HI-Quik Chikungunya IgG/IgM Rapid Card Test (Serum/Plasma) Package Insert

A rapid test for the qualitative detection of IgG and IgM antibodies to Chikungunya in human serum or plasma. For professional in vitro diagnostic use only

【INTENDED USE】

The HI-Quik Chikungunya IgG/IgM Rapid Card Test (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Chikungunya in human's serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with CHIK. Any reactive specimen with the HI-Quik Chikungunya IgG/IgM Rapid Card Test 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 Pakistan[1-2].

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[3]. 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[4].

【PRINCIPLE】

The HI-Quik Chikungunya IgG/IgM Rapid Card Test (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of IgG and IgM antibodies to Chikungunya in serum or plasma. The membrane is pre-coated with recombinant Chikungunya antigen on the test line region of the cassette. During testing, the serum or plasma specimen reacts with recombinant Chikungunya antigen conjugated colloid gold. The mixture migrates 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 colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

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

【PRECAUTIONS】

1. For *in vitro diagnostic* use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely before performing the test.
5. Bring all reagents to room temperature (15°C-30°C) before use.
6. Do not interchange the buffer and test cassettes of different lots.
7. Do not use hemolized blood specimen for testing.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch 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】

1. The HI-Quik Chikungunya IgG/IgM Rapid Card Test can be performed using serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Don't leave the specimens at room temp for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
4. 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.
5. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity.
6. If specimens are to be shipped, they should be packed in compliance with local regulations.

【MATERIALS 】 **Materials provided**

• Test cards • Sample droppers • Buffer • Package insert

Materials required but not provided

• Specimen collection contain • Centrifuge •Timer

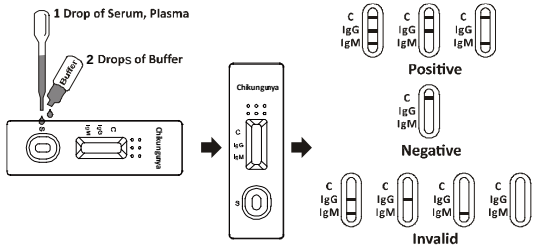
【DIRECTIONS FOR USE】

a. 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 assay is performed within one hour.

b. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (40µl) to the specimen well of the test cassette, then add 2 drops of buffer (80µl) ***** and start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.

c. Wait for the colored line(s) to appear. Read the result at 15 minutes, do not interpret the result after 20 minutes.

*** NOTE: It should be add one more drop of (approx. 40ul) buffer to the sample well of the test cassette if the specimen runs too slowly.**



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

IgG POSITIVE: Two distinct colored lines appear. One color line should be in the control region (C) and another color line should be in the IgG region.

IgM POSITIVE: Two distinct colored lines appear. One color line should be in the control region (C) and another color line should be in the IgM region.

IgG and IgM POSITIVE: Three distinct colored lines appear. One color line should be in the control region (C) and another two color lines should be in the IgG and IgM region.

NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of Chikungunya antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.

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

INVALID: Control line 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

【LIMITATIONS】

1. The Direction for Use and the Interpretation of Result must be closely when testing the presence of antibodies to Chikungunya in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HI-Quik Chikungunya IgG/IgM Rapid Card Test (Serum/Plasma) is limited to the qualitative detection of antibodies to Chikungunya in human serum or plasma. The intensity of the test band does not have linear correlation with 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 Chikungunya.
4. A negative result can occur if the quantity of 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.

【EXPECTED VALUES】

The HI-Quik Chikungunya IgG/IgM Rapid Card Test (Serum/Plasma) has been compared with a leading commercial Chikungunya ELISA test. The correlation between these two systems is over 96%

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

A total of 93 samples from susceptible subjects were tested by the HI-Quik Chikungunya IgG/IgM Rapid Test and by a commercial Chikungunya IgM EIA kit. Comparison for all subjects is shown in the following table.

IgM Results

Method		EIA		Total Result
Chikungunya IgG/IgM Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	65	0	65
	Negative	7	21	28
Total Result		72	21	93

Relative sensitivity: 90.3% (95%CI:*81.0%-96.0%)

Relative specificity: > 99.9% (95%CI:*86.7%-100%)

Accuracy: 92.5% (95%CI:*85.1%-96.9%) *Confidence Intervals

A total of 68 samples from susceptible subjects were tested by the HI-Quik Chikungunya IgG/IgM Rapid Card Test and by a commercial Chikungunya IgG EIA kit. Comparison for all subjects is shown in the following table.

IgG Results

Method		EIA		Total Result
Chikungunya IgG/IgM Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	33	1	34
	Negative	2	32	34
Total Result		35	33	68

Relative sensitivity:94.3% (95%CI:*80.8%-99.3%), Relative specificity: 97.0%(95%CI: *84.2%-99.9%), Accuracy: 95.6% (95%CI:*87.6%-99.1%) *Confidence Intervals

Precision

Intra-Assay: Within-run precision has been determined by using 20 replicates of three specimens: a negative, a Chikungunya IgM low titer positive, a Chikungunya IgM high titer positive, a Chikungunya IgG low titer positive and a Chikungunya IgG high titer positive. The negative, a Chikungunya IgM low titer positive, a Chikungunya IgM high titer positive, a Chikungunya IgG low titer positive and a Chikungunya IgG high titer positive values were correctly identified 100% of the time

Inter-Assay: Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a Chikungunya IgM low titer positive, a Chikungunya IgM high titer positive, a Chikungunya IgG low titer positive and a Chikungunya IgG high titer positive. Three different lots of the Chikungunya Rapid Card Test(Serum/Plasma) have been tested over a 3-month period using negative, a Chikungunya IgM low titer positive, a Chikungunya IgM high titer positive, a Chikungunya IgG low titer positive and a Chikungunya IgG high titer positive specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity: The Chikungunya IgG/IgM Rapid Card Test (Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances: The following potentially interfering substances were added to Chikungunya negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

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3. Myers RM and Carey DE. Concurrent isolation from patient of two arboviruses, Chikungunya and dengue type 2. Science 1967;157:1307-8.
4. 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.
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[Symbol Legends]

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
	Consult instruction for use		Do not re-use
	Do not use if package is damaged	Σ n	Contains sufficient for "n" tests
IVD	In vitro diagnostic device	REF	Catalog number
	Store at 2°c - 30°c	LOT	Batch code
	Date of manufacture		Manufacturer
	Use by (date or month of expiry)		

Manufactured by:

HELICO INTERNATIONAL

Plot # C-30, KSSIDC Industrial Area,

Doddaballapur - 561 203. Karnataka | India.

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