Anti-HSV-1 (gC1) ELISA (IgG)

- **Type-specific quantitative determination of IgG antibodies against HSV-1**
- **Based on highly purified recombinant glycoprotein C1 (gC1)**
- **Fully automated processing and evaluation**

Technical data

Antigen	Recombinant glycoprotein C1 (gC1) of herpes simplex virus 1
Calibration	Quantitative, in relative units per millilitre (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 2531-9601-2 G**

Clinical significance

Herpes simplex viruses type 1 (HSV-1) and type 2 (HSV-2) cause local skin and mucous membrane infections predominantly in the mouth and nose area and the genital regions. Initially, blisters occur on a reddened area, which burst and develop into painful ulcerous lesions. Primary infection and reinfection with HSV may lead to severe illness in pregnant women. The virus is transmitted transplacentally to the unborn child and can cause foetal infection. Infection of the unborn child can lead to intrauterine death, malformations and premature birth. Systemic herpes infections may affect the skin, whereby the spread of the virus is facilitated by pre-existing skin disease or burns. The involvement of various visceral organs such as the liver can occur as a complication in patients with suppressed T-cell-mediated immunity (lymphoma, AIDS). HSV-1 can cause severe cerebral infections, which are fatal in 70 % of cases if left untreated.

Diagnostic application

The use of HSV-1 glycoprotein C1 (gC1) as the antigen in the EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG) allows type-specific detection of IgG antibodies against HSV-1. A positive test result indicates contact with the virus. When acute processes are suspected, e.g. genital herpes, especially during pregnancy, or HSV encephalitis, direct detection should be performed.

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Reference range

The levels of anti-HSV-1 antibodies (IgG) were analysed with the EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG) in a panel of 500 healthy blood donors. With a cut-off value of 20 IU/ml, 60.4 % of the blood donors were anti-HSV-1 positive (IgG). This is in agreement with the known prevalence in adults.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 4 sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on three determinations performed in ten different test runs.

	Intra-assay variation, n = 20		Inter-assay variation, n = 3 x 10	
Serum	Mean value (RU/ml)	CV (%)	Mean value (RU/ml)	CV (%)
1	15	8.3	13	9.7
2	15	8.7	16	11.6
3	81	7.9	76	7.3
4	153	4.9	151	5.4

Quality assessment results

52 serologically and/or clinically characterised patient samples (quality assessment schemes by INSTAND, Germany) were analysed using the EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG). The agreement of the qualitative ELISA results with the specifications of the quality assessment institute was 98 %.

n = 52		Quality assessment targets		
		positive	borderline	negative
EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG)	positive	39	0	0
	borderline	0	0	0
	negative	1	0	12

Sensitivity and specificity

299 precharacterised patient samples (origin: Europe; reference method: EUROIMMUN Anti-HSV-1/HSV-2 gG-2 EUROLINE-WB IgG) were analysed using the EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG). The sensitivity of the ELISA was 99.5 %, with a specificity of 98.6 % (excluding borderline sera).

n = 299		EUROIMMUN Anti-HSV-1/HSV-2 gG-2 EUROLINE-WB (IgG)		
		positive	borderline	negative
EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG)	positive	219	1	1
	borderline	1	0	0
	negative	1	8	68

Cross reactivity

47 sera from patients with other herpes virus infections (positive IgG results) were investigated with the EUROIMMUN Anti-HSV-1 (gC1) ELISA (IgG). No cross reactions (CR) were found.

Antibodies against	n	CR
CMV	12	0 %
EBV-CA	12	0 %
HSV-2	11	0 %
VZV	12	0 %

Literature

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