Test Definition: DENGS

Dengue Virus, PCR, Serum

Overview

Useful For

Aiding in the diagnosis of acute infection caused by dengue virus

Testing Algorithm

See Mosquito-borne Disease Laboratory Testing in Special Instructions.

Special Instructions

- Mosquito-borne Disease Laboratory Testing

Highlights

Detection of dengue virus nucleic acid in serum is suggestive of recent exposure and acute infection with dengue virus.

The presence of dengue virus nucleic acid in serum can be used as a marker for acute-phase infection. Patients with a history of symptoms for more than 1 week may be negative by molecular tests (ie, real-time PCR) and may require serologic testing to confirm the diagnosis of dengue virus infection.

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

The presence of dengue virus nucleic acid in serum overlaps with the presence of dengue virus nonstructural protein 1 (NS1) antigen (DNSAG / Dengue Virus NS1 Antigen, Serum). Patients with a history of symptoms for more than 1 week may be negative by molecular tests (ie, real-time PCR) and may require serologic testing (DENVP / Dengue Virus Antibody/Antigen Panel, Serum) to confirm the diagnosis of dengue virus infection.

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container: Sterile container

Specimen Volume: 0.5 mL

Collection Instructions:

1. Collect whole blood in a serum gel tube.

2. Centrifuge and aliquot the serum into a sterile container within 6 hours of collection.

3. Label specimen as serum.

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244)with the specimen.

Reject Due To

Gross hemolysis	Reject
Heat-inactivated specimen	Reject

Specimen Minimum Volume

0.3 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Dengue virus (DV) is a globally distributed flavivirus with 4 distinct serotypes (DV-1, -2, -3, -4) and is primarily transmitted by the *Aedes aegypti* mosquito, found throughout the tropical and subtropical regions of over 100 countries. DV poses a significant worldwide public health threat with approximately 2.5 to 3 billion people residing in DV endemic areas, among whom 100 to 200 million individuals will be infected and approximately 30,000 patients will succumb to the disease, annually.

Following dengue infection, the incubation period varies from 3 to 7 days and while some infections remain asymptomatic, the majority of individuals will develop classic dengue fever. Symptomatic patients become acutely febrile and present with severe musculoskeletal pain, headache, retro-orbital pain, and a transient macular rash most often observed in children. Fever defervescence signals disease resolution in most individuals. However, children and young adults remain at increased risk for progression to dengue hemorrhagic fever and dengue shock syndrome, particularly during repeat infection with a new DV serotype.

Detection of DV nucleic acid in serum is a marker of acute infection with this virus. Importantly, the period of time that the virus can be detected in serum is brief and, therefore, molecular testing should be performed within the first week following onset of symptoms. After this time, serologic testing is the preferred method for diagnosis of DV infection.

Reference Values

Negative

Interpretation

Positive:

The detection of dengue virus nucleic acid in serum is consistent with acute-phase infection.

Dengue virus nucleic acid may be detectable during the first 1 to 7 days following the onset of symptoms.

Negative:

The absence of dengue nucleic acid in serum is consistent with the lack of acute-phase infection.

Dengue virus nucleic acid may not be detected if the serum specimen is collected immediately following dengue virus infection (<24-48 hours) and is rarely detectable following 7 days of symptoms.

Cautions

Results should be used in conjunction with clinical presentation and exposure history.

Negative dengue virus (DV) PCR results may occur if the specimen was collected more than 7 days following symptom onset. Serologic testing for the presence of IgM and IgG antibodies to DV is recommended in such cases.

Supportive Data

Assay Inclusivity:

The Altona RealStar Dengue virus RT-PCR assay was tested using control strains of each of the 4 dengue serotypes and was able to detect serotypes 1, 2, 3 and 4.

Accuracy:

A commercial panel (SeraCare) of known-positive samples for dengue virus serotypes 1, 2, 3, and 4 was tested. Each member of the panel was tested in triplicate, and all replicates were positive by the Altona RealStar Dengue assay.

Thirty analyte-negative serum samples were spiked (1:10 dilution) with plasma samples collected in South America during an outbreak of dengue virus and determined to be positive for the virus. Of the 30 spiked serum samples, 29 (97%) were positive by the Altona RealStar Dengue RT-PCR assay.

Limit of Detection (LoD):

The LoD in serum was determined to be the following:

Dengue serotype 1:14 genomic targets/mcL (7000 genomic targets/mL)

Dengue serotype 2: 2 genomic targets/mcL (1000 genomic targets/mL)

Dengue serotype 3: 1.6 genomic targets/mcL (800 genomic targets/mL)

Dengue serotype 4: 13 genomic targets/mcL (6500 genomic targets/mL)

Reference Range (Analytical Specificity):

A total of 20 serum samples collected from normal donors were analyzed by the Altona RealStar Dengue RT-PCR assay and all 20 were negative.

A cross-reactivity panel of bacteria (n=12), viruses (n=15), and parasites (n=2) was tested, and all were negative by the Altona Dengue RT-PCR assay.

Clinical Reference

1. Bhatt S, Gething PW, Brady OJ, et al: The global distribution and burden of dengue. Nature 2013;496:504-507

2. Dengue--an infectious disease of staggering proportions. Lancet 2013 Jun 22;381(9884):2136

3. Rigau-Perez JG, Clark GG, Gubler DJ, et al: Dengue and dengue haemorrhagic fever. Lancet 1998;352:971-977

4. Tang KF, Ooi EE: Diagnosis of dengue: an update. Expert Rev Anti Infect Ther 2012;10:895-907

5. Guzman MG, Kouri G: Dengue diagnosis, advances and challenges. Int J Infect Dis 2004;8:69-80

Performance

Method Description

The Altona Real Star (ARS) DENV is a qualitative, reverse transcription-PCR (RT-PCR) assay targeting the 3' UTR polyprotein gene. The assay includes a heterologous amplification system (internal control) to identify possible RT-PCR inhibition and to confirm the integrity of the reagents of the kit. Specimens are run on the LightCycler 480 following nucleic acid extraction using the NucliSENS EasyMag (BioMerieux). Real-time RT-PCR technology utilizes reverse-transcriptase (RT) reaction to convert RNA into complementary DNA (cDNA), PCR for the amplification of specific target sequences and target specific probes for the detection of the amplified DNA. The probes are labelled with fluorescent reporter and quencher dyes. Probes specific for DENV RNA are labelled with the fluorophore FAM. The probe specific for the Internal Control (IC) is labeled with the fluorophore JOE. Using probes linked to distinguishable dyes enables the parallel detection of DENV specific RNA and the internal control in corresponding detector channels of the real-time PCR instrument.(Package insert: RealStar Dengue RT-PCR Kit 2.0. Altona Diagnostics, Hamburg. 01/2017)

PDF Report

No

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with

CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87798

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
DENGS	Dengue Virus, PCR, Serum	94427-2

Result ID	Reporting Name	LOINC®
606372	Dengue Virus, PCR, Serum	94427-2