PATHKITS

SIMPLE Chikungunya IgG/IgM

Product Code: **PKRK026**
Kit Contents (**25 Kits**)
Shelf Life: 24 Months

Kit Components	Quantity (Units)
Test Strip	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

Chikungunya virus is a mosquito-transmitted *alpha virus* belonging to the *Togaviridae* family, first isolated in Tanzania in 1952. Three lineages with distinct genotypic and antigenic characteristics have been identified. Chikungunya virus is endemic to some parts of Africa and causes recurrent epidemic waves in Asia and the Indian subcontinent. At the end of 2013 the virus emerged in the Americas (1). Human beings serve as the main Chikungunya virus reservoir during epidemic periods. In Africa, some animals constitute the virus reservoir during non-epidemic periods sustaining virus circulation. Clinical signs of Chikungunya virus infection include sudden onset fever and severe arthralgia (joint pain) affecting mainly the extremities but also the larger joints. Erratic, relapsing, and incapacitating joint pain is the hallmark of Chikungunya virus. Up to 12% of patients still have chronic joint pain three years after the onset of their illness (2). Other symptoms of the infection (headache, fatigue and rash) are common among many arboviral infections including Chikungunya virus. There is no specific therapy for Chikungunya virus infection. Patients are symptomatically treated with anti-inflammatory medication. The death rate is not high, but excess mortality has been observed occurring together with larger Chikungunya virus outbreaks. Diagnosis is based on the detection of virus by molecular methods or by virus culture in the first days of infection before an antibody response is evident. IgM *anti-ChikV* is detectable two to three days at the onset of symptoms and persists for several weeks up to three months (3). Chikungunya virus specific IgG appears soon after IgM antibodies and persist for years. Simple Chikungunya IgG/IgM is a new generation rapid Immuno-chromatographic test using recombinant chikungunya viral antigens of both wild type and mutant type to detect specific antibody response.

Intended Use

SIMPLE Chikungunya IgG/IgM Rapid Test is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Chikungunya virus in human whole blood, serum or plasma. The assay is used as a screening test for Chikungunya viral infection.

Test Principle

Chikungunya fever is a viral disease transmitted through the bite of infected *Aedes aegypti* and *Aedes albopictus* mosquitoes. Chikungunya IgG/IgM Test utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well and followed by IgG line. As the test sample flows through the membrane within the test device, the colored–chikungunya specific recombinant antigen colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of chikungunya virus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti- ChikV antibodies in the specimen.

Warnings and Precautions

1. For professional *in vitro* diagnostic use only. Do not use it after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as if they contain infectious agents.
4. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. Humidity and temperature can adversely affect results.
7. Do not open the sealed pouch, unless ready to conduct the assay.
8. Do not use the components in any other type of test kit as a substitute for the components in this kit.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive controls in the same manner as the patient specimens.
11. Do not reuse the test device.
12. Use separate sample dropper or pipette tips for each sample in order to avoid cross contamination of samples which could cause erroneous results.

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

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Sample collection and Handling

Specimen to be tested should be obtained and handled by standard methods for their collections.

1. **Serum:** allow the blood to clot, then centrifuge to separate the serum.
2. **Plasma:** collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma
3. **Whole blood:** Fresh blood from finger prick/puncture may be used as a test specimen for collection of whole blood as a test specimen
4. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated with as early as possible an opportunity to avoid hemolysis.
5. 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 2-8°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 2-8°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.
6. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials Required but not provided

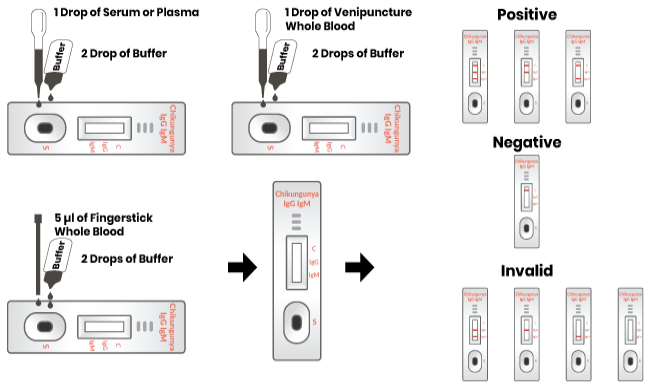
1. Timer or Stopwatch.
2. PPE and other consumables for collection and disposal of samples.

