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.

Specimen Minimum Volume
0.1 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>14 days</td>
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Clinical and 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


**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 µL 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

**Day(s) and Time(s) Test Performed**

Monday, Wednesday, Friday; 9 a.m.

**Analytic Time**

Same day/1 day

**Maximum Laboratory Time**

4 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved or is exempt by the U.S. 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

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<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>Leishmaniasis (Visceral) Ab, S</td>
<td>7958-2</td>
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<table>
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<td>86219</td>
<td>Leishmaniasis (Visceral) Ab, S</td>
<td>7958-2</td>
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