MAYO CLINIC LABORATORIES

Test Definition: CORAB

HBc Total Ab, w/Reflex, S

Overview

Useful For

Detection and differentiation between recent and past/resolved or chronic hepatitis B viral (HBV) infection

Diagnosis of recent HBV infection during the "window period" when both hepatitis B surface antigen (HBsAg) and antibodies to HBsAg are negative

This test is **not useful** for determining immunity to or recovery from hepatitis B viral (HBV) infection.

Testing Algorithm

If hepatitis B core (HBc) total antibodies is positive, then HBc IgM is performed at an additional charge.

Special Instructions

- Viral Hepatitis Serologic Profiles

Reflex Tests

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

Method Name

Chemiluminescence Immunoassay (CIA)

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 do not take multivitamins or dietary supplements

containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Centrifuge and aliquot serum into plastic vial within 24 hours.

Forms

If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Minimum Volume

0.4 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	28 days	
	Refrigerated	7 days	
	Ambient		

Clinical & Interpretive

Clinical Information

During the course of a typical case of acute hepatitis B viral (HBV) infection, IgM antibodies to hepatitis B core antigen (anti-HBc) IgM 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 rises in level and is present during the core window period (ie, after hepatitis B surface antigen disappears and before antibodies to hepatitis B surface antigen 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

Positive antibodies to hepatitis B core antigen (anti-HBc) total result may indicate recent, past/resolved, or chronic hepatitis B viral (HBV) infection.

Testing for anti-HBc IgM (HBIM / Hepatitis B Core Antibody, IgM, Serum) 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 HBV infection. Differentiation between past/resolved and chronic hepatitis B can be based on the presence of hepatitis B surface antigen (HBsAg) in the latter condition.

Negative anti-HBc total results indicate the absence of recent, past/resolved, or chronic hepatitis B. An inconclusive result for HBc total suggests presence of interfering substance in the patient's serum specimen.

Positive antibodies to 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

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

-Grossly icteric (total bilirubin level of >20 mg/dL)

-Grossly lipemic (triolein level of >3000 mg/dL)

-Grossly hemolyzed (hemoglobin level of >500 mg/dL)

-Containing particulate matter

-Cadaveric specimen

-Heat-inactivated specimen

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF: Diagnostic markers of chronic hepatitis B infection and disease. Antivir

Ther. 2010;15 Suppl 3:35-44. doi: 10.3851/IMP1622

2. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. Clin Liver Dis. 2004 May;8(2):267-281. doi: 10.1016/j.cld.2004.02.001

3. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. J Clin Virol. 2001 Jun;21(3):229-237.

4. LeFebre 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 Jul;161(1):58-66. doi:10.7326/M14-1018

5. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis (Hoboken). 2018 Aug;12(1):5-11. doi: 10.1002/cld.729

6. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. Gastroenterology. 2019 Jan;156(2):355-368. doi: 10.1053/j.gastro.2018.11.037

7. World Health Organization: WHO guidelines on hepatitis B and C testing. 2017. Accessed September 29, 2020. Available at www.who.int/hepatitis/publications/HEP17001_WEB11.pdf?ua=1

8. Division of Viral Hepatitis, National Center for HIV, Viral Hepatitis, STD, and TB Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. Centers for Disease Control and Prevention. Updated October 8, 2019. Accessed April 8, 2020. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm

Performance

Method Description

The VITROS antibody to hepatitis B core antigen (anti-HBc) assay is performed using a competitive immunoassay technique involving the reaction of anti-HBc in the sample with hepatitis B core antigen (HBcAg)-coated wells. Unbound sample is removed by washing. Horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-HBc) is then allowed to react with the remaining exposed HBcAg on the well surface. Unbound conjugate is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent are added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the system. The amount of HRP conjugate is indicative of the concentration of anti-HBc present in the sample.(Package insert: VITROS Anti-HBc Assay, no. GEM1211, version 14.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

PDF Report

No

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

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	Reporting Name	LOINC®
CORAB	HBc Total Ab, w/Reflex, S	13952-7