Overview

Useful For

Screening of pregnant women for hepatitis C in primary care settings, with or without risk factors for hepatitis C

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

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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.

Highlights

This test is intended for screening all women who are pregnant for hepatitis C during each pregnancy and to report positive results to the applicable local communicable disease surveillance agencies.

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
HCVRP	HCV RNA Detect/Quant Prenatal, S	Yes	No

Testing Algorithm

If the hepatitis C virus (HCV) antibody screen is reactive, then HCV RNA testing 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

Ordering Guidance

This test is intended for testing either symptomatic or asymptomatic women who are pregnant.

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.

Specimens that are repeatedly reactive by screening tests should be confirmed by a more hepatitis C virus (HCV)-specific test. Order HCVRP / Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR (RT-PCR), Prenatal.

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.

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-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 (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 following resolution of infection.

Current screening serologic tests to detect antibodies to HCV include enzyme 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 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 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 HCVRP / Hepatitis C Virus

(HCV) RNA Detection and Quantification, Real-Time Reverse Transcription-PCR Prenatal, 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 do 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.

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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 (CDC): Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR MorbMortal Wkly Rep 2013 May 10;62(18):362-365

2. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA): HCV guidance: Recommendations for testing, managing, and treating hepatitis C. AASLD, IDSA; Accessed January 28, 2021. Available at www.hcvguidelines.org/contents

3. US Preventive Services Task Force, Owens DK, Davidson KW, et al: Screening for hepatitis C virus infection in adolescents and adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2020 Mar 2;323(10):970-975. doi: 10.1001/jama.2020.1123

4. Society for Maternal-Fetal Medicine (SMFM), Hughes BL, Page CM, Kuller JA: Hepatitis C in pregnancy: screening, treatment, and management. Am J Obstet Gynecol. 2017 Nov;217(5):B2-B12

5. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Pregnancy and HIV, viral hepatitis STD and TB prevention: HCV challenges. CDC; Reviewed May 22, 2019. Accessed January 28, 2021. Available at www.cdc.gov/nchhstp/pregnancy/challenges/hcv.html

6. Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB: CDC recommendations for hepatitis C screening among adults-United States, 2020. MMWR Morb Mortal Wkly Rep 2020 Apr 10;69(2):1-17

Performance

Method Description

The VITROS anti-hepatitis C virus (HCV) assay is performed using the VITROS Anti-HCV Reagent Pack and VITROS Immunodiagnostic Products Anti-HCV Calibrator on the VITROS Immunodiagnostic System. An

immunometric technique is used, 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 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 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 Feb;42(2):610-617; package insert: VITROS Anti-HCV Assay, GEM 1243. Ortho-Clinical Diagnostics; V 14.1, 09/06/2019)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 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 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)

87522 (if appropriate)

LOINC® Information

Test Definition: HCVSP

HCV Ab Scrn Prenatal, S

Test ID	Test Order Name	Order LOINC Value
HCVSP	HCV Ab Scrn Prenatal, S	40726-2

Result ID	Test Result Name	Result LOINC Value
HCVA6	HCV Ab Prenatal, S	40726-2