

Dengue Rapid Test Kit

INTRODUCTION

Dengue IgM and/or IgG Rapid Test Cassette is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgM and IgG anti-dengue in human serum (or plasma). The kit is a diagnostic device for qualitative detection .

INTENDED USE

Dengue test is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to dengue virus in human whole blood, serum or plasma. The assay is used as a screening test for Dengue viral infection and as an aid for differential diagnosis of primary and secondary infections in conjunction with other criteria .

SUMMARY

When a specimen is added to the test, IgG and IgM antibodies in the specimen sample react with gold particles labeled with dengue envelope proteins. As this specimen/particle mixture migrates along the length of the test, the anti-dengue IgG and/or IgM antibody particle complex is captured by the relevant IgG and IgM test bands located in the test device window causing a pale to dark red band to form at the test region of the cassette window. The intensity of the bands will vary depending upon the amount of antibody present in the sample. The appearance of any color in test region should be considered as positive for IgG and/or IgM antibody. A red procedural control line should always develop in the test device window to indicate that the test has been performed properly.

SPECIMEN COLLECTION

For serum or plasma, collect blood into a container without anticoagulant. If the specimen cannot be tested on the day of collection, store the serum or plasma specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing.

TEST PROCEDURE

1. Open a pouch containing a cassette, remove the test kit from the pouch and place it horizontally on the desk.
2. Pipette 1 drop (5µl) of specimen into the same well and then drop 1 drop (about 50µl) of diluent into the same well.
3. Read results within 10 minutes. Do not read results after 20 minutes.

INTERPRETATION OF RESULTS

Negative: Only control pink band appears on test region of the cassette. This indicates that there is no anti-dengue IgM and IgG in the specimen.

Positive: Three pink bands (C,G,M) , two pink bands (C,G) or (C,M) appear on test region of the cassette. This indicates that the specimen contains detectable amount of anti-dengue

IgG and IgM, only IgG, only IgM.

Invalid: If without colored band appears at control region, this is an indication of a possible error in performing the test. The test should be repeated using a new one.

PRECAUTION

- 1, Must use fresh specimen and avoid repetitive freezing, the result will be invalid
- 2, Use it before expiry date.
- 3, The package of kit should not be opened until it reaches the room temperature if it taken out from the refrigerator. Use the test kit as soon as possible but within 1 hour after removal from pouch specially if the room temperature is more than 30°C and in high humidity environment.
- 4, Old serum can not be used. If the serum is thick, it can be used only after being separated.

LIMITATIONS

- 1, The test is for in-vitro diagnostic use only.
- 2, The test is qualitative filter detection, it can not be used as the final test for blood donor.

STORAGE AND STABILITY

The test kit can be stored at room temperature (18 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.