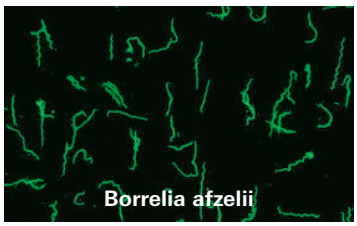
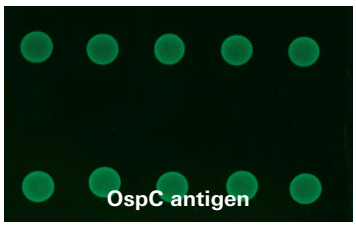
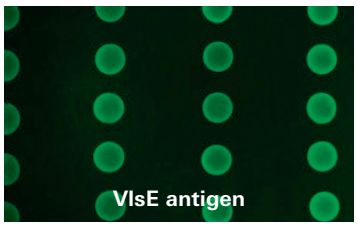
EUROPLUS: Anti-Borrelia IIFT plus VlsE and OspC







- **Immunfluorescence test for the detection of IgG or IgM antibodies against Borrelia**
- **High sensitivity through the use of BIOCHIPs containing the main target antigens VlsE and OspC**
- **Simple and standardised manual processing (TITERPLANE technique) – fully automatable**

Technical data

Antigene substrate	Smears of Borrelia afzelii and Borrelia burgdorferi sensu stricto and EUROPLUS BIOCHIPs with the antigens VlsE and OspC
Sample material	Serum or plasma
Sample dilution	IgG: qualitative evaluations: 1:100; quantitative evaluations: 1:100, 1:1000 etc. IgM: qualitative evaluations: 1:10; quantitative evaluations: 1:10, 1:100 etc.
Reagents	Ready for use, with the exception of the PBS Tween buffer
Test procedure	30 min (sample) / 30 min (conjugate), room temperature, automatable
Microscopy	Objektive: 40x, light source: EUROIMMUN LED, EUROStar Bluelight or mercury vapour lamp, 100 W; excitation filter: 450-490 nm, colour separator: 510 nm, blocking filter: 515 nm
Test kit format	10 or 20 slides, each containing 3, 5 or 10 test fields
Order no.	**FI 2136-####-1 G or 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

By combining bacterial smears (B. burgdorferi and B. afzelii) with recombinant VlsE and purified OspC, the serological hit rate is increased compared to conventional immunofluorescence tests. In those tests the VlsE antigen is missing because borrelia can only express VlsE in vivo and not in cell cultures. With its broad antigen spectrum the EUROPLUS Anti-Borrelia IIFT plus VlsE and OspC is able to provide a very high sensitivity. It is therefore ideally suited for screening.

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Reference range

In healthy blood donors (origin of samples: Germany) the following antibody prevalences (titer 1 : < 100 (IgG), 1 : < 10 (IgM)) were determined (see table).

Anti-Borrelia antigens	Prevalence IgG	Prevalence IgM
VlsE	5% (n = 201)	–
OspC	–	2.5% (n = 201)
Borrelia afzelii	17% (n = 150)	3% (n = 159)
Borrelia burgdorferi	18% (n = 150)	4% (n = 159)

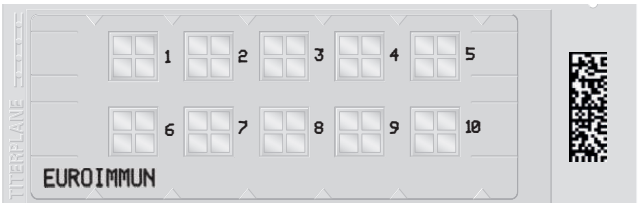
Clinical data

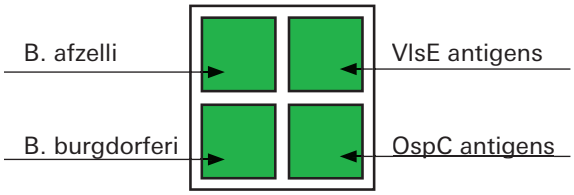
In a study 577 Polish forest workers and 100 healthy blood donors were tested for antibodies against Borrelia antigens. For the substrate combination Borrelia afzelii and Borrelia burgdorferi a sensitivity of 94% for IgG and 77% for IgM was found (reference: 137 (IgG) and 34 (IgM) sera with positive ELISA and Westernblot results). Using BIOCHIPs coated with VlsE or OspC these values increase to 98% and 91%. The single antigens showed a specificity of 100% (VlsE) and 98% (OspC) (reference: 234 (IgG) and 181 (IgM) sera with negative ELISA and Westernblot results).

Anti-Borrelia antigens	Sensitivity (precharacterised panel)		Prevalence blood donors	
	IgG (n = 137)	IgM (n = 34)	IgG (n = 87)	IgM (n = 92)
Borrelia afzelii	94%	77%	28%	3%
Borrelia burgdorferi	93%	71%	28%	3%
VlsE	89%	–	5%	–
OspC	–	85%	–	4%
B. afzelii + B. burgdorferi	94%	77%	28%	3%
B. afzelii + B. burgd. + VlsE	98%	–	29%	–
B. afzelii + B. garinii + OspC	–	91%	–	7%

BIOCHIP arrangement

The EUROPLUS Borrelia mosaic is available in three different formats: slides with 3, 5 or 10 fields. One test field contains four BIOCHIPs.





Literature

1. Burgdorfer W, et al. **Lyme disease – a tick-borne Spirochetosis?** Science 216 (1982) 1317-1319.
2. Christova I. **Enzyme-linked immunosorbent assay, immunofluorescent assay, and recombinant immunoblotting in the serodiagnosis of early Lyme borreliosis**. Int J Immuno-pathol Pharmacol 16 (2003) 261-268.
3. Lawrenz MB, et al. **Human antibody responses to VlsE antigenic variation protein of Borrelia burgdorferi.** J Clin Microbiol. 1999 Dec;37(12):3997-4004.
4. Aguero-Rosenfeld ME, et al. **Diagnosis of lyme borreliosis.** Clin Microbiol Rev. 2005 Jul;18(3):484-509.

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