MAYO CLINIC LABORATORIES

# Test Definition: HBIM

Hepatitis B Virus Core IgM Antibody, Serum

## Overview

### Useful For

Diagnosis of acute hepatitis B virus (HBV) infection

Identifying acute HBV infection in the serologic window period when HBV surface antigen and HBV surface antibody results are negative

Differentiation between acute, chronic, or past HBV infections in the presence of positive hepatitis B virus core total antibodies

### Testing Algorithm

For more information see 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

Electrochemiluminescence Immunoassay (ECLIA)

### NY State Available

No

## Specimen

### Specimen Type

Serum SST

### Necessary Information

**Date of collection is required.**

### Specimen Required

**Patient Preparation:** For 24 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
**Collection Container/Tube:** Serum gel (red-top tubes are **not acceptable**)
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 0.6 mL
**Collection Instructions:**
1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of

collection for BD Vacutainer tubes).
2. Aliquot serum into a plastic tube.

### Forms

If not ordering electronically, complete, print, and send 1 of the following:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

### Specimen Minimum Volume

0.6 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) | 90 days | |
| | Ambient | 72 hours | |
| | Refrigerated | 6 days | |

## 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, HBV 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 virus surface antibody (ie, serologic window period).

### Reference Values

Negative

See Viral Hepatitis Serologic Profiles

### Interpretation

A positive result indicates recent acute hepatitis B infection. Positive results should be correlated with hepatitis B virus core total antibody test result and the patient's epidemiologic exposure history.

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

## Cautions

This assay has not been licensed by the US Food and Drug Administration for the screening of blood, plasma, and tissue donors.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

Serum specimens from individuals taking biotin supplements of more than 20 mg per day may have false-negative hepatitis B core antibody (anti-HBc) IgM test results due to interference of biotin with the assay. Such individuals should stop taking these biotin-containing dietary supplements for a minimum of 12 hours before blood collection for this test.

False-positive results may occur due to the presence of interfering substances in the patient sample or non-specific reactivity of the assay.

Current methods for the detection of IgM antibodies to HBc may not detect all infected individuals. A nonreactive test result does not exclude the possibility of exposure to hepatitis B virus (HBV). In rare cases, interference due to high titers of antibodies to immunological components, streptavidin or ruthenium can occur.

The predictive value of a positive HBc IgM antibody test result is low when used to test specimens from patients with low prevalence of acute HBV infection.

Results obtained with the Elecsys Anti-HBc IgM immunoassay may not be used interchangeably with values obtained with different manufacturers' assay methods.

Assay performance characteristics have not been established for the following specimen characteristics or specimen types:
-Patients younger than 21 years, pregnant women, or in populations of immunocompromised or immunosuppressed patients
-Grossly icteric (total bilirubin level of >25 mg/dL)
-Grossly lipemic (Intralipid level of >1000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >2000 mg/dL)
-Containing particulate matter
-Cadaveric specimens
-Specimen types other than serum

## Clinical Reference

1. LeFevre 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(1):58-66. doi:10.7326/M14-1018
2. Jackson K, Locarnini S, Gish R. Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis (Hoboken). 2018;12(1):5-11. doi:10.1002/cld.729
3. Coffin CS, Zhou K, Terrault NA. New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. Gastroenterology. 2019;156(2):355-368.e3. doi:10.1053/j.gastro.2018.11.037
4. WHO guidelines on hepatitis B and C testing. Geneva: World Health Organization. Updated February 16, 2017. Accessed May 5, 2025. Available at www.who.int/publications/i/item/9789241549981

5. 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. Updated January 31, 2025. Accessed May 6, 2025. Available at www.cdc.gov/hepatitis-b/hcp/diagnosis-testing/
6. Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC recommendations - United States, 2023. MMWR Recomm Rep. 2023;72(1):1-25. doi:10.15585/mmwr.rr7201a1

## Performance

### Method Description

The Elecsys Anti-HBc (hepatitis B virus core antibody) IgM assay is performed with an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. Anti-HBc IgM present in patient's sample is pretreated with anti-Fdy reagent to block specific IgG. After addition of biotinylated monoclonal human IgM-specific antibodies, the complexes formed from reaction of ruthenium-labeled HBc antigen, streptavidin-coated microparticles, anti-HBc IgM present in the sample, and the biotinylated anti-human IgM become bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are washed away. Voltage is applied to the electrode that induces chemiluminescent emissions, that are measured by a photomultiplier. The test result is determined by comparing the electrochemiluminescence signal generated from the sample to the cutoff index value set from reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HBc IgM. Roche Diagnostics; v2.0, 12/2024)

### PDF Report

No

### Day(s) Performed

Monday through Friday, Sunday

### Report Available

Same day/1 to 2 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

## Fees & 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 account representative. For assistance, contact Customer Service.

# Test Definition: HBIM

Hepatitis B Virus Core IgM Antibody, Serum

## 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 |