



## SERION ELISA *classic* Leishmania IgG

### Intended use

- Qualitative and quantitative detection of human IgG antibodies in serum or plasma directed against Leishmania
- Support in the diagnosis of visceral leishmaniasis
- Confirmation of contact with the pathogen
- Determination of the immune status in epidemiological studies

### Diagnostic Efficiency

The SERION ELISA *classic* Leishmania IgG immunoassay was validated in an internal study. This consisted of the analysis of 203 serum samples from healthy blood donors and patients with suspected leishmaniasis using the commercially available ELISA of a competitor as a reference test.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Leishmania IgG	>99 %	> 99%

### Precision

#### SERION ELISA *classic* Leishmania IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.368	3.1	0.398	4.9
Serum 2	0.435	2.5	0.460	6.2
Serum 3	1.511	1.5	1.584	4.1

## Pathogen

Leishmaniasis is an infectious disease caused by protozoic parasites of the genus *Leishmania*. The disease occurs predominantly in tropical and subtropical climate zones. Primarily affected are farm and domestic animals, however the disease can also be transmitted to humans. Leishmaniasis is distributed worldwide with high incidences in Eastern Africa, Southern America and Asia. In Europe, the Mediterranean area is particularly affected. Around 12 million people are infected with *Leishmania* worldwide.

## Disease

Dogs and rodents serve as the main reservoirs for *Leishmania*, but also cats, horses, sheep and cattle may be afflicted. Sandflies (*phlebotominae*) or other moth flies (*psychodidae*) transmit the parasites to humans. The incubation period is very variable, ranging from a few weeks up to several years. Depending on the immune status, the various *Leishmania* species can induce different clinical manifestations, which are referred to as cutaneous, mucocutaneous or visceral leishmaniasis. Cutaneous leishmaniasis is frequently caused by *L. tropica*, *L. major* or *L. aethiopica*. Pro-

liferation of the parasites is mainly restricted to the site of infection. Following an erythematous rash, a non-painful ulcer with a diameter of up to five centimeters can develop. Mucocutaneous leishmaniasis (*uta, espundia*) is caused by *L. brasiliensis* and affects – besides the skin – also the mucous membranes, e.g. in the nasal region, the oral cavity or the pharyngeal region, more seldom the genitals. The disease manifests clinically with severe skin ulceration and tissue destruction. Infections with *L. donovani* and – in Europe – *L. infantum* may induce visceral leishmaniasis (*kala-azar*). The disease manifests primarily with flu-like symptoms, swollen lymph nodes and recurring fever accompanied by abdominal pain, nausea, vomiting and diarrhea. Depending on the organs involved, additional clinical symptoms may occur.

## Diagnosis

Due to the variety of clinical presentations, the diagnosis of leishmaniasis is based on direct pathogen detection methods, such as cytology, histology or PCR, as well as on the serological determination of specific IgG antibodies by IFT or ELISA tests.

Product	Order No.
SERION ELISA <i>classic</i> Leishmania IgG	ESR147G

## SERION ELISA control

Please visit our website for more information.

## Highlights

- Support in the diagnosis of visceral leishmaniasis
- Quantification of the IgG antibody activity for disease stage monitoring and therapy control
- Excellent diagnostic efficiency with high sensitivity and specificity