Dengue Fever IgG-IgM (S/WB/P) Rapid Test (Cassette)

Cat.No: DTS350

Lot. No. (See product label)

Intended Use

The Dengue IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti–dengue virus and IgM anti-dengue virus in human whole blood, serum or plasma. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with dengue viruses. Any reactive specimen with the Dengue IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

General Description

Dengue viruses, a family of four distinct serotypes of viruses (Den 1,2,3,4), are single-strained, enveloped, positive-sense RNA viruses. The viruses are transmitted by mosquitoes of the daytime-biting Stegemyia family, principally Aedes aegypti, and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia, and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

Serological detection is a common method for the diagnosis of infection with dengue viruses. IgM anti-dengue virus starts to appear at 3 days after initial exposure and remain in the circulation for about 30-60 days. IgG anti-dengue virus raise at around 7 days, peak at 2-3 weeks, and persist for the life.

The Dengue IgG/IgM Rapid Test detects IgG and IgM anti-dengue virus in one test within 25 minutes. The test is user friendly, without cumbersome laboratory equipment, and requires minimal staff trainings.

Principle Of The Test

The Dengue IgG/IgM 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 IgG component and an IgM component. In the IgG component, anti-human IgG is coated in test line region 1 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 1. If the specimen contains IgG antibodies to Dengue, a colored line will appear in test line region 1. In the IgM component, anti-ligand is coated in test line region 2 of the test. During testing, the specimen reacts with ligand anti-human IgM. Dengue IgM antibodies, if present in the specimen, reacts with the ligand anti-human IgM and the Dengue antigen-coated particles in the test strip, and this complex is captured by the anti-ligand, forming a colored line in test line region 2.
Therefore, if the specimen contains Dengue IgG antibodies, a colored line will appear in test line region 1. If the specimen contains Dengue IgM antibodies, a colored line will appear in test line region 2. 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 appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Reagents And Materials Provided

1. Each foil pouch contains with three items inside:
a. One cassette device.
b. One plastic dropper.
c. One desiccant.
2. Sample Diluent.
3. One package insert (instruction for use).
4. Positive Control.
5. Negative Control.

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Materials Required But Not Supplied

1. Clock or Timer

Storage

2°C-8°C

Specimen Collection And Preparation

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

Whole blood:
1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by veinpuncture.

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

Serum
1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Reagent Preparation

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°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.

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 sample:
Fill the dropper with the specimen then add 1 dropper of specimen into the sample well. The volume is around 10 µL. Making sure that there are no air bubbles.
Then add 2 drops (about 60-100 µL) of Sample Diluent immediately into the sample well.

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Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by a pipette capable to deliver 10 µL of volume.

For Plasma/Serum sample:
Fill the dropper with the specimen not to exceed the specimen line. The volume of the specimen is around 10 µL. Dispense the entire specimen into the center of the sample well making sure that there are no air bubbles.
Then add 2 drops (about 60-100 µL) of Sample Diluent immediately into the sample well.
Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by a pipette capable to deliver 10 µL of volume.

Step 5: Set up a timer.

Step 6: Read the result at 15 minutes.
Don't read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result.

Quality Control

1. Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
2. External Control: Good Laboratory Practice recommends using the external controls, positive and negative (provided upon request), to assure the proper performing of the assay, in particularly, under the following circumstances:
a. New operator uses the kit, prior to performing testing of specimens.
b. A new lot of test kit is used.
c. A new shipment of kits is used.
d. The temperature used during storage of the kit fall outside of 2°C-30°C.
e. The temperature of the test area falls outside of 15°C-30°C.

Interpretation Of Results

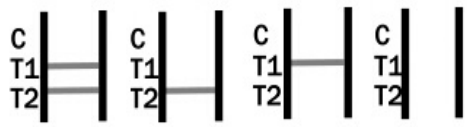
POSITIVE RESULT:

IgG POSITIVE:* The colored line in the control line region (C) appears and a colored line appears in test line region 1 (T1). The result is positive for Dengue virus specific-IgG and is probably indicative of secondary Dengue infection.
IgM POSITIVE:* The colored line in the control line region (C) appears and a colored line appears in test line region 2 (T2). The result is positive for Dengue virus specific-IgM antibodies and is indicative of primary Dengue infection.
IgG AND IgM POSITIVE:* The colored line in the control line region (C) appears and two colored lines should appear in test line regions 1 and 2 (T1 and T2). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary Dengue infection.
***NOTE:** The intensity of the color in the test line region(s) (T1 and/or T2) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the test line region(s) (T1 and/or T2) should be considered positive.

NEGATIVE RESULT:

The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (T1 or T2).

INVALID RESULT:



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Control line (C) falls to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Performance Characteristics

1. Clinical Performance For IgM Test
A total of 314 patient samples from susceptible subjects were tested by the Dengue IgG/IgM Rapid Test and by a reference EIA. Relative Sensitivity: 96.9%, Relative Specificity: 98.9%, Overall Agreement: 98.7%

2. Clinical Performance For IgG Test
A total of 326 patient samples from susceptible subjects were tested by the Dengue IgG/IgM Rapid Test and by a reference EIA. Relative Sensitivity: 97.3%, Relative Specificity: 99.3%, Overall Agreement: 99.1%

Precautions

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. 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.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

Limitations

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to dengue virus in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Dengue IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to dengue virus in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. The Dengue IgG/IgM Rapid Test can not be used to differentiate if the infection is primary or secondary. No information of dengue serotypes can be provided with this test.
4. Serological cross reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile, yellow fever, etc.), therefore, it is possible that patients infected with these viruses may show some level of the reactivity with this test.
5. A negative or non-reactive result for an individual subject indicates absence of detectable dengue virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with dengue virus.
6. A negative or non-reactive result can occur if the quantity of the dengue virus antibodies 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.
7. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8. If the symptom persists, while the result from Dengue IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
9. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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