

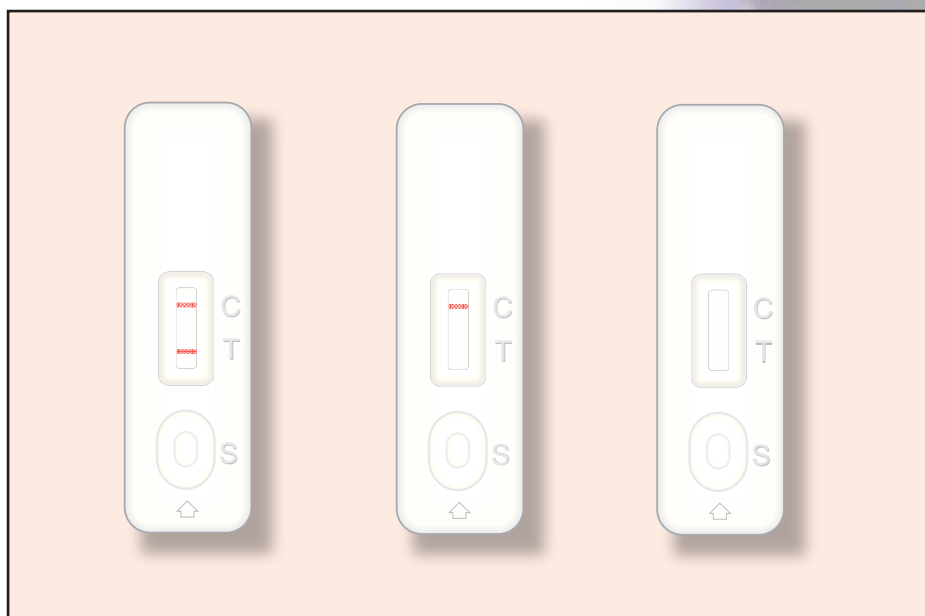
INSTRUCTION SHEET DYS040

# Leishmania Cartridge

## **RAPYDTEST**<sup>®</sup>

A rapid, one step test for the qualitative detection of  
Antibody to Visceral Leishmaniasis in Serum

**Single use device for in vitro diagnostic use only**



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



# Leishmania Cartridges **RAPYDTEST**<sup>®</sup>

## Summary

Leishmaniasis is a spectrum of disease caused by the Leishmania species. The Leishmania species is transmitted to humans and in the body it proliferates and disseminates throughout the reticuloendothelial system as obligate intracellular parasites.

The clinical manifestations of leishmaniasis vary depending on the Leishmania species and the T cell mediated immune responses of the host. There are three major forms of disease: cutaneous, mucocutaneous, and visceral leishmaniasis (VL). VL has been demonstrated as an important opportunistic infection associated with AIDS infection.

Visceral leishmaniasis (kala-azar) is typically caused by several species belonging to the *L. donovani* complex, involving the liver, spleen, and other parts of the reticuloendothelial system. Symptoms may be insidious or of sudden onset, including fever, malaise, anorexia, and weight loss. Hepatosplenomegaly is a hallmark of visceral leishmaniasis. Laboratory findings commonly show anaemia, neutropenia, and hypergammaglobulinemia. A presumptive diagnosis of visceral leishmaniasis is made by the classic clinical presentation in an endemic area. The diagnosis is confirmed by identifying intracellular Leishmania amastigotes in tissue, usually by splenic or bone marrow aspiration. Circulating antibody to a novel antigen conserved in amastigotes of visceral leishmaniasis-inducing Leishmania strains, appears to be sensitive and specific for active visceral infection.

The DiaSys Leishmania One Step Test is a rapid test to qualitatively detect the presence of antibody to visceral Leishmania in serum specimens. The test utilises a combination of protein A-colloidal gold conjugate and recombinant Leishmania antigen to selectively detect antibody to Leishmania in serum.

## Principle

The DiaSys Leishmania One Step Test is a qualitative, membrane based immunoassay for the detection of antibody to visceral Leishmania in serum or plasma. The membrane is pre-coated with recombinant visceral Leishmania antigen on the test line region and anti-protein A antibody on the control line region.

