# Hepatitis C Counseling and Rapid Testing Guidelines


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**PURPOSE**

The purpose of this document is to provide guidance regarding rapid testing for Hepatitis C (HCV). With this new technology, HCV testing will likely be offered in new settings and by new providers with minimal experience conducting HCV antibody testing, providing appropriate counseling to clients regarding test results and risk reduction strategies, or reporting communicable disease data to public health. This document outlines recommended actions for venues planning on initiating rapid HCV testing, background information on hepatitis C, recommendations regarding pre- and post-test counseling and risk reduction communication, as well as guidance regarding data collection, reporting and medical referrals.

**GOALS**

1) Improve knowledge regarding hepatitis C
2) Provide logistical recommendations for venues planning to implement rapid HCV testing
3) Ensure that individuals receiving rapid HCV testing are provided with information regarding hepatitis C transmission and prevention, and receive appropriate risk-reduction counseling
4) Ensure that individuals understand the meaning of their HCV test results
5) Ensure that individuals with reactive rapid HCV test results are successfully referred for confirmatory HCV nucleic acid testing and a medical evaluation by a liver or infectious disease specialist.
6) Ensure that individuals with reactive rapid HCV test results receive education regarding liver health and appropriate preventative care
7) Ensure that reactive rapid HCV test results are reported to the local health department, and to the client's primary care provider if applicable

**CONSIDERATIONS PRIOR TO IMPLEMENTING RAPID HCV TESTING**

**CLIA certification**

The Federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regulations that establish requirements for performing laboratory tests. Under CLIA, a clinical laboratory is defined as any facility that examines materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. Any facility that means this definition must have the appropriate CLIA certificate to perform laboratory tests. If a facility is only collecting specimens, a CLIA certificate is not required. The OraQuick HCV Rapid Antibody Test is classified as "waived" under CLIA. The federal agency that regulates CLIA certification is the Center for Medicare and Medicaid Services (CMS). Both federal and state regulations require that any facility performing this test must apply for and receive a CLIA Certificate of Waiver prior to beginning testing. The cost of the certificate is $150.00 every two years.

Visit http://www.michigan.gov/lara/0,4601,7-154-63294_72971_78688---,00.html for further information on CLIA and directions on how to apply for a Certificate of Waiver.

**Bloodborne pathogen exposure**

The FDA-approved rapid HCV testing currently requires collection of blood samples. Standard (universal) precautions should be followed in handling these specimens, i.e., all blood samples should be handled as if they could contain a potentially infectious organism. Furthermore, federal law and state regulations require that facilities collecting blood samples comply with the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) Bloodborne Pathogens standard.

The Michigan Occupational Health and Safety Administration (MIOSHA) has also issued standards to this effect. Requirements include training for all employees with occupational exposure, development of an exposure control plan, provision of personal protective equipment, employee training, post-exposure evaluation and follow-up, hepatitis B vaccination provision, and containment and disposal of bio-hazardous waste.

For more information, visit http://www.osha.gov/SLTC/bloodbornepathogens/. MIOSHA also has a training module available at http://www.michigan.gov/lara/0,4601,7-154-61256_11407_30453-89915--,00.html FDA requires all individuals operating the HCV test device be familiar with the CDC standard (universal) precautions guide https://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html

**Legal considerations**

Facilities planning to initiate testing must identify a medical authority who will provide standing delegation orders for the rapid HCV antibody test. Legal implications of conducting laboratory tests should be reviewed and assurances should be made that the appropriate liability/insurance coverage is in place for this activity.

**Quality assurance**

Although waived rapid HCV antibody tests are simple to use and can provide reliable results when the manufacturer's directions are followed, mistakes can occur at any point in the testing process. Implementing a quality assurance (QA) program can reduce mistakes. A QA program is a set of planned, step-by-step activities that ensure that kit controls are properly stored at correct temperatures, testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Information regarding storage of kit controls can be found in the HCV Rapid Antibody Test package insert. The FDA requires that any facility performing CLIA-waived rapid HIV antibody testing have a quality assurance program in place. While this is not a requirement for rapid HCV antibody testing, it is a recommended practice. Further guidance regarding QA can be found at: https://www.cdc.gov/hiv/pdf/testing_QA_Guidlines.pdf

**Staff qualifications and training**

**Test kit proficiency**

All staff performing HCV rapid testing must be fully trained in test performance prior to implementation. This training should be documented in the personnel record. Training should include proficiency in

collecting the sample, conducting the test, and interpreting the results of the test and the controls. Proficiency should be reassessed on a regular basis. Training or technical assistance on the test device can be arranged by contacting the local manufacturer representative. Details regarding testing procedure are available in the package insert and in Appendix B. The "Ready Set Go" module developed by CDC with regard to CLIA-waived testing should be reviewed and is available at: https://wwwn.cdc.gov/clia/resources/waivedtests/pdf/readysettestbooklet.pdf

**Client counseling, education and risk reduction**

Furthermore, all staff must receive education regarding Hepatitis C in order to field client questions. Optimally, staff should also be able to provide appropriate counseling and risk-reduction messages. A Hepatitis C overview begins on Page 6. Recommendations regarding appropriate pre- and post-test counseling as well as risk reduction messages begin on Page 12. The Centers for Disease Control and Prevention (CDC) developed a HCV counseling and testing manual which is available at https://www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtestingpc.pdf. Links to this website and other educational resources are listed in Appendix C.

## Maintaining client privacy and confidentiality

Facilities should have policies and procedures in place that specify how client privacy and confidentiality will be maintained. A quiet, private space should be available for performing the test, disclosing the results, and counseling. Testing records should be stored in a secure location and/or electronic medical record system with limited access.

## Medical records retention

In compliance with The Michigan Public Health Act No. 368, 333.16213, medical records must be retained for a minimum of seven years from the date of service. Medical records are defined by the act as including any information, oral or recorded in any form or medium, that pertains to a patient's health care, medical history, diagnosis, prognosis, or medical condition and therefore would include rapid HCV test results.

## Facility and other logistical recommendations

Testing locations should ideally be in an area exclusively dedicated to running tests. These areas should include adequate counter space, consistent room temperature, sufficient lighting, adequate storage area for supplies, proper refrigeration for kit controls, ability to limit access or lock room and allow for the maintenance of client confidentiality and the security of a client's files.

Considerations should be made to client flow through the testing process. Adequacy of staff should be ensured, particularly in the setting of delivering reactive HCV antibody test results and initiating the referral process. At least one staff member who has received training in delivering reactive results and initiating referral process should be present at all times while testing is being conducted.

**Reporting HCV results to local health department**

Hepatitis C is one of over 90 diseases and conditions that are required to be reported under Michigan Public Health Act No. 368 Communicable Disease Rules: R 325.171-3, 333.5111. In Michigan, all positive and negative HCV antibody, HCV RNA, and HCV genotype results are therefore reportable by law to the local health department in the jurisdiction where the client resides.

The Privacy Rule in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) allows for the disclosure of protected health information, without individual client or patient authorization, to public health authorities, who are legally authorized to receive such reports for the purpose of preventing or controlling disease.

Reportable diseases in Michigan are available at: https://www.michigan.gov/documents/mdch/Reportable_Diseases_Michigan_by_Condition_478488_7.pdf

Prior to initiating testing, facilities should contact the appropriate local health department regarding the preferred method for results reporting. A listing of local health departments is in Appendix D. At a minimum, reported information should include elements in the MDHHS Rapid HCV Reporting Form in Appendix E. Results should be reported within 24 hours.

