Overview

Useful For
Diagnosis of active visceral leishmaniasis

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

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

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<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*, *L. chagasi*, or *L. 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**

A positive result is consistent with a diagnosis of active visceral leishmaniasis.

**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% 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 (Kalazar Detect Rapid Test, InBios International). 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)
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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<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>LEIS</td>
<td>Leishmaniasis (Visceral) Ab, S</td>
<td>7958-2</td>
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<table>
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<td>Leishmaniasis (Visceral) Ab, S</td>
<td>7958-2</td>
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