Dengue Ns1 Rapid Test (WB,S,P)

Labgene biotech

INTENDED USE

Labgene Dengue NS1 Rapid Test is a lateral flow chromatographic immunoassay designed for the qualitative detection of Dengue NS1 antigen in human whole blood, serum or plasma samples.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG009-10T	10	1 X 2 mL	01 in an individual pouch	-
LG009-25T	25	1 X 3 mL		
LG009-30T	30	1 X 3 mL		
LG009-40T	40	2 X 2 mL		
LG009-50T	50	2 X 3 mL		
LG009-100T	100	4 X 3 mL		
LG009LS-10T	10	1 X 2 mL		10
LG009LS-25T	25	1 X 3 mL		25
LG009LS-30T	30	1 X 3 mL		30
LG009LS-40T	40	2 X 2 mL		40
LG009LS-50T	50	2 X 3 mL		50
LG008LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

Dengue virus belongs to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. It is transmitted principally by the mosquito types Aedes aegypti and Aedes albopictus. The virus is found commonly throughout the tropic and subtropic regions of the world. There are four known serotypes of Dengue. Symptoms of Dengue fever include high fever, headache, muscle pain and skin rash. Occasionally it develops into a potentially lethal complication called severe dengue (dengue hemorrhagic fever or dengue shock syndrome). There is no specific treatment for Dengue/ severe Dengue, but early detection and access to proper medical care lowers fatality rates. Dengue NS1 (nonstructural protein) is a highly conserved glycoprotein that is circulating in patient sera during the early clinical phase of the disease. NS1 antigen is found in patient samples from the first day up to 9 days after onset of fever. The detection of NS1 antigen provides a tool for the early diagnosis of Dengue infection before serological antibodies are detectable.

PRINCIPLE

Labgene Dengue NS1 Rapid Test is a lateral flow chromatographic immunoassay designed for the qualitative detection of Dengue NS1 antigen in human whole blood, serum or plasma samples. When a specimen sample is dispensed into the sample well, it flows through the filter efficiently. The Dengue NS1 antigen if present in the specimen sample forms a complex with the specific anti-Dengue NS1 antibodies conjugated to the colloidal gold nanoparticles. The antibody gold-Dengue NS1 antigen complex binds to the immobilized antibodies in the Test area. The Rabbit IgG conjugate complexes migrate out of the Test area and are later captured in Control area. Visible pinkish-red bands will appear in the Test and Control area. If a band is present in both test and control area, the test result is read as positive, indicating that the Dengue NS1 positive results. If a band is present only in the Control area, the test result is read as negative. If no band is present in the Control area, the test is invalid and another test must be run using a fresh device, regardless of the presence or absence of band in the Test area.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- 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 or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- 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.

SPECIMEN COLLECTION AND PREPARATION

The Dengue NS1 Rapid Test can be performed using either serum, plasma or whole blood.

Plasma :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum :

- Collect blood specimen into a collection tube containing no anticoagulants.
- Allow the blood to clot.
- Separate the serum by centrifugation,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2-8°C for up to three days if the tests cannot be performed immediately. The specimens should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature and mix gently. Do not use haemolysed sample.

Whole Blood :
Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

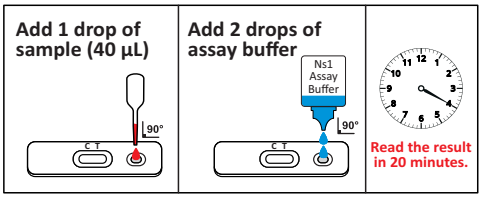
Collection using a lancet:

- Clean the area to be lanced with the alcohol swab
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

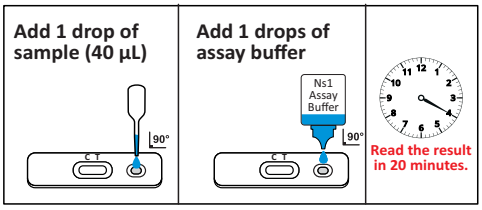
Dengue Ns1 PROCEDURE

1. Allow test device, specimen, to reach room temperature (15°C- 30°C) prior to testing.
2. Place the test device on a clean and level surface.
3. **For Serum or Plasma sample:** Hold the dropper vertically and transfer **1 drop of sample (40 µL)** to the sample well of the test device, then add **1 drop of assay buffer (40 µL)** and start the timer.
4. **For Whole blood sample:** Hold the dropper vertically and **transfer 1 drops of sample (40 µL)** to the sample well of the test device, then **add 2 drops of assay buffer (80 µL)** and start the timer.
5. Read the result in 20 minutes. Read results as shown under interpretation of Results

WHOLE BLOOD:



SERUM / PLASMA :



⚠ **Do not read the results after 25 minutes. For each sample, use a separate dropper and test cassette.**

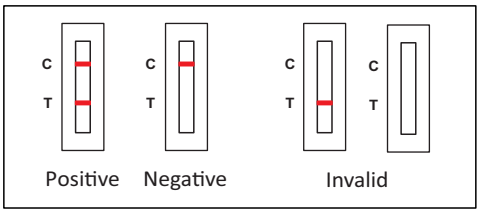
INTERPRETATION OF RESULTS

Positive Result : The presence of both band control band (C) and test band (T) within the result window indicate presence of Dengue NS1 antigen in the specimen .The result is positive for Dengue NS1.

Negative Result: If only the control (C) band is developed, within the result window the test indicate that no Dengue NS1 antigen is present in specimen. The result is negative for Dengue NS1.

INVALID: No visible band appears at the control region (C). 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

RESULTS:



LIMITATIONS

- The Dengue Ns1 Rapid test is for in vitro diagnostic use only.
- Humidity and temperature can adversely affect results.
- This test should be used for the detection of Dengue Ns1 Rapid test in human whole blood, serum or plasma specimens only.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results.

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PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out using clinical samples confirmed by Dengue ELISA and Lateral Flow test. The correlation between these two systems was found to be 100%.

Dengue NS1 Samples	Positive	Negative	Total
Positive	50	00	50
Negative	00	110	110
Total	50	110	160

Relative Sensitivity: 100.00%,
Relative Specificity: 100.00%,
Overall agreement: 100.00%

REFERENCES

1. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
2. Innis, BL, Nisalak, A., et.al. An enzyme-linked immunosorbent assay to characterize dengue infections where dengue and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene (1989), 40:418-427.
3. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
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 2002; 40: 376–381.

INDEX OF SYMBOLS

REF	Product Reference No.	ISO ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-009-03	

Manufactured by:

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