Indications: Test system for the in vitro determination of antibodies against Chlamydia trachomatis in human serum or plasma for the diagnosis of the following diseases: trachoma, conjunctivitis, urogenital infections, pneumonia in infants, lymphogranuloma venereum.

Clinical significance: Chlamydia trachomatis belongs to the chlamydiae group of human pathogens, together with Chlamydia psittaci and Chlamydia pneumoniae, and is the most common sexually transmitted infectious agent worldwide. It causes trachoma (serotypes A, B, and C), swimming pool conjunctivitis, urogenital infections (urethritis, cervicitis, adenitis, epididymitis, prostatitis), and, in newborns, pneumonia in addition to conjunctivitis (serotypes D to K). Lymphogranuloma venereum is caused by Chlamydia trachomatis serotypes L1 to L3.

Clinical data: The prevalence of antibodies against Chlamydia trachomatis was analyzed in 400 healthy blood donors, 200 healthy pregnant women, 134 high-risk persons (prostitutes) and 54 patients with reactive arthritis. The prevalences obtained were consistent with values in the literature. In the pregnant women the antibody prevalences were slightly higher than in the blood donors, due to the age range of this panel (20-29), at which the prevalence of Chlamydia trachomatis infections is at its highest. The sensitivity of the ELISA with respect to direct pathogen detection amounted to 75%. The remaining patients probably had a localized infection without production of antibodies.

Application of the Anti-Chlamydia trachomatis ELISA: In localized infections antibodies against Chlamydia trachomatis do not always appear in the serum. Furthermore, florid infections are not always accompanied by the formation of antibodies of class IgM or an increase in the IgG titer. Therefore, the detection of Chlamydia in infectious secretions by direct immunofluorescence or the identification of specific gene sequences by PCR is recommended. However, these methods are not successful in all cases, and the detection of antibodies is often the only way to confirm a Chlamydia infection.

The lipopolysaccharide coats of the different Chlamydia trachomatis serotypes as well as all three Chlamydia species are very similar. To avoid cross reactions, pathogen-specific MOMP (major outer membrane proteins) are employed as the antigenic substrate in the EUROIMMUN ELISA. Thereby, infections with C. trachomatis can be reliably differentiated from infections with C. psittaci and C. pneumoniae with this ELISA.

<table>
<thead>
<tr>
<th>Panel</th>
<th>n</th>
<th>IgA</th>
<th>IgG</th>
<th>IgM</th>
<th>IgA/IgG/IgM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donors, panel 1</td>
<td>200</td>
<td>0.5%</td>
<td>8.0%</td>
<td>3.0%</td>
<td>11.0%</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>200</td>
<td>1.5%</td>
<td>5.5%</td>
<td>2.5%</td>
<td>7.0%</td>
</tr>
<tr>
<td>High-risk persons</td>
<td>134</td>
<td>16.6%</td>
<td>42.5%</td>
<td>11.9%</td>
<td>48.5%</td>
</tr>
<tr>
<td>Reactive arthritis</td>
<td>54</td>
<td>5.6%</td>
<td>278%</td>
<td>13.0%</td>
<td>35.2%</td>
</tr>
<tr>
<td>C. trachomatis infection</td>
<td>100</td>
<td>54.0%</td>
<td>670%</td>
<td>270%</td>
<td>75.0%</td>
</tr>
</tbody>
</table>

Test Characteristics

Anti-Chlamydia trachomatis ELISA (IgG)

Linearity: The linearity of the ELISA was determined by assaying serial dilutions of several sera with high titers. The graph opposite shows the typical linearity data obtained, demonstrated using three sera.

Reproducibility: Coefficients of variation (CVs) were determined using data from three sera with values at different points on the standard curve. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on four measurements repeated on six different days.

Reference range: Levels of anti-Chlamydia trachomatis antibodies (IgG) were analyzed in a panel of 200 healthy blood donors using the EUROIMMUN ELISA. With a cutoff of 20 RU/ml, 4.0% of the blood donors were anti-Chlamydia trachomatis positive (IgG), which reflects the known percentage of infection in adults.

Technical data:

Antigen

The antigen used in this ELISA is purified MOMP (major outer membrane protein; a transmembrane protein present in the outer membrane of the elementary bodies), isolated from cell lysates of BGM cells infected with Chlamydia trachomatis serotype K.

Calibration

Quantitative, in relative units per ml (RU/ml).

Calibration serum 1: 200 RU/ml
Calibration serum 2: 20 RU/ml; cut-off value
Calibration serum 3: 2 RU/ml

Sample dilution

Serum or plasma; 1:101 in sample buffer.

Reagents

Ready to use, with the exception of the wash buffer (10x). Color-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits.

Test procedure

30 min / 30 min / 15 min. Room temperature. Fully automatable.

Measurement

450 nm. Reference wavelength 620 nm.

Kit format

96 single break-off wells. Kit includes all necessary reagents.

Order no.

EI 2191-9601 G