**Importance of medical referrals**

It is imperative that facilities conducting rapid HCV antibody testing have the ability to refer clients to appropriate medical and social services. A rapid HCV antibody test indicates that the client was exposed to the HCV virus at some point in their lifetime, but additional testing is needed to determine if the client currently is infected with the virus. In order to establish whether a reactive rapid HCV antibody test result indicates current infection or past infection, confirmatory nucleic acid testing (NAT) must be performed. Individuals with HCV nucleic acid (RNA) present in their blood have current HCV infection, are at risk for development of liver disease (e.g., cirrhosis or liver cancer), should be medically evaluated and may be candidates for curative antiviral treatment. A client with a reactive rapid HCV antibody result must be referred to a licensed health-care provider whose scope of practice includes the authority to order HCV NAT and is able to perform a medical evaluation to assess the client's liver health. If a client has a primary care provider, (PCP) they can be referred to the PCP office for NAT and liver function testing. However, referral to a hepatologist, gastroenterologist or infectious disease specialist is eventually necessary for HCV treatment. Many clients may not have a PCP or health insurance. Local health departments can be contacted for a list of potential providers.

Prior to initiating testing, the facility should identify a provider to whom they can refer clients with reactive results for HCV NAT and medical evaluation if the client does not have a PCP. Optimally, a facility can establish a written memorandum of understanding (MOU) that includes the roles and responsibilities of the referring agency (the testing facility) and the agency accepting the referral. The testing facility should have procedures in place for initiating the referral and tracking the client's follow-

up status. Referrals should be tracked to ensure client access and follow-up. A sample client referral form is available in Appendix G as part of the reactive result client paperwork.

Of note, a review of HCV surveillance data demonstrated that only half of persons reported to public health with a new Hepatitis C diagnosis had HCV NAT that confirmed the diagnosis (CDC MMWR 62;2013). Surveillance data also demonstrates a higher mortality rate among persons who are HCV antibody positive only as compared to those who have had HCV NAT performed. This may be due in part to differences in access to necessary health care. As a result, successful referral to a health-care provider for confirmatory HCV NAT and appropriate preventive services and medical management can have a significant impact on client outcome.

**Other referrals and access to care**

Individuals at-risk for hepatitis C infection may have significant medical comorbidities including STDs, HIV infection and substance abuse. The infrastructure for substance abuse, harm reduction and mental health referrals should be developed. Furthermore, individuals presenting for testing may not have a primary care provider, health insurance and/ or adequate monetary resources to cover the costs of HCV NAT or medical referral. Local sources of assistance with payment for testing, low-cost and free clinics such as federally-qualified health centers (FQHCs), enrollment in insurance through the Affordable Care Act Health Insurance Marketplace, and county health plan information should be available. The local health department can be contacted prior to initiating testing to connect the facility with these locally appropriate resources. Selected referral resources are available in Appendix H.

**Facility protocol/operations manual**

Prior to initiating testing, each facility should develop a site-specific protocol detailing the testing flow, training requirements, referral mechanism, data storage and reporting, CLIA application and bloodborne pathogen exposure.

## HEPATITIS C OVERVIEW

Staff providing HCV testing and counseling should understand the basic features of hepatitis C, including populations at risk, mode of transmission, laboratory diagnosis, symptoms and complications. It is imperative that testing staff are able to field questions from clients regarding hepatitis C.

Often clients will be confused regarding the differences between hepatitis A, B and C. Clarifying the differences between types of viral hepatitis is important. Facts about viral hepatitis are summarized in Table 1 below.

| | Hepatitis A | Hepatitis B | Hepatitis C |
|---|---|---|---|
| Caused by | Hepatitis A virus (HAV) | Hepatitis B virus (HBV) | Hepatitis C virus (HCV) |
| U.S. statistics | Estimated 24,900 new infections in 2018 | ▪ Estimated 21,600 new infections in 2018<br>▪ Estimated 862,000 persons living with chronic HBV in 2016 | ▪ Estimated 50,300 new infections in 2018<br>▪ Estimated 2.4mil persons living with chronic HCV in 2016 |
| Michigan statistics | 70 confirmed infections in 2011 | ▪ 65 confirmed acute infections in 2019<br>▪ 1024 newly diagnosed chronic infections in 2019 | ▪ 133 confirmed acute infections in 2019<br>▪ 6036 newly diagnosed chronic infections in 2019 |
| Routes of transmission | Ingestion of fecal material, which can occur with:<br>▪ close or sexual contact with an infected person<br>▪eating/drinking contaminated food/beverages | Contact with blood, semen, and other bodily fluids containing HBV through:<br>▪ birth to an infected mother<br>▪ sexual contact with infected person<br>▪ sharing contaminated needles, syringes or other injection drug equipment with infected person<br>▪ needlesticks or sharp medical instrument injuries | Contact with blood of infected person through:<br>▪ sharing contaminated needles, syringes, or other injection drug equipment with an infected person<br><br>Less commonly:<br>▪ sexual contact with infected person<br>▪ birth to infected mother<br>▪ needlesticks or sharp medical instrument injuries<br>▪ sharing implements for inhaling illicit drugs (e.g., cocaine) |
| Who is at risk | ▪ Travelers to areas with intermediate or high rates HAV infection<br>▪ Sex contacts of infected persons<br>▪ Household members or caregivers of infected persons including daycare workers<br>▪ Men who have sex with men<br>▪ Users of certain illegal drugs (injection and non-injection)<br>▪ Persons with clotting factor disorders | ▪ Infants of infected mothers<br>▪ Sex partners of infected persons<br>▪ Persons with multiple sex partners<br>▪ Persons with a sexually transmitted disease (STD)<br>▪ Men who have sex with men<br>▪ Injection drug users<br>▪ Household contacts of infected persons<br>▪ Healthcare/public safety workers exposed to blood on the job<br>▪ Hemodialysis patients<br>▪ Residents and staff of facilities for developmentally disabled persons<br>▪ Travelers to areas with intermediate/ high rates of HBV infection<br>▪ Adults with diabetes | ▪ Current or former injection drug users<br>▪ Received clotting factor concentrates before 1987<br>▪ Received blood transfusions or donated organs before July 1992<br>▪ Long-term hemodialysis patients<br>▪ Persons with known exposures to<br>▪ HCV (e.g., healthcare workers after needlesticks, recipients of blood or organs from a donor who later tested positive for HCV)<br>▪ HIV-infected persons<br>▪ Infants born to infected mothers<br>▪ Individuals born between 1945-1965 (one time test unless have continuing other HCV risk factor) |
| Symptoms of acute infection | Similar for all types of viral hepatitis and can include 1 or more of the following:<br>Fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, yellowing of the skin or eyes (jaundice), gray colored bowel movements, joint pain | | |
| Acute symptoms? | <10% children < 6 yrs<br>40-50% of children 6-14<br>70-80% of persons > 14 | < 1% of infants < 1 year<br>5%–15% of children 1-5 years<br>30%–50% of persons > 5 years | 20%–30% of newly infected persons develop symptoms of acute disease |
| Chronic infection? | No | >90% of infected infants<br>25-50% of children 1-5 yrs<br>6-10% of older children , adults | 75-85% of infected persons<br>15-25% of newly infected persons clear the virus |

