Lyme ELISA (IgG/IgM)

- **Combination of recombinant VlsE and OspC for simultaneous detection of IgG and IgM antibodies**
- **Superior sensitivity compared to single antigen ELISAs (based on e.g. the C6 peptide)**
- **Reduced cross-reactivity compared to whole cell systems**

Technical data

Antigen	The microplate wells are coated with recombinant VlsE from Borrelia burgdorferi sensu stricto and Borrelia OspC
Calibration	Qualitative, calculation of a ratio from the extinction of the sample and the extinction of the calibrator
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Reagents	Ready for use. Exception: Wash buffer (10x). Colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA test kits
Result interpretation	EUROIMMUN recommends interpreting the results as follows: Ratio < 0.8: negative Ratio ≥ 0.8 to < 1.1: borderline Ratio ≥ 1.1: positive
Test procedure	60 min (37 °C) / 30 min / 15 min (room temperature), fully automatable
Measurement	450 nm. Reference wave length between 620 nm and 650 nm
Test kit format	96 break-off wells, kit includes all necessary reagents
Order number	**EI 2132-9601-24 O**

Clinical significance

Lyme disease is a tick-borne disease caused by bacteria of the genus Borrelia. The diagnosis of Lyme disease is based on the patient anamnesis, clinical findings and the detection of antibodies against Borrelia antigens. With respect to the serodiagnosis of Lyme disease the CDC (Atlanta, USA) calls for a two-tier strategy. First, a sensitive screening test (ELISA or IIFT) is performed. Sera with a positive or borderline screening result are then further investigated using an immunoblot to differentiate between Borrelia-specific and unspecific reactions. Since antibodies against Borrelia are first produced 2 to 6 weeks after infection, serological tests performed in the early stage of Lyme borreliosis can be negative. Early antibiotic treatment may also prevent antibody production. In suspected cases of neuroborreliosis, the presence of intrathecal synthesis of Borrelia-specific antibodies can be investigated by parallel analysis of a CSF/serum sample pair.

Diagnostic application

The Lyme ELISA (IgG/IgM) allows reliable diagnosis of borreliosis already in early disease stages, provided that detectable antibodies are present. The ELISA uses VlsE and OspC, which are the major target antigens in the IgG and IgM mediated immune response to a Borrelia infection. IgM antibodies against OspC and IgG antibodies against VlsE are produced very early after infection. According to guidelines for serological Borrelia diagnostics (e.g. from CDC, Atlanta, USA), a positive or borderline ELISA result should always be followed by a confirmatory test (immunoblot).

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Prevalence

The prevalence of Borrelia-specific antibodies (IgG/IgM) was determined in a panel of 198 healthy blood donors from the USA (98 from an endemic area, 100 from a non-endemic area). At a ratio of 1.0 as the cut-off, 3.1% (endemic area), respectively 5.0% (non-endemic area) of the blood donors yielded equivocal or positive results.

Panel	n	EUROIMMUN Lyme ELISA (IgG/IgM)			
		positive	borderline	negative	prevalence [%]
Blood donors from an endemic area (Pennsylvania)	98	3	0	95	3.1
Blood donors from a non-endemic area (Tennessee)	100	2	3	95	5.0

Clinical data

40 samples of various reactivity, acquired from the Centers for Disease Control and Prevention in Atlanta, GA, were tested with the EUROIMMUN Lyme ELISA (IgG/IgM). Of the 40 samples, 5 samples were from healthy blood donors and 35 samples were from patients diagnosed with Lyme disease (clinically characterised borreliosis, stratified by disease stage).

Panel/Disease stage	n	EUROIMMUN Lyme ELISA (IgG/IgM)	
		positive or borderline	agreement with clinical diagnosis
Healthy blood donors	5	0	100.0%
< 1 month after onset	6	6	100.0%
1–3 months after onset	11	10	90.9%
1–12 months after onset	11	9	81.8%
> 12 months after onset	7	7	100.0%
Total	40	32	92.5%

Sensitivity study

A study consisting of 100 clinically characterised Lyme disease specimens was conducted with the EUROIMMUN Lyme ELISA (IgG/IgM) in parallel with the C6 Lyme ELISA from Immunetics. These specimens contain samples from early, disseminated and late phases of the disease. The panel consisted of 36 men, 52 women and 12 persons of unknown sex. The age ranged from 16 to 80 years. The EUROIMMUN Lyme ELISA (IgG/IgM) achieved a higher sensitivity than the Immunetics C6 Lyme ELISA, particularly in the early phase of the disease (< 3 months after onset).

Disease stage	n	EUROIMMUN Lyme ELISA (IgG/IgM)		Immunetics C6 Lyme ELISA	
		positive or borderline [n]	sensitivity [%]	positive or borderline [n]	sensitivity [%]
Acute Erythema migrans or culture positive, < 3 months after onset	46	44	95.7%	35	76.1%
Convalescent Erythema migrans or culture positive, 3–12 months after onset	30	27	90.0%	25	83.3%
Late Lyme disease with presentations other than Erythema migrans, onset unknown or > 1 year	24	24	100.0%	22	91.7%
Total	100	95	95.0%	82	82.0%

Literature

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