Chikungunya IgG/IgM Rapid Test (WB,S,P)

Labgene biotech

INTENDED USE

Labgene Chikungunya IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay designed for the qualitative detection and differentiation of IgG and/or IgM antibodies against Chikungunya virus 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
LG013-10T	10	1 X 2 mL	01 in an individual pouch	-
LG013-25T	25	1 X 3 mL		
LG013-30T	30	1 X 3 mL		
LG013-40T	40	1 X 3 mL		
LG013-50T	50	2 X 3 mL		
LG013-100T	100	4 X 3 mL		
LG013LS-10T	10	1 X 2 mL		10
LG013LS-25T	25	1 X 3 mL		25
LG013LS-30T	30	1 X 3 mL		30
LG013LS-40T	40	1 X 3 mL		40
LG013LS-50T	50	2 X 3 mL		50
LG013LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

The Chikungunya virus (CHIKV) is an enveloped, positive strand, RNA virus belonging to family Togaviridae with genus Alphavirus, first identified in 1953. CHIK fever is transmitted to humans by the bite of a variety of mosquitoes including Ae.aegypti, Ae. Albopictus, Aedes africanus, Ae. luteocephalus, Ae. furcifer and Ae. Taylori. CHIKV has caused outbreaks in East Africa (Tanzania and Uganda), in Austral Africa (Zimbabwe and South Africa), in West Africa (Senegal and Nigeria), and in Central Africa (Central African Republic and Democratic Republic of the Congo). In Asia, CHIKV outbreaks have been reported in India, Sri Lanka, Myanmar, Thailand, Indonesia, the Philippines, Cambodia, Vietnam, Hong Kong and Malaysia. Symptoms of sudden onset of fever, chills, headache, nausea, vomiting, joint pain with or without swelling, low back pain, and rash are very similar to those of Dengue. Both diseases are transmitted by the same species of the mosquitos Aedes aegypti and Ae. Albopictus and mixed outbreak of chikungunya, with sporadic cases of Dengue has been reported in Andhra Pradesh state, India. However, unlike Dengue, there is no hemorrhagic or shock syndrome form. Therefore, the ability to distinguish CHIKV infection from Dengue virus infection would be extremely beneficial, particularly in areas where Dengue virus infection is endemic or epidemic.

PRINCIPLE

Labgene Chikungunya IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay designed for the qualitative detection and differentiation of IgG and/or IgM antibodies against Chikungunya virus in human whole blood, serum or plasma samples. When a specimen sample is dispensed into the sample well, the sample flows through the filter efficiently after adding buffer solution. The gold-antigen conjugate will bind to Chik antibodies if present in the sample specimen which in turn will bind with anti-human IgG & anti-human IgM antibodies coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-human IgG & anti-human IgM antibodies on the membrane will bind the Chik antibody-gold-antigen complex at the relevant G and or M test lines causing pale or dark pink or red lines to form at the G or M region of the test membrane. The intensity of the lines will vary depending upon the amount of antibodies present in the sample. The appearance of the colored line in a specific test region (G or M) should be considered as positive for that particular Chik antibody type (IgG or IgM). 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 Chikungunya IgG/IgM 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.

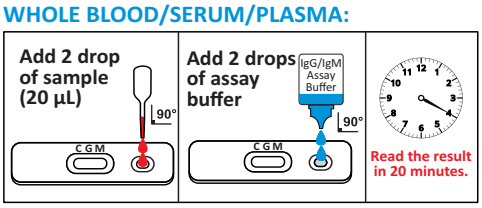
PROCEDURE

Follow the same procedure for serum/plasma and whole blood

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. Hold the dropper vertically and transfer 2 drops of sample (20 µL) to the specimen well of the test device and add 2 drops of buffer (80 µL) and start the timer.
4. Read the result in 25 minutes. Read results as shown under interpretation of Results

⚠ **Strong positive specimens may produce Positive result in as little as 1 minute.**

WHOLE BLOOD/SERUM/PLASMA:



INTERPRETATION OF RESULTS

POSITIVE:

IgG and IgM positive: In addition to the band in the control area marked 'C', appearance of two pink-red coloured bands in the test region 'G' and region 'M', indicates the presence of Chikungunya virus specific IgG and IgM antibodies.

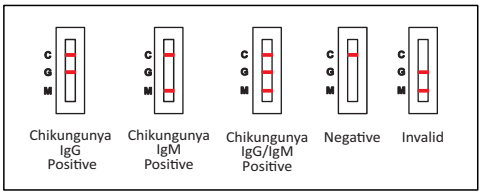
IgM positive: In addition to the control band in the control area marked 'C', appearance of a pink-red coloured band in the test region 'M', indicates the presence of Chikungunya virus specific IgM antibodies.

IgG positive: In addition to the control band in the control area marked 'C', the appearance of a pink-red coloured bandin the test region 'G', indicates the presence of Chikungunya virus specific IgG antibodies.

NEGATIVE: Only one colored line appears in the control line region (C). No apparent colored line appears in the test line regions (G or M), indicates the absence of specific antibodies against Chikungunya virus or that the amount of antibodies is below the detection limit of the test.

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 Chikungunya IgG/IgM 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 IgG and/or IgM antibodies against Chikungunya virus in human whole blood, serum or plasma specimens only.

- This test will only indicate the qualitative results of Chikungunya IgG/IgM antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Chikungunya infection.
- 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Chikungunya IgG Samples	Positive	Negative	Total
Positive	25	00	25
Negative	00	50	50
Total	25	50	75

Chikungunya IgM Samples	Positive	Negative	Total
Positive	15	00	15
Negative	00	50	50
Total	15	50	65

Relative Sensitivity: 100%,
Relative Specificity: 100%,
Overall agreement: 100%

REFERENCES

1. Evaluation of the first commerical chikungunya virus indirect immunofluorescence test, Litzba N., et. al., J. Virol Methods, 2008, Apr. 149(1): 175-9
2. Surveillance and management of Chikungunya disease, Disease Control Division, Ministry of Health, Malaysia, March 2006
3. Alpha Viruses, S.K. Lam and K.b. Chua, WHO Collaborating Centre for Arbovirus Reference and Research, Department of medical microbiology, Faculty of Medicine, University of Malaya.
4. Chikungunya Virus in US Travelers Returning from India, 2006, Robert S. Lanciotti, et. al., Emerging Infectious Desease, Vol. 13, No.5, Maay 2007.
5. New Tests Helps Tackle India's Chikungunya Viruses in India (1963-2006) with special reference to the 2005-2006 Explosive Epidemic, Journal of General Virology (2207), 88, 1967-1976.

INDEX OF SYMBOLS

REF	Product Reference No.	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-013-03	

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