Filariasis IgG/IgM Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

REF IFIL-402

English

A rapid test for the qualitative detection of IgG and IgM antibodies to Filariasis parasites (W. Bancrofti and B. Malayi) in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENTED USE

The Filariasis IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Filariasis parasites (W. Bancrofti and B. Malayi)* in whole blood, serum, or plasma to aid in the diagnosis of Filariasis infection.

SUMMARY

The lymphatic filariasis known as Elephantiasis, mainly caused by W. bancrofti and B. malayi, affects about 120 million people over 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 commercially available. Its usefulness is limited for 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 suggest current infection, whereas, IgG corresponds to late stage of infection or past infection[5]. Furthermore, identification of conserved antigens allows 'pan-filaria' test to be applicable. Utilization of recombinant proteins eliminates cross-reaction with individuals having other parasitic diseases[6]. The Filariasis Rapid Test uses conserved recombinant antigens to simultaneously detect antibody to the W. bancrofti and B. malayi parasites without the restriction on specimen collection.

PRINCIPLE

The Filariasis IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) 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, colored line will appear indicating a positive result. If the specimen does not contain *Filariasis* antibodies, a colored line will not appear in IgG/IgM region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains *Filariasis* antigen coated particles and anti-human IgG/IgM coated on the IgG/IgM region of membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Filariasis IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
    - Allow 1 hanging drop of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. 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.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

MATERIALS

Materials provided

• Test Cassettes • Droppers • Buffer • Package insert

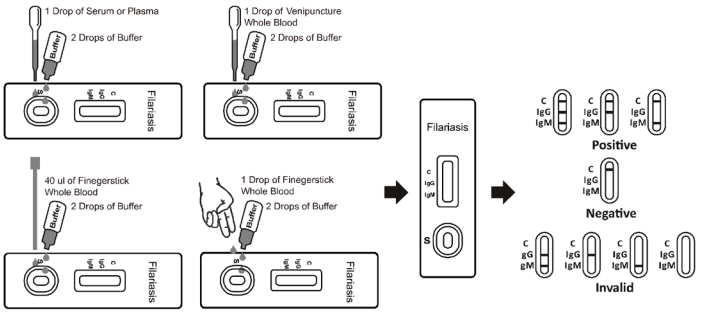
Materials required but not provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. 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 40μL) to the specimen area, then **add 2 drops of buffer** (approximately 80 μL),and start the timer, see illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer1 drop of whole blood** (approximately 40 μL) to the specimen area, then **add 2 drops of buffer** (approximately 80μL), and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 40 μL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
   - To use hanging drops: Allow **1 hanging drop of fingerstick whole blood specimen** (approximately 40 μL) to fall into the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result at 15 minutes**, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration)

POSITIVE:* Two or three colored lines appear. One colored line should always appear in the control line region (C) and another one or two colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: A colored line appears in control region (C), another colored line appears in IgM region. It indicates a IgM positive test result for antibodies to Filariasis.

IgG Positive: A colored line appears in control region (C), another colored line appears in IgG region. It indicates a IgG positive test result for antibodies to Filariasis.

***NOTE**: The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Filariasis antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

INVALID: 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 cassette. 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 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

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to filarial parasites in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Filariasis Rapid Test 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.
3. 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*.
4. 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.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

IgG Results

40 samples from patients with chronic lymphatic filariasis and 251 samples collected from a non-filariasis region were tested by the Filariasis IgG/IgM Rapid Test. Comparison for all subjects is showed in the following table

Method		ELISA		Total Results
Filariasis IgG/IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	37	4	41
	Negative	3	247	250
Total Results		40	251	291

Relative Sensitivity: 92.5% (95%CI*: 79.6%-98.4%) *Confidence Interval
Relatively Specificity: 98.4% (95%CI*: 96.0%-99.6%)
Accuracy: 97.6% (95%CI*: 95.1%-99.0%)

IgM Results

32 samples from patients with chronic lymphatic filariasis and 251 samples collected from a non-filariasis region were tested by the Filariasis IgG/IgM Rapid Test. Comparison for all subjects is showed in the following table

Method		ELISA		Total Results
Filariasis IgG/IgM Rapid Test Cassette	Results	Positive	Negative	
	Positive	31	3	34
	Negative	1	248	249
Total Results		32	251	283

Relative Sensitivity: 96.9% (95%CI*: 83.8%-99.9%) *Confidence Interval
Relatively Specificity: 98.8% (95%CI*: 96.5%-99.8%)
Accuracy: 98.6% (95%CI*: 96.4%-99.6%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the *Filariasis* IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Sera containing known amounts of antibodies to *Filariasis* have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the *Filariasis* IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high degree of specificity for antibodies to *Filariasis*.

Interfering Substances

The *Filariasis* IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

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IVD	For *in vitro* diagnostic use only
30°C 2°C	Store between 2-30°C
	Do not use if package is damaged
REF	Catalog #
Σ	Tests per kit
	Use by
LOT	Lot Number
	Manufacturer
	Do not reuse
	Consult Instructions for Use

Manufacturer

Hangzhou Alltest Biotech Co., Ltd.
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