PRATHAM®

Filariasis Antibody test (IgM/IgG)

PRODUCT INSERT

INTENDED USE

Filariasis Antibody Test (IgG/IgM) is a rapid immunoassay based upon chromatography principle for the qualitative detection of IgM & IgG Ab to Filariasis parasites (W. Bancrofti and B. Malayi) present in the human Serum / plasma / Whole Blood. For professional and in-vitro diagnostic use only.

INTRODUCTION

The lymphatic filariasis known as Elephantiasis, mainly caused by W. bancrofti and B.malayi, affects about 120 million people over 80 countries. The disease is transmitted to humans by the bites of infected mosquitoes within which the microfilariae sucked from an infected human subject develops into third-stage larvae. Generally, repeated and prolonged exposure to infected larvae is required for establishment of human infection. The definitive parasitologic diagnosis is the demonstration of microfilariae in blood samples. However, this gold standard test is restricted by the requirement for nocturnal blood collection and lack of adequate sensitivity. Detection of circulating antigens is commercially available. Its usefulness is limited for W. bancrofti. In addition, microfilaria and antigenemia develop from months to years after exposure.

TEST PRINCIPLE

Filariasis Antibody Test (IgG/IgM) is a qualitative membrane based immunoassay for the detection of IgG and IgM antibodies to Filariasis in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the IgG line region of the test, anti-human IgM is immobilized in the IgM line region of the test. After specimen is added to the specimen well of the device, it reacts with Filariasis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG/ anti-human IgM in respective line. If the specimen contains Filariasis antibodies, a coloured line will appear indicating a positive result. If the specimen does not contain Filariasis antibodies, a coloured line will not appear in IgG/IgM region indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. one desiccant
2. Plastic Dropper for sample
3. Assay Buffer
4. Instructions for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

Filariasis Antibody Test (IgM/IgG) device should be stored at 2-40°C in the cool & driest place. Once the pouch is opened, test card must be used immediately. The kit should not be frozen & must be protected from exposure to humidity and direct sunlight.

SPECIMEN COLLECTION AND STORAGE

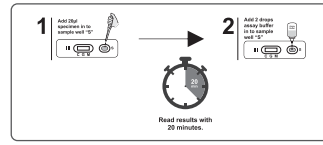
1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at - 20°C or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

WARNING AND PRECAUTION

- Use product insert to perform the assay.
- Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips any were discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The Test shall be performed by competent person only
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add 20µl of serum/plasma/whole blood into the sample well with the help of provided disposable dropper in the kit.
5. Add 2 drops of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results within 20 minutes. Don't interpret results after 20 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: Appearance of only one colored band at control line region "C". The result should be considered as negative for Filariasis Antibody IgG/IgM.

IgG Positive: Appearance of colored bands, one at test line region 'IgG' and other at control line region 'C'. The result should be considered as positive for Filariasis IgG Antibody.

IgM Positive: Appearance of colored bands, one at test line region 'IgM' and other at control line region 'C'. The result should be considered as positive for Filariasis IgM Antibody.

Filariasis IgG/IgM Positive: Appearance of 3 colored bands, one at test line region 'IgG' and second test line region 'IgM', and third control line region 'C'. The result should be considered as positive for Filariasis IgG & IgM Antibody.

INVALID: Appearance of no colored band at the control region C, the result should be considered as invalid. Repeat the test with a new test card.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A coloured line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environmental conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis., whether positive or negative in the use of this product.

REFERENCES

1. Eberhard ML, Lammie PJ. Laboratory diagnosis of filariasis. Clin. Lab Med 1991; 11:977-1010.
2. More SJ, Copeman DB. A highly specific and sensitive monoclonal antibody-based ELISA for the detection of circulating antigen in bancroftianfilariasis. Trop Med Parasitol 1990; 41:403-406.
3. Lammie PJ, Weil G, et al: Recombinant antigen-based antibody assays for the diagnosis surveillance of lymphatic filariasis-a multiplecenter trial. FlariaJornal 2004: 3: 9-18.

SYMBOLS

	Read instructions for use		Name of Manufacturer
	For single use only		Date of manufacturing of IVD Kit
	No. of test		Expiry Date of Kit.
IVD	In-vitro diagnostic use		Keep away from Sunlight
	Storage Condition	REF	Reference Catalogue Number

Version No: ADPL-IFU-30-00

Manufactured By:

ASTAM DIAGNOSTICS PVT. LTD.

Plot NO. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Ext., Alwar, Rajasthan-301019 (INDIA)

For feedback/queries contact customer care : 011-27358101