Visceral Leishmaniasis Antibody Detection by Rapid Test

*FOR THE QUALITATIVE DETECTION OF ANTI-*LEISHMANIA *ANTIBODIES*

Test Highlights

IgG-specific assay that replaces a total antibodies assay.

Disease Overview

- Visceral leishmaniasis (VL) is also known as kala-azer (Hindi for "black fever").
- VL is a specific form of leishmaniasis caused by *L. donovani*, *L. chagasi*, and *L. infantum*. Antigenic similarities between these species make IgG testing for *Leishmania donovani* highly sensitive and specific for the disease.
- Parasite is transmitted to humans by sandflies.
- Clinical symptoms of VL are chronic fever, hepatosplenomegaly, anemia, and growth retardation in children; may be fatal if untreated.

Immunology

- Following the onset of symptoms, IgG antibodies are typically measurable in over 90 percent of visceral leishmaniasis cases.
- Testing for IgM antibodies has no demonstrated clinical utility.

Epidemiology

- Visceral leishmaniasis is endemic in the tropics, subtropics, and southern Europe, with the majority of cases occurring in India, Brazil, and Sudan.
- It is estimated that 500,000 people become symptomatic for VL each year, with as many as 350 million people at risk of infection.
- Up to 10 percent of cases remain asymptomatic.
- Military personnel returning from Iraq are at risk for developing VL.
- Infection may be transmitted through blood products.

Indications for Ordering

- This test should be ordered if exposure to sandflies is suspected and visceral leishmaniasis symptoms exist.
- Individuals who have traveled to areas endemic for *Leishmania spp*. may be considered for testing even if asymptomatic, since symptoms may present months following initial infection or not at all.

Interpretation

A positive result of one unit or greater indicates presence of serum IgG antibodies against *Leishmania donovani*.

Limitations

- This test has been validated for serum and plasma samples only. No other sample types may be used.
- This test should not be used in the diagnosis of cutaneous or mucosal leishmaniasis, as an antibody response is not observed in either form of the disease.
- Serological testing has limited utility in acute diagnosis.

Methodology

Patient sample is added to the base of a nitrocellulose strip. The presence of a solid line after incubation indicates a positive result.

References

1. Mandell G, Bennett J, Dolin R, eds. Principles and Practice of Infectious Diseases. 5th ed. 2000; New York: Churchill Livingston.
2. Davidson R. N. Visceral leishmaniasis in clinical practice. *J Infect* 1999;39:112–6.
3. Herwaldt B. L. Leishmaniasis. *Lancet* 1999;354:1191–9.
4. Package Insert for *Kalazar Detect*™ Rapid Test. InBios International, Inc. 2007.

Test Information

0051726 ***Leishmania*** **Antibody, IgG (Visceral Leishmaniasis)**

For specific collection, transport, and testing information, refer to the ARUP Web site at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.

ARUP LABORATORIES • JULY 2008

500 Chipeta Way, Salt Lake City, UT 84108 • (800) 522-2787 • (801) 583-2787 • www.aruplab.com • www.arupconsult.com