Overview

Useful For
Determining infectivity of hepatitis B virus (HBV) carriers
Monitoring infection status of individuals with chronic hepatitis B
Monitoring serologic response of chronically HBV-infected patients receiving antiviral therapy
Determining the level of hepatitis B e-antigen

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
Chemiluminescence Immunoassay

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Additional Testing Requirements
If ordered with HBVQN / Hepatitis B Virus (HBV) DNA Detection and Quantification by Real-Time PCR, Serum; send separate vials.

Necessary Information
Date of collection 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: 1 mL

- Collection Instructions: Centrifuge and aliquot serum within 24 hours.
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>Specimen Type</th>
<th>Mild OK; Gross reject</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
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<td></td>
</tr>
<tr>
<td>Lipemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Icterus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</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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<tbody>
<tr>
<td>Serum SST</td>
<td>Frozen (preferred)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
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<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
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**Clinical and Interpretive**

**Clinical Information**

Hepatitis B e-antigen (HBeAg) is found in the early phase of hepatitis B infection soon after hepatitis B surface antigen becomes detectable. Serum levels of both antigens rise rapidly during the period of viral replication. The presence of HBeAg correlates with hepatitis B virus (HBV) infectivity, the number of infectious virions, and the presence of HBV core antigen in the infected hepatocytes.

In HBV carriers and patients with chronic hepatitis B, positive HBeAg results usually indicate presence of active HBV replication and high infectivity. A negative HBeAg result indicates very minimal or no HBV replication.

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

**Reference Values**

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

**Interpretation**

Presence of hepatitis B e-antigen (HBeAg) and absence of HBe antibody (anti-HBe) usually indicate active hepatitis B virus (HBV) replication and high infectivity.

Absence of HBeAg with appearance of anti-HBe is consistent with loss of HBV infectivity.

**Cautions**

Biotin (vitamin B7) is a common ingredient in multivitamins and dietary supplements to enhance hair, nail, and skin
Biotin can interfere with the assay performance and cause possible false-negative hepatitis B e-antigen (HBeAg) and false-positive anti-HBe results. Patients should be instructed to stop taking such multivitamins and dietary supplements for at least 24 hours prior to blood collection.

Disappearance of HBeAg or appearance of anti-HBe in serum does not completely rule-out chronic hepatitis B carrier state or infectivity.

Performance characteristics of this assay have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. This assay is not licensed by FDA for testing cord blood specimens or screening donors of blood, plasma, human cell or tissue products.

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

- Grossly icteric (total bilirubin level >20 mg/dL)
- Grossly lipemic (triolein level >3,000 mg/dL)
- Grossly hemolyzed (hemoglobin level >61 mg/dL)
- Specimen containing particulate matter

**Clinical Reference**


**Performance**

**Method Description**

This test is performed using the FDA-approved VITROS HBeAg Reagent Pack and the Immunodiagnostic Product hepatitis B e-antigen (HBeAg) Calibrator on the VITROS Immunodiagnostic Systems based on chemiluminescence immunoassay principle. An immunometric technique is used. This involves the simultaneous reaction of HBeAg in the sample with biotinylated mouse monoclonal HBeAg antibody and horseradish peroxidase (HRP)-labeled mouse monoclonal HBeAg antibody in the conjugate. The immune complex is captured by streptavidin on the wells, and unbound materials are 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. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of HBeAg present in the sample. (Package insert: VITROS Immunodiagnostic Product HBeAg Reagent Pack, No. GEM1222_US_EN, version 8.0; Ortho-Clinical Diagnostics, Rochester, NY 14626-5101, 09/22/2017)

**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
87350

LOINC® Information

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<th>Test Order Name</th>
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<td>EAG</td>
<td>Hepatitis Be Ag, S</td>
<td>13954-3</td>
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<table>
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<th>Result ID</th>
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