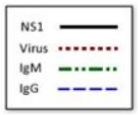
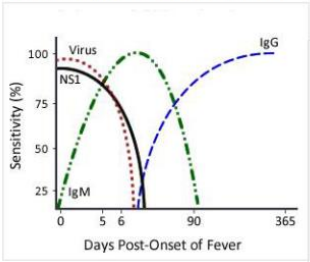
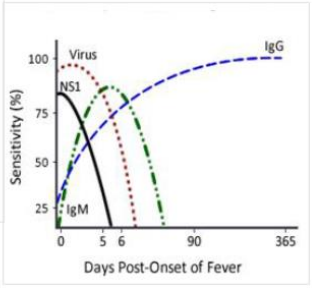
Louisiana Office of Public Health Laboratories	
Test Name	Dengue IgM
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86790
Synonyms	DENV IgM
Brief Description of Test	**Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.** This procedure is for the qualitative detection of IgM antibodies to DEN recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. This assay is intended for use only in patients with clinical symptoms consistent with either dengue fever or dengue hemorrhagic fever. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current CDC guidelines for diagnosis of this disease.
Possible Results	• ***Negative**:* No detectable IgM antibody; individual does not appear to be infected with Dengue virus. The result does not rule out Dengue virus infection. An additional sample should be tested within 7 – 14 days if early infection is suspected. Other Dengue virus assays such as Dengue NS1 assays, PCR or culture should be performed to rule out early acute infection. • ***Equivocal**:* Samples should be retested before reporting. • ***Presumptive Positive**:* Presence of detectable IgM antibody; presumptive infection with Dengue virus. The result should be confirmed by plaque reduction neutralization test (PRNT) or by using the latest CDC guideline for diagnosis of this disease. A positive IgM result does not indicate a recent infection because IgM may persist for several months after infection.
Reference Range	Negative
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap tube for pour-off
Minimum volume accepted:	Request 1 mL 300 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.

	The same 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 2 days or • For shipments that are delivered >2 days from collection, specimens should be kept frozen (≤ -20°C). If serum specimen is to be frozen, do not freeze in original blood serum collection tube. Pour-off serum into a screw cap tube.
Causes for Rejection	• Unspun • Short Draw/Overfill • Received outside acceptable transport conditions • Incorrect source • Incorrect labeling • Expired collection tubes • Not approved for testing by Infectious Disease Epidemiology
Limitations of the Procedure	• All reactive samples must be confirmed by PRNT or by using the latest CDC guideline for diagnosis of this disease. • Since this is a presumptive positive assay, the presence of false positive and false negative results must be considered. • Serological cross-reactivity across the flavivirus group is very common. Certain sera from patients infected with Japanese Encephalitis, West Nile, and or Saint Louis viruses may give false positive results. Therefore, any Dengue positive sera must be confirmed with other tests. • Cross-reactiviey with Malaria IgM has not been evaluated with the DENV Detect IgM Capture ELISA. • Assay performance characteristics have not been established for visual result determination. • Assay performance characteristic have not been established for matrices other than serum. • Results from immunosuppressed patients must be interpreted with caution. • Assay results should be interpreted only in the context of other laboratory findings and the total clinical status of the patient.
Interfering Substances	• High cholesterol levels (>300 mg/dL) appear to give variable results and may affect the DENRA OD values. • High triglyceride levels (>3000 mg/dL) appear to exhibit a slight effect of raising the ISRs of low positive sera. • Hemoglobin (>1600 mg/dL) appears to affect some serum samples by lowering the ISRs.
References	Package Insert: InBios DENV Detect™ IgM Capture ELISA
Additional Information	Anti-dengue virus IgM antibody is produced transiently during primary and secondary infection. In patients with primary dengue virus infection, IgM antibodies develop rapidly and are detectable by days 3 to 5 of illness in half of hospitalized patients. Anti-dengue virus IgM levels peak at about 2 weeks post infection and then decline to undetectable levels over 2 to 3 months.

	In patients with secondary dengue virus infections, while the kinetics of IgM production are similar to those observed in patients with primary infections, IgM levels are significantly lower. Anti-dengue IgM antibodies also peak at about 2 weeks post infections, begin to wane thereafter, and are still detectable in about 30% of patients 2 months after the onset of symptoms. **Legend**  DENV-reactive IgG DENV-reactive IgM Dengue viral protein, NS1 Primary DENV Infection  Secondary DENV Infection 
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