

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 Dr., Silver Spring, MD, 20910

Hepatitis B Surface Antigen (HBsAg) Confirmatory Assay Test Specification

| Test Name: Hepatitis B Surface Antigen (HBsAg) Confirmatory Assay | | | | |
|--|--|---|---|---|
| Clinical Significance | Specimen Requirements | Transport/Storage Temperature | Test Approved For | Turn Around Time (After Receipt at HDRL) |
| <p>The GS HBsAg Confirmatory Assay 3.0 is a qualitative assay intended for the confirmation of HBsAg repeat reactive specimens detected by the GS HBsAg EIA 3.0 assay.</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>Ship frozen if sample will not be received at HDRL within 48 hours at HDRL.</p> <p>When shipping frozen, use 2+ lbs. dry ice per day of transport. Shipment on 6 lbs. additional dry ice is 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 repeat 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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