

Hepatitis B Virus Core Total Antibodies, with Reflex to Hepatitis B Virus Core IgM Antibody, Serum

Overview

Useful For

Detection and differentiation between recent, past/resolved, or chronic hepatitis B

Diagnosis of recent hepatitis B virus (HBV) infection during the "window period" when both hepatitis B surface (HBs) antigen and anti-HBs are negative

This test is **not useful** for determining immunity to or recovery from HBV infection.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBIM	HBc IgM Ab, S	Yes	No

Testing Algorithm

If the hepatitis B virus core (HBc) total antibodies test result is positive, then anti-HBc IgM is performed at an additional charge.

Special Instructions

• Viral Hepatitis Serologic Profiles

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

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



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supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).

Collection Container/Tube: Sarstedt Aliquot Tube, 5 mL (T914)

Submission Container/Tube: Plastic vial

Specimen Volume: 0.7 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 vial.

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	Reject
hemolysis	
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	90 days	
	Refrigerated	6 days	
	Ambient	72 hours	

Clinical & Interpretive

Clinical Information

During the course of a typical case of acute hepatitis B, hepatitis B virus (HBV) core IgM antibodies (anti-HBc IgM) to hepatitis B virus core antigen are present in the serum shortly before clinical symptoms appear. Anti-HBc total is detectable during the prodromal, acute, and early convalescent phases when it exists as anti-HBc IgM. Anti-HBc IgM increase in level and are present during the core window period (ie, after hepatitis B virus surface (HBs) antigen disappears and before anti-HBs appear). Anti-HBc total may be the only serologic marker remaining years after exposure to HBV.

Reference Values



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Negative

Interpretation depends on clinical setting.

See Viral Hepatitis Serologic Profiles

Interpretation

Negative hepatitis B virus core total antibody (anti-HBc total) results indicate the absence of recent, past/resolved, or chronic hepatitis B.

Positive anti-HBc total result may indicate recent, past/resolved, or chronic hepatitis B.

An inconclusive result for anti-HBc total suggests presence of interfering substance in the patient's serum specimen.

Testing for anti-HBc IgM is necessary to confirm the presence of acute or recent hepatitis B. A positive anti-HBc total result with a negative anti-HBc IgM result indicates past or chronic hepatitis B virus (HBV) infection. Differentiation between past/resolved and chronic hepatitis B can be based on the presence of hepatitis B virus surface antigen (HBsAg) in the latter condition.

Positive anti-HBc total results with negative anti-HBc IgM results in infants younger than 18 months may be due to passively acquired maternal IgG antibodies. Additional testing, such as HBsAg, anti-HBc IgM, and hepatitis Be antigen, are necessary to confirm a diagnosis of acute or recent hepatitis B in these infants.

Cautions

Specimens containing sodium azide may cause false-positive results and should not be tested. Lipemic and precipitated samples may give inconsistent results.

Serum specimens from individuals taking biotin supplements of 20 mg or more per day may have false-positive hepatitis B core total antibody 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.

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

- --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 >800 mg/dL)
- -Containing particulate matter
- -Cadaveric specimen
- -Heat-inactivated specimen

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.



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Serum

doi:10.7326/M14-1018

- 2. WHO guidelines on hepatitis B and C testing. World Health Organization, 2017. Accessed December 22, 2023. Available at www.who.int/publications/i/item/9789241549981
- 3. 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
- 4. 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. doi:10.1053/j.gastro.2018.11.037
- 5. 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) II assay is based on the competitive immunoassay principle and performed using an electrochemiluminescence immunoassay on the automated cobas e 801 immunochemistry analyzer. The patient's sample is pretreated first with a reducing reagent, and after the addition of synthetic HBc antigen (HBcAg), complexes are formed with anti-HBc in the sample. The remaining unbound sites on the HBcAg become occupied after addition of biotinylated antibodies and ruthenium complex-labeled antibodies specific for HBcAg. The entire complex binds to the streptavidin-coated microparticles (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. After unbound substances are washed away, voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Test result is determined by comparing the electrochemiluminescence signal generated from the reaction product in the sample to the cutoff index value set from assay reagent lot-specific assay calibration. (Package insert: Elecsys Anti-HBc II. Roche Diagnostics; v1.0, 04/2022)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester



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Fees & Codes

Fees

- Authorized users can sign in to <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact <u>Customer Service</u>.

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

86704

86705 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value	
CORAB	HBc Total Ab, w/Reflex, S	13952-7	

Result ID	Test Result Name	Result LOINC® Value
CORAB	HBc Total Ab, w/Reflex, S	13952-7