| | Hepatitis A | Hepatitis B | Hepatitis C |
|---|---|---|---|
| Severity | ▪ Rarely fatal<br>▪ Most recover with no residual liver damage | ▪ Acute HBV infection is rarely fatal<br>▪ 15-25% of chronically infected will develop chronic liver disease such as cirrhosis, liver failure or liver cancer | ▪ Acute HCV infection is rarely fatal<br>▪ 60-70% of chronic infections develop chronic liver disease<br>▪ 5-25% develop cirrhosis over 10-20 yr<br>▪ 1-4% have annual risk for hepatocellular carcinoma |
| Treatment | ▪ No medication available<br>▪ Supportive treatment | Acute: No medication available, supportive treatment<br>Chronic: regular medical monitoring, some patients receive antiviral drugs | Acute: Antivirals, supportive treatment<br>Chronic: over 90% living with HCV can be cured regardless of genotype with 8-12 weeks of oral therapy |
| Prevention | Vaccination available:<br>▪ 2 doses, 6-18 months apart<br>▪ Recommended for those at increased risk (above); all infants vaccinated<br><br>Prevention measures:<br>▪ Wash hands after using the bathroom, changing a diaper and before preparing, serving or eating food | Vaccination available:<br>▪ Adults: 2 doses, 1 month apart or 3 doses over a 6-month period (depending on manufacturer)<br>▪ Children: 3-4 doses over 6-18 months<br>▪ Recommended for those at increased risk (above); all infants vaccinated at birth<br>Prevention measures:<br>▪ Don't share needles to inject drugs, tattooing equipment, razors, toothbrushes, glucose monitors, fingernail clippers<br>▪ Pregnant women screened for HBV<br>▪ Use standard precautions in occupations with possible exposure to blood and body fluids | No vaccine available<br><br>Prevention measures:<br>▪ Don't share needles to inject drugs, tattooing equipment, razors, toothbrushes, glucose monitors, fingernail clippers<br>▪ Use standard precautions in occupations with possible exposure to blood and body fluids |
| Screening for chronic infection recommended for: | Not recommended/not applicable (no chronic infection stage) | ▪ All pregnant women<br>▪ Infants born to HBsAg-positive mothers<br>▪ People born in areas with intermediate and high HBV endemicity<br>▪ People born in the U.S. not vaccinated as infants whose parents were born in regions with high HBV endemicity<br>▪ Household or sexual contacts of people who are HBsAg-positive<br>▪ Men who have sex with men<br>▪ People who inject, or have injected, drugs<br>▪ Patients with elevated liver enzymes of unknown etiology<br>▪ People with end-stage renal disease including hemodialysis patients<br>▪ People receiving immunosuppressive therapy<br>▪ People with HIV<br>▪ Donors of blood, plasma, organs, tissues, or semen | ▪ All adults aged 18 years and older, at least once<br>▪ All pregnant women during each pregnancy<br>▪ People who currently inject drugs and share needles, syringes, or other drug preparation equipment (routine periodic testing) and people who ever injected drugs<br>▪ People with HIV<br>▪ People who receive maintenance hemodialysis (routine periodic testing) or who ever did<br>▪ People with persistently abnormal ALT levels<br>▪ Prior recipients of transfusions or organ transplants, including: people receiving clotting factor concentrates before 1987, receiving a blood transfusion or organ transplant before July 1992, and people receiving blood from a donor who later tested positive for HCV<br>▪ Healthcare, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood<br>▪ Children born to mothers with HCV infection<br>▪ Any person who requests hepatitis C testing should receive it |

Hepatitis C is caused by infection with the hepatitis C virus (HCV). An estimated 2.4 million people in the United States have hepatitis C, and many are not aware of their infection. More than 75% of individuals who get infected with hepatitis C are not able to clear the virus from their system and develop a chronic lifelong infection.

**Natural history**

Hepatitis C virus attacks the liver. The liver is an important organ in the abdomen. Its functions include ridding the blood of toxins, breaking down nutrients into a form the body can use, and synthesizing proteins needed to help the blood and immune system function properly. Once the hepatitis C virus invades liver cells, our body's immune system attacks the affected cells and kills them. This can cause liver scarring (or fibrosis) which can cause the liver to malfunction. Extensive scarring is called cirrhosis. Cirrhosis usually happens over a 10 to 20 year time period, although it can happen quicker in some individuals with HIV infection or other liver disease from alcohol or hepatitis B infection. A person may or may not have symptoms of liver disease until the damage is very severe. Long-standing hepatitis C infection is also a leading cause of liver cancer in the United States.

**Transmission**

Hepatitis C virus is spread when blood from an infected person gets into the blood of an uninfected person. The most common way this happens is by:

- sharing needles or other equipment used to inject drugs
- blood transfusions or organ transplants that occurred prior to 1992 (before a test was available to screen blood and organ donors for infection)
- long-term hemodialysis for kidney disease
- accidental needle sticks with blood from a person with HCV

Less common modes of transmission include:

- Spread of virus from mother to baby
- Getting body piercings or tattoos with needles that have not been adequately sterilized. This would most likely occur when this is done in prison, at home, or on the street
- Sharing personal items that might have blood on them, such as razors, toothbrushes or blood glucose monitoring supplies
- Inhaling/snorting illicit drugs, including cocaine
- Rarely, having unprotected sex with a person infected with hepatitis C. The risk of transmission among monogamous partners is extremely low. However, the risk of sexual transmission of the virus is greater among men who have sex with men, individuals with multiple sexual partners, and those who engage in rough sex where there is a possibility of bleeding

Hepatitis C is not spread by casual contact (shaking hands, hugging), kissing, sharing food or utensils, coughing or sneezing, mosquitos or other bug-bites, or animals.

**Persons at risk for hepatitis C infection**

HCV testing is recommended for anyone at increased risk for HCV infection, including:

- All adults aged 18 years and older, at least once
- All pregnant women during each pregnancy
- People who currently inject drugs and share needles, syringes, or other drug preparation equipment (routine periodic testing), or people who ever injected drugs
- People with HIV
- People who receive maintenance hemodialysis (routine periodic testing) or who ever received maintenance hemodialysis
- People with persistently abnormal ALT levels
- Prior recipients of transfusions or organ transplants, including: people who received clotting factor concentrates produced before 1987, transfusion of blood or blood components or organ transplant before July 1992, or received blood from a donor who later tested positive for HCV infection
- Healthcare, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to mothers with HCV infection
- Any person who requests hepatitis C testing should receive it

**Treatment**

Hepatitis C virus can be treated with medications called antivirals that can clear the virus from the body, slow down liver damage, and reduce the chances of developing cirrhosis. Treatment for hepatitis C virus has evolved substantially. Current available treatments involve 8-12 weeks of oral therapy with minimal side effects and the ability to achieve sustained virologic response (SVR). SVR is defined as the absence of detectable virus 12 weeks after completion of treatment, which is an indicator for cure of HCV infection.

For a complete list of currently approved therapies by the Food and Drug Administration (FDA) to treat hepatitis C, visit http://www.hepatitisc.uw.edu/page/treatment/drugs

**Diagnosis**

Accurate testing for HCV helps health care providers correctly identify persons who are currently infected with HCV and offer them appropriate preventive services, medical care, and treatment. It also allows HCV-infected persons make informed decisions regarding their medical care and following healthy liver practices that can limit the progression of their disease.

This recommended testing sequence should be implemented by providers using the HCV rapid antibody test and who are following CDC guidance regarding screening for HCV infection. This is not intended to be used for the diagnosis of acute hepatitis C infection. If rapid HCV testing is being performed outside of a medical provider's office, individuals with symptoms of acute liver disease (e.g., jaundice, fever, abdominal pain) should be referred to a licensed medical provider for assessment. The testing sequence for Hepatitis C is detailed below and can also be visualized in Figure 1.

