Anti-EBV-CA ELISA (IgM)

- Highly specific and sensitive test for the detection of Epstein-Barr virus antibodies
- Optimal for the diagnosis of acute infection
- Option of combined, fully automated processing of EUROIMMUN ELISA

Technical data

**Antigen**
Epstein-Barr virus capsid antigen gp 125 purified by affinity chromatography; antigen source: cell lysates of human B cells infected with Epstein-Barr virus of strain P3HR1

**Calibration**
Semiquantitative; calculation of a ratio from the extinction of the sample and the extinction of the calibrator

**Result interpretation**
- Ratio < 0.8: negative
- Ratio ≥ 0.8 to < 1.1: borderline
- Ratio ≥ 1.1: positive

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

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

**Order number**
EI 2791-9601 M

Clinical significance

EBV (Epstein-Barr virus) and herpes simplex virus types 1 and 2 belong to the most ubiquitous human-pathogenic herpes viruses in adults. The virus is the causative agent of infectious mononucleosis (glandular fever), a febrile disease usually accompanied by pharyngitis and lymphadenopathy, frequently by hepatosplenomegaly and more rarely by exanthema. EBV infections are also found in connection with Burkitt’s lymphoma and nasopharyngeal carcinoma. The clinical picture of EBV infection can be diverse. The symptoms are unspecific and often overlap with those of other diseases. EBV infection should be differentiated diagnostically from infections with CMV, Toxoplasmosa, Streptococcus, parvovirus B19 and HIV.

Diagnostic application

Since direct detection of EBV is often difficult, serological tests are routinely used for diagnosing EBV infections. The immune response after infection is characterised by the development of antibodies against the EBV capsid antigen (EBV-CA), the EBV nuclear antigens (EBNA-1 to EBNA-6) and the EBV early antigens (EBV-EA). In over 90% of cases an acute EBV infection can be characterised serologically by the detection of anti-EBV-CA IgM and an increase in titer of anti-EBV-CA IgG using ELISA. An at least twofold increase in the anti-EBV-CA IgG titer and the absence of antibodies against EBNA-1 is characteristic for the early phase of acute EBV infection. Serologically challenging constellations, such as persistent anti-EBV-CA IgM antibodies or the absence of specific anti-EBV-CA IgM antibodies in fresh infections, can be clarified by measuring the avidity of anti-EBV-CA IgG antibodies (e.g. using the EUROIMMUN Anti-EBV-CA ELISA (IgG), order no. EI 2791-9601-1 G).
Detection limit

The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable antibody titer. The lower detection limit of the Anti-EBV-CA ELISA (IgM) is 0.08.

Reference range

Levels of anti-EBV-CA antibodies (IgM) were analysed in a group of 500 healthy blood donors using the EUROIMMUN ELISA. At a ratio of 1.0 as cut-off, 1% of blood donors were anti-EBV positive (IgM).

Reproducibility

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

Specificity and sensitivity

A panel of 258 clinically and serologically precharacterised patient samples (quality assessments by INSTAND, Germany / Labquality, Finland / NEQAS, UK) were investigated using the EUROIMMUN ELISA. The specificity was 99.4% and the sensitivity 100%.

Prevalence

Sera from children, pregnant women and healthy blood donors were investigated for IgG and IgM antibodies using the EUROIMMUN Anti-EBV-CA ELISA. The prevalences corresponded to the data found in literature (e.g. Bauer, G: Rationale und rationelle Epstein-Barr-Virus-Diagnostik, Clin Lab, 1995).

<table>
<thead>
<tr>
<th>Panel</th>
<th>n</th>
<th>Positive results EUROIMMUN Anti-EBV-CA ELISA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy children ≤ 3 years</td>
<td>25</td>
<td>IgG 20.0% IgM 0.0% IgG IgM 20.0%</td>
</tr>
<tr>
<td>Healthy children 4 – 10 years</td>
<td>63</td>
<td>IgG 49.2% IgM 1.6% IgG IgM 49.2%</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>100</td>
<td>IgG 98.0% IgM 0.0% IgG 98.0%</td>
</tr>
<tr>
<td>Healthy blood donors</td>
<td>500</td>
<td>IgG 93.4% IgM 1.0% IgG IgM 93.6%</td>
</tr>
</tbody>
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Literature