MAYO CLINIC LABORATORIES

Test Definition: HCVL

Hepatitis C Virus Antibody Confirmation, Serum

Overview

Useful For

Confirming the presence of hepatitis C virus (HCV)-specific IgG antibodies in serum specimens that are reactive by HCV antibody screening tests

Distinguishing between true- and false-reactive HCV antibody screening test results

This test is **not intended for** use as an HCV antibody screening test for blood or human cells/tissue donors.

This assay is **not useful for** detection of early or acute hepatitis C (<2 months from exposure) as immunocompromised patients may not develop detectable HCV antibodies in blood until 6 months after infection.

This assay is **not useful for** differentiating between past (resolved) and chronic hepatitis C.

Testing Algorithm

This test is available as a confirmatory test for reactive Hepatitis C virus (HCV) antibody screening test results.

For more information see Hepatitis C: Testing Algorithm for Screening and Diagnosis

Special Instructions

- Hepatitis C: Testing Algorithm for Screening and Diagnosis

Highlights

This test is indicated for individuals with reactive hepatitis C virus (HCV) antibody results but undetectable HCV RNA levels.

Method Name

Line Immunoassay (LIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This test does not differentiate between past (resolved) and chronic hepatitis C. To distinguish between past (resolved)

and chronic hepatitis C, order HCVQN / Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR, Serum.

For screening of asymptomatic individuals for HCV, order HCSRN / Hepatitis C Virus (HCV) Antibody Screen with Reflex to HCV RNA, PCR, Asymptomatic, Serum.

For detection of HCV in symptomatic at-risk individuals, order HCVDX / Hepatitis C Virus (HCV) Antibody with Reflex to HCV RNA, PCR, Symptomatic, Serum.

Necessary Information

Date of collection is required.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.4 mL Serum
Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send 1 of the following:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

Serum: 0.1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	30 days	
	Refrigerated	7 days	

Clinical & Interpretive

Clinical Information

Laboratory testing for hepatitis C virus (HCV) infection in patients and donors of organ, blood, cells, tissue, and tissue products usually begins by screening for the presence of HCV antibodies (anti-HCV) in serum, using an US Food and Drug Administration or Food and Drug Administration approved anti-HCV screening test. Specimens that are repeatedly reactive by screening tests should be confirmed by more HCV-specific tests, such as direct detection of HCV RNA by the reverse transcriptase-polymerase chain reaction assay or confirmatory detection of HCV antibodies by serologic assays using recombinant HCV-specific antigens. In patients with reactive HCV antibody screening test results but negative or undetectable HCV RNA test results, HCV antibody confirmatory tests would be useful to distinguish between true- and false-reactive HCV antibody screening test results.

HCV antibodies are usually not detectable during the first 2 months following infection, and they are usually detectable by the late convalescent stage (>6 months after onset) of infection. These antibodies do not neutralize the virus, and they do not provide immunity against this viral infection. Loss of HCV antibodies may occur in the years following resolution of infection.

Despite the value of serologic confirmation of HCV infection, several limitations of this test exist:
-There may be a long delay (up to 6 months) between exposure to the virus and development of detectable HCV antibodies, especially in immunocompromised patients
-A positive test result does not distinguish between past (resolved) and chronic HCV infection
-Serologic tests cannot predict or monitor response to antiviral therapy

For more information see Hepatitis C: Testing Algorithm for Screening and Diagnosis.

Reference Values

Negative

Interpretation

A positive result indicates the presence of hepatitis C virus (HCV)-specific IgG antibodies due to past (resolved) or chronic hepatitis C. Past (resolved) HCV infection (accounting for about 25% of all HCV-infected patients) can be distinguished from chronic HCV infection (about 75% of all cases) only by direct detection of HCV RNA using molecular test methods; eg, HCVQN / Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR (RT-PCR), Serum. HCV RNA is present in acute or chronic hepatitis C but not in past (resolved) HCV infection.

A negative result indicates the absence of HCV-specific IgG antibodies. A reactive HCV antibody screening test result with a negative HCV antibody confirmatory result indicates a probable false-reactive screening test result.

An indeterminate result indicates that HCV-specific IgG antibodies may or may not be present. Indeterminate results should be interpreted along with patient's risk factors for HCV infection and clinical findings. Individuals at risk for HCV infection with indeterminate results should be retested with an HCV antibody confirmatory test in 1 to 2 months to determine the definitive HCV antibody status. Molecular tests to detect HCV RNA may be necessary to determine HCV infection status in those at-risk immunocompromised patients with indeterminate HCV antibody confirmatory test

results due to delayed appearance of fully complement of HCV-specific antibodies.

An unreadable result indicates nonspecific cross reactivity was present and HCV-specific antibody bands could not be visualized reliably. Repeat confirmatory serologic testing in 1 to 2 months or HCV RNA (HCVQN / Hepatitis C Virus [HCV] RNA Detection and Quantification by Real-Time Reverse Transcription-PCR, Serum) is recommended for at-risk patients.

Cautions

Performance characteristics have not been established for the following types of specimens:
-Cadaveric specimens
-Grossly hemolyzed (hemoglobin level of >100 mg/dL)
-Presence of particulate matter

Clinical Reference

1. American Association for the Study of Liver Diseases/Infectious Diseases Society of America/International Antiviral Society-USA. Recommendations for Testing, Managing, and Treating Hepatitis C. Updated March 2025. Accessed December 26, 2025. Available at www.hcvguidelines.org
2. Carithers RL Jr, Marquardt A, Gretch DR. Diagnostic testing for hepatitis C. Semin Liver Dis. 2000;20(2):159-171
3. Pawlotsky JM. Use and interpretation of hepatitis C virus diagnostic assays. Clin Liver Dis. 2003;7(1):127-137
4. Centers for Disease Control and Prevention: Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. MMWR Morb Mortal Wkly Rep. 2003;52(No. RR-3):1-14. Accessed December 26, 2025. Available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5203a1.htm
5. Centers for Disease Control and Prevention (CDC). Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR Morb Mortal Wkly Rep. 2013;62(18):362-365

Performance

Method Description

The MP Diagnostics Hepatitis C Virus (HCV) Blot 3.0 is a line immunoassay that utilizes a nitrocellulose strip containing 4 bands corresponding to recombinant HCV proteins derived from the capsid (C), NS3, NS4, and NS5 regions of the HCV genome. The HCV proteins are expressed as glutathione-S-transferase (GST) fusion proteins, so a GST control band is also present on each strip to indicate reactivity to native GST. Each strip also contains an IgG control band and an anti-IgG band. Individual strips are incubated with either diluted clinical serum specimens or assay controls. Specific antibodies to HCV, if present in the specimen, will bind to the HCV proteins on the strips. The strips are washed to remove unbound materials and then incubated with affinity purified antihuman IgG conjugated with alkaline phosphatase. The conjugated antibody will bind to any antigen-antibody complexes formed on the strips. Unbound conjugate is removed by washing. A BCIP/NBT (5-bromo-4-chloro-3-indolyl-phosphate/nitro blue tetrazolium) substrate is added to visualize reactive protein bands on the strips.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Tuesday

Report Available
1 to 14 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
86804

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HCVL	HCV Ab Confirmation, S	40726-2

Result ID	Test Result Name	Result LOINC® Value
63063	HCV Ab Confirmation, S	40726-2