SCREEN® Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IDES-402 English

A rapid test for a qualitative detection of NS1 antigen of dengue virus in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of NS1 antigen of Dengue virus in human whole blood, serum, or plasma as an aid in the diagnosis of Dengue infections.

【SUMMARY】

Dengue is a flavivirus, transmitted by *Aedesaegypti* and *Aedesalbopictus* mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world,[1] and causes up to 100 million infections annually.[2] Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash. NS1 is one of 7 Dengue Virus non-structural proteins which are thought to be involved in viral replication. NS1 exists as a monomer in its immature form but is rapidly processed in the endoplasmic reticulum to form a stable dimer. A small amount of NS1 remains associated with intracellular organelles where it is thought to be involved in viral replication. The rest of NS1 is found either associated with the plasma membrane or secreted as a soluble hexadimer. NS1 is essential for viral viability but its precise biological function is unknown. Antibodies raised in response to NS1 in viral infection can cross react with cell surface antigens on epithelial cells and platelets and this has been implicated in the development of Dengue Hemorrhagic fever.
The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of Dengue antibody coated colored particles for the detection of Dengue NS1 antigen in human whole blood, serum, or plasma.

【PRINCIPLE】

The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue NS1 antigen in whole blood, serum, or plasma. During testing, the specimen reacts with Dengue antibody-conjugate in the test cassette. 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 a colored line to form in the test line region of the test membrane. The intensity of the color will vary depending upon the amount of antigen present in the sample. The appearance of colored line in the test region should be considered as positive result.

【REAGENTS】

The test cassette contains anti-Dengue NS1 antibody conjugated gold particles and anti-Dengue NS1 antibody coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use beyond the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test cassette by using **a capillary tube**:
  - Touch the end of the capillary tube to the blood until filled to approximately 75μL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.
- EDTA K2, Heparin sodium, Sodium citrate and Potassium oxalate can be used as the anticoagulant for collecting the specimen.

【MATERIALS 】

Materials provided

- Test cassettes
- Buffer
- Droppers
- Package insert

Materials required but not provided

- Specimen collection containers
- Capillary tubes
- Lancets (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma specimen**:

- Hold the dropper vertically and transfer **3 drops of serum or plasma** (approximately 75μL) to the specimen well, and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimen:

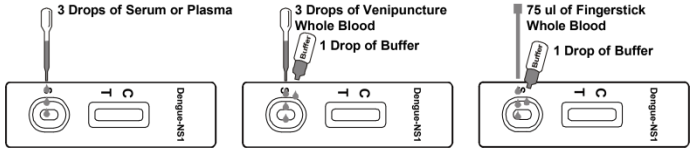
- Hold the dropper vertically and transfer **3 drops of whole blood** (approximately 75μL) to the specimen well, then add **1 drop of buffer** (approximately 40μL), and start the timer. See illustration below.

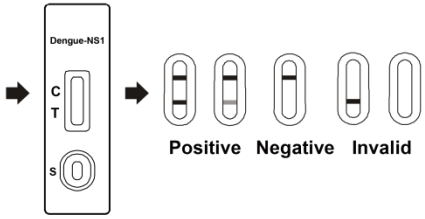
For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately **75μL of fingerstick whole blood** specimen to the specimen well of test cassette, then add **1 drop of buffer** (approximately 40μL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. Read result at 10 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 30 days after opening the vial.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: * **Two distinct colored lines appear.** One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Dengue NS1 antigen present in the specimen. Therefore, any shade of color in the test region should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
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.

【LIMITATIONS】

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of dengue Ag in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is limited to the qualitative detection of dengue Ag in human whole blood, serum or plasma. The intensity of the test band does not linear correlate with dengue Ag titer of the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with dengue viruses.
4. A negative result can occur if the quantity of dengue Ag present in the specimen is below the detection limits of the assay, or the dengue Ag that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptom persists, while the result from Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device such as PCR, ELISA.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
8. The hematocrit of the whole blood should be between 25% and 65%.

【EXPECTED VALUES】

The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Dengue Ag ELISA test. The correlation between these two systems is 96.0%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) has passed a seroconversion panel and compared with a leading commercial Dengue Ag ELISA test using clinical specimens.
The results show that the relative sensitivity of the Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is 95.8%, and the relative specificity is 96.1%.

Method		Dengue Ag ELISA Test		Total Results
Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	137	8	145
	Negative	6	200	206
Total Results		143	208	351

Relative sensitivity: 137/143*100%=95.8% (95%CI*: 91.1%~98.4%);
Relative specificity: 200/208*100%=96.1% (95%CI*: 92.6%~98.4%);
Accuracy: (137+200)/(137+6+8+200)*100%=96.0%(95%CI*: 93.4%~97.8%)
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three different lots of the Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma)

have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by anti-HAMA IgG, anti-RF IgG, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis IgG, anti-HIV, anti-HCV IgG, anti-H. pylori IgG, anti-MONO IgM, anti-CMV IgG, anti-CMV IgM, anti-Rubella IgG, anti-Rubella IgM, anti-TOXO IgG and anti-TOXO IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Dengue negative and positive specimens.

Acetaminophen: 20mg/dL
Acetylsalicylic Acid: 20mg/dL
Ascorbic Acid: 2g/dL
Creatin: 200mg/dL
Bilirubin: 1g/dL
Caffeine: 20mg/dL
Gentisic Acid: 20mg/dL
Albumin: 2g/dL
Hemoglobin 1000mg/dL
Oxalic Acid: 60mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Halstead SB, Selective primary health care: strategies for control of disease in the developing world: XI, Dengue. Rev. Infect. Dis. 1984; 6:251-264.
2. Halstead SB, Pathogenesis of dengue: challenges to molecular biology. Science 1988; 239:476-481.

Index of Symbols

	Consult Instructions For Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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