Chikungunya IgM
(Serum / Plasma / Whole Blood)

INTENDED USE
The Chikungunya IgM Rapid Test is a lateral flow chromatographic immunocassay for the qualitative detection of IgM anti-chikungunya virus (CHIK) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with CHIK.

SUMMARY AND EXPLANATION OF THE TEST
The Chikungunya IgM Rapid Test utilizes recombiant antigens derived from its structure protein, it detects IgM anti-CHIK in patient serum or plasma within 15 minutes. Chikungunya is a rare viral infection transmitted by the bite of an infected Aedes aegypti mosquito. It is characterized by a rash, fever, and severe joint pain (arthralgias) that usually lasts for three to seven days. The name is derived from the Makonde word meaning “that which bends up” in reference to the stopped posture developed as a result of the arthritic symptoms of the disease. It occurs during the rainy season in tropical areas of the world, primarily in Africa, South-East Asia, southern India and Pakistan. The symptoms are most often clinically indistinguishable form those observed in dengue fever. Indeed, dual infection of dengue and chikungunya has been reported in India. Unlike dengue, hemorrhagic manifestations are relatively rare and most often the disease is a self limiting febrile illness. Therefore it is very important to clinically distinguish dengue from CHIK infection.

TEST PRINCIPLE
The Chikungunya IgM Rapid Test is a lateral flow chromatographic immunocassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing CHIK antigens conjugated with colloid gold (CHIK conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with anti-human IgM reagent, and the C band is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The IgM antibody to CHIK, if present in the specimen will bind to the CHIK conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM reagent, forming a burgundy colored T band, indicating a CHIK IgM positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED
1. Test Devices.
2. Sample Droppe rs.
3. Sample Diluent.
4. Package Insert.

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use
1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and device.
8. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.
9. Do not smoke, drink, or eat in areas where specimen or kit reagents are being handled.
10. Do not open the sealed pouch, unless ready to conduct the assay.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. Dispose of all specimens and materials used to perform the test as biohazardous waste.
13. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

STORAGE INSTRUCTIONS
Store unused test device unopened at 2° C-30° C. If stored at 2° C-8° C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma
1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin by vein puncture).
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum
1. Collect blood specimen into a tube by vein puncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen’s ID number.
Step 4: For whole blood test
Apply 1 drop of whole blood (about 40-50 µL) into the sample well.
Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.

For serum or plasma test
Fill the pipette dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.
Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.

Result
1 drop of specimen 1 drop of sample diluent 15 minutes

Step 5: Set up timer.
Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.
Don’t read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C band is developed, the test indicates that no detectable IgM anti-CHIK is present in the specimen. The result is negative.
2. POSITIVE RESULT: If both C and T bands are developed, the test indicates for the presence of IgM anti-CHIK in the specimen. The result is positive.
**Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.**

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

**PERFORMANCE CHARACTERISTICS**

An evaluation study was carried out at Unité de virologie, Institute de Medecine Tropicale de Service de Sante des Armees, Ministere De la Defense, France.

The evaluation specimen panel consisted of 72 recently infected specimens diagnosed by MAC-ELISA and 21 specimens containing 10 from other arbovirus infection, 3 from O’Nyong nyong infection, and 8 negative for all the tests. The evaluation data are shown in the following table.

<table>
<thead>
<tr>
<th></th>
<th>MAC-ELISA Positive</th>
<th>MAC-ELISA Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chikungunya IgM Rapid Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>65</td>
<td>7</td>
<td>72</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>21*</td>
<td>21</td>
</tr>
<tr>
<td>Total</td>
<td>65</td>
<td>28</td>
<td>93</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 90.3%, Relative Specificity: 100%, Overall Agreement: 92.4%

**LIMITATIONS OF TEST**

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of IgM anti-CHIK in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2. The Chikungunya IgM Rapid Test is limited to the qualitative detection of IgM anti-CHIK in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable IgM anti-CHIK. However, a negative test result does not preclude the possibility of exposure to or infection with CHIK.

4. A negative result can occur if the quantity of IgM anti-CHIK present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

**REFERENCES**


**Index of CE Symbols**

- IVD: For in vitro diagnostic use only
- REF: Catalog #
- LOT: Lot Number
- Authorized Representative
- Date of manufacture
- Store between 2-30°C
- Do not reuse
- Use by
- Tests per kit

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