

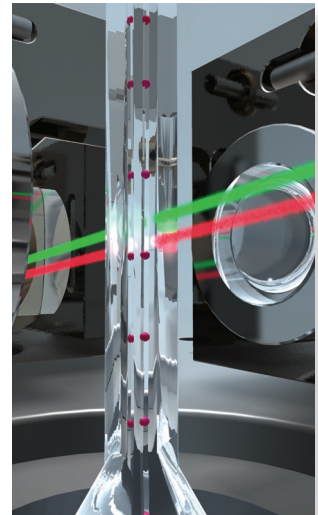
# Borrelia burgdorferi

## recomBead Borrelia IgG recomBead Borrelia IgM

Fluorescence based particle immunoassay using recombinant antigens for the detection of IgG or IgM antibodies against *Borrelia burgdorferi* sensu lato in human serum, plasma or CSF

The bacterium *Borrelia burgdorferi* sensu lato, a spirochete, is the responsible agent 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. 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 like *recomWell* Borrelia are mainly used for screening. For confirmation of borderline and positive results strip assays like the *recom-Line* Borrelia are approved and safe detection systems. The modern multiplex technology integrates the advantages from ELISA and stripe assays: quantitative detection of antibodies against individual antigens. The *recomBead* Borrelia is using the approved and highly specific recombinant antibodies.



### Product Advantages

- Recombinant antigens
  - High sensitivity and specificity
  - Immunodominant antigens of the five pathogenic genospecies: *B. burgdorferi* sensu strictu, *B. garinii*, *B. afzelii*, *B. spielmanii* and *B. bavariensis*
  - Minimised cross reactivity
- Ideal screening or confirmation assay for high sample throughput
- Automated interpretation with feasible connection with LIMS
- Integration of advantages from ELISA and confirmation assay: Quantitative detection of antibodies against individual antigens
- Very high measuring accuracy and very good reproducibility of test results, therefore reliable testing of follow-up samples
- Integrated controls - no additional control samples necessary
- Small sample volume (10 µl)
- Standardised CSF-serum-analysis available
- CE label: the *recomBead* Borrelia tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
- Ideal amendment as confirmation test for the *recomWell* Borrelia tests (ELISA)
- Conform to MiQ Lyme Borreliosis<sup>1</sup> and DIN 58969-44<sup>2</sup>

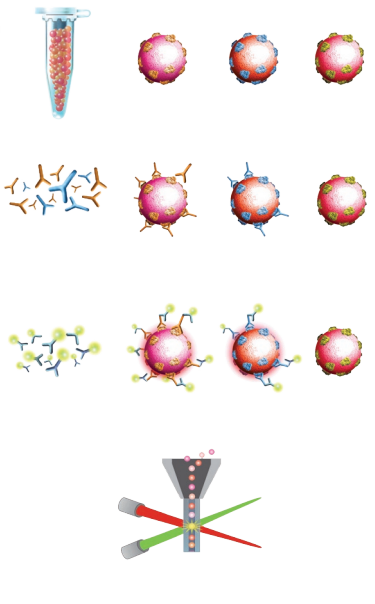
1) Wilske B, Zöller L, Brade V, Eiffert H, Göbel UB, Stanek G, and Pfister HW: MiQ 12, Lyme-Borreliose. In Qualitätsstandards in der mikrobiologisch-infektiologischen Diagnostik. H. Mauch and R. Lütticken, eds. Munich, Germany, Urban & Fischer Verlag, 2000, pp. 1–59

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	Function	Origin
p100	uncharacterised Borrelia specific antigen	<i>B. afzelii</i>
VlsE	vmp (variable major protein) like sequence expressed outer surface lipoprotein	Fusion protein, representing the immunodominant VlsE epitopes of different genospecies
p58	Oligopeptide permease	<i>B. garinii</i>
p39	Borrelial membrane protein A (BmpA)	<i>B. afzelii</i>
OspA	Outer surface protein A	<i>B. afzelii</i>
OspC	Outer surface protein C	<i>B. burgdorferi</i> sensu stricto, <i>B. afzelii</i> , <i>B. garinii</i>
p18	Syn.: Decorin binding protein A (=DbpA), Osp17, Outer surface protein	<i>B. burgdorferi</i> sensu stricto, <i>B. afzelii</i> , <i>B. garinii</i> , <i>B. spielmanii</i> , <i>B. bavariensis</i>

## Test Principle and Procedure



- 1<sup>st</sup> Incubation**      Microspheres coated with *Borrelia* specific antigens are incubated with diluted serum or plasma for **60 min.**
- wash 3 times
- 2<sup>nd</sup> Incubation**      Phycoerythrin marked anti-human antibodies (IgG or IgM specific) are added. Incubate for **30 min.**
- Aspirate and add system fluid
- Measurement**      Either with Luminex® 100™ or Luminex® 200™ system

## Evaluation

### Seroprevalence

	IgG positive	IgM positive	IgG/IgM positive
Blood donors (n = 200)	27 (13,5 %)	11 (5,5 %)	35 (17,5 %)*

\* Within the 35 (17,5%) IgG/IgM positive samples 30 (15,0%) showed the typical antibody pattern of an infection with *Borrelia burgdorferi*. The remaining 5 samples (2,5%) exhibit weak unspecific reactivities (background).

### Sensitivity

	IgG positive	IgM positive	IgG/IgM positive
Arthritis (n = 27)	27 (100 %)	6 (22 %)	27 (100 %)
Acrodermatitis (n = 11)	11 (100 %)	2 (18 %)	11 (100 %)
Neuroborreliosis (n = 30)	26 (87 %)	16 (53 %)	28 (93 %)
Erythema migrans (n = 38)	21 (55 %)	25 (66 %)	30 (79 %)

## Article-No

- 4252      **recomBead Borrelia IgG**  
Reagents for 96 determinations
- 4253      **recomBead Borrelia IgM**  
Reagents for 96 determinations

## Storage and Shelf Life

At +2°C - +8°C  
12 months from the date of production