

In vitro Diagnostics

INTENDED USE

Sensit Dengue IgG/IgM - NS1 Combo Rapid Test Kit is a lateral flow immunoassay for the simultaneous detection of Dengue NS1 Ag and the differential IgG/IgM antibodies to Dengue virus in plasma or serum. This test is intended to be used as a screening test and as an aid in the diagnosis of Dengue viral infection, and reactive samples should be confirmed by any supplemental assay such as ELISA.

SUMMARY & TEST DESCRIPTION

Dengue viruses, transmitted by the *Aedes aegypti* and *Aedes albopictus* mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes (dengue virus 1, 2, 3 and 4). In children, infection is often subclinical or causes a self-limited febrile disease. However, if the patient is infected a second time with a different serotype, a more severe disease, dengue hemorrhagic fever or dengue shock syndrome, is more likely to occur. Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality it causes. Traditionally, the serological diagnosis of an acute dengue virus infection has relied on showing a 4-fold or greater rise in anti-dengue virus antibody between paired acute and convalescent phase sera from a patient.

Sensit Dengue IgG/IgM - NS1 Combo Rapid Test can be used to diagnose and differentiate between early acute dengue infection via Dengue NS1 Ag test and primary/secondary infection via Dengue IgG/IgM test.

TEST PRINCIPLE

Sensit Dengue IgG/IgM - NS1 Combo Rapid Test contains two test panels

a) Dengue NS1 Ag test and b) Dengue IgG/IgM test.

The Dengue NS1 Ag test is an immunochromatographic assay for the detection of Dengue NS1 Ag for diagnosis of early acute infection. The test cassette consists of 1) a pink colored conjugate pad containing Monoclonal Anti-Dengue NS1 antibody conjugated with colloid gold, 2) a nitrocellulose membrane strip containing test band (T) and a control band (C). The T band is pre-coated with Monoclonal Anti-Dengue NS1 antibody for the capture of Dengue NS1 antigen.

The Dengue IgG/IgM test is an immunochromatographic assay for the qualitative and differential detection of IgG/IgM antibodies to dengue virus in human serum/plasma. This differential detection helps in the presumptive diagnosis between primary and secondary infection. The test cassette consists of 1) a pink colored conjugate pad containing Dengue antigen (all serotypes D1, D2, D3 and D4) conjugated with colloid gold) a nitrocellulose membrane strip containing two test bands; G: Anti-Human IgG and M: Anti-Human IgM, and a control band (C).

The test specimen with adequate amount of buffer migrates along the conjugate pad and further across the coated membrane by capillary action. If the sample is positive, the analyte gets complexed with the detection molecule on the conjugate pad and gets captured on to the immobilized antibody on the test line to give a pink colored band. If the sample is negative, no reaction occurs at the test line and no line is formed. The sample then migrates further along the strip until it reaches the control band and produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

- Each test kit contains 10 test devices, each sealed Foil pouch containing following items:
 - Dengue IgG/IgM - NS1 Combo Test card
 - Desiccant
- Dropper -10 µl for Dengue IgG/IgM test
- Dropper -25 µl for Dengue NS1 test
- Assay Diluent for IgG/IgM - In dropper bottle
- Instruction Leaflet

PRECAUTIONS & WARNING

- Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
 - Do not use with specimen containing precipitates
 - Use within 10 minutes after opening pouch.
 - Do not reuse test kit.
 - Use a separate pipette tip for each specimen.
 - Use only the buffer supplied along with the kit.
 - Do not mix components from different kits.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

SAMPLE PREPARATION & STORAGE

Plasma:

- Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Centrifuge the blood to get plasma specimen as supernatant.

Serum:

- Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

Note:

- If the specimen is not used for testing immediately, they should be refrigerated at 2-8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

Take out the test card from the foil pouch and place it on a horizontal surface.

Dengue NS1 Ag Test

- Add 2-3 drops of specimen to the sample well on the test card.
- Wait for 10 minutes and interpret results. All results after 15 minutes and where control band does not appear are considered invalid.

Dengue IgG/IgM Test

- Add only 10 µl of serum (For 10 µl sample, aspirate only up to the bubble point of the dropper; Refer Diagram 1) to the sample well on the test card.
- When the sample is fully absorbed, add 2 drops of the diluent provided with the assay
- Wait for 10 minutes and interpret results. Test is considered invalid after 15 minutes. All results where control band does not appear are considered invalid.

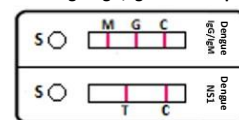
Diagram. 1



INTERPRETATION OF TEST RESULT

1. Positive and negative results:

1.1. Dengue IgG, IgM and NS1 present



1. 2. Dengue IgG, IgM and NS1 absent



1.3. Dengue IgM absent; IgG and NS1 present



1. 4. Dengue IgG & IgM absent; NS1 present



1. 5. Dengue IgG absent; IgM & NS1 present



2. Invalid: No bands at C



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