BIOGENIX
INC. PVT. LTD.

Dengue Combo (NS1+IgG/IgM) Rapid Test

INTENDED USE:
The Dengue Combo test (Serum/Plasma) Is a rapid chromatographic immunoassay for the qualitative detection of NS1 Antigen and IgG/IgM Antibodies of Dengue Virus in human serum and plasma.

PRINCIPLE OF THE TEST:

Dengue NS1 Antigen device is a chromatographic immunoassay kit 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 anti-dengue NS1 antibodies are immobilized on the membrane. When dengue antigen-positive specimen is loaded into sample point/sample hole, the antigen is captured the immobilized anti-dengue NS1 antibodies. And then, the antigen is reacted with dengue NS1-specific antibodies-gold complex to make a visible band in the test region.

Dengue IgG/IgM Antibody device is a chromatographic immunoassay kit 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 dengue antibody-positive specimen is loaded into sample injection point (sample hole) the antibodies are captured the immobilized anti-human antibodies. And then, the antibodies are reacted with dengue-specific antigen-gold complex to make a visible band in the test line regions. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line. Dengue IgG/IgM can detect the antibodies against 4 serotypes of dengue virus, so that the device is suitable for the diagnosis of all types of dengue virus infections.

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
4. Product insert

PRECAUTIONS:
1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For *in-vitro* diagnostic use only. Do not re-use the testdevice.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose gloves, swabs, test tubes, and the used strips properly after test, in accordance with GLP.
6. Do not eat or smoke while handing specimens.
7. Decontaminate and dispose of all specimens, reaction waste, in a biohazard container.

SPECIMEN COLLECTION AND STORAGE:
1. Specimen to be tested should be obtained and handled by standard methods for their collections.
A. Serum: allow the blood to clot, then centrifuge to separate the serum.
B. Plasma: collect the whole blood into the tube contained anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
2. All specimens should be tested as soon as early they are prepared. If necessary, they may be stored at 2-8 ℃ for up to 24 hours or at -20℃ 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 either samples which could cause erroneous results.

TEST PROCEDURE:

A) <u>For DengueNS1</u>
1. Place all specimens, test devices, and allow them to room temperature prior to testing (15-30 min).
2. Prepare the test device as you need, and then mark the patient's ID onto the device. Please perform the test immediately after removing the device from foil pouch.
3. Load 2 drops (50 $\mu\ell$) of serum/plasma into the sample well (S) in the test device.
4. After 15-20 minutes, interpret the results.

(NOTE: Pick the sample volume using dropper or micropipette)

*** Please do not read the results after 20 minutes of the testing.**

B) <u>For Dengue IgG/IgM</u>
1. Place all specimens, test devices, and Assay Buffer and allow them to room temperature prior to testing (15-30min).
2. Add 5 $\mu\ell$ of serum/plasma into the sample well (S) using micropipette**.**
3. Add 2 drops (approx. 60 ul) of assay buffer into the buffer well (B) in the device. And then, after 15-20 minutes, interpret the test results.

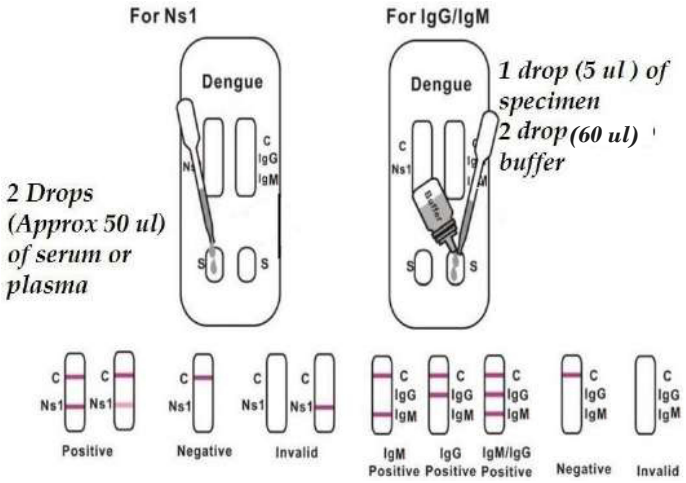
*** Please do not read the results after 20 minutes of this testing**.

INTERPRETATION OF THE RESULTS:

A) <u>For DengueNS1</u>
1. **Negative result:** ONLY one band in the control line(C).
2. **Positive result:**Two bands are appeared in the test line (T) and control line (C).
3. **Invalid result:** If at 20 minutes, the red color band does not appear in the control line (C), even if any shade of a pink-to-red test line (T) appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test device.

B) <u>For Dengue IgG/IgM</u>

1. **Negative:** ONLY one band in the control line (C). No dengue-specific IgG and IgM were detected. Re-test in 3-5 days if dengue infection is suspected.
2. **IgM Positive:** Two bands are appeared in the IgM line(M) and control line(C). This is positive for IgM antibodies to dengue virus and indicative of a primary dengue infection.
3. **IgG Positive:** Two bands are appeared in the IgG line (G) and control line (C). This is positive for IgG antibodies and indicative of a secondary or previous dengue infection.
4. **IgG and IgM Positive**: Three bands are appeared in the IgG line (G), IgM line (M) and control line (C). This is positive for both IgG and IgM antibodies and indicative of a late primary or early secondary dengue infection.
5. **Invalid:** if at 20 minutes, the red color band does not appear in the control line (C), even if any shade of a pink-to-red test line (T) appears, the result is considered invalid.If the test is invalid, a new test should be performed with a new patient sample and a new test device.



LIMITATIONS OF THE TEST:
Dengue Combo (NS1/IgG/IgM) is designed for primary screening test of dengue infections. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

WASTE MANAGEMENT OR DISPOSABLE:
The contents of RDTs can be divided into :
Infectious waste:
- sharps (lancets, needles, scalpel blades)
- blood collection devices (tubes, straws, and loops); gloves; swabs; and cotton
- used cassettes.

Non-infectious waste (Recyclable):
- packaging materials, desiccant, buffer, and unused or unusable RDTs.

*****You must collect and dispose each type of waste in separate containers as per your waste management policies.***

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

<u>For in vitro diagnostic use only, not for medical use</u>

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