Test Definition: HCCAD

HCV Ab Cadaver/Hemolyzed Screen, S

Overview

Useful For

Screening cadaveric or hemolyzed serum specimens for hepatitis C virus (HCV) infection in asymptomatic individuals with or without risk factors for HCV infection

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

This test is **not intended for** screening blood, cell, or tissue donors.

This test is **not intended for** testing symptomatic individuals (ie, diagnostic purposes).

This test is **not useful for** ruling out acute HCV infection.

This test is **not useful for** differentiation between resolved and acute or chronic HCV infection.

Highlights

Indicated for testing **asymptomatic** individuals (screening purposes) with or without risk factors for hepatitis C virus infection.

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
HCVL	HCV Ab Confirmation, S	Yes	No

Testing Algorithm

If screen is reactive, then confirmation will be performed at an additional charge.

See Hepatitis C: Testing Algorithm for Screening and Diagnosis in Special Instructions.

Special Instructions

- Hepatitis C: Testing Algorithm for Screening and Diagnosis

Method Name

Enzyme Immunoassay (EIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Advisory Information

For testing hemolyzed specimens from **symptomatic** patients with or without risk factors for hepatitis C virus (HCV) infection, order HCCDD / Hepatitis C Virus Antibody in Cadaveric or Hemolyzed Specimens, Symptomatic, Serum.

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume:0.5 mL

Collection Instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge 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

0.2 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	28 days	
	Ambient	7 days	
	Refrigerated	7 days	

Clinical and Interpretive

Clinical Information

Hepatitis C virus (HCV) is recognized as the cause of most cases of post-transfusion 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.

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

Despite the value of serologic tests to screen for HCV infection, several limitations of serologic testing are known:

-There may be a long delay (up to 6 months) between exposure to the virus and the development of detectable antibodies.

-False-reactive screening test results 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 antiviral therapy.

Positive screening serologic test results should be followed by a confirmatory or supplemental test, such as line immunoassay (HCVL / Hepatitis C Virus Antibody Confirmation, Serum) for HCV antibodies or a nucleic acid test for HCV RNA. Although nucleic acid tests provide a very sensitive and specific approach to directly detect HCV RNA in a patient's blood, they are not suitable for use in testing cadaveric blood specimens due to interference of heme with the nucleic acid amplification processes.

Reference Values

Negative

Interpretation

All specimens with signal-to-cutoff ratios of 1.0 or greater will be considered reactive and reflex to the hepatitis C virus (HCV) antibody confirmatory test by line immunoassay (HCVL / Hepatitis C Virus Antibody Confirmation, Serum) at an additional charge. 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 antibody levels below the limit of detection of this assay or lack of reactivity to the HCV antigens used in this assay. Patients with 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).

Cautions

Infants born to hepatitis C virus (HCV) infected mothers may have false-reactive HCV antibody screening test results and false-positive HCV antibody confirmatory test results due to transplacental passage of maternal HCV-specific IgG antibodies). HCV antibody testing is not recommended until at least 18 months of age in these infants.

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

-Grossly hemolyzed (hemoglobin level of >800 mg/dL).

-Grossly icteric (total bilirubin level of >30 mg/dL).

-Grossly lipemic (triglyceride level of >3000 mg/dL).

-Presence of particulate matter

-Heat-treated specimens

Clinical Reference

1. Carithers RL, Marquardt A, Gretch DR: Diagnostic testing for hepatitis C. Semin Liver Dis. 2000;20(2):159-171

2. Pawlotsky JM: Use and interpretation of virological tests for hepatitis C. Hepatology. 2002;36:S65-S73

3. 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 May 10;62(18)362-365

Performance

Method Description

The ORTHO HCV Version 3.0 ELISA Test System is a 3-stage test carried out in a microwell coated with a combination of recombinant hepatitis C virus (HCV) antigen (c22-3, c200 and NS5). In the first stage, a diluted test specimen or appropriate controls are incubated in the test well for a specified length of time. If antibody reactive to any of the 3 antigens is present in the specimen, antigen-antibody complexes will be formed on the microwell surface. If anti-HCV is not present, complexes will not be formed. In the subsequent washing step, unbound serum proteins will be removed. In the second stage, murine monoclonal antibody conjugated to horseradish peroxidase is added to the microwell. The conjugate binds specifically to the human IgG portion of the antigen-antibody complexes. If antigen-antibody complexes are not present, the unbound conjugate will be removed by subsequent washing. In the third stage, an enzyme detection system composed of o-phenylenediamine (OPD) and hydrogen peroxide is added to the test well. If bound conjugate is present, the OPD will be oxidized, resulting in a colored end product. In this reaction, peroxidase is divalently oxidized by hydrogen peroxide to form an intermediate compound, which is, in turn, reduced to its initial state by subsequent interaction with hydrogen ion donating OPD. The resulting oxidized form of OPD has an orange color. Sulfuric acid is then added to stop the reaction. The color intensity is dependent upon the amount of bound conjugate andÂ is a function of the concentration of anti-HCV present in the specimen. The color intensity is measured with a microwell reader (photometer) designed to measure light absorbance in a microwell. (Package insert: Hepatitis C Virus Encoded Antigen [Recombinant c22-3, c200, and NS5], ORTHOHCV Version 3.0 ELISA Test System. Ortho Clinical Diagnostics; 01/2017)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday, Thursday; Varies

Analytic Time

1 day

Maximum Laboratory Time

7 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

G0472

86804 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HCCAD	HCV Ab Cadaver/Hemolyzed Screen, S	13955-0

Result ID	Test Result Name	Result LOINC Value
87858	HCV Ab Cadaver/Hemolyzed Screen, S	13955-0