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 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).

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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 ratio 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.

	Intra-assay variation, n=20		Inter-assay variation, n=4x6	
Serum	Mean value (ratio)	CV (%)	Mean value (ratio)	CV (%)
1	8.3	5.7	8.2	6.9
2	4.4	5.8	4.5	5.5
3	2.6	3.3	2.5	6.4

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%.

n=258		INSTAND/Labquality/NEQUAS		
		positive	borderline	negative
EUROIMMUN Anti-EBV-CA ELISA (IgM)	positive	82	0	1
	borderline	0	0	1
	negative	0	0	174

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).

Panel	n	Positive results EUROIMMUN Anti-EBV-CA ELISA		
		IgG	IgM	IgG, IgM
Healthy children ≤ 3 years	25	20.0 %	0.0 %	20.0 %
Healthy children 4 – 10 years	63	49.2 %	1.6 %	49.2 %
Pregnant women	100	98.0 %	0.0 %	98.0 %
Healthy blood donors	500	93.4 %	1.0 %	93.6 %

Literature

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