MAYO CLINIC LABORATORIES

Test Definition: LEIS

Leishmaniasis (Visceral) Ab, S

Overview

Useful For

Aiding in the diagnosis of active visceral leishmaniasis

This test should **not be used** as the sole criteria for diagnosis.

Method Name

Immunochromatographic Strip Assay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.2 mL

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Specimen Minimum Volume

0.1 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Visceral leishmaniasis (kala azar) is a disseminated intracellular protozoal infection that targets primarily the reticuloendothelial system (liver, spleen, bone marrow) and is caused by *Leishmania donovani, Leishmania chagasi,* or *Leishmania infantum (L donovani* complex).

Transmission is by the bite of sandflies. Clinical symptoms include fever, weight loss, and splenomegaly; pancytopenia and hypergammaglobulinemia are often present. Most (90%) new cases each year arise in rural areas of India, Nepal, Bangladesh, Sudan, and Brazil, but the disease has a worldwide distribution, including the Middle East.

Definitive diagnosis has required the microscopic documentation of characteristic intracellular amastigotes in stained smears from culture of aspirates of tissue (spleen, lymph node) or bone marrow. The detection of serum antibodies to the recombinant K39 antigen of *L donovani* is an alternative noninvasive sensitive (95%-100%) method for the diagnosis of active, visceral leishmaniasis.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

Negative:

Negative results indicate the absence of antibodies to members of the *Leishmania donovoni* complex. Repeat testing in 2 to 3 weeks if clinically indicated. Immunocompromised patients frequently have low or undetectable antibodies to Leishmania species.

Positive:

Positive results indicate the presence of antibodies to members of the *L donovoni* complex, the causative agents of

visceral leishmaniasis. Results should not be used as the sole criterion for diagnosis or treatment of visceral leishmaniasis and should not be used to diagnose other forms of leishmaniasis. False-positive reactions due to malaria infection have been reported.

Cautions

This test indicates only the presence of antibodies and should not be used as the sole criteria for diagnosis.

False-positive results may occur in patients with malaria or in the presence of rheumatoid factor.

Specimens containing glycerol or other viscous materials may interfere with the test.

Patients coinfected with HIV and *Leishmania* may fail to produce antibodies.

Supportive Data

Manufacturer's reported sensitivity and specificity (for endemic areas) are 90% or more and 93% to 100% respectively (InBios Kalazar Detect Rapid Test product insert). Validation studies in the Mayo Clinic Division of Clinical Microbiology provided a sensitivity of 94% (panel of 16 known positives) and specificity of 100% (panel of 50 normal blood donors plus 16 positives for other parasitic infections).

Clinical Reference

1. Sundar S, Sahu M, Mehta H, et al: Noninvasive management of Indian visceral leishmaniasis: clinical application of diagnosis of K39 antigen strip testing at a kala-azar referral unit. Clin Infect Dis. 2002 Sep 1;25(5):581-586

2. Aronson NE, Copeland NK, Magill AJ: *Leishmania* species: visceral (Kala-Azar), cutaneous, and mucosal leishmaniasis. In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020:3321-3339

Performance

Method Description

Immunochromatographic strip assay for the qualitative detection of antibodies to the *Leishmania donovani* complex in serum. The test strip membrane is coated on the bottom with a band of recombinant K39 antigen and on the top with immobilized antiprotein A antibody to detect IgG. A protein A-gold conjugate is used as the detection reagent. For this test, 20 mcL of serum is added to the test strip. The appearance of both a control and test band is considered a positive result.(Carvalho SF, Lemos EM, Corey R, Dietze R: Performance of recombinant K39 antigen in the diagnosis of Brazilian

visceral leishmaniasis. Am J Trop Med Hyg. 2003;68:321-324; package insert: Kalazar Detect Rapid Test for Visceral Leishmaniasis. InBios International, Inc; 05/01/2018)

PDF Report

No

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86717

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
LEIS	Leishmaniasis (Visceral) Ab, S	7958-2

Result ID	Reporting Name	LOINC®
86219	Leishmaniasis (Visceral) Ab, S	7958-2