LordsMed Dengue IgG/IgM Antibody Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
DABLMR01	10 Test Device	Serum/Plasma/WholeBlood
DABLMR02	25 Test Device	Serum/Plasma/WholeBlood
DABLMR03	10 Test Device	Serum/Plasma
DABLMR04	25 Test Device	Serum/Plasma

INTENDED USE

LordsMed Dengue IgM/IgG Ab Rapid Test is an immunochromatographic assay for the qualitative Detection of IgG and IgM antibodies to dengue virus in human wholeblood/serum/plasma.

PRINCIPLE

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

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.Do not touch the membrane.
7.Keep out of the reach of children.
8.For in vitro diagnostic use. Not to be taken internally.
9.Do not eat the desiccant in the package.

MATERIAL PROVIDED

1. Test Device
2. Assay Buffer
3. Sample dropper
4. Desiccant
5. Product insert

MATERIAL NEEDED BUT NOT PROVIDED

1. Timer

SPECIMEN STORAGE AND STABILITY

1. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum, Plasma and Whole blood specimens may be stored at 2-8°C for up to 3 days. For long term storage, serum/plasma should be kept below -20°C.
2. 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.

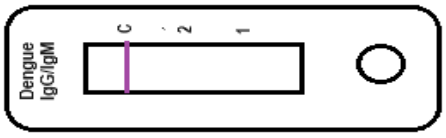
PROCEDURE

For LordsMed Dengue IgG/IgM Ab Rapid Test

1.Allow the Test Device and sample reach to room temperature (20°C to 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. Add 10µlof serum, plasma or whole blood sample in well and add 2 drop (50-60µl) of assay buffer in sample well.
4. Start the timer.
5. Read the result at 10-15 minutes. Do not read the result after 20 minutes.

TEST INTERPRETATION (REFER TO FIGURE)

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'.



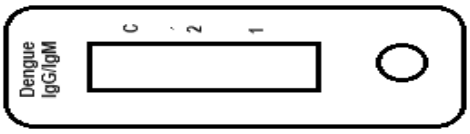
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INVALID: The test should be considered invalid if

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

PERFORMANCE CHARACTERISTICS

The results demonstrated 96.66% sensitivity and 100% specificity with an overall accuracy of 97.92%

SENSITIVITY & SPECIFICITY

	Positive sample	Negative sample	Rate
Positive sample	46	00	96.66% (Sensitivity)
Negative sample	01	28	100% (Specificity)
Total	47	28	97.92% (Total accuracy)

BIBLOGRAPHY

1. Clinical Evaluation of a rapid immunochromatographic test for the diagnosis of Dengue Virus Infection, Chew Theng Sang, Lim Siew Hoon, Andrea Cuzzubbo, Peter Devine. Clinical and Diagnostic Laboratory Immunology, May 1998, Vol. 5, No. 3 p. 407-409.

2. Innis BL, and Nisalak A, et al: An enzyme-linked immunosorbent assay to characterize dengue infections where denude and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene. 1989: 40: 418-427.Songee L. ranch and Paul N.Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin. Diagn. Lab. Immunol. Vol. 6(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

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