USEFUL FOR

Aiding in the diagnosis of recent infection with Chikungunya virus in patients with recent travel to endemic areas and a compatible clinical syndrome

CLINICAL INFORMATION

Chikungunya virus (ChikV) is a single-stranded RNA alphavirus and a member of the Togaviridae family of viruses. The name Chikungunya is derived from the language of the Makonde ethnic groups in southeast Africa and means “that which bends” or “stooped walk.” This is in reference to the hunched-over appearance of infected individuals due to the characteristically painful and incapacitating arthralgia caused by the virus. ChikV is endemic throughout Africa, India, and more recently the Caribbean islands. In 2014, the first case of autochthonous or local transmission in the United States occurred in Florida.

Humans are the primary reservoir for ChikV and Aedes species mosquitoes are the primary vectors for transmission. Unlike other mosquito-borne viruses such as West Nile virus (WNV) and Dengue, the majority of individuals who are exposed to ChikV become symptomatic, with the most severe manifestations observed at the extremes of age and in those with suppressed immunity. Once exposed to ChikV virus, individuals develop lasting immunity and protection from reinfection.

The incubation period, prior to development of symptoms, ranges on average from 3 to 7 days. Infected patients typically present with sudden onset high fever, incapacitating joint pain, and often a maculopapular rash lasting anywhere from 3 to 10 days. Notably, symptom relapse can occur in some individuals 2 to 3 months following resolution of initial symptoms. Currently, there are no licensed vaccines and treatment is strictly supportive care.

INTERPRETATION

IgM and IgG Negative
No serologic evidence of exposure to Chikungunya virus. Repeat testing on a new specimen collected in 5 to 10 days is recommended if clinical suspicion persists.

IgM and IgG Positive
IgM and IgG antibodies to Chikungunya virus detected, suggesting recent or past infection. IgM antibodies to Chikungunya virus may remain detectable for 3 to 4 months postinfection.

IgM Positive, IgG Negative
IgM antibodies to Chikungunya virus detected, suggesting recent infection. Repeat testing in 5 to 10 days is recommended to demonstrate anti-Chikungunya virus IgG seroconversion to confirm current infection.

IgM Negative, IgG Positive
IgG antibodies to Chikungunya virus detected, suggesting past infection.

IgM and/or IgG Borderline
Repeat testing in 10 to 14 days is recommended.

MOBILE APPS FROM MAYO MEDICAL LABORATORIES

Lab Catalog for iPad and Lab Reference for iPhone and iPod Touch

Requires iOS 5.1+

REFERENCE VALUES

IgM: Negative
IgG: Negative

Reference values apply to all ages.

ANALYTIC TIME

Same day/1 day

CONTENT AND VALUES SUBJECT TO CHANGE. SEE THE MAYO MEDICAL LABORATORIES TEST CATALOG FOR CURRENT INFORMATION.
SUPPORTIVE DATA

ACCURACY

IgM Antibodies to Chikungunya Virus

Originally 87 serum samples tested by the Focus Diagnostics Inc. anti-Chikungunya virus IgM immunofluorescence assay (IFA) were also evaluated by the EuroImmun anti-Chikungunya virus IgM enzyme-linked immunofluorescence assay (ELISA) and the results are indicated below.

<table>
<thead>
<tr>
<th></th>
<th>FOCUS DIAGNOSTICS CHIKV IGM IFA</th>
<th>EUROMMUN CHIKV IGM EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POSITIVE</strong></td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td><strong>NEGATIVE</strong></td>
<td>3</td>
<td>41</td>
</tr>
<tr>
<td><strong>BORDERLINE</strong></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Positive Agreement: 93.5% (43/46); 95% Confidence Index (CI): 81.9%-98.4%
Negative Agreement: 100% (41/41); 95% CI: 89.8%-100%
Overall Agreement: 96.6% (84/87); 95% CI: 89.9%-99.2%

Comparison of the EuroImmunn ChikV IgG ELISA and the Focus Diagnostics ChikV IgG IFA

IgG Antibodies to Chikungunya Virus

Originally 101 serum samples tested by the Focus Diagnostics Inc. anti-Chikungunya virus IgG IFA were also evaluated by the EuroImmunn anti-Chikungunya virus IgG ELISA and the results are indicated below.

<table>
<thead>
<tr>
<th></th>
<th>FOCUS DIAGNOSTICS CHIKV IGG IFA</th>
<th>EUROMMUN CHIKV IGG EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POSITIVE</strong></td>
<td>39</td>
<td>5</td>
</tr>
<tr>
<td><strong>NEGATIVE</strong></td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td><strong>BORDERLINE</strong></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*All 7 samples were positive by both the Focus and EuroImmunn IgM assays. Also, 4 of 7 samples had low titers (≤1:20) by the IFA assay.
Positive Agreement: 84.8% (39/46); 95% CI: 71.5%–92.7%
Negative Agreement: 90.9% (50/55); 95% CI: 80.0%–96.5%
Overall Agreement: 88.1% (89/101); 95% CI: 80.2%–93.2%

Reference Range:
Of serum samples collected from normal donors, 74/75 (98.7%) and 90/90 (100%) were negative by the EuroImmunn anti-Chikungunya virus IgG and IgM assays, respectively.

Analytical Specificity:
1. Sixty serum samples previously characterized as positive for IgG-class antibodies to West Nile virus (n=29), Dengue virus (n=15), St. Louis encephalitis virus (n=8), California encephalitis virus (n=6), and Western equine encephalitis virus (n=2) were analyzed by the EuroImmunn anti-Chikungunya virus IgG assay. One sample, positive for IgG antibodies to Dengue virus was also positive by the Chikungunya IgG assay, giving an overall specificity of 98.3% (59/60).

2. Thirty three serum samples previously characterized as positive for IgM-class antibodies to West Nile virus (n=8), Dengue virus (n=11), St. Louis encephalitis virus (n=6), California encephalitis virus (n=6), and Western equine encephalitis virus (n=2), were analyzed by the EuroImmunn anti-Chikungunya virus IgM assay. Two samples, positive for IgM antibodies to Dengue virus were also positive by the Chikungunya IgM assay, giving an overall specificity of 93.9% (31/33).

Note: Dengue and Chikungunya virus cocirculate in endemic areas and are transmitted by the same mosquito genera, so the 3 specimens with antibodies to both viruses may indicate coinfection or past exposure to both viruses.