

Borrelia burgdorferi



recomLine Borrelia IgG recomLine Borrelia IgM

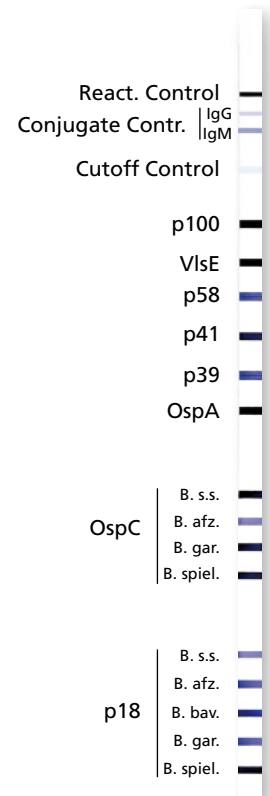
Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG or IgM antibodies against *Borrelia burgdorferi* in human serum, plasma or CSF

The bacterium *Borrelia burgdorferi*, a spirochete, is responsible for Lyme borreliosis. This disease is transmitted to humans by ticks. Lyme borreliosis is a multisystemic disease with diverse manifestations which make clinical diagnosis difficult. Direct detection of the pathogen is also problematic. Therefore, in routine diagnosis, the serological detection of *Borrelia*-specific antibodies represents the easiest and safest method for the detection of a *Borrelia* infection.

Enzyme immunoassays are mainly used for screening. In comparison with the screening assays, *recomLine Borrelia* exhibits additional criteria with regard to sensitivity and specificity and is used to confirm the results of enzyme immunoassays. Highly specific, genetically engineered, immunodominant *Borrelia* proteins are used.

Only the *recomLine Borrelia* detects antibodies against all four of the so far known as immunopathogenic genospecies (*B. burgdorferi sensu stricto*, *B. garinii*, *B. afzelii*, *Borrelia spielmanii* and *B. bavariensis*) on one single test strip:

- VlsE from different genospecies
- OspC from all genospecies
- p18 (Decorin binding protein A = DbpA) from all genospecies



Product Advantages

- Recombinant antigens
 - High sensitivity and specificity
 - Easy and clear interpretation due to easy to read bands
 - Optimum presentation without cross-reacting *Borrelia* proteins
 - Immunodominant antigens of the four genospecies: *B. burgdorferi sensu stricto*, *B. garinii*, *B. afzelii*, *B. spielmanii* and *B. bavariensis*
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recomScan* software
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Separate detection of IgG and IgM antibodies
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Standardised CSF-serum-analysis available
- CE label: The *recomLine Borrelia* tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
- Complement as confirmation tests ideally the *recomWell Borrelia* tests (ELISA)
- Conform with MiQ Lyme Borreliosis¹ and DIN 58969-44²

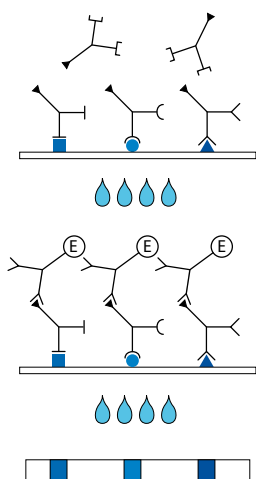
1) Wilske B, Zöller L, Brade V, Eiffert H, Göbel UB, Stanek G, and Pfister HW: MIQ 12, Lyme-Borreliose. In Qualitätsstandards in der mikrobiologisch-infektiologischen Diagnostik. H. Mauch and R. Lütticken, eds. Munich, Germany, Urban & Fischer Verlag, 2000, pp. 1-59

2) DIN 58969-44: Medizinische Mikrobiologie - Serologische und molekularbiologische Diagnostik von Infektionskrankheiten - Teil 44: Immunoblot (IB); Spezielle Anforderungen für den Nachweis von Antikörpern gegen *Borrelia burgdorferi*

Recombinant Borrelia Antigens

Antigen	Strain
p100	<i>B. afzelii</i>
VlsE	different <i>Borrelia</i> -Genospezies
p58	<i>B. garinii</i>
p41	<i>B. burgdorferi sensu stricto</i>
p39	<i>B. afzelii</i>
OspA	<i>B. afzelii</i>
OspC	<i>B. burgdorferi sensu stricto</i> , <i>B. afzelii</i> , <i>B. garinii</i> , <i>B. spielmanii</i>
p18	<i>B. burgdorferi sensu stricto</i> , <i>B. afzelii</i> , <i>B. garinii</i> , <i>B. spielmanii</i> , <i>B. bavariensis</i>

Test Principle and Procedure



- 1st Incubation** A test strip loaded with *Borrelia* antigens is incubated with diluted serum or plasma in a dish for **1 hour**.
- wash 3 times
- 2nd Incubation** Peroxidase conjugated anti-human antibodies (IgG or IgM specific) are added. Incubate for **45 minutes**.
- wash 3 times
- Color reaction** **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Diagnostic Specificity

<i>recomLine Borrelia</i>	Two comparison tests negative	
	IgG	IgM
Negative	170	169
Borderline	1	0
Positive	0	0
Specificity	99.4 %	100 %

Detection Rate

	IgG positive/ borderline	IgM positive/ borderline	IgG/IgM positive/ borderline
Blood donor sera* (n = 200)	24 (12 %)	5 (2.5 %)	28 (14 %)

* from the south German region

Diagnostic Sensitivity

	IgG positive/ borderline	IgM positive/ borderline	IgG/IgM positive/ borderline
Lyme arthritis (n = 28)	27 (96.4 %)	6 (21.4 %)	27 (96.4 %)
ACA* (n = 11)	11 (100 %)	1 (9.1 %)	11 (100 %)
Neuroborreliosis (n = 35)	32 (91.4 %)	18 (51.4 %)	34 (97.1 %)
Erythema migrans (n = 42)	18 (42.9 %)	30 (71.4 %)	33 (78.6 %)

* Acrodermatitis chronica atrophicans

Article-No

- 4272 ***recomLine Borrelia IgG***
Reagents for 20 determinations
- 4273 ***recomLine Borrelia IgM***
Reagents for 20 determinations
- 4276 ***recomLine Borrelia IgG***
Reagents for 200 determinations
- 4277 ***recomLine Borrelia IgM***
Reagents for 200 determinations

Storage

At +2°C to +8°C