Test Definition: HBAGP

HBs Antigen Prenatal, S

Overview

Useful For

Screening pregnant women for evidence of chronic hepatitis B virus (HBV) (or hepatitis B carrier state) to identify neonates who are at high risk of acquiring HBV at birth

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

This test is **not useful for** diagnosis of hepatitis B during the “window period” of acute HBV infection (ie, after disappearance of hepatitis B surface antigen and prior to appearance of hepatitis B surface antibody).

Testing Algorithm

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

Special Instructions

- Viral Hepatitis Serologic Profiles

Highlights

This test should be used to test or screen for chronic hepatitis B in **pregnant** individuals.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HBNTP	HBs Ag Confirmation Prenatal, S	No	No

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 who may or may not have risk factors for hepatitis B virus (HBV) infection. For testing such individuals, order HBAG / Hepatitis B Surface Antigen, 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 HBGSN / Hepatitis B Surface Antigen Screen, Serum.

This test **is not intended** for testing cadaver or grossly hemolyzed specimens. For testing such patients, order HBGCD / Hepatitis B Surface Antigen for Cadaveric or Hemolyzed Specimens, Serum, which is FDA-approved for testing on these sources.

Additional Testing Requirements

Testing for acute hepatitis B virus (HBV) infection should also include HBIM / Hepatitis B Core Antibody, IgM, Serum, as during the acute HBV infection "window period," hepatitis B surface (HBs) antigen and HBs antibody may not be detected.

Necessary Information

1. Date of collection is required.

2. Indicate if specimens are from autopsy/cadaver or hemolyzed sources so that the proper FDA-licensed assay can be performed.

Specimen Required

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 2 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 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

0.6 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 endemic throughout the world. The infection is spread primarily through percutaneous contact with infected blood products (eg, blood transfusion, sharing of needles by intravenous drug addicts). The virus is also found in various human body fluids, and it is known to be spread through oral and genital contacts. 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 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.

Reference Values

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

A reactive screen result confirmed as positive by hepatitis B surface antigen (HBsAg) confirmatory test is indicative of acute or chronic hepatitis B virus (HBV) infection or chronic HBV carrier state.

Specimens with initially reactive test results but negative (not confirmed) by HBsAg confirmatory test results are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. These unconfirmed HBsAg-reactive screening test results should be interpreted in conjunction with test results of other HBV serologic markers (eg, hepatitis B surface antibody; hepatitis B core antibody, total and IgM). Repeat testing at a later date is recommended if clinically indicated.

Confirmed presence of HBsAg is frequently associated with HBV replication and infectivity, especially when accompanied by the presence of hepatitis B envelope antigen (HBe) and/or detectable HBV DNA.

Cautions

Confirmed positive hepatitis B surface antigen (HBsAg) test results should be reported to the State Department of Health, as required by law in some states.

Individuals, especially neonates and children, who recently received hepatitis B vaccination may have transient-positive HBsAg test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass.

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

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;21:229-237. 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;8:267-281. 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;161:58-66. 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;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;156:355-368. 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

Specimens are first tested by the VITROS hepatitis B surface antigen (HBsAg) assay. Per assay manufacturer's recommendation, all hepatitis B surface antigen (HBsAg)-reactive specimens (signal-to-cutoff ratios > or =1.00) in prenatal screening should be confirmed by the VITROS HBsAg Confirmatory assay.

Chemiluminescence Immunoassay:

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal hepatitis B surface antibody (anti-HBs) coated onto the wells and a horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBs 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, Pub. No. GEM1201, version 13.1. Ortho-Clinical Diagnostics, Inc; 09/06/2019)

Confirmation:

The VITROS HBsAg Confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: one 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, Pub. 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
87340

87341 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HBAGP	HBs Antigen Prenatal, S	5196-1

Result ID	Reporting Name	LOINC®
HBSAP	HBs Antigen Prenatal, S	5196-1