Sensit Filariasis IgG/IgM Rapid Test

Cat No.: S004-03

Sensit Filariasis Antibody Rapid Test
In vitro Diagnostics

INTENDED USE

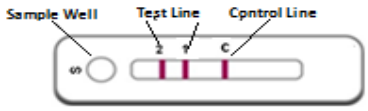
Sensit *Filariasis* antibody Rapid Test is a lateral flow immunoassay for detection of anti-lymphatic filarial parasites (*W. Bancrofti and B. Malayi)* in human whole blood, plasma or serum. This test is intended to be used as a screening test and as an aid in the diagnosis of infection with lymphatic filarial parasites.

SUMMARY & TEST DESCRIPTION

The lymphatic filariasis known as Elephantiasis, mainly caused by *W. bancrofti and B. malayi,* has been reported for about 120 million people worldwide and approximately 1 billion people are at the risk of infection. Filariasis is a disease group affecting humans and animals caused by nematode parasites of the order Filariidae, commonly called filariae. The parasite is transmitted by the bite of infected speciesof various genera of mosquitoes, including *Culex, Aedes, Anopheles*,and *Mansonia. W bancrofti*S welling of arms, breasts and legs are the major symptoms of filaria. Filariasis is usually diagnosed by identifying microfilariae on a Giemsa-stained thick blood film. However, this is relatively insensitive unless microfilaraemia is high.
Sensit Filariasis antibody Rapid Test provides an early means to detect filaria parasite infection.

TEST PRINCIPLE

Sensit Filariasis antibody Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of 1) a pink-colored conjugate pad containing Filaria antigen conjugated with colloid gold, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2) and a control band (C). The T bands are pre-coated with T1: Anti-Human IgG and T2: Anti-Human IgM.



Test specimen, with adequate amount of buffer, migrates along the conjugate pad and further across the coated membrane by capillary action. Anti-Filarial antibodies present in the sample, complex with the Filaria Antigen present in the conjugate pad and gets captured onto the coated Anti-Human IgG and Anti-Human IgM on test line. Thus giving a colored test band, indicating a W. bancrofti or B. malayi positive test result. If the respective antibody is not present in the sample, no reaction occurs and no test line is formed. The sample then migrates further along the strip until it reaches the control band, where it produces a second visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended

REAGENTS & MATERIALS PROVIDED

1. Each Kit contains 10 test devices, each sealed in a foil pouch containing following items:
   a. One test card
   b. Desiccant
   c. Dropper
2. Assay Diluent - In dropper bottle
3. Instruction Leaflet

PRECAUTIONS & WARNING

1. Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
2. Do not use haemolysed blood for the testing.
3. Do not use with specimen containing precipitates
4. Use within 10 minutes after opening pouch.
5. Do not reuse test kit.
6. Use a separate pipette tip for each specimen.
7. Do not touch result window.
8. Use only the buffer supplied along with the kit.
9. Do not mix components from different kits.
10. Use only for in-vitro diagnostic purpose.
11. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.

SAMPLE PREPARATION & STORAGE

- Blood Specimen: Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- Plasma: Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture.Centrifuge the blood to get plasma specimen as supernatant.
- Serum: Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes.Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5days, freezing is recommended. Store at -20^{0}C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

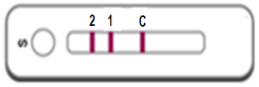
TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface. Add 10 µl of the specimen to the sample hole (marked S) on the test card.
2. When the sample is fully absorbed, add two drops of the diluents provided with the assay
3. Wait for 10-15 minutes and interpret results. The result is considered invalid after 20 minutes. All results where control band does not appear are considered invalid.

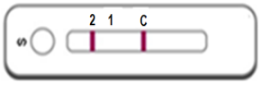
INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE EMBOSSED 'C' , '1' &'2' ON THE DEVICE AS SHOWN BELOW. DONOT CONSIDER 'C' & 'T')

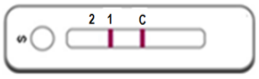
Filaria IgG & IgM Positive



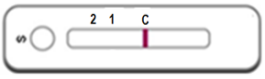
Filaria IgM Positive



Filaria IgG Positive



Filaria Negative



Invalid

Reference:

1. Lymphatic Filariasis, A Manual For National Elimination Programmes, World Health Organization WHO/HTM/NTD/PCT/2011.4
2. Supali T et al. Detection of filarial-specific IgG4 antibodies using Brugia Rapid test in individuals from an area highly endemic for Brugiatimori. ActaTropica, 2004, 90:255–261.