Dengue NS1 Rapid Test Device
Package Insert

Cat: HIDN-402A
Version:03
Specimens: Whole Blood/Serum/Plasma
Effective Date: 2024-06

For professional *in vitro* diagnostic use only.

INTENDED USE

The Dengue NS1 Rapid Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of dengue virus antigen (Dengue Ag) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Dengue viruses. Any reactive specimen with the Dengue NS1 Rapid Test Device must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Dengue viruses, a family of four distinct serotypes of viruses (Den 1,2,3,4), are single-strained, enveloped, positive-sense RNA viruses. The viruses are transmitted by mosquitoes of the daytime-bitting Stegemyia family, principally Aedes aegypti, and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia, and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis[1-3].

Serological detection of IgM antibody is the most common method for the diagnosis of dengue virus infection. Lately, detection of antigens released during virus replication in the infected patient showed very promising result. It enables diagnosis from the first day after the onset of fever up to day 9, once the clinical phase of the disease is over, thus allows early treatment in placed promptly[4].

The Dengue NS1 Rapid Test is developed to detect circulating dengue antigen in human whole blood, serum or plasma. The test can be performed by untrained or minimally skilled personnel, without laboratory equipment.

PRINCIPLE

The Dengue NS1 Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-dengue NS1 antigen conjugated with colloid gold (Dengue Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with rabbit anti-dengue NS1 antigen, and the C band is pre-coated with goat anti-mouse IgG antibody. The antibodies to dengue antigen recognize the antigens from all the four serotypes of the dengue virus. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. Dengue NS1 Ag if present in the specimen will bind to the Dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated rabbit anti-NS1 antibody, forming a burgundy colored T band, indicating a Dengue Ag positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Individually packed test devices	Each device contains colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Droppers	For adding specimens use.
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction.

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 testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand then allow to dry. Massage the hand without touching the puncture. 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 device by using a capillary tube or hanging drops.
- 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 local regulations covering the transportation of etiologic agents.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Lancets (for fingerstick whole blood only)
- Timer
- Disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: **For whole blood samples:**

Fill the dropper with the specimen then add 2 drops (about 50µL) of specimen and 1 drop of buffer (about 40µL) into sample well, making sure that there are no air bubbles.

For Plasma/ Serum samples:

Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2 drops (about 50µL) of specimen and 1 drop of buffer (about 40µL) into the sample well, making sure that there are no air bubbles.

Step 5: Set up a timer.

Step 6: Read the result at 15 minutes.

Don't read results after 30 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

* A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:

One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

A procedural control is included in the test. A colored 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.

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 OF THE TEST

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 Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial enzyme immunoassay (EIA) test. The correlation between these two systems is 95.6%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Dengue NS1 Rapid Test Device (Whole Blood/Serum/Plasma) has been tested with a leading commercial Dengue NS1 EIA test using clinical specimens.

	Dengue NS1 Rapid Test		
Dengue Ag EIA Test	**Positive**	**Negative**	**Total**
Positive	66	3	69
Negative	2	43	45
Total	68	46	114

Relative Sensitivity: 95.7%,
Relative Specificity: 95.6%,
Overall Agreement: 95.6%* *95% Confidence Interval

PRECISION

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens containing negative, low positive and high positive samples. The negative and positive values were correctly identified >99% of the time

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: negative, low positive sample and high positive sample of Dengue NS1. Three different lots of the Dengue NS1 Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Gubler DJ, Clark GG. Dengue/dengue hemorrhagic fever. The emergence of a global health problem. Emerg Infect Dis 1995;1(2):55–57.
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3. Monath TP. Dengue: The risk to developed and developing countries. Proc Natl Acad Sci U S A 1994; 91:2395–2400.
4. Alcon S, Talarmin A., Debruyne M., et al: Enzyme-Linked Immunosorbent Assay Specific to Dengue Virus Type 1 Nonstructural Protein NS1 Reveals Circulation of the Antigen in the Blood during the Acute Phase of Disease in Patients Experiencing Primary or Secondary Infections. Journal of Clinical Microbiology, 40: 376–381

Index of Symbols

	Consult instruction for use		Contains sufficient for <n> tests	EC REP	Authorized Representative
IVD	In vitro diagnostic use		Use-by date	②	Do not re-use
2°C 30°C	Store between 2-30℃	LOT	Batch code	REF	Catalog number
	Do not use if package is damaged	CE	European conformity		

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Rm 1209, Desian Plex, 424, Yangcheon-ro, Gangseo-gu Seoul, 07573, Korea

EC REP Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

CE IVD