DENGUE DUO CARD

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC04

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

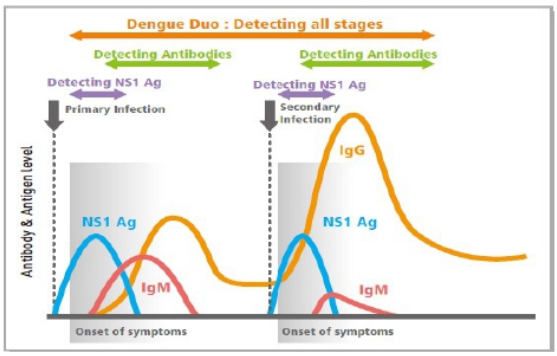
INTENDED USE: Test for detection of both NS1 antigen and IgG/IgM antibody against Dengue virus in serum and plasma.

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.

Dengue NS1 Antigen Dengue IgG/IgM Antibody

For NS1 Antigen: 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 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.

For IgG/IgM Antibodies: 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 assay buffer for IgG/IgM Ab. And assay Buffer, swab, lancet for NS1 Test.

PRECAUTIONS

1. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch just before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
5. Follow the testing procedure exactly as mention in the insert.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed 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.

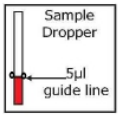
TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

For NS1 Antigen:

1. Place the test device on a clean and level surface. Pipette 10 µl of serum, plasma or whole blood into the sample well.
2. Add 1 drop (30 µL) of assay Buffer to 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 Antibodies:



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 sample well.
3. Wait for the pink line(s) to appear. The test result should be read at between 15 and 30 minutes.

Note: Please not the Two separate dropper provided with kit for sample dispensing Dropper with notch use for dispense 5 µL Serum/plasma for Dengue IgG/IgM and capillary dropper for 10 µL NS1

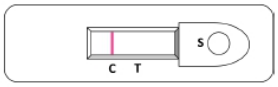
For NS1 Antigen For IgG/IgM Antibodies

INTERPRETATION OF THE RESULTS

FOR NS1 ANTIGEN:

NEGATIVE RESULT:

Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative



POSITIVE RESULT:

In addition to the colored line in the control region a clearly distinguishable pink purple colored line also appears in the test region 'T' (Test line) indicating a positive result.

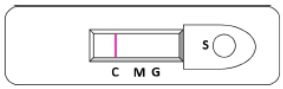
INVALID TEST:

If no line appears in the control as well as the test region, the test should be repeated with fresh card.

FOR IgG/IgM ANTIBODIES:

NEGATIVE RESULT:

One band appears in the control region (C). No apparent bands appears in the test regions (1 or 2).



POSITIVE RESULT:

IgG Positive:

The presence of a band at 'C' and at 'G' within the Result Window, indicates a positive result for IgG antibodies.

IgM Positive:

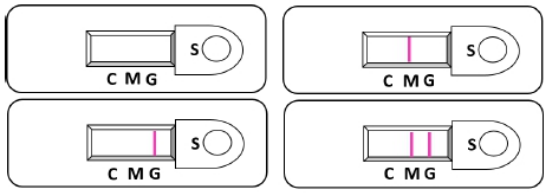
The presence of a band at 'C' and at 'M' within the Result Window, indicates a positive result for IgM antibodies.

IgG and IgM Positive:

The presence of a band at 'C' and bands at 'G' and 'M' within the Result Window, no matter which band appear first, indicates a positive result for IgG and IgM antibodies respectively.

INVALID RESULT:

No visible band at the control region. Repeat with a new test device.



QUALITY CONTROL

Although the testing device contains an internal quality control (coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

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.

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE