**Dengue IgG/IgM Rapid**

(A rapid test for detection of Dengue Fever)

**INTENDED USE**

Dengue Fever Rapid IgG/IgM is an immunochromatographic assay designed for the qualitative detection and differentiation of specific IgM and IgG antibodies to dengue virus in human serum or plasma. It is intended to be used as in vitro diagnostic of dengue fever. The test provides a differential detection of anti-dengue IgM and anti-dengue-IgG antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection. The results obtained should not be the sole determinant for clinical decision.

**SUMMARY AND EXPLANATION OF THE TEST**

Dengue virus, a virus belonging to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. Transmitted principally by the mosquito types *Aedes aegypti* and *Aedes albopictus*, the virus is found commonly throughout the tropic and sub-tropic regions of the world. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash. The complications often associated with this infection are dengue hemorrhagic fever or dengue shock syndrome.

The immune response to this virus includes the production of IgM antibodies by the 5th day of symptoms, which remain in the circulatory system for 30-60 days. IgG antibodies appear by the 14th day of infection and persist for life. A secondary infection often results in high fever and, in many cases, initiates hemorrhagic events and circulatory failure. A secondary infection also induces an IgM antibody response after 20 days of infection and IgG antibodies rise within 1-2 days after the onset of symptoms. Therefore, patients with secondary infections will have a positive IgG result, usually with a positive IgM result as well. Thus, the use of a reliable and sensitive rapid serological test that can simultaneously detect the presence of anti-dengue IgG and IgM antibodies is of great clinical utility.

**PRINCIPLE OF THE TEST**

The Dengue Fever Rapid IgG/IgM provides an excellent methodology for specifically detecting anti-dengue IgG and IgM antibodies. The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample. By using a mixture of highly purified dengue proteins, the test is able to detect all 4 Dengue serotypes. Additional advantages include:

- Fast, simple and reliable
- Simple to perform and no additional sample preparation required
- No special equipment is needed
- Results are easy to interpret
- Minimal sample volume used

**PERFORMANCE CHARACTERISTICS**

Sensitivity and specificity for Dengue Fever Rapid IgG/IgM are 96% and 95% respectively. Based on a limited number of samples, the test did not detect an IgG or IgM response with positive JE samples.

For a more comprehensive list for the sensitivity, specificity and cross-reactivity study for the test, please refer to separate sheets that can be obtained from the manufacturer.

**REAGENTS AND MATERIALS SUPPLIED**

1. Dengue IgG/IgM Rapid cassette (25 pieces packed in individually sealed aluminum pouch)
2. One bottle of assay buffer
3. One copy of instruction manual (product insert)

**MATERIALS REQUIRED BUT NOT SUPPLIED**

1. Lancets, sample collection and preparation device and disinfecting sterile wipes
2. Sample dispensing apparatus such as pipettes capable of delivering 2-10 µl sample volume
3. Clock or timer

**STORAGE AND STABILITY**

Store at 4-28 °C, do not freeze. Keep the test device sealed until used. Keep away from direct sunlight, moisture and heat.

**WARNINGS AND PRECAUTIONS**

1. For professional in vitro diagnostic use only.
2. This product insert must be strictly followed in order to produce accurate test results.
3. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
4. All test devices, reagents and specimens must be at room temperature (15-30°C) before running the assay.
5. Do not use device if the sealed pouch is visibly damaged.
6. Do not use the kit contents beyond the expiration date.
7. Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste.
8. Wipe any spills of sera or plasma promptly with 1% sodium hypochlorite solution.
9. Do not reuse test device.

**LIMITATION OF THE TEST**

1. This product is designed for use with human serum, plasma or whole blood only.
2. This test detects the presence of antibodies to dengue in the specimen and should not be used as the sole criterion for the diagnosis of a dengue viral infection.
3. The test is a qualitative assay and is not for quantitative determination of antibodies concentration levels. The intensity of the band does not have linear correlation with the antibody titer of the specimen.
4. The results obtained should only be interpreted in conjunction with other diagnostic results and clinical information. If the test result is negative and a dengue infection suspicion still exists, additional follow-up testing using other clinical methods is recommended.
5. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patients may not produce detectable levels of antibody within the first seven to ten days of infection. A negative serological result at any time does not preclude the possibility of an early infection of Dengue virus.
6. The use of icteric or lipemic samples should be avoided. This test should not be used on specimens from immunosuppressed individuals.
7. This test cannot be used to monitor therapy or to estimate the relative antibody titer.

**SAMPLE COLLECTION AND PREPARATION**

1. Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste.
2. Specimen should be collected aseptically by venipuncture according to the standardized methods. The use of grossly lipemic or turbid samples should be avoided. Plasma or serum is separated from the whole blood using standard procedures.
3. If serum or plasma specimens cannot be tested immediately, they should be refrigerated at 2 to 8 °C. For storage periods longer than three (3) days, freeze the specimen at -20°C or below.

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ASSAY PROCEDURE

1. Bring test cassette and chase buffer to room temperature (if precipitates are noted in the chase buffer reagent, shake the bottle vigorously and allow to warm up further).
2. Gently tear open the pouch and remove the test cassette. Lay the test device on a clean, flat work surface.
3. Label the test cassette with the sample name.
4. Pipette 5 µl of serum, plasma, or whole blood into the upper portion of the sample well (as marked in the image above). Make sure that there are no air bubbles.
5. Add 2 drops of buffers into the same sample well of the test device. Sample will start wicking up.
6. Read the test result within 20 minutes. Negative results must be confirmed only after 20 minutes. Do not read results after 30 minutes.

QUALITY CONTROL

1. Positive and negative controls are not included and are optional.
2. If the control line at position C does not become visible, the test is invalid and the test must be repeated. Positive samples will have additional coloured band at position 1 and/or 2.

INTERPRETATION OF RESULTS

1. **Negative**: Only control line (C) is visible. No IgG or IgM antibodies were detected. The result does not exclude dengue infection. If symptoms persist, a new sample should be drawn from the patient in 3-5 days and then should be retested (see the limitations section).
2. **Positive for IgM**: Coloured bands appear at the control line (C) and test line (T2). The test is positive for IgM antibodies. This is indicative of a primary dengue infection (see the limitations section).
3. **Positive for IgM and IgG**: Coloured bands appear at the control line (C) and both test lines (T1 and T2). The test is positive for IgM and IgG antibodies. This is indicative of a secondary dengue infection (see the limitations section).
4. **Positive for IgG**: Coloured bands appear at the control line (C) and test line (T1). The test is positive for IgG antibodies. This is indicative of a past dengue infection (see the limitations section).

EXPECTED VALUES:

- Primary dengue is characterized by the presence of detectable IgM antibodies 5 days after the onset of infection.
- Secondary dengue is characterized by the elevation of specific IgM antibodies and the elevation of specific IgG antibodies. Usually IgM antibodies will rise within 1-2 days after the onset of symptoms and IgG antibodies will be detectable after 20 days of infection.

WARRANTY AND LIMITED LIABILITY

The performance characteristics stated were obtained by using the assay procedure in this insert. Failure to follow the assay procedure may derive inaccurate results. In such event, the manufacturer disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

The manufacturer will not be liable for any damage caused by misuse, improper handling and storage, non-compliance with warnings and procedures, damage caused by events occurring after the product is released, failure to ensure the product is in proper condition before use, or any warranty given by independent distributor.

REFERENCES


ORDER INFORMATION

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Packing Size</th>
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<tr>
<td>RDG-RD0102</td>
<td>Dengue IgG/IgM Rapid</td>
<td>25 tests / kit</td>
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