Dengue Virus IgM
Test Code: 5219229

Clinical and Procedure

Clinical Utility
The DENV Detect™ IgM CAPTURE ELISA is for the qualitative detection of IgM antibodies to DENV recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. The 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.

Procedure
Biological matrix is diluted in buffer and incubated in microtiter wells coated with monoclonal antibody bound to recombinant Dengue antigen (DENRA) and normal cellular antigen (NCA) separately. Wells are then treated with a human IgG-specific monoclonal antibody labeled with horseradish peroxidase. After a second incubation, the wells are incubated with tetramethylbenzidine. An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is measured by absorbance at 450 nanometers. The ratio of each sample’s paired DENRA and NCA absorbances are used to calculate the Immune Status Ratio (ISR). Compared to threshold points, the ISR value determines whether antibodies to Dengue virus are present.

Specificity
Serological cross-reactivity across the flavivirus group is common. Certain sera from patients infected with Japanese Encephalitis, West Nile, and/or Saint Louis Viruses may give false positive results.

Turnaround Time
2-3 business days from receipt of specimen

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>serum</td>
<td>5219229</td>
<td>86790</td>
<td>Yes</td>
<td>1 mL</td>
<td></td>
</tr>
</tbody>
</table>

Less than 1.65 ISR: Negative - No significant level of detectable dengue fever virus IgG antibody.

1.65-2.84 ISR: Equivocal - Questionable presence of antibodies. Repeat testing in 10-14 days may be helpful.

Greater than 2.84 ISR: Positive - IgG antibody to dengue fever virus detected, which may indicate a current or past infection.

Special Instructions
- Whole blood should be collected in serum tube, allowed to clot for a minimum of 30 minutes.
- Centrifuge and 1 mL serum removed.
- Serum samples should be frozen immediately (-20°C).
- Ship frozen in dry ice Monday through Friday.
Less than 1.65 ISR: Negative - No significant level of detectable dengue fever virus IgM antibody.

1.65-2.84 ISR: Equivocal - Questionable presence of antibodies. Repeat testing in 10-14 days may be helpful.

Greater than 2.84 ISR: Positive - IgM antibody to dengue fever virus detected, which may indicate a current or recent infection.

However, low levels of IgM antibodies may occasionally persist for more than 12 months post-infection.

**Shipping**

Ship Monday through Friday. Label Friday shipments with Saturday delivery. All specimens must be labeled with patients name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086.

**Causes for Rejection**

Specimen types other than serum. Grossly lipemic or hemolyzed.

**Disclaimer**

Specimens are approved for testing in New York only when indicated in the Specimen Information field above. The CPT codes provided are based on Viracor Eurofins’ interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

**References**


3. Effler PV, Halstead SB. Immune enhancement of viral infection. *Progress in Allergy* 1982; 31:301-64.


6. The Dengue Update, CDC, Vol. 3 No. 1 2011

