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# Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AASLD</td>
<td>American Association for the Study of Liver Disease</td>
</tr>
<tr>
<td>ALT</td>
<td>Alanine aminotransferase</td>
</tr>
<tr>
<td>AST</td>
<td>Aspartate aminotransferase</td>
</tr>
<tr>
<td>BCD</td>
<td>Bureau of Communicable Diseases</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CIA</td>
<td>Chemiluminescence immunoassay</td>
</tr>
<tr>
<td>CSTE</td>
<td>Council for State and Territorial Epidemiologists</td>
</tr>
<tr>
<td>DAA</td>
<td>Direct-acting antiviral</td>
</tr>
<tr>
<td>DHS</td>
<td>Department of Health Services</td>
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<tr>
<td>DPH</td>
<td>Division of Public Health</td>
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<tr>
<td>EIA</td>
<td>Enzyme immunoassay</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>HAV</td>
<td>Hepatitis A virus</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B virus</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C virus</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>IDSA</td>
<td>Infectious Disease Society of America</td>
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<tr>
<td>LHD</td>
<td>Local health department</td>
</tr>
<tr>
<td>NAT</td>
<td>Nucleic acid test</td>
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<tr>
<td>NAAT</td>
<td>Nucleic acid amplification test</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic acid</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
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<tr>
<td>WEDSS</td>
<td>Wisconsin Electronic Disease Surveillance System</td>
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</table>
Introduction

The purpose of this document is to provide local health departments (LHDs) information on following up, preventing, and identifying cases of hepatitis C virus (HCV) infection.

This introduction describes the purpose of disease reporting for HCV, provides a brief overview of the disease, and describes the epidemiology of HCV in the U.S. and Wisconsin.

Disease Reporting

The Wisconsin Department of Health Services (DHS), Division of Public Health (DPH), Bureau of Communicable Diseases (BCD), coordinates statewide communicable disease surveillance and control activities under the authority of Wis. Stat. ch. 252. Hepatitis C is to be reported to the patient’s local health officer or to the local health officer’s designee within 72 hours of recognition of a case or suspected case, per Wis. Admin Code § DHS 145.04(3)(b). It is to be reported electronically through the Wisconsin Electronic Disease Surveillance System (WEDSS) or by mailing or faxing a completed Acute and Communicable Disease Case Report (F-44151) to the address on the form. According to Wis. Admin Code § DHS 145.04(1), reporting is the responsibility of persons licensed under Wis. Stat. ch. 441 or 448, laboratories, health care facilities, teachers, principals, or nurses serving a school or day care center, and any person who knows or suspects that a person has a communicable disease identified in Appendix A.

The purpose of disease reporting and surveillance is to:

• Identify sources of infection and prevent further transmission.
• Identify new groups at risk and reduce the number of new cases.
• Inform cases about treatment options and prevent additional liver damage.
• Educate individuals about transmission of HCV and how to reduce the risk of transmission.
• Better understand the epidemiology of HCV infection and the burden of morbidity.

HCV Disease

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

Symptoms

Most persons with newly acquired HCV infections are either asymptomatic or experience mild symptoms that do not result in a health care visit. Only 20–30% of newly infected persons experience symptoms, which may include:

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

Because the majority of people with HCV infection do not experience any symptoms, many do not know they have HCV.
Transmission

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

- Sharing needles, syringes, or other equipment used to prepare or inject drugs (sometimes referred to as “works”).
- Occupational exposures, such as a needle stick injury in a health care setting.
- Birth to a mother who has HCV.
- Receipt of blood, blood products, or organs from a donor with HCV. (This was a common method of transmission before 1992, when HCV blood screening became available).

Less commonly, HCV can be spread through:

- Sharing personal care items that have come into contact with the blood of a person who has HCV (for example, toothbrushes, razors, nail clippers).
- Sexual contact with a person who has HCV.
- Tattoos and body piercings done somewhere other than a licensed tattoo facility or with nonsterile instruments.

