LordsMed Dengue Combo (NS1+ IgG/IgM) Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
DCMLMR01	10 Test Device	WholeBlood/Serum/Plasma
DCMLMR02	25 Test Device	WholeBlood/Serum/Plasma
DCMLMR03	10 Test Device	Serum/Plasma
DCMLMR04	25 Test Device	Serum/Plasma

INTENDED USE

LordsMed Dengue Combo (NS1+IgG/IgM) Rapid test is an immunochromatographic assay for the qualitative Detection of NS1 Antigen and IgM/IgG Antibodies to Dengue virus in human serum/plasma & wholeblood.

PRINCIPLE

A) Dengue NS1 Antigen Test:

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.

B) Dengue IgM/IgG Test:

LordsMed Dengue IgG/IgM Ab Rapid Test is a qualitative, membrane-based immunoassay for the detection of IgG/IgM antibodies in human serum/plasma/wholeblood.

LordsMed Dengue IgG/IgM Ab Rapid Test consists of two components, an IgG component and an IgM component. Dengue IgG/IgM Ab test device contains three lines, C (Control line) IgG and IgM (Tests Lines) IgM test line is pre-coated with anti-human IgG and IgM Ab test line is pre-coated with anti-human IgG. When a sample and buffer added to the device the mixture migrates upward on the membrane chromatographically by capillary action and reacts with anti-human IgG or IgM antibodies coated on the membrane respectively, colloidal gold complex containing dengue antigens is captured by the anti-dengue IgG or IgM Ab on respective T lines. If the specimen does not contain dengue antibodies no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTION

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

MATERIALS PROVIDED

1.Test Devices.
2. Product Insert
3. Silica gel
4. Assay Buffer for Dengue Combo.
5. Plastic dropper for Dengue NS1.
6. Plastic dropper for Dengue IgG/IgM.

MATERIALS NEEDED BUT NOT PROVIDED

1. Timer
2. Sample container

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 samples may be stored at 2°C to 8°C for up to 7 days or frozen at -20°C or lower for up to 30 days.
3. Wholeblood may be stored at 2°C to 8°C for up to 3 days and do not freeze it.

PROCEDURE

For Dengue NS1 Antigen & Dengue IgG/IgM Ab 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.a **For Dengue Ns1:** Hold the dropper vertically and transfer 1 drop of serum, plasma or wholeblood (approximately 25µl) to the specimen well (S) of the test cassette. Then add 2 drops of buffer (approximately 60-70µl) and start the timer.
3.b **For Dengue IgG/IgM :** Hold the dropper vertically and transfer 1 drop of serum, plasma or wholeblood (approximately 10µl) to the specimen well (S) of the test cassette. Then add 2 drops of buffer (approximately 60-70µl) and start the timer.
4. Wait for the colored line(s) to appear.
5. For Dengue Ns1 & Dengue IgG/IgM Ab : Read the result at 15-20 minutes. Do not read the result after 20 minutes.

TEST INTERPRETATION (REFER TO FIGURE)

A) For Dengue NS1 Test:

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".



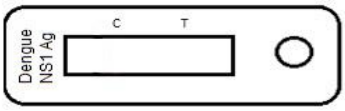
INVALID:

The test should be considered invalid if

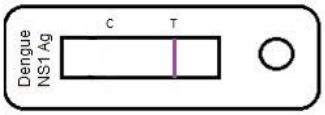
LordsMed Dengue Combo (NS1+ IgG/IgM) Rapid Test

(Wholeblood/Serum/Plasma)

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

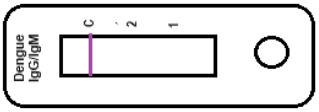


B) No Purplish pink colour line appears in 'C' region and line appear in 'T' region



B) For Dengue IgM/IgG Test:

NEGATIVE: Purplish pink colored line appears on the control region 'C' only



POSITIVE: **A)** A distinct purplish pink colored line appears on the control region 'C' and on the test region '2' 'IgG' and test region '1''IgM'.



B) A distinct purplish pink colored line appears on the control region 'C' and on the test region '1''IgM'.

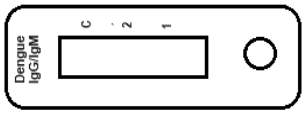


C) A distinct purplish pink colored line appears on the control region 'C' and on the test region '2''IgG'.



INVALID: The test should be considered invalid if

A) No purplish pink colored line appears in 'C' region '2' 'IgG' and '1' 'IgM' region



B) No purplish pink colored line appears in 'C' region and line appear in '1' 'IgM'and '2' 'IgG' region.



C) No purplish pink colored line appears in 'C' and in '1' 'IgM' region and line appear and '2' 'IgG' region.



D) No purplish pink colored line appears in 'C' and in '2' 'IgG' region and line appear and '1' 'IgM' region



NOTE: The intensity of the purplish pink color in the test line region will vary depending upon the infection

1. This product is designed for use with human serum, plasma or whole blood only. 2. This test detects the presence of antibodies to dengue in the specimen and should not be used as the sole criteria for the diagnosis of a dengue viral infection. 3. The test is a qualitative assay and is not for quantitative determination of antibodies concentration levels. The intensity of the band does not have linear correlation with the antibody titer of the specimen.

BIBLOGRAPHY

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, Talarmin A, 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.

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/DCM/02 Rev No. : 01 Dated.:21/10/2024

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