Limitations

1. The TEST PROCEDURE and the INTERPRETATION OF RESULTS sections must be followed closely when testing for the presence of antibodies to Chikungunya in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. Simple Chikungunya IgG/IgM is limited to the qualitative detection of antibodies to Chikungunya in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable Chikungunya antibodies. However, a negative test result does not preclude the possibility of exposure to Chikungunya.
4. A negative result can occur if the quantity of Chikungunya antibodies 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. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Test Procedure

1. Bring the kit components and specimen to be tested to room temperature before testing.
2. Open the test card from the pouch prior to use and place it on a flat and dry surface. The test should be performed immediately after removing the test card from the pouch.
3. **For Serum or Plasma Specimens**: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µl) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.
4. **For Venipuncture Whole Blood Specimens:** Hold the dropper vertically and transfer 1 drop of venipuncture whole blood to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.
5. **For Fingerstick Whole Blood Specimens:** Allow 1 hanging drops of fingerstick whole blood (approximately 5µl) to fall into the center of the specimen well (S) on the test device, then add 2 drop of buffer (approximately 80 µl) and start the timer. See illustration below
6. Allow the reaction to occur for 15 minutes.



7. Observe the results in 15 minutes. Do not read the result after 20 minutes. Reading beyond prescribed time may give false results.
8. Discard the test card immediately after reading the results at 20 minutes.

Interpretation of results

Positive Results

(Please refer to the illustration Below)

- **IgG POSITIVE:** Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the IgG region.
- **IgM POSITIVE:** Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the IgM region.

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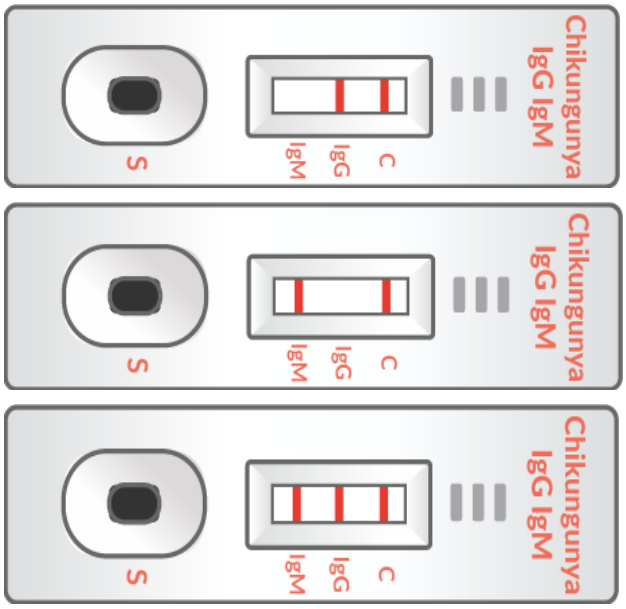
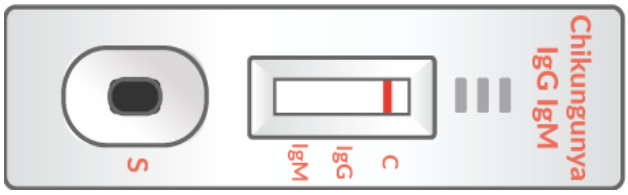
- **IgG and IgM POSITIVE:** Three distinct colored lines appear. One colored line should be in the control region (C) and another two-colored lines should be in the IgG and IgM regions.



NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of Chikungunya antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive

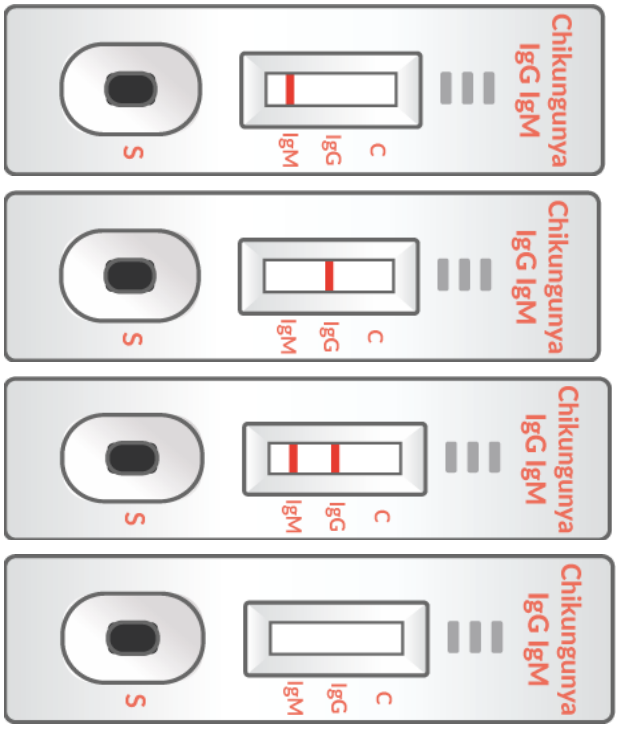
Negative Result

One colored line appears in the control region (C). No apparent red or pink line appears in the IgG and IgM region.



Invalid Results

Control line does not appear in the Control (C) region. If no C line develops, the assay is invalid regardless of color development only the IgG and IgM line. Repeat the assay with a new device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If the problem persists, discontinue using the test kit immediately and contact your local distributor



Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

References

1. Lee, H., Ryu, J.H., Yun, S., Jang, J.H., Choi, A.R., Cho, S.Y., Park, C., Lee, D.G. and Oh, E.J., 2020. Evaluation of a Newly Developed Rapid Automated Fluorescent Lateral Flow Immunoassay to Detect IgG and IgM Antibodies to Chikungunya Virus. *Infection & Chemotherapy*, *52*(4), p.611.
2. Pialoux, G., Gaüzère, B.A., Jauréguiberry, S. and Strobel, M., 2007. Chikungunya, an epidemic arbovirosis. *The Lancet infectious diseases*, *7*(5), pp.319-327.
3. Jaffar-Bandjee, M.C., Das, T., Hoarau, J.J., Trotot, P.K., Denizot, M., Ribera, A., Roques, P. and Gasque, P., 2009. Chikungunya virus takes centre stage in virally induced arthritis: possible cellular and molecular mechanisms to pathogenesis. *Microbes and infection*, *11*(14-15), pp.1206-1218.

Technical Assistance

For customer support, please contact our Technical Support:
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Food and Drugs Administration Haryana
SCO-94, SEC-5, Panchkula

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt.,
4th Floor, 28, 29 Electronic City, Sector -18,
Gurgaon, Haryana

Dated: 20-05-2022

Subject: **Regarding additional items.**

With reference to your application no. MFG/IVD/2022/58713 dated 22.05.2022 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069 Endorsement No 06.

Manmohan Taneja
Digitally signed by Manmohan Taneja
Date: 2022.05.20 10:03:32 +05'30'

State Drugs Controller Haryana

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 6

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 4th Floor, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Chikungunya Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Chikungunya virus Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Chikungunya Antibody (IgG/IgM) Test Kit
2	Generic Name:Filaria Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is an immunoassay for the simultaneous detection and differentiation of anti-lymphatic filarial parasites (W.bancrofti and B.malayi) IgG and IgM in human serum, plasma, or whole blood. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Filaria Antibody (IgG/IgM) Test Kit

3	Generic Name:H.Pylori Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:H. pylori Antibody Rapid Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM) against Helicobacter pylori (H. pylori) in human serum, plasma or whole blood. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE H.Pylori Antibody (IgG/IgM) Test Kit

Place:

Date20-May-22

Manmohan Taneja
Digitally signed by Manmohan Taneja
Date: 2022.05.20 10:04:33 +05'30'

State Licensing Authority