Testing Recommendations

Testing for HCV is recommended for:

- People who inject or formerly injected drugs, including those who injected only once many years ago.
- Everyone born from 1945 through 1965 (baby boomers).
- Recipients of clotting factor concentrates made before 1987.
- Recipients of donated blood or organs prior to 1992.
- Chronic hemodialysis patients.
- People with known exposures to HCV, such as:
  - Health care workers after needle sticks involving HCV-positive blood.
  - Recipients of blood or organs from a donor who tested HCV-positive.
- People living with HIV.
- Children born to mothers who have HCV.
- People who are or who have been incarcerated.
- People who use intranasal drugs.
- People who get a tattoo somewhere other than a licensed tattoo facility.

Treatment

Hepatitis C can be treated. An acute infection may clear on its own without treatment in about 15-25% of people. Since 2011, new treatments, known as direct-acting antivirals (DAAs), have become available and have been shown to cure 95% of HCV-infected persons 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.

As new therapies are available, health care professionals can access timely 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).
Epidemiology of HCV in the U.S. and Wisconsin

In the U.S., an estimated 2.4 million people have chronic HCV infection. However, it is estimated that only half of these people are aware of their diagnosis.

In Wisconsin, an estimated 70,000-95,000 residents are living with HCV, fewer than half of whom have been diagnosed with the virus. The majority of HCV reports in Wisconsin are among baby boomers (born between 1945 and 1965) and young people who inject drugs. In recent years, several states, including Wisconsin, have reported that the number of infants born to women who have HCV has increased. In 2018, to monitor the number of children infected with HCV through perinatal exposure, the CDC implemented a new case definition for HCV perinatal infection.

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.

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: 1) screening tests that detect hepatitis C antibody, and 2) confirmatory tests that detect HCV RNA. The CDC-recommended testing sequence (see Figure 1, page 12) consists of an initial hepatitis C antibody test. A positive or reactive hepatitis C antibody test is followed by an HCV RNA test.

1. 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.

Types of tests

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

- **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.
- **Chemiluminescence Immunoassay (CIA):** The CIA test is a laboratory-conducted assay. It is comparable to the EIA test but is used much less frequently.
- **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 fingerstick 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 health departments.

The signal-to-cut-off ratio is no longer used in the HCV testing algorithm.
Positive antibody test
If the HCV antibody test is positive or reactive, HCV antibody is detected. The presence of HCV antibody indicates one of the following:
1. Current HCV infection.
2. Past HCV infection that has resolved.
3. False positivity.
Further testing needs to be done to identify if there is current HCV infection.

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

For people who might have been exposed to HCV within the past six months, testing for HCV RNA or follow-up testing for HCV antibody at a later time is recommended. For people with compromised immune systems, an HCV antibody test may not work and testing for HCV RNA can be considered.

2. Confirmatory Test—Detects Hepatitis C RNA
A positive or reactive HCV antibody test should be followed by testing for HCV RNA. Tests that detect HCV RNA are confirmatory tests that determine whether a person has 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.

- **Qualitative HCV RNA**: Qualitative HCV RNA tests indicate whether detectable HCV RNA is present in the sample or not. These tests do not provide a quantitative level of HCV and are not used for baseline HCV RNA levels or for monitoring response to treatment.
- **Quantitative HCV RNA**: Quantitative HCV RNA tests generate an actual HCV RNA level that may provide useful information as a baseline HCV RNA or to monitor response to treatment.
- **Genotyping**: There are seven distinct genotypes and more than 67 subtypes of HCV. Genotype information may be important for deciding which medications will be used to treat the patient’s HCV.

Positive (detected) confirmatory test
If the test indicates that HCV RNA was detected, there is current HCV infection and the patient should be linked to care.

Negative (not detected) confirmatory test
If the test indicates that HCV RNA was not detected, 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.

To differentiate past resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. A person should have repeat HCV RNA testing if the person is suspected to have had HCV exposure within the past six months, has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.
**Additional HCV-Related Tests**

**Alanine aminotransferase (ALT):**
Elevated ALT results may indicate HCV infection. ALT levels greater than 200 IU/L are included in the CDC case definition for HCV. It is common for patients with chronic hepatitis C to have liver enzyme levels that fluctuate, with periodic returns to normal or near normal levels. Liver enzyme levels can remain normal for over a year despite chronic liver disease.

**Aspartate aminotransferase (AST):**
Elevated AST levels may indicate liver disease and can be used to monitor the disease and assess the effectiveness of treatment.

