CHIKUNGUNYA ANTIBODY CARD (IgG/IgM) IMMUNOPAK

(Whole Blood/Serum/Plasma)

Last update 10-2020

Ref. RDT-CHI.115, 10 Test
RDT-CHI.115U, 25 Test

INTENDED USE

The Chikungunya IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG/IgM anti-chikungunya virus (CHIK) antibodies in human serum/plasma or whole blood.

INTRODUCTION

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 posture 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 IgG/IgM Rapid Test utilizes recombinant antigens derived from its structure protein, it detects IgG/IgM anti-CHIK antibodies in patient serum/plasma or whole blood within 15 minutes.

PRINCIPLE

Chikungunya IgG/IgM test device has 3 pre-coated lines, "G" (Chikungunya IgG Test Line), "M" (Chikungunya IgM Test Line) and "C" (Control Line) on the nitrocellulose membrane. CHIK-specific antigen complexed with gold conjugate) and rabbit IgG-gold conjugates are placed in the conjugate pad and anti-human lgG and anti-human lgM are immobilized on the membrane.

When chikungunya antibody-positive specimen is loaded into sample well, the antibodies are reacted with CHIK-specific antigen-gold complex moves laterally on the membrane by capillary action. The antibody-antigen gold conjugate complex are captured by the immobilized anti-human antibodies to make visible pink-purple line in the test region. To serve as a procedural control, an additional line of Goat anti-rabbit IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with rabbit IgG gold conjugate as a control line.

PRESENTATION

	10 Test	25 Test
Chikungunya Antibody Test Cards	10 Cards	25 Cards
Assay Buffer	1 bottle	1 bottle

PRECAUTION

1. For professional in vitro diagnostic use only.
2. Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Read the entire procedure carefully prior to performing any tests.
5. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Humidity and temperature can adversely affect results.
7. The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

Chikungunya IgG/IgM test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND STORAGE

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

- **Whole blood** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
- **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 or supernatant.
- **Plasma** Collect the whole blood into the collection tube (containing anticoagulant such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

TEST PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

3. Be sure to label the device with specimen's ID number.
4. Holding the dropper vertically, add 1 drop (about 25 µl) of specimen **(W.B./Serum/Plasma)** into sample well making sure that there are no air bubbles. Then add 2 drops (about 70-100µl) of assay buffer immediately.
5. Results can be read in 15 minutes. Positive results can be visible in as short as 5 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result

INTERPRETATION OF RESULTS

- **Negative**

The control line is only visible on the test device. No anti-CHIK antibody is detected in the specimen. The result is negative.

- **IgM Positive**

The control line (C) and IgM line (M) are visible on the test device. The test indicated for the presence of anti-CHIK IgM in the specimen. The result is IgM positive.

- **IgG Positive**

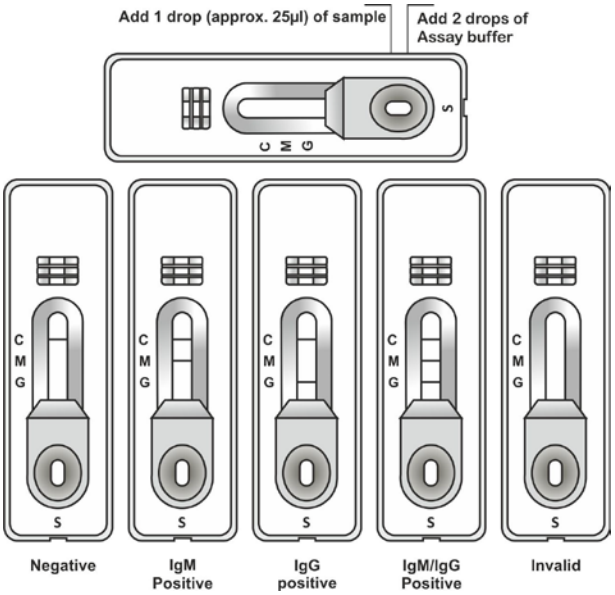
The control line (C) and IgG line (G) are visible on the test device. The test indicated for the presence of anti-CHIK IgG in the specimen. The result is IgG positive.

- **IgM and IgG Positive**

The control line (C), IgM and IgG are visible on the test device. The test indicated for the presence of anti-CHIK IgM and IgG in the specimen. The result is both IgM and IgG positive.

- **Invalid**

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be reason for control line failure. Repeat the test using a new test device.



LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of IgG/IgM anti-CHIK in serum/plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Chikungunya IgG/IgM Rapid Test is limited to the qualitative detection of IgG/IgM anti-CHIK in human serum/plasma or whole blood. The intensity of the test band does not have the linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable IgG/IgM anti-CHIK. However, a negative test result does not preclude the possibility of exposure to or infection with CHIK.
4. A negative result can occur if the quantity of IgG/IgM anti-CHIK present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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