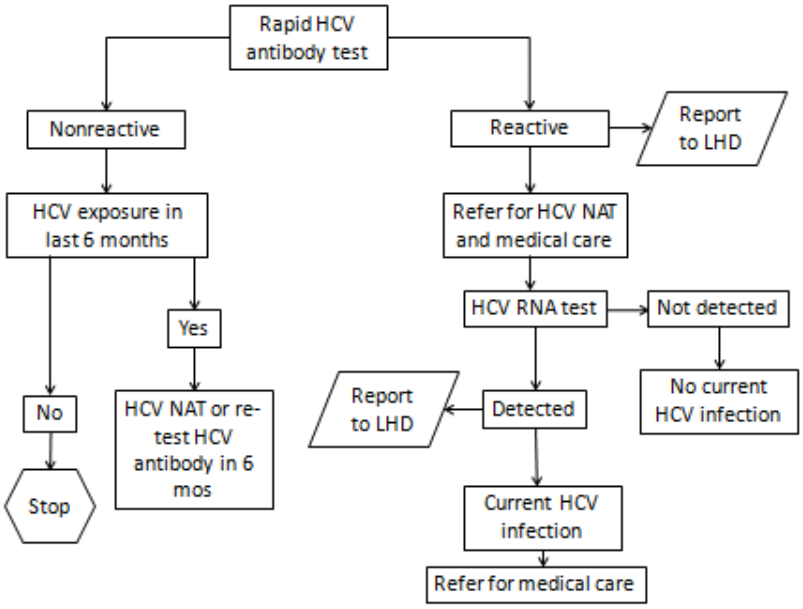
**1) Rapid (or laboratory-conducted assay for HCV antibody**) - These tests detect antibodies produced by a person against HCV.

> **Non-reactive** = no HCV antibody detected. This could indicate that a person is not infected with HCV, is in the Window Period (discussed below), or, if the person is immunocompromised, may not have the ability to develop antibodies against HCV.
>
> **Window Period** = the time period after HCV infection when antibodies have not yet been produced at a high enough level to be detected by available tests. Most HCV infected individuals (90%) develop antibodies between 4-12 weeks after infection. 97% of HCV infected persons have developed antibodies within 6 months. If an individual's exposure falls within in this time frame or is continuous (e.g., ongoing injection drug use), the Window Period is a concern. If client is being tested because of exposure within past 6 months, referral for HCV nucleic acid testing, or follow-up antibody testing is recommended.
>
> **Reactive** = Current HCV infection, past HCV infection that has resolved, or false positivity. This person should be referred to a health-care provider for performance of a nucleic acid test (NAT).

2) **HCV nucleic acid test (NAT) –** This test detects the presence of the hepatitis C virus in the blood. It may also be referred to as a HCV RNA polymerase-chain reaction (PCR) test. A person should be referred for HCV NAT if rapid or laboratory conducted HCV antibody test is positive, if a person has had exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

> **RNA detected** = current HCV infection. Any person with these results should be linked to medical care and results reported to the local health department.
>
> **RNA not detected** = past, resolved HCV infection or false HCV antibody positivity. Further testing may be indicated as is medically appropriate.

**Figure 1. HCV rapid antibody testing flowchart**




## Prevention

There currently is no vaccine for HCV. The risk of infection can be reduced by using safer injection practices, following infection control guidelines in healthcare settings, and not sharing personal items such as razors, toothbrushes, nail clippers or blood glucose monitors. In persons infected with HCV, healthy liver practices, such as eliminating alcohol intake, and vaccination against hepatitis A and B viruses can reduce the risk of developing liver damage.

**PROTOCOL FOR PERFORMING RAPID HEPATITIS C TESTING**

## Pre-test client assessment

The tester should ask the following questions of the client:

1) abdominal pain, fatigue, loss in appetite, change in stools, excess bleeding
   Any signs or symptoms of hepatitis in past 3 months - including jaundice , nausea, vomiting,

   - if a client is currently having any of these symptoms, they may have acute hepatitis. They should be referred to a licensed medical provider for HCV diagnostic testing and further diagnostic evaluation including testing for hepatitis A, hepatitis B and other causes. The testing facility should also contact their local health department to notify them of a possible acute case.

2) Medication history - including NSAIDs, aspirin, Tylenol, statins, herbal or other dietary supplements

3) Medical history - including any history of HIV, STDs, liver or gallbladder problems, diabetes, bleeding problems, history of heavy alcohol use

4) Ever tested for hepatitis C before? Did a doctor ever tell them they had chronic HCV infection? Confirm if client is linked to care, and if not, make a referral. If previously HCV-antibody positive, refer to provider capable of confirmatory testing. If not previously diagnosed with HCV or unsure, offer test.

**Pre-test counseling**

The pre-test counseling session includes basic HCV education, a review of the client's risk assessment, and should help the client to consider appropriate risk reduction activities. This can take place during the 20 minute waiting period. Hepatitis C education can include audio/visual materials and printed fact sheets/brochures. Language barriers and low literacy are considerations in selecting appropriate educational materials. Components of pre-test counseling are:

**1) Establish rapport** - Developing trust is key to a successful interaction. Individuals conducting testing should convey concern, respect and empathy towards the client. Information provided to the client should include an introduction to the tester's role, the purpose of testing, and the confidentiality of the client-tester interaction. An opportunity should be made for the client to ask questions.

**2) Educate regarding hepatitis C** - The tester should first assess the client's knowledge regarding hepatitis C. Based on the client's knowledge base, the tester should provide additional information regarding hepatitis C, particularly that blood exposure is the primary route of transmission. The tester should have adequate background knowledge to be able to address questions regarding the difference between hepatitis A, B and C viruses, HIV and other STDs. Information regarding the potential seriousness of HCV, including complications such as cirrhosis and liver cancer, should be provided. Misconceptions should be corrected.

**3) Assess client risk factors** - Testers should perform a standardized risk assessment for each client. A sample risk assessment form is provided in Appendix I. Some individuals may have current risk factors (e.g., ongoing injection drug use) and may benefit from referral to appropriate medical/social services (e.g., HIV, STD testing, substance abuse programs, syringe service programs, hepatitis A and B vaccine). Such discussions should occur in a compassionate, nonjudgmental manner. Others may have had risk factors in the past (e.g., past injection drug use, blood transfusion before 1992). Some testing sites may also be performing risk assessment for STDs, HIV, and hepatitis B infection. Risk assessment for hepatitis C should be integrated into those efforts.

**4) Provide information on HCV antibody testing** - The meaning of reactive and non-reactive results should be introduced. The need for multiple tests in order to confirm HCV infection, including referral to a provider who can perform confirmatory testing, should be explained. The difference between antibodies and tests for current presence of the virus should be covered. The concept of the Window Period should be introduced, particularly emphasizing the need to retest in 6 months if non-reactive but with

recent or ongoing exposures. The importance of testing should be discussed. Benefits to testing include reassurance if not infected and early referral to medical care if infected. The tester should let the client know that rapid HCV antibody test results will be provided today. The client should be provided ample opportunity for asking questions.

**Specimen collection and test kit operation**

Package insert from OraQuick HCV Rapid Antibody Test is included in Appendix B.

**Disclosure and post-test counseling**

The post-test counseling session includes provision of HCV test results to the client. This should include education regarding the meaning of the results. Arrangements for confirmatory testing, medical referrals and referrals for applicable social services should be made. Results should be given in a neutral tone, in an empathetic non-judgmental manner by the same staff member as performed the test. Results should be provided in a private environment and adequate time should be allowed for the client to process the results, ask questions and receive appropriate referrals. The client should also be provided with a copy of HCV test results. This test result form should include the result as well as the meaning of the result. Separate sample forms for reactive and non-reactive results are available in Appendix F,G.

**Disclosure of non-reactive result**

A non-reactive result means that no HCV antibody was detected in the client's blood. This could indicate that a person is not infected with HCV, is in the Window Period, or if the person is immunocompromised, may not have the ability to develop antibodies against HCV. A client should be allowed to express relief. The meaning of these results should be outlined for the client and tailored based on their risk factors. For instance, a client with ongoing exposure should receive information regarding the Window Period and developing a plan for re-testing and risk reduction.

Clients may only be interested in receiving their test results. However, post-test counseling is still important for clients with non-reactive results. Clients should again be provided with information on how to prevent HCV infection as knowledge regarding HCV transmission is often limited. It should be emphasized that non-reactive results do not mean they are immune to HCV infection in the future. The difference between Hepatitis A, B and C should be re-iterated, including the need for hepatitis A and/or hepatitis B vaccination.

