Anti-Leishmania donovani IIFT

Positive reaction

Negative reaction

Antibodies against Leishmania donovani

Indications: Test system for the in vitro determination of antibodies against Leishmania donovani in human serum or plasma for the diagnosis of the following diseases: leishmaniasis, post-kala-azar dermal leishmaniasis, splenomegaly, hepatomegaly, anaemia, erythematous skin lesions.

Clinical significance: The genus Leishmania contains at least 13 human pathogenic species. Within Europe the species L. donovani and L. infantum are found in southern regions. About 12 million people worldwide are infected with Leishmania, and the number of new infections is estimated to be 1-2 million annually. The main forms of disease caused by Leishmania infections are visceral leishmaniasis, cutaneous leishmaniasis and mucocutaneous leishmaniasis. In visceral leishmaniasis (kala-azar) the parasites attack the reticuloendothelial system of the inner organs, in particular the liver and spleen. Clinical symptoms are fever and hepatosplenomegaly, often with anaemia and gastrointestinal complaints. The incubation time ranges from several weeks to two years. Post-kala-azar dermal leishmaniasis, characterized by diffuse erythematous and later nodular skin lesions can occur following visceral leishmaniasis. With cutaneous leishmaniasis (oriental boil) usually only the skin around the bite is affected. A papule forms, which after several weeks evolves further into an extensive inflammatous necrotizing sore. In most cases the sore heals spontaneously within six months. Mucocutaneous leishmaniasis begins similarly to cutaneous leishmaniasis and affects predominantly the mucous membranes. This form of disease leads to severe or even life-threatening tissue disorders.

Because of increased travel, infections with Leishmania can also occur in northern Europe. Therefore, in patients with unspecific symptoms (such as fever, night sweat, exhaustion) and non-healing skin diseases a Leishmania infection should be taken into consideration.

Relevance of the Anti-Leishmania donovani IIFT: The indirect immunofluorescence test (IIFT) is one of the standard methods for detection of a Leishmania infection. Antibodies occur predominantly in visceral leishmaniasis, and their detection can secure a diagnosis.

Immunofluorescence patterns

Positive reaction: Antibodies against Leishmania result in a smooth, either complete or in part, rimmed fluorescence of the cell body. Cells must be clearly identifiable in every field examined, preferably in several areas. Fluorescence of single parasites or only a small area of parasites should not be evaluated as positive.

Negative reaction: No specific fluorescence of the parasites is observed, although their outline can often be recognized.

Evaluation data: Antibodies against Leishmania donovani were investigated in 10 Leishmania-positive and 200 Leishmania-negative sera (Institute for Tropical Medicine, Hamburg; Robert-Koch Institute, Berlin; University of Lübeck, Germany) using the EUROMMUN IIFT. The sensitivity and specificity as well as the positive predictive value of the EUROMMUN IIFT amounted to 100%. Cross reactions with sera from patients with infectious diseases (tuberculosis, malaria; n = 50) were only detected in one case. This was probably a co-infection with Plasmodium (malaria) and Leishmania.
## Test Characteristics

### Anti-Leishmania donovani IIFT

**Test principle:** The indirect immunofluorescence test is an in vitro assay for the determination of specific antibodies against Leishmania donovani. BIOCHIPs coated with Leishmania donovani are fixed onto the reaction fields of a microscope slide. With EUROIMMUN BIOCHIP Mosaics™ different substrates can be positioned next to each other on one reaction field and incubated simultaneously with one serum dilution, allowing a detailed patient antibody profile to be established with a single test.

**Test procedure:** EUROIMMUN BIOCHIP slides are incubated using the proprietary TITERPLANE™ Technique, which enables multiple samples to be incubated next to each other and simultaneously under identical conditions. Results are evaluated by fluorescence microscopy. Incubation of the substrates with the positive and negative controls provided in each kit verifies correct performance of the test and aids evaluation.

**Inter-lot variation:** Slides from at least 3 different anti-Leishmania donovani IIFT kit lots were incubated with the positive and negative calibration sera from the Robert-Koch Institute (Berlin, Germany). The deviation amounted to no more than ±1 fluorescence intensity level.

**Reference range:** Sera from 201 healthy blood donors were investigated for anti-Leishmania-donovani antibodies using the EUROIMMUN IIFT. With a dilution of 1:320 (cut-off IgG) and a dilution of 1:100 (cut-off IgA and IgM) none of the blood donors’ sera showed positive results.

### Technical data:

<table>
<thead>
<tr>
<th>Component</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td><strong>Antigen substrate</strong></td>
<td>Leishmania donovani L08.</td>
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<tr>
<td><strong>Sample material</strong></td>
<td>Serum or plasma.</td>
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<tr>
<td><strong>Sample dilution</strong></td>
<td>IgG</td>
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<tr>
<td><strong>Qualitative evaluations</strong></td>
<td>1:320</td>
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</tbody>
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### Incubation with the TITERPLANE™ Technique

**Light source:** EUROIMMUN LED or mercury vapor lamp, 100 W

**Excitation filter:** 488 nm, color separator: 510 nm, blocking filter: 520 nm

**Quantitative evaluations:** dilutions of 1:320 (cut-off), 1:1,000, 1:10,000, etc.

**Qualitative evaluations:** 1:320

**Test procedure:** 30 min (sample) / 30 min (conjugate). Room temperature.

**Microscopy:** Objective 40x

**Excitation filter:** 488 nm, color separator: 510 nm, blocking filter: 520 nm

**Light source:** EUROIMMUN LED or mercury vapor lamp, 100 W

**Reagents**

- Ready for use, with the exception of the PBS-Tween buffer (for dilution and washing).

**Stability**

All kit components are stable for at least 18 months from the date of manufacture.

**Kit formats**

- 10 or 20 slides, each containing 3, 5 or 10 test fields.
- Kits include all necessary reagents.

**Order no.**

FI 2231-1005 G

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*Currently not available as IVD in the EU.*

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