under- or uninsured and include sufficient options to ensure client choice. When linking clients to HCV care, agency staff should:

- Inform clients of oral HCV medications, which are 8–12-week courses and have a greater than 95% cure rate.
- Identify and discuss the costs of accessing HCV care, along with available payment assistance programs.
- Inform clients testing that any link to HCV care will require their name and, therefore, initiate a case report.
- Provide information on what happens at an initial medical visit.
- Assist the client in determining what questions they may have for the medical provider.
- Offer the client assistance with scheduling their HCV care appointment.

Agencies are encouraged to maintain referral lists and referral processes for HCV-positive people.

Appendices

Appendix A: Rapid Testing Temperature Log

Thermometer location: _____
Acceptable temperature range*: _____
Month/Year: _____

Day	Initials	High Temp	Low Temp	Corrective action taken when temperature is out of range
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
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*The acceptable range for **OraQuick test kit** storage is 2 to 30° C or 36 to 86° F and the acceptable range for control storage is 2 to 8°C or 36 to 46° F.

Reviewed by: _____

Date reviewed: _____

Appendix B: Rapid Test and Controls Inventory Log

Log each box of tests or external controls received at your agency.

Item Received (Tests or Controls)	**Date Received**	**Lot #** (on box)	**Exp. Date**	**Date when item first used**

Appendix C: Instructions for Rapid Testing Log

Agency	Fill in name of Agency.
Location	Fill in location of testing: for example, Smith Clinic or outreach.
For each rapid test fill out…	
Other Test/Manufacturer	Fill in the type of test (HCV) and the manufacturer of the test.
Device Lot # and Expiration Date	Fill in Lot Number (on outside of box for Determine) and Expiration Date of test devices. For Determine, the expiration date is determined by the shortest dated test kit component, on box or pouch.
Package Insert Revision Date	Fill in the revision date of the package insert for this box of tests. Revision date is **typically listed at the end of the package insert**.
Control Lot No. and Expiration Date:	Fill in Lot Number (on box for Determine) and Expiration Date of most recent control performed.
Date	Fill in date of rapid test.
Client name or +/- Control	• If testing a Positive Control, fill in "+ Control". • If testing a Negative Control, fill in " – Control". • If testing a client sample, fill in Test ID number (or use sticker).
Staff Initials	Fill in the initials of staff conducting the rapid test.
Temperature	Fill in the current temperature of the testing site.
Start Time	Write the exact time that the buffer was added to the test strip for OraQuick or other rapid test was started.
Read Time	Write the exact time that the result was read.
Internal Control Valid	• If control line is present, write "Y" for yes. • If there is no control line, write "N" for no – the test is invalid. (Explain your next steps under the comment section).
Result	• For a nonreactive result – write "neg ". • For a reactive result—write "react". • For an invalid– write "inv".
Confirmatory Sample sent?	• If yes – write "Y". • If no – write "N". • If not applicable (in the case of controls) – write "NA".
Confirmatory Result?	• For a positive final result - write "pos" and indicate whether the positive result is an early (Ag only) or established (Ab positive) infection. • For a negative final result – write "neg". • If not applicable (in the case of controls) – write NA.
Comments	• If conducting either a Positive or Negative Control, indicate reason. • If test is invalid, indicate next steps. • If rapid test is reactive, indicate whether client received confirmatory test results and/or next steps.

Appendix D: Rapid Testing Log

Agency: _____ **Location:** _____

OraQuick Tests and Controls	
Device Lot Number:	
Device Expiration Date:	
Package Insert Revision Date:	
Control Lot No.	
Control Exp. Date	

OraQuick Tests and Controls	
Device Lot Number:	
Device Expiration Date:	
Package Insert Revision Date:	
Control Lot No.	
Control Exp. Date	

Date	Client name or +/- Control	Staff Initials	Temperature	Start Time	Read Time	Internal control valid?	Result* Pos/Neg /Inv (If Pos: Ag+, Ab+, or Ag/Ab+)	Confirmatory Result** pos/neg	Comments -Indicate reason for running control -If test is invalid, indicate next steps -If rapid test is reactive, indicate whether client received confirmatory test results

Rapid test log cont.

Appendix E: Blood Sample Guidelines for Hepatitis C Tests

Wisconsin State Lab of Hygiene (WSLH)

Last Reviewed: February 2023

	Hepatitis C Antibody and PCR Tests
Tube Type	Tiger Top (also called Marble Top or Red Top)
Amount of blood required for State Lab to process the test.	• Ideally: Full tube • Minimum: 3 mL blood • If only have 1-2 mL blood encouraged to still send in to see if testing can be completed
Rejection Criteria—Any unique factors that would cause WSLH to reject the sample? *(Standard collection protocols for submission still apply)*	Must receive sample within 72 hours of collection
Special Processing Requirements	• Wait to allow blood to clot (15-30 min) in an upright rack • Spin in centrifuge within 24 hours of collection
Storage Requirements	Keep between 36° and 46° F
Processing Time	Hep C antibody tests: 1-3 days Viral Load PCR tests: 3-7 days

*WSLH must receive the sample within 72 hours of collection.

