Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis A
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86708 (total) 86709 (IgM)
Synonyms	Total Antibodies to Hepatitis A Virus, Anti-HAV Total (IgG and IgM), Antibody to Hepatitis A Virus IgM , Anti-HAV IgM
Brief Description of Test	Hepatitis A Total with reflex to Hepatitis A IgM The MONOLISA™ Anti-HAV EIA is an in vitro enzyme immunoassay for use in the qualitative detection of total antibodies (IgG and IgM) to hepatitis A virus (anti-HAV) in human (adult and pediatric) serum. This assay is indicated as an aid in the diagnosis of acute or past hepatitis A virus (HAV) infection or as an aid in the identification of HAV-susceptible individuals for vaccination. The MONOLISA™ Anti-HAV IgM EIA is an enzyme immunoassay (IgM antibody capture format) for use in the qualitative detection of IgM antibodies to hepatitis A virus (anti-HAV IgM) in human (adult and pediatric) serum. This assay is indicated for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis. Assay results, in conjunction with other serological or clinical information, may be used for the laboratory diagnosis of individuals with acute or recent hepatitis A.
Possible Results	Nonreactive Borderline Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap aliquot tube
Minimum volume accepted:	Request 1 mL 250 µL serum for HAV Total; additional 220 µL for HAV IgM
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 • Hemolyzed • Lipemic • Contaminated • Received outside acceptable transport conditions • Incorrect source • Expired collection tubes
Limitations of the Procedure	Diagnosis of an infectious disease should not be established on the basis of a single test result. Any diagnosis should take into consideration the patient's clinical history and symptoms, as well as other laboratory data. Performance has not been established with immunosuppressed or immunocompromised patients, cord blood, neonatal specimens, cadaveric specimens, heat-inactivated specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids. **HAV Total** • A reactive anti-HAV result does not exclude co-infection by another hepatitis virus. • The nonreactive result does not exclude the possibility of infection with hepatitis A virus. Levels of Anti-HAV may be below the cutoff in early infection. • The MONOLISA™ Anti-HAV EIA detects both anti-HAV IgG and IgM antibodies. However, assays detecting total antibodies are known to be more sensitive for anti-IgG than IgM. **HAV IgM** • Detection of anti-HAV IgM does not necessarily imply an acute HAV infection due to the longevity of anti-HAV

	IgM. The detection of anti-HAV IgM can be useful for the differential diagnosis of hepatitis A from other forms of viral hepatitis. Any diagnosis should take into consideration the patient's clinical history and symptoms, as well as other laboratory data. • Patients with specimens exhibiting borderline results should be retested at approximately two week intervals. • A reactive anti-HAV IgM result does not exclude co-infection by another hepatitis virus. • A nonreactive result does not exclude the possibility of infection with hepatitis A virus. Levels of Anti-HAV IgM may be below the cutoff in early infection.
Interfering Substances	Heterophilic antibodies, bacterial contamination, hyperhemolysis, hyperlipemia
References	BioRad MONOLISA™ Anti-HAV EIA Package Insert. EVOLIS™ Operator Manual BioRad MONOLISA™ Anti-HAV IgM EIA package insert. EVOLIS™ Operator Manual
Additional Information	Specimens positive for HAV Total will automatically reflex to HAV IgM.
Release Date	03/15/2018
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