**Bilirubin:**
Jaundice (yellow color in the skin or eyes) can be a sign of acute HCV infection. This yellow color is caused by elevated bilirubin levels because the liver is not functioning properly. Elevated bilirubin levels (≥3.0 mg/dL) are included in the CDC case definition for HCV as a laboratory measure of jaundice.
Figure 1. HCV Testing Sequence

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

- **HCV antibody**
  - Nonreactive: No HCV antibody detected → STOP*
  - Reactive: HCV RNA
    - Not Detected: No current HCV infection → Additional testing as appropriate†
    - Detected: Current HCV infection → Link to care

* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV 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.

# Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions

## Table: Interpretation of Results and Further Actions

<table>
<thead>
<tr>
<th>Test Outcome</th>
<th>Interpretation</th>
<th>Further Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV antibody nonreactive</td>
<td>No HCV antibody detected</td>
<td>Sample can be reported as nonreactive for HCV antibody. No further action required.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If recent exposure in person tested is suspected, test for HCV RNA.</td>
</tr>
<tr>
<td>HCV antibody reactive</td>
<td>Presumptive HCV infection</td>
<td>A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.</td>
</tr>
<tr>
<td>HCV antibody reactive, HCV RNA detected</td>
<td>Current HCV infection</td>
<td>Provide person tested with appropriate counseling and link person tested to care and treatment.</td>
</tr>
<tr>
<td>HCV antibody reactive, HCV RNA not detected</td>
<td>No current HCV infection</td>
<td>No further action required in most cases.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In certain situations, follow up with HCV RNA testing and appropriate counseling.</td>
</tr>
</tbody>
</table>

*If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

*It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

*If the person tested is suspected of having HCV 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.

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*Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratories. MMWR 2015;64(19).*
Local Health Jurisdiction Guidelines for Conducting HCV Investigations

The following information outlines the process for hepatitis C case investigation. If these steps cannot be completed for all cases, guidance on prioritizing cases has been included. Prioritization of HCV cases may vary across jurisdictions due to capacity limitations determined by the local health department.

Routine case investigation

**Step 1** Determine if the case was previously reported to the Wisconsin Electronic Disease Surveillance System (WEDSS) as an HCV case (of any type: hepatitis C acute, hepatitis C chronic, hepatitis C perinatal, or hepatitis C).

A. If the case was previously reported, attach all new lab reports (positive antibody and positive/negative RNA results) to the existing WEDSS incident for the patient. There should only be one disease incident of HCV per person in their lifetime.

   1. If the patient was previously reported as a **confirmed chronic case**, no further investigation is needed. Do not proceed with the following steps.
   2. If the patient was previously reported as a **probable chronic case**, the case was reported during the current calendar year and has not been finalized in WEDSS, and the new laboratory evidence **confirms** infection, update the resolution status to **confirmed**.
   3. If the case has been previously investigated, no further investigation is needed and you do not proceed with the following steps.

B. If the case was not previously reported in Wisconsin, further investigation is needed. Proceed with the following steps.

**Step 2** Contact the medical provider (or laboratory, if needed) to collect information to determine the correct HCV case definition.

A. Ask about:

   1. The reason for testing.
   2. Results of any previous HCV testing.
   3. Symptoms: jaundice, fever, malaise (general feeling of being unwell), nausea, diarrhea, headache, anorexia, vomiting, abdominal pain, or joint pain.
   4. Liver enzyme (ALT) test results.
   5. Bilirubin test results.
   6. The date of illness onset.
   7. The possible source of infection and risk factors during the period two weeks to six months (14-180 days) before onset of illness.
   8. Was there an alternate diagnosis that explains any of the symptoms or other clinical findings (elevated ALT, elevated bilirubin)? For example, does the person have liver disease due to alcohol exposure or hemochromatosis? Or does the...
person have advanced liver disease due to a pre-existing chronic HCV infection? Or does the person have a different acute viral hepatitis infection (hepatitis A virus or hepatitis B virus)?

