MAYO CLINIC LABORATORIES

Test Definition: HBC

Hepatitis B Virus Core Total Antibodies, Serum

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-HB 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 diagnostic test should be used to test **symptomatic** individuals suspected with viral hepatitis.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

No

Specimen

Specimen Type

Serum SST

Ordering Guidance

This test **should not be used** to screen or test **pregnant** individuals who may or may not have risk factors for hepatitis B virus (HBV) infection. For testing such patients, order HBCPR / Hepatitis B Virus Core Total Antibodies Prenatal, Serum.

This test **should not be used** to screen or test **asymptomatic, non-pregnant** individuals with or without risk factors for HBV. For testing such patients, order HBCSN / Hepatitis B Virus Core Total Antibodies Screen, Serum.

If a hepatitis B core total antibody test that reflexes to hepatitis B virus core IgM is needed, order test 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 forms with the specimen:
-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	
	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 anti-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.
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.

An inconclusive result suggests the presence of an interfering substance in the patient's serum specimen.

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

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 specimens
-Heat inactivated specimens

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. World Health Organization, 2017. Accessed September 9, 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 antibodies) II assay is performed using an electrochemiluminescence immunoassay on the automated cobas e 801 analyzer. Anti-HBc present in the patient's sample is pretreated first with a reducing reagent, and after the addition of hepatitis B virus core 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, together with streptavidin-coated microparticles. The entire complex becomes 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. After unbound substances are washed away, voltage is applied to the electrode that induces chemiluminescent emissions, which are measured by a photomultiplier. Results are determined by comparing the electrochemiluminescence signal generated from the reaction product of 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 Friday, Sunday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Jacksonville

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
HBC	HBc Total Ab, S	13952-7

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