Version-1.0

RAPITEST™

Dengue NS1

INTRODUCTION

Dengue NS1 is a rapid immunochromatographic test for the qualitative detection of dengue virus NS1 antigen in human serum/plasma for early diagnosis of acute infection. Dengue virus belongs to Flaviviridae family, common in tropical and sub-tropical regions, which is found in four distinct serotypes (1, 2, 3 and 4). Dengue fever is transmitted by mosquitoes, of the species Aedes aegypti and Aedes albopictus. Primary dengue infection results mostly in a self-limiting mild to high fever, while secondary infection is more common and potentially fatal resulting in severe conditions like Dengue Hemorrhagic Fever (DHF) and Dengue Shock Syndrome (DSS). The following table gives the duration for detectable rise in NS1 antigen in blood in cases of primary and secondary infections:

Ag	Primary Infection	Secondary Infection
NS1	1-9 days upto 15 days	1-9 days

NS1 antigen appears from day 1 in blood and helps in early diagnosis which reduces risks of complications.

PRINCIPLE

The Dengue NS1 test device consists of a membrane coated with monoclonal anti-dengue NS1 at the test region "T" and goat anti-rabbit IgG at the control region "C". As the sample moves through the membrane assembly, the NS1 antigen in the sample reacts and complexes with the monoclonal anti-dengue NS1-gold conjugate and moves further to get immobilized at the test region "T" and forms a pink/purple colored band. This indicates a positive result. The absence of this band shows a negative result.

The unreacted complexes move even further and are immobilized at the control region "C" and form a pink/purple colored band. Absence of control line "C" indicates an INVALID TEST.

KIT CONTENTS

Dengue NS1 test is supplied with:

1. Dengue NS1 device test cassettes – pouched with a sample dropper and a silica gel.
2. Instructions manual.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 2°C and 30°C in the sealed pouch to the date of expiration. The test should be kept away from direct sunlight, moisture and heat.

PRECAUTION

1. For in vitro diagnostic use only. For Professional use.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not intermix reagents of different lots.
5. Follow instructions carefully to get accurate results.
6. Not for medicinal use.
7. Follow standard guidelines for personal safety, handling and disposal of potentially infectious materials.
8. Testing of pooled samples is not recommended.

SPECIMEN COLLECTION & PREPARATION

The Dengue NS1 test can be run on serum/plasma samples. The test works best on fresh samples. For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. For plasma samples, collect blood into a container with anticoagulant and separate the plasma by centrifugation. If the serum/plasma specimen cannot be tested on the day of collection, store the specimen in a refrigerator (2 to 4°C) for upto 3 days and at -20°C for longer storage. Bring the samples to room temperature before testing. Do not freeze and thaw the samples repeatedly.

TEST PROCEDURE

When you are ready to begin testing, open the sealed pouch by tearing diagonally along the notch. Remove the test device from the pouch and use it as soon as possible.

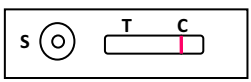
1. Add 2 drops of serum/plasma sample into the sample well "S" using the sample dropper.
2. Read test results within 5 - 20 minutes.

INTERPRETATION OF RESULTS:

DENGUE NS1:

NEGATIVE:

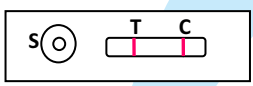
Only one colored band appears in the control (C) region. No apparent band in the test (T) region.



NEGATIVE

POSITIVE:

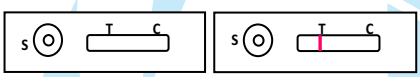
In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region.



POSITIVE

INVALID:

A total absence of color in region "C" indicates procedure error and / or that the test reagent has deteriorated. Repeat test with a new test. If problem persists discontinue using the kit immediately.



INVALID

PERFORMANCE AND CHARACTERISTICS

In an in-house trial, two hundred and fifty six samples were tested in parallel with a licensed commercially available device and Dengue NS1. The results obtained are as follows:

Sample	No. of Samples	Licensed Kit	Dengue NS1
Negative	200	200	194
NS1 Positive	56	56	55

Based on this evaluation, the sensitivity of Dengue NS1 is 98.24% and specificity 97.08%.

LIMITATIONS:

1. As with all diagnostic tests, all results must be compared with other clinical information available to the physician. A definite clinical interpretation should be made only by the physician after all clinical and laboratory findings have been evaluated.
2. The test should be used for the detection of Dengue NS1 antigen in human serum/plasma samples.
3. If the test result is negative yet symptoms persist, confirmation using other clinical methods is recommended. A negative result at any time does not preclude the possibility of dengue infection.
4. Sample found to be positive by the above screening test must be confirmed by standard supplemental assay.
5. 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 are not present during the stage of disease in which the sample was collected.
6. Serological cross-reactivity across the Flavivirus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.

BIBLIOGRAPHY

1. Clarke, D. H. and Casals, J. Techniques for Hemagglutination and hemagglutination inhibition with arthropodborne viruses. *Am. J. Trop. Med. Hyg. 1958,* 7, 561-573.
2. Alcon S., Talamin A., Debryyne M., Falconar A., Deubel V., Falmand M., Enzyme-linked immunosorbent assay specific to dengue virus type 1 non structural protein NS1 reveals circulation of theantigen in the blood during acute phase of disease in patients experiencing primary or secondary infections. *J. Clin. Microbiol.* 2002, 40, 376-381
3. Songee L. Ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue viurs. *Clin. Diagn. Lab. Immunol*. 1999, 6, 555-667.
4. Dengue haemorrhagic fever: Diagnosis, treatment, prevention and contril. WHO 2nd Edition,1997
5. Sutherst, R. W. (1993). Arthropods as disease Vectors in a changing environment. In environmental change and human health. CIBA foundation symposia 1993, 175, 124-145.
6. Shu, P., Huang, J. Current advances in dengue diagnosis. *Clin. Diagn. Lab. Immunol.* 2004,11, 642-650.

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