B. If no RNA test has been done, discuss the importance of confirming the diagnosis with an RNA test. This may be a good time to talk to the healthcare provider about the importance of ordering an HCV test that ‘reflexes’ to RNA. This means that the specimen is first tested for HCV antibody, and if the specimen is positive for HCV antibody then an HCV RNA test is automatically conducted on the specimen.

Step 3  
Contact the case to collect information.

A. If no RNA test has been done, discuss the importance of confirming the diagnosis with an RNA test through their healthcare provider or other testing site

B. If an acute HCV infection is suspected, attempt to determine:
   1. The date of onset of any symptoms.
   2. Symptoms: jaundice, fever, malaise (general feeling of being unwell), nausea, diarrhea, headache, anorexia, vomiting, abdominal pain or joint pain.
   3. The source of infection by asking about potential exposures. Pay particular attention to the period two weeks to six months (14-180 days) before onset of illness. Exposure Information should include:
      a. Injection drug use.
      b. Occupational or other needle stick injuries.
      c. Receipt of blood transfusion or other blood products, organs or tissues.
      d. Potential medical or dental exposures within six months prior to onset of current illness.
      e. Other exposures within the six months prior to onset of current illness, including but not limited to tattooing, piercing, or acupuncture.
      f. Accidental exposure of skin, eyes, mucous membranes, or a wound to the blood of another person.
      g. High-risk sexual contact (multiple partners, history of other sexually transmitted infections [STIs], anal sex, etc.).

C. If a chronic HCV infection is suspected, collect as much information as possible, including the information on the lab clinical and risk tabs in WEDSS.
**Step 4** Educate the case about hepatitis C.

Focus on:

- **Testing:** For people who might have been recently infected with HCV within the past six months, testing for HCV RNA at a later time is recommended.
- **Treatment:** There are treatments available that can cure HCV. Patients should talk with their primary care provider about treatment options.
- **Minimizing disease progression.**
  - Avoid or reduce alcohol intake.
  - Be evaluated for other conditions that may accelerate liver damage, such as hepatitis B or HIV.
  - Get vaccinated against hepatitis A and hepatitis B.
- **Reducing risk of transmission**
  - Do not donate blood, body organs, other tissues, or semen.
  - Do not share personal care items that might have blood on them, such as toothbrushes, razors, nail clippers, blood testing equipment, etc.
  - HCV is not spread by sharing eating utensils, breastfeeding, hugging, kissing, holding hands, coughing, or sneezing. It is also not spread through sharing food or drink.
  - Cover cuts and sores on the skin to keep from spreading infectious blood or secretions.
  - Use protection if sexually active.
  - Do not share needles, syringes, water, cleaning materials, “works” or other equipment used to prepare drugs.
  - If you are a health care worker, always follow routine barrier precautions and safely handle needles or other sharps.
  - Only get tattoos or body piercings from licensed facilities.
  - Persons with HCV should **not** be excluded from work, school, play, child care, or other settings on the basis of their HCV infection status. The risk of transmission is low.

**Step 5** Identify and manage contacts of the case.

- Needle-sharing partners and long-term sexual contacts should be educated about transmission of HCV and be tested.
- If the case is a health care worker, evaluate the potential for exposing patients. Encourage the person to seek out counseling from employee health services regarding risk reduction strategies and to practice standard precautions.
- Determine if case has donated blood or plasma in the six months prior to onset or any time thereafter. If so, notify the blood bank or plasma center with particulars (date, etc.).
- Recommend that contacts that are not already immune be vaccinated against other forms of hepatitis—hepatitis A virus and hepatitis B virus—to prevent dual infections.
- Household (nonsexual) contacts of HCV infected patients do not need to be tested for HCV unless personal care items have been shared.
Managing Special Situations

Case age is younger than 36 months at positive HCV test result (possible perinatal case)

- If RNA test has not been done, contact health care provider to encourage RNA testing at age 2 months or later. **Note:** HCV antibody testing is not recommended for infants under age 18 months.
- If the mother has not been tested for HCV, recommend HCV testing for the mother to determine if the child was infected perinatally.
- If mother has HCV, educate and follow up as for a normal case.
- Inform the birth mother that women with HCV infection have a 5% risk of transmitting HCV to future children during future pregnancies and deliveries.
- Recommend hepatitis A and hepatitis B vaccines for the infant (hepatitis B vaccine series starting at birth and the hepatitis A series starting at age 1 year), the mother, and for future children.

