

CHIKUNGUNYA IgG SPOT TEST

A Rapid test for the detection of IgG antibodies to chikungunya in human serum / plasma

INTENDED USE : Chikungunya IgG Spot Test is an immuno concentration based assay for the detection of IgG antibodies to chikungunya in human serum or plasma.

INTRODUCTION : Chikungunya is a relatively rare form of viral fever caused by an alphavirus that is spread by mosquito bites from the *Aedes aegypti* mosquitos. Major symptoms include flu, high fever, severe back pain, joint pain (sometimes for months), rash on the trunk and limbs, vomiting and mild hemorrhaging (in children). Diagnosis can be done based on the presence of Chikungunya antigen or antibodies to Chikungunya, in the sample.

PRINCIPLE : Chikungunya is diagnosed based on IgG captured immunoassay utilizing recombinant antigens (E1 and E2) derived from its structural proteins, which are immobilized on a nitrocellulose membrane. As the sample passes through the membrane, if Chikungunya IgG is present, that will bind to immobilized antigens. The bound IgG is visualized by reacting with anti-human IgG gold conjugate, which gives distinct red spot against white background. Proper test performance is verified by the appearance of a spot next to C produced by binding of anti human IgG gold to the control antibody immobilized next to C.

STORAGE : The Reagent box has to be stored at 2 - 8°C. DO NOT FREEZE. Other contents of the kit to be stored at room temperature (25 - 30°C). Reagents must be brought to room temperature prior to use.

When not in use return the Reagent Box to 2 - 8°C.

PACK SIZE : Available in packs of 10 test.

CONTENTS OF THE KIT :

1 Test Device	10 Units
2 Buffer Solution (Ready to use)	6.0 ml
3 Gold Conjugate (Ready to use)	1 x 1.5 ml
4 Droppers	10 Units

WARNINGS :

1. For in vitro diagnostic use only.
2. Wear disposable latex gloves while handling specimens and kit reagents.
3. After the test, wash hands carefully.
4. Reagents to be stored between +2°C and +8°C.
5. Prewarm all reagents to 25±5°C before use.
6. The expiration date is printed on each component and on the package.
7. Do not expose the conjugate to excessive light and high temperature.
8. Once opened, the components must be closed tightly.

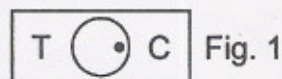
SPECIMEN : Fresh Serum or Plasma can be used.

ASSAY PROCEDURE : Gold Conjugate is stable for 18 months, when stored at 2-8°C and should be avoided repeated exposure to room temperature for long time.

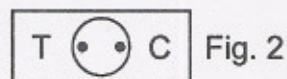
- 1 Bring all the reagents and specimens to room temperature (25-30°C)
- 2 Add 2 drops of buffer solution to the test device.
- 3 Add 1 drop of serum/plasma.
- 4 Add 4 drops of buffer solution.
- 5 Add 2 drops of gold conjugate.
- 6 Add 4 drops of buffer solution and read the result.
- 7 Read the result immediately. Do not read after 5 minutes. Hold the dropper vertically and ensure free falling of drops. At each step allow the solution to drain through the membrane before adding the next solution.

INTERPRETATION OF RESULTS :

1. Negative Result : If only one red spot (control spot) appears as shown in Fig 1, the specimen does not contain IgG antibodies to Chikungunya.



2. Positive Result : If two red spots (control spot and test spot) appear as shown in Fig 2, the specimen is reactive for IgG antibodies Chikungunya.



3. Invalid Test : If neither of the spot appears or only test spot appears after the test is complete, as shown in Fig 3 & Fig. 4 the test has been performed incorrectly. Repeat the test with new device.

