First Romanian rapid tests manufacturer !

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CE

"See Now" Dengue IgG/IgM antibody + NS1 antigen Cassette Test

Serum/ Plasma/Whole Blood

For in vitro Diagnosis Use

Product Code: SN 8.4

INTENDED USE

The *"See Now"* Dengue Combo test is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies and NS1 antigen 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

See Now 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.

See Now Dengue NS1 antigen test it is a solid phase immunochromatographic assay.

As the test sample flows through the membrane within the test device, and mobilize the gold anti-NS1 conjugate that it is coted on the conjugate pad. If NS1 it is present then the result it is the formation of colored band it the test (T) line region.

REAGENTS AND MATERIALS SUPPLIED

- Individually wrapped test devices; sample buffer, transfer pipette for Dengue NS1 and capillary pipette for Dengue IgG/IgM
- One Instruction Sheet.

MATERIALS REQUIRED BUT NOT SUPPLIED

- A clean container for the specimen collection;
- 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 Combo test is 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.

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.

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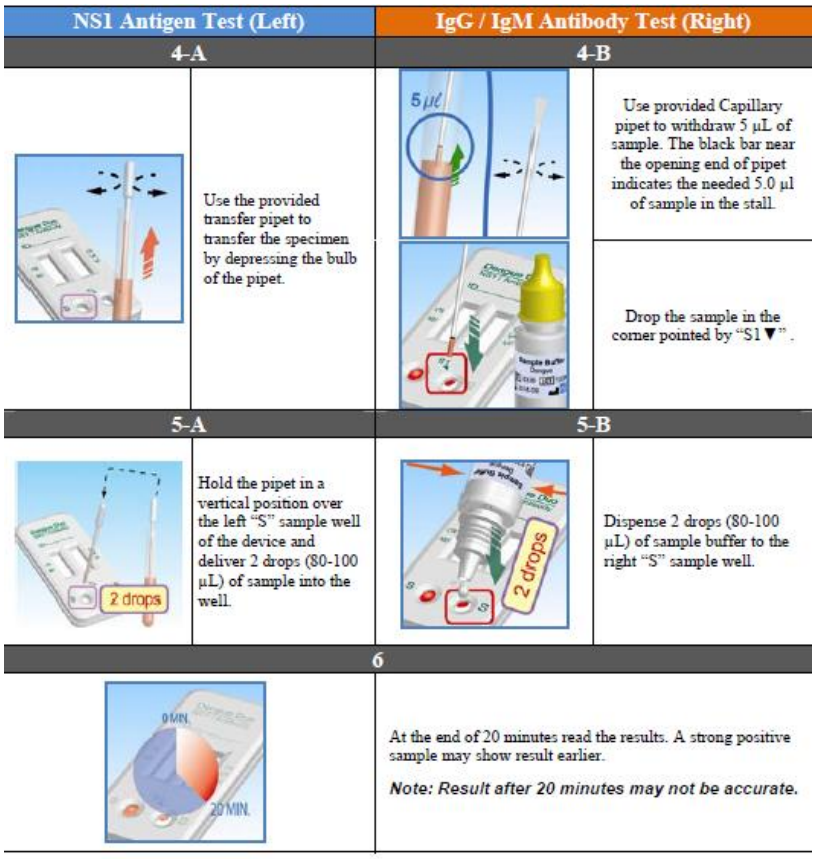
TEST PROCEDURE



INTERPRETATION OF RESULTS

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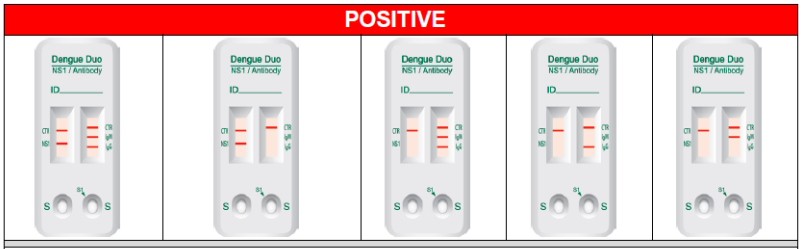

Visible Control Line				
NS1 Positive	NS1 Positive	NS1 Negative	NS1 Negative	NS1 Negative
IgM Positive	IgM Negative	IgM Positive	IgM Negative	IgM Positive
IgG Positive	IgG Negative	IgG Positive	IgG Positive	IgG Negative

PERFORMANCE CHARACETERISTICS

1. Accuracy

A panel of 51 suspected patient sera was tested with a reference rapid Dengue Test, for both types, antibody and antigen.

Number of sample	NS1	IgM	IgG	Percentage
17	Positive	Negative	Negative	33.3%
14	Positive	Positive	Negative	25.9%
5	Positive	Negative	Positive	9.8%
4	Positive	Positive	Positive	7.8%
1	Negative	Positive	Negative	2.0%
4	Negative	Negative	Positive	7.8%
1	Negative	Positive	Positive	2.0%
5	Negative	Negative	Negaive	9.8%

33,3% of samples showed positive NS1 results before antibodies were able to detect. It proves that NS1 test can help to detect dengue infection during the window periodof the infection, when antibodies have not risen to the detectable level. With NS1 alone the positive rate it is 78,4%. With antibodies tests the total positive rate it is increased at 90,2%.. It proves that the combination of both dengue NS1 and antibody tests can enhance the sensitivity of early dengue infection.

2.Specificity.

A total of 80 samples from healthy blood donors were tested. The specificity with the tested samples was 100%.

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