Dengue Combo (NS1/IgG/IgM)

Antigen & Antibody Detection Card Test
Serum/Plasma

INTENDED USE:

The Dengue Combo Test (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of NS1 Antigen and IgG/IgM Antibodies to Dengue Virus in human serum and plasma.

PRINCIPLE OF THE TEST:

Dengue NS1 Antigen device is a chromatographic immunoassay test for the rapid detection of dengue virus non-structural protein 1 (NS1) antigen, using human serum/plasma. Dengue NS1-specific antibodies complexed with gold conjugate are placed in the conjugate pad and another set of anti-dengue NS1 antibodies are immobilized on the membrane. The NS1 antigen in the sample reacts with specific antibodies conjugated with gold colloid particles. The antigen – antibody-gold colloid complex flows chromatographically through the nitro-cellulose membrane and gets captured and immobilized by the second set of specific antibodies coated on the test region (T), thus forming a visible red band in the test region (T). The solution continues to migrate towards the control region (C) and produces a second red line, on the control region (C).

Dengue IgG/IgM Antibody device is a chromatographic immunoassay test for rapid and differential detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) against all types of dengue viruses, using human serum and plasma. Dengue-specific antigen complexed with gold conjugate is placed in the conjugate pad and anti-human IgG and anti-human IgM are coated on the membrane. When a sample positive for dengue antibodies (IgG/IgM) is loaded into the sample well (S), the antibodies are captured by the dengue- specific antigen complexed with gold colloid particles. This antibody-antigen-gold colloid complex flows chromatographically through the nitro-cellulose membrane and gets captured and immobilized by the anti-human IgG and or IgM antibodies coated on the membrane in the test region, thus forming a visible red band/s in the IgG/IgM marked region on the test region. The solution continues to migrate towards control region (C) and produces a red line, on the control region (C).

MATERIALS PROVIDED:

Dengue Combo (NS1/IgG/IgM) kit contains the following items:

1. Test devices with a desiccant.
2. Assay Buffer for Dengue IgG/IgM.
3. Dropper-1 for Dengue NS1.
4. Dropper-2 for Dengue IgG/IgM.
5. Product insert.

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Specimen collection container/tube.
2. Timer.

PRECAUTIONS:

1. For *in - vitro* diagnostics use only. IVD
2. Wear protective gloves while handling the kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed off as potential biohazards.
4. Do not use kit components beyond the expiry date.
5. Dispose off all used materials in an appropriate container. Treat as potential biohazard.

SPECIMEN COLLECTION AND STORAGE:

1. Specimens to be tested should be obtained and handled by standard methods for their collection.

A. Serum: Allow the blood to clot, then centrifuge to separate the serum.

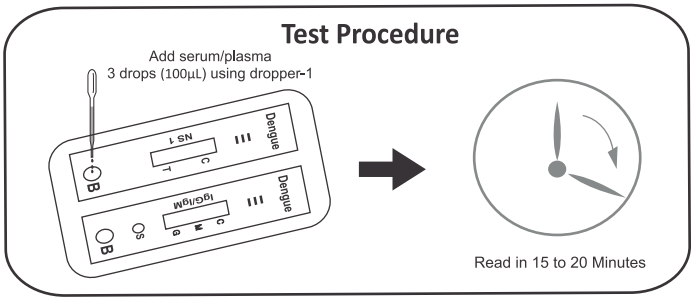
B. Plasma: Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.

2. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8 °C for up to 24 hours or at -20°C for longer periods.
3. Anti-coagulants such as heparin, EDTA and citrate do not affect the test result.
4. Use separately disposable capillary tubes or pipette tips for each sample in order to avoid cross-contamination of samples which could cause erroneous results.

TEST PROCEDURE:

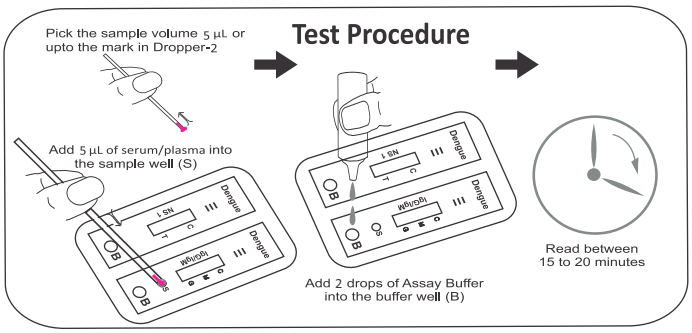
A) For Dengue NS1

1. Place all specimens and test devices. Allow them to equilibrate to room temperature prior to testing (15-30 min).
2. Take out the test device from the pouch and then mark the patient's ID on the device. Perform the test immediately after removing the device from the foil pouch.
3. Dispense 3 drops (100$\mu\ell$) of serum/plasma into the sample well (B) in the test device using **dropper-1 or micropipette**.
4. After 15 to 20 minutes, interpret the results.
5. Do not read the results after 25 minutes.