Case is pregnant

- Inform the pregnant patient that the risk of transmitting HCV to a fetus during a pregnancy and delivery is about 5%.
- Recommend pregnant women talk to their health care provider about hepatitis A and hepatitis B vaccination.
- Recommend pregnant women speak to their health care provider about receiving HCV treatment after delivery and before any subsequent pregnancies.

Case has a needle stick or similar exposure, is a health care worker, has a suspected iatrogenic infection, or is a recent blood donor or recipient

Questions about significant exposure should be directed to the **Wisconsin Healthcare-Associated Infection (HAI) Prevention Program** at 608-267-7711.

HCV Prevention Messages

- Currently there is not a 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 needles, syringes, or other equipment to prepare or inject drugs, steroids, hormones, or anything else.
- Do not use personal items that may have come into contact with the blood of a person with HCV, such as toothbrushes, razors, nail clippers, needles, syringes, blood testing equipment, etc.
- 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 water. Gloves should be worn when cleaning up blood spills.
Hepatitis C Case Definitions

After the ‘Local Health Jurisdiction Guidelines for Conducting HCV Investigations’ have been followed, the case should be classified according to the CDC definitions below.

Acute Case (CDC 2020)

Clinical Criteria:
All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally.

One or more of the following:
- Jaundice
- OR
- Peak elevated total bilirubin levels ≥ 3.0 mg/dL
- OR
- Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L

AND

The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Laboratory Criteria for Diagnosis:
Confirmatory laboratory evidence:
- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)
  - OR
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)

Presumptive laboratory evidence:
- A positive test for antibodies to hepatitis C virus (anti-HCV)

Criteria to Distinguish a New Case from an Existing Case:
- A new acute case is an incident case that is over the age of 36 months and has not previously been reported meeting case criteria for chronic hepatitis C or for whom there is laboratory evidence of re-infection. Cases under the age of 36 months should be classified under the Perinatal HCV Position Statement (17-ID-08) unless the exposure mode is not perinatal (e.g., healthcare acquired).
- Acute cases determined via anti-HCV test conversion do not need to have a positive HCV viral detection test reported to be considered confirmed acute cases.
- For probable acute cases, the presence of a negative HCV viral detection test result, in the absence of criteria that would allow for confirmation, indicates that a case should not be classified as probable acute and should not be reported to CDC.
Case Classification:

**Probable**
- A case that meets clinical criteria and has presumptive laboratory evidence
  - AND
- Does not have a hepatitis C virus detection test reported
  - AND
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months

**Confirmed**
- A case that meets clinical criteria and has confirmatory laboratory evidence
  - OR
- A documented negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis
  - OR
- A documented negative HCV antibody OR negative hepatitis C virus detection test (in someone without a prior diagnosis of HCV infection) followed within 12 months by a positive hepatitis C virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis

**Chronic Case (CDC 2020)**

Clinical Criteria:
All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally.

One or more of the following:
- Jaundice
  - OR
- Peak elevated total bilirubin levels ≥ 3.0 mg/dL
  - OR
- Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L

AND

The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Laboratory Criteria for Diagnosis:
Confirmatory laboratory evidence:
- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)
  - OR
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)

Presumptive laboratory evidence:
- A positive test for antibodies to hepatitis C virus (anti-HCV)
Criteria to Distinguish a New Case from an Existing Case:

