PATHKITS

SIMPLE Filaria Antibody

Product Code: **PKRK025**
Kit Contents (**25 Kits**)
Shelf Life: **24 Months**

Kit Components	Quantity
Test Strips	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

Filariasis is a parasitic infection caused by thread-like nematodes (filariae). The filariae worms are spread by black flies and mosquitoes. The lymphatic filariasis known as Elephantiasis, mainly caused by filariae worms: *W. bancrofti* and *Brugia malayi*, affects about 120 million people over 72 countries (1). These infestations are common in tropical countries such as sub-Saharan Africa, southern Asia, the western Pacific islands, Brazil and Guyana. Diagnosis of lymphatic filariasis using traditional microscopy methods can be difficult and requires accurate and conscientious techniques, as it involves the identification of microfilariae in the blood of the infected person (2). Microscopy requires skilled handling of the sample preparation and an experienced technologist for interpretation of the blood smear (3). Simple Filaria test card uses conserved recombinant antigens to simultaneously detect IgG and IgM to the *W. bancrofti* and *B. malayi* parasites without the restriction on specimen collection.

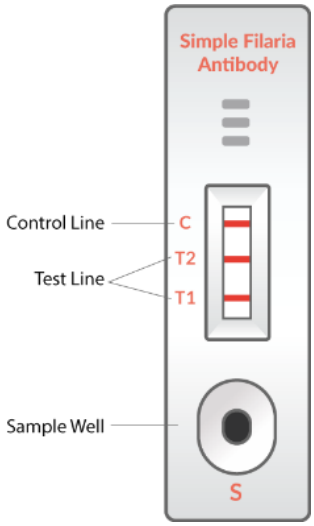
Intended Use

Simple Filaria test card 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. The kit is intended for professional use and as a preliminary test result to aid in the diagnosis of infection with lymphatic filarial parasites.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method should be considered to confirm the test result obtained by this device.

Test Principle

Simple Filaria test card is a membrane based lateral flow immunoassay for the detection of *W. bancrofti and B. malayi* IgG/IgM in human serum, plasma or whole blood. The test cards contain recombinant *W. bancrofti* and *B. malayi* common antigens conjugated with colloid gold (Filariasis conjugates)1 and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti- *W. bancrofti* and *B.* malayi, T2 band is pre-coated with reagents for the detection of IgG anti-*W. bancrofti* and *B. malayi*, and the C band is pre-coated with goat anti rabbit IgG.



When a suitable amount of test specimen is dispensed into the sample well of the card, the specimen migrates by capillary action across the card. Anti-*W. bancrofti* or *B. malayi* IgM antibodies if present in the specimen will bind to the Filariasis conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored T1 band, indicating a Anti- W. bancrofti or B. malayi IgM positive test result. Anti-*W. bancrofti* or *B. malayi* IgG antibodies if present in the specimen will bind to the Filariasis conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored T2 band, indicating a Anti-W. bancrofti or B. malayi IgG positive test result. Absence of any T bands (T1 and T2) 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 any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

Warnings and Precautions

1. For professional *in vitro* diagnostic use only. Do not use it after the expiration date.

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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.

Specimen 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. 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.
5. Do not freeze whole blood specimens.
6. Whole blood collected by fingerstick should be tested immediately.
7. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
8. 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

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

Limitations of Test

- As with all the diagnostic tests, the interpretation of assay results must always be correlated with clinical findings.
- Any modifications to the given procedure or use of other reagents will invalidate the test procedure.
- It is intended for screening use only, not for use in diagnostic procedures.
- Simple Filaria antibody test card is limited to the qualitative detection of antibodies to *W. bancrofti* and *B. malayi* in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable *W. bancrofti* and *B. malayi* antibodies. However, a negative test result does not preclude the possibility of exposure to *W. bancrofti* and *B. malayi*.
- A negative result can occur if the quantity of *W. bancrofti* and *B. malayi* 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.

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 specimen**: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25µl) to the specimen well of test Cassette, then add 1 drop of buffer (approximately 40µl) and start the timer.
4. Avoid trapping air bubbles in the specimen well. See the illustration below.

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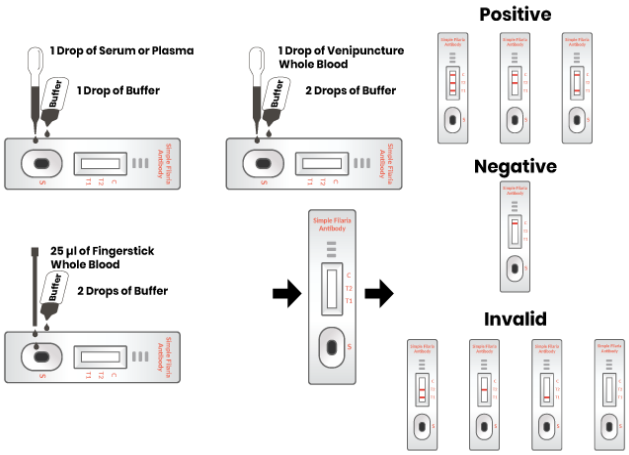
5. **For Venipuncture Whole Blood specimen**: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25µl) to the specimen well, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.
6. **For Finger stick Whole Blood specimen**: Fill the capillary tube and transfer approximately 25µl of finger stick whole blood specimen to the specimen area of test cassette, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.



