Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis B Immunization Status
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86706
Synonyms	Antibody to Hepatitis B Surface Antigen, Anti-HBs, Hep B Immunization status
Brief Description of Test	The Bio-Rad MONOLISA™ Anti-HBs EIA is used for the detection of antibody to hepatitis B surface antigen in human serum. The assay results may be used as an aid in the determination of susceptibility to hepatitis B virus (HBV) infection in individuals prior to or following HBV vaccination or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.
Possible Results	Nonreactive Borderline Reactive
Reference Range	Reactive
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap aliquot tube
Minimum volume accepted:	Request 1 mL 275 µL minimum
Collection Instructions	Specimen Container – Serum Separator Tubes (SST) or Screw Cap Aliquot Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form.

	Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	• 2-8°C for 7 days or • For shipments that are delivered >7 days from collection, specimens should be kept frozen (≤ -20°C). Do not freeze on the clot. Aliquot specimens.
Causes for Rejection	• Unspun • Short Draw/Overfill • Received outside acceptable transport conditions • Incorrect source • Expired collection tubes
Limitations of the Procedure	For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. A nonreactive test result does not exclude the possibility of exposure to hepatitis B virus. Results obtained with the MONOLISA™ Anti-HBs EIA assay may not be used interchangeably with values obtained with different manufacturers' anti-HBs assay methods. Results from immunosuppressed patients should be interpreted with caution. This assay does not differentiate between a vaccine-induced immune response and an immune response induced by infection with HBV. To determine if the anti-HBs response is due to vaccine or HBV infection, a total anti-HBc assay may be performed. Performance characteristics have not been established for therapeutic monitoring. A reactive anti-HBs result does not exclude co-infection by another hepatitis virus. Individuals that have received blood component therapy (e.g., whole blood, plasma, immune globulin administration) during the previous 3 to 6 months may have a false reactive anti-HBs result due to passive transfer of anti-HBs. The performance of the MONOLISA™ Anti-HBs EIA has not been established with cord blood, neonatal specimens, cadaver specimens, heat-inactivated specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids.
Interfering Substances	None of the interferents at the levels tested below produced a change in clinical interpretation. • Hemolyzed: 500 mg/dL of hemoglobin • Lipemic: 1000 mg/dL of triglycerides • Icteric: 20 md/dL of bilirubin • Proteinemic: 15 g/dL of protein
References	BioRad MONOLISA™ Anti-HBs EIA Package Insert. EVOLIS™ Operator Manual

Additional Information	None
Release Date	03/17/2017
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