# *Advantage* Chikungunya IgM Card

CE

***Rapid Diagnostic Test For the Qualitative Detection of Chikungunya Specific IgM antibodies in Human Serum/Plasma***

## INTENDED USE

**ADVANTAGE CHIKUNGUNYA IgM CARD** is a visual, rapid, sensitive, qualitative immnunoassay for the detection of Chikungunya specific IgM antibodies in human serum or plasma.

## INTRODUCTION

**Chikungunya** virus (CHIKV) is an insect-borne virus, of the genus *Alphavirus*, that is transmitted to humans by virus-carrying *Aedes* mosquitoes. There have been recent breakouts of CHIKV associated with severe illness. CHIKV causes an illness with symptoms similar to dengue fever. CHIKV manifests itself with an acute febrile phase of the illness lasting only two to five days, followed by a prolonged arthralgic disease that affects the joints of the extremities. The pain associated with CHIKV infection of the joints persists for weeks or months, or in some cases years. As clinical symptoms & signs of this infection resemble those of many other infectious diseases including Dengue fever, clinical findings need to be confirmed by laboratory diagnostic techniques.

## PRINCIPLE (ANTIGEN-ANTIBODY REACTION)

**ADVANTAGE CHIKUNGUNYA IgM CARD** is one step immunochromatographic assay. The test sample is introduced to and flows laterally through an absorbent pad where it mixes with the conjugate. If the sample contains Chikungunya specific IgM antibodies, it forms a complex with the chikungunya antigen gold colloid conjugate. The complex then migrates through the nitrocellulose membrane by caplillary action. When the complex meets the line of immobilized Anti-human IgM antibodies (Test line, 'T'), it generates a pink purple line, indicating that the sample is reactive. To serve as a procedural control, an additional control line 'C' has been immobilized at a distance from the test line on the strip. If the test is performed correctly, this will result in the formation of a pinkish-purple line at the control region upon contact with the conjugate.

## MATERIAL PROVIDED

1. Advantage Chikungunya Card
2. Sample Dropper
3. Instruction Manual

## DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on J. Mitra diagnostic products and packing. These symbols are the most common ones appearing on medical devices and their packing. They are explained in more detail in the European Standard EN ISO 15223-1:2016.

| | | | |
|---|---|---|---|
| | Manufactured By | IVD | *In vitro* diagnostic medical device |
| Σ | No. of tests | | See Instruction for use |
| LOT | Lot Number Batch Number | 2°C 30°C | Temperature Limitation |
| | Manufacturing Date | | Caution, see instruction for use |
| | Expiry Date | REF | Catalogue Number |
| | Do not use if package is damaged | EC REP | Authorized Representative in the European Community |
| | Single use only | | Keep away from sunlight |
| | Keep Dry | | |

## KIT PRESENTATION

10 Test Pack & 25 Test Pack

## STORAGE AND SHELF LIFE

**ADVANTAGE CHIKUNGUNYA IgM CARD** kit should be stored at 2-30ºC in the cool and driest area available. Expiry date on the kit indicates that beyond which the kit should not be used. The kit should not be frozen and must be protected from exposure to humidity. Advantage Chikungunya Card should be used within one hour after removal from the foil pouch.

## WARNING FOR USERS

⚠ **CAUTION:** ALL THE SAMPLES TO BE TESTED SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION. NO TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT HUMAN BLOOD PRODUCTS WILL NOT TRANSMIT INFECTION.

1. The use of disposable gloves and proper biohazardous clothing is STRONGLY RECOMMENDED while running the test.
2. In case there is a cut or wound in hand, DO NOT PERFORM THE TEST.
3. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
4. Tests are for *in vitro* diagnostic use only and should be run by competent person only.
5. Do not pipette by mouth.
6. All materials used in the test and samples should be disposed off in accordance with established safety procedures/ guidelines.
7. Wash hands thoroughly with soap or any suitable detergent, after the use of the kit. Consult a physician immediately in case of accident or contact with eyes, in the event that contaminated material are ingested or come in contact with skin puncture or wounds.
8. Spills should be decontaminated promptly with Sodium Hypochlorite or any other suitable disinfectant.
9. Do not open the foil pouch to remove the product until it attains room temperature and you are ready to perform the test.

**Optimal test performance requires strict adherence to the test procedure described in the Instruction Manual.**

## PRECAUTIONS

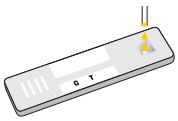
1. Do not reuse test card.
2. Do not use kit beyond the stated expiry date mentioned on the kit.
3. Interpret the results at the end of 15 minutes only.
4. Use a separate sample dropper for each sample and discard it as biohazardous waste.

