Overview

Useful For
Diagnosis of acute, recent, or chronic hepatitis B infection
Determination of chronic hepatitis B infection status

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</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) screen is reactive with signal-to-cutoff (S/CO) ratio in the range of 1.00 to 100.0 then HBsAg confirmation will be performed at an additional charge.

The following algorithms are available in Special Instructions:
- HBV Infection-Diagnostic Approach and Management Algorithm
- HBV Infection-Monitoring Before and After Liver Transplantation

Special Instructions
- Viral Hepatitis Serologic Profiles
- HBV Infection-Monitoring Before and After Liver Transplantation
- HBV Infection-Diagnostic Approach and Management Algorithm

Method Name
Chemiluminescence Immunoassay

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Necessary Information
1. Date of draw 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: 2mL

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
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
</tr>
</thead>
<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>
</tr>
</tbody>
</table>

Specimen Stability Information

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

Clinical and 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.

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum at 6 to 16 weeks following exposure to HBV. In acute infection, HBsAg usually disappears in 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6 months in duration indicates development of either a chronic carrier state or chronic HBV infection.
See the following in Special Instructions:

- HBV Infection-Diagnostic Approach and Management Algorithm
- HBV Infection-Monitoring Before and After Liver Transplantation
- Viral Hepatitis Serologic Profile

**Reference Values**

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

**Interpretation**

A reactive screen result (signal-to-cutoff ratio: S/CO \( \geq 1.00 \), but \( < = 100.0 \)) confirmed as positive by hepatitis B surface antigen (HBsAg) confirmatory test (see Method Description) or a positive screen result (S/CO \( > 100.0 \)) is indicative of acute or chronic hepatitis B virus (HBV) infection, or chronic HBV carrier state.

Specimens with reactive screen results but negative (ie, not confirmed) HBsAg confirmatory test results are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. Repeat testing is recommended at a later date if clinically indicated.

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

See the following in Special Instructions:

- HBV Infection-Diagnostic Approach and Management Algorithm
- HBV Infection-Monitoring Before and After Liver Transplantation
- Viral Hepatitis Serologic Profile

**Cautions**

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

Not useful 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 hepatitis B core IgM antibody (anti-HBc IgM).

Positive screen results (ie, signal-to-cutoff ratio: S/CO \( > 100.0 \)) without need for confirmation testing should be interpreted in conjunction with test results of other HBV serologic markers (eg, anti-HBs, anti-HBc total, and anti-HBc IgM).

Not suitable as stand-alone prenatal screening test of HBsAg status in pregnant women.

Positive HBsAg test results should be reported by the health 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.
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 >500 mg/dL)
- Containing particulate matter
- Cadaveric specimens

**Clinical Reference**


**Performance**

**Method Description**

Specimens are first tested by the VITROS hepatitis B surface antigen (HBsAg) assay. With modification to the assay manufacturer's instructions for use, specimens yielding signal-to-cutoff (S/CO) ≥ 1.00 but ≤ 100.0 will be confirmed by the VITROS HBsAg Confirmatory assay. Specimens that are strongly positive (ie, S/CO >100.0) do not require this confirmation.

**HBsAg:**

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, Pub. No. GEM1201, version 12.0; Ortho-Clinical Diagnostics Inc, Rochester, NY 6/22/17)

**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, Pub. No. GEM4201, version 12.0; Ortho-Clinical Diagnostics Inc, Rochester, NY 6/22/17)
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

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-HBsAg

87341-HBsAg confirmation (if appropriate)

LOINC® Information

<table>
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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>HBAG</td>
<td>HBs Antigen, S</td>
<td>5196-1</td>
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<table>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>H_BAG</td>
<td>HBs Antigen, S</td>
<td>5196-1</td>
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