

CHIKUNGUNYA ANTIBODY (IgG/IgM)

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC22



INSTRUCTIONS FOR USE

INTENDED USE: Test for qualitative detection of Chikungunya IgG/IgM in human serum, plasma and whole blood samples.

SUMMARY OF TEST

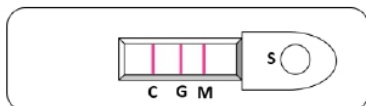
Chikungunya is a rare viral infection transmitted by the bite of an infected *Aedes aegypti* mosquito. It is characterized by a rash, fever, and severe joint pain (arthralgias) that usually lasts for three to seven days. The name is derived from the Makonde word meaning 'that which bends up' in reference to the stooped posture developed as a result of the arthritic symptoms of the disease. It occurs during the rainy season in tropical areas of the world, primarily in Africa, South-East Asia, southern India and Pakistan¹⁻².

The symptoms are most often clinically indistinguishable from those observed in dengue fever. Indeed, dual infection of dengue and chikungunya has been reported in India³. Unlike dengue, hemorrhagic manifestations are relatively rare and most often the disease is a self-limiting febrile illness. Therefore it is very important to clinically distinguish dengue from chikungunya infection.

Chikungunya is diagnosed based on serological analysis and viral isolation in mice or tissue culture. An IgM immunoassay is the most practical lab test method⁴.

PRINCIPLE

The Chikungunya IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of IgG and IgM antibodies to Chikungunya in whole blood, serum or plasma. The membrane is pre-coated with recombinant Chikungunya antigen on the test line region of the cassette.



During testing, the whole blood, serum or plasma specimen reacts with recombinant Chikungunya antigen conjugated colloid gold. The mixture upward on the membrane chromatographically by capillary action to react with mouse anti-human IgG or/and mouse anti-human IgM on the membrane and generate a coloured line. Presence of this coloured line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. 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.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.

REAGENTS

The test cassette contains recombinant Chikungunya antigen conjugated colloid gold, mouse anti-human IgG and mouse anti-human IgM coated on the membrane.

STORAGE & STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

1. The Chikungunya IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens, wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
3. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4. Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
5. Allow 1 hanging drop of fingerstick whole blood to fall into the centre of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the centre of the specimen area. Avoid touching the finger directly to the specimen area.

OR

6. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
7. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, specimens should be kept at -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
8. 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.
9. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

A. For Serum or Plasma specimen:

Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25µL) to the specimen area (S), then add 1 drop of buffer (approximately 40 µL), and start the timer.

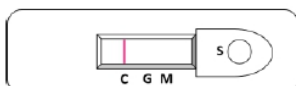
B. For Venipuncture Whole Blood specimen:

Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25 µL) to the specimen area, then add 1 drop of buffer (approximately 40 µL), and start the timer.

Wait for the coloured line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:



One colour line appears in the control region (C). No apparent red or pink line appears in the IgG and IgM region.

POSITIVE RESULT:

IgG Positive: Two distinct coloured lines appear. One colour line should be in the control region (C) and another colour line should be in the IgG region.



IgM Positive: Two distinct coloured lines appear. One colour line should be in the control region (C) and another colour line should be in the IgM region.

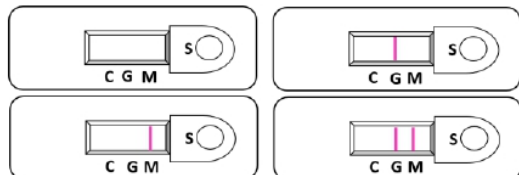


IgG and IgM Positive: A clear pink control line (C) and two detectable test line 1 and 2 appears, as seen in the image below, it indicates positive results for *S. typhi* and *paratyphi*, mixed infection.



INVALID TEST:

No visible band at the control region. Repeat with a new test device.



QUALITY CONTROL

Although the testing device contains an internal quality control (pink coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY FOR IgM

Chikungunya IgG/IgM Rapid Test			
IgM EIA	Positive	Negative	Total
Positive	65	0	65
Negative	7	21	28
Total	72	21	93
Relative Sensitivity		90.3%	
Relative Specificity		99.9%	
Accuracy		92.50%	

SENSITIVITY AND SPECIFICITY FOR IgG

Chikungunya IgG/IgM Rapid Test			
IgG EIA	Positive	Negative	Total
Positive	33	1	34
Negative	2	32	34
Total	35	33	68
Relative Sensitivity		94.3%	
Relative Specificity		97.0%	
Overall Agreement		95.6%	

BIBLIOGRAPHY

- Shah KV, Gibbs CJ Jr, Banerjee G. Virological investigation of the epidemic of haemorrhagic fever in Calcutta: isolation of three strains of Chikungunya virus. Indian J Med Res 1964; 52 :676-83.
- Powers AM, Brault AC, Tesh RB, Weaver SC. Re-emergence of Chikungunya and O'nyong-nyong viruses: evidence for distinct geographical lineages and distant evolutionary relationships. J Gen Virol 2000;81:471-9
- Myers RM and Carey DE. Concurrent isolation from patient of two arboviruses, Chikungunya and dengue type 2. Science 1967;157:1307-8.
- Thein S, La Linn M, Aaskov J, Aung MM, Aye M, Zaw A, Myint A. Development of a simple indirect enzyme-linked immunosorbent assay for the detection of immunoglobulin M antibody in serum from patients Following an outbreak of chikungunya virus infection in Yangon, Myanmar. Trans R Soc Trop Med Hyg. 1992 86:438-42.

SYMBOLS:



Read Instruction for use

In Vitro Diagnostic Use Only

Manufactured by

Expiry Date

Storage Temperature

ANAMOL LABORATORIES PVT. LTD.

61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.

Customer Care: +91-9823388695.

admin@anamollabs.com

exports@anamollabs.com

www.anamollabs.com

ISO 9001 : 2015

ISO 13485 : 2003

GMP

CE