LordsMed Chikungunya Antibody Rapid Test

(Wholeblood/Serum/Plasma)

Catalog No.	Pack Size	Specimen Type
CHKLMR01	10 Test Device	Serum/Plasma/WholeBlood
CHKLMR02	25 Test Device	Serum/Plasma/WholeBlood
CHKLMR03	10 Test Device	Serum/Plasma
CHKLMR04	25 Test Device	Serum/Plasma

INTENDED USE

LordsMed Chikungunya Ab Rapid Test that qualitatively detects the presence of IgG and IgM antibodies against chikungunya virus in human serum/plasma/wholeblood. It is used for professional use only.

PRINCIPLE

LordsMed Chikungunya Ab Rapid Test device utilizes a strip coated with anti-human IgM and Anti-human IgG antibodies are immobilized along with control specific antibodies on the nitrocellulose membrane as three individual test lines (control, IgM line and IgG line). When sample and buffer is added in sample well, the test sample flows through the membrane within the test device and chikungunya specific recombinant antigen conjugated colloidal gold conjugate forms complexes with chikungunya specific recombinant antigen conjugated colloidal gold conjugate forms complexes with chikungunya specific antibodies (IgM and/or IgG) present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test result. Absence of this colored band in the test window indicated a negative test result. A control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-Chik V IgG and/or IgM antibodies in the specimen.

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

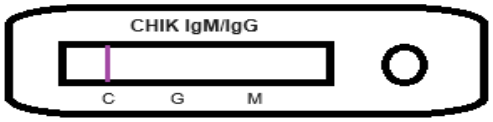
For LordsMed Chikungunya Ab Rapid Test (Wholeblood/Serum/Plasma)

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. **For Serum or Plasma specimen:** Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 10 µl) to the specimen well, then add 2 drop of buffer and start the timer.
4. **For Wholeblood specimen:** Hold the dropper vertically and transfer 2 drop of wholeblood (approximately 20 µl) to the specimen well, then add 2 drops of buffer and start the timer.
5. Wait for the colored line to appear. Read results attend of 15 minutes.

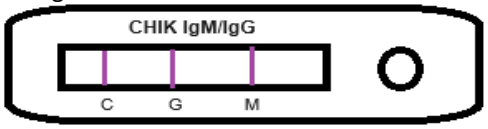
Note: Do not read the result after 30 minutes.

TEST INTERPRETATION (REFER TO FIGURE)

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

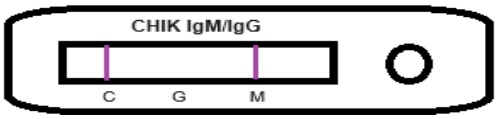


POSITIVE: **A)** A distinct purplish pink colored line appears on the control region 'C' and on the test region 'IgM' and test region 'IgG'.

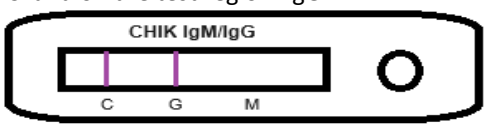


B) A distinct purplish pink colored line appears on the control region 'C' and on the test region 'IgM'.

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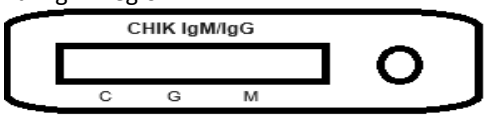


C) A distinct purplish pink colored line appears on the 'C' and on the test region 'IgG'.

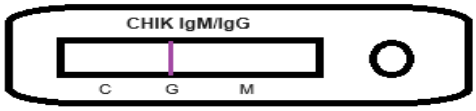


INVALID: The test should be considered invalid if

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



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



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



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



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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