Dengue Antigen - NS1 CARD

IMMUNOPAK

(Serum/Plasma)

Last update 10-2020

Ref. RDT-DEG.101M, 10 Test
RDT-DEG.101MU, 25 Test

INTENDED USE

Dengue NS1 Antigen test is rapid and qualitative test for the detection of dengue virus NS1 antigen in human serum / plasma.

INTRODUCTION

Dengue viruses transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes, are widely distributed throughout the tropical and sub topical areas of the world. There are four known distinct serotypes (dengue virus 1, 2, 3 and 4). Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality associated with it. 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. Usually IgM does not become detectable until 5 to 10 days after the onset of illness in cases of primary dengue infection and until 4 to 5 days after onset of illness in secondary infections. In primary infections, IgG appears on the 14th day and persist for life. Secondary infections shows that IgG rise within 1~2 days after the onset of symptoms and induces IgM response after 20 days of infection.

PRINCIPLE

Dengue NS1 antigen test utilizes the human serum / plasma followed by solid-phase immuno-chromatographic technology for the qualitative detection of dengue virus NS1 antigen. The membrane strip of the device is pre-coated with anti-dengue NS1 monoclonal antibody on the test region (T), and goat anti-mouse IgG is pre-coated on the control region (C). During testing, if the sample containing dengue NS1 Ag, the complex of the antibody-dengueNS1 Ag-gold conjugate moves laterally on the membrane by capillary action. In this case, the pink-purple line will appear on the membrane in test line (T). To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	10 Tests	25 Tests
Dengue NS1 Test Cards	10 Cards	25 Cards

PRECAUTION

1. For in vitro diagnostic use only. Do not re-use the test device.
2. The instruction must be followed exactly to get accurate results.
3. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
4. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction waste, in a biohazard container.
7. Do not mix and interchange different specimen.
8. The presence of humidity may decrease the stability of the reagents. Thus, carry out the test immediately after removing the device from the oil pouch.
9. Do not use it beyond the expiration date.

STORAGE AND STABILITY

Dengue NS1 test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on Pouch as well as carton label. The test kit should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND STORAGE

1. Specimen collection

- Serum
  Collect the whole blood into the collection tube (Not containing Anticoagulants such as heparin, EDTA, and sodium citrate) by Venipuncture, leave to settle for 30 minutes for blood coagulation and centrifuge blood to get serum specimen or supernatant.
- Plasma
  Collect the whole blood into the collection tube (Containing Anticoagulants such as heparin, EDTA, and sodium citrate) by Venipuncture and then centrifuge blood to get plasma specimens.

2. Specimen storage

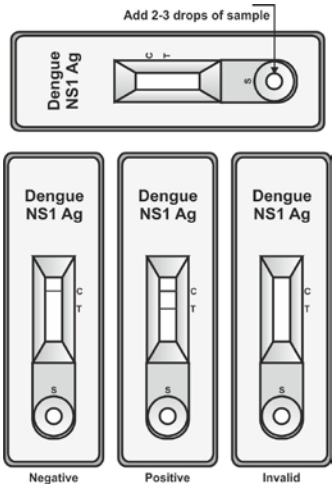
- All specimens should be tested as soon as they are prepared. If specimens are not immediately tested. They should be stored at 2°C~8°C for 3 days, -20°C for longer period than 3 days.

TEST PROCEDURE

1. Place all specimens, test device and solution. Allow them to room temperature prior to testing (15~30 min.)
2. Please perform the test immediately after removing the device from the foil pouch.
3. With a disposable dropper, add 2 to 3 drops (approx. 50 to 75 µl) of specimen into the sample well (S) in the test device.
4. Interpret the test results between 15~20 minutes. Do not read the results after 20 minutes.

INTERPRETATION OF RESULTS

- NEGATIVE
  The presence of only one pink-purple line (control line) in control region indicates a negative result.
- POSITIVE
  Two lines ("T" line and "C" line) are appeared in the test line and control line.
- INVALID
  If no line or only T line is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: Not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen should be retesting using a new test cassette.



LIMITATIONS

Dengue NS1 antigen test is designed for primary screening test of dengue virus NS1 antigen. Although this can provide fast and easy way to get a result, the testing do not completely exclude the possibility of false positive or negative result caused by various factor. So, refer to the result of the kit, please make a final decision with clinical manifestation, other test results and doctor's view collectively.

REFERENCES

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