■ Test Procedure



Read the results after 2 minutes

Interpretation of Results

Note: Results should not be read beyond 10 minutes









One dot at C

Two dots at T & C

Dot only at T

No Dot

Ordering Information

Product	Code No.	
Signal- MF	57FT100-05	05 Tests
	57FT100-10	10 Tests
	57FT100-50	50 Tests

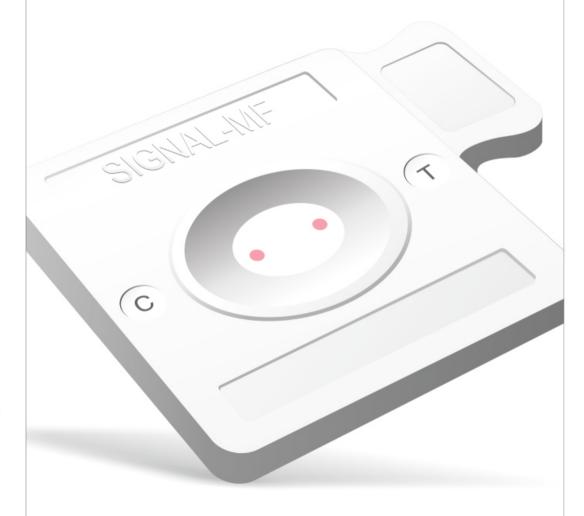


THE MANUFACTURING SITE'S QMS IS CERTIFIED FOR ISO 13485:2003, ISO 9001:2008





Signal-MF



Flow through

immunodot test format for detection of

Antibodies to Microfilariae in serum or plasma

■ Fact File



Approximately 20% of world population is at the risk of infection. More than 120 million people in 80 tropical countries worldwide are estimated to be infected with Filarial parasites.

The largest number of Filaria cases occurs in India. At least 6 million cases of acute Filariasis occur every year in India. The endemic area is mainly along the sea coast and bank of large rivers.

Diagnosis of Filariasis

Clinical diagnosis of Filaria is insensitive and not specific for detecting active infection.

Microscopic detection of microfilaria (MF): Most popular and traditional method in peripheral blood is time consuming and lacks consistency due to many factors such as

- · Time of blood collection
- Dependability on volume of blood collected
- · Expertise in microscopic examination

Antigen detection method: Simple and sensitive as compared to microscopic method but it fails to detect infection in patients with clinical filariasis which are amicrofilaraemic (chronic clinical Filariasis and early stage of Filarial infection).

Antifilarial antibodies detection method: Most sensitive and accurate method, provides evidence of ongoing exposure to filarial infection long before the development of antigenemia or microfilaria, where detectable level of antigen is low due to slow growing nature of disease, while detectable level of antibodies is reached faster.

Nucleus of Signal-MF - wbSXP-1 Antigen

WbSXP-1 is 28 KDa protein from nematode protein family. It is equally sensitive for Wuchereria bancrofti and Brugia malayi. Important aspect of WbSXP-1 is its non-reactivity with sera from individuals infected with other Nematodes, Protozoa, Dengue fever, Scrub fever, Hepatitis, Salmonella typhi and mixed infection.

WbSXP-1 has been found to be most reliable marker for detection of Prepatent stage, Asymptomatic or Carrier stage of infection. Anti-SXP-1 IgG4 is not detectable in sera from chronic pathology patients or endemic normals".

Antibody detection helps in early prognosis of disease.

Signal MF is a recombinant antigen based assay for detection of antibodies against Microfilaria, addresses limitation of traditional diagnostic approach and offers many other advantages.

Salient Features



Visual two dots assay with inbuilt control dot to validate successful completion of assay procedure giving result in 10 minutes.



Highly immunogenic recombinant protein *WbSXP-1* as a capture antigen makes it highly sensitive & specific test for both Bancroftian & Brugian Filariasis.



Detection of Anti-Microfilarial antibodies ensures early diagnosis.



Sample (serum / plasma, fresh or frozen) collected any time during the day can be used. Most convenient for patients as well as laboratories.



Unique cassette design with handle for maximum user safety and convenience along with self dropping bottles ensuring maximum ease of use.



Optimally designed test protocol with proprietary washing buffer ensures highest specificity by removing all non specific interfering proteins.



Proprietary conjugate containing uniform sized gold particle ensures prominent appearance of dots for unambiguous interpretation of test results.

Performance*

Overall Sensitivity of 91.4% and 90.8% with microfilaria positive samples of Bancroftian and Brugian infection respectively.

None of the sera from non-endemic areas showed positive results indicating an excellent Specificity of the test.

* Data published in Microbiology & Immunology, 48(7), 519 - 525, 2004