MAYO CLINIC LABORATORIES

Test Definition: HBABY

Hepatitis B Perinatal Exposure, S

Overview

Useful For

Determining hepatitis B virus infection and immunity status (with or without perinatal prophylaxis) in infants born to mothers with chronic hepatitis B

Testing Algorithm

If hepatitis B surface antigen (HBsAg) is reactive, then HBsAg confirmation will be performed at an additional charge.

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 ordered for infants born to mothers with chronic hepatitis B only.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
HBAG	HBs Antigen, S	Yes	Yes
HBC	HBc Total Ab, S	Yes	Yes
HBAB	HBs Antibody, S	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBGNT	HBs Antigen Confirmation, S	No	No

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1.5 mL

Collection Instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions.

2. Aliquot serum into plastic vial.

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

1 mL

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Hepatitis B virus (HBV) is a DNA virus that is endemic throughout the world. After a course of acute illness, HBV persists

in about 10% of patients who were infected during adulthood. Some carriers are asymptomatic; others may develop chronic liver disease including cirrhosis and hepatocellular carcinoma.

HBV can be transmitted from mother to child during delivery through contact with blood and vaginal secretions, but it is not commonly transmitted transplacentally. Infection of the infant can occur if the mother is a chronic hepatitis B surface antigen (HBsAg) carrier or has an acute HBV infection at the time of delivery. Transmission is rare if an acute infection occurs in either the first or second trimester of pregnancy.

Without postexposure prophylaxis (a combination of HBV vaccination and hepatitis B immune globulin), the risk of an infant acquiring HBV from an infected mother as a result of perinatal exposure is 70% to 90% for infants born to mothers who are positive for HBsAg and hepatitis B e antigen (HBeAg). The risk is 5% to 20% for infants born to HBsAg-positive but HBeAg-negative mothers.

HBV is also spread primarily through percutaneous contact with infected blood products (ie, blood transfusion, sharing of needles by drug addicts). The virus is found in virtually every type of human body fluid and also is spread through oral and genital contact.

See the following in Special Instructions:

-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

-Viral Hepatitis Serologic Profiles

Reference Values

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in blood 6 to 16 weeks after exposure to HBV. A confirmed positive HBsAg result is indicative of acute or chronic hepatitis B. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6-months duration indicates development of either a chronic carrier state or chronic hepatitis B.

Hepatitis B surface antibody (HBsAb) appears with the resolution of HBV infection and disappearance of HBsAg. A positive result indicates recovery from acute or chronic hepatitis B, or acquired immunity from HBV vaccination. This

assay does not differentiate between a vaccine-induced immune response and recovery from HBV infection. Per assay manufacturer's instructions for use, positive results are defined as HBsAb levels of 12.0 mIU/mL or greater, with adequate immunity to hepatitis B after recovery from past infection or HBV vaccination. Per current CDC guidance, individuals with HBsAb levels of 10 mIU/mL or greater after completing an HBV vaccination series are considered protected from hepatitis B.(1)

Negative results, defined as HBsAb levels of less than 5.0 mIU/mL, indicate a lack of recovery from acute or chronic hepatitis B or inadequate immune response to HBV vaccination. Indeterminate results, defined as HBsAb levels in the range of 5.0 to 11.9 mIU/mL, indicate inability to determine if HBsAb is present at levels consistent with recovery or immunity. Repeat testing is recommended in 1 to 3 months.

Hepatitis B core (HBc) total antibodies (combined IgG and IgM) appear shortly after the onset of symptoms of HBV infection and may be the only serologic marker remaining years after exposure to HBV. A positive result indicates exposure to HBV infection. A positive HBsAb result along with a positive HBc total antibody result is indicative of recovery from HBV infection. A positive HBsAb result with a negative HBc total antibody result is consistent with immunity to hepatitis B from HBV vaccination.

See the following in Special Instructions:

-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

-Viral Hepatitis Serologic Profiles

Cautions

Assay 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)

-Contain particulate matter

-Cadaveric specimens

-Heat inactivated specimens

Clinical Reference

1. Advisory Committee on Immunization Practices; Centers for Disease Control and Prevention (CDC). Immunization of

health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2011 Nov 25;60(RR-7):1-45

2. Mast EE, Margolis HS, Fiore AE, Advisory Committee on Immunization Practices (ACIP), et al: A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP);Part 1: Immunization of Infants, Children, and Adolescents. MMWR Recomm Rep. 2005 Dec 23;54(RR-16):1-31. Erratum in: MMWR Morb Mortal Wkly Rep. 2006 Feb 17;55(6):158-9. Erratum in: MMWR Morb Mortal Wkly Rep. 2007 Dec 7;56(48):1267

3. Centers for Disease Control and Prevention: Interpretation of hepatitis B serologic test results. Accessed October 2, 2020. Available at www.cdc.gov/hepatitis/HBV/PDFs/SerologicChartv8.pdf

4. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF: Diagnostic markers of chronic hepatitis B infection and disease. Antiviral Ther. 2010;15(3):35-44

5. Centers for Disease Control and Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. Accessed April 8, 2020. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm

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

7. 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

8. WHO Guidelines Development Group: World Health Organization: Guidelines on hepatitis B and C testing.World Health Organization; 2017. Accessed September 29, 2020. Available at www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en/

Performance

Method Description

Hepatitis B surface Antibody:

VITROS hepatitis B surface antibody (anti-HBs) assay is performed using an immunometric technique in which the anti-HBs present in the clinical serum sample reacts with hepatitis B surface antigen (HBsAg) (ad and ay subtypes) coated onto the assay reaction wells. A horseradish peroxidase (HRP)-labeled HBsAg conjugate (ad and ay subtypes) then complexes with the bound anti-HBs forming an "antigen sandwich." Unbound materials are removed by washing. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. HRP in the bound conjugate catalyzes the oxidation of the luminol derivative to produce light. The electron transfer agent increases the level and duration of the light produced. The light signals are detected by the system. The amount of HRP conjugate bound is directly proportional to the concentration of anti-HBs antibody present.(Package insert: VITROS Anti-HBs Quantitative Assay, No GEM1208, version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

Hepatitis B core Total Antibodies:

The VITROS hepatitis B core antibody (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. 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, No GEM1211, version 14.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

Hepatitis B surface Antigen Screen:

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal anti-HBs coated onto the wells, and a HRP-labeled mouse monoclonal anti-HBs antibody in the conjugate. Unbound conjugate is removed by washing. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is 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 level of HBsAg present in the sample.(Package insert: VITROS HBsAg assay, No GEM1201, version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

Hepatitis B surface Antigen Confirmation:

The VITROS HBsAg confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: the first aliquot is incubated with a neutralizing reagent containing high-titer anti-HBs (the confirmatory antibody); the second aliquot is incubated with a non-neutralizing control reagent (the sample diluent). The confirmatory antibody binds to HBsAg in the sample, inhibiting its reaction in the VITROS HBsAg assay. This leads to a reduced result compared to that for the non-neutralized control sample.(Package insert: VITROS HBsAg Confirmation assay, No GEM4201, version 13.1. 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

86706

86704

87340

87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HBABY	Hepatitis B Perinatal Exposure, S	77190-7

Result ID	Reporting Name	LOINC®
HBC	HBc Total Ab, S	13952-7
HB_AB	HBs Antibody, S	10900-9
HBSQN	HBs Antibody, Quantitative, S	5193-8
H_BAG	HBs Antigen, S	5196-1