Dengue IgM/IgG Rapid Test
(Whole Blood/Serum/Plasma)

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Dengue virus in whole blood, serum, or plasma. For professional in vitro diagnostic use only.

INTENDED USE
The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay 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
Dengue is a flavivirus, transmitted by Aedes aegypti and Aedes albopicus mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world, and causes up to 120 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. IgM antibodies generally persist for 30 to 90 days. Most Dengue patients in endemic regions have secondary infections, resulting in high levels of specific IgG antibodies prior to or simultaneously 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 IgM/IgG Rapid Test Device (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
The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue antibodies in whole blood, serum, or plasma. This test consists of two components, an IgM component and an IgG component. In the IgM component, anti-human IgM is coated in test line region 1(IgM) of the test. During testing, if the Dengue IgM antibodies present in the specimen, reacts with the Dengue antigen-coated particles in the test strip, and this complex is captured by the anti-human IgM forming a colored line in test line region 1(IgM). In the IgG component, anti-human IgG is coated in test line region 2(IgG) of the test. During testing, the specimen reacts with Dengue antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in test line region 2(IgG). If the specimen contains IgG antibodies to Dengue, a colored line will appear in test line region 2(IgG).

Therefore, if the specimen contains Dengue IgM antibodies, a colored line will appear in test line region 1(IgM). If the specimen contains Dengue IgG antibodies, a colored line will appear in test line region 2(IgG). If the specimen does not contain Dengue antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always change from red to blue in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS
The test device contains Dengue antigen-coated particles, Anti-human IgM and Anti-human IgG in the test line regions.

PRECAUTIONS
- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
- The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- To collect Fingerstick Whole Blood Specimen:
  - Wash the site with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood on the puncture site.
- Add the Fingerstick Whole Blood specimen to the test device by using a dropper or micropipette measuring 10µL. The dropper provided with the test dispenses approximately 10 µL in one drop even if more blood is aspirated in the dropper.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. 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. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS
Materials Provided:
Materials Required But Not Provided:

DIRECTIONS FOR USE
Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.

For Serum or Plasma Specimens:
- Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 5 µL), and transfer the specimen to the specimen well (S) of the test device, then add 2 drops of Buffer (approximately 80 µL) and start the timer. See illustration below. Avoid trapping air bubbles in the specimen well (S).
- For Whole Blood (Venipuncture/Fingerstick) Specimen:
- To use a dropper: Hold the dropper vertically, draw the specimen 0.5-1 cm above the Fill Line, and transfer 1 drop of whole blood (approximately 10 µL) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below.
- To use a micropipette: Pipet and dispense 10 µL of whole blood to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS
IgM POSITIVE:* The colored line in the control line region (C) changes from red to blue, and a colored line appears in test line region 1(IgM). The result is positive for Dengue virus specific-IgM and is probably indicative of primary Dengue infection.
The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA test.

**PERFORMANCE CHARACTERISTICS**

**Clinical Sensitivity, Specificity and Accuracy**

The Dengue IgM/IgG Rapid Test Device has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA test.

### Dengue Infection

<table>
<thead>
<tr>
<th>Result</th>
<th>IgM</th>
<th>IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td>Negative</td>
<td>55</td>
<td>55</td>
</tr>
<tr>
<td>Relative Sensitivity</td>
<td>82.4%</td>
<td>6%</td>
</tr>
<tr>
<td>Secondary Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Negative</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Relative Sensitivity</td>
<td>70.9%</td>
<td>&gt;99.0%</td>
</tr>
<tr>
<td>Non-Dengue Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>37</td>
<td>37</td>
</tr>
<tr>
<td>Relative Sensitivity</td>
<td>&gt;99.0%</td>
<td>&gt;99.0%</td>
</tr>
</tbody>
</table>

For the primary and secondary infection, the overall sensitivity is 95.6%, the overall specificity is >99.0% and the overall accuracy is 99.3%.

### PRECISION

**Intra-Assay**

Within-run precision has been determined by using 10 replicates of four specimens: a negative, an IgG positive, an IgM positive and an IgM/IgG dual positive. The specimens were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, an IgG positive, an IgM positive and an IgM/IgG dual positive. Three different lots of the Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

### BIBLIOGRAPHY


### INDEX OF SYMBOLS

- **IDV**: For in vitro diagnostic use
- **RAPID**: Uses by
- **LOT**: Do not reuse
- **REF**: Authorized Representative
- **LOT number**: Catalog#