Filariasis IgG/IgM Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Filariasis IgG/IgM in human serum, plasma or whole blood. *For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Filariasis IgG/IgM Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 tests/kit

INTENDED USE

The Filariasis IgG/IgM Rapid Test Kit 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. Any reactive specimen with the Filariasis IgG/IgM Combo Rapid Test must be confirmed with alternative testing method(s).

SUMMARY AND EXPLANATION THE TEST

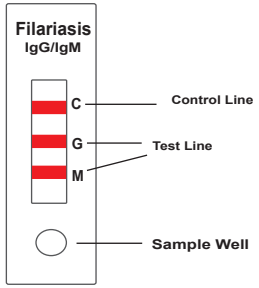
The lymphatic filariasis known as Elephantiasis, mainly caused by W. bancrofti and B. malayi, affects about 120 million people over 80 countries. The disease is transmitted to humans by the bites of infected mosquitoes within which the microflariae sucked from an infected human subject develops into 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. 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, 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. 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 Combo 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

The Filariasis IgG/IgM Rapid Test Kit 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 colloid 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 IgM 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) 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 test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch, unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°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 pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
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 in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

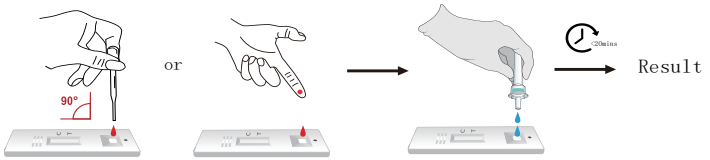
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

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.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.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.
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**

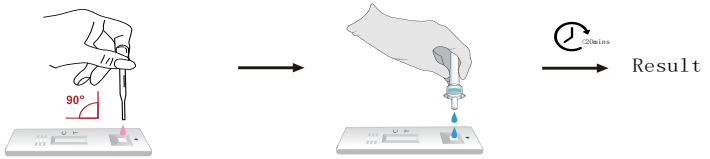
- Apply 1 drop of whole blood (about 20 μL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30 μL-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5:Set up timer.
Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

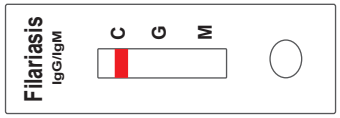
QUALITY CONTROL

Using individual Filariasis IgG/IgM Rapid Test Kit cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:
1.A new operator uses the kit, prior to performing testing of specimens.
2.A new test kit is used.
3.A new shipment of kits is used.
4.The temperature used during storage of the kit falls outside of 2°C-30°C.

5.The temperature of the test area falls outside of 15°C-30°C.
Expected results are as follows:

Negative Control

Only the C band shows color development, the two test bands (M and G) show no color development.



Positive Control

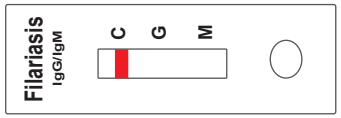
The C band and two test bands (M and G) show color development.

The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

INTERPRETATION OF ASSAY RESULT

Negative Control

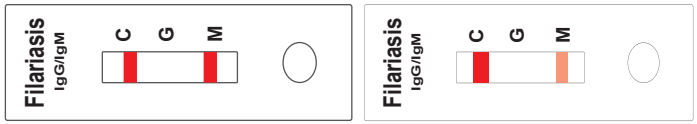
If only the C band is present, the absence of any burgundy color in the both test bands (M and G) indicates that no anti-W. bancrofti or -B. malayi antibody is detected in the specimen. The result is negative.



Positive Control

IgG Positive: 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 positive.

IgM Positive: 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 positive.

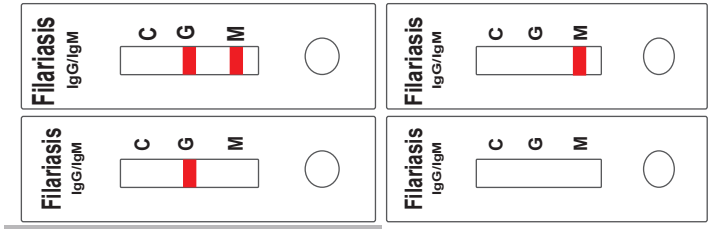


IgG/IgM Positive: In addition to the presence of C band, both M and G bands are developed, the test indicates for the presence of both IgG and IgM anti-W. bancrofti or B. malayi. The result is also positive.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

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.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

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

	Filariasis IgG/IgM Rapid Test		
Clinical Status	Positive	Negative	Total
Acute filariasis	53	1	54
Negative	0	200	200
Total	53	201	254

Relative Sensitivity:98% , Relative Specificity:99.33%, Overall Agreement: 99%

2. Clinical Performance For IgG Test

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

	Dengue IgG/IgM Rapid Test		
IgG EIA Test	Positive	Negative	Total
Positive	55	1	56
Negative	1	199	200
Total	56	200	256

Relative Sensitivity:98.21% , Relative Specificity:99.5%, Overall Agreement: 99.22%

LMITATIONS 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 Kit 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.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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