Chikungunya IgM Rapid Test (Serum/Plasma/Whole Blood)

INTENDED USE

The Chikungunya IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgM anti-Chikungunya virus (CHIK) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with CHIK. This test provides only a preliminary test result. Therefore, reference test, ELISA, PCR must be used in order to obtain a confirmation of Chikungunya infection.

SUMMARY AND EXPLANATION OF THE TEST

The Chikungunya virus (CHIKV) is an enveloped, positive strand, RNA virus belonging to family Togaviridae with genus Alphavirus, first identified in 1953. CHIK virus is transmitted to humans by the bite of a variety of mosquitoes including Aedes aegypti, Aedes albopictus, Aedes africanus, Ae. luteocephalus, Ae. furcifer and Ae. taylori. CHIKV has caused outbreaks in East Africa (Tanzania and Uganda), in Austral Africa (Zimbabwe and South Africa), in West Africa (Senegal and Nigeria), and in Central Africa (Central African Republic and Democratic Republic of the Congo). In Asia, CHIKV outbreaks have been reported in India, Sri Lanka, Myanmar, Thailand, Indonesia, the Philippines, Cambodia, Vietnam, Hong Kong and Malaysia. Symptoms of sudden onset of fever, chills, headache, nausea, vomiting, joint pain with or without swelling, low back pain, and rash are very similar to those of dengue. Both diseases are transmitted by the same species of the mosquitoes Aedes aegypti and Aedes albopictus and mixed outbreak of chikungunya, with sporadic cases of dengue has been reported in Andhra Pradesh state, India. However, unlike dengue, there is no hemorrhagic or shock syndrome form. Therefore, the ability to distinguish CHIKV infection from dengue virus infection would be extremely beneficial, particularly in areas where dengue virus infection is endemic or epidemic.

The Chikungunya IgM Rapid Test Cassette utilizes recombinant antigens derived from its structure protein, it detects IgM anti-CHIK in patient serum or plasma or whole blood within 15 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

TEST PRINCIPLE

The Chikungunya IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing CHIK antigens conjugated with colloidal 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 sample 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 rejected with another device.

REAGENTS AND MATERIALS PROVIDED

1. Chikungunya IgM tests
2. Pipette dropper
3. Desiccant
4. Sample diluent
5. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARRANTS AND PRECAUTIONS

1. For in vitro diagnostic use only. DO NOT RE-USE test device.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. The instruction must be followed exactly to get accurate results.

REAGENT PREPARATION AND STORAGE

All reagents are ready to use as supplied. Store unused test device unopened at 2°C–8°C. If stored at 2°C–8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

1. The Chikungunya IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
2. To collect Fingerstick Whole Blood specimens:
   - Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
   - Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
     - Touch the end of the capillary tube to the blood until filled to approximately 50 μL. Avoid air bubbles.
     - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
     - Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
       - Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device.
       - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient’s finger so that the hung drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2°C–8°C for up to 3 days. For long term storage, specimens should be kept below -20°C whole blood collected by venipuncture should be stored at 2°C–8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Fresh specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE

Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30μL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40μL) and start the timer. See illustration below.

For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50μL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40μL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 μL) to fall into the center of the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF ASSAY RESULT

(Please refer to the illustration above)

1. NEGATIVE RESULT: If only the C band is developed, the test indicates that no detectable IgM anti-CHIK is present in the specimen. The result is negative.

2. POSITIVE RESULT: If both C and T bands are developed, the test indicates the presence of IgM anti-CHIK in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. INVALID: If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line and reference failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS OF THE TEST

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, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

3. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. Also a negative result does not preclude the possibility of an infection of Chikungunya.

REFERENCES


INDEX OF SYMBOLS

- Consult instruction for use
- Tests per lot
- Authorized Representative
- Storage between 2-30°C
- Lot number
- Catalog#