Anti-Borrelia Select ELISA (IgG)

- **Based on highly specific recombinant Borrelia antigens, including VlsE**
- **Significantly reduced cross reactivity in comparison with whole antigen tests**
- **Simple and fast test performance – fully automatable**

Technical data

Antigen	Specific recombinant antigens from different human pathogenic Borrelia strains, including VlsE
Calibration	Quantitative, in relative units per milliliter (RU/ml) Calibrator 1: 200 RU/ml Calibrator 2: 20 RU/ml Calibrator 3: 2 RU/ml Recommended upper limit 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, largely exchangeable with those in other EUROIMMUN ELISA kits.
Test procedure	60 min (37 °C) / 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, test kit includes all necessary reagents
Order No.	**EI 2132-9601-5 G**

Clinical significance

Borrelia are the causative agent of Lyme borreliosis, a bacterial disease which is transmitted through bites from ticks of the genus Ixodes. The most important human pathogenic Borrelia genospecies are B. afzelii, B. burgdorferi and B. garinii. Lyme borreliosis can manifest itself dermatologically, neurologically or through internal disorders. The radially spreading erythema migrans is a characteristic early symptom, which occurs a few days to several weeks after the infection. This is often accompanied by influenza-like general symptoms, such as fever, shivering, headaches and vomiting. The advanced stage of the disease is characterised by neurological (e.g. facial paresis), cardiac (e.g. myocarditis) and rheumatological (e.g. arthritis) manifestations. In chronic Lyme borreliosis, involvement of the joints, epidermis (acrodermatitis chronica atrophicans) and central nervous system as well as fatigue are typically found. For the serological diagnosis of anti-Borrelia-specific antibodies, the German Association for Hygiene and Microbiology (DGHM), the Robert Koch Institute and the CDC (Atlanta, Georgia) call for a two-stage strategy. Firstly, a sensitive screening test (ELISA or IIFT) is performed. Sera with a positive or borderline screening result are investigated further using an immunoblot to differentiate between Borrelia-specific and unspecific reactions.

Diagnostic application

The Anti-Borrelia Select ELISA (IgG) is based on a mixture of highly specific recombinant antigens of different human pathogenic Borrelia strains. Alongside others, this test contains VlsE, which is the main antigen for the detection of Borrelia-specific IgG antibodies. The Anti-Borrelia Select ELISA (IgG) shows far less cross reactivity than a lysate-based ELISA, e.g. in patients with autoimmune or other diseases. With its specifically composed antigen mixture, the Anti-Borrelia Select ELISA (IgG) provides a high sensitivity and is therefore ideally suited for use as a screening test.

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Reference range

The prevalence of Borrelia-specific IgG antibodies was determined by investigating a panel 500 healthy blood donors (Medical University of Lübeck) with the EUROIMMUN Anti-Borrelia Select ELISA (IgG). With a cut-off of 20 RU/ml, 3.4 % of the blood donors were seropositive.

Reproducibility

To investigate the reproducibility, the intra- and inter-assay coefficients of variation (CV) were determined using three sera. The intra-assay CVs were based on 20 determinations, the inter-assay CVs on 4 determinations in 6 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	18	2.7	18	6.7
2	64	2.2	69	5.1
3	84	2.5	81	6.5

Agreement with quality assessment results

78 samples from quality assessment scheme providers (INSTAND e.V., Germany; EQUALIS, Sweden; IQS, Germany; Labquality, Finland and RfB, Germany) were investigated with the EUROIMMUN Anti-Borrelia Select ELISA (IgG). The agreement of the qualitative ELISA results with the specifications of the quality assessment institutes was 100% (excluding borderline sera).

n = 78		Specifications of the quality assessment		
		positive	borderline	negative
EUROIMMUN Anti-Borrelia Select ELISA (IgG)	positive	38	0	0
	borderline	1	2	0
	negative	0	0	37

Test results with respect to critical sera

Owing to the targeted selection of highly specific recombinant antigens from human pathogenic Borrelia strains, the Anti-Borrelia Select ELISA (IgG) shows a lower cross reactivity compared to a lysate-based test (e. g. Anti-Borrelia-plus-VlsE ELISA (IgG)). The number of positive findings in patients with Treponema pallidum infection or autoimmune diseases were significantly lower when the investigation was performed with the Anti-Borrelia Select ELISA (IgG).

Panel	n	Anti-Borrelia-IgG results ≥ 20 RU/ml (cut-off) with respect to EUROIMMUN	
		Anti-Borrelia-plus-VlsE ELISA (IgG)	Anti-Borrelia Select ELISA (IgG)
Anti-Treponema pallidum highly positive sera	92	65 (70.7 %)	3 (3.3 %)
Autoimmune diseases	27	6 (22.2 %)	5 (18.5 %)

Clinical data

33 sera from patients with clinically characterised early stage Lyma borreliosis (Erythema migrans) were investigated with the Anti-Borrelia Select ELISA (IgG, IgM) and the Anti-Borrelia-plus-VlsE ELISA (IgG) and Anti-Borrelia ELISA (IgM). In the parallel determination of IgG and IgM antibodies, the Anti-Borrelia Select ELISA (IgG, IgM) achieved the same sensitivity as the lysate-based tests (91 %).

Test system*	ELISA results (n = 33)	
	IgG or IgM	IgG plus IgM
Anti-Borrelia Select ELISA (IgG)	21 (63.6 %)	30 (91 %)
Anti-Borrelia Select ELISA (IgM)	22 (66.7 %)	
Anti-Borrelia-plus-VlsE ELISA (IgG)	27 (81.8 %)	30 (91 %)
Anti-Borrelia ELISA (IgM)	25 (75.8 %)	

*Cut-off, ≥ 20 RU/ml

Literature

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