Overview

Useful For

Screening pregnant women for chronic hepatitis B

Determining the level of infectivity of chronic hepatitis B in pregnant women

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
HBAGP	HBs Antigen Prenatal, S	Yes	Yes

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
EAG	Hepatitis Be Ag, S	Yes	No
HEAB	HBe Antibody, S	Yes	No
HBNTP	HBs Ag Confirmation Prenatal, S	No	No

Testing Algorithm

If hepatitis B surface antigen (HBsAg) prenatal is reactive, then HBsAg confirmation prenatal will be performed at an additional charge. If HBsAg confirmation is positive, then hepatitis Be-antigen (HBe) and HBe-antibody tests will be performed at an additional charge.

Special Instructions

- Viral Hepatitis Serologic Profiles

Method Name

Chemiluminescence Immunoassay (CIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of draw is required.

Specimen Required

Patient Preparation: For 24 hours before this test 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: 2.5 mL

Collection Instructions: Spin down and remove serum from gel within 24 hours.

Specimen Minimum Volume

2 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)		
	Refrigerated	7 days	
	Ambient	24 hours	

Clinical and 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 is 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.

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

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum 6 to 16 weeks following hepatitis B virus (HBV) infection. A confirmed positive result for HBsAg 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 indicates development of either a chronic carrier state or chronic liver disease. Hepatitis B surface antibody (anti-HBs) appears with the resolution of HBV infection after the disappearance of HBsAg.

Hepatitis Be-antigen (HBeAg) appears at approximately the same time as HBsAg and indicates that the virus is replicating and the individual is infectious. Appearance of hepatitis Be antibody (anti-HBe) after the disappearance of HBsAg and HBeAg usually indicates recovery and loss of infectivity.

Cautions

Not useful for diagnosis of hepatitis B during the "window period" of acute hepatitis B virus (HBV) infection (ie, after disappearance of hepatitis B surface antigen [HBsAg] and prior to appearance of hepatitis B surface antibody [anti-HBs]). Testing for acute HBV infection should also include anti-hepatitis B core IgM.

Positive hepatitis B surface antigen (HBsAg) test results should be reported by the patient care provider 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.

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 >3,000 mg/dL)

-Grossly hemolyzed (hemoglobin level of >61 mg/dL)

-Contain particulate matter

-Cadaveric specimens

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, et al: Diagnostic markers of chronic hepatitis B infection and disease. Antiviral Therapy 2010;15(3):35-44

2. Vranckx R, Alisjahbana A, Meheus A: Hepatitis B virus vaccination and antenatal transmission of HBV markers to neonates. J Viral Hepat 1999;6:135-139

Performance

Method Description

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

HBsAg Screening:

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse-monoclonal antihepatitis B surface (anti-HBs) antibody coated onto the wells, and a horseradish peroxidase (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 VITROS Immunodiagnostic System. The amount of HRP conjugate bound is indicative of the level of HBsAg present in the sample.(Package insert: VITROS HBsAg assay, GEM1201, version 12.0; Ortho-Clinical Diagnostics, Inc, Rochester, NY, 06/22/2017)

HBsAg Confirmation:

The VITROS HBsAg Confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: 1 aliquot is incubated with a neutralizing reagent containing high-titer anti-HBs (the confirmatory antibody); the second aliquot is incubated with a nonneutralizing 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 nonneutralized control sample.(Package insert: VITROS HBsAg Confirmation assay, GEM4201, version 12.0; Ortho-Clinical Diagnostics, Inc, Rochester, NY. 06/22/2017)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

1 day

Maximum Laboratory Time

4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and 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 or approved by the U.S. 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

86707 (if appropriate)

87341 (if appropriate)

87350 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PHSP	Prenatal Hepatitis Evaluation	In Process

Result ID	Test Result Name	Result LOINC Value
HBSAP	HBs Antigen Prenatal, S	5196-1