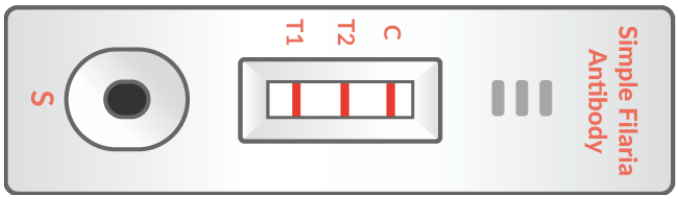
7. Wait for the colored line(s) to appear. The result should be read in 15 minutes. Do not interpret results after 20 minutes.
8. Observe the results in 15 minutes. Do not read the result after 20 minutes. Reading beyond prescribed time may give false results.
9. Discard the test card immediately after reading the results at 20 minutes.

Interpretation of results

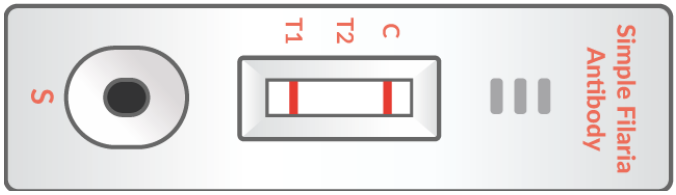
Positive Results

(Please refer to the illustration Below)

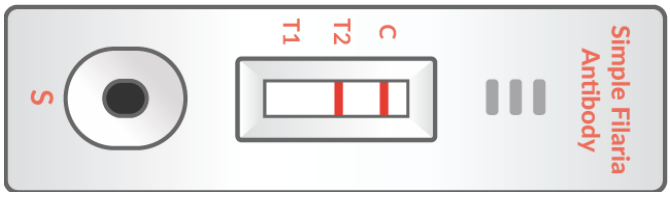
- **Three lines appear**: One colored line should always appear in the control line region (C), if both the T1 and the T2 lines develop, the test indicates the presence of both *anti-W. bancrofti or B. malayi* IgG and IgM.



- **IgM Positive**: Along with line in Control region (C), if only the T1 region line develops, the test indicates the presence of anti-*W. bancrofti* or anti-*B. malayi* IgM antibody. The result is IgM reactive or positive.

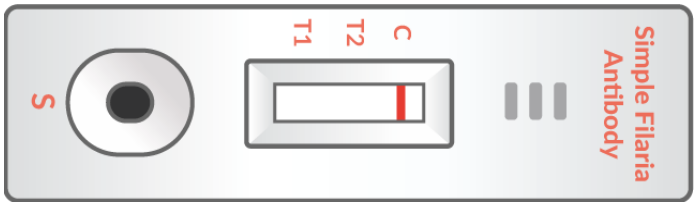


- **IgG Positive:** Along with line in Control region (C), if only the T2 region line develops, the test indicates the presence of *anti-W. bancrofti* or anti-*B. malayi* IgG antibody. The result is IgG reactive or positive.



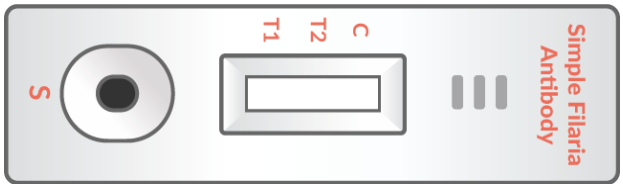
Negative Result

- Appearance of only one coloured line at Control (C) region indicates that the sample is non-reactive for *W. bancrofti* or B. malayi IgG IgM antibody.



Invalid Results

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



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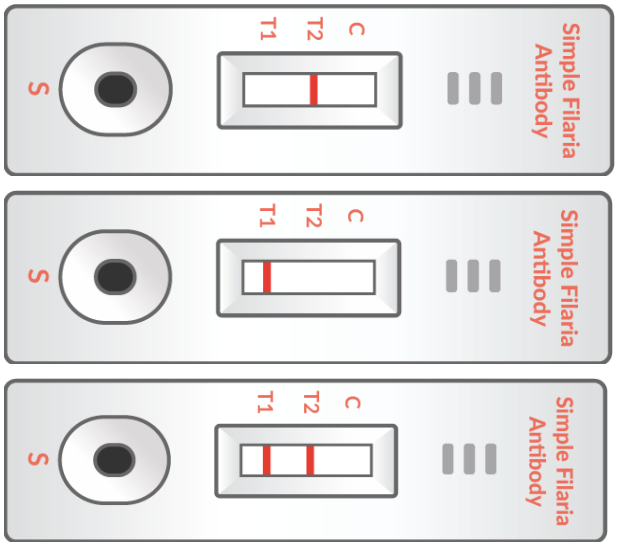

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume.

Reference

1. Michael, E., Bundy, D.A.P. and Grenfell, B.T., 1996. Re-assessing the global prevalence and distribution of lymphatic filariasis. *Parasitology*, *112*(4), pp.409-428.
2. Utzinger, J., Becker, S.L., Knopp, S., Blum, J., Neumayr, A.L., Keiser, J. and Hatz, C.F., 2012. Neglected tropical diseases: diagnosis, clinical management, treatment and control. *Swiss medical weekly: official journal of the Swiss Society of Infectious Diseases, the Swiss Society of Internal Medicine, the Swiss Society of Pneumology*, *142*.
3. Utzinger, J., Becker, S.L., Knopp, S., Blum, J., Neumayr, A.L., Keiser, J. and Hatz, C.F., 2012. Neglected tropical diseases: diagnosis, clinical management, treatment and control. *Swiss medical weekly: official journal of the Swiss Society of Infectious Diseases, the Swiss Society of Internal Medicine, the Swiss Society of Pneumology*, *142*.

Technical Assistance

For customer support, please contact our Technical Support:
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Gurgaon -122001, India Customer care No.: +91-7303429198
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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