The tester should verify that the client understands their HCV test results. The client's risk behaviors should be acknowledged, and opportunities for risk reduction should be addressed. The client should leave with a list of resources, for instance, for STD testing, HIV testing and/or substance abuse programs.

**Disclosure of reactive result**

A reactive result means that antibodies to HCV were detected in the client's blood. This means they have been infected with Hepatitis C virus at some time and may still be infected. Clients with reactive rapid HCV antibody results need a second blood test, the HCV NAT, to determine if they are currently infected or have cleared virus on their own. This type of testing can only be ordered by a medical provider.

Test results should be delivered in a neutral tone. Testing staff should notify the facility manager that they will be delivering a reactive result in order to accommodate additional time for counseling and referrals. The client should be allowed time to process the result. Upon receiving the result, the client may have an emotional reaction. They may ask many questions and want information right away, or they may not know what to say. If the client expresses fear regarding the result, they should be reassured that getting this test gives them information that will allow them to protect their health. While the seriousness of these results should be conveyed, the tester should explain that HCV progresses slowly and many people have no symptoms or mild symptoms for many years.

After the client has had the chance to process the result, additional information regarding hepatitis C infection should be provided, including what "hepatitis" is, how HCV is transmitted, and what the antibody result means. The need for a second test, the HCV NAT, should be addressed. The tester should verify that the client understands that the antibody test alone does not tell them whether or not they are currently infected.

The client should be advised to behave as though they are infected with hepatitis C prior to confirmatory testing. This includes reviewing key messages regarding how to reduce the chances of HCV transmission to others. Safe liver practices should also be reviewed such as reducing alcohol intake, and hepatitis B and hepatitis A vaccination as appropriate. Furthermore, the client should leave with a list of resources, for instance, for STD testing, HIV testing, and substance abuse programs.

**Referral process**

The details of the referral process should be discussed with clients with a reactive HCV antibody result. They should be told that they will be sent to another health care provider for the confirmatory HCV NAT which can detect the hepatitis C virus genetic material in the blood and determine whether or not they are currently infected. The testing logistics, including who will perform the test, and when and where the test will be performed, should be reviewed. Details regarding the appointment, or how they will be contacted to schedule their appointment, should be provided verbally and in writing- for instance on the sample reactive test results report sheet (Appendix G). Transportation to and from the appointment as well as appointment cost should be discussed. Facilities may have referral relationships with one or multiple health care providers. Consideration should be given to identifying referral providers who are convenient and affordable for their client population.

If possible, the client should be scheduled for a referral appointment while still at the testing facility. If this is not feasible, they should be advised they will be contacted by staff at the testing or referral facility regarding appointment scheduling. The client's preferred contact phone number should be obtained.

Testing facility staff should maintain a referral log for reactive clients . Each facility should establish a follow-up procedure to assess whether or not reactive clients present for referral and their confirmatory test results.

**Disclosure of invalid result**

An invalid test result means the test was unable to determine if the result was reactive or non-reactive. This can occur when the internal control line on the test does not appear, or the lines are not appropriately aligned in the result window. A client with this result should be offered a retest. If the retest is invalid, the facility should contact OraSure Technology Customer Service at 1-800-672-7873.

**REFERENCES:**

CDC. Vital Signs: Evaluation of Hepatitis C Virus Infection Testing and Reporting - Eight U.S. Sites, 2005-2011. MMWR. 62(18);357-361.

CDC. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratories. MMWR. 62(18);362-365.

CDC. HCV Testing and Counseling Manual. At https://www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtestingpc.pdf.

CDC. Hepatitis C Information for Health Professionals. At http://www.cdc.gov/hepatitis/HCV/index.htm.

Accessed July 22, 2013.

Moyer VA, on behalf of the U.S. Preventive Services Task Force. Screening for hepatitis C virus infection in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013.

Smith BD, Morgan RL, Beckett GA, Falck-Ytter Y, Holtzman D, Teo CG, et al; Centers for Disease Control and Prevention. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. MMWR Recomm Rep. 2012;61(RR-4):1-32.

Holmberg SD, Spradling PR, Moorman AC, Denniston MM. Hepatitis C in the United States. N Engl J Med. 2013;368:1859-61.

**APPENDICES:**

A: MDHHS contact information

B: Rapid HCV testing procedures

C: Hepatitis C resources

D: Local health department listing

E: Rapid HCV reporting form and summary sheet

F: Sample Client non-reactive results reporting form

G: Sample Client reactive results reporting form and referral form

H: Other client referral resources

I: Facility preparation checklist

Appendix A

## Michigan Department of Health and Human Services (MDHHS) contacts

### MDHHS Viral Hepatitis Surveillance and Prevention Unit

Phone: 517-335-8165
Fax: 517-335-8263
Email: MDHHS-Hepatitis@michigan.gov
Web: www.michigan.gov/hepatitis

### MDHHS Bureau of Laboratories

Phone: 517-335-8063
Fax: 517-335-9631
Email: MDHHSLab@michigan.gov
Web: www.michigan.gov/mdhhslab

### MDHHS Regional Epidemiologists

| Region | Counties | Name | Phone | Email |
|---|---|---|---|---|
| 1 | Clinton, Eaton, Gratiot, Hillsdale, Ingham, Jackson, Lenawee, Livingston, Shiawassee | Meghan Weinberg | 517-749-2153 | WeinbergM1@michigan.gov |
| 2N | Macomb, Oakland, St. Clair | Nicole Parker-Strobe | 517-930-6906 | ParkerStrobeN@michigan.gov |
| 2S | Detroit City, Monroe, Washtenaw, Wayne | Joyce Lai | 517-930-6958 | LaiJ@michigan.gov |
| 3 | Alcona, Arenac, Bay, Genesee, Gladwin, Huron, Iosco, Lapeer, Midland, Ogemaw, Oscoda, Saginaw, Sanilac, Tuscola | Tim Bolen | 517-930-6910 | BolenT1@michigan.gov |
| 5 | Allegan, Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren | Bethany Reimink | 517-719-0407 | ReiminkB@michigan.gov |
| 6 | Clare, Ionia, Isabella, Kent, Lake, Mason, Mecosta, Montcalm, Muskegon, Newaygo, Oceana, Osceola, Ottawa | Fatema Mamou | 517-204-6086 | MamouF@michigan.gov |
| 7 | Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford | Roger Racine | 517-930-6914 | RacineR@michigan.gov |
| 8 | Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft | Scott Schreiber | 517-930-3089 | SchreiberS@michigan.gov |

Appendix B

Linking People to Care

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

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

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

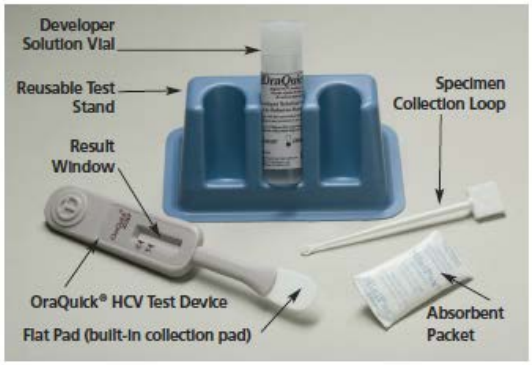
*Failure to follow the instructions, or modifications to the Test instructions, will result in the Test no longer meeting the requirement for Waived Classification and will be subject to all applicable CLIA requirements.*

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

OraQuick® Rapid Antibody Test HCV

Item#3001-1529-70 rev. 11/11
OQ HCV Step-by-Step, US

Accurate – Rapid Result – Easy to Use




## INTENDED USE:

The OraQuick® HCV Rapid Antibody Tests is a single-use immunoassay for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in fingerstick whole blood specimens and venipuncture whole blood specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate) from individuals 15 years or older. The OraQuick® HCV Rapid Antibody Test results, in conjunction with other laboratory results and clinical information, may be used to provide evidence of infection with HCV (state of infection or associated disease not determined) in persons with signs or symptoms of hepatitis and in persons at risk for hepatitis C infection.