During testing, the serum sample reacts with the dye conjugate (protein A-colloidal gold conjugate) which has been pre-coated in the test device. The mixture then migrates upward on the membrane chromatographically by capillary action to react with recombinant visceral Leishmania antigen on the membrane and generate a red line. Presence of this red line indicates a positive result, while its absence indicates a negative result. Regardless of the presence of antibody to visceral Leishmania, as the mixture continues to migrate across the membrane to the immobilised anti-protein A region, a red line at the control line region will always appear. The presence of this red line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

## Storage

The sealed pouch containing the test cartridge is designed to be stored at room temperature (20°C - 28°C) for the duration of its shelf life. The bottle containing the Chase Buffer is designed to be stored at 2°C - 8°C for the duration of its shelf life. Exposure to temperatures over 30°C can impact the performance of the test and should be minimized. The strips should not be frozen. The test should be used within 1 hour after removal from the pouch or vial to prevent exposure to humidity.

## Materials Provided

DiaSys Leishmania cartridge and Chase Buffer

## Materials Required but not Provided

Tubes for serum collection procedure, centrifuge, timer.

## Precautions

- For professional in-vitro diagnostic use only. Do not use after expiration date.
- Handle all sera and kits used as if they contain infectious agents. Observe established precautions against microbiological hazards while performing all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing, eye protection and disposable gloves while performing the assay. Wash hands thoroughly when finished.

# Leishmania Cartridges **RAPYDTEST**<sup>®</sup>



- Avoid all contact between hands and eyes or mucous membranes during testing.
- Do not eat, drink or smoke in the area where the sera and kits are handled.
- Chase Buffer contains a preservative; avoid all possible contact with skin and mucous membranes.

## Specimen Collection

- Human serum must be used with this test cassette. Whole blood or dilutions of serum cannot be tested directly.
- Remove serum from the clot of red cells as soon as possible to avoid hemolysis.
- Test should be performed as soon as possible after sera collection. Do not leave sera at room temperature for prolonged periods. Sera can be refrigerated at 2-8°C for up to 3 days. Otherwise sera should be stored frozen.
- Bring serum to room temperature prior to testing. Frozen serum must be completely thawed prior to testing. Serum should not be repeatedly frozen and thawed.
- If sera are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.

## Test Procedure

- Allow the sera and Chase Buffer to reach room temperature prior to testing.
- Remove the cartridge from the foil pouch.
- Add 20µl of serum to the sample well of the cartridge device marked 'S'.
- Add 2 drops (100µl) of the Chase Buffer solution provided with this test kit to the sample well marked 'S'.
- 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 (C) and test line (T) appear in the test area as shown. A faint line is considered a positive result. As a guide for interpretation, the red color in the test region will vary depending on the concentration of anti-Leishmanial antibodies present. The test line for 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 antibodies.)



### Negative

The test is negative when only the control line (C) appears. No test line is present, as in Figure 1.



### Invalid

No lines appear at either the control line (C) or the test line (T) areas. The test is also invalid if no control line (C) appears, but a test line is seen (T). It is recommended to retest using a new Kalazar Detect™ Rapid Cartridge Test and fresh serum.

**Note:** The red color 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.



# Leishmania Cartridges RAPIDTEST®

## Performance Characteristics

The DiaSys Leishmania Cartridge Test was clinically tested using sera from 175 patients with parasitologically proven diagnosis for Visceral Leishmaniasis. All 175 (100%) tested positive. Forty endemic healthy asymptomatic controls (first-degree relatives living along with patients in the endemic area) were also tested. Of these, 38 (95%) were negative and two (5%) were positive for the antibodies. Work for performance characteristics with a larger sample population is in progress.

## Limitations

- This test will only indicate the presence of antibodies to Visceral Leishmaniasis in the human serum and should not be used as the sole criterion for the diagnosis of Leishmaniasis. (As with all diagnostic tests, all results must be considered with other clinical information available to the doctor.)
- If the result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result does not preclude the possibility of Leishmaniasis.
- Do not use serum or plasma samples containing any glycerol or other viscous materials. This will compromise the sensitivity of the assay dramatically.

- Persons with advanced HIV infection or other immunocompromised diseases frequently have low or undetectable anti-Leishmanial antibodies.

## References

1. WHO, 1990, *Control of the Leishmaniasis*, 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.

## Ordering Information

Product	Pack Size	Ordering Code
DiaSys Leishmania Cartridge Rapydtest	40	1603

Order product direct from DiaSys or appointed distributor



DiaSys updates its home pages on the Internet regularly with new product announcements, applications and company news. Visit our web page for all the latest information: <http://www.diasys.com> or e-mail on: [sales@diasys.co.uk](mailto:sales@diasys.co.uk)



Unit 5, The Sapphire Centre, Fishponds Road, Wokingham, Berkshire, RG41 2QL, England  
Tel: +44 (0)118 9795 566 Fax: +44 (0)118 9795 186



V4 04/2008