INTENDED USE

The Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunnoassay for the qualitative detection of IgG and IgM antibodies to Dengue virus in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary Dengue infections.

SUMMARY AND EXPLANATION OF THE TEST

Dengue is a flavivirus, transmitted by Aedes aegypti and Aedes albopictus mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world, and causes up to 100 million infections annually. Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash. Primary Dengue infection causes IgM antibodies to increase to a detectable level in 3 to 5 days after the onset of fever. Most Dengue patients in endemic regions have secondary infections, resulting in high levels of specific IgG antibodies prior to or simultaneous with IgM response. Therefore, the detection of specific anti-Dengue IgM and IgG antibodies can also help to distinguish between primary and secondary infections. The Dengue Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of Dengue antigen coated colored particles for the detection of IgG and IgM Dengue antibodies in human whole blood, serum, or plasma.

PRINCIPLE OF THE TEST

The Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunnoassay for the detection of Dengue antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with Dengue antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to Dengue, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM Dengue IgM antibodies, if present in the specimen, reacts with the anti-human IgM and the Dengue antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.

Therefore, if the specimen contains Dengue IgG antibodies, a colored line will appear in the IgG test line region. If the specimen contains Dengue IgM antibodies, a colored line will appear in the IgM test line region. If the specimen does not contain Dengue antibodies, no colored line will appear in either of the test line regions, indicating a negative result.

REAGENTS

The test cassette contains Dengue antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

PRECAUTIONS

For professional in vitro diagnostic use only. Do not use after expiration date. Do not eat, drink or smoke in the area where the specimens or kits are handled. Handle all specimens as if they contain infectious agents. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood, collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.

TEST PROCEDURE

Remove the Dengue IgG/IgM Ab Rapid test devices from the foil pouch and assure that all test specimens are allowed to reach room temperature.

1. Add 5µl of serum/plasma or 10µl of whole blood to the sample well of the test device followed by 1 drop buffer.

   (when using a sample dropper (5µl) take sample up to the fill line as indicated in the diagram below)

2. Wait for the colored line (S) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

- **Negative**
  - Pink/ purple line at C

- **IgM Positive**
  - Pink/ purple line at C & IgM

- **IgG Positive**
  - Pink/ purple line at C & IgG

- **IgG & IgM Positive**
  - Pink/ purple line at C, IgM & IgG

- **Invalid**
  - No line at C

Specimens should not be frozen and thawed repeatedly.

MATERIAL

Material provided
- Test cassettes
- Droppers
- Buffer
- Package Insert

Material required but not provided
- Specimen Collection containers
- Centrifuge (for Plasma Only)
- Micropipette
- Lancets (for fingerstick whole blood only)

(If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly)
QUALITY CONTROL

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

The Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of Dengue antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Dengue antibody concentration can be determined by this qualitative test.

The Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Dengue antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Dengue.

In the early onset of fever, anti-Dengue IgM concentrations may be below detectable levels. For primary infection, an IgM antibody-capture enzyme-linked immunosorbent assay (MAC-ELISA) showed that 80% of the Dengue patients tested exhibited detectable levels of IgM antibody by the fifth day after infection, and 99% of the patients tested IgM positive by day 10. It is recommended that patients be tested within this time. For the secondary infection, a low molar fraction of anti-Dengue IgM and a high molar fraction of IgG that is broadly reactive to flaviviruses characterize the antibodies. The IgM signal may be faint and the cross reaction in the region of IgG line may appear.

Serological cross-reactivity across the flavivirus group (Dengue 1, 2, 3 & 4, St. Louis encephalitis, West Nile virus, Japanese encephalitis and yellow fever viruses) is common. Positive results should be confirmed by other means.

As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Dengue infection.

PERFORMANCE CHARACTERISTICS

The Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated inhouse with positive and negative clinical samples tested by commercially available ELISA test. Data as follows.

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>No of Specimen</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dengue IgG Positive</td>
<td>80</td>
<td>0</td>
</tr>
<tr>
<td>Dengue IgG Negative</td>
<td>750</td>
<td>748</td>
</tr>
</tbody>
</table>

Sensitivity 100% Specificity: 99.7%

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>No of Specimen</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dengue IgM Positive</td>
<td>50</td>
<td>01</td>
</tr>
<tr>
<td>Dengue IgM Negative</td>
<td>500</td>
<td>497</td>
</tr>
</tbody>
</table>

Sensitivity 98.01% Specificity: 99.4%

BIBLIOGRAPHY


DISCLAIMER

While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING

The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, cost or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.