Chikungunya Antigen Rapid Test Kit

Instructions for Use

RNS92326

FOR PROFESSIONAL USE ONLY

Intended Use

This kit is a rapid, serological, lateral flow chromatographic immunoassay for the qualitative detection of Chikungunya Virus (CHIK) E1 protein antigen in human whole blood , serum, or plasma specimens to aid in the diagnosis of infection with CHIK. The test only provides preliminary analysis results but not critical diagnosis criteria. Any reactive specimen with the Chikungunya Antigen Rapid Test must be analyzed and confirmed with alternative testing method(s) and clinical findings. The test is intended for healthcare professional use.

Principle

The Chikungunya Antigen Rapid Test Kit is a qualitative membrane-based immunoassay for the detection of chikungunya virus E1 protein antigen in human whole blood , serum, or plasma specimens. The test device consists of: 1) a burgundy-colored conjugate pad containing mouse anti-Chikungunya E1 antigen conjugated with colloid gold (Chikungunya Ab conjugates), 2) a nitrocellulose membrane strip containing a test line region (T) and a control line region (C). The test line region (T) is pre-coated with rabbit anti-Chikungunya E1 antigen, and the control line region (C) is pre-coated with goat anti-mouse IgG antibody. When an adequate volume of specimen is added to the specimen well (S) of the device, the specimen migrates by capillary action across the device and interacts with the immobilized antibodies. If the specimen contains sufficient chikungunya virus E1 protein antigen, the specimen will bind to the Chikungunya Ab conjugates. The immunocomplex will be then captured on the membrane by the precoated rabbit anti-Chikungunya E1 antibody, forming a burgundy-colored line in the test line region (T), indicating a Chikungunya Ag positive result. Absence of test line (T) suggests a negative result.

An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines,regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.

Storage and Stability

- Store the test kit between 2°C~30°C in a place out of direct sunlight, product expiration date 24 months.
- After the foil pouch is opened, the test card should be used as soon as possible within 1 hour.

Components

- Test Card
- Sample Diluent Buffer
- Sterile Lancets
- Dropper
- Alcohol Pad
- Instructions for Use

Precautions

- This kit is a disposable in vitro diagnostic reagent, please do not reuse, and do not use expired products.
- The aluminum foil pouch contains a desiccant and should not be taken internally.
- Fresh samples are recommended.
- Components in different lot kits should not be cross-used to avoid erroneous results.
- The temperature of the experimental environment should be avoided from being too high, and the test card should be restored to room temperature before opening it to avoid moisture absorption.
- After the test, the used test card, sample diluent, straw, etc. will be disposed of as biomedical waste.
- Please pay attention to safety measures during operation, such as wearing protective clothing and gloves.
- As with all diagnostic reagents, the final diagnosis should be made by the physician after taking into account the various test indicators and clinical symptoms.

Sample Collection and Preparation

1. Whole blood samples collection: Fingertip or venous blood was collected using anticoagulant tubes or blood collection tubes pre-added with anticoagulant (heparin, EDTA, sodium citrate and other anticoagulants are recommended), and then shaken for later use. The sample should be used as soon as possible after collection: If it cannot be tested immediately, the sample can be refrigerated at 2-8℃, and the whole blood sample should be tested within 3 days.
2. Serum/plasma sample collection: Venous blood is collected, after blood coagulation, the supernatant is drawn directly or after centrifugation, which is the serum. Blood is collected with a collection tube or anticoagulant tube added with anticoagulant (it is recommended to use heparin, EDTA, sodium citrate, etc.), and the upper layer of light yellow clear liquid is taken after centrifugation or resting, which is the plasma sample. If the serum/plasma samples cannot be

tested in time, they should be refrigerated at 2-8 ° C for two weeks. If long-term storage is required, they should be refrigerated at -20 ° C and returned to room temperature before testing.

3. Note: A high concentration of jaundice samples (the visual appearance of the sample solution is yellow), a high hemolysis sample (free hemoglobin concentration >9g/L), or a visually visible chylous sample will interfere with the interpretation of the test results, so attention should be paid to the appearance of the sample before using the sample.

Test Procedure

Before conducting the test, please read the user manual completely. Before use, restore the test card and samples to room temperature and number them.

1. Take the test card out of the packaging bag and use it within one hour.

2. Place the test card on a clean, level table, and mark it.

3. Test the collected whole blood, serum and plasma: Use a dropper to draw the sample and add 1 drop into the sample well of the test card. Then, drop 2 drops sample diluent buffer into the sample well. Start timing.

4. Test for fingertip blood: First, wipe the fingertip with the alcohol pad. Then, place a sterile lancets against the fingertip and press it down slightly with force. Squeeze out a drop of fingertip blood and draw it with a dropper. Add 1 drop into the sample well of the test card. Next, drop 2 drops sample diluent buffer into the sample well. Start timing.

5. The final result should be read within 10 minutes. The result read after 20 minutes has no clinical significance.

Interpretation of Results

Positive: Two red lines, that is, one red reaction line in the detection area (T) and one in the quality control area (C).

Negative: One red line, that is, a red response line appears only in the quality control area (C).

Invalid: No red reaction line appears in the quality control area (C). The test is invalid, it is recommended to re-test with a new test card at this time, especially pay attention to whether the added sample is enough.

Limitations

1. This kit is only for the qualitative detection of Chikungunya virus antigen in samples.

2. A negative result will occur when the Chikungunya virus antigen in the test sample is below the minimum detection limit or is absent at some stage of infection. A negative result does not rule out the possibility of recent infection.

3. The test results of this product are for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with their symptoms/signs, medical history, other laboratory tests, treatment response and epidemiological information.

Performance Index

1. Sensitivity: The minimum detection limit of the kit is not higher than the standard.

2. Cross reaction: No cross reaction with measles, rubella, influenza A, typhoid fever, leptospirosis, septicemia, epidemic cerebrospinal meningitis, hemorrhagic fever with renal syndrome, hepatitis B virus, hepatitis C virus samples. High concentrations of rheumatoid factor or heterophile antibodies may lead to false positives.

3. The kit can be used to detection human serum, plasma and whole blood samples, and the results are consistent.

INDEX OF SYMBOLS

Symbol			
Symbol	**Meaning**	**Symbol**	**Meaning**
IVD	In Vitro Diagnostic Medical Device		Storage Temperature Limit
	Manufacturer	EC REP	Authorized Representative In The European Community
	Date of Manufacture		Use By Date
	Do Not Reuse		Consult Instruction For Use
LOT	Batch Code	CE	CE Conformity Marking

Shenzhen Reagent Technology Co., Ltd.
Room 801, Building No.2, YESUN INTELLIGENT COMMUNITY I, No.1301-72, Guanguang Road, Xinlan Community, Guanlan Street, Longhua District, Shenzhen City,Guangdong Province,China

EC REP
CMC Medical Devices & Drugs S.L
C/Horacio Lengo No.18
29006, Malaga, Spain
+34 951214054
Info@cmcmedicaldevices.com

Rev. A1

Rel. 2025/08/02