First Romanian rapid tests manufacturer !

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CE

"See Now" Dengue NS1 antigen Cassette Test

Serum/ Plasma/Whole Blood

For in vitro Diagnosis Use

Product Code: SN 8.3

INTENDED USE

The *"See Now"* Dengue test is a rapid immunochromatographic assay for the detection of 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 fever, 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

The Dengue NS1 Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-dengue NS1 antigen conjugated with colloid gold (Dengue Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with rabbit anti-dengue NS1 antigen, and the C band is pre-coated with goat anti-mouse IgG antibody. The antibodies to dengue antigen recognize the antigens from all the four serotypes of the dengue virus.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. Dengue NS1 Ag if present in the specimen will bind to the Dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated rabbit anti-NS1 antibody, forming a burgundy colored T band, indicating a Dengue Ag positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS SUPPLIED

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

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 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

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

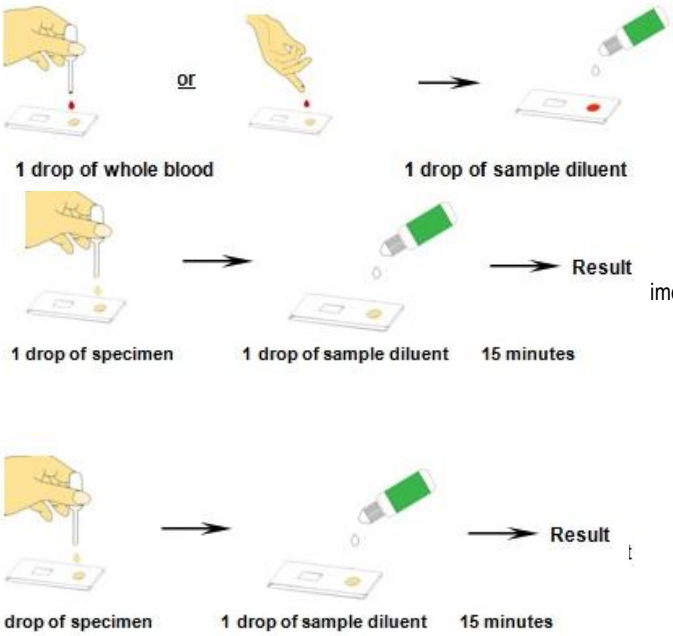
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

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

Step 4: **For whole blood test**

- Apply 1 drop of whole blood (about 40-50 μL) into the sample well.

1 drop of whole blood　　1 drop of sample diluent



Step 5: Set up timer.

Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 25 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

1. **NEGATIVE RESULT**: If only the C band is developed, the test indicates that the level of dengue Ag in the specimen is undetectable. The result is negative or non-reactive.

2. **POSITIVE RESULT**: If both C and T bands are developed, the test indicates that the specimen contains dengue Ag. The result is positive or reactive.

Samples with positive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

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

Clinical Performance

A total of 114 patient samples from susceptible subjects were tested by the Dengue NS1 Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Dengue NS1 Rapid Test		
Dengue NS1 EIA Test	**Positive**	**Negative**	**Total**
Positive	66	3	69
Negative	2	43	45
Total	68	46	114

R **Relative Sensitivity: 95,6%; Relative Specificity: 95,5% Accuracy: 95,6 %**

LIMITATION OF TEST

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of dengue Ag in serum ,plasma or whole blood. from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Dengue NS1 Rapid Test is limited to the qualitative detection of dengue Ag in human serum ,plasma or whole blood.. The intensity of the test band does not linear correlate with dengue Ag titer of the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with dengue viruses.
4. A negative result can occur if the quantity of dengue Ag present in the specimen is below the detection limits of the assay, or the dengue Ag that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptom persists, while the result from Dengue NS1 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device such as PCR, ELISA.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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