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

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

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

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

**NOTE: Handle all blood specimens and materials contacting specimens as if capable of transmitting infectious agents. Dispose of all test specimens and materials used in the test procedure in a biohazard container.[1]**

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

Appendix B

## FOR *IN VITRO* DIAGNOSTIC USE

## THE FOLLOWING ITEMS ARE NEED TO DO THE TEST:

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

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

**NOTE: The pouch is divided into two chambers. One chamber holds the Test Device while the other chamber holds the Developer Solution Vial.**

### Materials Provided in the Kit:

- Reusable Test Stands
- Package Insert
- Specimen Collection Loops

### Materials Required But Not Provided:

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

## EXTERNAL QUALITY CONTROL

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

### Run the Kit Controls under the following circumstances:

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

### Test Procedure for Kit Controls

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

## SET UP YOUR WORKSPACE

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

## GENERAL TEST PREPARATION

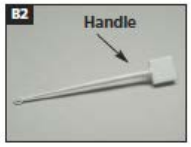

Two Chambers



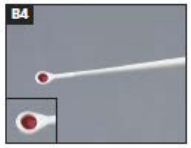
- If you are a new operator, you **MUST** be able to interpret all devices provided in the OraQuick® HCV Visual Reference Panel prior to using the Oraquick® HCV Rapid Antibody Test.
- Allow all components to come to operating temperature (15°–37°C, 59°–99°F).
- Place the resuable Test Stand on your workspace.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

Appendix B

## SPECIMEN COLLECTION PROCEDURE – FINGERSTICK WHOLE BLOOD



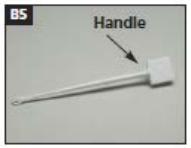



**NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

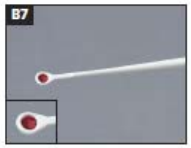
### Step 1A – COLLECT

- Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to air dry.
- Using a sterile lancet, puncture the skin just off the center of the finger pad.
- Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (*see picture B1*).
- Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
- Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (*see picture B2*).
- Put the "rounded" end of the Loop on the drop of blood (*see picture B3*). Make sure that the Loop is completely filled with blood (*see picture B4*).

## VENIPUNCTURE WHOLE BLOOD







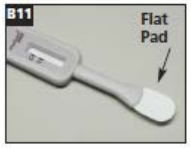

**NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.

### Step 1B – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium/lithium heparin (green top), or sodium citrate (light blue top). **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 2°– 8°C (36°– 46°F) for up to 7 days or at 15°– 30°C (59°– 86°F) for up to 3 days.
- Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous specimen.
- Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (*see picture B5*).
- Put the "rounded" end of the Loop into the tube of blood (*see picture B6*). Make sure the Loop is completely filled with blood (*see picture B7*).

## TESTING PROCEDURE




### Step 2 – MIX

- Immediately insert the blood-filled end of the Loop all the way into the Vial (*see picture B8*).
- Use the Loop to stir the blood sample in the Developer Solution ("Solution") (*see picture B9*).
- Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.
- Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (*see picture B10*). If the Solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.





### Step 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture B11*).
- Check to make sure that an Absorbent Packet is included with the Device (*see picture B12*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (*see picture B13*). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (*see picture B14*).
- Start timing the test (*see picture B15*). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops.
- Wait 20 minutes.
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Test Result and Interpretation* section in these instructions.

Appendix B

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

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

**REACTIVE:** Lines in C and T Zones

Line in T Zone | Line in T Zone | Faint Line in T Zone

### Test is Reactive if:

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

**NON-REACTIVE:** Lines in C Zone Only

Line in C Zone
No HCV antibodies detected.

### Test is Non-Reactive if:

- A line appears in the C Zone and NO line appears in the T Zone.
- A Non-Reactive test result means that HCV antibodies were not detected in the specimen.
- Patient is presumed not to be infected with HCV.

**INVALID:** No Lines in C Zone or Partially Developed Lines

No Line in C Zone | Red background obscures results

Partial Line on one side of C or T Zones

### Test is Invalid if:

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

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

## GENERAL TEST CLEAN UP

- Dispose of the used test materials in a biohazard waste container.
- Change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

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

| Order Information | Description | Reimbursement Information | CPT Code |
|---|---|---|---|
| | Box of 25 tests<br>Box of 100 tests<br>Controls<br>OraQuick® HCV Visual Reference Panel | | 86803 |

OraQuick® Rapid Antibody Test HCV

OraSure Technologies
220 East First Street
Bethlehem, PA 18015 USA
*phone:* 800.ORASURE
*web:* www.orasure.com
Made in the USA

Appendix C

**HEPATITIS C RESOURCES**

**General Hepatitis C information**

MDHHS Hepatitis C website:

www.michigan.gov/hepatitis

MDHHS Syringe Services Program website:

www.michigan.gov/SSP

CDC Hepatitis C website:

www.cdc.gov/hepatitis/HCV/index.htm

CDC Hepatitis C Patient Education resources:

www.cdc.gov/hepatitis/HCV/PatientEduHCV.htm

CDC Guide to Comprehensive Hepatitis C Counseling and Testing:

www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtestingpc.pdf

**Health professional HCV training:**

University of Washington Hepatitis training module:

https://www.hepatitisc.uw.edu/

CDC Hepatitis serology training:

www.cdc.gov/hepatitis/Resources/Professionals/Training/Serology/training.htm

Appendix D

**Michigan Local Health Departments**

# DIRECTORY OF MICHIGAN HEALTH DEPARTMENTS

*In general, health care providers should seek consultation regarding communicable disease prevention and control services through their local health department.*