Appendix F: External Quality Control Failure Checklist

What to do if the external quality controls fail:

1. Identify the problem using the following list of potential problem areas.

    - ☐ Were the tests **stored** within the proper temperature range?
    - ☐ Was the temperature of the **testing area** within the proper range?
    - ☐ Were the controls stored between 35°F and 46°F?
    - ☐ Were there controls brought to room temperature prior to use?
    - ☐ Were the tests used prior to the expiration date?
    - ☐ Were the controls used prior to the expiration date?
    - ☐ Was the test brought to room temperature prior to testing?
    - ☐ Was the lighting in the testing area adequate for proper testing?
    - ☐ Was the test performed on a flat, level surface?
    - ☐ Was the desiccant present in the test pouch?
    - ☐ Was a new blood loop used with each control vial?
    - ☐ Were the tests labeled correctly? (for example, positive on a positive control and negative on a negative control)?
    - ☐ Was the sample added to the buffer solution? (Do not use the buffer for controls).

2. If it is determined that any of the above conditions caused the external controls to fail, staff should document on the testing log in the "Comments" section the troubleshooting process; actions taken; and how staff verified that corrective action taken addressed the problem.
3. If it is determined that none of the above conditions caused the external controls to fail, perform a second rapid test on another set of controls.
4. Take a picture of the test strip with the control bottle used and send the picture to the hepatitis prevention coordinator.
5. If the problem resolves with the second set of controls, dispose of the first set of controls.
6. If the problem remains with the second set of controls, contact the hepatitis prevention coordinator.

Appendix G: Invalid Rapid Test Checklist

What to do when a rapid test is invalid:

1. Identify the problem using the following list of potential problem areas:
    - ☐ Were the tests **stored** within the proper temperature range?
    - ☐ Was the temperature of the **testing area** within the proper range?
    - ☐ Was the test used prior to the expiration date?
    - ☐ Was the test kit at room temperature prior to testing?
    - ☐ Was the lighting in the testing area adequate for proper testing?
    - ☐ Was the desiccant present in the test pouch?
    - ☐ Was the first drop of blood wiped away and testing performed on the second drop?
    - ☐ Was all of the blood from the blood loop added to the sample pad?
    - ☐ Was the test device properly placed on a flat surface?
    - ☐ Was the buffer solution added to the test device?
    - ☐ Was the test result read between 20 and 30 minutes after the test was completed?
2. If it is determined that any of the above conditions caused the invalid test result, staff should document on the *Testing Log* in the "Comments" section the troubleshooting process; actions taken; and how staff verified that the corrective action taken addressed the problem.
3. If it is determined that none of the above conditions caused the invalid result, perform a second rapid test either with another client specimen or with a set of external quality controls.
4. Take a picture of the test strip and email it to the HCV prevention coordinator. This may help with troubleshooting.
5. If a client specimen was used and the second test is also invalid, run a set of external quality controls.
6. If the control tests come back invalid, discontinue testing. Report the problem to the hepatitis prevention coordinator.

Appendix H: Quality Assurance Program Checklist

Quality assurance program requirements checklist

- ☐ Review counseling practices for cultural appropriateness.
- ☐ Evaluate the physical space and client confidentiality system of in-agency testing services.
- ☐ Evaluate the physical space, client confidentiality system, and client and staff safety in outreach-based testing settings and venues.
- ☐ Review and/or update treatment referral lists **annually**.
- ☐ Review record keeping, security practices, and accuracy of data collection and entry **quarterly**.

Test sites should implement these additional quality assurance measures to the extent possible based on agency type, size, and staffing level:

Quality assurance additional recommendations checklist

- ☐ Supervisors should observe probationary staff during testing sessions.
- ☐ Ask for feedback from clients to ensure services are meeting their needs.
- ☐ Host monthly check-ins with testing staff.
- ☐ Review testing outcomes at testing site, at minimum, annually.
- ☐ Compare surveillance data and testing data if receiving HCV rapid tests from DHS HCV Program.

