

## Overview

### Useful For

Diagnosis of recent or past hepatitis B in pregnant individuals

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 anti-HBe

This assay is **not useful** for differentiating among acute, chronic, and 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 **pregnant** individuals who may or may not have 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 **asymptomatic, nonpregnant** individuals with or without risk factors for

HBV infection. For testing such patients, order HBCSN / Hepatitis B Virus Core Total Antibodies Screen, Serum.

If hepatitis B core total antibody test that reflexes to hepatitis B virus core IgM, 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

**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 with the specimen:

[-Infectious Disease Serology Test Request \(T916\)](#)

[-Gastroenterology and Hepatology Test Request \(T728\)](#)

## 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 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 total may be the only serologic marker remaining years after exposure to hepatitis B virus.

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.

For more information, 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 IgM Antibody, 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 IgM Antibody, 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

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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. False positive results may also occur in a limited number of patients positive for antibodies to 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 or low 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.

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 19, 2023. Available at [www.who.int/publications/i/item/9789241549981](http://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

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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 antibodies) 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 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. The test result is 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

Same day/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

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
HBCPR	HBc Total Ab Prenatal, S	13952-7

Result ID	Test Result Name	Result LOINC® Value
HBCPR	HBc Total Ab Prenatal, S	13952-7