

Chikungunya IgG/IgM Rapid Test Cassette
(Serum/Plasma/Whole Blood)

Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA ANTIBODIES IGG/IGM IN HUMAN SERUM/PLASMA/WHOLE BLOOD.
For Professional In Vitro Diagnostic Use Only.

INTENDED USE

The Chikungunya IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Chikungunya IgG and Chikungunya IgM in human serum, plasma or whole blood. This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with Chikungunya. Any reactive specimen with the Chikungunya IgG/IgM Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

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 CHIK infection.

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

The Chikungunya IgG/IgM Rapid Test Cassette utilizes recombinant antigens derived from its structure protein5, it detects IgM anti-CHIK in patient serum or plasma within 15 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Chikungunya IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay. The test consists of: 1) a red colored conjugate containing recombinant Chikungunya antigens conjugated with colloid gold (recombinant Chikungunya antigens conjugates) and rabbit igg-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands(IgG and IgM bands)and a control band(C band). The IgM band is pre-coated with monoclonal anti-human IgM for detection of IgM anti-CHIKV, IgG band s pre-coated with monoclonal anti-human IgG for detection of IgG anti-CHIKV, and the C band is pre-coated with goat anti rabbit IgG When an adequate volume of test specimen is applied into the sample pad of the test, the specimen migrates by capillary action across the strip. IgM anti-CHIKV if present in the specimen will bind to the CHIKV conjugates. The immune complex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a red colored IgM band indicating a CHIKV positive test result.

IgG anti-CHIKV if present in the specimen will bind to the CHIKV conjugates. The immune complex is then captured by the pre-coated reagents on the membrane, forming a red colored IgG band, indicating a CHIKV IgG positive test result. Absence of any T bands (IgM and IgG) suggests a negative result. The test contains an internal control(C band)which should exhibit a red colored band of the immune complex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS

The test contains mouse anti-human IgG and mouse anti-human IgM pre-coated on the surface of the membrane. And CHIKV antigen conjugated colloid gold.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.

- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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 and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Chikungunya IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Finger stick Whole Blood specimens:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Touch the end of the capillary tube to the blood until filled to approximately 20µl. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test Cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. 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 below -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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

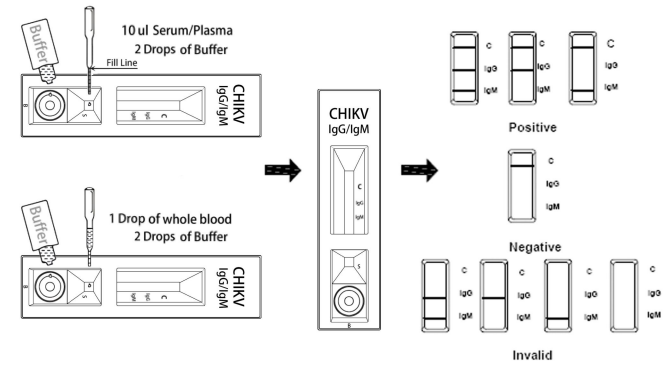
Materials provided			
• Test Cassette	• Dropper	• Buffer	• Package Insert
Materials required but not provided			
• Specimen collection containers	• Timer		
• Lancets (for fingerstick whole blood only)	• Centrifuge		

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the test cassette on a clean and level surface.
For Serum or Plasma specimens: Hold the dropper vertically and draw the serum or plasma up to the fill line as shown in illustration below (approximately

- 10µL). Transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 80µL) to the specimen well (B), and start the timer. See illustration below.
- For Venipuncture Whole Blood specimens: Using the provided 10µL dropper and transfer 1 drop (about 20µL) of whole blood to the specimen area, then add 2 drops of buffer (approximately 80µL) to the buffer hole and start the timer. See illustration below.
- For Finger stick Whole Blood specimens: To use a capillary tube: Fill the capillary tube and transfer 20 µL of fingerstick whole blood specimen to the specimen area of test device, then add 2 drops of buffer (approximately 80µl) to the specimen well (B) and start the timer. See illustration below.
- Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line should be in the test line region (IgM or IgG).

IgM Positive: Along with line in Control region (C), a line appears in IgM region. It indicates a positive test result for IgM antibodies to Chikungunya.

IgG Positive: Along with line in Control region (C), a line appears in IgG region. It indicates a positive Test result for IgG antibodies to Chikungunya.

***NOTE:** The intensity of the color in the test line region (IgM or IgG) will vary depending on the concentration of Chikungunya present in the specimen. Therefore, any shade of color in the test line regions should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored lines appear in any of the test line region (IgM or IgG). This indicates that the concentration of Chikungunya are below the minimum detection levels.

INVALID: Control line (C) fails to appear. 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The assay procedure and the test result Interpretation must be followed closely when testing the presence of antibodies to Chikungunya in serum/plasma/whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2. The Chikungunya IgG/IgM Rapid Test Cassette is limited to the qualitative detection of the antibodies to Chikungunya in human serum/plasma/whole blood. The intensity of the test band does not linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable Chikungunya antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with Chikungunya.
4. A negative result can occur if the quantity of the Chikungunya antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity

The Chikungunya IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood) has been evaluated with a leading commercial Chikungunya IgG/IgM EIA test using clinical specimens. The results show that relative to leading EIA tests, the Chikungunya IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood) exhibits 98.45% sensitivity and 99.1% specificity for IgG, 97.66% sensitivity and 99.49% specificity for IgM.

Chikungunya IgG Test vs. EIA				
Method		EIA		Total Results
Chikungunya IgG Test	Results	Positive	Negative	
	Positive	127	2	129
	Negative	2	220	222
Total Results		129	222	351

Relative Sensitivity: 98.45% (95%CI*: 94.17%~99.93%)*

Relative Specificity: 99.1% (95%CI*:96.56%~99.97%)*

Accuracy: 98.86% (95%CI*: 97.0%~99.66%)*

*Confidence Interval

Chikungunya IgM Test vs. EIA				
Method		EIA		Total Results
Chikungunya IgM Test	Results	Positive	Negative	
	Positive	125	1	126
	Negative	3	197	200
Total Results		128	198	326

Relative Sensitivity: 97.66% (95%CI*: 93.03%~99.5%)*

Relative Specificity: 99.49% (95%CI*: 96.91%~99.99%)*

Accuracy: 98.77% (95%CI*:96.77%~99.64%)*

*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens:a negative, a low positive,and a high positive.The negative,low,positive,and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens,a negative,a low positive,and a high positive.Three different lots of the Chikungunya IgG/IgM Rapid Test Cassette(Serum/Plasma/Whole blood) have been tested over a 3-day period using negative,low positive,and high positive specimens.The specimens were correctly identified >99% of the time.

Cross-reactivity

The Chikungunya IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole blood) has been tested for Toxo, HBV, HCV, HIV, RF, Syphilis, H. Pylori, CMV, Rubella,HSV 1/2 positive specimens.The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the Chikungunya IgG/IgM Rapid

Test Cassette (Serum/Plasma/Whole blood) and no interference was observed.

Hemoglobin	2000mg/dl
Bilirubin	1000mg/dl
human serum Albumin	2000mg/dl

BIBLIOGRAPHY

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer		Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
	Batch code		Meet the requirements of EC Directive 98/79/EC

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