

Overview

Useful For

Diagnosis of recent or past hepatitis B

Determination of occult hepatitis B in otherwise healthy hepatitis B virus carriers with negative test results for hepatitis B surface (HBs) antigen, anti-HBs, anti-hepatitis B core IgM, hepatitis Be (HBe) antigen, and HBe antibody

This assay is **not useful** for differentiating between acute, chronic, past, or resolved hepatitis B.

This test **should not be used** as a screening or confirmatory test for blood donor specimens.

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](#)

Highlights

This test should be used to screen or test **asymptomatic, nonpregnant** individuals with or without risk factors for hepatitis B virus infection.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

This test should **not be used to test symptomatic** individuals (ie, diagnostic purposes) suspected with viral hepatitis. For testing such patients with or without risk factors for hepatitis B virus (HBV) infection, order HBC / Hepatitis B Virus Core Total Antibodies, Serum.

This test should **not be used to screen or test pregnant** individuals with or without risk factors for HBV. For testing such

patients, order HBCPR / Hepatitis B Virus Core Total Antibodies Prenatal, Serum.

If a hepatitis B core total antibody test that reflexes to hepatitis B core IgM is needed, order CORAB / Hepatitis B Virus Core Total Antibodies, with Reflex to Hepatitis B Virus Core Antibody IgM, Serum.

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: 0.7 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 hemolysis	Reject
Gross lipemia	Reject
Gross Icterus	Reject
Heat-inactivated specimen	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

[Hepatitis B virus core antibodies \(anti-HBc\)](#) appear shortly after the onset of symptoms of hepatitis B infection and soon after the appearance of hepatitis B virus surface antigen (HBsAg). Initially, anti-HBc consist almost entirely of the IgM antibody class, followed by the appearance of anti-HBc IgG for which there is no commercial diagnostic assay.

The HBc total antibody test, which detects both IgM and IgG antibodies, and the test for anti-HBc IgM may be the only markers of recent hepatitis B detectable in the "window period." The window period begins with the clearance of HBsAg and ends with the appearance of anti-HBs. Anti-HBc may be the only serologic marker remaining years after exposure to hepatitis B virus (HBV).

This assay is US Food and Drug Administration approved for in vitro diagnostic use and not for screening cell, tissue, and blood donors.

Reference Values

Negative

Interpretation depends on clinical setting.

See [Viral Hepatitis Serologic Profiles](#)

Interpretation

Negative hepatitis B virus core total antibody (anti-HBc total) test results indicate the absence of exposure to hepatitis B virus and no evidence of recent, past/resolved, or chronic hepatitis B.

A positive result indicates acute, chronic, or past or resolved hepatitis B.

Positive anti-HBc total test results should be correlated with the presence of other hepatitis B virus serologic markers, elevated liver enzymes, clinical signs and symptoms, and a history of risk factors.

If clinically indicated, testing for anti-HBc IgM (HBIM / Hepatitis B Virus Core Antibody, IgM, Serum) is necessary to confirm an acute or recent infection.

Neonatal patients (<1 month old) with positive anti-HBc total results from this assay should be tested for anti-HBc IgM (HBIM / Hepatitis B Virus Core Antibody, IgM, Serum) to rule out possible maternal anti-HBc causing false-positive results. Repeat testing using this assay for anti-HBc total within 1 month is also recommended for these neonatal patients.

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 20 mg or more per day may have false-positive hepatitis B core (HBc) 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.

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

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

Drug interference studies were performed in vitro and may not assess the potential interferences that might be seen after the drugs are metabolized in vivo.

False positive results were observed in a limited number of patients positive for hepatitis C virus, hepatitis E virus, human T cell lymphotropic virus, and HIV.

A reactive anti-HBc result does not exclude co-infection by another hepatitis virus.

Negative anti-HBc results may occur during early infection due to delayed seroconversion.

False negative results may occur due to antibody levels below the detection limit of this assay or if the patient's antibodies do not react with the antigen used in this test.

False positive results due to non-specific reactivity cannot be ruled out with the Elecsys Anti-HBc II assay.

Results obtained with the Elecsys Anti-HBc II 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 >800 mg/dL)
- Containing particulate matter
- Cadaveric specimens
- Heat inactivated 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. WHO guidelines on hepatitis B and C testing. Geneva: World Health Organization; February 2017. Accessed December 20, 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 analyzer. Patient's sample is pretreated first with a reducing reagent, and after the addition of synthetic HBc antigen (HBcAg), complexes are formed with HBc antibodies present in the sample. The remaining unbound sites on the HBcAg become occupied with the added 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. The test results are determined by comparing the electrochemiluminescence signal generated from the reaction product in the sample to the cutoff index (COI) 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

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 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

G0499 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBCSN	HBc Total Ab Scrn, S	13952-7

Result ID	Test Result Name	Result LOINC® Value
HBCSN	HBc Total Ab Scrn, S	13952-7