**Anti-Chlamydia pneumoniae ELISA (IgG)**

- Based on purified cell lysate
- Sensitive detection of antibodies against *Chlamydia pneumoniae*
- Fully automated processing and evaluation

### Technical data

**Antigen**
Highly purified cell lysate of HL cells infected with *Chlamydia pneumoniae* of strain CWL-029

**Calibration**
Quantitative, in relative units per millilitre (RU/ml)
- Calibration serum 1: 200 RU/ml
- Calibration serum 2: 20 RU/ml
- Calibration serum 3: 2 RU/ml

Recommended upper threshold for non-infected individuals (cut-off): 20 RU/ml

Semiquantitative evaluation possible via ratio

**Sample dilution**
- Serum or plasma, 1:101 in sample buffer

**Reagents**
- Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits

**Test procedure**
- 60 min (37 °C) / 30 min / 15 min, room temperature, fully automatable

**Measurement**
- 450 nm, reference wavelength between 620 nm and 650 nm

**Test kit format**
- 96 break-off wells; kit includes all necessary reagents

**Order no.**
- EI 2192-9601 G

### Clinical significance

The pathogen *Chlamydia pneumoniae* (synonym: *Chlamydophila pneumoniae*) is recognised as the third *Chlamydia* species alongside *Chlamydia trachomatis* and *Chlamydia psittaci*. *C. pneumoniae* is a worldwide spread, exclusively human pathogen which is transmitted by aerosols. Approximately half of infections proceed asymptptomatically or may cause a mildly sore throat at the most. All other cases of infections with *C. pneumoniae* are characterised predominantly by persisting unproductive cough, headache and fever. Chronic illnesses associated with *C. pneumoniae* are bronchial asthma, coronary heart diseases and atherosclerosis as well as more rare diseases such as meningoccephalitis, myocarditis and Guillain Barré syndrome. Secondary reactive *C. pneumoniae* arthritis, which is often accompanied by synovialitis or tendovaginitis, is of particular importance. More than 50% of adults over 20 years of age have experienced a *C. pneumoniae* infection and developed antibodies against the pathogen.

### Diagnostic application

Since the diagnosis of *C. pneumoniae* infections by means of symptoms or radiography is not entirely reliable owing to the large variety of manifestations, laboratory diagnostics play a significant role. The Anti-Chlamydia pneumoniae ELISA (IgG) is excellently suited for the serological detection of a *C. pneumoniae* infection and is a useful supplement to the direct detection method. A positive IgM and/or IgA result together with a significant increase in the IgG titer of a follow-up sample taken after two to eight weeks indicate an acute infection. Moreover, serological analyses can provide information about the epidemiology of *C. pneumoniae* infections.
Reference range

The levels of anti-C. pneumoniae antibodies (IgG) were analysed with the EUROIMMUN Anti-Chlamydia pneumoniae ELISA (IgG) in a panel of 500 healthy blood donors. With a cut-off value of 20 IU/ml, 72.2 % of the blood donors were anti-C. pneumoniae positive (IgG).

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using three samples. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on four determinations performed in six different test runs.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Intra-Assay variation, n = 20</th>
<th>Inter-Assay variation, n = 4 x 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean value (RU/ml)</td>
<td>CV (%)</td>
</tr>
<tr>
<td>1</td>
<td>57</td>
<td>3.9</td>
</tr>
<tr>
<td>2</td>
<td>83</td>
<td>2.5</td>
</tr>
<tr>
<td>3</td>
<td>116</td>
<td>2.1</td>
</tr>
</tbody>
</table>

Quality assessment results

111 clinically precharacterised patient samples from quality assessment institutes (INSTAND e.V., Germany; Labquality, Finland) were tested using the EUROIMMUN Anti-Chlamydia pneumoniae ELISA (IgG). The agreement of the qualitative ELISA results with the specifications of the quality assessment institutes was 99 % (excluding borderline sera).

Sensitivity and specificity

143 precharacterised patient samples (origin: Europe; reference method: commercially available ELISA from another manufacturer) were investigated using the EUROIMMUN Anti-Chlamydia pneumoniae ELISA (IgG). The sensitivity of the EUROIMMUN ELISA was 98 %, with a specificity of 100 %.

Cross reactivity

216 sera from patients with acute infections by different pathogens (positive IgG results) without previous C. pneumoniae infections were investigated with the EUROIMMUN ELISA (IgG). No cross reactions (CR) were found.

Literature