ACCUCARE

DENGUE DUO CARD TEST

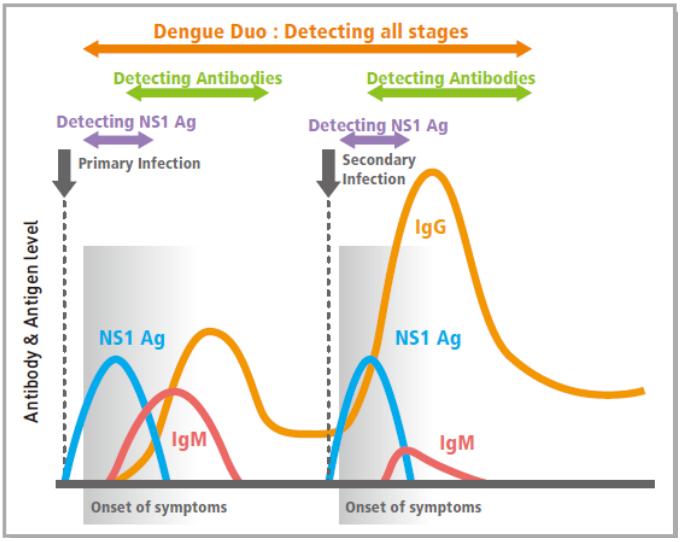
(NS1 AND IgG+IgM DETECTION TEST)

For rapid qualitative detection of both Dengue NS1 Antigen and antibody (IgG/IgM) against dengue virus in human serum and plasma.
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

REF	Cont.
DENC 10	10 Test
DENC 25	25 Test

CLINICAL SIGNIFICANCE



The NS1 antigen is expected to be detected 1 day after the onset of fever and persist upto 9 days in both primary and secondary dengue infection. But the detection of NS1 is inhibited, if anti-NS1 is produced. Primary dengue is characterized by the presence of detectable IgM 3-4 days after the onset infection. Secondary dengue is characterized by the elevation of IgG 1-2 days after the onset infection and in majority of cases this is generally accompanied by an elevation of IgM.
Dengue virus, a virus belonging to the Flavavirus 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 subtropic 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.
Dengue NS1 antigen is highly conserved glycoprotein that seems to be essential for viral viability, but has no established biological activity. Specially, NS1 is produced in both membrane associated and secreted forms. The NS1 Ag present at high concentration in sera of infected persons during the early clinical stage.

PRINCIPLE

The Dengue NS1 Antigen Test Device (Serum/ Plasma/Whole Blood) is a qualitative test for the detection of NS1 antigen to dengue virus in human serum or plasma. Only serum and plasma samples may be used with this test. First a specimen is dispensed 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 pale 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 membrane will bind the IgG or IgM antigen complex at the relevant IgG and or IgM test lines causing pale 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.

KIT COMPONENTS

Test Cassette Device, Instructions for Use, sample dropper and buffer for IgG/IgM Ab. Test.

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 mention 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. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
2. 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.
3. 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.
4. 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.

For NS1 Test

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. Pipette 60-70 µL (3 drops) of serum, plasma or whole blood into the sample well.
3. Wait for the red line(s) to appear. The test result should be read at between 15 and 30 minutes. Results may be read upto 30mins.

For IgG/IgM Test

1. Place the test device on a clean and level surface. Pipette 5 µL of serum, plasma into the sample well.
2. Add 2 drops (60 µl) of test buffer to buffer well.
3. Wait for the red line(s) to appear. The test result should be read at between 15 and 30 minutes.

Note: Do not interpret the result after 30 minutes.

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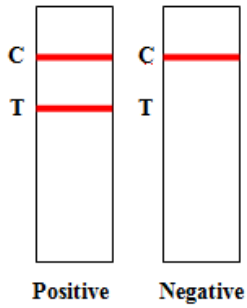
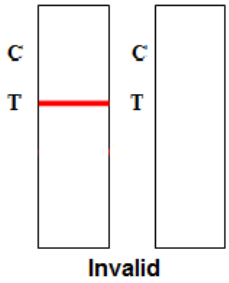
INTERPRETATION OF RESULTS:

INTERPRETATION OF DENGUE NS1 TEST



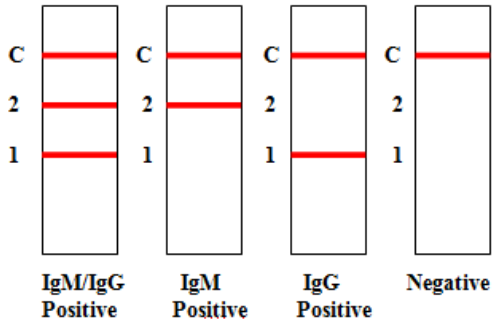
1) Positive Reaction
The presence of two color bands indicates a positive result for Dengue NS1 antigen.
2) Negative reaction
The presence of only one band in the control region of the result window indicates a negative result.
3) Invalid
The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new strip
NOTE: The intensity of the red color in the test line region will vary depending on the concentration of NS1 antigen present in the specimen. However, neither the quantitative value nor the rate of increase in NS1 antigen can be determined by this qualitative test.



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 studies and clinical evaluations were conducted in correlation with PCR and Viral Culture Tests.

INTERPRETATION OF DENGUE IgG/IgM TEST:

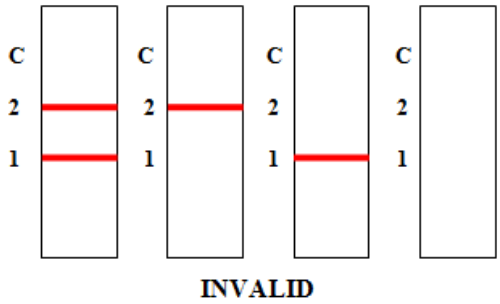


IgM and IgG POSITIVE: Three distinct red lines appear. The control line (C), IgM (2) and IgG (1) lines are visible on the test cassette. The test is positive for IgM and IgG antibodies.

IgG POSITIVE: Two distinct red lines appear. The control line (C) and IgG (1) 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 (2) line are visible on the test cassette. The test is positive for IgM antibodies.

NEGATIVE: One distinct red line appears. The control line (C) is the only line visible on the test cassette. No IgG or IgM antibodies were detected. The result does not exclude dengue infection. A new sample should be drawn from the patient in 3-5 days and then should be retested.



INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of lines in the IgG (1) or IgM (2) region of the cassette. Repeat the test using a new cassette.

BIBLIOGRAPHY

1. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.

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