Anti-EBV-CA ELISA (IgG)

- **Highly specific and sensitive test for the detection of Epstein-Barr virus antibodies***
- **Ideally suited for the determination of the EBV immune status (seronegativity/seropositivity)**
- **More tests available for avidity determination and CSF diagnostics**

Technical data

Antigen	Purified Epstein-Barr virus capsid antigens; antigen source: inactivated cell lysate of human B cells infected with Epstein-Barr virus of strain P3HR1
Calibration	Quantitative, in relative units per ml (RU/ml) Calibration serum 1: 200 RU/ml Calibration serum 2: 20 RU/ml Calibration serum 3: 2 RU/ml Recommended upper threshold of the reference range for non-infected individuals (cut-off): 20 RU/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	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 G**

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, *Toxoplasma*, *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 an acute EBV infection. Serologically challenging constellations can be clarified by measuring the avidity of the anti-EBV-CA IgG antibodies (EI 2791-9601-1 G). EBV infections of the central nervous system can be diagnosed by determining the anti-EBV-CA antibodies of class IgG in the cerebrospinal fluid (EI 2791-9601-L G).

* The test is not intended to be used for the determination of suitability of sample material for transfusion, transplantation or cell administration in accordance with EU regulation 2017/746.

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Linearity

The linearity of the Anti-EBV-CA ELISA (IgG) was determined by performing four serial dilutions of different serum samples. The linear regression R^2 was > 0.95 for all samples. The Anti-EBV-CA ELISA (IgG) is linear in the investigated concentration range (4–141 RU/ml).

Reference range

Levels of anti-EBV-CA antibodies (IgG) were analysed in a group of 500 healthy blood donors using the EUROIMMUN ELISA. With a cut-off value of 20 RU/ml, 93.4% of the blood donors were anti-EBV-CA positive (IgG), in agreement with the known infection level in adults.

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 = 4 x 6	
Serum	Mean value (RU/ml)	CV (%)	Mean value (RU/ml)	CV (%)
1	47	7.4	47	8.2
2	90	5.8	90	3.2
3	93	4.2	93	5.4

Specificity and sensitivity

In a panel of 175 clinically and serologically precharacterised patient samples (quality assessments by INSTAND, Germany / Labquality, Finland) were investigated using the EUROIMMUN ELISA. The specificity and sensitivity were each 100%, excluding borderline sera.

n = 175		INSTAND/Labquality		
		positive	borderline	negative
EUROIMMUN Anti-EBV-CA ELISA (IgG)	positive	145	0	0
	borderline	3	1	0
	negative	0	0	26

Prevalence

Sera from children, pregnant women and healthy blood donors were investigated for IgG and IgM antibodies using the Anti-EBV-CA ELISA from EUROIMMUN. 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

1. Maeda E, et al. **Spectrum of Epstein-Barr virus-related diseases: a pictorial review.** Jpn J Radiol 27(1):4-19 (2009).
2. EUROIMMUN AG. Stöcker W, Schlumberger W. **Alle Beiträge zu den Themen Autoimmundiagnostik und Labordiagnostik der Infektionskrankheiten.** In: Gressner A, Arndt T (Hrsg.) Lexikon der Medizinischen Laboratoriumsdiagnostik. 2. Aufl., Springer Medizin Verlag, Heidelberg (2012)
3. Balfour Jr H, et al. **Infectious mononucleosis.** Clin Transl Immunology 4(2):e33 (2015).

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