

Louisiana Office of Public Health Laboratories	
Test Name	Dengue Real Time rt-PCR
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	87798 x 4
Synonyms	DENV
Brief Description of Test	<p>Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.</p> <p>The CDC DENV-1-4 Real-Time RT-PCR Assay is intended for use on the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument:</p> <ul style="list-style-type: none"> • For the diagnosis of dengue in serum collected from patients with signs and symptoms consistent with dengue (mild or severe) during the acute phase; • For the identification of dengue virus serotypes 1, 2, 3 or 4 from viral RNA in serum or plasma (sodium citrate) collected from human patients with dengue during the acute phase; • To provide epidemiologic information for surveillance of circulating dengue viruses.
Possible Results	Negative for Dengue Positive for Dengue 1 Positive for Dengue 2 Positive for Dengue 3 Positive for Dengue 4 Inconclusive
Reference Range	Negative
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	300 µL
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within

	<p>2 hours of collection to prevent erroneous test results according to NCCLS guidelines.</p> <p>Follow the package insert for the collection tube you use.</p> <p>Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique.</p> <p>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, onset date, test requested, and submitter's name, address, and contact number.</p> <p>Two unique identifiers MUST be recorded on the tube AND the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place.</p> <p>Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.</p>
<p>Storage and Transport Instructions</p>	<p>Once there is a clinical diagnosis of suspected dengue, take a venous, whole blood sample.</p> <p>Follow serum or plasma specimen collection devices manufacturer instructions for proper collection, separation and storage methods. We recommend that separated serum samples are frozen at -20°C and sent or shipped in dry ice to the testing laboratories. If dry ice is not available, we recommend that separated serum is maintained on ice or in a refrigerator for no longer than 2 hours before it is either frozen at -20° C or tested.</p> <ul style="list-style-type: none"> • Transport/ship human serum samples in dry ice. Document the date and time sample was frozen.
<p>Causes for Rejection</p>	<p>Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.</p>
<p>Limitations of the Procedure</p>	<ul style="list-style-type: none"> • This device is subject to a special control requiring that distribution be limited to laboratories with (i) experienced personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and (ii) appropriate biosafety equipment and containment (21CFR866.3332(b)(2)). • Negative results do not preclude dengue virus infection and should not be used as the sole basis for treatment or other patient management decisions. A negative specimen collected between days 3-7 after onset of the febrile illness should be retested with an anti-DENV IgM test to increase the likelihood of making the diagnosis of dengue.

	<ul style="list-style-type: none"> • A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen. • Do not use any reagent past the expiration date. • The performance of this test has not been established for monitoring treatment of dengue. • The performance of this test has not been established for screening of blood or blood product for the presence of DENV infection. • Detection of viral RNA may not indicate the presence of infectious virus or that dengue is the causative agent for clinical symptoms. • This test cannot rule out diseases caused by other bacterial, viral or parasitic pathogens. • Assay performance characteristics have not been established for prenatal screening, or for general population screening without symptoms consistent with Dengue Fever. The test is not FDA cleared for the screening of blood or plasma donors.
Interfering Substances	N/A
References	Package Insert: CDC DENV-1-4 Real Time RT-PCR Assay
Additional Information	If more than one DENV marker crosses the threshold line within cycle 37 (<37 Ct), the result may indicate “dual DENV infection.” Dual infections have been rarely reported. If there is an indication of dual infection, sample will be sent to the CDC-Dengue Branch for confirmatory testing.
Release Date	03/15/2016
<p>Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.</p>	