

Overview

Useful For

Diagnosis of acute hepatitis B infection

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Identifying acute hepatitis B virus (HBV) infection in the serologic window period when hepatitis B surface antigen (HBsAg) and antihepatitis B surface (anti-HBs) are negative

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Differentiation between acute and chronic or past hepatitis B viral infections in the presence of positive anti-hepatitis B core

Testing Algorithm

See [HBV Infection-Diagnostic Approach and Management Algorithm](#) in Special Instructions.

Special Instructions

- [Viral Hepatitis Serologic Profiles](#)
- [HBV Infection-Diagnostic Approach and Management Algorithm](#)

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of draw is required.

Specimen Required

Patient Preparation: For 24 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions.

2. Aliquot serum into plastic tube.

Forms

If not ordering electronically, complete, print, and send a [Gastroenterology and Hepatology Client Test Request \(T728\)](#) with the specimen.

Specimen Minimum Volume

0.5 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	7 days	
	Ambient	24 hours	

Clinical and Interpretive

Clinical Information

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. In the initial (acute) phase of infection, anti-hepatitis B core antibodies (anti-HBc) consist almost entirely of the IgM antibody class and appear shortly after the onset of symptoms. Anti-HBc IgM antibody can be detected in serum and is usually present for up to 6 months after acute HBV infection. Anti-HBc IgM may be the only serologic marker of a recent hepatitis B infection detectable following the disappearance of hepatitis B surface antigen (HBsAg) and prior to the appearance of hepatitis B surface antibody (anti-HBs) (ie, serologic window period).

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

Reference Values

Negative

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

Interpretation

A positive result indicates recent acute hepatitis B infection.

A negative result suggests lack of recent exposure to the virus in preceding 6 months.

Cautions

The predictive value of a positive anti-hepatitis B core (anti-HBc) IgM test result is low when used to test specimens from patients with low prevalence of acute hepatitis B virus infection.

Performance characteristics have not been established for the following specimen characteristics:

- 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)
- Containing particulate matter
- Cadaveric specimens

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, et al: Diagnostic markers of chronic hepatitis B infection and disease. *Antiviral Therapy*. 2010;15(Suppl. 3):35-44
2. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. *J Clin Virol*. 2001;21:229-237
3. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. *Clin Liver Dis*. 2004;8:267-281
4. LeFebre ML: U.S. Preventive Services Task Force: Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;161:58-66. doi: 10.7326/M14-1018
5. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. *Clin Liver Dis*. 2018;12(1):5-11. doi: 10.1002/cld.729
6. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. *Gastroenterol*. 2019;156:355-368. doi: 10.1053/j.gastro.2018.11.037
7. WHO Guidelines Development Group: World Health Organization: Guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed September 29, 2020. Available at: www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en/
8. Centers for Disease Control and Prevention. Testing and public health management of persons with chronic hepatitis B virus infection. Accessed April 8, 2020. Available at: www.cdc.gov/hepatitis/hbv/testingchronic.htm

Performance

Method Description

An antibody class capture technique is used. This involves the dilution of the sample and the simultaneous reaction of IgM in the diluted sample with biotinylated mouse monoclonal antihuman-IgM antibody. The immune complex is captured by streptavidin on the wells. Unbound materials are removed by washing. Horseradish peroxidase (HRP)-labeled mouse monoclonal anti-hepatitis B core (anti-HBc) IgM antibody, which has been complexed with recombinant HBc antigen (conjugate), is then captured by anti-HBc specific IgM bound to the wells. Unbound material is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. 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 light signals are read by the system. The amount of HRP conjugate

bound is indicative of the concentration of anti-HBc IgM present in the sample. (Package insert: VITROS Anti-HBc IgM assay, Pub. No. GEM0216, Version 14.1, Ortho-Clinical Diagnostics; 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

86705

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HBIM	HBc IgM Ab, S	24113-3

Result ID	Test Result Name	Result LOINC Value
HBIM	HBc IgM Ab, S	24113-3