- All jurisdictions are encouraged to track negative HCV viral detection tests to document both spontaneous clearance of infection or sustained viral response to HCV treatment. Cases that have evidence of having cleared the infection at time of initial report or are considered false positive should not be reported to CDC.
- If evidence indicating resolution of infection is received after a confirmed chronic case has been reported to CDC, the case report does not need to be modified as it was a confirmed case at the time of initial report. However, negative HCV viral detection test results received on confirmed chronic cases, subsequent to an initial positive result, should be appended to case reports, as feasible, and considered for the purpose of data analysis by each jurisdiction.
- Evidence for re-infection may include a case of confirmed chronic HCV infection that has at least two sequential negative HCV viral detection tests reported, indicative of treatment initiation and sustained virologic response, followed by a positive HCV viral detection test. Under current treatment recommendations, those two negative tests should be at least three months apart, however, the timing may change as standard of care for HCV treatment evolves. Other evidence of reinfection should be considered, including a report of a new genotype on a case that has previously cleared a different genotype. Jurisdictions are encouraged to ensure that cases of HCV treatment failure are not classified as new cases of HCV infection to the extent that it can be determined. Jurisdictions tracking re-infection should also consider collecting data on prior treatment completion (when relevant and possible to document), treatment failure, change in reported genotype if that applies, and the known time frame for reinfection.
- For probable chronic cases, the presence of a negative HCV viral detection test result, in the absence of criteria that would allow for confirmation, indicates that a case should not be classified as probable chronic and should not be reported to CDC.
- A new chronic case is a newly reported case that does not have evidence of being an acute case of HCV infection.
- Jurisdictions are also encouraged to track and classify possible re-infection cases that may have been previously submitted to CDC as a confirmed or probable chronic HCV infection case. Jurisdictions tracking re-infection should also consider collecting data on prior treatment completion (when relevant and possible to document), treatment failure, change in reported genotype if that applies, and the known time frame for reinfection.

Case Classification:

Probable
- A case that does not meet OR has no report of clinical criteria
  AND
- Has presumptive laboratory evidence
  AND
- Has no documentation of anti-HCV or RNA test conversion within 12 months
  AND
- Does not have an HCV RNA detection test reported

Confirmed
- A case that does not meet OR has no report of clinical criteria
  AND
- Has confirmatory laboratory evidence
  AND
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months
Perinatal Infection (CDC 2018)

Clinical Criteria:
Perinatal hepatitis C in pediatric patients may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria for Diagnosis:
- HCV RNA positive test results for infants between 2 to 36 months of age
  OR
- HCV genotype test results for infants between 2 to 36 months of age or greater
  OR
- HCV antigen test results for infants between 2 to 36 months of age or greater.

Epidemiologic Linkage:
Maternal infection with HCV of any duration, if known. Not known to have been exposed to HCV via a mechanism other than perinatal (for example, not acquired via health care).

Criteria to Distinguish a New Case from an Existing Case:
Test results prior to 2 months of age should not be used for classification. Test results after 36 months of age should be reported under the 2020 Acute and Chronic HCV Infection case classification and not as perinatal HCV infection. Cases in the specified age range that are known to have been exposed to HCV via health care, and not perinatally, should be reported under the 2020 case definition. Event date should be based on earliest relevant laboratory test date within the 2 to 36 month window.

Case Classification:
Confirmed
Infant who has a positive test for HCV RNA nucleic acid amplification test (NAAT), HCV antigen, or detectable HCV genotype at ≥2 months and ≤36 months of age and is not known to have been exposed to HCV via a mechanism other than perinatal.
## Hepatitis C Case Classification Table

<table>
<thead>
<tr>
<th>HCV test results</th>
<th>No, does not have enough information to meet clinical criteria above</th>
<th>Yes, meets clinical criteria above</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The classification below is for persons age ≥2 months and ≤36 months at the time of specimen collection who are suspected to have been exposed perinatally.

- Meets age requirement and had positive HCV RNA or detectable HCV genotype results.
- The classifications below are for persons age >36 months only, unless a person age ≤36 months was known to have been exposed non-perinatally.

<table>
<thead>
<tr>
<th>HCV antibody positive only, without a positive HCV RNA result in the same calendar year.</th>
<th>Probable, Chronic</th>
<th>Probable, Acute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any HCV RNA (nucleic acid) test positive or HCV antigen test positive.*</td>
<td>Confirmed, Chronic</td>
<td>Confirmed, Acute</td>
</tr>
<tr>
<td>HCV antibody positive followed by a negative HCV RNA in the same calendar year. (And never had a positive HCV RNA test result.)</td>
<td>Not a Case</td>
<td>Not a Case</td>
</tr>
<tr>
<td>A documented negative HCV antibody test result followed within 12 months by a positive HCV antibody test result (anti-HCV test conversion).</td>
<td>Confirmed, Acute</td>
<td>Confirmed, Acute</td>
</tr>
<tr>
<td>A documented negative HCV antibody test result or negative HCV RNA test result followed within 12 months by a positive HCV RNA test result (HCV RNA test conversion), in the absence of a more likely diagnosis.</td>
<td>Confirmed, Acute</td>
<td>Confirmed, Acute</td>
</tr>
</tbody>
</table>

