LordsMed Dengue NS1 Antigen Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
DNSLMR01	10 Test Device	WholeBlood/Serum/Plasma
DNSLMR02	25 Test Device	WholeBlood/Serum/Plasma
DNSLMR03	10 Test Device	Serum/Plasma
DNSLMR04	25 Test Device	Serum/Plasma

INTENDED USE

LordsMed Dengue NS1 antigen test is an immunochromatographic assay for the qualitative Detection of non-structural protein 1 (NS1) in human serum/plasma and wholeblood.

TEST PRINCIPLE

The LordsMed Dengue NS1 Antigen Rapid Test is an immunoassay based on the principle of the double antibody-sandwich technique. During testing, anti-Dengue antibody is immobilized in the test line region of the device. After a Serum/Plasma and Wholeblood specimen is placed in the specimen well, it reacts with anti-Dengue antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-Dengue antibody. If the specimen contains dengue virus 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 colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTION

1. Please read all the information in this package insert before performing the test.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place at 2 to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Do not reuse the test device.
7. Dispose of hygienically in domestic waste.
8. Do not touch the membrane.
9. Keep out of the reach of children.
10. For in vitro diagnostic use. Not to be taken internally.

Do not eat the desiccant in the package.

MATERIALS PROVIDED

1. Test Device
2. Dropper
3. Desiccant
4. Package Insert
5. Assay Buffer

MATERIALS NEEDED BUT NOT PROVIDED

1. Timer
2. Sample container

STORAGE AND STABILITY

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

SPECIMEN COLLECTION

1. Testing should be performed as early as possible after collection. Do not leave serum/Plasma at room temperature for prolonged periods.
2. The specimen may be stored at 2-8°C for upto 7 days or frozen at -20°C or lower for up to 30 days.

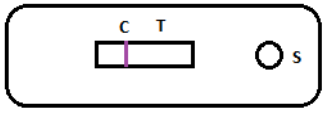
PROCEDURE

For LordsMed Dengue NS1 Rapid Test

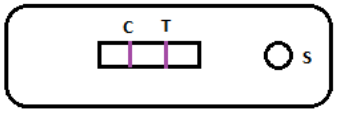
1. Allow the Test Device and sample to reach room temperature (20-30°C) before opening the foil pouch.
2. Remove the Test Device and desiccant from the pouch and use it as early as possible.
3. For serum,plasma and wholeblood: Hold the dropper vertically and transfer 1 drop of serum, plasma or wholeblood (approximately 10µl) to the specimen well (S) of the test cassette.
4. Then add 2 drops of buffer (approximately 70-80µl) and start the timer
5. Wait for the colored line(s) to appear. Read results at 20 to 25 minutes. Do not interpret the result after 30 minutes.

TEST INTERPRETATION (REFER TO FIGURE)

NEGATIVE: Only one purplish pink appears on the control region 'C' only.



POSITIVE: Two Purplish pink appears on the control region 'C' and on the test region "T".



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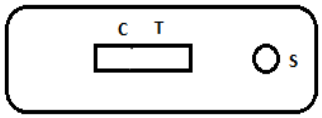
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(Wholeblood/Serum/Plasma)

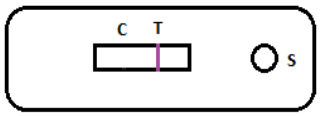
INVALID:

The test should be considered invalid if

A) No Purplish pink colour line appears in 'C' region and 'T' region



B) No Purplish pink colour line appears in 'C' region and line appear in 'T' region



LIMITATION

1. For professional in vitro diagnostic use only.
2. Humidity and temperature can adversely affect results. Similarly avoid excessive air flow or strong air-conditioning while performing the test.
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.

PERFORMANCE CHARACTERISTICS

The results demonstrated 98.0% sensitivity and 100% specificity with an overall accuracy of 98.33%

SENSITIVITY & SPECIFICITY

	Positive sample	Negative sample	Rate
Positive sample	49	00	98.0% (Sensitivity)
Negative sample	01	10	100% (Specificity)
Total	50	10	98.33% (Total accuracy)

BLIOGRAPHY

1.Pang L, Kitsutani P, Vorndam V, Nakata M, Ayers T,ElmJ,Tom T, Reiter P, Rigau-Perez JG, Hayes JM, Mills K, Napier M, Clark GG, Gubler DJ; Hawaii Dengue Outbreak Investigation Team. Dengue fever, Hawaii, 2001-2002. Emerg Infect Dis. 2005; 11(5)

2.Alcon-LePoder S, Sivard P, Drouet MT, TalarminA, Rice C, Flamand M. Secretion of flaviviral non-structural protein NS1: from diagnosis to pathogenesis.

3.Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin.Diagn. Lab. Immunol. Vol6 (4) p 555-557, 1999.

4.Seth, J. (1991. standardization & quality assurance. In principle and practice of immunoassay, Ed. C.P. Price & D.J. Newman. Macmillan Publishers, pp.154-189.

REF	Catalog No		Attention Caution
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer	Σ	No. of Tests

IFU/DNS/01 Rev No. : 00 Dated:15/07/2024

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