

**Test Menu**

TOPIC	DESCRIPTION
Test Name	Hepatitis B Surface Antigen (HBsAg)
Other Name (s)	HBsAg
Analyte(s)	Hepatitis B Surface Antigen
Test Code	0300
Lab location	Jacksonville, Miami, and Tampa locations
Department	Serology
Pre-Approval Required	None
Additional Required Forms	None
Specimen Source	Blood, Serum
Special Specimen Preparation	None
Minimum Volume	2 ml serum (preferred) or 5-6 ml whole blood
Storage Conditions	Specimens may be stored on or off the clot, red blood cells, or separator gel for up to 24 hrs at RT or up to 6 days at 2-8C. If testing will be delayed more than 6 days, remove serum or plasma from the clot, red blood cells or separator gel and store at -20C or colder. Avoid more than 3 freeze/thaw cycles.
Collection Media	Serum (tiger or yellow top SST) preferred
Specimen Labeling	Specimen must be labeled with at least two unique patient identifiers, Ex: Name and DOB. <b>Electronic lab order preferred, HMS, Etc.</b> <b>Information on the specimen must match the requisition.</b>
Packaging and Shipping Instructions and Handling	Ship in a cooler with ice packs at 2-8C for overnight delivery and to be received no more than 6 days from collection date.
Test Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)
Turnaround Time	48-96 hrs
Result Indicator	Nonreactive or reactive.
Unsatisfactory Specimen	Grossly hemolyzed, heat-inactivated, pooled and contaminated samples. Cadaveric specimens and fluids other than human serum or plasma. Specimens that exceed the storage limitations listed above.
Interferences and Limitations	<ol style="list-style-type: none"> <li>Liquid anticoagulants may have a dilution effect resulting in lower S/CO values for individual patient specimens.</li> <li>For accurate results, specimen should be free of fibrin, red blood cells, and other particulate matter.</li> <li>This assay is not verified for use in screening blood, plasma or tissue donors.</li> <li>Current methods for the detection of HBsAg may not detect all potentially infected individuals. A nonreactive test result does not exclude the possibility of exposure to or infection with hepatitis B virus. A nonreactive test result in individuals with prior exposure to hepatitis B may be due to antigen levels below the detection limit of the assay or lack of antigen reactivity to the antibodies in this assay.</li> <li>If the results are inconsistent with clinical evidence, additional testing is suggested to confirm this result.</li> <li>For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection.</li> <li>Results obtained with this assay may not be used interchangeably with values obtained with different manufacturers' assay methods.</li> <li>Patients routinely exposed to animals or to animal serum products can be prone to interference and anomalous results may be observed.</li> <li>Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values.</li> <li>A reactive HBsAg result does not exclude co-infection by another hepatitis virus.</li> </ol>
Additional Information & Notes	<p>Non-reactive: Specimen considered negative for HBsAg. A non-reactive test result does not exclude the possibility of exposure to or infection with hepatitis B virus. For individuals with prior exposure to hepatitis B, a nonreactive test result may be due to antigen levels below the detection limit of the assay or lack of antigen reactivity to the antibodies in the assay.</p> <p>Reactive: Specimen considered repeatedly reactive; confirm using the ARCHITECT HBsAg Qualitative Confirmatory assay.</p>
Reference Range	Nonreactive
Reference Lab	None
Reflex testing	If HBsAg is reported as reactive, the specimen needs confirmation and will reflex to Test 0305 Hepatitis B Surface Antigen Confirmation. The result of the confirmatory assay, if done, is reported separately