SERION ELISA classic
Leptospira IgG / IgM

The SERION ELISA classic Leptospira IgG and IgM tests are qualitative and quantitative immunoassays for the detection of genus-specific antibodies directed against Leptospira ssp. in human serum or plasma. The SERION ELISA classic Leptospira IgM test is recommended for the determination of acute leptospirosis, whereas the SERION ELISA classic Leptospira IgG test may be used in addition to the SERION ELISA classic Leptospira IgM test to provide a complete immunological picture.

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 blood, central nervous system, kidneys and liver. 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 disease is characteristic for a Leptospira infection. In severe cases of 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.

**SERION ELISA **classic** Leptospira IgG / IgM**

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.

**Sensitivity and Specificity**

<table>
<thead>
<tr>
<th>SERION ELISA classic</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leptospira IgG / IgM</td>
<td>94.7 %</td>
<td>&gt; 99 %</td>
</tr>
</tbody>
</table>

**Precision**

**SERION ELISA classic Leptospira IgG**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Value OD</th>
<th>Intraassay CV (%) (n=20)</th>
<th>Mean Value OD</th>
<th>Interassay CV (%) (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum 1</td>
<td>0.065</td>
<td>7.0</td>
<td>0.070</td>
<td>8.8</td>
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<tr>
<td>Serum 2</td>
<td>0.557</td>
<td>4.6</td>
<td>0.637</td>
<td>13.2</td>
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<tr>
<td>Serum 3</td>
<td>1.536</td>
<td>3.8</td>
<td>1.752</td>
<td>7.6</td>
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</table>

**SERION ELISA classic Leptospira IgM**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean Value OD</th>
<th>Intraassay CV (%) (n=20)</th>
<th>Mean Value OD</th>
<th>Interassay CV (%) (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum 1</td>
<td>0.274</td>
<td>9.3</td>
<td>0.309</td>
<td>6.0</td>
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<tr>
<td>Serum 2</td>
<td>0.732</td>
<td>7.7</td>
<td>0.993</td>
<td>7.8</td>
</tr>
<tr>
<td>Serum 3</td>
<td>1.378</td>
<td>4.4</td>
<td>1.600</td>
<td>6.4</td>
</tr>
</tbody>
</table>

**Highlights of SERION ELISA classic Leptospira IgG/IgM**

- Use of native membrane extract from *Leptospira biflexa* with genus-specific antigens for the demonstration of IgG and IgM antibodies directed against all *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
- Quantification of IgG and IgM antibodies for disease stage monitoring and therapy control
- High cost efficiency by using break-apart microtiter strips and single-point calibration
- Consistent incubation times for combination of SERION ELISA classic IgA, IgG and IgM immunoassays in one microtiter frame
- Ready-to-use and barcoded test components, optimized for automation

**Order Information**

SERION ELISA classic Leptospira IgG  
Order Nr.: ESR 125 G

SERION ELISA classic Leptospira IgM  
Order Nr.: ESR 125 M

SERION ELISA control  
Please visit our website www.virion-serion.com for more information on our SERION ELISA classic products.