

In vitro Diagnostics

INTENDED USE

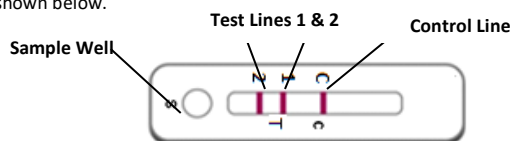
The Sensit Chikungunya IgG/ IgM antibody Rapid Test is a lateral flow immunoassay for the qualitative detection of IgG and IgM antibodies against Chikungunya in whole blood, plasma or serum. This test is intended to be used as a screening test and as an aid in the diagnosis of Chikungunya infection. Any reactive specimen with the Sensit Chikungunya antibody Rapid Test must be confirmed with alternative testing methods.

SUMMARY & TEST DESCRIPTION

Chikungunya is a viral disease transmitted to humans by infected mosquitoes. It is an RNA virus that belongs to the alpha virus genus of the family Togaviridae. Chikungunya is characterized by an abrupt onset of fever frequently accompanied by joint pain. Other common signs and symptoms include muscle pain, headache, nausea, fatigue and rash. The joint pain is often very debilitating, but usually lasts for a few days or may be prolonged to weeks. Sensit Chikungunya IgM/ IgG antibody Rapid Test is for the qualitative determination of IgM and IgG antibodies developed during Chikungunya infection.

TEST PRINCIPLE

Sensit Chikungunya IgG/ IgM antibody Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad which contains Chikungunya Recombinant Antigen, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines; T2: Antihuman IgM, T1: Antihuman IgG Control Line; C:Goat anti mouse which are housed in a test device as shown below.



Test sample that is added to the sample well (S), with adequate amount of assay diluent migrates from the sample pad along the conjugate pad. Chikungunya IgG/IgM antibodies if present in the sample will bind to Colloidal Gold conjugate bound antigen to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized antibodies to human IgG and IgM (on test lines 1 & 2 respectively) producing a visible line on the membrane. If the respective analyte is not present in the sample, no reaction occurs in the respective capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane as control line C irrespective of the presence of IgM and IgG antibodies against Chikungunya virus in the sample. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

- Each Kit contains 30 test devices, each sealed in a foil pouch containing following items:
 - One Test card
 - Dropper
 - Desiccant
- Assay Diluent- In dropper bottle
- Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

- Use within 10 minutes after opening pouch.
- Do not touch result window.
- Use only the buffer supplied along with the kit.
- Do not mix components from different kits.
- Do not reuse the test device; each test can be used ONLY SINGLE TIME.
- Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

- Blood Specimen:** Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- Serum:** Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

- If the specimen is not used for testing immediately, it should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

- Take out the test device from the foil pouch and place it on a horizontal surface.
- Sample Addition**
 - Serum/Plasma:** Add 10µl of serum or plasma to the Sample well "S" using the dropper provided. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample well directly from the dropper bottle.
 - Whole Blood:** Add 10 µl of whole blood to the Sample well "S" using the dropper provided. **(To take 10 µl, aspirate only up to the bubble point in the dropper provided. (Refer Diagram .1.)** When the sample is fully absorbed, add two drops of the diluent provided with the assay to the Sample well "S" directly from the dropper bottle.
- Wait for 10-15 minutes and interpret results. All results where control band does not appear are considered invalid.

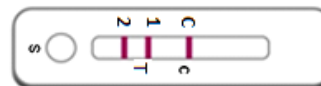
Diagram. 1



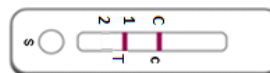
INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS C, 1 & 2 ON THE DEVICE AS SHOWN BELOW.)

Positive for IgM and IgG antibodies in sample: Pink Color bands at position C, 1 & 2



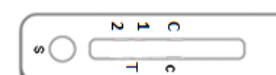
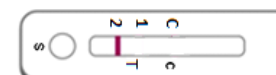
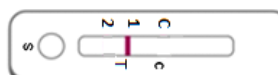
IgM Negative and IgG Positive:
Color bands at position 1 and C



IgG Negative and IgM Positive:
Color bands at position 2 and C



Invalid: Color band at C does not appear



- Rao T R, Carey D E, Pavri K M. preliminary isolation and identification of Chikungunya virus from cases of dengue – like illness in madras city. Indian J Med Res. 1965 Aug, 53(8)
- <http://www.who.int/mediacentre/factsheets/fs327/en/>.

Product Disclaimer:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the use of this product occurs outside of the control of the manufacturer and distributor and the result may accordingly be affected by environmental factors and / or user error. The result should be further confirmed by consulting a doctor.

Warning: The manufacturer and distributors of this product shall not be liable for any losses, for any liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis whether positive or negative, in the use of this product.]

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