One Step IgM Antibodies to Chikungunya virus Test

SD BIO LINE Chikungunya IgM

Explanation of the test

[INTRODUCTION]

The Chikungunya virus(CHIKV) is an enveloped, positive strand, RNA virus belonging to family Togaviridae with genus Alphavirus, first identified in 1953. CHIK fever is transmitted to humans by the bite of a variety of mosquitoes including *Ae. aegypti*, *Ae. 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 mosquitos Aedes aegypti and Ae. 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.

[INTENDED USE]

SD BIOLINE Chikungunya IgM test is solid phase immunochromatographic assay for rapid, qualitative detection of IgM antibodies to Chikungunya in human serum, plasma or whole blood. This test is intended for professional use as an aid in the clinical laboratory diagnosis of patients with clinical symptoms consistent with chikungunya. 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.

[PRINCIPLE]

The SD BIOLINE Chikungunya IgM (CHIK IgM) test have 2 pre-coated lines, "T" (Chikungunya recombinant structural protein), and "C" (Goat anti-mouse IgG) on the surface of the device. These lines in result window are not visible before applying any samples. The monoclonal anti-human IgM is conjugated with colloidal gold. The gold colloid will react specially with IgM antibodies to Chikungunya in human serum, plasma or whole blood. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple "T" line will be visible in the result window if there are enough IgM antibodies to Chikungunya in the sample. If IgM antibodies to Chikungunya are not present in the sample, there in no color appears in "T".

Materials provided/ Active ingredients of main components

1. SD BIOLINE Chikungunya IgM kit contains the following items to perform the assay.
- Test devices individually foil pouched with a desiccant
- Assay diluent
- Disposable droppers
- Instruction for use
2. Active ingredients of main components
- 1 test device included : Gold conjugates (as main component) : Mouse monoclonal anti-human IgM – gold colloid (1±0.2μg), Test Line (as main component) : Recombinant Chikungunya structural protein (5 ±1μg), Control Line (as main component) : Goat anti-mouse IgG (2.5±0.5μg)

Kit Storage and Stability

1. The SD BIOLINE Chikungunya IgM test should be stored at 1~30℃.
2. The test device is sensitive to humidity and as well as to heat.
3. Perform the test immediately after removing the test strip from the foil pouch.
4. Do not use it beyond the expiration.

Specimen Collection, Storage and Precaution

1. **Whole blood**
- Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
- If blood specimens are not immediately tested, they should be refrigerated at 2~8℃.
- When stored at 2~8℃, the blood specimens should be used within 3 days.
- For storage period longer than 3 days, freezing is recommended. They should be brought to room temperature prior to use.
- Using the blood specimens in the long-term keeping more than 3 days can cause non-specific reaction.

2. **Plasma or Serum**
- [Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
- [Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- If plasma or serum specimens are not tested immediately, they should be refrigerated at 2~8℃. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.
- Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

3. **Precaution**
- Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
- As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.
- Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

Warnings

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. Check the desiccant for color change of the humidity indicator and to throw away the pouch if the color indicates saturation.
9. The instruction must be followed exactly to get accurate results.

Procedure of the test

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 50μl) of serum or plasma into the sample well (S) of the test device.
- Add 1 drop of assay diluent into the sample well (S).
Or,
[Whole blood]
- Hold the dropper vertically, draw sample. And then add **2 drops** (about 100μl) of whole blood into the sample well (S) of the test device.
3. Interpret test results at 10 minutes.
Caution : Do not read test results after 10 minutes. Reading too late can give false results

Interpretation of the test (Refer to figure)

1. **Negative result**
The presence of only one band ("C") within the result window indicates a negative result.
2. **Positive result**
The presence of two bands ("T" and "C") within the result window, no matter which band appears first indicates a positive result.
3. **Invalid result**
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.

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, 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.

Internal Quality Control

The SD BIOLINE Chikungunya IgM test device has "Test line" and "Control Line" on the surface of the cassette. Both the Test line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. The control line of the RDT only shows that the diluent has been applied successfully, and that the active ingredients of main components on the strip was still functional, but is not a guarantee that the sample has been properly applied and does not represent a positive sample control.

Performance characteristics

The performance of SD BIOLINE Chikungunya IgM was evaluated with commercial CHIK IgM capture ELISA and Rapid test. We used 137 samples for positive and 270 samples for negative. We found the relative sensitivity is 97.1% (133/137), the relative specificity is 98.9% (267/270). The results are summarized in the following tables.

			SD CHIK IgM		Company " C "	
			POS	NEG	POS	NEG
IgM capture ELISA	POS	137	133	4	110	27
	NEG	270	3	267	5	265
			97.1% (133/137)	98.9% (267/270)	80.3% (110/137)	98.1% (265/270)
			Sensitivity	Specificity	Sensitivity	Specificity

Bibliography of suggested reading

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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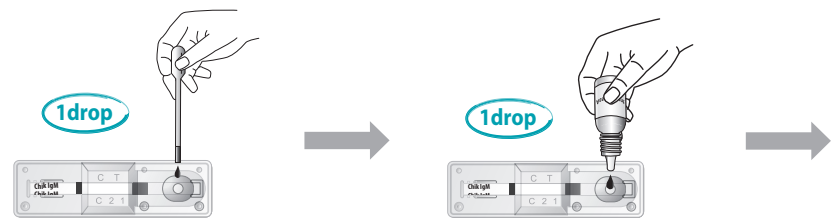
Test Procedure

[Serum or Plasma]

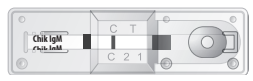


[Whole Blood]

Interprete test results at 10 minutes.

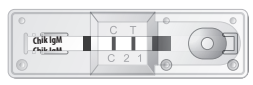
Interpretation

Negative



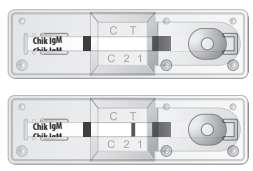
The presence of only color line within the result window indicates a negative result.

Positive



The presence of two color lines ("T" and "C") within the result window, no matter which line appears first, indicates a positive result.

Invalid



- No control (C) line in result window.
- It is recommended that the specimen br re-tested.