Test Definition: HCVDX

Hepatitis C Virus (HCV) Antibody with Reflex to HCV RNA, PCR, Symptomatic, Serum

Overview

Useful For

Diagnosis of recent or chronic hepatitis C virus (HCV) infection in symptomatic patients

This test **should not be used** as a screening or confirmatory test for hepatitis C in blood or human cells/tissue donors.

This test profile is **not useful for** detection or diagnosis of acute hepatitis C, since HCV antibodies may not be detectable until after 2 months following exposure and HCV RNA testing is not performed on specimens with negative HCV antibody screening test results.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HCVQN	HCV RNA Detect/Quant, S	Yes	No

Testing Algorithm

If hepatitis C virus (HCV) antibody screen is reactive, then HCV RNA by reverse transcription polymerase chain reaction will be performed at an additional charge.

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

Special Instructions

- Viral Hepatitis Serologic Profiles
- Hepatitis C: Testing Algorithm for Screening and Diagnosis

Highlights

This diagnostic test is indicated for testing **symptomatic** individuals that may or may not have risk factors for a hepatitis C virus infection.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

This test is **not intended** for testing **asymptomatic** individuals (ie, screening purposes). For testing such patients with or without risk factors for hepatitis C virus (HCV) infection, order HCSRN / Hepatitis C Virus (HCV) Antibody Screen with Reflex to HCV RNA, PCR, Asymptomatic, Serum.

For testing autopsy/cadaver or hemolyzed specimens, order HCCAD / Hepatitis C Virus Antibody Screen for Cadaveric or Hemolyzed Specimens, Asymptomatic, Serum for asymptomatic individuals or HCCDD / Hepatitis C Virus Antibody in Cadaveric or Hemolyzed Specimens, Symptomatic, Serum for symptomatic individuals.

For patients with acute or recent HCV infections (<3 months from time of exposure) or who are repeatedly reactive by screening tests and should be confirmed by a more HCV-specific test, order HCVQN / Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR, Serum.

If testing is desired to distinguish between true positivity and biologic false positivity for HCV antibody, then testing may be done with a second HCV antibody assay approved by the US Food and Drug Administration for diagnosis of HCV infection that is different from the assay used for initial antibody testing (HCCAD / Hepatitis C Virus Antibody Screen for Cadaveric or Hemolyzed Specimens, Asymptomatic, Serum).

Shipping Instructions

If shipment will be delayed for more than 24 hours, freeze serum at -70 degrees C until shipment and transport on dry ice.

Necessary Information

Date of collection is required.

Specimen Required

Patient Preparation: For 24 hours before specimen collection, patient should **not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Serum gel (red-top tubes are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 1.3 mL Serum
Collection Instructions:
1. Centrifuge blood collection tube per 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 forms with the specimen:
-Kidney Transplant Test Request
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

Specimen Minimum Volume

Serum: 0.9 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	84 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

Hepatitis C virus (HCV) is recognized as the cause of most cases of posttransfusion hepatitis and is a significant cause of morbidity and mortality worldwide. In the United States, HCV infection is quite common, with an estimated 2.4 million chronically HCV-infected individuals.

Laboratory testing for HCV infection usually begins by screening for the presence of HCV-specific antibodies in serum, using an US Food and Drug Administration-approved screening test. Specimens that are repeatedly reactive by screening tests should be confirmed with HCV tests with higher specificity, such as direct detection of HCV RNA by reverse transcription polymerase chain reaction or HCV-specific antibody confirmatory tests.

Hepatitis C virus antibodies are usually not detectable during the first 2 months following infection, but 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.

Current screening serologic tests to detect antibodies to HCV include enzyme immunoassay and chemiluminescence immunoassay.

Despite the value of serologic tests to screen for HCV infection, several limitations of serologic testing exist:
-There may be a long delay (up to 6 months) between exposure to the virus and the development of detectable HCV-specific antibodies in immunocompromised individuals
-False-reactive screening test result can occur
-A reactive screening test result does not distinguish between past (resolved) and present HCV infection
-Serologic tests cannot provide information on clinical response to anti-HCV therapy

Reactive screening test results should be followed by a supplemental or confirmatory test, such as nucleic acid test for HCV RNA or HCV antibody confirmatory test. Nucleic acid tests provide a very sensitive and specific approach for the direct detection of HCV RNA.

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

Reference Values

Negative

For more information see Viral Hepatitis Serologic Profiles

Interpretation

Reactive hepatitis C virus (HCV) antibody screening results with cutoff index (COI) values less than or equal to 20.0 with this assay are not predictive of the true HCV antibody status. Additional testing is available to confirm HCV antibody status.

