Dengue NS1 Rapid Test (Serum/Plasma/Whole Blood)

INTENDED USE

PRECISION Dengue NS1 Rapid Test is an immunochromatographic strip assay for the qualitative presumptive detection of non-structural protein 1 (NS1) in human Serum/Plasma/WB.

SUMMARY AND EXPLANATION OF THE TEST

Dengue virus is a flavivirus found largely in areas of the tropic and sub-tropics. There are four distinct but antigenically related serotypes of dengue viruses, and transmission is by mosquito, principally Aedes aegypti and Aedes albopictus. The mosquito-borne dengue viruses (serotype 1-4) cause dengue fever, a severe flu-like illness. The disease is prevalent in third world tropical regions and spreading to sub-tropical developed countries - including the United States. WHO estimates that 50-80 million cases of dengue fever occur worldwide each year, including a potentially deadly form of the disease called dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS). Primary infection with dengue virus results in a self-limiting disease characterized by mild to high fever lasting 3 to 7 days, severe headache with pain behind the eyes, muscle and joint pain, rash and vomiting. Secondary infection is the more common form of the disease in many parts of Southeast Asia and South America. IgM antibodies are not detectable until 5- 10 days in case of primary dengue infection and until 4-5 days in secondary infection after the onset of illness. IgG appear after 14 days and persist for life in case of primary infection and rise within 1-2 days after the onset of symptoms in secondary infection. This form of the disease is more serious and can result in DHF and DSS. The major clinical symptoms can include high fever, hemorrhagic events, and circulatory failure, and the fatality rate can be as high as 40%. Early diagnosis of DSS is particularly important, as patients may die within 12 to 24 hours if appropriate treatment is not administered. Primary dengue virus infection is characterized by elevations in specific NS1 antigen levels 0 to 9 days after the onset of symptoms; this generally persists upto 15 days. Earlier diagnosis of Dengue reduces risk of complication such as DHF or DSS, especially in countries where dengue is endemic.

TEST PRINCIPLE

Dengue NS1 Rapid Test is a qualitative, membrane based immunoassay for the detection of NS1 antigen in human Serum/Plasma. The rapid test membrane is pre-coated with a NS1 specific antibody on the test line region and utilizes a separate control to assure assay flow and performance. During testing, the test sample added directly to the sample region, Serum/Plasma interacts with NS1-specific monoclonal antibodies conjugated to gold nanoparticles. The solution migrates upward on the membrane (via capillary action) to react with the anti-NS1 antibody on the membrane. If NS1 antigen is present, a red line will appear at the test line. The red line at the control region should always appear if the assay is performed correctly. The presence of this red line verifies that proper flow has occurred and catastrophic failure of the conjugate has not occurred.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   - One cassette device
   - One desiccant
2. Plastic droppers
3. Buffer Bottle
4. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C - 30°C) before use.
5. Do not use components from any other type of test kit as a substitute for the components in this kit.
6. Do not use heamolized blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The test results should be read within 20 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the results after 20 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C - 30°C. If stored at 2°C - 8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

Step 1: Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by veinpuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into new pre-labeled tube.

Serum/Whole Blood

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by veinpuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the Serum by centrifugation.
Step 4: Carefully withdraw the Serum/Plasma/WB into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 4°C-8°C if not tested immediately for up to 5 days. Specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE

Dengue Ns1 :

1. Allow test device, specimen, to reach room temperature (15°C - 30°C) prior to testing.
2. Place the test device on a clean and level surface.
3. For Serum or Plasma sample : Hold the dropper vertically and transfer 1 drop of sample (25 µL) to the sample well of the test device, then add 2 drop of assay buffer (80µL) and start the timer.
4. **For Whole blood Sample** : Hold the dropper vertically and transfer 1 drops of sample (25µL) to the sample well of the test device, then add 2 drops of assay buffer (80µL) and start the timer.
5. Read the result in 20 minutes. Read results as shown under interpretation of Results

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of test kits is used.
   d. The temperature used during storage of the kits fall outside of 2°C - 30 C.
   e. The temperature of the test area falls outside of 15°C - 30 C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

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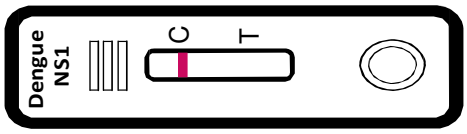
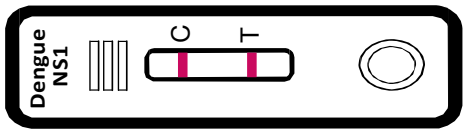
INTERPRETATION OF ASSAY RESULT

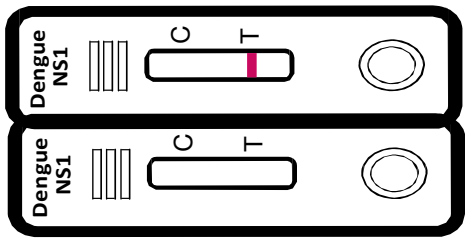
1. **NEGATIVE RESULT**: If only the C line is present, the absence of any burgundy color in test region T indicates that no NS1 antigen is detected. The result is nonreactive.



2. **POSITIVE RESULT**:
   2.1 In addition to the presence of the C line, if the T line is developed, the test indicates the presence of NS1 antigen of Dengue virus. The result is reactive.
   Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.



3. INVALID: If no C line is developed, the assay is invalid regardless of any burgundy color in the test line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

PRECISION Dengue NS1 Test kit has been evaluated in-house with the known panel of fresh as well as frozen Dengue NS1 antigen positive and Negative samples. The performance of the test was evaluated and compared with ELISA test. The samples included cross-reacting samples; Epstein-Barr virus, Malaria, Rheumatoid factor, Leptospirosis, Japanese encephalitis, yellow fever and West Nile viruses. Following is the in-house evaluation.

	***PRECISION* Dengue NS1 Rapid Test**		
	Positive	**Negative**	**Total**
Dengue NS1 Positive	35	0	35
Dengue NS1 Negative	0	50	50

Sensitivity: 100% , Specificity: 99.90%

2**. Cross Reactivity**

No cross reactivity with Epstein-Barr virus, Malaria, Rheumatoid factor, Leptospirosis, Japanese encephalitis, yellow fever and West Nile viruses.

LIMITATIONS OF TEST

1. The test is for in vitro diagnostic use only.
2. This test detects the presence of Dengue NS1 antigen of dengue virus in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
3. Serological cross-reactivity across the Flavivirus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.
4. As with all diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of Dengue virus.
5. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and serological test like haemagglutination inhibition test, more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

WASTE MANAGEMENT & DISPOSABLE

The contents of RDTs can be divided into :
Infectious waste:
• sharps (lancets, needles, scalpel blades)
• blood collection devices (tubes, straws, and loops); gloves; swabs; and cotton
• used cassettes.
Non-infectious waste (Recyclable):
• packaging materials, desiccant, buffer, and unused or unusable RDTs.

*****You must collect and dispose each type of waste in separate containers as per your waste management policies.***

REFERENCES

1. Halstead, S.B. (1981), The pathogenesis of Dengue. Amer. J. Epidemiol 114: 632.

2. Henchal, E. A. and Putnuk, R. J., The Dengue viruses, Clin. Microl. Rev., Oct. 376 – 396, 1990.

3. Guzman M.G. & Kourig Clinical & Diagnostic Laboratory Immunology (1996) Vol. 3, No. 6, 621-627. 2. Young P.R., Hilditch P.A., etal J. Clinical Microbiology (2000) Vol. 38, No.3, 1053-1057.

For in vitro diagnostic use only, not for medical use

Manufacturing For:
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