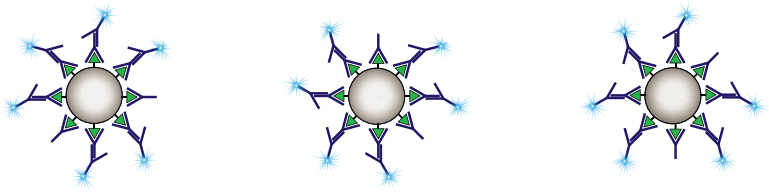
Anti-Borrelia-ChLIA (IgM)



- **Chemiluminescence immunoassay (ChLIA) for quantitative in vitro determination of human IgM antibodies against *Borrelia burgdorferi, B. afzelii* and *B. garinii***
- **Based on highly specific recombinant *Borrelia* antigens including dimeric OspC advanced**
- **Automated processing with the IDS-i10 or the IDS-iSYS Multi-Discipline Automated System**

Technical data

Test procedure	Exclusively automated, with the IDS-i10 or the IDS-iSYS Multi-Discipline Automated System with software from version 15.06a; validation was carried out on the RA Analyzer 10 (identical in construction to IDS-i10).
Antigen	Specific recombinant antigens from *Borrelia burgdorferi* sensu lato, e.g. dimeric OspC advanced (magnetic particles)
Contents of the test kit	Cartridge, incl. ready-for-use reagents for 100 analyses
Calibration	Quantitative, in relative chemiluminescence units per millilitre (CU/ml) with 2 calibrators; stored master curve
Sample material	Serum or plasma
Measurement	Chemiluminescence signal, concentrations in CU/ml
	Measurement range: 0 – 200 CU/ml
	Cut-off: 10 CU/ml
Order no.	**LI 2132-10010 M**
Additional materials	LR 2132-20210 M Control set Anti-Borrelia ChLIA (IgM)

Clinical significance

Borrelia is 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 determination of *Borrelia*-specific antibodies, the German Association for Hygiene and Microbiology (DGHM), the Robert Koch Institute and the CDC (Atlanta, Georgia) recommend a two-stage strategy. Firstly, a sensitive screening test (ChLIA, 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.

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Reference range

Samples from 120 healthy blood donors were investigated with the EUROIMMUN Anti-Borrelia ChLIA (IgM). With a cut-off value of 10 CU/ml, 5.8% of the blood donors were anti-*Borrelia* positive (IgM).

Diagnostic sensitivity and specificity

The performance of the Anti-Borrelia ChLIA (IgG) was investigated with 134 samples from patients with suspected *Borrelia* infections and clinically and serologically precharacterised samples from a reference institute (panels 1–6). Since the antibody detection depends on the phase of *Borrelia* infection and the result may be affected by antibiotic treatment, the sample panels are grouped according to clinical symptoms which allows conclusions to be drawn on the phase of infection, as well as according to the therapy status. The reference panel for investigation of test specificity consisted of 81 samples. These included negative samples from the reference institute as well as samples from clinically inconspicuous children, in whom *Borrelia* infection is unlikely, but cannot be ruled out completely due to the natural infection rate (panel 7).

Panel	Total	EUROIMMUN Anti-Borrelia ChLIA (positive results in %)		
	n	IgG (%)	IgM (%)	IgG and/or IgM (%)
1. Acute Lyme borreliosis (aLB) / erythema migrans (EM)	69	40.6	73.9	78.3
2. Neuroborreliosis (NB)	3	100	66.7	100
3. Lyme borreliosis (LB) under / after treatment	37	54.1	73.0	91.9
4. Past Borrelia infection with persisting IgM antibodies /past Borrelia infection	17	94.1	17.6	94.1
5. Chronic Lyme borreliosis (cLB)	6	100	33.3	100
6. Acrodermatitis chronica atrophicans Herxheimer (ACA)	2	100	50.0	100
7. Healthy donors without clinical indications of Lyme borreliosis (reference panel)	81	0	3.7	3.7

Correlation / Method comparison

271 samples from patients with suspected *Borrelia* infections (n = 197, European laboratory practice, daily laboratory routine; n = 34, samples from patients with clinically and serologically confirmed *Borrelia* infections, consecutive samples, European laboratory practice; n = 40, characterised quality assessment samples, Reference Institute for Bioanalytics RfB, Germany) were investigated with the EUROIMMUN Anti-Borrelia ChLIA (IgM) and the Anti-Borrelia Select ELISA (IgM).

n = 271		EUROIMMUN Anti-Borrelia Select ELISA (IgM)			
		positive	borderl.	negative	total
EUROIMMUN Anti-Borrelia ChLIA (IgM)	positive	110	7	13	130
	borderline	4	4	8	16
	negative	5	3	117	125
	total	119	14	138	271

Evaluation	Without borderline samples	
	Value	95% confidence interval
Negative agreement	90.0%	83.5–94.6%
Positive agreement	95.7%	90.1–98.6%
Concordance (%)	92.7%	
Total	245	

IDS-i10 and IDS-iSYS Multi-Discipline Automated System (software from version 15.06a)

- Random access instruments for batch, continuous and STAT loading
- Minimal calibration effort due to stored master curves
- Connection to lab track possible for IDS-i10
- Autoimmune and infection parameters as well as antigen detection on one instrument
- Short reaction times of the EUROIMMUN tests, for fast and reliable results after only 25 minutes
- High throughput – up to 85 assays per hour
- Convenient and safe operation due to distinct barcode identification of samples and reagents

IDS-i10

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LI_2132_D_UK_B02, 04/2022