Overview

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

Determination of chronic hepatitis B infection status

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

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>
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</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.

See the following 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

Advisory Information

This test is not intended for stand-alone prenatal screening for chronic hepatitis B in pregnant women.

For testing such patients, order HBAGP / Hepatitis B Surface Antigen Prenatal, 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 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:** 2mL

**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. Transfer 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>Gross hemolysis</th>
<th>Reject</th>
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<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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<tr>
<td>Gross icterus</td>
<td>Reject</td>
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</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<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>
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</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

Reference Values
Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation
A reactive screen result (signal-to-cutoff ratio [S/CO]: > or =1.00, but < or =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 initially reactive screen 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 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 B e 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 Profiles

Cautions
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).

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 < or =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.

Chemiluminescence Immunoassay:

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 13.0; Ortho-Clinical Diagnostics Inc, Rochester, NY 10/03/17)

Confirmation:

The VITROS HBsAg Confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: the first 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 13.0; Ortho-Clinical Diagnostics Inc, Rochester, NY 10/05/17)

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

87341 (if appropriate)

LOINC® Information
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<th>Test Order Name</th>
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<td>HBs Antigen, S</td>
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