MAYO CLINIC LABORATORIES

Test Definition: HBCPR

Hepatitis B Core Total Antibodies Prenatal, Serum

Overview

Useful For

Diagnosis of recent or past hepatitis B infection in pregnant individuals

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

This assay is **not useful** for differentiating among acute, chronic, and past or resolved hepatitis B infection

This test is **not offered** as a screening or confirmatory test for blood donor specimens.

Testing Algorithm

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 (HBV) infection.

Method Name

Chemiluminescence Immunoassay (CIA)

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 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 Core Total Antibodies Screen, Serum.

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

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

0.4 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)	28 days	
	Refrigerated	7 days	
	Ambient	24 hours	

Clinical & Interpretive

Clinical Information

Hepatitis B core antibodies (anti-HBc) appear shortly after the onset of symptoms of hepatitis B infection and soon after

the appearance of hepatitis B surface antigen (HBsAg). Initially, anti-HBc consist almost entirely of the IgM class, followed by appearance of anti-HBc IgG, for which there is no commercial diagnostic assay.

The HBc total antibodies test, which detects both IgM and IgG antibodies, and the test for HBc IgM antibodies may be the only markers of a recent hepatitis B infection detectable in the "window period." The window period begins with the clearance of HBsAg and ends with the appearance of antibodies to hepatitis B surface antigen. HBc total antibodies may be the only serologic marker remaining years after exposure to hepatitis B.

This assay is U.S. 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 anti-hepatitis B core (anti-HBc) total test results indicate the absence of exposure to hepatitis B virus (HBV) 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 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 HBIM / Hepatitis B Core Antibody, IgM, Serum is necessary to confirm an acute or recent infection.

Neonates (<1 month old) with positive anti-HBc total results from this assay should be tested for anti-HBc IgM (HBIM / Hepatitis B 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 in these neonates.

Cautions

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

-Heat inactivated specimens

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF: Diagnostic markers of chronic hepatitis B infection and disease. Antivir Ther. 2010;15(3):35-44. doi: 10.3851/IMP1622
2. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. J Clin Virol. 2001 Jun;21(3):229-237. doi: 10.1016/s1386-6532(01)00147-0
3. 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
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 1;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. 2018 Aug 22;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. WHO Guidelines Development Group: WHO guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed July 8, 2021.Available at www.who.int/publications/i/item/9789241549981
8. Centers for Disease Control and Prevention. Testing and public health management of persons with chronic hepatitis B virus infection. CDC: Updated October 8, 2019. Accessed April 8, 2020. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm

Performance

Method Description

The VITROS anti-hepatitis B core (anti-HBc) assay is a competitive immunoassay method based on 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 bound is indicative of the concentration of anti-HBc present in the sample.(Package insert: VITROS Anti-HBc Assay, Pub. No. GEM1211, v 14.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

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 Regional Manager. 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