Appendix I: Staff Training and QA Checklist

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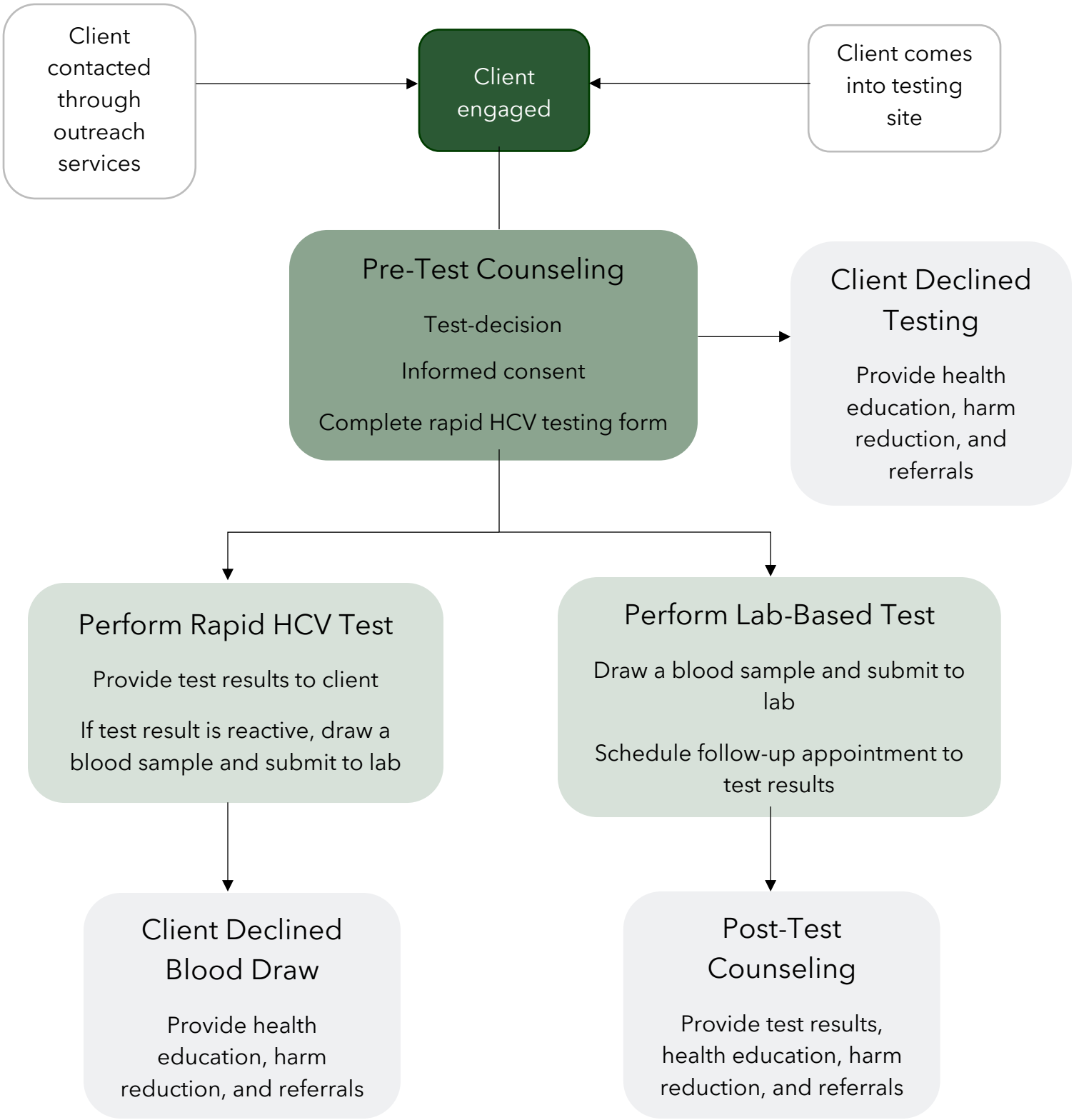
Staff training and QA requirements checklist

- ☐ Attend the Wisconsin HCV Program training courses, including the HIV Counseling, Testing, and Referral New Provider Training (in-person).
    - Review and understand OraQuick package insert and testing instructions as needed.
- ☐ Participate in online HCV Basic Facts course (online).
- ☐ Demonstrate competence in conducting fingerstick blood draws.
- ☐ Establish knowledge of and adherence to package insert instructions for the rapid test (c.).
- ☐ Complete a competency assessment by testing samples and accurately reading the results prior to testing clients.
- ☐ Demonstrate accurate test administration and interpretation of test results for both positive and negative controls prior to testing clients.
- ☐ Participate in the state proficiency program to assure staff competency in testing at each agency.
- ☐ Assign a lead staff person responsible for overseeing rapid testing and all QA activities on-site.
- ☐ Use external controls as required in the protocol.
- ☐ Document testing process and results.
- ☐ Record the storage temperature of test devices and external controls.

Communicate testing problems to the on-site lead staff person, the WSLH, or the Wisconsin HCV Program as appropriate, and take action to ensure that the test is providing valid and reliable results.

Appendix J: Overview of Client Engagement Process



Appendix K: Rapid Testing Algorithm