MAYO CLINIC LABORATORIES

Test Definition: CORAB

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 testing 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

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:
-Kidney Transplant Test Request
-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	
	Ambient	72 hours	
	Refrigerated	6 days	

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 HBc 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 HBV 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
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.

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
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 more than 20 mg of biotin supplements per day may have false-positive hepatitis B virus 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 May 5, 2025. 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 the anti-HBc in the sample. The remaining unbound sites on the HBcAg become occupied after the addition of biotinylated antibodies and ruthenium complex-labeled antibodies specific to 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 value set from assay reagent lot-specific assay calibration.(Package insert: Elecsys Anti-HBc II. Roche Diagnostics; v2.0, 12/2024)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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
86705 (if appropriate)

LOINC® Information

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

MAYO CLINIC LABORATORIES

Test Definition: CORAB

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

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