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## Overview

### Useful For

Diagnosis of acute hepatitis B virus (HBV) infection

Identifying acute HBV infection in the serologic window period when hepatitis B surface antigen and anti-hepatitis B surface are negative

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

### Testing Algorithm

[Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management](#)

### Special Instructions

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

### Method Name

Chemiluminescence Immunoassay (CIA)

### NY State Available

Yes

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## Specimen

### Specimen Type

Serum SST

### Necessary Information

Date of collection 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.

**Reject Due To**

Gross hemolysis    Reject  
Gross lipemia      Reject  
Gross icterus      Reject

**Specimen Minimum Volume**

0.5 mL

**Specimen Stability Information**

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

**Clinical & Interpretive**

**Clinical Information**

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. In the initial (acute) phase of infection, 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 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 and prior to the appearance of hepatitis B surface antibody (ie, serologic window period).

See [Viral Hepatitis Serologic Profiles](#)

**Reference Values**

Negative

See [Viral Hepatitis Serologic Profiles](#)

**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 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, Liaw YF: Diagnostic markers of chronic hepatitis B infection and disease. *Antivir Ther.* 2010;15 Suppl 3:35-44. doi: 10.3851/IMP1622
2. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. *J Clin Virol.* 2001 Jun;21(3):229-237. doi: 10.1016/s1386-6532(01)00147-0
3. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. *Clin Liver Dis.* 2004 May;8(2):267-281. doi: 10.1016/j.cld.2004.02.001
4. LeFebvre 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 Jul 1;161(1):58-66.

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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 Aug 22;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. Gastroenterology. 2019 Jan;156(2):355-368. doi: 10.1053/j.gastro.2018.11.037

7. [World Health Organization: WHO guidelines on hepatitis B and C testing. 2017. Accessed September 29, 2020. Available at \[www.who.int/hepatitis/publications/HEP17001\\\_WEB11.pdf?ua=1\]\(https://www.who.int/hepatitis/publications/HEP17001\_WEB11.pdf?ua=1\)](https://www.who.int/hepatitis/publications/HEP17001_WEB11.pdf?ua=1)

8. Division of Viral Hepatitis, National Center for HIV, Viral Hepatitis, STD, and TB Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. [Centers for Disease Control and Prevention](https://www.cdc.gov/hepatitis/hbv/testingchronic.htm). Updated October 8, 2019. Accessed April 8, 2020. Available at [www.cdc.gov/hepatitis/hbv/testingchronic.htm](https://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, 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

### Specimen Retention Time

14 days

### Performing Laboratory Location

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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**

86705

**LOINC® Information**

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

Result ID	Reporting Name	LOINC®
HBIM	HBc IgM Ab, S	24113-3