

## SPECIMEN SUBMISSION GUIDELINES

HIV Diagnostics and Reference Laboratory, Diagnostics and Countermeasures Branch  
 Center for Infectious Disease Research, Walter Reed Army Institute of Research  
 508 Research Drive, Silver Spring, MD 20910

### *Hepatitis B Surface Antigen (HBsAg) Confirmatory Assay Test Specification*

<b>Test Name: Hepatitis B Surface Antigen (HBsAg) Confirmatory Assay</b>				
<b>Clinical Significance</b>	<b>Specimen Requirements</b>	<b>Transport/Storage Temperature</b>	<b>Test Approved For</b>	<b>Turn Around Time (After Receipt at HDRL)</b>
<p>The GS HBsAg Confirmatory Assay 3.0 is a qualitative assay intended for the confirmation of HBsAg repeatedly reactive specimens detected in the GS HBsAg EIA 3.0.</p> <p>Test employed: licensed commercially available: Bio-Rad GS HBsAg Confirmatory Assay 3.0</p> <p>Reference Range: Negative</p>	<p>3 ml Serum or Plasma</p> <p>Acceptable anticoagulants: EDTA, heparin, sodium citrate, CPDA-1, ACD</p>	<p>Shipping:                      Ambient (15-30°C)                      Refrigerated (2-8°C)                      Frozen (-20°C)</p> <p>Test must be performed within 7 days of draw if shipped with cold packs or ambient temperature.</p> <p>Ship frozen if sample will not be received at HDRL within 7 days.</p> <p>When shipping frozen, use 2+ lbs. dry ice per day of transport. Shipping on 6 lbs. additional dry ice recommended in case of shipment delay.</p>	<p>GS HBsAg Confirmatory Assay 3.0 is FDA approved as a neutralization procedure for confirmatory testing of repeatedly reactive HBsAg EIA samples.</p>	<p>5 business days</p>
<p>Note: Test performed on HBsAg EIA repeatedly reactive specimens per CDC guidelines</p>				

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