Zika Virus IgM
Test Code: 30294

Clinical and Procedure

Clinical Utility
The ZIKV Detect™ IgM Capture ELISA is intended for the presumptive detection of Zika virus IgM antibodies in human sera collected from individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). The assay is intended for use in laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, consistent with the latest CDC guideline for the diagnosis of Zika virus infection.

Procedure
The ZIKV Detect™ IgM Capture ELISA is an enzyme linked capture immunoassay for the detection of human IgM antibodies targeting the ZIKV envelope glycoproteins. The ZIKV Detect™ IgM Capture ELISA has been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
False positive results are possible in patients with a history of infection with other Flaviviruses (Dengue, West Nile, Japanese Encephalitis, and Saint Louis encephalitis (SLE)). Confirmation of the presence of anti-Zika IgM antibodies in presumptive positive specimens requires additional testing according to the latest CDC guideline for the diagnosis of Zika virus infection.

Note: In the case of specimens originating from regions with a known West Nile virus outbreak, an FDA-cleared West Nile virus IgM assay should be run in parallel with the ZIKV Detect™ IgM Capture ELISA.

Turnaround Time
2-5 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>30294</td>
<td>86794</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>Presumptive Zika Positive: Presence of detectable Zika IgM antibody, possible recent infection with ZIKV. The result should be confirmed by the latest CDC guideline for the diagnosis of Zika virus infection. Possible Zika Positive: Specimens that fall in this category may still have levels of Zika IgM antibody present in serum and follow-up testing is</td>
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Special Instructions
- Collect 4-5 mL whole blood in red top tube.
- Centrifuge and transfer 2 mL serum to sterile, screw top tube.
- Can be shipped ambient, on cold pack, or frozen Monday through Friday.
- Samples are stable for 14 days ambient or refrigerated and 4 weeks frozen.

Shipping
Ship Monday through Friday. Label Friday shipments for Saturday delivery. All specimens must be labeled with patient's 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.

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.