

# Hepatitis C

## Interpretation of Laboratory Reports

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

#### Acute Hepatitis C

##### Clinical Description

An acute illness with a discrete onset of any sign or symptom\*\* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain) and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >400IU/L.

\*\*A documented negative HCV antibody laboratory test result followed within 6 months by a positive test (as described in the laboratory criteria for diagnosis) result does not require an acute clinical presentation to meet the surveillance case definition.

##### Laboratory Criteria for Diagnosis

One or more of the following two criteria:

- Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios: <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm>) OR
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)

AND, if done, meets the following two criteria:

- Absence of IgM antibody to hepatitis A virus (IgM anti-HAV)
- AND**
- Absence of IgM antibody to hepatitis B core antigen (IgM anti-HBc)

##### Case Classification

##### **Confirmed**

A case that meets the clinical case definition is laboratory confirmed and is not known to have chronic hepatitis C.

#### 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 (except in persons less than 18 months of age, for whom only criteria 3 would meet the case classification criteria):

- Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios: <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm>) OR
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)

##### Case Classification

##### **Probable**

A case that does not meet the case definition for acute hepatitis C, is anti-HCV positive (repeat reactive) by EIA, and has alanine aminotransferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cut-off ratio is unknown.

##### **Confirmed**

A case that meets the clinical case definition is laboratory confirmed and is not known to have acute hepatitis C. Chronic (Past or Present) Case Definition- May be symptomatic or asymptomatic; can be probable or confirmed. Does not meet definition of acute hepatitis C AND is laboratory confirmed.

### 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.

### Hepatitis C Screening Test Names

- Hepatitis C Antibody
- Hepatitis C Antibody by EIA
- Hepatitis C Antibody by CHLIA
- Hepatitis C Ab
- Hepatitis C Virus Ab
- Hepatitis C Virus Ab IgG
- Hep C Ab
- Hep C Ab QL
- Hep C IgG
- 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 SerPI PCR
- HCV NAT
- HCV PCR
- HCV Qual
- HCV RNA
- HCV RNA (International Units)
- HCV RNA Detect/Qual
- HCV RNA PCR
- HCV RNA Qnt Real-time PCR
- HCV RNA Quant
- HCV RNA Quant by PCR
- HCV RNA Quant by PCR, interp
- HCV RNA SerPI 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

Lab Test Name	Lab Test Type	Where Test is Used (Provider)
HCV ANTIBODY BY CHLIA	Screen	Blood Centers (e.g.; American Red Cross)
HCV ANTIBODY BY EIA	Screen	Blood Centers (e.g.; American Red Cross)
DHCV NAT	Confirmatory	Blood Centers (e.g.; American Red Cross)
HCV NAT AMPLISCREEN	Confirmatory	Blood Plasma Centers (e.g.; Indiana Blood Center)
NHCV	Confirmatory	Blood Plasma Centers
HCV VM, PCR	Confirmatory	Blood Plasma Centers
ULTRIO Assay	Confirmatory	Blood Plasma Centers

### 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 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 Health (ISDH). Health Department contact number: 317.233.7125