

INTENDED USE

Dengue NS1 Antigen test is rapid and qualitative test for the detection of dengue virus NS1 antigen in human serum / plasma. This kit is for professional use and only for the initial screening test and reactive samples should be confirmed by a supplemental assay such as nucleic acid test and other immunological assays.

EXPLANATION OF THE TEST

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 kit contains pre-coated with anti-dengue NS1 monoclonal antibody on the test band region(T), and goat anti-mouse IgG is pre-coated on the control band 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 colored band will appear on the membrane in test line (T). Control line (C) should always appear if the test procedure is performed properly.

MATERIALS PROVIDED

Dengue NS1 antigen test contains following items to perform the assay

1. Test device in aluminum pouch with a desiccant
2. Disposable dropper
3. Insert

PRECAUTIONS

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. Do not eat or smoke while handling specimens.
5. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
6. Avoid splashing or aerosol formation
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Decontaminate and dispose of all specimens, reaction waste, in a biohazard container.
9. Do not mix and interchange different specimen.
10. The presence of humidity may decrease the stability of the reagents. Thus, carry out the test immediately after removing the device from the foil pouch.
11. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

1. Specimen collection

- 1) serum/Plasma

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.

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 2-8 °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, load 3 drops (100 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.

INTERPRETAION OF THE TEST

1. A color band will appear in the upper section ("C" Zone) of the window to show that the test is working properly. This band is the control band.
2. The down section ("T" Zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is the test band.

A. NEGATIVE RESULTS:

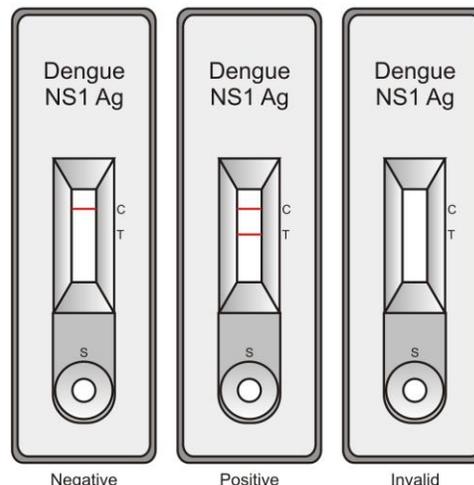
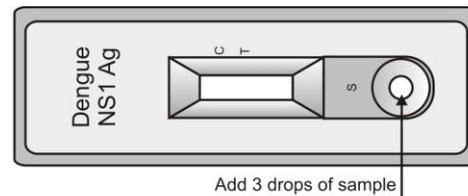
The presence of only one purple band (control band) within the window indicates a negative result.

B. POSITIVE RESULTS:

Two bands ("T" band and "C" band) are appeared in the test line and control line; it shall be suggested to do sample dilution and re-testing process. The re-test result is true. If the re-test still showed two bands, the result is positive for dengue NS1 Ag.

C. INVALID RESULTS:

If no band 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 kit.



Negative

Positive

Invalid

STORAGE & EXPIRATION

- 1) Dengue NS1 Antigen test should be stored between 4~30 °C
- 2) Expiration date of this kit is 24 months after its manufacture date.

LIMITATIONS OF THE TEST

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 and 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:

1. Sabin, AB and Schlesinger RW. Production of immunity to Dengue with virus modified by propagation in mice: Science (1945), 101:640.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
3. Innis, BL, Nisalak, A., et.al. An enzyme-linked immunosorbent assay to characterize dengue infections where dengueJapanese
4. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
5. Siti-Strong. Diagnosis, prevention, and treatment of tropical disease, 7th ed., Philadelphia, the Ablakiston Company.

