RapidTech Plus Dengue IgG/IgM

A one step assay for the simultaneous detection of IgG and IgM antibodies to Dengue virus in serum or whole blood.

INTENDED USE

The RapidTech Plus Dengue IgG/IgM Test is a rapid one step, visual test for the qualitative detection of specific IgG and IgM antibodies to Dengue virus in human whole blood, serum or plasma. This kit is intended as an aid in the diagnosis of Dengue virus infection in human.

SUMMARY

The Dengue virus belongs to the Flavavirus group of viruses. This virus is commonly found throughout the tropics and Australia. The symptoms of Dengue fever are sudden onset fever, headache, pain in the back and limbs, lymphaderopathy, maculopapular rash and retrobulbar pain.

Dengue fever causes approximately 20,000 deaths annually with nearly 3 million children hospitalized over the past 3 decades as a result of Dengue. The virus is transmitted by a day biting mosquito (Aedex). This species is common in urban settings. Tests such as ELISA and PCR are being used to aid in the diagnosis of Dengue fever.

New serological tests such as the ONE STEP Dengue IgG/IgM rapid test are among the simplest and fastest means of identifying Dengue antibodies.

PRINCIPLE

The RapidTech Plus Dengue IgG/IgM test kit is a rapid membrane based screening test to detect the presence of antibodies to Dengue virus. This test is the newer generation lateral flow immunochromatographic type assay.

The test can be used either with serum or whole blood. The test employs the use of an antibody binding protein conjugated to a colloidal gold particle and a unique combination of Dengue antigens immobilized on the membrane.

Once the sample is added to the test cassette along with the diluent, the mixture passes through the antibody binding/gold complex, which then binds the immunoglobulins in the sample. As this complex passes over the immobilized antigens on the membrane, if any antibodies to Dengue (IgG or IgM) are present the antigens capture them in turn. This produces a pink/purple band in the B zone of the test card. The remaining complex continues to migrate to a control area in the test card and produces a pink/purple band in the C area. This control band indicates that the test has been performed properly.

REAGENTS AND MATERIALS SUPPLIED

1. Test cards, 25 tests
2. Diluent in dropper vial

STABILITY AND STORAGE CONDITIONS

The RapidTech Plus Dengue IgG/IgM test is stable at any room temperature between 2° to 30°C when stored in the sealed pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

PRECAUTIONS

1. The test is for In Vitro Diagnostic Use only.
2. Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
3. Do not pipet any samples or reagents by mouth.
4. All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5°C for 1 hour or treat with Sodium hypochlorite (1 percent solution).
5. Do not use test beyond the expiration date indicated.

SAMPLE COLLECTION AND STORAGE

The Rapid Tech Plus Dengue IgG/IgM test can be run on serum or whole blood.

The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2° to 8°C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at –20°C or colder. Whole blood samples cannot be frozen and it is recommended that finger prick blood be used.

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TEST PROCEDURE

1. Remove as many test cards from the pouches as needed. Lay on a clean flat surface.
2. For WHOLE BLOOD - add 10 µls of sample to the (A) well of the test card using a measuring pipet.
   For SERUM – add 5 µls of sample to the (A) well of the test card using a measuring pipet.
3. Follow sample addition with 6 drops of the diluent provided in the dropper bottle by holding the bottle vertically over the (A) well.
4. Results are then read in as little as 10 minutes for strong positives or up to 45 minutes for weaker positives and to make sure negatives are confirmed.

NOTE: IgG positive samples typically produce a more intense test line than IgM positive samples. However, ANY visible line in the B (Test) area of the card that appears within 45 minutes should be interpreted as a positive.

NOTE: If the dye has not cleared the membrane or blood is still present, one or two drops more of diluent may be added to the (A) well.

INTERPRETATION OF RESULTS

Negative

Only one pink/purple band appears in the C well
**Positive**
Two pink/purple bands appear. One in the B well - Test area of the test card. One in the C well - Control area.

**EXPECTED VALUE**
The number of antibody positive subjects in a population depends on two factors: disease prevalence and clinical criteria used to select the tested population. Because very few positives should be seen in a randomly screened population in a non-endemic area, most serology tests are not specific enough to screen non-endemic populations. Even in an endemic region, serology screening often yields many false positives if used to randomly screen patients. Serology tests are useful to test patients in an endemic region with signs and symptoms consistent with the disease.

Antibody levels are generally low or absent during very early infection. Symptomatic patients may have no antibody during the first 1-2 weeks after exposure and the antibody titer will rise with time.

**PERFORMANCE CHARACTERISTICS**
As there are no true standards established for determining the absence or presence of Dengue IgG or IgM antibodies in serum or whole blood samples. It is recommended that the performance of the kit be compared to established serum panels or reference materials. The RapidTech Plus Dengue IgG/IgM kit is tested against characterized serum panels and has shown to be highly sensitive and specific for Dengue IgG and IgM antibodies.

**REFERENCES**

Genix Technology
Vancouver, Canada.

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