Dengue IgG/IgM)
Antibody Detection Card Test
Serum/Plasma

INTENDED USE:

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

PRINCIPLE OF THE TEST:

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 device.

MATERIALS PROVIDED:

Dengue IgG/IgM kit contains the following items:

1. Test devices with a desiccant.
2. Assay Buffer for Dengue IgG/IgM.
3. 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.

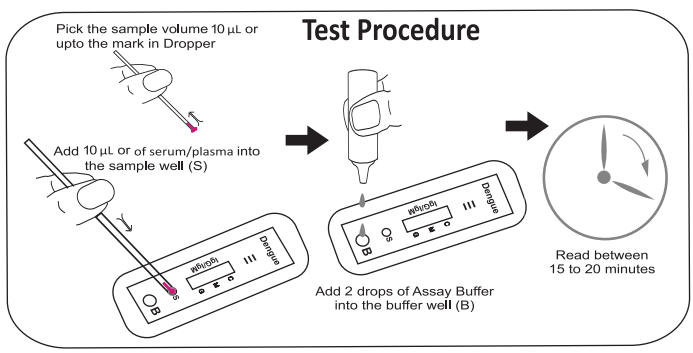
A. Serum: Allow the blood to clot, then centrifuge to separate the serum.

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:

1. Place all specimens, test devices, Assay Buffer. Allow them to equilibrate to room temperature prior to testing (15-30 min).
2. Dispense 10 $\mu\ell$ of serum/plasma into the sample well (S) **using dropper or micropipette.**
   (NOTE: Pick the sample volume, only up to mark in Dropper).
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:

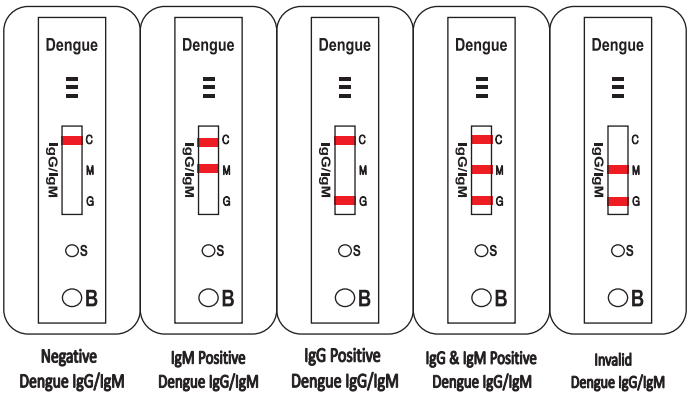
1. **NEGATIVE:** If only the control line (C) is visible.It indicates that there are no Dengue antibodies detectable in the sample.

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.



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 IgG/IgM is designed for 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: 98.1%

Relative Specificity: 97.3%

REFERENCES:

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

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