### Hepatitis C Criteria for Case Diagnosis and Classification*

#### Clinical Criteria

**Acute Hepatitis C**
An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, abdominal pain) AND either a) jaundice, OR b) elevated serum alanine aminotransferase (ALT) levels >200 IU/L, during the period of acute illness.

**Laboratory Criteria for Diagnosis**
- A positive test for antibodies to hepatitis C virus (anti-HCV)
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)

**Criteria to Distinguish a New Case from an Existing Case**
A new acute case is an incident acute hepatitis C case that meets the case criteria for acute hepatitis C and has not previously been reported.

**Case Classification**

**Probable**
- A case that meets clinical criteria and has a positive anti-HCV but has no positive confirmatory HCV tests AND
- Does not have test conversion within 12 months or has no report of test conversion

**Confirmed**
- A case that meets clinical criteria and has a positive confirmatory HCV test OR
- A documented negative HCV antibody or confirmatory HCV test followed within 12 months by a positive result of any of these tests (test conversion).

#### Chronic Hepatitis C

**Clinical Description**
Most hepatitis C virus (HCV)-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe.

**Laboratory Criteria for Diagnosis**
**One or more** of the following two criteria:
- A positive test for antibodies to hepatitis C virus (anti-HCV)
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)

**Criteria to Distinguish a New Case from an Existing Case**

**Case Classification**

**Probable**
- A case that does not meet clinical criteria and has no report of clinical criteria AND
- Does not have test conversion within 12 months or no report of test conversion AND
- Has a positive anti-HCV but has no positive confirmatory HCV tests

**Confirmed**
- A case that does not meet clinical criteria and has no report of clinical criteria AND
- Does not have test conversion within 12 months or no report of test conversion AND
- Has a positive confirmatory HCV test(s)

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### What is a Screening Test?

Hepatitis C antibody results mean that hepatitis C antibodies were found in the blood and a client has been infected with Hepatitis C at some point in time. Results may be reported as:
- Positive
- Reactive
- Highly reactive
- Strongly reactive

### What is a Confirmatory Test?

Hepatitis C confirmatory test methods describe the viral load a client has and determines how infectious they are. “Viral load” is the amount of virus a person has in his or her body for a specific condition. Any positive RNA, NAT, or PCR result indicates active hepatitis C infection.

The genotype test tells the physician what type of treatment may be best for a person infected with the hepatitis C virus. Some individuals may be infected with more than one genotype at a time.

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*Case diagnosis criteria based on 2016 Council for State and Territorial Epidemiologists (CSTE) Case Definitions*
Hepatitis C Screening Test Names

- Hepatitis C Antibody
- Hepatitis C Antibody by EIA
- Hepatitis C Antibody by CHLIA
- Hepatitis C Ab
- HCV Ab
- HCV Ab Screen
- Anti-HCV
- Signal to Cut Off Ratio

Hepatitis C Confirmatory Test Names

- HCN QN bDNA (RNA)
- HCV Ab Confirmation
- HCV Amplification
- HCV ELUT: Singlet (NAT)
- HCV Genotype
- HCV Genotype by Sequencing
- HCV Genotype Lipa
- HCV Genotype SerPl PCR
- HCV NAT
- HCV PCR
- HCV Qual
- HCV RNA
- HCV RNA (International Units)
- HCV RNA Detect/Qual
- HCV RNA PCR
- HCV RNA Quant
- HCV RNA Quant by PCR
- HCV RNA Quant by PCR, interp
- HCV RNA SerPl PCR- Log IU
- FibroSURE
- HCV Subtypes
- Hep C Ab Supplemental
- Hep C QN PCR
- Hep C Quant (IU/mL)
- Hep C SerPI QL PCR
- Hep C Viral RNA QN
- Hepatitis C Quantitation
- Hepatitis C Virus RNA
- Hepatitis C Virus RNA Qual PCR
- Heptimax HCV RNA

Lab Tests Commonly Used by Blood and Plasma Centers

<table>
<thead>
<tr>
<th>Lab Test Name</th>
<th>Lab Test Type</th>
<th>Where Test is Used (Provider)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV ANTIBODY BY CHLIA</td>
<td>Screen</td>
<td>Blood Centers (e.g. American Red Cross)</td>
</tr>
<tr>
<td>HCV ANTIBODY BY EIA</td>
<td>Screen</td>
<td>Blood Centers (e.g. American Red Cross)</td>
</tr>
<tr>
<td>DHCV NAT</td>
<td>Confirmatory</td>
<td>Blood Centers (e.g. American Red Cross)</td>
</tr>
<tr>
<td>HCV NAT AMPLISCREEN</td>
<td>Confirmatory</td>
<td>Blood &amp; Plasma Centers (e.g., CSL Plasma)</td>
</tr>
<tr>
<td>HCV Supplemental Test</td>
<td>Confirmatory</td>
<td>Blood &amp; Plasma Centers (e.g., CSL Plasma)</td>
</tr>
<tr>
<td>NHCV</td>
<td>Confirmatory</td>
<td>Blood &amp; Plasma Centers (e.g., Saturn Biomedical)</td>
</tr>
<tr>
<td>HCV VM, PCR</td>
<td>Confirmatory</td>
<td>Blood &amp; Plasma Centers</td>
</tr>
<tr>
<td>ULTRIO Assay</td>
<td>Confirmatory</td>
<td>Blood &amp; Plasma Centers</td>
</tr>
</tbody>
</table>

Blood and Plasma

Blood is used for transfusions, during chemotherapy treatments, to have on hand for emergency purposes, etc. Plasma is used for the creation of treatments (immunological disorders, wound healing), therapies (treatment of bleeding disorders, shock and burns), and other therapeutic formulations.

FibroSURE

FibroSURE testing makes an assessment of liver status following a diagnosis of hepatitis C. It determines the baseline status of the liver before initiating HCV therapy, and is used for post-treatment assessment of liver status six months after completion of therapy. FibroSURE can also be used for a noninvasive assessment of liver status in patients who are at increased risk of complications from a liver biopsy.

NOTE: If unsure about whether or not a lab test is for hepatitis C screening or confirmatory, please consult the lab testing facility or Indiana State Department of Health (ISDH). The Health Department contact number is 317.233.7125