

Overview

Useful For

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

This test is **not offered** as a screening or confirmatory test for hepatitis C virus (HCV) for blood, human cells, or tissue donors.

This test profile is **not useful for** detection or diagnosis of acute 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 anti-HCV screening test results.

Highlights

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

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 (RT-PCR) will be performed at an additional charge.

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

Special Instructions

- [Viral Hepatitis Serologic Profiles](#)
- [Hepatitis C: Testing Algorithm for Screening and Diagnosis](#)

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Advisory Information

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, Serum for asymptomatic individuals or HCCDD / Hepatitis C Virus Antibody in Cadaveric or Hemolyzed Specimens, Serum for symptomatic individuals.

For patients with acute or recent HCV infections (<3 months from time of exposure) or \hat{A} 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, Real-Time Reverse Transcription-PCR (RT-PCR), Serum.

Shipping Instructions

If shipment will be delayed for >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 a [Gastroenterology and Hepatology Client Test Request \(T728\)](#) with the specimen.

Specimen Minimum Volume

1 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) | 28 days | |
| | Refrigerated | 5 days | |

Clinical and 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 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-PCR (RT-PCR) 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 after resolution of infection.

Current screening serologic tests to detect antibodies to HCV include enzyme immunoassay (EIA) and chemiluminescence immunoassay (CIA). 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 a detectable HCV antibody
- 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.

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

Reference Values

Negative

See [Viral Hepatitis Serologic Profiles](#) in Special Instructions.

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 anti-HCV status.

Reactive results with S/Co ratios of 8.0 or greater are highly predictive (95% or greater probability) of the true anti-HCV 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 (triglyceride 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;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. 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 MN: 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;42:610-617; package insert: VITROS Anti-HCV Assay, no.

GEM 1243. version 14.1. Ortho-Clinical Diagnostics, Inc;Â 09/06/2019)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

Same day/1 day

Maximum Laboratory Time

2 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved or is exempt by the U.S. 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 | 13955-0 |

| Result ID | Test Result Name | Result LOINC Value |
|-----------|------------------|--------------------|
| HCVA4 | HCV Ab, S | 13955-0 |