**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

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Strain</th>
</tr>
</thead>
<tbody>
<tr>
<td>p100</td>
<td>B. afzelii</td>
</tr>
<tr>
<td>VlsE</td>
<td>different Borrelia genospecies</td>
</tr>
<tr>
<td>p58</td>
<td>B. garinii</td>
</tr>
<tr>
<td>p41</td>
<td><em>B. burgdorferi</em> sensu stricto</td>
</tr>
<tr>
<td>p39</td>
<td>B. afzelii</td>
</tr>
<tr>
<td>OspA</td>
<td>B. afzelii</td>
</tr>
<tr>
<td>OspC</td>
<td><em>B. burgdorferi</em> sensu stricto, B. afzelii, B. garinii, B. spielmanii</td>
</tr>
<tr>
<td>p18</td>
<td><em>B. burgdorferi</em> sensu stricto, B. afzelii, B. garinii (different strains), B. spielmanii</td>
</tr>
</tbody>
</table>

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
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**

<table>
<thead>
<tr>
<th></th>
<th>IgG positive</th>
<th>IgM positive</th>
<th>IgG/IgM positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donors (n = 200)</td>
<td>17 (8.5 %)</td>
<td>3 (1.5 %)</td>
<td>20 (10 %)</td>
</tr>
</tbody>
</table>

**Sensitivity**

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

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