Filariasis IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood)

The Filariasis IgG/IgM Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to lymphatic filarial parasites (W. Bancrofti and B. Malayi) in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PFLR 01
05 Tests	PFLR 05
10 Tests	PFLR 10
25 Tests	PFLR 25
50 Tests	PFLR 50

CLINICAL SIGNIFICANCE

Lymphatic filariasis, commonly known as Elephantiasis, is mainly caused by W. bancrofti and B. malayi and affects about 120 million people across 80 countries[1,2]. The disease is transmitted to humans by the bites of infected mosquitoes within which the microflariae 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 microflariae in blood samples[3]. However, this gold standard test is restricted by the requirement for nocturnal blood collection and lack of adequate sensitivity. Detection of circulating antigens is another commercially available diagnostic method, but its usefulness is limited to infection with W. bancrofti[4]. In addition, microfilaremia and antigenemia develop from months to years after exposure. Antibody detection provides an early means to detect filarial parasite infection. Presence of IgM to the parasite antigens suggests current infection, whereas, presence of IgG corresponds to late stage of infection or past infection[5]. Furthermore, identification of conserved antigens allows 'pan-filaria' tests to be applicable. Utilization of recombinant proteins eliminates cross reaction with individuals having other parasitic diseases[6]. The Filariasis IgG/IgM Rapid Test uses conserved recombinant antigens to simultaneously detect IgG and IgM to the W. bancrofti and B. malayi parasites without the restriction on specimen collection.

PRINCIPLE

Filariasis IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing recombinant W. bancrofti and B. malayi common antigens conjugated with colloidal gold (Filariasis conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (M and G lines) and a control line (C line). The M line is pre-coated with monoclonal anti-human IgM for the detection of IgM to W. bancrofti and B. malayi, the G line is pre-coated with reagents for the detection of IgG to W. bancrofti and B. malayi, and the C line is pre-coated with a control antibody.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-W. bancrofti or anti-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 colored M line, indicating anti-W. bancrofti or anti-B. malayi IgM positive test result. Anti-W. bancrofti or anti-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 colored G line, indicating an anti-W. bancrofti or anti-B. malayi IgG positive test result. Absence of any test lines (M and G) suggests a negative result.
The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies regardless of the color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only)
• Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The Filariasis IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by vein puncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by vein puncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer
4. **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 80 µL) and start the timer
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL (1 drop) of fingerstick whole blood specimen to the specimen well of test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer.
5. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Do not interpret the result after 20 minutes.

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INTERPRETATION OF RESULTS

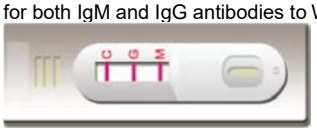
1) **IgG POSITIVE:** In addition to the presence of the C line, if only the G line develops, the test indicates the presence of anti-W. bancrofti or anti-B. malayi IgG antibody. The result is IgG reactive or positive.



2) **IgM POSITIVE:** In addition to the presence of the C line, if only the M line develops, the test indicates the presence of anti-W. bancrofti or anti-B. malayi IgM antibody. The result is IgM reactive or positive



3) **IgG/IgM POSITIVE:** IgG and IgM Positive The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to W. bancrofti or B. malayi



4) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible on the test cassette. No IgM/IgG antibodies were detected. The result does not exclude W. bancrofti or B. malayi infection.



5) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM(M)/IgG(G) region of the cassette. Repeat the test using a new cassette.



Quality Control

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

Limitations of the Test

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The Filariasis IgG/IgM Ab Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of antibodies for Filariasis in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of Filariasis can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- Filariasis 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. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

A total of 247 specimens were collected (including susceptible subjects) and tested by Filariasis IgG/IgM Ab Rapid Test and a commercially available Filariasis IgG/IgM Ab Rapid Test as reference. Comparison for all subjects is showed in the following table.

	Clinical performance for IgM Test		
IgM Test	Positive	Negative	Total
Positive	24	0	24
Negative	0	200	200
Total	24	200	224

	Clinical performance for IgG Test		
IgG test	Positive	Negative	Total
Positive	23	0	23
Negative	0	200	200
Total	23	200	223

IgM Relative Sensitivity: 100% (95% CI: 98.8-99.9%), IgG Relative Sensitivity: 100% (95% CI: 98.8-99.9%), Relative Specificity: 100% (95% CI: 98.8-99.9%), Overall Agreement: 100% (95% CI: 98.8-99.9%)

Cross-reactivity

The Filariasis IgG/IgM Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Filariasis IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/dl

BIBLIOGRAPHY

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

GLOSSARY OF SYMBOL

IVD	For in vitro Diagnostic use only
REF	Catalog Number
	Store between
	Manufacturer
	Do not reuse

India office
BIOBOON BIOTECH INDIA LLP
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