CHIKUNGUNYA IgM ANTIBODY TEST DEVICE

(Serum, Plasma)

A Rapid and sensitive test for the qualitative detection of Chikungunya IgM in human faeces.
Only for *In vitro diagnostic* use

CLINICAL SIGNIFICANCE

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 posure 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.
The symptoms are most often clinically indistinguishable from those observed in dengue fever. Indeed, dual infection of dengue and Chikungunya has been reported in India. 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.
The Chikungunya IgM Combo Rapid Test utilizes recombinant antigens derived from its structure protein, it detects IgM anti-CHIK in patient serum or plasma within 15 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Chikungunya IgM Antibody Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing CHIK antigens conjugated with colloid gold (CHIK conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with anti-human IgM reagent, and the C band is pre-coated with goat anti-rabbit IgG.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The IgM antibody to CHIK, if present in the specimen will bind to the CHIK conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM reagent, forming a burgundy colored T band, indicating a CHIK IgM positive test result.
Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG*/*rabbit IgG-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and product insert.

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (4-30°C). The test device must remain in the sealed pouch until use. Do not freeze.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
Plasma & Serum
1. Collect whole blood into an appropriate blood collection tube with or without anticoagulant (EDTA, citrate or heparin) for plasma or serum respectively.
2. Separate plasma or serum by centrifugation.
3. Carefully withdraw the plasma or serum, label and store in at 2-8°C for upto two weeks. Those may be stable upto one year, if store at -20°C.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after expiration date.
3. The test should remain in the sealed pouch until use.
4. Do not use the test if pouch is damaged.
5. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
6. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. The test should be discarded in a proper biohazard container after testing.
8. The test must be carried out within 2 hours of opening the sealed bag.

DIRECTIONS FOR USE

1. Allow all kit components and specimen to room temperature prior to testing.
2. Remove the test device from the foil pouch, and place it on a flat, dry surface.
   [Serum or Plasma]
   - Hold the dropper vertically, draw sample. And then add **1 drop** (about 20 µl) of serum or plasma into the sample well (S) of the test device.
   - Add 1 drop of assay buffer into the sample well(S).
     Interpret test results at 10 minutes.

Caution: Do not read test results after 20 minutes. Reading too late can give false results.

INTERPRETATION OF THE RESULTS

POSITIVE: The presence of two bands (“T” and “C”) within the result window, no matter which band appears first indicates a positive result.

NEGATIVE: The presence of only one band (“C”) within the result window indicates a negative result.

INVALID: If the purple color band is not visible or only test line (“T”) is visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

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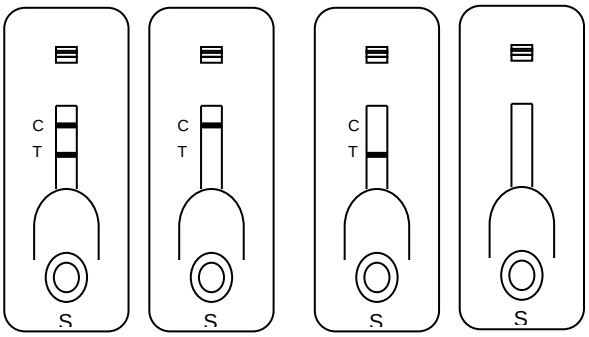
(Serum, Plasma)



Positive Negative Invalid

LIMITATIONS

1. This test detects the presence of IgM antibodies to Chikungunya in the specimen and should not be used as the sole criterion for the diagnosis of Chikungunya.
2. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. Also a negative results does not preclude the possibility of an infection of Chikungunya.

BIBLIOGRAPHY

1. Sam IC, AbuBakar S. Chikungunya virus infection. Med J Malaysia. 2006 Jun;61(2):264-9.
2. Pialoux G, Gaüzère BA, Strobel M. Chikungunya virus infection: Med Mal Infect. 2006 May;36(5):253-63.4.
3. Kamath S, Das AK, Parikh FS. Chikungunya. J Assoc Physicians India. 2006 Sep;54:725-6
4. Rao TR, Carey DE, Pavri KM. Preliminary isolation and identification of chikungunya virus from cases of dengue-like illness in Madras city. Indian J Med Res. 1965 Aug;53(8):689-93

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