

# RAPYDTEST®

A RAPID, ONE STEP TEST FOR THE QUALITATIVE DETECTION OF ANTIBODY TO VISCERAL LEISHMANIASIS IN SERUM

APACOR

Leishmania Dipstick  
RAPYDTEST®

## Performance Benefits

- Ten minutes one step test
- Rapid chromatographic immunoassay
- Detection in serum
- High sensitivity / specificity (rK39)



## Field Studies

The Kalazar Detect™ test for visceral leishmaniasis.

Site 1: Brazilian Study Kalazar Detect Test compared to Microscopy				
		+	-	
Kalazar Detect™	+	115	0	
	-	13	59	
		128	59	187
Sensitivity	89.844		Specificity	100
Std error	2.67			0
95% CI	(82.936,94263)		(92.384,100)	

Site 2: Indian Study Kalazar Detect Test compared to Microscopy				
		+	-	
Kalazar Detect™	+	225	14	
	-	0	190	
		225	204	429
Sensitivity	100		Specificity	93.137
Std error	0			1.77
95% CI	(97.908,100)		(88.517,96.054)	

Note: Site 2 had a high prevalence of VL patients.



PARASITOLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE



**Materials Provided**

1. Individually sealed foil pouches containing test device.
2. Chase buffer.
3. One package insert (instruction for use).

**Test Procedure**

- Allow the sera and Chase Buffer to reach room temperature prior to testing.
- Remove the dipstick from the foil pouch.
- Add 20µl of serum to the dipstick in the area below the arrow.
- Place the dipstick into a test tube, or well of a 96 well tissue culture plate so that the end of the strip is facing downward as indicated by the arrows on the strip.
- Add 2-3 drops (150µl) of the Chase Buffer solution provided with this test kit.
- Read the results in 10 minutes. It is significant that the background is clear before reading the test, especially when sera have low titer of anti-Leishmanial antibody, and only a weak band appears in the test region (T). Results interpreted after 10 minutes can be misleading.

**Note: Do not test this product with the Chase Buffer solution alone. 20µl of human serum must be added first.**

**Interpretation of Results**

**Positive**



The test is positive when a control line and test line appear in the test area as shown. A positive result indicates that the dipstick detected antibodies to members of L.donovani complex. A faint line is considered a positive result. As a guide for interpretation, the red colour in the test region will vary depending on the concentration of anti-Leishmanial antibodies present. The test line for “weakly positive” sera samples may show results between a weak positive red line to a faintly red, almost white background. (“Weakly positive” samples are those with low affinity or low titer antibodies against the recombinant test antigen.)

**Negative**



The test is negative when only the control line appears. A negative result indicates that the Leishmania dipstick did not detect antibodies to members of L.donovani complex. No test line is present.

**Invalid**



No lines appear at either the control or test areas. The test is also invalid if no control line appears, but a test line is seen. It is recommended to retest using a new dipstick and fresh serum.

**Note: The red colour in the test region will vary depending on the concentration of anti-Leishmanial antibodies present. However, neither the quantitative value nor the rate of increase in antibodies can be determined by this qualitative test.**

**References**

1. WHO, 1990, Control of the Leishmaniases, World Health Organization, Technical Report Series No. 793.
2. Marsden, P.D. 1984. Rev. Inf. Dis. 6:736-744.
3. Jeronimo S.M.B., R.M. Oliveira, S. Mackay, et al., 1994 Trans. R. Soc. Trop. Med. Hyg. 88(4): 368-386.
4. Berenguer J., S. Moreno, E. Cercenado, et al. 1989. Ann. Intern. Med. 111:129-132.
5. Ashford D.A., R. Badaro, C. Eulalio, et al. 1993. Am. J. Med. Hyg.48(1)1-8.
6. Neogy, A.B., I. Vouldoukis, A.S. Otamires, et al. 1993 Am J. Trop. Med. Hyg. 47:772-777.
7. Evans, T.G., I.A.B. Vasconcelos, J.N. Lima, et al. 1990 Am. J. Trop. Med. Hyg. 42:118-123.
8. Alvar J., R. Molina, M. San Andres, et al. 1994 Ann. Trop. Med. & Parasit. 88 (4)371-8.
9. Allain, D.S., and I.G. Kagan. 1975, Am. J.Trop. Med. Hyg. 24:232-236.
10. Badaro, R., S.G. Reed, and E.M. Carvallio. 1983, Am. J. Trop. Med. Hyg. 32(3) 480-484.
11. Reed, S.G., W.G. Shreffler, J.M. Burns, et al. 1990. Am. J. Trop. Med. Hyg. 43 (6) 632-9
12. Burns, Jr. J.M., W.G. Shreffler, D.R. Benson, et al. 1993. Proc. Natl. Acad.Sci. 90:775-779.
13. Houghton, R. et al. 1998 J. Infectious Dis. 177 (5) 1339-1344.
14. Sundar, S et al. 2002 Annals of Tropical Medicine & Parasitology, Vol 96, No.1, 19-23.

PRODUCT	PACK SIZE	CODE
Leishmania Dipstick Rapydtest®	40	1601

Products can be ordered direct from Apacor or from an appointed distributor  
Visit our website for all the latest information [www.apacor.com](http://www.apacor.com) or email on: [sales@apacor.com](mailto:sales@apacor.com)



UNIT 5 SAPPHIRE CENTRE  
FISHPONDS ROAD, WOKINGHAM  
BERKSHIRE, RG41 2QL, ENGLAND  
TEL: +44 (0)118 979 5566  
FAX: +44 (0)118 979 5186

