Dengue NS1+IgM/IgG Combo test kit (Serum / Plasma/ Whole Blood)

INTENDED USE

The Dengue NS1+IgM/IgG Combo rapid test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti– dengue virus, IgM anti-dengue virus and dengue antigen (Dengue Ag) in human serum, plasma or whole blood. It is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with dengue virus. Any reactive specimen with the Dengue Ag NS1-IgM/IgG rapid test must be confirmed with alternative testing method(s).

SUMMARY

Dengue virus is an enveloped, single-stranded, positive-sense RNA virus that comprises four related but distinct serotypes (Den 1, 2, 3, and 4). The virus is transmitted by mosquitoes of the daytime-biting Stegomyia family, principally Aedes aegypti and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

Serological detection is a common method for the diagnosis of infection with dengue virus. IgM anti-dengue virus starts to appear at 3 days after initial exposure and remains in circulation for about 30-60 days. IgG anti-dengue virus is raised at around 7 days, peaks at 2-3 weeks and persists for the duration of life4-6. Detection of antigens released during virus replication in the infected patient show very promising results; it enables diagnosis from the first day after the onset of fever up to day 9 once the clinical phase of the disease is over, thus, allowing early detection and prompt treatment.

The Dengue Ag NS1-IgM/IgG rapid test detects IgG and IgM anti-dengue virus and circulating dengue antigen in one test within 20 minutes. The test is user friendly, does not require cumbersome laboratory equipment and requires minimal staff training.

STORAGE ANDSTABILITY

1. All reagents are ready to use as supplied.
2. Store unused test device unopened, preferably at 2℃-30℃.
3. Keep the temperature at 15℃-30℃ during the test.
4. Do not freeze the kit.
5. The positive and negative controls should be kept at 2°C-8°C.
6. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening.
7. The test device is stable through the expiration date printed on the sealed pouch if it is stored at 2°C-30°C.

PRECAUTIONS

1. For in vitro diagnostic use and professional use only.
2. Read the package insert instruction before use the kit.
3. Do not use beyond the expiration date which appears on the package label.
4. Do not open the sealed pouch, unless ready to conduct the assay.
5. Bring all reagents to room temperature (15°C-30°C) before use.
6. Haemolized blood may be used for the testing, but do not take precipitants.
7. Wear protective clothing and disposable gloves while assaying samples. Wash hands thoroughly after performing the test.
8. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5 to 1% solution of sodium hypochlorite for one hour before disposal.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Read result after 30 minutes may give erroneous results.
11. Do not perform the test in a room with strong air flow, an electric fan or strong air-conditioning.
12. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
13. Excess sample volume (>5μL) can give false positives.

TEST PROCEDURE

Step 1:
Bring the specimen and test components to room temperature, if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2:
When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3:
Be sure to label the device with specimen's ID number.

For detection of Dengue Ag NS1
Add 1 drops (approximately 30ul) of serum / plasma or whole blood into sample well with a pipette. Then add 2 drop (approximately 80ul) of wash buffer provided in the dropper bottle holding the bottle vertically from the sample well.

For detection of Dengue IgG/IgM
Add 1 drops (approximately 30ul) of serum / plasma or whole blood into sample well with a pipette. Then add 2 drop (approximately 80ul) of wash buffer provided in the dropper bottle holding the bottle vertically from the sample well.

Step4:
Set up timer.

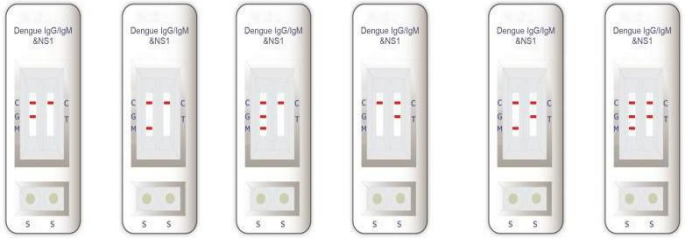
Step5:
Results can be read 15~20 minutes.Do not read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

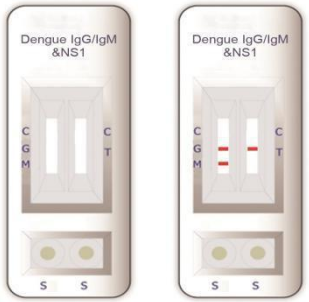
NEGATIVE RESULT:
If only the C line is present, the absence of any pink color in the G, M or T lines
indicates that neither anti-dengue virus antibodies or dengue virus antigens are detected. The result is negative or non-reactive.

POSITIVE RESULT:

IgG	IgM	IgG/IgM	Ns1	Ns1/IgM	Ns1/IgG/IgM
Positive	Positive	Positive	Positive	Positive	Positive



INVALID:
If no C line is developed, the assay is invalid regardless of any burgundy color in the G, M or T lines as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

Clinical Performance for IgM Test: A total of 387 samples from susceptible subjects were tested with the Dengue IgG/IgM rapid test and by a commercial EIA. Comparison for all subjects is shown in the following table:

	Dengue IgG/IgM rapid test		
IgM EIA Test	**Positive**	**Negative**	**Total**
Positive	**121**	**5**	**126**
Negative	**7**	**254**	**261**
Total	**128**	**259**	**387**

Relative Sensitivity: 96.0% , Relative Specificity: 97.3%, Overall Agreement: 96.9%

2. Clinical Performance for IgG Test: A total of 441 samples from susceptible subjects were tested with the Dengue IgG/IgM rapid test and by a commercial EIA. Comparison for all subjects is shown in the following table:

	Dengue IgG/IgM rapid test		
IgG EIA Test	**Positive**	**Negative**	**Total**
Positive	**153**	**7**	**160**
Negative	**11**	**270**	**281**
Total	**164**	**277**	**441**

Relative Sensitivity: 95.6% , Relative Specificity: 96.1%, Overall Agreement: 95.9%

3. Clinical Performance For Ag Test: A total of 438 patient samples from susceptible subjects were tested by the Dengue Ag rapid test and by a commercial EIA. Comparison for all subjects is shown in the following table:

	Dengue Ag rapid test		
Dengue Ag EIA Test	**Positive**	**Negative**	**Total**
Positive	**135**	**5**	**140**
Negative	**12**	**286**	**298**
Total	**147**	**291**	**438**

Relative Sensitivity: 96.4%, Relative Specificity: 96.0%, Overall Agreement: 96.1%

MATERIAL

Material provided

1. 25 Individual sealed pouches, each containing:
   - Test device
   - Desiccant pouch
2. 25 Extraction tubes.
3. One extraction buffer in a dropper bottle (6mL): 0.01M phosphate buffer saline (PBS).
4. Leaflet with instructions for use.

Material Required But Not Provided

Timer

INDEX OF SYMBOLS

	See instruction for use	Σ	Tests per kit		Manufacturing date
IVD	For *in vitro* diagnostic use only		Expiry date		Do not reuse
2°C 30°C	Store between 2 ~ 30 ℃	LOT	Batch number	REF	Catalog #
	Keep away from sunlight		Keep dry	EC REP	Authorized Representative

ISO

our company is certified by ISO quality system