Fastep®

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Dengue NS1 Ag Test Device

(Whole Blood/Serum/Plasma)

INTENDED USE

The Dengue NS1 Ag Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of dengue virus NS1 antigen in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary Dengue infections.

INTRODUCTION

Dengue viruses, transmitted by the mosquito, Aedes aegypti and Aedes albopictus mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes (dengue virus 1, 2, 3 and 4). In children, infection is often subclinical or causes a self-limited febrile disease. However, if the patient is infected second times with a different serotype, a more severe disease, dengue hemorrhagic fever or dengue shock syndrome, is more likely to occur. Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality it causes. NS1 is a highly-conserved glycoprotein that is present at high concentrations in the sera of dengue-infected patients during the early clinical phase of the disease. NS1 antigen is found from the first day and up to 9 days after onset of fever in sample of primary or secondary dengue infected patients.

The Dengue NS1 Ag Test Device (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of anti-dengue NS1 Ag coated colored particles for the detection of Dengue NS1 antigen in human whole blood, serum, or plasma.

PRINCIPLE

The Dengue NS1 Ag Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue NS1 antigen in whole blood, serum, or plasma. During testing, the specimen reacts with anti-dengue NS1 -coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-dengue NS1 Ag in test line region. If the specimen contains Dengue virus NS1, a colored line will appear in test line region. If the specimen does not contain Dengue virus NS1, no colored line will appear in the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Buffer
- Package insert

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Micropipette
- Timer
- Lancets

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30 ℃ until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Dengue NS1 Ag Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 ℃ for up to 3 days. For long term storage, specimens should be kept below -20 ℃. Whole blood collected by venipuncture should be stored at 2-8 ℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30 ℃) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Transfer 3 drops of serum/plasma (approximately 75 µL) to the specimen well (S) of the device with the provided disposable pipette, and start the timer.
   Allow 2 drops of whole blood (approximately 50 µL) to fall into the center of the specimen well(s) of the test device then add 1 drop of buffer, and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. A negative result can occur if the quantity of Dengue virus NS1 antigen present in the specimen is below the detection limits of the assay, or the antigens that are detected are not present during the stage of disease in which a sample is collected.
2. A negative test result cannot exclude a recent infection.
3. The presence of detectable Dengue virus NS1 Ag may mean positive for early Dengue Infection. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Dengue NS1 Ag Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of Dengue NS1 antigen in whole blood, serum or plasma specimens only.
2. The Dengue NS1 Ag Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Dengue NS1 antigen in the specimen and should not be used as the sole criteria for the diagnosis of Dengue.

EXPECTED VALUES

The NS1 is expected to be detected 1 day after the onset of fever and persist up to 9days in both primary and secondary dengue infection. But if anti-NS1 antibodies produced, the detection of NS1 is inhibited.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Dengue NS1 Ag Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by culture.

Dengue NS1 Ag Test Device vs. Culture

Relative Sensitivity:92.8%

Relative Specificity:98.4%

Overall Agreement:96.3%

		Culture +	Culture -	Total
Dengue NS1 Ag	+	104	3	107
	-	8	186	194
		112	189	301

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of negative and positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the negative and positive specimens.Three different lots of The Dengue NS1 Ag Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

LITERATURE REFERENCES

1. Pryor MJ. Wright PJ. The effects of site-directed mutagenesis on the dimerization and secretion of the NS1 protein specified by dengue virus. Virology 1993; 194:768-80
2. SHU, P.,HUANG, J. Current advances in dengue diagnosis. Clin. Diagn. Lab. Immunol. 2004 Jul; 11(4):642-50.
3. Alcon S., Talamin A., Debryyne M., Falconar A., Deubel V., Falmand M. 2002. Enzyme-linked immunosorbent assay specific to dengue virus type 1 non structural protein NS1 reveals circulation of the antigen in the blood during acute phase of disease in patients experiencing primary or secondary infections. J. Clin. Microbiol. 40:376-381.
4. Jan Groen et al. Evaluation of six immunoassays for detection of dengue-virus specific immunoglobulin M and G Antibodies. Clin.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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Effective date: 2013-08-15