Anti-EBV-EA-D ELISA (IgG)

- **Highly specific and sensitive test for the detection of Epstein-Barr virus antibodies***
- **Additional marker for acute infection (antibody persistence is possible)**
- **Option of combined, fully automated processing of EUROIMMUN ELISA**

Technical data

Antigen	Recombinant Epstein-Barr virus early antigen (EBV-EA-D)
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 2795-9601 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. IgG antibodies against early EBV proteins (EBV-EA) occur in 70–80% of patients with infectious mononucleosis, although only temporarily during the acute phase. Persisting IgG antibodies against EBV-EA can occur in 10–30% of healthy blood donors. 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-EA-D ELISA (IgG) was determined by assaying serial dilutions of patient sera with high antibody concentrations. The linear regression R^2 was > 0.95 for all samples. The Anti-EBV-EA-D ELISA (IgG) is linear in the measurement range of 2–158 RU/ml.

Detection limit

The lower detection limit is defined as a value of three times the standard deviation of an analyte-free sample and is the lowest clearly detectable concentration of antibodies. The lower detection limit of the Anti-EBV-EA-D ELISA (IgG) is 1 RU/ml.

Reference range

The levels of anti-EBV-EA-D antibodies (IgG) were analysed with the EUROIMMUN ELISA in a panel of 297 healthy blood donors. With a cut-off value of 20 IU/ml, 5% of the blood donors were anti-EBV-EA-D positive (IgG).

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	32	4.0	33	4.5
2	102	4.1	107	7.0
3	142	3.1	146	5.2

Specificity and sensitivity

A panel of 35 clinically and serologically precharacterised sera was investigated using the Anti-EBV-EA-D ELISA (IgG) from EUROIMMUN. The ELISA showed a sensitivity and specificity of 100%, excluding borderline sera.

n = 35		INSTAND target values		
		positive	borderline	negative
EUROIMMUN Anti-EBV-EA-D ELISA (IgG)	positive	3	0	0
	borderline	0	0	0
	negative	0	2	30

Prevalence

Sera from children, pregnant women and healthy blood donors were investigated for IgG antibodies using the Anti-EBV-EA-D ELISA from EUROIMMUN. The prevalences were as shown in the table.

Panel	n	Positive results EUROIMMUN Anti-EBV-EA-D ELISA (IgG)
Healthy children ≤ 3 years	25	0 %
Healthy children 4–10 years	63	3.2 %
Pregnant women	100	9.0 %
Healthy blood donors	500	6.2 %

Literature

1. Maeda E, et al. **Spectrum of Epstein-Barr virus-related diseases: a pictorial review.** Jpn J Radiol 27(1):4-19 (2009).
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3. Balfour Jr H, et al. **Infectious mononucleosis.** Clin Transl Immunology 4(2):e33 (2015).

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