



SERION ELISA *classic*

# Leptospira IgG/IgM

## Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum or plasma directed against *Leptospira ssp.*
- Detection of IgM antibodies for the determination of acute leptospirosis
- Detection of IgG antibodies to provide a complete immunological picture

## Diagnostic Efficiency

For the evaluation of the performance characteristics of the SERION ELISA *classic* Leptospira IgG and IgM immunoassays, a panel of 63 serum samples from patients with suspected leptospirosis as well as healthy blood donors have been analyzed in

an internal study using the serovar-specific Complement Fixation Tests (CFT) as references. As the CFT does not differentiate between IgG and IgM antibodies, the results obtained with SERION ELISA *classic* Leptospira IgG and IgM were summated.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Leptospira IgG / IgM	94.7 %	>99 %

## Precision

### SERION ELISA *classic* Leptospira IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.065	7.0	0.070	8.8
Serum 2	0.557	4.6	0.637	13.2
Serum 3	1.536	3.8	1.752	7.6

## SERION ELISA *classic* Leptospira IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.274	9.3	0.309	6.0
Serum 2	0.732	7.7	0.993	7.8
Serum 3	1.378	4.4	1.600	6.4

### Pathogen

Leptospirosis is an infectious disease which occurs worldwide and is caused by bacteria of the genus *Leptospira*. More than 250 serovars have been identified and grouped into 24 serovars on the basis of their surface antigens. Wild and domesticated animals act as reservoirs for this pathogen. *Leptospira* can survive for extended periods in the kidney tubules of infected animals and are excreted in the urine. Transmission to humans occurs by contact with urine, blood or tissues of infected animals, and contaminated water. The bacteria gain access to the body via skin lesions or contact with mucous membranes.

### Disease

Replication of the bacterium proceeds primarily in organs (e.g. kidneys and liver) as well as the central nervous system. As a consequence, infections are frequently misdiagnosed as meningitis or hepatitis from other causes. Approximately 90% of cases of leptospirosis are accompanied by flu-like symptoms including the sudden onset of fever, severe headache, muscle ache and nausea. A biphasic course of disease is characteristic for a *Leptospira* infection. In severe cases called Morbus Weil Disease, liver and kidney damages may lead to a morbidity rate of 30%

if left untreated.

### Diagnosis

During the initial disease phase, isolation of leptospira from blood samples is possible. However, cultivation of the pathogen is often too time-consuming to allow for an effective antibiotic treatment. Consequently, diagnosis based on antibody detection such as Microagglutination tests (Gold Standard), CFT or ELISA is more frequently employed to affect a more rapid diagnosis of *Leptospira* infections. Once the second disease phase has started, the only effective diagnostic methodology is serology. IgM and IgG are detectable for a considerable period, however, less than 90% of patients actually produce IgG antibodies.

Product	Order No.
SERION ELISA <i>classic</i> Leptospira IgG	ESR125G
SERION ELISA <i>classic</i> Leptospira IgM	ESR125M

### SERION ELISA *control*

Please visit our website for more information.

## Highlights

- Use of native membrane extract from *Leptospira biflexa* with genus-specific antigens for the demonstration of IgG and IgM antibodies directed against *Leptospira ssp.*
- Sensitive demonstration of IgM antibodies for detection of acute primary infections
- Specific demonstration of IgG antibodies for determination of a contact with *Leptospira ssp.* and confirmation of the infection, particularly in the secondary stage of a biphasic disease
- No significant cross-reactivity with antibodies against *Borrelia burgdorferi*, *Treponema pallidum*, EBV and with rheuma factors
- Quantification of IgG and IgM antibodies for disease stage monitoring and therapy control

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