DENGUE NS1
Antigen Detection Card Test
Serum/Plasma

INTENDED USE:

Dengue NS1 Antigen Detection Card Test is a rapid chromatographic immunoassay, for the qualitative detection of Dengue NS1 Antigen, in human serum and plasma.

PRINCIPLE OF THE TEST:

Dengue NS1 Antigen device is a chromatographic immunoassay test for the rapid detection of Dengue virus non-structural protein 1 (NS1) antigen, using human serum/plasma. Dengue NS1-specific antibodies complexed with gold conjugate are placed in the conjugate pad and another set of anti-dengue NS1 antibodies are immobilized on the membrane. The NS1 antigen in the sample, reacts with specific antibodies conjugated with gold colloid particles. The antigen-antibody-gold colloid complex flows chromatographically through the nitrocellulose membrane and gets captured and immobilized by the second set of specific antibodies coated on the test region (T), thus forming a visible red band in the test region (T) indicating a positave result. A second red line appears in the control region (C) for all valid test results.

MATERIALS PROVIDED:

Dengue NS1 Antigen kit contains the following items:

1. Dengue NS1 Antigen test device with a desiccant & dropper.
2. Product insert.

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Specimen collection container/tube.
2. Timer.

PRECAUTIONS:

1. For *in-vitro* diagnostic use only IVD .
2. Wear protective gloves while handling the kit components and test specimens.
3. Patient specimens and inactivated positive control may contain infectious agents and should be handled and disposed off, as potential biohazards.
4. Do not use the kit components beyond the expiration date.
5. Dispose off all used materials in an appropriate container. Treat as potential biohazard.

SPECIMEN COLLECTION AND STORAGE:

1 Specimens/samples to be tested should be obtained and handled by standard methods, for their collections.

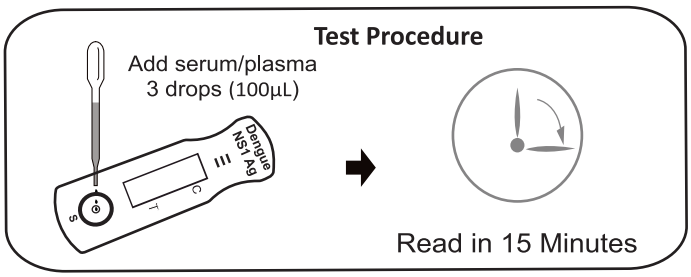
A. Serum: Allow the blood to clot, then centrifuge to separate the serum.

B. Plasma: Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.

2. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8 °C up to 24 hours or at-20°C for longer periods.
3. Anti-coagulants such as heparin, EDTA and citrate do not affect the test results.
4. Use separately disposable capillary tubes or pipette tips for each sample in order to avoid cross-contamination of samples which could cause erroneous results.

TEST PROCEDURE:

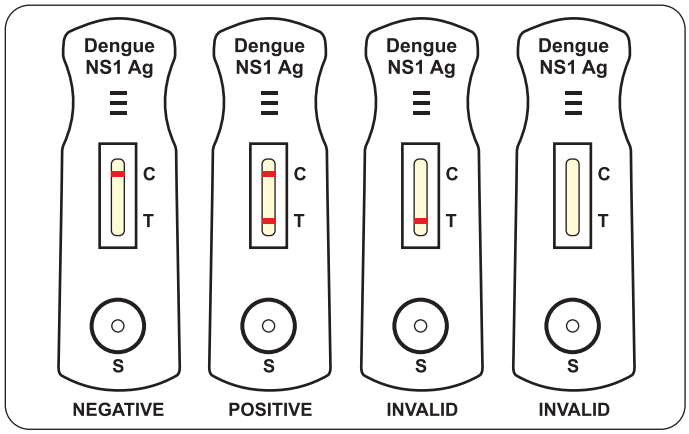
1. Place all specimens and test devices and allow them to equilibrate to room temperature prior to testing (15 - 30 min).
2. Take out the test device from the pouch and then mark the patient's ID on the device. Perform the test immediately after removing the device from the foil pouch.
3. Dispense 3 drops (100$\mu\ell$) of serum/plasma into the sample well (S) in the test device using the dropper or micropipette.
4. After 15 - 20 minutes, interpret the results.
5. Do not read the results after 25 minutes.



INTERPRETATION OF THE RESULTS:

1. NEGATIVE: If only the control line (C) is visible. It indicates that there are no Dengue NS1 antigens detectable in the sample.

2. **POSITIVE:** If along with the control line (C), the band for test line (T) is also visible. It indicates that the sample contains detectable levels of Dengue NS1 antigens.
3. **INVALID:** If the control line (C) does not appear. In this case, the test should be repeated following the exact test procedure.



STORAGE & EXPIRATION:

1. Dengue NS1 Antigen kit should be stored between 4^0 to 30^0C.
2. Expiry date of this kit is as mentioned on the label.

QUALITY CONTROL:

A procedural control is included in the test, a colour line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Controls/standard are not provided with this kit, however, it is recommended that positive and negative controls be tested as a Good Laboratories Practice, to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST:

Dengue NS1 Antigen test is designed for primary screening of dengue virus NS1 antigen. This kit can provide a fast and easy way to results, however, it does not completely exclude the possibility of false positive or false negative results caused by various factors. Results obtained should be correlated clinically.

PERFORMANCE CHARACTERISTICS:

Relative Sensitivity:	98.1%
Relative Specificity:	97.3%

REFERENCES:

1. World Health Organization-Geneva (2000) new perspectives Dengue diagnosis.

Manufactured by:
Vanguard Diagnostics Private Limited
C-123, Phase-I, Okhla Industrial Area
New Delhi-110 020, INDIA.

Tel: 011-4172 7222,
Email:info@vanguarddiagnostics.com
Website : www.vanguarddiagnostics.com

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