## SPECIMEN COLLECTION & STORAGE

1. ADVANTAGE CHIKUNGUNYA IgM CARD test should be performed in human serum or plasma only immediately after collection.
2. If not tested immediately, specimen should be refrigerated at 2-8ºC for upto 24 hours following collection.
3. If testing within 24 hours is not possible, specimen should be frozen at -20ºC for 3 months or -70°C for longer period.
4. Specimen containing visible precipitates or cloudy specimens may give inconsistent test results. Such specimens should be clarified prior to testing by high speed centrifugation i.e. 10,000 rpm for 10 minutes before testing.
5. Haemolysed specimen or specimen with microbial contamination should be discarded and fresh aliquot should be collected.
6. Repeated freezing & thawing of the specimen should be avoided.

## TEST PROCEDURE

R.T. 20-30°



1. Bring the complete kit & sample to be tested to room temperature prior to testing. Once the pouch is opened, it should be used within one hour.
2. Remove the test card from the foil pouch prior to use.
3. Add 2 drops (70 $\mu$l) of serum/plasma sample using sample dropper into the sample well of the Test Card.
4. Allow reaction to occur during the next 15 minutes.
5. Read results at 15 minutes. Positive results may appear as early as 2-10 minutes. However, negative results must be confirmed after 15 minutes only.
6. Discard the Advantage Chikungunya Card immediately after reading result at 15 minutes, considering it to be potentially infectious.

## INTERPRETATION OF RESULT

### REACTIVE

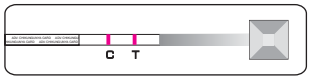



Fig. (a)

If two distinct pink lines; one at 'C' region and other at 'T' region appear, the test should be interpreted as reactive for Chikungunya IgM antibodies [as shown in Fig. (a)]. A difference of intensity in colour may occur between the test line and control line depending on the concentration of the Chikungunya specific IgM antibodies in the serum/ plasma but this does not affect the interpretation of the result.

### NON REACTIVE

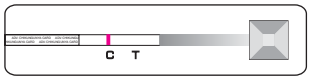



Fig. (b)

If only one distinct pink line appears at 'C' region [control line, as shown in Fig. (b)] the specimen is non-reactive for Chikungunya specific IgM antibodies.

### INVALID

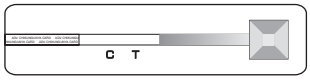



Fig. (c)

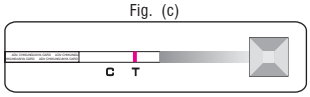



Fig. (d)

If neither control line nor test line or only test line shows up [as shown in Fig. (c) & (d)] the test is considered to be invalid, which may be because of the following reasons :

(1) Improper storage at temperature other than the recommended temperature.

(2) Wrong procedure

(3) Long atmospheric exposure of the test device after opening the pouch.

(4) Use of turbid/ lipemic/ haemolyzed sample.

**In case of invalid result, the test sample should be centrifuged at 10,000 rpm for 15 minutes and retest using new Card.**

## LIMITATIONS OF THE PROCEDURE

1. The ADVANTAGE CHIKUNGUNYA IgM CARD is for *in vitro* diagnostic use only.
2. The test is a qualitative screening assay and is not suggested for use in determining quantitative levels.
3. This is only a screening test. All samples detected reactive must be confirmed by using confirmatory test. Therefore for definitive diagnosis, the patient's clinical history, symptomatology as well as serological data, should be considered.
4. If Advantage Chikungunya IgM Card test is non-reactive and clinical symptoms persist, the test should be repeated with a second sample collected at a later date.
5. False positive results can be obtained due to cross reaction with Epstein-BARR virus, Influenza A & B, Brucella, Dengue Virus. This occurs in less then 1% of the sample tested.

## PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups. Based on test panel of 2,000 plasma and serum samples, following is the sensitivity & specificity:

(i) SENSITIVITY: **97.5%**

(ii) SPECIFICITY: **99.1%**

**Precision:** Within-run and between-run precisions have been determined by testing 10 replicates of eight specimens : four negative, four positive (two weak, a medium and a strong positive). The C.V.(%) of negative and positive positive samples were within 10% of time.

## LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an *in-vitro* diagnostic assay within the limitations and specifications as described in the product instruction-manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to for claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

## BIBLIOGRAPHY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*in vitro* diagnostic Reagent, not for medicinal use

VER-02 R-02


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