Overview

Useful For
Identifying previous exposure to hepatitis B virus
Determining adequate immunity from hepatitis B vaccination

Highlights
This assay provides both qualitative and quantitative results.

Testing Algorithm
See HBV Infection-Diagnostic Approach and Management Algorithm in Special Instructions.

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

Method Name
Chemiluminescent Immunoassay (CIA)

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Advisory Information
If patient has had a liver transplant, order HBABT / Hepatitis B Surface Antibody Monitor, Post-Transplant, Serum.

Necessary Information
Date of draw 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 1 of the following forms with the specimen:

- **General Request** (T239)
- **Gastroenterology and Hepatology Client Test Request** (T728)

### Specimen Minimum Volume

0.5 mL

### Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
</tbody>
</table>

### Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum SST</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
<td></td>
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### Clinical and Interpretive

#### Clinical Information

Hepatitis B virus (HBV) infection, also known as serum hepatitis, is endemic throughout the world. The infection is spread primarily through blood transfusion or percutaneous contact with infected blood products, such as sharing of needles among injection drug users. The virus is also found in virtually every type of human body fluid and has been known to be spread through oral and genital contact. HBV can be transmitted from mother to child during delivery through contact with blood and vaginal secretions, but is not commonly transmitted via the transplacental route.

The incubation period for HBV infection averages 60 to 90 days (range of 45-180 days). Common symptoms include malaise, fever, gastroenteritis, and jaundice (icterus). After acute infection, HBV infection becomes chronic in 30% to 90% of infected children younger than 5 years of age and in 5% to 10% of infected individuals age 5 or older. Some of these chronic carriers are asymptomatic, while others progress to chronic liver disease, including cirrhosis and hepatocellular carcinoma.

Hepatitis B surface antigen (HBsAg) is the first serologic marker, appearing in the serum 6 to 16 weeks following HBV infection. In acute cases, HBsAg usually disappears 1 to 2 months after the onset of symptoms with the appearance of hepatitis B surface antibody (anti-HBs). Anti-HBs also appears as the immune response following hepatitis B vaccination.

See [HBV Infection-Diagnostic Approach and Management Algorithm](#) in Special Instructions

### Reference Values

**HEPATITIS B SURFACE ANTIBODY**
Unvaccinated: negative
Vaccinated: positive

HEPATITIS B SURFACE ANTIBODY, QUANTITATIVE
Unvaccinated: <5.0 mIU/mL
Vaccinated: ≥12.0 mIU/mL

See Viral Hepatitis Serologic Profiles in Special Instructions.

**Interpretation**

A positive result indicates recovery from acute or chronic hepatitis B virus (HBV) infection or acquired immunity from HBV vaccination. This assay does not differentiate between a vaccine-induced immune response and an immune response induced by infection with HBV. A positive total antihepatitis B core (anti-HBc) result would indicate that the hepatitis B surface antibody (anti-HBs) response is due to past HBV infection.

Per assay manufacturer's instructions for use, positive results, defined as anti-HBs levels of 12.0 mIU/mL or greater, indicate adequate immunity to hepatitis B from past hepatitis B or HBV vaccination. However, per current CDC guidance, (1) individuals with anti-HBs levels greater than 10 mIU/mL after completing an HBV vaccination series are considered protected from hepatitis B.

Negative results, defined as anti-HBs 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. The US Advisory Committee on Immunization Practices does not recommend more than 2 HBV vaccine series in nonresponders.

Indeterminate results, defined as anti-HBs levels in the range from 5 to 11.9 mIU/mL, indicate inability to determine if anti-HBs is present at levels consistent with recovery or immunity. Repeat testing is recommended in 1 to 3 months.

See -HBV Infection-Diagnostic Approach and Management Algorithm in Special Instructions.

**Cautions**

Individuals who have received blood component therapies (eg, whole blood), plasma, or intravenous immunoglobulin infusion) in the previous 3 to 6 months may have false-positive hepatitis B surface antibody (anti-HBs) results due to passive transfer of anti-HBs present in these products.

Individuals possessing IgM anti-rubella virus may have falsely high results with the VITROS Anti-HBs quantitative test.

Anti-HBs levels from past hepatitis B or hepatitis B virus (HBV) vaccination may fall below detectable levels over time.

A positive anti-HBs result does not exclude infection by another hepatitis virus.

Performance characteristics have not been established for the following specimen characteristics:

- Grossly icteric (total bilirubin level of >20 mg/dL)
- Grossly lipemic (triglyceride level of >3,000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
Test Definition: HBAB
HBs Antibody, S

-Containing particulate matter
-Cadaveric specimens
-Body fluids other than serum (eg, saliva, urine, CSF, amniotic, peritoneal, or pleural fluids)

Clinical Reference
1. Immunization of Health-Care Personnel. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention, MMWR 2011;60(7):5

Performance

Method Description
VITROS hepatitis B surface antibody (anti-HBs) quantitative 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, publication no GEM1208_US_EN, version 13.0; Ortho-Clinical Diagnostics, Inc, Rochester, NY, 10/03/17)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; Varies

Analytic Time
1 day

Maximum Laboratory Time
2 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester
Test Definition: HBAB
HBs Antibody, S

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
86706

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>HBAB</td>
<td>HBs Antibody, S</td>
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<table>
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<th>Result ID</th>
<th>Test Result Name</th>
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<tbody>
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<td>HBs Antibody, S</td>
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<tr>
<td>HBSQN</td>
<td>HBs Antibody, Quantitative, S</td>
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