Anti-EBNA-1 ELISA (IgG)

- **Highly specific and sensitive test for the detection of antibodies against Epstein-Barr virus**
- **Reliable late phase marker: differentiation between acute and past infections**
- **Option of combined, fully automated processing of EUROIMMUN ELISA**

Technical data

Antigen	Recombinant EBNA-1 (Epstein-Barr virus nuclear antigen 1)
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 no.	**EI 2793-9601 G**

Clinical significance

EBV (Epstein-Barr virus) and herpes simplex virus types 1 and 2 belong to the most ubiquitous human herpes viruses in adults. 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 the pathogenesis of 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. Antibodies against EBNA are considered as late-phase markers of EBV infection. The EBNA antigens are synthesised early after an infection, but they are presented to the immune system much later, i.e. only after B cell destruction. The presence of anti-EBNA IgG antibodies generally indicates a past infection. Anti-EBNA-1 antibodies persist lifelong in immunocompetent persons. Serologically challenging constellations can be clarified by measuring the avidity of 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).

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Linearity

The linearity of the Anti-EBNA-1 ELISA (IgG) was determined by performing four serial dilutions of different patient samples. The linear regression R^2 was > 0.95 for all samples. The Anti-EBNA-1 ELISA (IgG) is linear in the investigated concentration range (7 RU/ml to 176 RU/ml).

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-EBNA-1 ELISA is 0.9 RU/ml.

Reference range

Levels of Anti-EBNA-1 antibodies (IgG) were analysed in a group of 500 healthy blood donors using the EUROIMMUN ELISA. With a cut-off of 20 RU/ml, 93 % of the blood donors were anti-EBNA-1 positive (IgG), in agreement with the known infection level in adults.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficient of variation (CV) using three sera. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on four measurements performed in 6 different test runs.

Serum	Intra-assay variation, n=20		Inter-assay variation, n=4 x 6	
	Mean value (RU/ml)	CV (%)	Mean value (RU/ml)	CV (%)
1	27	5.9	28	10.1
2	73	2.8	76	5.1
3	140	5.5	135	10.9

Specificity and sensitivity

In a panel of 174 clinically and serologically precharacterised sera (from quality assessments by INSTAND, Germany / Labquality, Finland) were analysed with the EUROIMMUN Anti-EBNA-1 ELISA (IgG). The specificity and sensitivity of the ELISA were each 100 %.

n=174		INSTAND/Labquality		
		positive	borderline	negative
EUROIMMUN Anti-EBNA-1 ELISA (IgG)	positive	91	0	0
	borderline	0	0	0
	negative	0	0	83

Prevalence

Sera from children, pregnant women and healthy blood donors were investigated for IgG antibodies using the EUROIMMUN Anti-EBNA-1 ELISA. The prevalences were as shown in the table.

Panel	n	Positive results EUROIMMUN Anti-EBNA-1 ELISA (IgG)
Healthy children ≤ 3 years	25	12.0 %
Healthy children 4–10 years	63	46.0 %
Pregnant women	100	93.0 %
Healthy blood donors	500	93.0 %

Literature

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EI_2793_D_UK_A04 06/2015