CE IVD

Chikungunya IgG/IgM Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Chikungunya IgG/IgM in human serum ,plasma or whole blood. *For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Chikungunya IgG/IgM Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit;5 tests/kit;1 test/kit

INTENDED USE

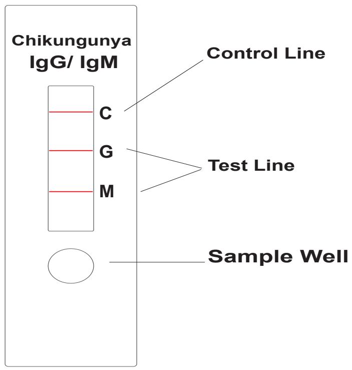
The Chikungunya IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Chikungunya virus IgG/IgM antibody in human serum ,plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Chikungunya viruses.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

SUMMARY AND EXPLANATION THE 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 Pakistan. The symptoms are most often clinically indistinguishable form those observed in dengue fever. Indeed, dual infection of dengue and chikungunya has been reported in India. 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 method. The Chikungunya IgG/IgM Rapid Test utilizes recombinant antigens derived from its structure protein, it detects IgG/IgM anti-CHIK in patient serum or plasma within 20 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Chikungunya IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing Chikungunya recombinant envelope antigens conjugated with colloid gold (dengue conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (G and M bands) and a control band (C band). The G band is pre-coated with the antibody for the detection of IgG anti-Chikungunya virus, M band is coated with antibody for the detection of IgM anti-Chikungunya virus, and the C band is pre-coated with goat anti rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-Chikungunya virus if present in the specimen will bind to the Chikungunya conjugates. Reagents of different batch numbers cannot be used interchangeably. The immunocomplex is then captured by the reagent coated on the G band, forming a burgundy colored G band, indicating a Chikungunya virus IgG positive test result and suggesting a recent or repeat infection. IgM anti-Chikungunya virus, if present in the specimen, will bind to the Chikungunya conjugates. The immunocomplex is then captured by the reagent pre-coated on the M band, forming a burgundy colored M band, indicating a Chikungunya virus IgM positive test result and suggesting a fresh infection. Absence of any test bands (G and M) suggests a negative result.The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex 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 AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

2.Do not open the sealed pouch, unless ready to conduct the assay.

3.Do not use expired devices.

4.Bring all reagents to room temperature (15°C-30°C) before use.

5.Do not use the components in any other type of test kit as a substitute for the components in this kit.

6.Do not use hemolized blood specimen for testing.

7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.

8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

10.Dispose of all specimens and materials used to perform the test as biohazardous waste.

11.Handle the Negative and Positive Control in the same manner as patient specimens.

12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.

13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.

2.Separate the plasma by centrifugation.

3.Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.

2.Allow the blood to clot.

3.Separate the serum by centrifugation.

4.Carefully withdraw the serum into a new pre-labeled tube.

5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.

6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

ASSAY PROCEDURE

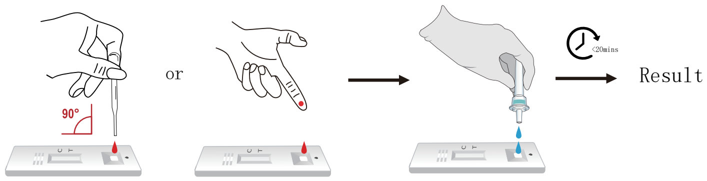
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen's ID number.

Step 4: For whole blood test

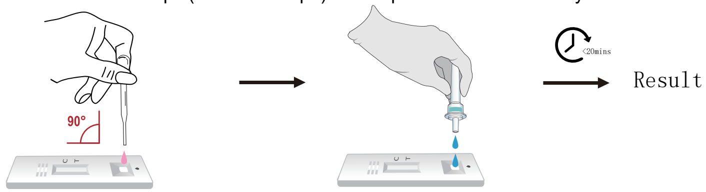
- Apply 1 drop of whole blood (about 20 μL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5: Set up timer.

Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

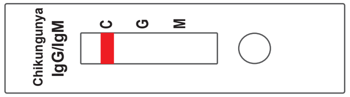
QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

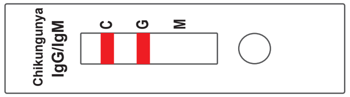
External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:
a. New operator uses the kit, prior to performing testing of specimens.
b.A new lot of test kit is used.
c.A new shipment of kits is used.
d.The temperature used during storage of the kit fall outside of 2°C -30°C .
e.The temperature of the test area falls outside of 15°C -30°C .

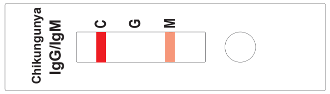
INTERPRETATION OF ASSAY RESULT

Negative Control
If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti- Chikungunya virus antibodies are detected. The result is negative or non-reactive.

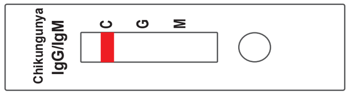


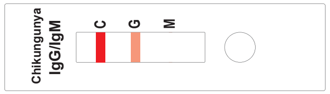
Positive Control
IgG Positive: In addition to the presence of C band, if only G band is developed, indicates for the presence of IgG anti- Chikungunya virus; the result suggests past infection or re-infection of Chikungunya virus.



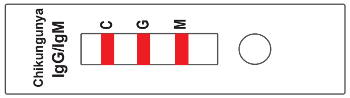


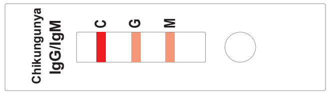
IgM Positive: In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-Chikungunya virus. The result suggests fresh infection of Chikungunya virus.





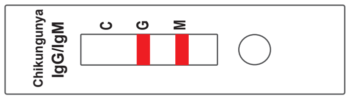
IgG/IgM Positive: In addition to the presence of C band, both G and M bands are developed, indicates for the presence of IgG and IgM anti-Chikungunya virus. The result suggests current infection or secondary infection of Chikungunya virus.

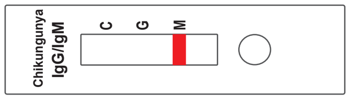


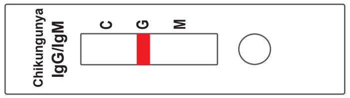


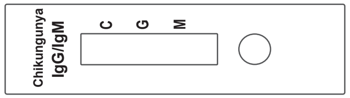
Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:
If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(G and M) as indicated below. Repeat the assay with a new device.









PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test
A total of 224 patient samples from susceptible subjects were tested by the Chikungunya IgG/IgM Combo Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Chikungunya IgG/IgM Combo Rapid Test		
IgM EIA Test	Positive	Negative	Total
Positive	50	2	52
Negative	1	171	172
Total	51	173	224
Relative Sensitivity:96.15% , Relative Specificity:99.41%, Overall Agreement: 98.66%.			

2. Clinical Performance For IgG Test
A total of 276 patient samples from susceptible subjects were tested by the Chikungunya IgG/IgM Combo Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Chikungunya IgG/IgM Combo Rapid Test		
IgM EIA Test	Positive	Negative	Total
Positive	48	2	50
Negative	1	225	226
Total	49	227	276
Relative Sensitivity: 96.0% , Relative Specificity: 99.56%, Overall Agreement: 98.91%.			

LMITATIONS OF TEST

1.The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to Chikungunya virus in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2.The Chikungunya IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to Chikungunya virus in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3.The Chikungunya IgG/IgM Rapid Test can not be used to differentiate if the infection is primary or secondary.
4.Serological cross reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile, yellow fever, etc.), therefore, it is possible that patients infected with these viruses may show some level of the reactivity with this test.
5.A negative or non-reactive result for an individual subject indicates absence of detectable Chikungunya virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with Chikungunya virus.
6.A negative or non-reactive result can occur if the quantity of the dengue virus 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. Therefore, a follow up test or alternative tests such antigen test or PCR test method is recommended if the clinical findings strongly suggest an infection or when there is an outbreak.
7.If the symptom persists, while the result from Chikungunya IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
8.Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
9.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP **SUNGO Europe B.V.**
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.