Reactive results with COI values of greater than 20.0 with this assay are highly predictive (95% or greater probability) of the true HCV antibody status, but additional testing is needed to differentiate between past (resolved) and chronic hepatitis C. Based on Centers for Disease Control and Prevention recommendations, reactive HCV antibody screen results should be followed by HCV RNA testing (HCVQN / Hepatitis C Virus [HCV] RNA Detection and Quantification by Real-Time Reverse Transcription-PCR, Serum). Detection of HCV RNA indicates current HCV infection. If HCV RNA is not detected, that indicates either past, resolved HCV infection, or false HCV antibody positivity.

A negative screening test result does not exclude the possibility of exposure to or infection with HCV. Negative screening test results in individuals with prior exposure to HCV may be due to low antibody levels that are below the limit of detection of this assay or lack of reactivity to the HCV antigens used in this assay. Patients with acute or recent HCV infections (<2 months from time of exposure) may have false-negative HCV antibody results due to the time needed for seroconversion (average of 8 to 9 weeks). Testing for HCV RNA using HCVQN / Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR, Serum is necessary for detection of HCV infection in such patients.

Cautions

This assay is not licensed by the US Food and Drug Administration for the screening of blood, plasma, and tissue donors.

For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

A reactive hepatitis C antibody (anti-HCV) result does not exclude co-infection by another hepatitis virus.

False positive results due to non-specific reactivity cannot be ruled out with the Elecsys Anti-HCV II assay. In rare cases, interference due to extremely high titers of antibodies to streptavidin or ruthenium can occur, causing false-reactive anti-HCV results.

Infants born to HCV-infected mothers may have false-reactive HCV antibody test results due to transplacental passage of maternal HCV IgG antibodies. HCV antibody testing is not recommended until at least 18 months in these infants.

A single negative hepatitis C virus (HCV) RNA test result together with a reactive anti-HCV screen result with a cutoff index value greater than 20.0 does not rule out the possibility of chronic HCV infection. Repeat testing for HCV RNA in 1 to 2 months is recommended in patient at risk for chronic hepatitis C.

Serum specimens from individuals taking biotin supplements at 20 mg or more per day may have false-negative HCV antibody test results with this assay due to interference of biotin. Such individuals should stop taking these biotin-containing dietary supplements for a minimum 12 hours before blood collection for this test.

Negative anti-HCV test results from immunosuppressed individuals should be interpreted with caution.

Results obtained with the Elecsys Anti-HCV II assay may not be used interchangeably with values obtained with different manufacturers' assay methods.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:
-Grossly icteric (total bilirubin level of >66 mg/dL)
-Grossly lipemic (intralipid level of >2000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >1000 mg/dL)
-Biotin level >1200 ng/mL
-Rheumatoid factor level >1200 IU/mL
-Albumin level >7 g/dL
-IgA level >1600 mg/dL
-IgG level >7000 mg/dL
-IgM level >1000 mg/dL
-Presence of particulate matter
-Cadaveric specimens
-Specimen types other than serum

Clinical Reference

1. Centers for Disease Control and Prevention (CDC). Testing for HCV infection: an update of guidance for clinicians and laboratorians. Morb Mortal Wkly Rep. 2013;62(18):362-365
2. Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB. CDC Recommendations for hepatitis C screening among adults - United States, 2020. MMWR Recomm Rep. 2020;69(2):1-17
3. Chou R, Dana T, Fu R, et al. Screening for hepatitis C virus infection in adolescents and adults: updated evidence report and systematic review for the U.S. Preventive Services Task Force. JAMA. 2020;323(10):976-991
4. American Association for the Study of Liver Diseases and Infectious Diseases Society of America: HCV guidance: Recommendations for testing, managing, and treating hepatitis C. Updated October 24, 2022. Accessed December 26, 2025. Available at www.hcvguidelines.org/evaluate/testing-and-linkage

Performance

Method Description

The Elecsys Anti-HCV (hepatitis C virus) II assay is based on the sandwich immunoassay principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. HCV-specific antibodies present in the patient’s sample react with biotinylated HCV-specific antigens and a reagent containing

HCV-specific antigens labeled with a ruthenium complex to form sandwich complexes. After addition of streptavidin-coated microparticles (solid phase), these complexes bind to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then washed away and voltage is applied to the electrode which induces chemiluminescent emissions that are measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the patient's sample to the cutoff index value set from reagent lot-specific assay calibration. (Package insert: Elecsys Anti-HCV II. Roche Diagnostics; v1.0, 03/2023)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
Same day/1 to 3 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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
86803
87522 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HCVDX	HCV Ab w/Reflex to HCV PCR, S	40726-2

Test Definition: HCVDX

Hepatitis C Virus (HCV) Antibody with Reflex to HCV RNA, PCR, Symptomatic, Serum

Result ID	Test Result Name	Result LOINC® Value
HCVA4	HCV Ab, S	40726-2