B) For Dengue IgG/IgM

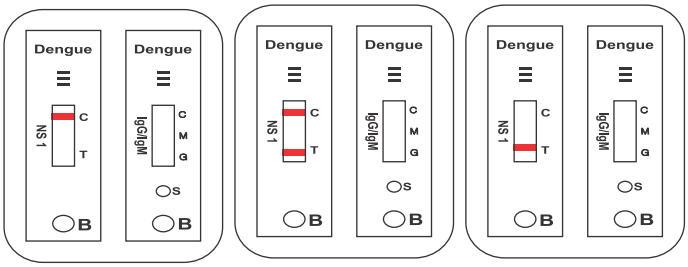
1. Place all specimens, test devices, Assay Buffer. Allow them to equilibrate to room temperature prior to testing (15-30 min).
2. Dispense 5 $\mu\ell$ of serum/plasma into the sample well (S) **using dropper-2 or micropipette.**
   (NOTE: Pick the sample volume, only up to mark in Dropper-2).
3. Add 2 drops of Assay Buffer into the buffer well (B) in the device. After 15 to 20 minutes, interpret the test results.
4. Do not read the results after 30 minutes.



INTERPRETATION OF THE RESULTS:

A) For Dengue NS1

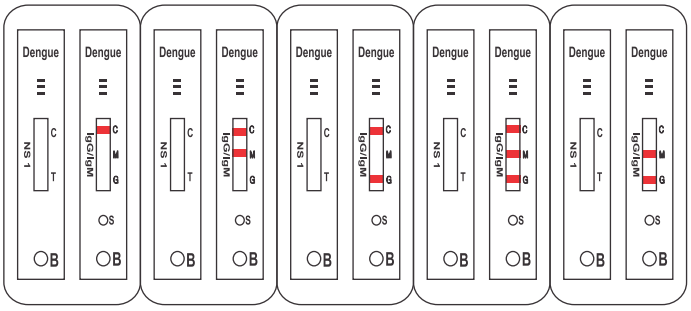
1. **NEGATIVE:** If only the control line (C) is visible, it indicates that there are no Dengue NS1 antigens detectable in the sample.
2. **POSITIVE:** If along with the control line (C), the band for test line (T) is also visible, it indicates that the sample contains detectable levels of Dengue NS1 antigen.
3. **INVALID:** If the control line (C) does not appear. In this case, the test should be repeated following the exact test procedure.



Negative Dengue NS1 | Positive Dengue NS1 | Invalid Dengue NS1

B) For Dengue IgG/IgM

1. **NEGATIVE:** If only the control line (C) is visible.It indicates that there are no Dengue antibodies detectable in the sample.
2. **IgM POSITIVE:** If along with the control line (C), the band for Dengue IgM (M) is also visible. It indicates that the sample contains detectable levels of Dengue IgM antibodies in the sample.
3. **IgG POSITIVE:** If along with the control line (C), the band for Dengue IgG (G) is also visible. It indicates that the sample contains detectable levels of Dengue IgG antibodies in the sample.
4. **IgG & IgM POSITIVE:** If along with the control line (C), both the bands for Dengue IgG (G) and Dengue IgM (M) are also visible. It indicates that the sample contains detectable levels of Dengue IgG and Dengue IgM antibodies in the sample.
5. **INVALID:** If the control line (C) does not appear. In this case, the test should be repeated following the exact test procedure.



Negative Dengue IgG/IgM | IgM Positive Dengue IgG/IgM | IgG Positive Dengue IgG/IgM | IgG & IgM Positive Dengue IgG/IgM | Invalid Dengue IgG/IgM

STORAGE & EXPIRATION:

1. Dengue Combo kit should be stored between 4 to 30°C.
2. Expiry date of this kit is as mentioned on the label.

QUALITY CONTROL:

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. 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.

LIMITATIONS OF THE TEST:

Dengue Combo (NS1/ IgG/IgM) is designed for the primary screening test of Dengue infections. This kit can provide fast and easy way to get a result, however, it does not completely exclude the possibility of false positive or false negative results caused by various factors. Results obtained should be correlated clinically.

PERFORMANCE CHARACTERISTICS:

Relative Sensitivity: 98.2%
Relative Specificity: 97.4%

REFERENCES:

World Health Organization-Geneva (2000) new perspectives Dengue diagnosis.

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