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recombigen

DENGUE COMBO RAPID TEST DEVICE

(Dengue Ns1 Ag and IgG & IgM Ab in Serum/Plasma)

CLINICAL SIGNIFICANCE

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. 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. The Dengue IgG and IgM Combo Rapid Test is a qualitative test for the detection of IgG and IgM antibodies to dengue virus in human serum plasma. The test provides a differential detection of anti-dengue IgG and anti-dengue-IgM antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection. Serum, plasma, samples may be used with this test. This test is able to detect all 4 Dengue serotypes.

PRINCIPLE

Dengue combo test kit consists of two tests;one test for Dengue NS1 Ag in Serum/Plasma/ and second for Dengue IgG/IgM in serum/plasma.

The Dengue NS1 Antigen Test Device is a qualitative test for the detection of NS1 antigen to dengue virus in human serum/plasma/. First a specimen is dispensed with buffer; the Gold antibody conjugate will bind to Dengue antigen in the specimen sample which in turn will bind with Anti-Dengue NS1 coated on the membrane.As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind the antibody-antigen complex causing light or dark pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result.

First a specimen is dispensed with sample buffer, the Gold antigen conjugate will bind to anti-Dengue IgG and IgM antibodies in the specimen sample which in turn will bind with Anti-Human IgG and Anti-Human IgM coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-Human antibodies on the 5*-membrane will bind the IgG or IgM antigen complex at the relevant IgG and or IgM test lines causing light or dark pink lines to form at the IgG or IgM region of the test membrane. The intensity of the lines will vary depending upon the amount of antibody present in the sample. The appearance of pink line in a specific test region (IgG or IgM) should be considered as positive for that particular antibody type (IgG or IgM).

KIT COMPONENTS

Test Device (NS1Ag and IgG/IgM Ab), Ag/Ab Buffer , Sample dropper for each test and Instructions for Use

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mentioned in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

1. The test can be used to test /Serum/Plasma specimens.
2. To collect , serum or plasma specimens following regular clinical laboratory procedures.
3. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
5. 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.
6. If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

A- Dengue NS1 Antigen: SERUM/PLASMA

1. Bring the pouch to room temperature before opening it. 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.
3. Add 9-10 drops (90-100µl) of serum/plasma into the sample well. No assay buffer is used in serum/plasma specimens.
4. Wait for the red line(s) to appear. Read the result at 15 minutes. Do not read the result after 20 minutes.

B - Dengue IgG/IgM Antibody: SERUM/PLASMA

1. Place the test device on a clean and level surface. Add 1 drop (10µl) of serum/plasma into the sample well.
2. Add 2 drops (70µl) of assay buffer to the sample well.
3. Wait for the red line(s) to appear. Read the result at 15 minutes. Do not read the result after 20 minutes.

Note: Do not interpret result after 20 minutes. (For 1 drop of sample, aspirate Sample up to the narrow portion of the dropper provided and it contains 10µl of Sample). **See fig. (a, b, c)**

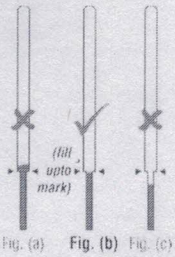
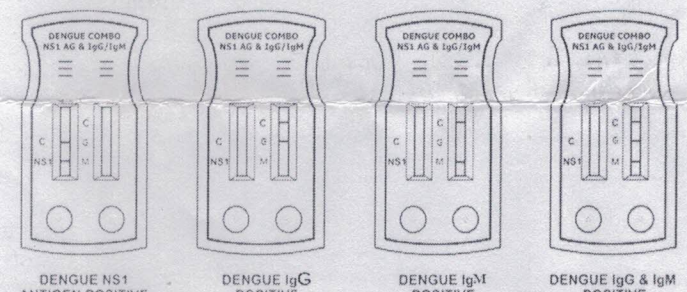


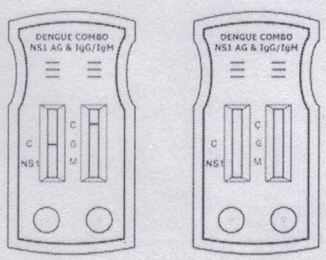
Fig. (a) **Fig. (b)** Fig. (c)

INTERPRETATION OF RESULTS

(A) Dengue NS1 Antigen	
Positive Reaction	The presence of two color bands indicates a positive result for Dengu NS1 antigen.
Negative reaction	The presence of only one band in the control region of the result window indicates a negative result.
Invalid	The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new device.
(B) Dengue IgG/IgM Antibody	
IgM and IgG Positive	Three distinct red lines appear. The control line (C), IgM (M) and IgG (G) lines are visible on the test cassette. The test is positive for IgM and IgG antibodies.
IgG Positive	Two distinct red lines appear. The control line (C) and IgG (G) line are visible on the test cassette. The test is positive for IgG antibodies.
IgM Positive	Two distinct red lines appear. The control line (C) and IgM (M) lines are visible on the test cassette. The test is positive for IgM antibodies.
Negative	No any distinct red line appears in front of M & G.
Invalid	The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new device.



DENGUE NS1 ANTIGEN POSITIVE | DENGUE IgG POSITIVE | DENGUE IgM POSITIVE | DENGUE IgG & IgM POSITIVE



NEGATIVE | INVALID

LIMITATIONS

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required. Control standards are not supplied with this kit; however,it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. The overall sensitivity of Dengue NS1 Antigen Test is 94.5% and specificity is 98.9%.

The intensity of the red color in the test line regions (T) will vary depending on the concentration of IgG/IgM present in the specimen. However, neither the quantitative value nor the rate of increase in IgG/IgM can be determined by this qualitative test. A negative result can occur if the quantity of the anti- Dengue antibodies present in the specimen is below the detection limits. Other clinically available tests are required.

BIBLIOGRAPHY

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