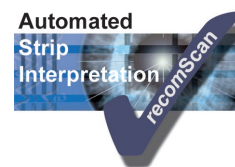


NEW



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 liquor

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 (*Borrelia burgdorferi sensu stricto*, *Borrelia garinii*, *Borrelia afzelii* and *Borrelia spielmanii*) on one single test strip:

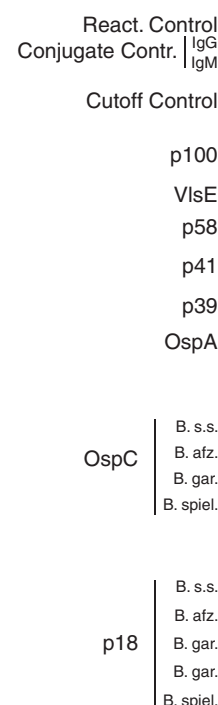
- VlsE from different genospecies
- OspC from all genospecies
- p18 (Decorin binding protein A = DbpA) from all genospecies and different *B. garinii* strains

Product Advantages

- **Recombinant antigens**, therefore
 - 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* and *B. spielmanii***
- 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 serum-liquor-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

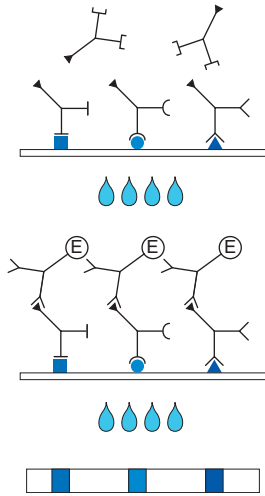
Recombinant Borrelia Antigens

Antigen	Strain
p100	<i>B. afzelii</i>
VlsE	different <i>Borrelia</i> genospecies
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> (different strains), <i>B. spielmanii</i>



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 molekularebiologische Diagnostik von Infektionskrankheiten - Teil 44: Immunoblot (IB); Spezielle Anforderungen für den Nachweis von Antikörpern gegen *Borrelia burgdorferi*

■ Test Principle and Procedure



1. Inkubation: A test strip loaded with *Borrelia* antigens is incubated with diluted serum or plasma in a dish for **1 h**.

Wash 3 times

2. Inkubation: Peroxidase conjugated anti-human antibodies (IgG or IgM specific) are added. Incubate for **45 min**.

Wash 3 times

3. Inkubation: **8 ± 2 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

■ Evaluation

Sero prevalence

	IgG positive	IgM positive	IgG/IgM positive
Blood donors (n = 200)	17 (8,5 %)	3 (1,5 %)	20 (10 %)

Sensitivity

	IgG positive	IgM positive	IgG/IgM positive
Arthritis (n = 28)	27 (96 %)	4 (14 %)	27 (96 %)
Acrodermatitis (n = 11)	11 (100 %)	2 (18 %)	11 (100 %)
Neuroborreliosis (n = 35)	28 (80 %)	19 (54 %)	33 (94 %)
Erythema migrans (n = 42)	19 (45 %)	27 (64 %)	34 (81 %)

■ Storage and Shelf Life

At 4 °C 12 months from the time of production

■ Commercial Product

Article No. 4272	recomLine Borrelia IgG Reagents for 20 determinations
Article No. 4273	recomLine Borrelia IgM Reagents for 20 determinations
Article No. 4276	recomLine Borrelia IgG Reagents for 200 determinations
Article No. 4277	recomLine Borrelia IgM Reagents for 200 determinations