JusChek®

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

A rapid test for a qualitative test for the 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 antibodies 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 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.

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 after 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 by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 75 μL. 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 area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
- Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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.

MATERIALS

Materials provided

- Test cassettes
- Buffer
- Droppers
- Package insert

Materials required but not provided

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

DIRECTIONS FOR USE

Allow the test, 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 75 μL) to the specimen area, and start the timer. See illustration below.

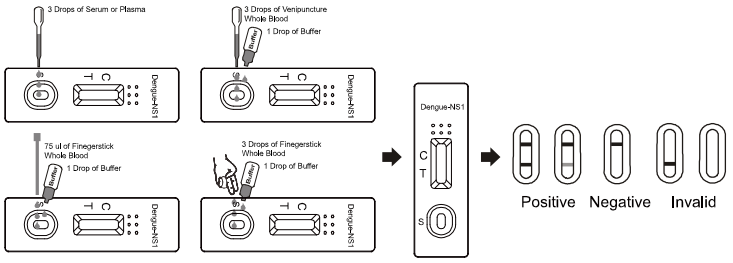
For **Venipuncture Whole Blood** specimen:

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

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 75 μL of fingerstick whole blood specimen to the specimen area of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.
- To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 μL) to fall into the specimen area of test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.

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



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * Two distinct colored lines appear. One color line should be in the control region (C) and another color 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 red in the test region should be considered positive.

NEGATIVE: One color 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 color 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 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 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.

EXPECTED VALUES

The Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Dengue Ag EIA 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 EIA 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 EIA Test		Total Result
Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	137	8	145
	Negative	6	200	206
Total Result		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

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

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

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