ACCUCARE

DENGUE NS1 Ag DETECTION TEST

For rapid qualitative detection of NS1 Antigen to dengue virus in human serum, plasma or whole blood.
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

REF	Cont.
DENC 10	10 Test
DENC 25	25 Test

CLINICAL SIGNIFICANCE

Dengue virus, a virus belonging to the Flavavirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. Transmitted principally by the mosquito types *Aedes aegypti* and *Aedes albopictus*, the virus is found commonly throughout the tropic and subtropic regions of the world. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash. The complications often associated with this infection are dengue hemorrhagic fever or dengue shock syndrome.
Dengue NS1 Antigen Test provides an excellent methodology for specifically detecting Dengue NS1 antigen within up to 1 day of infection.

PRINCIPLE

The Dengue NS1 Antigen Test Device (Serum/ Plasma/Whole Blood) is a qualitative test for the detection of NS1 antigen to dengue virus in human serum or plasma. Only serum, plasma, or whole blood samples may be used with this test. First a specimen is dispensed buffer; the Gold antibody conjugate will bind to Dengue antigen in the specimen sample which in turn will bind with Anti-Dengue NS1 coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind the antibody-antigen complex causing pale or dark pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result.

KIT COMPONENTS

Test Cassette Device and Instructions for Use

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (4-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

1. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

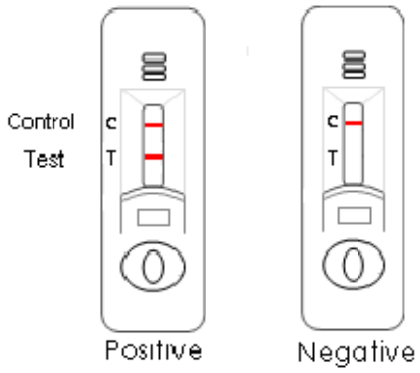
DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Pipette 60-70 µL (3 drops) of serum, plasma or whole blood into the sample well.
3. Wait for the red line(s) to appear. The test result should be read at between 15 and 20 minutes. Results may be read upto 30mins.

Note: Do not interpret the result after 40 minutes.
When using finger prick or EDTA whole blood the appearance of C &T line can take up to 10 minutes to appear and wait till 20 minutes to interpret the results in this case.

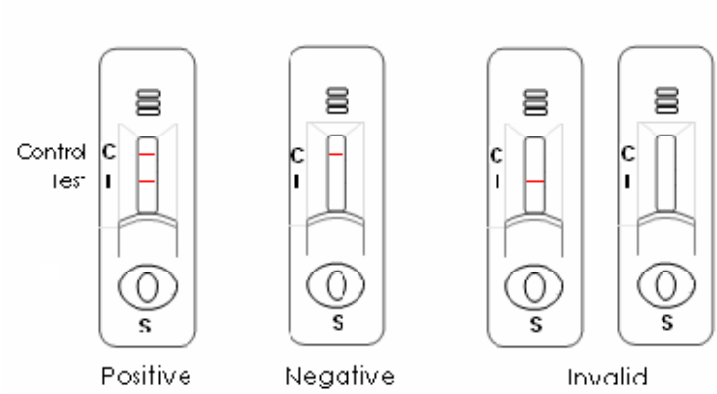
INTERPRETATION OF RESULTS



1) Positive Reaction
The presence of two color bands indicates a positive result for Dengue NS1 antigen.
2) Negative reaction
The presence of only one band in the control region of the result window indicates a negative result.
3) Invalid
The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new strip

NOTE: The intensity of the red color in the test line region will vary depending on the concentration of NS1 antigen present in the specimen. However, neither the quantitative value nor the rate of increase in NS1 antigen can be determined by this qualitative test.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com



A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required. Control standards are not supplied with this kit; however, 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.

The overall sensitivity of Dengue NS1 Antigen Test is 94.5% and specificity is 98.9%. The studies and clinical evaluations were conducted in correlation with PCR and Viral Culture Tests.

BIBLIOGRAPHY

1. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
3. Siti-Strong. Diagnosis, prevention, and treatment of tropical disease, 7th ed., Philadelphia, the Ablakiston Company.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 ▪Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com