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 levels of both hepatitis B e-antigen and antibody

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>EAG</td>
<td>Hepatitis Be Ag, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>HEAB</td>
<td>HBe Antibody, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Special Instructions
- Viral Hepatitis Serologic Profiles

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
Test Definition: HEAG
Hepatitis Be Ag and Ab, S

Specimen Volume: 1.5 mL

Collection Instructions: Centrifuge and aliquot serum from gel within 24 hours.

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>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>Serum SST</td>
<td>Frozen (preferred)</td>
<td></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 e-antigen (HBeAg) is a small polypeptide that exists in a free form in the serum of individuals during the early phase of hepatitis B infection, soon after hepatitis B surface antigen (HBsAg) becomes detectable. Serum levels of both HBeAg and HBsAg rise rapidly during the period of viral replication. The presence of HBeAg in serum correlates with hepatitis B virus (HBV) infectivity, the number of infectious virions, and the presence of HBV core antigen in the infected hepatocytes.

During recovery from acute hepatitis B, HBeAg level declines and becomes undetectable in the serum, while hepatitis B e-antibody (anti-HBe) appears and becomes detectable in the serum. Anti-HBe usually remains detectable for many years after recovery from acute HBV infection.

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. Positive anti-HBe results usually indicate inactivity of the virus and low infectivity. Positive anti-HBe results in the presence of detectable HBV DNA in serum also indicate active viral replication in these patients.

Reference Values
HEPATITIS Be ANTIGEN

Negative
Hepatitis Be ANTIBODY

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.

Although resolution of chronic HBV infection generally follows the appearance of anti-HBe, the HBV carrier state may persist.

Cautions

Biotin (vitamin B7) is a common ingredient in multivitamins and dietary supplements to enhance hair, nail, and skin growth. 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 these 2 assays have not been established in patients under the age of 2 or in populations of immunocompromised or immunosuppressed patients. These 2 assays are not licensed by FDA for testing cord blood samples 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 of >20 mg/dL)
- Grossly lipemic (triolein level of >3,000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >61 mg/dL)
- Specimen containing particulate matter

Clinical Reference


Performance
Method Description

Hepatitis B e-antigen (HBeAg) Assay:

This test is performed using the FDA-approved VITROS HBeAg Reagent Pack and the Immunodiagnostic Product 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 hepatitis B e-antibody and horseradish peroxidase (HRP)-labeled mouse monoclonal HB e-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)

Hepatitis B e-antibody (Anti-HBe) Assay:

This test is performed using the FDA-approved VITROS Anti-HBe Reagent Pack and the VITROS Anti-HBe Calibrator on the VITROS Immunodiagnostic Systems based on chemiluminescence immunoassay principle. A competitive technique is used which involves pre-incubation of anti-HBe IgG in the sample with a fixed weight of HBeAg in the assay reagent, followed by incubation with a conjugate reagent that contains biotinylated mouse monoclonal anti-HBe IgG and horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBe IgG. The immune complex is captured by streptavidin on the wells. 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 anti-HBe IgG present in the sample. (Package insert: VITROS Immunodiagnostic Product Anti-HBe Reagent Pack, No. GEM1223, version 5.1; Ortho-Clinical Diagnostics, Rochester, NY 14626-5101, 09/22/2017)

This test is performed using the FDA-approved VITROS Anti-HBe Reagent Pack and the VITROS Anti-HBe Calibrator on the VITROS Immunodiagnostic Systems based on chemiluminescence immunoassay principle. A competitive technique is used which involves pre-incubation of anti-HBe IgG in the sample with a fixed weight of HBeAg in the assay reagent, followed by incubation with a conjugate reagent that contains biotinylated mouse monoclonal anti-HBe IgG and horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HBe IgG. The immune complex is captured by streptavidin on the wells. 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 anti-HBe IgG present in the sample.
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 anti-HBe IgG present in the sample. (Package insert: VITROS Immunodiagnostic Product Anti-HBe Reagent Pack, No. GEM1223, version 5.1; 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
86707
87350

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEAG</td>
<td>Hepatitis Be Ag and Ab, S</td>
<td>77176-6</td>
</tr>
<tr>
<td>Result ID</td>
<td>Test Result Name</td>
<td>Result LOINC Value</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>EAG</td>
<td>Hepatitis Be Ag, S</td>
<td>13954-3</td>
</tr>
<tr>
<td>HEAB</td>
<td>HBe Antibody, S</td>
<td>33463-1</td>
</tr>
</tbody>
</table>