Test Definition: LEIS

Leishmaniasis (Visceral) Antibody, Serum

Overview

Useful For

Aid 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

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.2 mL Serum

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume

Serum: 0.1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

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 most commonly caused by *Leishmania donovani, Leishmania chagasi,* or *Leishmania infantum (L donovani* complex). Transmission *of* Leishmania species occurs via the bite of sandflies. Infection with these intracellular protozoa typically leads to a disseminated infection that primarily affects the reticuloendothelial system (liver, spleen, bone marrow). Clinical symptoms include fever, weight loss, and splenomegaly; pancytopenia and hypergammaglobulinemia are also 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 of visceral leishmaniasis requires 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 method for the diagnosis of active, visceral leishmaniasis.

Reference Values

Negative
Reference values apply to all ages.

Interpretation

Negative:
No antibodies to members of the *Leishmania donovoni* complex detected. Repeat testing in 2 to 3 weeks if clinically indicated. Immunocompromised patients frequently have low or undetectable antibodies to *Leishmania* species.

Positive:
Antibodies to members of the *L donovoni* complex detected. 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 may occur.

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.

Antibodies to *Leishmania* species not associated with visceral leishmaniasis will not be detected by this assay.

Clinical Reference

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[3]:321-324; package insert: Kalazar Detect Rapid Test for Visceral Leishmaniasis. InBios International, Inc; 12/15/2025)

PDF Report

No

Day(s) Performed

Tuesday, Thursday

Report Available

Same day/1 to 4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

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.

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CPT Code Information

86717

LOINC® Information

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

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