Filariasis IgG/IgM
(Serum / Plasma / Whole Blood)

INTENDED USE
The Filariasis IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM anti-lymphatic filarial parasites (W. bancrofti and B. malayi) in human serum, plasma or whole blood. This test is intended to be used as a screening test and as an aid in the diagnosis of infection with lymphatic filarial parasites.

SUMMARY AND EXPLANATION OF THE TEST
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, microfilariaemia 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. 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. 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.

TEST PRINCIPLE
The Filariasis IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant W. bancrofti and B. malayi common antigens conjugated with colloidal gold (Filariasis conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgG for the detection of IgM anti-W. bancrofti and B. malayi. G 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 an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. 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 M band, indicating a W. bancrofti or B. malayi IgM positive test result.

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 G band, indicating a W. bancrofti or B. malayi IgG positive test result. Absence of any test bands (M and G) indicates that no anti-W. bancrofti or -B. malayi antibodies is detected in the specimen. The test result is invalid and the specimen must be retested with another device.

INTERPRETATION OF ASSAY RESULT

Store unused test devices unopened at 2°C -30°C. If stored at 2°C -8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed kit. Do not freeze the kit or expose the kit to over 30°C.

Specimen Collection and Handling
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma
1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin by venipuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum
1. Collect blood specimen into a red top collection tube (containing no anticoagulants) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately. Specimens at 2°C to 8°C can be stored for up to 5 days. Specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood
Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen’s ID number.

Step 4: For whole blood test
   - Apply 1 drop of whole blood (about 40-50 µL) into the sample well.
   - Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.
   - Fill the pipette dropper with the specimen.
   - Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.
   - Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.

Step 5: Set up timer for 15 minutes.

Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

Interpretation of Assay Result
1. NEGATIVE RESULT: If only the C band is present, the absence of any burgundy color in the both test bands (M and G) indicates that no anti-W. bancrofti or B. malayi antibody is detected in the specimen. The result is nonreactive.

For in Vitro Diagnostic Use
This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

1. Do not open the sealed pouch, unless ready to conduct the assay.
2. Do not use expired devices.
3. Bring all reagents to room temperature (15°C -30°C) before use.
4. Do not use hemolyzed blood specimen for testing.
5. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
6. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
7. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimen and materials used to perform the test as biohazardous waste.
9. Handle the Negative and Positive Control in the same manner as patient specimens.
10. The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 15 minutes may give erroneous results.
11. Do not perform the test in a room with strong air flow, ie, an electric fan or strong air-conditioning.

Warnings and Precautions
- Biologically amplified tests
- Use of new test methods
- Negative results
- Standard controlled studies
- Positive results
- Sample dilution
- Sample collection
- Test materials
- Test strategy
- Uncovering new diagnostic information

Reagents and Materials Provided
1. Test Devices
2. Sample Droppers
3. Sample Diluent
4. Package Insert
2. **POSITIVE RESULT:**

2.1 In addition to the presence of C band, if only M band is developed, the test indicates for the presence of anti-W. bancrofti or B. malayi IgM antibody. The result is reactive.

2.2 In addition to the presence of C band, if only G band is developed, the test indicates for the presence of anti-W. bancrofti or B. malayi IgG antibody. The result is reactive.

2.3 In addition to the presence of C band, both M and G bands are developed, the test indicates for the presence of both IgG and IgM anti-W. bancrofti or B. malayi. The result is also reactive.

Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

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**PERFORMANCE CHARACTERISTICS**

1. **Clinical Performance For IgM Test**

24 samples from patients with acute lymphatic filariasis and 200 samples collected from a non-filariasis region were tested by the Filariasis IgG/IgM Rapid Test. Comparison for all subjects is shown in the following table:

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<th>Clinical Status</th>
<th>Filariasis IgG/IgM Rapid Test</th>
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<tr>
<td></td>
<td>Positive</td>
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<tr>
<td>Acute filariasis</td>
<td>23</td>
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<tr>
<td>Negative</td>
<td>0</td>
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<tr>
<td>Total</td>
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Relative Sensitivity: 95.8%; Relative Specificity: 100%; Overall agreement: 99.6%.

2. **Clinical Performance For IgG Test**

26 samples from patients with chronic lymphatic filariasis and 200 samples collected from a non-filariasis region were tested by the Filariasis IgG/IgM Rapid Test. Comparison for all subjects is shown in the following table:

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<th>Filariasis IgG/IgM Rapid Test</th>
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<td>Positive</td>
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<td>Chronic filariasis</td>
<td>24</td>
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<tr>
<td>Negative</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>24</td>
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Relative Sensitivity: 92.3%; Relative Specificity: 100%; Overall agreement: 99.1%.

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**LIMITATIONS OF TEST**

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 IgG/IgM 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 nonreactive result for an individual subject indicates absence of detectable W. bancrofti and B. malayi antibodies. However, a nonreactive test result does not preclude the possibility of exposure to W. bancrofti and B. malayi.

4. A nonreactive 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. If the symptom persists, while the result from Filariasis IgG/IgM Rapid Test is nonreactive result, it is recommended to re-sample the patient few days late or test with an alternative test methods such as ELISA.

6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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**REFERENCES**


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**Index of CE Symbols**

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