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

Highlights
This test should be ordered for infants born to mothers with chronic hepatitis B only.

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBAG</td>
<td>HBs Antigen, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>HBC</td>
<td>HBc Total Ab, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>HBAB</td>
<td>HBs Antibody, S</td>
<td>Yes</td>
<td>Yes</td>
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Reflex Tests

<table>
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<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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</thead>
<tbody>
<tr>
<td>HBGNT</td>
<td>HBs Antigen Confirmation, S</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

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

Special Instructions
- Viral Hepatitis Serologic Profiles
- HBV Infection-Diagnostic Approach and Management Algorithm

Method Name
Chemiluminescence Immunoassay (CIA)

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Necessary Information
Date of draw 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. Pour off serum into aliquot tube.

**Forms**

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

**Specimen Minimum Volume**

1 mL

**Reject Due To**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Other</td>
<td>Plasma</td>
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**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>Serum SST</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
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<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
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**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 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:
- HBV Infection-Diagnostic Approach and Management Algorithm
- Viral Hepatitis Serologic Profile

**Reference Values**

**Negative**

**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:
- HBV Infection-Diagnostic Approach and Management Algorithm
- Viral Hepatitis Serologic Profiles

**Cautions**

Assay performance characteristics have not been established for the following specimen characteristics:
Test Definition: HBABY
Hepatitis B Perinatal Exposure, S

-Grossly icteric (total bilirubin level of >20 mg/dL)
-Grossly lipemic (triolein level of >3,000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >500 mg/dL)
-Contain particulate matter
-Cadaveric specimens
-Heat inactivated specimens

Clinical Reference
1. CDC: Immunization of health-care personnel. Mortal Morbid Wkly Rpt 2011;60[No SS-7]:5

Performance
Method Description
Hepatitis B surface (HBs) Antibody:

VITROS anti-HBs assay is performed using the VITROS Anti-HBs Quantitative Reagent Pack and VITROS Immunodiagnostic Products Anti-HBs Calibrators on the automated VITROS Immunodiagnostic System. This chemiluminescent immunoassay is based on 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 VITROS Immunodiagnostic 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 12.0; Ortho-Clinical Diagnostics Inc, Rochester, NY, 6/22/17)

Hepatitis B core (HBC) Total Antibodies:

The VITROS 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 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 VITROS Immunodiagnostic 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 12.0; Ortho-Clinical Diagnostics Inc, Rochester, NY, 6/22/17)
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 VITROS Immunodiagnostic 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 12.0; Ortho-Clinical Diagnostics Inc, Rochester, NY, 2/14/17)

Hepatitis B surface (HBs) Antigen Screen:

This immunometric technique involves the simultaneous reaction of HBsAg in the sample with mouse monoclonal anti-hepatitis 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, No GEM1201, version 12.0; Ortho-Clinical Diagnostics Inc, Rochester, NY, 06/22/17)

Hepatitis B surface (HBs) 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: 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, No GEM4201, version 12.0; Ortho-Clinical Diagnostics, Inc, Rochester, NY, 06/22/17)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

1 day

Maximum Laboratory Time

3 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.
Test Definition: HBABY
Hepatitis B Perinatal Exposure, S

- 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
86706
86704
87340
87341 (if appropriate)

LOINC® Information

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<th>Order LOINC Value</th>
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<td>Hepatitis B Perinatal Exposure, S</td>
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<table>
<thead>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<td>HBc Total Ab, S</td>
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<tr>
<td>HB_AB</td>
<td>HBs Antibody, S</td>
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<td>HBs Antibody, Quantitative, S</td>
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