Anti-Toxoplasma gondii ELISA (IgG)

- ELISA for the sensitive and specific determination of IgG antibodies against Toxoplasma gondii
- Quantification in IU/ml with respect to the international standard of the WHO
- Simple and fast test performance – fully automatable

### Technical data

**Antigen**
Detergent extract of purified Toxoplasma gondii organisms

**Calibration**
Quantitative, in international units per ml (IU/ml); based on the 3rd international standard preparation of the World Health Organization (WHO)
- Calibration serum 1: 200IU/ml
- Calibration serum 2: 10IU/ml
- Calibration serum 3: 1IU/ml

Recommended upper threshold for non-infected persons (cut-off): 10IU/ml

**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**
- 30 min / 30 min / 15 min, room temperature, fully automatable

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

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

**Order no.**
- EL 2410-9601 G

### Clinical significance

The sporozoan Toxoplasma gondii is the causative agent of the worldwide distributed zoonosis toxoplasmosis. The main host animal is the cat. Oocysts are produced in the cat intestine during the sexual development cycle. During the asexual cycle, the Toxoplasma parasites develop in the brain, muscles, liver, spleen and in other organs of a warm-blooded animal, where they become encapsulated. Humans are generally infected perorally by ingestion of oocysts with viable trophozoites, which are contained in the faeces of infected cats or in meat products (raw flesh) from infected animals. Toxoplasmosis proceeds inapparently in >90% of cases. Cysts containing trophozoites form in the tissues and can persist for years. The symptoms of the manifest disease include fever, lymphadenopathy, encephalitis, chorioretinitis, myositis, myocarditis, pneumonia, hepatosplenomegaly and exanthema, depending on the affected organs. Toxoplasma gondii can also be transmitted diaplacentally when a pregnant woman is infected for the first time. After an intrauterine infection with the pathogen in the first trimester, placenta and embryo are severely affected, resulting in rejection of the embryo. An infection in the second or third trimester results in foetal symptoms which vary in intensity depending on the time point of infection, the dose of the infection and the immune status of mother and foetus. Among the most important symptoms are the following: hepatosplenomegaly, pneumonia, myocarditis, purpura, hydrocephalus and intracranial anomalies (in particular intracerebral calcification), chorioretinitis and optic nerve oedema with concurrent distant active lesions. Connatalely infected children mostly show severe damage, as they are treated too late.

### Diagnostic application

Since direct detection of Toxoplasma is seldom successful, serological methods play an important role in the diagnosis of a Toxoplasma gondii infection. Antibodies of class IgM and IgG are detectable around 8 days after infection. The IgM antibodies disappear after a few months, whereas IgG antibodies persist lifelong. In most cases the determination of IgG and IgM antibodies can establish the presence of a fresh infection which could pose a risk to a pregnancy. For confirmation, specific IgA antibodies are investigated and the avidity of specific IgG antibodies is determined. A positive IgG detection prior to pregnancy is considered proof of immunity.
Levels of anti-Toxoplasma gondii antibodies were analysed in a group of 500 healthy blood donors using the EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG). With a cut-off value of 10 IU/ml, 39% of the blood donors were anti-Toxoplasma gondii positive. This corresponds to the known infection level in Germany. In a further panel of 200 healthy pregnant women, antibodies of class IgG against Toxoplasma gondii were detected in 33% of samples.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using four sera. 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>Serum</th>
<th>Mean value (IU/ml)</th>
<th>CV (%)</th>
<th>Mean value (IU/ml)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>58</td>
<td>3.3</td>
<td>68</td>
<td>9.6</td>
</tr>
<tr>
<td>2</td>
<td>124</td>
<td>4.8</td>
<td>122</td>
<td>5.5</td>
</tr>
<tr>
<td>3</td>
<td>135</td>
<td>3.1</td>
<td>131</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Correlation

Antibodies against Toxoplasma gondii were determined in a cohort of 63 serologically precharacterised patient samples and 42 sera from healthy blood donors (origin: Turkey) using the EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG) and the bioMérieux VIDAS Toxoplasma (IgG). The agreement between the qualitative results for the two ELISAs was 99%.

<table>
<thead>
<tr>
<th>n = 105</th>
<th>bioMérieux VIDAS Toxoplasma (IgG)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>positive</td>
</tr>
<tr>
<td>EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG)</td>
<td>62</td>
</tr>
</tbody>
</table>

Quality assessment results

395 clinically precharacterised patient samples from quality assessment service providers (INSTAND, Germany; LABQUALITY, Finland; MQ, Switzerland; NEQAS, UK and RfB, Germany) were analysed using the EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG). The qualitative results of the ELISA showed an agreement of 99.7% with the specifications from the quality assessment institutes (excluding borderline sera).

<table>
<thead>
<tr>
<th>n = 395</th>
<th>Targets from QA institutes</th>
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<tr>
<td></td>
<td>positive</td>
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<tr>
<td>EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG)</td>
<td>265</td>
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</tbody>
</table>

Literature