Hepatitis B Virus Surface Antigen (HBsAg) Confirmatory EIA
Test Code: 30829

Please contact Client Services to set up a Pre-transplant account to order this assay.

Clinical and Procedure

Clinical Utility
The GS HBsAg Confirmatory Assay 3.0 is a qualitative assay intended for the confirmation of HBsAg reactive specimens detected in the GS HBsAg EIA 3.0.

About Hepatitis B Virus
Hepatitis B virus (HBV) is a major public health problem worldwide, with significant transmission of the virus occurring through the use of contaminated donor blood and plasma. Because the presence of circulating Hepatitis B Surface Antigen (HBsAg) closely follows the course of infection, screening for HBsAg is used to detect potentially infectious blood and plasma. Enzyme immunoassays to detect HBsAg have replaced relatively insensitive gel diffusion methods, and have been reported to have equivalent sensitivity to radioimmunoassay methods. The application of monoclonal antibodies for the detection of HBsAg has previously been reported.

The GS HBsAg Confirmatory Assay 3.0 is an HBsAg neutralization procedure using anti-HBs (Human) to confirm the presence of HBsAg in specimens found to be repeatedly reactive by the GS HBsAg EIA 3.0. A repeatedly reactive specimen should be confirmed by a licensed neutralization procedure utilizing human anti-HBs (HBsAg Confirmatory Assay). Only those specimens in which the HBsAg can be neutralized by the confirmatory test procedure may be designated as positive for HBsAg.

Procedure
The repeatedly reactive specimen is incubated with HBsAg Confirmatory Reagent [Antibody to Hepatitis B Surface Antigen (Human)]. If HBsAg is present in the specimen, it will be neutralized by the HBsAg Confirmatory Reagent. The treated specimen is re-assayed using the GS HBsAg EIA 3.0. The neutralized HBsAg is prevented from binding to the HBsAg antibody-coated microwells, which results in a reduction of signal.

A non-neutralized control of the specimen [treated with HBsAg Negative Control (Human)] in place of HBsAg Confirmatory Reagent] is tested in parallel to the neutralized specimen for comparison of signal.

GS HBsAg EIA3.0 repeatedly reactive specimens are confirmed positive by the GS HBsAg Confirmatory Assay 3.0 if the reduction in signal of the neutralized sample and the non-neutralized specimen signal is greater than or equal to the assay cutoff. Test performed by VRL Eurofins, 6933 S. Revere Parkway, Centennial, CO 80112. This test has been cleared or approved for diagnostic use by the U.S. Food and Drug Administration. See package insert for more information.

Turnaround Time
Within 24 hours from receipt of specimen (Monday - Friday).

Specimen Information

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<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
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<tbody>
<tr>
<td>Plasma</td>
<td>30829</td>
<td>87341</td>
<td>Yes</td>
<td>1 mL (min 500 μL)</td>
<td>Qualitative</td>
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<tr>
<td>Serum</td>
<td>30829</td>
<td>87341</td>
<td>Yes</td>
<td>1 mL (min 500 µL)</td>
<td>Qualitative</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect whole blood in an EDTA, lavender top tube. Whole blood in ACD, Lithium Heparin, Sodium Citrate, or Sodium Heparin tubes are also accepted. Do not freeze whole blood.
- Sample sent in original vacutainer tube can be shipped at ambient or refrigerated temperature, must be received within 7 days.
- If not shipping in original container, centrifuge and transfer 1 mL (min 500 µL) plasma to a screw top tube. Plasma shipped at ambient or refrigerated temperature must be received within 7 days of collection or frozen.

**Shipping**
All specimens must be labeled with patient's name and collection date. A Viracor/VRL Eurofins Pre-Transplant test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: VRL Eurofins, 6933 S. Revere Parkway, Centennial, CO 80112.

**Causes for Rejection**
Whole blood frozen, specimens beyond their acceptable length of time from collection as listed in the specimen handling, or specimen types other than those listed.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above. The CPT codes provided are based on VRL Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. VRL Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.