MD Dengue NS1 + IgG/IgM Dual Lane Test

For the qualitative detection of Dengue Virus NS1 antigen and IgG/IgM antibodies to Dengue virus in whole blood, serum or plasma.

Product Code: MDDENNGM001
Version: 210521

Intended use

The Dengue NS1 + IgG/IgM Dual Lane Test is a rapid chromatographic immunoassay for the qualitative detection of dengue virus NS1 antigen and IgG/IgM antibodies to dengue virus in whole blood, serum or plasma to aid in the diagnosis of dengue viral infection.

Principle of the test

The Dengue NS1 antigen rapid test (left lane) is a qualitative strip-based immunoassay for the detection of Dengue virus NS1 antigen in whole blood, serum or plasma. In this test, anti-Dengue NS1 antibody is immobilized in the test line region of the device. The blood specimen reacts with the anti-Dengue NS1 antibody coated particles that have been applied to the conjugate. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-Dengue NS1 antibody coated on the membrane. If the specimen contains Dengue virus NS1 antigen, a coloured line will appear at the test line region indicating a positive result. If the specimen does not contain Dengue virus NS1 antigen, a coloured line will not be present in the test line region indicating a negative result. To serve as a procedural control, a coloured line will always appear at the control line region indicating that the test was performed correctly.

The Dengue IgM/IgG rapid test (right lane) 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 (Middle line) and an IgM component (bottom line). In the IgG component, anti-human IgG is coated in the test line region (middle line) of the test. During testing, if the Dengue IgG antibody is present in the specimen, it reacts with Dengue antigen coated particles in the test strip, and this complex is captured by the anti-human IgG, forming a coloured line in the test line region (middle). In the IgM component, anti-human IgM is coated in the test line region (bottom) 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 IgM in test line region (middle). If the specimen contains IgM antibodies to Dengue, a coloured line will appear in the test line region (bottom). If the specimen does not contain Dengue antibodies, no coloured line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a coloured line will always appear at the control line region, indicating that the test was performed correctly.

Reagents and material provided in the kit

Units	Components
25	Single pouched test cassettes with desiccant
25	Disposable blood collection devices (10µl)
25	Sterile Wipes
25	Lancets
2	Reaction Buffer 4ml (for all 25 tests)
1	Instructions for use

Timer required but not provided

Storage conditions and shelf life

The following indications must be adhered to, in order to ensure optimal test performance:

1. Store kits at room temperature between 4 and 40°C.
2. Store in a dry place, humidity can affect test performance.
3. The test devices must remain pouched until usage.
4. The kits will have a shelf-life of 24 months after manufacturing.
5. Verify the expiration date printed on the kits and pouches.
6. Kits should not be frozen

Precautions and warnings

1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure exactly as shown in the insert to ensure accurate results.
4. Do not open the sealed pouch, unless ready to conduct the assay.
5. Verify the expiration date, do not use expired tests.
6. Do not mix reagents and components of different lots.
7. Do not use the test if pouch is damaged or if the seal is broken.
8. Do not eat, drink or smoke while handling specimens and test devices.
9. Wear protective gloves and eye protection while handling specimens.
10. Respect standard procedures to dispose specimens and potentially contaminated material, in biohazard containers.
11. The MD Dengue NS1 antigen test device does not present any risk to the user if used as recommended.

Specimen collection and storage

Collection by venipuncture

1. Collect the whole blood into the collection tube (containing EDTA, citrate, or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2 - 8°C. They should be brought to room temperature prior to use. Do not use the specimen after three days as this may cause non-specific reactions.

Collection using a lancet

1. Clean area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take a sample pipette provided, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample pipette up to the second line (10µl).

Test Procedure

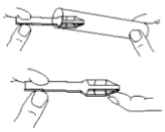
Prior to use, allow the test in the foil bag to reach room temperature.

Open the foil bag to be used, only prior to conducting the test, exposing the cassette.

Select the finger for puncture, usually the side of the third or fourth finger. Clean with the alcohol swab and allow to air dry.

Puncture the finger with a sterile lancet. Blood will well to the surface, re-do procedure on another finger if necessary.

Touch the collection device supplied to the blood spot and allow the blood to fill up to the second (10µl)line.



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Step 1
Transfer blood to the test cassette by gently touching the nozzle to the small sample well for both wells.

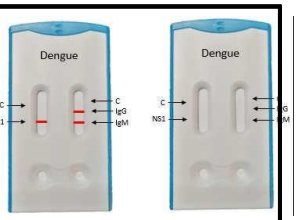
Step 2

Place 4 drops of the reaction buffer into both wells.

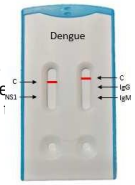
Step 3
Allow the reaction to proceed for 10 minutes.
Read the result and dispose of the cassette after use.

Interpretation of results

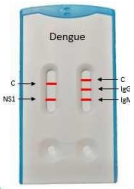
Invalid:
Either no lines are observable, or the test line is present without a top (control) line present. Improper test procedure was carried out or reagents have deteriorated. Re-test.



Negative:
The top (control) line is present, and no test line present, demonstrating the test was performe correctly, but no Dengue antigens or antibodies Dengue are present.



Positive:
The top (control) line is present, The left lane ol has a control line (top) and a Dengue antigen N line (bottom of left lane). The right lane have lines, the control line (top) the IgG line (middle right lane) and the IgM line (bottom of right lane



Limitations of the test

1. The MD Dengue NS1 antigen test is for professional in vitro diagnostic use. It is intended to be used for the qualitative detection of Dengue NS1 antigens only.

2. 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 rule out the existence of Dengue NS1 antigens in blood, because the antigens may be below the minimum detection level of the test.

3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

4. Definitive clinical diagnosis should not be made until the physician has evaluated the result in combination with other clinical and laboratory findings.

Internal quality control

The MD Dengue NS1 antigen immunoassay includes a control line which is used for procedural control. It should always appear confirming the test procedure has been performed accurately.

Symbols

IVD	For in-vitro diagnostic use only	For single use only	
Σ	Content	Expiry date	
LOT	Lot number	Storage temperature	

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