1. A more likely diagnosis may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic HCV infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.
2. And not known to have been exposed to HCV via a mechanism other than perinatal.
3. Any antibody result, regardless of the signal-to-cutoff ratio; includes rapid tests.
4 Nucleic acid tests for HCV RNA include quantitative, qualitative and genotype testing.
5 When and if a test for HCV antigen is approved by FDA and available.
6 A test result for HCV RNA or antigen that indicates ‘HCV RNA not detected’, ‘Negative’, or below the level of detection for the test.
7 A case with documented anti-HCV test conversion is automatically classified as ‘Confirmed, Acute’ regardless of clinical criteria.
8 A case with documented HCV RNA test conversion, in a person without a prior diagnosis of HCV infection and without a more likely diagnosis, is classified as ‘Confirmed, Acute’ regardless of clinical criteria.

* WDPH is not reclassifying HCV cases in which spontaneous clearance of infection or sustained viral response to treatment has occurred. Therefore, a previously ‘Confirmed, Chronic’ or ‘Confirmed, Acute’ case that has a negative HCV RNA result will remain a ‘Confirmed’ case in WEDSS.
Resources

For Health Care Professionals

Continuing Education

- [Hepatitis C: Basic Facts](#) – Wisconsin Hepatitis C Program and University of Wisconsin HIV Training System
- [Viral Hepatitis Serology Training](#) – Centers for Disease Control and Prevention
- [Hepatitis C Online](#) - University of Washington National Hepatitis Center
- [HIV/HCV Coinfection: An AETC National Curriculum](#) – AIDS Education & Training Center

Hepatitis C Testing

Centers for Disease Control and Prevention (CDC), Viral Hepatitis, Hepatitis C

- [Testing Recommendations for Hepatitis C Virus Infection](#)
- [Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection](#)
- [Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions](#)

Hepatitis C Treatment

- [FDA-approved medications](#) — This link provides information on all HCV treatment medications. Source: [Hepatitis C Online](#), University of Washington National Hepatitis Center.
- [Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD–IDSA)](#) — This link provides recommendations for testing, managing, and treating Hepatitis C.

Wisconsin and National Agencies

- [Wisconsin Department of Health Services, Division of Public Health, Hepatitis C Program—Hepatitis C Fact Sheet](#) (Available in English, Hmong and Spanish)
- [Wisconsin State Laboratory of Hygiene](#)
- [Wisconsin Electronic Disease Surveillance System (WEDSS)](#)

Centers for Disease Control and Prevention (CDC), Viral Hepatitis, Hepatitis C

- HCV Case Definitions: [Acute](#), [Chronic](#), and [Perinatal Infection](#)
- [Hepatitis C FAQs for Health Professionals](#)
- [Hepatitis C FAQs for the Public](#)

National Viral Hepatitis Roundtable (NVHR)

This national coalition’s goal is to eliminate hepatitis B and C in the U.S. The website includes patient and provider resources, and continuing education opportunities.
For Patients

**Help 4 Hep**
This nonprofit provides a peer-to-peer helpline for patients.

**Hep**
A print and online brand for people living with and affected by viral hepatitis, Hep and HepMag.com offer educational and social support for people living with hepatitis.

**American Liver Foundation**
This foundation provides patient education resources for people living with liver disease.

**Vivent Health (formerly known as AIDS Resource Center of Wisconsin / ARCW)**
This organization is an HIV medical care home in Wisconsin with prevention services, including needle exchange services and hepatitis C testing.

**Wisconsin Treatment Directory for Opioid Use Disorder**
This directory for opioid treatment programs provides information on medications combined with counseling and other services.

Acknowledgements

In developing these guidelines, the Wisconsin Hepatitis C Program referenced information from the Centers for Disease Control and Prevention, Washington State Department of Health, and *Hepatitis C Online*, University of Washington National Hepatitis Center.