RAPYDTEST®

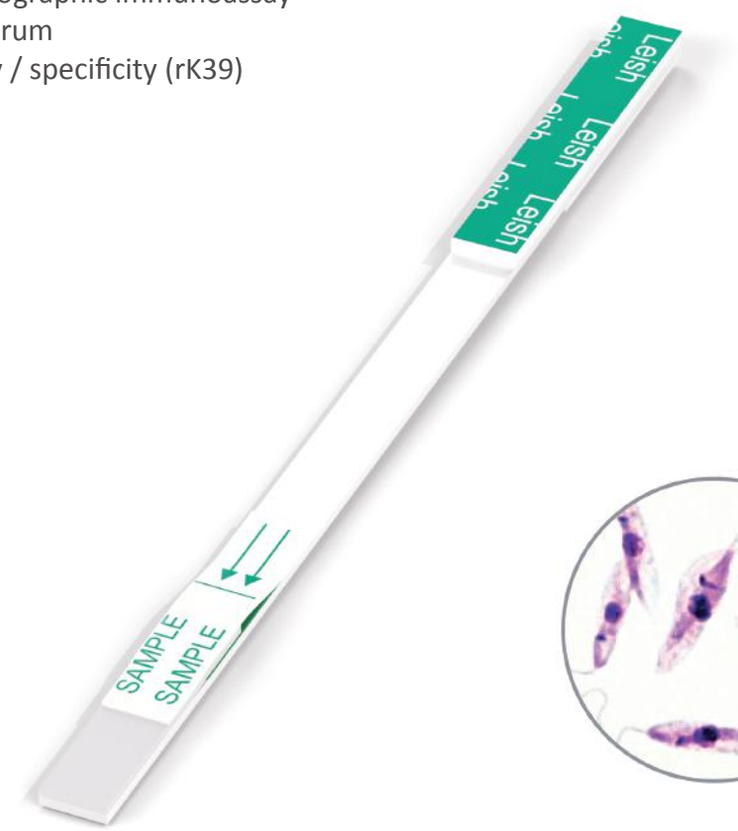
A RAPID, ONE STEP TEST FOR THE QUALITATIVE DETECTION OF ANTIBODY TO VISCERAL LEISHMANIASIS IN SERUM

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

Leishmania Dipstick
RAPYDTEST®

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.

Note: If migration of the gold is not observed within 10-15 seconds after the addition of Chase Buffer, apply light pressure on the sample tape region of test strip until gold migration is observed.

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.donavani 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 line 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
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