



Leishmania IgG/IgM Rapid Test Strip

The Leishmania IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant *L. donovani* specific antigen RK-39 conjugated with colloid gold (Leishmania conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with recombined antigen RK-39 and the C band is pre-coated with chicken anti-protein A.

When an adequate volume of test specimen is dispensed onto the sample pad of the test strip, the specimen migrates by capillary action across the strip. Anti- *L. donovani* Ab if present in the specimen will bind to the RK-39 antigen conjugates. The immunocomplex is then captured on the membrane by the pre-coated recombined antigen RK-39, forming a burgundy colored T band, indicating a *L. donovani* Ab positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of antibody- chicken anti-protein A -gold conjugate regardless of the color development on the C band. Otherwise, the test result is invalid and the specimen must be retested with another strip.



PERFORMANCE CHARACTERISTICS

Clinical Performance

A total of 267 patient samples from susceptible subjects were tested by the Leishmania IgG/IgM Rapid Test and by a commercial *L. donovani* IgG/IgM ELISA kit. Comparison for all subjects is showed in the following table.

EIA	Leishmania IgG/IgM Rapid Test		Total
	Positive	Negative	
Positive	52	2	54
Negative	1	212	213
Total	53	214	267

Relative Sensitivity: 96.3 %, Relative Specificity: 99.5%, Overall Agreement: 98.9%

PRODUCT	TEST TYPE	SAMPLE TYPE	KIT SIZE
The Leishmania IgG/IgM Rapid Test	Strip	Whole Blood/Serum/Plasma	50