CE IVD

Chikungunya 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 IgM in human serum ,plasma or whole blood. *For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Chikungunya IgM Rapid Test-kit (Colloidal Gold)

SPECIFICATION

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

INTENDED USE

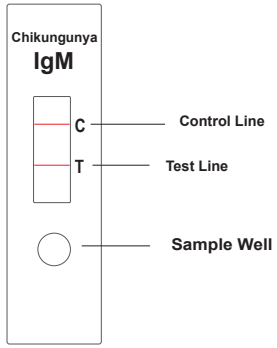
The Chikungunya IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Chikungunya virus IgM antibody in human serum ,plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Chikungunya viruses. Any reactive specimen with the Chikungunya 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 IgM Rapid Test utilizes recombinant antigens derived from its structure protein5, 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 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 test band (T band) and a control band (C band). The T 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. 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 band (T) 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	5ml/bottle	1ml/bottle	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

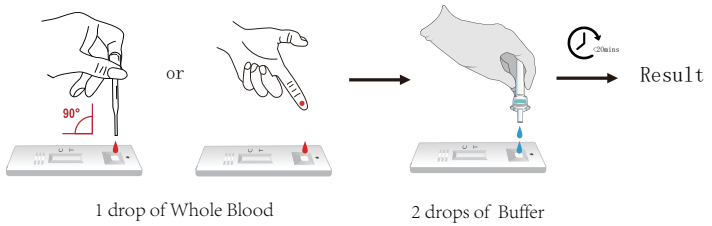
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.
Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw 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.

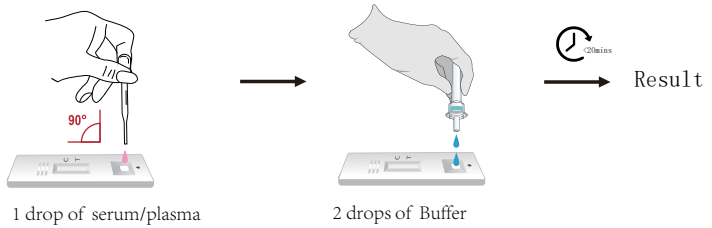
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.

Step 4: For whole blood test
- Apply 1 drop of whole blood (about 30-35 uL) into the sample well.
- Then add 2 drops (about 60-70 µL) of Sample Diluent immediately.



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.



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.

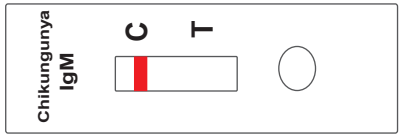
QUALITY CONTROL

Using individual Chikungunya IgM Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:
1.A new operator uses the kit, prior to performing testing of specimens.
2.A new test kit is used.
3.A new shipment of kits is used.
4.The temperature used during storage of the kit falls outside of 2°C -30°C.
5.The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

Negative Control

Only the C band shows color development. The T band shows no color development.



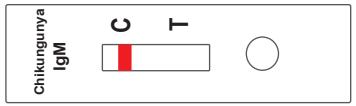
Positive Control

Both C and T bands show color development

INTERPRETATION OF ASSAY RESULT

Negative Control

If only the C band is developed, the test indicates that no detectable IgM anti-CHIK is present in the specimen. The result is negative.



Positive Control

If both C and T bands are developed, the test indicates for the presence of IgM anti-CHIK in the specimen. The result is positive.

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 color development on the T band as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1.Comparison of the CHIK IgM Rapid Test with MAC-ELISA

An evaluation study was carried out at Unite de virologie , Institute de Medecine Tropicale de Service de Sante des Armees, Ministere De la Defense, France.The evaluation specimen panel consisted of 75 recently infected specimens diagnosed by MAC-ELISA and 21 specimens containing 10 from other arbovirus infection, 3 from O'Nyong nyong infection, and 180 negative for all the tests. The evaluation data are showed in the following table.

	CHIK IgM Rapid Test		
MAC-ELISA	**Positive**	**Negative**	**Total**
Positive	72	3	75
Negative	0	21	21
Negative	1	179	180
Total	73	203	276
Relative Sensitivity: 97.33% , Relative Specificity: 99.5%, Overall Agreement:98.55%			

2.Comparison of the CHIK IgM Rapid Test with CHIK IHA and CHIK Neutralization Test

ID	Dengue Titer*	Yellow Fever Titer*	CHIK IHA** Titer*	CHIK Neutralization	CHIK IgM
140	<10	10	>=1280	Positive	Positive
547	160	160	>1280	80% neg 50% pos	Positive
1959	<10	<10	40	Positive	Doubtful
41	<10	80	>=1280	Positive	Positive
1709	>=1280	>=1280	<10	N/A	Positive
1793	>=1280	>=1280	<10	N/A	Positive
1016	10	40	>=1280	80% neg 50% pos	Positive
746	<10	320	>=1280	80% neg 50% pos	Negative
701	<10	20	>=1280	80% neg 50% pos	Positive
660	<10	640	>=1280	80% neg 50% pos	Positive
659	<10	40	>=1280	80% neg 50% pos	Positive
1505	<10	>=1280	<10	N/A	Negative
340	<10	10	>=1280	Positive	Positive
359	<10	10	80	N/A	Positive
429	<10	<10	>=1280	Positive	Doubtful
557	<10	<10	>=1280	Positive	Positive
430	<10	<10	<10	Negative	Negative
562	<10	10	>1280	Positive	Positive
1817	<10	<10	>=1280	N/A	Positive

*: Titer < 10: Negative.

**: IHA: Indirect hemagglutination Test

LMITATIONS OF TEST

1.The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of IgM anti-CHIK in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.

2.The Chikungunya IgM Rapid Test is limited to the qualitative detection of IgM anti-CHIK in human serum or plasma. The intensity of the test band does not have the linear correlation with the antibody titer in the specimen.

3.A negative result for an individual subject indicates absence of detectable IgM anti-CHIK. However, a negative test result does not preclude the possibility of exposure to or infection with CHIK

4.A negative result can occur if the quantity of IgM anti-CHIK 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.

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

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