| COUNTY | HEALTH DEPT. | CO. OFFICE | AREA | PHONE | FAX | COUNTY | HEALTH DEPT. | CO. OFFICE | AREA | PHONE | FAX |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Alcona | District 2 | Harrisvile | 989 | 724-6757 | 343-1894 | Lake | District 10 | Baldwin | 231 | 745-4663 | 745-2501 |
| Alger | LMAS DHD | Munising | 906 | 387-2297 | 387-2224 | Lapeer | Lapeer County | Lapeer | 810 | 667-0448 | 667-0232 |
| Allegan | Allegan County | Allegan | 269 | 673-5411 | 673-2163 | Leelanau | Benzie-Leelanau DHD | Lake Leelanau | 231 | 256-0200 | 256-7399 |
| Alpena | District 4 | Alpena | 989 | 356-4507 | 356-3529 | Lenawee | Lenawee County | Adrian | 517 | 264-5243 | 264-0790 |
| Antrim | Health Dept. of NW MI | Bellaire | 231 | 533-8670 | 547-6238 | Livingston | Livingston County | Howell | 517 | 546-9850 | 545-9685 |
| Arenac | Cent MI DHD | Standish | 989 | 846-6541 | 846-0431 | Luce | LMAS DHD | Newberry | 906 | 293-5107 | 293-5724 |
| Baraga | Western UP Dist | L'Anse | 906 | 524-6142 | 524-6144 | Mackinac | LMAS DHD | St. Ignace | 906 | 643-1100 | 643-0239 |
| Barry | Barry-Eaton DHD | Hastings | 269 | 798-4152 | 517-541-2666 | Macomb | Macomb County | Mt. Clemens | 586 | 783-8190 | 493-0075 |
| Bay | Bay County | Bay City | 989 | 895-2039 | 895-2083 | Manistee | District 10 | Manistee | 231 | 723-3595 | 723-0150 |
| Benzie | Benzie-Leelanau DHD | Benzonia | 231 | 882-4409 | 882-0143 | Marquette | Marquette County | Negaunee | 906 | 475-7844 | 475-4435 |
| Berrien | Berrien County | Benton Harbor | 269 | 926-7121 | 926-8129 | Mason | District 10 | Ludington | 231 | 845-7381 | 845-9374 |
| Branch | Branch/Hills/St Jo | Coldwater | 517 | 279-9561x0105 | 278-2923 | Mecosta | District 10 | Big Rapids | 231 | 592-0130 | 592-9464 |
| Calhoun | Calhoun County | Battle Creek | 269 | 969-6370 | 969-6488 | Menominee | Delta-Men Dist | Menominee | 906 | 863-4451 | 863-7142 |
| Cass | Van Buren-Cass DHD | Dowagiac | 269 | 782-0064 | 782-0121 | Midland | Midland County | Midland | 989 | 832-6666 | 837-6524 |
| Charlevoix | Health Dept. of NW MI | Charlevoix | 231 | 547-6523 | 547-6238 | Missaukee | District 10 | Lake City | 231 | 839-7167 | 839-7908 |
| Cheboygan | District 4 | Cheboygan | 231 | 627-8850 | 989-356-3529 | Monroe | Monroe County | Monroe | 734 | 240-7832 | 240-7838 |
| Chippewa | Chippewa County | Sault Ste. Marie | 906 | 635-1566 | 635-7081 | Montcalm | Mid-MI DHD | Stanton | 989 | 831-3615 | 831-3666 |
| Clare | Cent MI DHD | Harrison | 989 | 539-6731 | 539-4449 | Montmorency | District 4 | Atlanta | 989 | 785-4428 | 356-3529 |
| Clinton | Mid-MI DHD | St. Johns | 989 | 227-3111 | 227-3126 | Muskegon | Muskegon County | Muskegon | 231 | 724-1287 | 724-1325 |
| Crawford | District 10 | Grayling | 989 | 348-7800 | 348-5346 | Newaygo | District 10 | White Cloud | 231 | 689-7300 | 689-5295 |
| Delta | Delta-Men Dist | Escanaba | 906 | 786-4111 | 789-8148 | Oakland | Oakland County | Pontiac | 248 | 858-1286 | 858-0178 |
| Dickinson | Dick-Iron Dist | Kingsford | 906 | 774-1868 | 779-7232 | Oceana | District 10 | Hart | 231 | 873-2193 | 873-4366 |
| Eaton | Barry-Eaton DHD | Charlotte | 517 | 541-2641 | 541-2666 | Ogemaw | District 2 | West Branch | 989 | 345-5020 | 343-1899 |
| Emmet | Health Dept. of NW MI | Petoskey | 231 | 347-6014 | 547-6238 | Ontonagon | Western UP Dist | Ontonagon | 906 | 884-4485 | 884-2358 |
| Genesee | Genesee County | Flint | 810 | 257-1017 | 257-3247 | Osceola | Cent MI DHD | Reed City | 231 | 832-5532 | 832-1020 |
| Gladwin | Cent MI DHD | Gladwin | 989 | 426-9431 | 426-6952 | Oscoda | District 2 | Mio | 989 | 826-3970 | 343-1895 |
| Gogebic | Western UP Dist | Bessemer | 906 | 667-0200 | 667-0020 | Otsego | Health Dept. of NW MI | Gaylord | 989 | 732-1794 | 231-547-6238 |
| Gd. Traverse | Grand Traverse Co | Traverse City | 231 | 995-6100 | 995-6126 | Ottawa | Ottawa County | Holland | 616 | 396-5266 | 393-5767 |
| Gratiot | Mid-MI DHD | Ithaca | 989 | 875-1019 | 875-1032 | Presque Isle | District 4 | Rogers City | 989 | 734-4723 | 356-3529 |
| Hillsdale | Branch/Hills/St Jo | Hillsdale | 517 | 437-7395x0307 | 437-0166 | Roscommon | Cent MI DHD | Prudenville | 989 | 366-9166 | 366-8921 |
| Houghton | Western UP Dist | Hancock | 906 | 482-7382 | 482-9410 | Saginaw | Saginaw County | Saginaw | 989 | 758-3887 | 758-3888 |
| Huron | Huron County | Bad Axe | 989 | 269-9721 | 269-4181 | St. Clair | St. Clair County | Port Huron | 810 | 987-5300 | 985-4340 |
| Ingham | Ingham County | Lansing | 517 | 887-4308 | 887-4379 | St. Joseph | Branch/Hills/St Jo | Three Rivers | 269 | 273-2161x0241 | 273-2452 |
| Ionia | Ionia County | Ionia | 616 | 527-5341 | 527-8208 | Sanilac | Sanilac County | Sandusky | 810 | 648-4098x162 | 648-5276 |
| Iosco | District 2 | Tawas City | 989 | 362-6183 | 362-5211 | Schoolcraft | LMAS DHD | Manistique | 906 | 341-6951 | 341-5230 |
| Iron | Dick-Iron Dist | Iron River | 906 | 265-9913 | 265-4174 | Shiawassee | Shiawassee County | Corunna | 989 | 743-2355 | 743-2362 |
| Isabella | Cent MI DHD | Mt. Pleasant | 989 | 773-5921 | 773-4319 | Tuscola | Tuscola County | Caro | 989 | 673-8114 | 673-7490 |
| Jackson | Jackson County | Jackson | 517 | 768-1662 | 788-4256 | Van Buren | Van Buren-Cass DHD | Hartford | 269 | 621-3143 | 621-2725 |
| Kalamazoo | Kalamazoo County | Kalamazoo | 269 | 373-5267 | 373-5060 | Washtenaw | Washtenaw County | Ypsilanti | 734 | 544-6700 | 544-6706 |
| Kalkaska | District 10 | Kalkaska | 231 | 258-8669 | 258-2805 | Wayne (out-Wayne) | Wayne County | Wayne | 734 | 727-7078 | 313-967-3044 |
| Kent | Kent County | Grand Rapids | 616 | 632-7228 | 632-7085 | Detroit | Detroit City | Detroit | 313 | 876-4000 | 877-9286 |
| Keweenaw | Western UP Dist | Hancock | 906 | 482-7382 | 482-9410 | Wexford | District 10 | Cadillac | 231 | 775-9942 | 775-4127 |

**STATE OF MICHIGAN CONTACTS**

**Immunization Division**
Ph: 517-335-8159
Fax: 517-335-9855

**Communicable Disease Division**
Ph: 517-335-8165
Fax: 517-335-8263

**Bureau of Laboratories**
Ph: 517-335-8063
Fax: 517-335-9631

Updated January 2018

**STATE OF MICHIGAN COMMUNICABLE DISEASE AFTER HOURS CONTACT: (517) 335-9030**

**Michigan Department of Health and Human Services**
333 South Grand Avenue
Lansing, MI 48909

# HEPATITIS C – CASE REPORT FORM

Reporting is expressly allowed under HIPAA and required by Michigan Public Act 368 of 1978, 333.5111.
Report to local health departments within 24 hours (unless otherwise noted) if the agent is identified by clinical or laboratory diagnosis.

