Anti-Cytomegalovirus ELISA (IgG)

Indications: Test system for the in vitro determination of antibodies against cytomegalovirus in human serum or plasma for the diagnosis of the following diseases: fever, hepatitis, pneumonia, retinitis.

Clinical significance: Cytomegalovirus (CMV) belongs to the human herpes group of viruses. These viruses characteristically remain in the organism latently after a primary infection. Therefore, a reactivation of the disease can occur, usually with mild symptoms. In Germany around 50% of adults are infected with CMV. The level of infection increases with age. The disease course of a CMV infection is strongly influenced by the immune status of the patient. Persons with an intact immune system show mostly no or only mild flu-like symptoms. In individuals with a weakened immune system (transplant patients, HIV-infected persons) severe complications can occur affecting one or more organs, such as the lungs, liver, CNS and retina of the eye. CMV infections play a decisive role in pregnancy. A foetus is particularly at risk if the mother comes into contact with the virus for the first time during pregnancy. Around 1% of newborns are infected with the virus, 10% of these show severe symptoms which can lead to mental and physical damage. A CMV infection in pregnancy is notifiable. Persons with a high risk of disease can be passively immunized with specific immunoglobulins. Freshly infected persons are treated with virostatics.

Clinical data: Sera from 58 clinically characterized patients (Instand e.V. Duesseldorf, Germany; UK NEQAS, London) were tested for antibodies against CMV using the EUROIMMUN ELISA. For both IgG and IgM there was a 100% correlation with the clinical data.

Correlation of the EUROIMMUN ELISA with CFT: Sera from 144 blood donors (Dr Riegel, Wiesbaden, Germany) were investigated for anti-CMV antibodies using the EUROIMMUN ELISA and a commercially available complement fixation test (CFT). Excluding borderline sera the correlation between the two tests was 96%.

Application of the Anti-CMV ELISA: A CMV infection does not result in characteristic symptoms. Therefore, laboratory tests are necessary to confirm a diagnosis. Direct detection of viral DNA by the polymerase chain reaction or the CMV antigen pp65 is possible but costly. Antibody detection methods such as immunofluorescence or ELISA are preferred for determination of the immune status or detection of a fresh infection. Antibodies of class IgM reliably indicate a fresh infection. Their detection cannot, however, be used to distinguish between a primary infection or a reactivation, since they can occur in both. A primary CMV infection can be confirmed by demonstrating seroconversion or determining the avidity of specific IgG antibodies. Low-avidity IgG antibodies with an avidity index of under 40% indicate a fresh infection.

With CNS symptoms which are suspected to be caused by a CMV infection, the presence of antibodies in the cerebrospinal fluid should be investigated. For this therapy-relevant application EUROIMMUN offers an Anti-CMV ELISA developed specifically for CSF diagnostics. The immune status should be investigated in healthy individuals in the following cases: blood and organ donors are tested to avoid transmission of the virus to seronegative recipients. In women of child-bearing age knowledge of the immune status is decisive for risk assessment of an acute infection. Women without sufficient immunological protection against CMV should be serologically monitored during pregnancy for a CMV infection. The ELISA technique is the method of choice for analysing large patient panels due to its speed and ease of use. Moreover, in contrast to the (outdated) CFT it allows the separate determination of IgG and IgM antibodies.

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## Test Characteristics

### Anti-Cytomegalovirus ELISA (IgG)

#### 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-CMV antibodies were analysed in a group of 300 healthy blood donors (Medical University of Luebeck, Germany) using the EUROIMMUN ELISA. With a cut-off value of 20 RU/ml, 40% of blood donors were anti-CMV positive (IgG), in agreement with the known infection level in adults. In a separate panel of 200 healthy pregnant women, 48% of the sera were anti-CMV positive (IgG).

#### Cross reactivity:
Cross reactions as a result of similarities with other viruses can be excluded. In the EUROIMMUN ELISA, a highly purified cell lysate is used as the antigen to minimize cross reactions. Patients (n = 112) with specific antibodies against other viruses were investigated using this ELISA. No cross reactivities were found.

#### Correlation of the EUROIMMUN ELISA with another commercial ELISA:
92 serum samples (EUROIMMUN, Lübeck, Germany) were investigated for anti-CMV antibodies using the EUROIMMUN ELISA and the Enzygnost Anti-CMV ELISA from Dade Behring. Excluding borderline sera, there was a 99% correlation between the two ELISA.

#### Technical Data:

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thyroglobulin (TG)</td>
<td>Thyroid peroxidase (TPO)</td>
</tr>
<tr>
<td>Calcitonin</td>
<td>Glucagon (Glu)</td>
</tr>
</tbody>
</table>

### Intra- and Inter-assay variability:

<table>
<thead>
<tr>
<th>Serum</th>
<th>Intra-assay (% CV)</th>
<th>Inter-assay (% CV)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (RU/ml)</td>
<td>Mean (RU/ml)</td>
</tr>
<tr>
<td>1</td>
<td>19</td>
<td>4.2</td>
</tr>
<tr>
<td>2</td>
<td>57</td>
<td>5.4</td>
</tr>
<tr>
<td>3</td>
<td>165</td>
<td>4.5</td>
</tr>
<tr>
<td>4</td>
<td>210</td>
<td>8.5</td>
</tr>
<tr>
<td>5</td>
<td>300</td>
<td>5.7</td>
</tr>
</tbody>
</table>

### Infection serology:

#### EBV:
21 %

#### HSV:
12 %

#### VZV:
21 %

#### Measles virus:
20 %

#### Mumps virus:
16 %

#### Rubella virus:
22 %

### Detectable antigens:
- CMV (IgG)
- HSV (IgG)
- VZV (IgG)
- Measles (IgG)
- Mumps (IgG)
- Rubella (IgG)

### Software/Automation:
- EUROBlotScan
- EUROBlotMaster

### Quality controls:
- Calibration serum 1: 200 RU/ml
- Calibration serum 2: 20 RU/ml
- Calibration serum 3: 2 RU/ml

### Measurement:
450 nm. Reference wavelength >620 nm.

### Reagents:
- Ready to 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.

### Kit format:
96 break-off wells. Kit includes all necessary reagents.

### Order no.:
EL 2570-9601 G

### Related products:
- Anti-CMV ELISA (IgM)
- Anti-CMV ELISA for avidity determination
- Anti-CMV ELISA for CSF diagnostics