Anti-Borrelia ELISA (IgM)

- **Based on whole antigen extracts from Borrelia burgdorferi, B. afzelii, and B. garinii, including OspC**
- **Complete antigen spectrum – highest diagnostic sensitivity**
- **Simple and fast test performance – fully automatable**

Technical data

Antigen	Whole antigen extracts from the strains Borrelia burgdorferi sensu stricto, B. afzelii and B. garinii
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	30 min / 30 min / 30 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 2132-9601 M**

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 ELISA (IgM) is based on native whole extracts of the strains B. burgdorferi sensu stricto, B. garinii and B. afzelii. The antigen mixture used contains all diagnostically relevant proteins, amongst others OspC, which is usually the target of IgM antibodies during the early phase of borreliosis. With its wide antigen spectrum, the Anti-Borrelia ELISA (IgM) achieves a high sensitivity and is therefore ideally suited for use as a screening test. It is recommended that the IgM determination be supplemented by an analysis of Borrelia-specific antibodies of class IgG, for example using the EUROIMMUN Anti-Borrelia plus VlsE ELISA (IgG). In this way the serological detection rate can be increased in all stages of the disease.

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Reference range

The prevalence of Borrelia-specific IgM antibodies was determined by investigating a panel of 500 healthy blood donors (Medical University of Lübeck) using the EUROIMMUN Anti-Borrelia ELISA (IgM). With a cut-off of 20 RU/ml, 1.6% 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 are based on 20 determinations and the inter-assay CVs on 4 determinations performed 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	75	4.3	78	6.9
2	103	2.9	109	6.2
3	115	3.4	122	4.7

Agreement with quality assessment results

200 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 ELISA (IgM). The agreement of the qualitative ELISA results with the specifications of the quality assessment institutes was 99% (excluding borderline sera).

n = 200		Specifications of the quality assessment		
		positive	borderline	negative
EUROIMMUN Anti-Borrelia ELISA (IgM)	positive	47	1	1
	borderline	1	1	3
	negative	0	2	144

Clinical data

364 sera from patients with clinically characterised borreliosis at different disease stages and 573 control sera (53 patients with other infectious diseases, 20 patients with rheumatic diseases, 500 healthy blood donors) were screened using the EUROIMMUN Anti-Borrelia ELISA (IgM) and the Anti-Borrelia-plus-VlsE ELISA (IgG). In the parallel investigation of IgG and IgM antibodies the test systems achieved a sensitivity of 91% to 100%, depending on the patient panel.

Panel (n = 364)	n	EUROIMMUN Anti-Borrelia-plus-VlsE ELISA (IgG) Anti-Borrelia ELISA (IgM)		
		IgG	IgM	IgG/IgM
Erythema migrans	205	76%	68%	91%
Neuroborreliosis	80	90%	49%	96%
Lyme arthritis	49	84%	43%	94%
Acrodermatitis chron. atrop.	14	93%	21%	93%
Facial paresis	16	100%	50%	100%

The prevalence of anti-Borrelia antibodies in the control panels (other infectious diseases: anti-CMV positive, n = 18, anti-EBV-positive, n = 28, anti-Toxoplasma-positive, n = 7; rheumatic diseases: APF-positive, n = 10, RF-(IgM)-positive, n = 10) corresponds to the values described in literature (Robert Koch Institute, Epidemiologisches Bulletin 14/98).

Panel (n = 573)	n	EUROIMMUN Anti-Borrelia-plus-VlsE ELISA (IgG) Anti-Borrelia ELISA (IgM)	
		IgG	IgM
Other infectious diseases	53	13%	11%
Rheumatic diseases	20	15%	0%
Blood donors	500	5%	2%
Prevalence	573	6%	2%

Literature

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