## Case Identification

| **First:** | **Last:** | **Middle:** | |
|---|---|---|---|
| **Street Address:** | | | |
| **City:** | **County:** | **State:** | **Zip:** |
| **Home Phone:** ( ) | **Cell/Other Phone:** ( ) | | |

## Case Demographics

| **Sex:** ☐ Male ☐ Female ☐ Unknown | **Date of Birth** _ _/ _ _/ _ _ _ _ | **Age:** | **Age Units:** ☐ Days ☐ Months ☐ Years |
|---|---|---|---|

**Race (Check all that apply):**

☐ Caucasian ☐ Black/African American ☐ American Indian/Alaskan Native

☐ Asian ☐ Hawaiian/Pacific Islander ☐ Unknown ☐ Other (Specify): _____

| **Hispanic Ethnicity:** ☐ Hispanic/Latino ☐ Non-Hispanic/Latino ☐ Unknown | **Arab Ethnicity:** ☐ Arab ☐ Non-Arab ☐ Unknown |
|---|---|

## Clinical Information

| **Testing Date:** _ _/ _ _/ _ _ _ _ | **Test Result:** ☐ Positive ☐ Negative ☐ Unknown |
|---|---|

**Is the patient experiencing any symptoms of Hepatitis C infection (e.g. fever, headache, malaise, anorexia, abdominal discomfort, diarrhea, nausea, vomiting)?**

☐ Yes ☐ No ☐ Unknown

| **Is or was the patient jaundiced?** ☐ Yes ☐ No ☐ Unknown | **Has the patient ever been previously told they were positive for hepatitis C?** ☐ Yes ☐ No ☐ Unknown |
|---|---|

**Was the patient counseled?:**

☐ Yes ☐ No ☐ Unknown

**Was the patient linked to care?:**

☐ Yes ☐ No ☐ Unknown If yes, where? _____

## Testing Agency

| **Name of Testing Agency:** | **Phone:** ( ) |
|---|---|

**Additional Information:**

**Michigan Department of Health and Human Services**
333 South Grand Avenue
Lansing, MI 48909

# HCV Rapid Antibody Test – Summary Sheet

Please complete the tables below and send this Summary Sheet to the Viral Hepatitis Prevention and Surveillance Unit at MDHHS-Hepatitis@michigan.gov.

| **Testing Agency** | |
|---|---|
| **Name of Testing Agency:** | **Point-of-Contact:** |
| **Phone:** (  ) | **E-mail:** |
| **Name of Testing Event (if applicable):** | |

| NUMBER OF TESTS PERFORMED | NUMBER OF PEOPLE SCREENED HCV ANTIBODY-POSITIVE | NUMBER OF PEOPLE LINKED TO CARE |
|---|---|---|
| | | |

| **Additional Comments/Information** |
|---|
| |

AGENCY OR FACILITY LETTERHEAD

## Rapid Hepatitis C Antibody Test Result

| | |
|---|---|
| **Client Name:** | **Test Date:** _ _ / _ _ / _ _ _ _ |
| **Client Date of Birth:**<br>_ _ / _ _ / _ _ _ _ | |
| **Counselor/Tester Name:** | |

**The Hepatitis C Antibody result from the Rapid Hepatitis C Antibody Test is:** ☐ **NONREACTIVE**

**What does a non-reactive result mean?**

- No antibodies to the Hepatitis C virus were found in your blood.
- You are most likely not infected with Hepatitis C at this time; however, it can take up to 6 months after being exposed to Hepatitis C for your body to make enough antibodies for this test to measure them.
- If you were exposed to Hepatitis C, or used drug injection or preparation equipment in the past 6 months, **you should get tested again 6 months from now or 6 months from the day of your last exposure.**
- This test result does not mean you cannot be infected with Hepatitis C in the future.

**How do I STAY Hepatitis C- Negative?**

- Do not share needles, syringes, or other equipment (e.g. cookers, spoons, cotton, filters, and water) used to prepare or inject drugs. Do not re-use needles. Bleaching needles or syringes does not work to kill the Hepatitis C virus.
- Do not share personal items that could have infected blood on them, including toothbrushes, razors, or glucose monitoring equipment.
- Do not get tattoos, body art, or body piercings in a non-licensed, informal place (e.g. homes or jails).
- Practice safe sex.

AGENCY OR FACILITY LETTERHEAD

## Rapid Hepatitis C Antibody Test Result

| **Client Name:** | **Test Date:** _ _ / _ _ / _ _ _ _ |
|---|---|
| **Client Date of Birth:**<br>_ _ / _ _ / _ _ _ _ | |
| **Counselor/Tester Name:** | |

**The Hepatitis C Antibody result from the Rapid Hepatitis C Antibody Test is:** ☐ **REACTIVE**

| **What does a reactive result mean?** |
|---|
| • You have been infected with the Hepatitis C virus at some time and may still have the virus in your blood right now.<br>• Some people clear the virus from their bodies after infection, but most do not. |
| **Next Steps** |
| • To find out if you still have the virus in your blood, you need to have a second blood test called a HCV PCR test.<br>• To get the HCV PCR test, you need to see a doctor. If the test shows that you currently have hepatitis C virus in your blood, you will see the doctor again to talk about your liver health and treatment options. |
| **How do I avoid spreading Hepatitis C to others?** |
| • Do not share needles, syringes, or other equipment (e.g. cookers, spoons, cotton, filters, and water) used to prepare or inject drugs. Do not re-use needles. Bleaching needles or syringes does not work to kill the Hepatitis C virus.<br>• Do not share personal items that could have infected blood on them, including toothbrushes, razors, or glucose monitoring equipment.<br>• Do not get tattoos, body art, or body piercings in a non-licensed, informal place (e.g. homes or jails).<br>• Practice safe sex. |

**Referral Information:**

## It is important that you keep this appointment.

| **Appointment Date:** _ _ / _ _ / _ _ _ _ **Appointment Time:** _ _ : _ _ ☐ AM ☐ PM | |
|---|---|
| **Organization:** | |
| **Contact Person:** | **Phone Number:**<br>(  ) |

Appendix H

# Client Referral Resources

## HEALTH INSURANCE ENROLLMENT RESOURCES

- U.S. Health Insurance Marketplace
  www.healthcare.gov
- State of Michigan – Department of Insurance and Financial Services Consumer Marketplace Assistance
  https://www.michigan.gov/difs/
- Michigan County Health Plans
  www.michigan.gov/mdhhs/0,5885,7-339-71547_2943_52115-203917--,00.html

## FINANCIAL RESOURCES

- Free or Low-Cost Healthcare Resources
  www.michigan.gov/mdhhs/0,5885,7-339-71547_2943_52115---,00.html
- Vaccine Payment Assistance
  www.michigan.gov/documents/mdhhs/Helping_Adults_Pay_Vaccine_514117_7.pdf

## SUPPORT GROUPS

- Hepatitis C Support Groups - Michigan
  https://www.hepatitiscentral.com/hepatitis-c/support/mi/

## PROGRAM RESOURCES

- Michigan Harm Reduction/Syringe Service Programs
  https://www.michigan.gov/
  mdhhs/0,5885,7-339-71550_2941_4871_93142_93144-498269--,00.html
- Michigan Community Mental Health Services Programs
  www.michigan.gov/documents/cmh_8_1_02_37492_7.PDF

## OTHER RESOURCES

- Regional Substance Abuse Coordinating Agencies
  www.michigan.gov/documents/PIHPDIRECTOR_97962_7.pdf
- HIV Counseling and Testing Locations
  https://miunified.org/Services/Prevention

Appendix I

## Rapid Hepatitis C Antibody Testing – Facility Preparation Checklist

*Testing Agency:*

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| No. | ITEM | COMPLETED (✓) |
|---|---|---|
| 1. | Valid CLIA Waiver obtained | |
| 2. | Bloodborne pathogen training completed | |
| 3. | Quality assurance plan developed (including appropriate storage conditions for kit controls) | |
| 4. | Authorizing healthcare provider | |
| 5. | Written policies and procedures manual | |
| 6. | Referral relationship established for reactive results | |
| 7. | Local health department contacted and results reporting mechanism in place | |
| 8. | Referral resources for low-cost primary care, STD and HIV testing, substance abuse and mental health available | |
| 9. | Testing supplies – kits, thermometer, timer, disinfectant solution, medical waste containers | |
| 10. | Referral tracking mechanism | |
| 11. | Client record storage and retention policy in place | |
| 12. | Staff test kit training | |
| 13. | Staff hepatitis C education and counseling training | |