

Chikungunya IgM

(One Step Detection Kit for Chikungunya IgM)

EXPLANATION OF THE TEST

Chikungunya fever is a viral disease transmitted through the bite of Infected *Aedes aegypti* and *Aedes albopictus* mosquitoes. Its Symptoms are a fever frequently accompanied by joint pain, muscle pain, headache, nausea, fatigue and rash.

Angcard Chikungunya IgM is a chromatographic immunoassay kit for rapid and qualitative detection of chikungunya IgM antibodies in serum, plasma and whole blood from human. The nitrocellulose membrane of the test is immobilized with the recombinant chikungunya antigen. And also anti human IgM monoclonal antibody is conjugated to 40nm of colloidal gold particles. This conjugate is placed on polyester or glass pad as conjugated pad. When the sample is dropped into the sample well on the device, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the recombinant antigen that immobilized onto the nitrocellulose. If the sample contains IgM antibodies chikungunya, the result is visible within 10 minutes in the form of a red line that develops on the membrane. The solution continuous to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.

MATERIALS PROVIDED

Angcard chikungunya IgM kit contains the following components:

1. Test device individually, desiccant & dropper.
2. Instruction manual for use

PRECAUTIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the specimens and kits properly after test, in accordance with GLP.

SPECIMEN COLLECTION AND STORAGE

1. Specimen to be tested should be obtained and handled by standard methods for their collections.

- A. Serum: allow the blood to clot, then centrifuge to separate the serum.
 - B. Plasma: collect the whole blood into the tube contained anti-coagulants such as heparin, citrate or EDTA. Centrifuge the blood and separate the plasma.
 - C. Whole blood: whole blood should be collected over heparin, citrate or EDTA. Mix the blood by inversion and use it to the test.
2. All specimens should be tested as soon early they are prepared. If necessary, they may be stored at 2-8 °C for up to 24 hours or at -20 °C for longer periods.

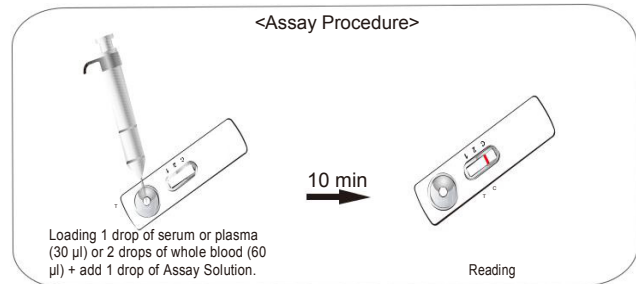
TEST PROCEDURE

Read the instruction for use with care before running a test.

- (1) Place all specimens, test devices, and Assay Solution and allow them to room temperature prior to testing. (15 – 30 min).
- (2) Prepare the test device as you need, and then mark the patient ID on to the device. Please perform the test immediately after removing the device from foil pouch.
- (3) Load 1 drop (30 µl) of serum/plasma or 2 drops (60 µl) of whole blood into the sample well (S) in the test device.
- (4) Hold the dropping bottle vertically, and add 1 drops (30 µl) of Assay Solution into the sample well (S) of the test device.
- (5) After 10 minute interpret the results.

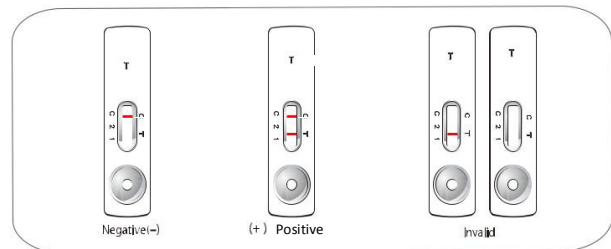
STORAGE & EXPIRATION

1. Angcard chikungunya IgM rapid kit should be stored between 2 to 30 °C (36 - 86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.



INTERPRETATION OF THE RESULTS











1. Negative result: Only one band in the control line (C)
2. Positive result: Two bands are appear in the test line (T) and control line (C).
3. Invalid result: If at 10 minutes the red color band does not appear in the control line (C) even if any shade of pink to red test line (T) appears the result is considered invalid. If the test is invalid a new test should be performed with a new patient sample and a new test device.



LIMITATIONS OF THE TEST

Angcard chikungunya IgM is designed for primary screening test. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view.

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 4-30°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by