

Overview

Useful For

Screening for hepatitis C in primary care settings in high-risk persons with a current or previous history of illicit injection drug use or a history of receiving a blood transfusion prior to 1992

Screening for hepatitis C in primary care settings in non-high-risk persons born from 1945 through 1965

Screening at least once in a lifetime for all adults greater or equal to 18 years old, except in settings where the prevalence of HCV infection is less than 0.1%

This test is **not offered** 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 virus (HCV), 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.

Testing Algorithm

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

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

Note: In accordance with National Coverage Determination guidance, this test is indicated for asymptomatic patients born from 1945 through 1965, those with a history of injection drug use, or a history of receiving blood transfusion prior to 1992.

Reflex Tests

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

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen**Specimen Type**

Serum SST

Ordering Guidance

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

For testing autopsy/cadaver or hemolyzed specimens, order HCCAD / Hepatitis C Virus Antibody Screen for Cadaveric or Hemolyzed Specimens, 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 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 (RT-PCR), Serum.

Shipping Instructions

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

Necessary Information

Date of collection is required.

Specimen Required

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 2 mL

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 Gastroenterology and Hepatology Client Test Request \(T728\)](#) with the specimen.

Reject Due To

Gross hemolysis Reject
Gross lipemia Reject
Gross icterus Reject

Specimen Minimum Volume

1 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	28 days	
	Refrigerated	5 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 chronic HCV carriers.

Laboratory testing for HCV infection usually begins by screening for the presence of HCV-specific antibodies in serum, using an FDA-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.

HCV 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. Decrease in the HCV antibody level in serum may occur following resolution of infection.

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

- 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 a 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.

See [Hepatitis C: Testing Algorithm for Screening and Diagnosis](#).

Reference Values

Negative

See [Viral Hepatitis Serologic Profiles](#)

Interpretation

Reactive hepatitis C virus (HCV) antibody screening results with signal-to-cutoff (S/Co) ratios of below 8.0 are not predictive of the true HCV antibody status and additional testing is recommended to confirm HCV antibody status.

Reactive results with S/Co ratios of 8.0 or greater 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.

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 (<3 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 (RT-PCR), Serum is recommended for detection of HCV infection in such patients.

Cautions

A single negative hepatitis C virus (HCV) RNA test result together with a reactive HCV antibody screen result with a signal-to-cutoff ratio of 8.0 or greater 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.

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 of age in these infants.

Performance characteristics have not been established for the following types of serum specimen:

- Individuals under 10 years of age
- Grossly icteric (total bilirubin level of >20 mg/dL)
- Grossly lipemic (triolein level of >3000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- Presence of particulate matter
- Cadaveric specimens

Clinical Reference

1. Centers for Disease Control and Prevention: Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR Morb Mortal Wkly Rep. 2013 May 10;62(18):362-365
2. American Association for the Study of Liver Diseases and Infectious Diseases Society of America: HCV guidance: Recommendations for testing, managing, and treating hepatitis C. Accessed September 29, 2020. Available at www.hcvguidelines.org/contents

Performance**Method Description**

The VITROS anti-hepatitis C virus (HCV) assay is an immunometric technique involving a 2-stage reaction. In the first stage, HCV antibody present in the sample binds to HCV recombinant antigens coated on the reaction wells, and unbound sample is removed by washing. In the second stage, horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal antihuman IgG) binds to human IgG captured on the well in the first stage. Unbound conjugate is removed by washing. A reagent containing luminogenic substrates (a luminal derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminal derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The emitted light signals are detected and measured by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is directly proportional to the level of anti-HCV antibodies present in a given sample. (Ismail N, Fish GE, Smith MB: Laboratory evaluation of a fully automated chemiluminescence immunoassay for rapid detection of HBsAg, antibodies to HBsAg, and antibodies to hepatitis C virus. J Clin Microbiol. 2004 Feb;42[2]:610-617; package insert: VITROS Anti-HCV Assay, no. GEM 1243. version 14.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

PDF Report

No

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes**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

G0472 (if appropriate for government payers)

87522 Hepatitis C, quantification (if appropriate)

LOINC® Information

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

Result ID	Reporting Name	LOINC®
HCVA5	HCV Ab Screen, S	40726-2