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CE

"See Now" Dengue IgG/IgM antibody Cassette Test

Serum/ Plasma/Whole Blood

For in vitro Diagnosis Use

Product Code: SN 8.2

INTENDED USE

The *"See Now"* Dengue IgG/IgM 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.

INTRODUCTION

Dengue fever is one of the most important mosquito-borne diseases in the world in the terms of morbidity, mortality. Dengue fever virus (serotypes 1 – 4) belongs to the group flavivirus, and is transmitted in nature by day-biting Aceder mosquitos. The most important mosquito vector is highly domesticated and urban species, *Aedes aegypti*. Primary Dengue infection, also known as Dengue Fever, is the most common type of dengue illness. It is associated with mild to high ffever, headache, muscle pain and skin rash. Secondary infection is known as Dengue Hemorrhagic Fever (DHF) or Dengue Shock Syndrome, and often results in high fever and in many cases, with hemorrhagic events and circulatory failure. The fatality rate in patients with Dengue Shock Syndrome can be as high as 44%. Dengue presents typically as a fever of sudden onset with headache, retrobullar pain, pain in the back and limbs (break-bone fever), lymphaderopathy and maculopaplar rash. Patients diagnosed with dengue in endemic areas generally have secondary infection, whereas patients in non-endemic areas are usually diagnosed with primary infection. Specific antibody responses to Dengue virus enable serodiagnosis and differentiation between primary and secondary dengue infections. Rapid Dengue Test is *a* new generation rapid Immuno-chromatographic test using recombinant dengue viral antigens of all four serotypes to detect specific antibody response.

PRINCIPLE

Rapid Dengue Test utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. As the test sample flows through the membrane within the test device, the colored–Dengue specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of Dengue virus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-Dengue virus antibodies in the specimen

REAGENTS AND MATERIALS SUPPLIED

- Individually wrapped test devices; sample buffer.
- One Instruction Sheet.

MATERIALS REQUIRED BUT NOT SUPPLIED

- A clean container for the specimen collection;
- 1-20 µL plastic pipette
- Timer

STORAGE AND STABILITY

The test kit is to be stored at temperature (15-25℃) in the sealed pouch for the duration of the shelf-life.

PRECAUTIONS

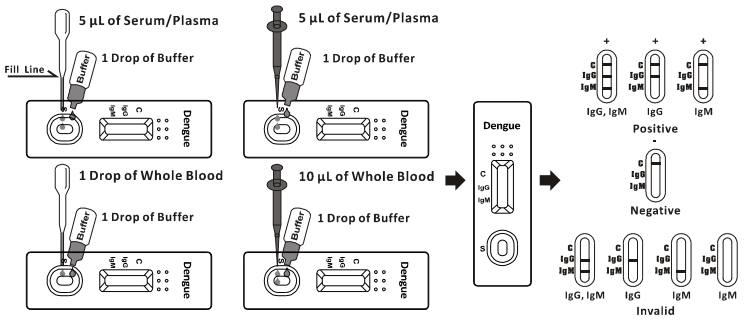
- *FOR IN-VITRO DIAGNOSTIC USE.*
- For professional use only.
- The test device should remain in the sealed pouch until use. Do not use it after the expiration date.
- All patient samples should be treated as if capable of transmitting disease.

SPECIMEN COLLECTION AND STORAGE

- The *"See Now"* Dengue testis performed on human serum, plasma, whole blood.
- Remove the serum or plasma from the clot or red cells, respectively, as soon as possible to avoid hemolysis. Lipemic ，icteric, or hemolyzed specimens may give inconsistent test result. Specimens, of containing precipitate, should be clarified prior to testing.
- If specimens are not to be tested they should be refrigerated immediately at 4 to 8℃ ，if storage periods greater than 5 days are anticipated, the specimen should be frozen.
- Do not use heat-inactive specimens.

TEST PROCEDURE

- Review "Specimen Collection" instructions. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
- Draw **10µL** of sample (serum/plasma/whole blood) into the pipette (micro-pipette or disposable pipette), and dispense it into the **sample well** area marked on the cassette.
- Add one drop **40-50 µL** of sample buffer to the sample well marked S**.**
- Wait 10 minutes and read results. Do not read results after 20 minutes.



INTERPRETATION OF RESULTS

IgG and IgM POSITIVE:* **Three lines appear**. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary Dengue infection.

IgG POSITIVE:* **Two lines appear**.One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for Dengue virus specific-IgG and is probably indicative of secondary Dengue infection.

IgM POSITIVE:* **Two lines appear**.One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for Dengue virus specific-IgM antibodies and is indicative of primary Dengue infection.

*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

NEGATIVE: **One colored line should be in the control line region (C)**. No line appears in IgG and IgM test line region(s).

INVALID: **Control line fails to appear**. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region (C) of the membrane indicates proper performance of the test and the device.

PERFORMANCE CHARACETERISTICS

	Reference ELISA Dengue Kit			Total
	Positive		Negative	
Rapid Dengue test	Positive	300	0	300
	Negative	0	500	500
Total		300	500	800

Sensitivity (%) = (Positive / Total Confirmed Positive) x 100% = (300/300) x 100% = **100%**

Specificity (%) = (Negative / Total Confirmed Negative) x 100% = (500/500) x 100%= **100%**

Accuracy (%) = (Total Confirmed Positive + Total Confirmed Negative) / (Positive + Negative) x 100% = (300+500)/ (300+500) x 100% = **100%**

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