Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis B Panel
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	Anti-HBc 86704, (reflex) Anti-HBc IgM 86705 HBsAg 87340
Synonyms	Total Antibodies to Hepatitis B Nucleocapsid Antigen (Core) EIA, Anti-HBc Total (IgG and IgM), Anti-HBc IgM, Hep B Surface Antigen, HBsAG
Brief Description of Test	**Hepatitis B Core Total with a reactive reflex to Hepatitis B Core IgM** The MONOLISA™ Anti-HBc EIA is an enzyme immunoassay intended for use in the qualitative detection of total antibodies to hepatitis B core antigen (anti-HBc) in human serum. Assay results may be used with other HBV serologic markers for the laboratory diagnosis of HBV disease associated with HBV infection. The MONOLISA™ Anti-HBc IgM EIA is an enzyme immunoassay intended for use in the qualitative detection of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum. Assay results may be used with other HBV serologic markers for the laboratory diagnosis of HBV disease associated with HBV infection. **Hepatitis B Surface antigen** The HBsAg EIA is used to detect for circulating Hepatitis B Surface Antigen (HBsAg) in human serum. It is used as a detection method for early acute or chronic hepatitis B infection. **Hepatitis B Surface Antigen Confirmatory** The Hepatitis B Surface Antigen Confirmatory assay is no longer being offered. A new specimen will be requested and will be outsourced to a reference laboratory.
Possible Results	**Anti-HBc and Anti HBc IgM** Nonreactive Borderline Reactive **HBsAg** Nonreactive Reactive

Reference Range	Nonreactive or Negative
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap aliquot tube
Minimum volume accepted:	Request 3 mL 220 µL serum (does not allow for repeat testing) Anti-HBc 210 µL serum Anti-HBc IgM 300 µL serum (does not allow for repeat testing) HBsAg
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	**Anti-HBc** 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-HBc EIA assay may not be used interchangeably with values obtained with different manufacturers' Anti-HBc assay methods. Results from immunosuppressed patients should be interpreted with caution.

	A reactive anti-HBc result does not exclude co-infection by another hepatitis virus. The performance of the MONOLISA™ Anti-HBc EIA has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids. **Anti-HBc IgM** A nonreactive test result does not exclude the possibility of exposure to hepatitis B virus. Results from immunosuppressed patients should be interpreted with caution. A reactive anti-HBc IgM result does not exclude co-infection by another hepatitis virus. The performance of the BioRad MONOLISA™ Anti-HBc EIA has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids. **HBsAg** A designation of reactive for HBsAg must not be based on a single reactive test result. Additional testing, such as confirmatory testing, is required to establish the specificity of any specimen reactive by the screening procedure. Initially reactive specimens must be retested in duplicate to validate the initial test results. If, after repeat testing, the absorbance values of both duplicate specimens are less than the cutoff value, the original specimen may be considered non-repeatedly reactive and negative for HBsAg. If, after repeat testing, the absorbance value of either of the duplicates is greater than or equal to the cutoff value, the specimen must be considered repeatedly reactive.
Interfering Substances	Heterophilic antibodies
References	BioRad MONOLISA™ Anti-HBc EIA Package Insert BioRad MONOLISA™ Anti-HBc IgM EIA Package Insert BioRad Genetic Systems HBsAG EIA 3.0 package insert
Additional Information	Specimens positive for Anti-HBc will automatically reflex to Anti-HBc IgM.
Release Date	10/18/2019