Dengue NS1 Antigen Rapid Test Kit

INTENDED USE

The Dengue NS1 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of dengue virus NS1 antigen in blood serum or plasma to aid in the diagnosis of Dengue viral infection.

INTRODUCTION

The Dengue NS1 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of dengue virus NS1 antigen in blood serum or plasma to aid in the diagnosis of Dengue viral infection. Dengue viruses, transmitted by the Aedes aegypti and Aedes albopictus mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. NS1 tests find the dengue virus's non-structural protein NS1. When dengue is present, this protein is produced in the blood. For usage in serum, NS1 assays have been developed. To find the dengue NS1 protein, the majority of these techniques use synthetically labelled antibodies. During the acute stage of dengue virus infections, NS1 can be found. In the initial 0–7 days after the onset of symptoms, NS1 testing can be just as sensitive as molecular tests. NS1 testing is not advised after day 7.

PRINCIPLE

The Dengue NS1 Antigen Rapid Test is a qualitative lateral flow-based immunoassay for the detection of dengue virus NS1 antigen in Whole Blood / Serum / Plasma. In this test procedure, anti-Dengue NS1 antibody is immobilised in the test line region of the membrane. After a Whole Blood / Serum / Plasma specimen is placed in the specimen well, it reacts with anti-Dengue NS1 antibody-coated particles that have been applied to the conjugation pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilised anti-Dengue antibody. If the specimen contains dengue virus NS1 antigen, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain dengue virus antigen, a coloured line will not appear in this region, indicating a negative result. To serve as a procedural control, a coloured line will always appear at the control line region, indicating that a proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS AND METHOD

1. Individual sealed pouches, each pouch containing:
   a. 1 × Test Kit
   b. 1 × Desiccant Pouch
   c. 1 × Dropper
2. Buffer Tube

STORAGE AND STABILITY

- Keep the test kit between 2 - 30°C in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for use.

SPECIMEN COLLECTION

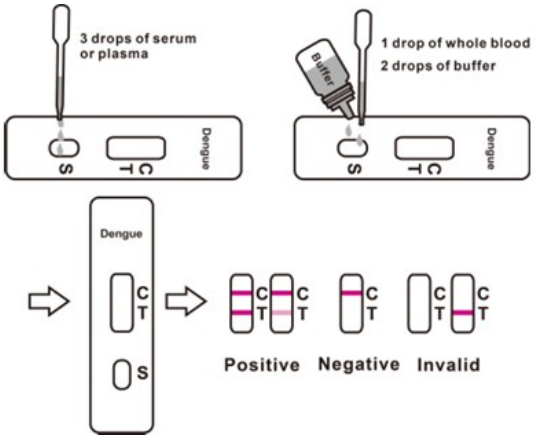
1. The Dengue NS1 Antigen Test can be performed using Whole Blood, Serum or Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-hemolyzed specimens. You can use whole blood, too.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2-8 °C for up to 7 days. For long-term storage, specimens should be kept below -20 °C.
5. Bring specimens to room temperature prior to testing.
6. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

7. Do not use samples showing gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

TEST PROCEDURE

Allow the test kit, specimen and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test kit from the sealed pouch and use it within one hour.
2. Place the kit on a clean and level surface.
3. **For Whole Blood specimens:** Hold the dropper vertically and transfer 1 drop of whole blood (approx. 35 µL) to the specimen area and then add 2 drops of buffer (approximately 70 µL), and start the timer. **For Serum or Plasma specimens:** Hold the dropper vertically and transfer 3 drops of serum or plasma (approx. 100 µL) to the specimen area, and start the timer.
4. Wait for the colored line(s) to appear. Read the results in 10-15 minutes. Do not interpret the result after 20 minutes.



RESULT:

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)
4. Pink line in (T) and No pink line in (C) - (INVALID)

PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the Dengue NS1 Antigen Rapid Test and commercially available Dengue rapid tests. A statistical comparison was made between the results, yielding a clinical sensitivity of 99.42%, a clinical specificity of 99.86% and an accuracy of 99.71%.

LIMITATIONS

1. The Dengue NS1 Antigen Rapid Test (Whole Blood/Serum/Plasma) is limited to providing a qualitative detection.
2. To ensure an appropriate diagnosis, the test results, like any other diagnostic technique, should be analysed in conjunction with the patient's clinical findings, medical history, and results from additional diagnostic procedures.
3. When recovering from dengue or convalescing, the NS1 antigen may continue to be detectable in the blood for a considerable amount of time. If the patient has a history of dengue, this prolonged remaining time might result in false-positive results.
4. For accurate results, blood samples must be handled and stored properly. Hemolysis, contamination, or sample deterioration may impact the test's performance.
5. It's possible that this test won't reveal the dengue virus serotype that's infected.

REFERENCES

1. Halstead SB, Pathogenesis of dengue: challenges to molecular biology. Science 1988; 239:476-481.
2. World Health Organization. Dengue: Guidelines for Diagnosis, Treatment, Prevention and Control. Geneva: World Health Organization; 2009.

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