DiaMex GmbH

Highend diagnostic products

Luminex® Technology:

# Lyme Disease Assays

# HPV Genotyping Kit

## The System



## Lyme Disease Assays



## Lyme Disease Assays



## HPV Test

# Introducing the Luminex® Technology



Luminex® xMAP® technology is highly sensitive, accurate, and precise, yet designed for high throughput and faster time-to-results. The notion of a 'suspended array' as opposed to a flat, solid array, allows true representative quality control during manufacturing and assay prep. In other words, an aliquot from a stock suspension can be QC'd (quality control tested) and it will accurately represent the remainder of the stock solution. Not so with a solid array, which has to be consumed to achieve the same quality test. Furthermore, multiplexing allows truly internal controls within the same sample well.

xMAP® enables laboratory efficiency. Using xMAP® technology, more tests can be run on smaller sample volumes than with many competing technologies — 50 microliters or less of sample (only a few drops), as opposed to up to 100 times that volume with competing ELISA technology. Because multiplexing with xMAP® technology enables researchers to see the reactions of multiple analytes from a single, small sample volume, it provides information that would simply be unavailable for researchers using single plex ELISA with limited sample (such as pediatric, mouse, or biopsy material).

Because of its flexible, open-architecture design, a single xMAP® technology-based platform may be configured to perform a wide variety of bioassays throughout the drug-discovery and diagnostics fields, as well as basic research. A single system is also compatible with kits from many different vendors, all partners of Luminex®. And finally, xMAP® assays may be custom designed to include only the number of analytes and controls you need for your particular assay, what we call 'focused multiplexing.' Only xMAP® technology offers this focused multiplexing that scales accurately and efficiently from one to 100 tests per sample — the very range in which most of the industry need exists.

## Advantages of the Luminex® Technology

**Accuracy/Precision**

- Sensitive assays
- Internal controls in each well
- High specificity

**Efficiency**

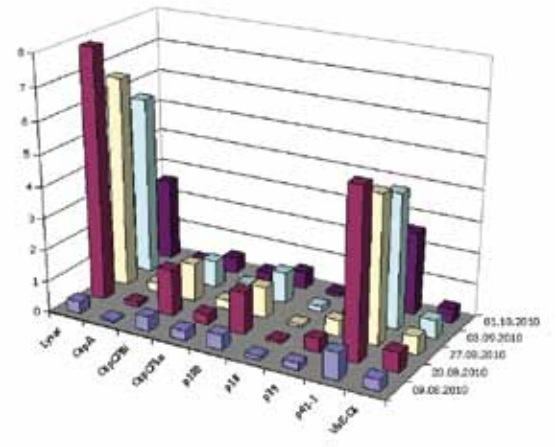
- More data by multiplexing
- Reduced labor and costs
- Small sample volume

**Flexibility**

- Multi-format assays: DNA, immuno, enzyme
- Kits or custom assays
- Expand or reduce assay panels easily



## Patient Monitoring



**Monitoring of therapeutic success**

Borrelia IgM profiling in a patient with Erythema migrans during anti-biotic treatment

# Consumables

Below is a list of consumables which are necessary for the day to day operation.

**Ordering information**

| Cat. No. | Content | Unit |
|---|---|---|
| MM1101 | Sheath Fluid | 20 l |
| MM1107 | Sheath Fluid (20x concentrate) | 1 l |
| MM1050 | MAGPIX® | 1 pc |
| MM1130 | MAGPIX® Calibration Kit | 1 pc |
| MM1131 | MAGPIX® Performance Verification Kit | 1 pc |
| MM1060 | Magnetic Plate Separator | 1 pc |
| MM1112 | MAGPIX® Drive Fluid | 4 x 750 ml |
| MM1102 | Calibrator CAL-1 | 5 ml |
| MM1103 | Calibrator CAL-2 | 5 ml |
| MM1104 | Control CON-1 | 5 ml |
| MM1105 | Control CON-2 | 5 ml |
| MM1120 | Lx 200™ Calibration Kit | 1 pc |
| MM1121 | Lx 200™ Performance Verification Kit | 1 pc |
| MMLBLXXX-01 | LumAvidin Beads Region XXX | 1 ml |

# Optiplex Borrelia IgG and IgM

**Bead-based Immunoassays (confirmatory test) for Detection of IgM or IgG Antibodies against Borrelia Antigens in Human Serum and Cerebrospinal Fluid**


Lyme borreliosis is the most common tick-borne infectious disease in the Northern hemisphere. In most European endemic regions, 20-40% of the tick vector Ixodes ricinus carry at least one of the three known pathogenic bacteria species Borrelia burgdorferi sensu stricto, Borrelia garinii, and the most common pathogen in Europe, Borrelia afzelii.

## Clinical symptoms

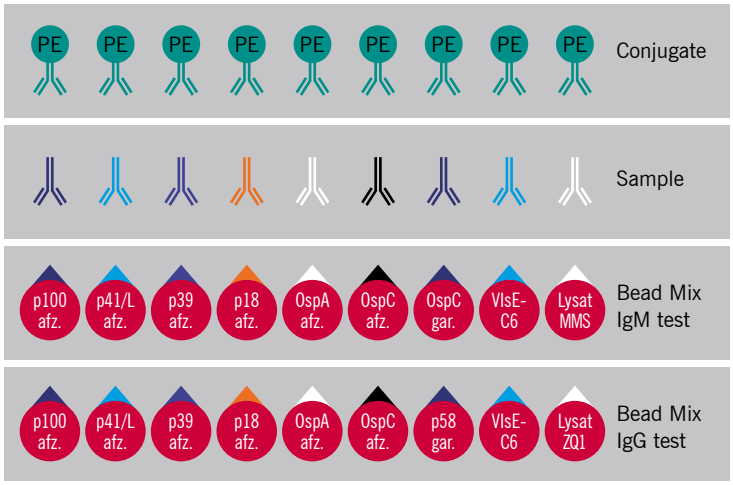
Lyme borreliosis is a multi-systemic disease with initial manifestations limited to characteristic ring-shaped skin lesions (erythema migrans), which can progress to systemic infection. The course of disease is divided into 3 stages (I-III).

The clinical symptoms of Lyme disease are heterogeneous and depend on the tropism of the infectious agent. Preferential targets of the pathogen are connective tissues of skin and joints, and the nervous system. A correlation between individual Borrelia species and defined clinical symptoms has been observed. However, conventional serological tests often fail to reliably diagnose the disease, particularly in cases of severe or chronic manifestations. The Optiplex Borrelia IgG and IgM test is now available as a more sensitive and specific diagnostic tool for diagnosing borreliosis.

| Stage I | Stage II | Stage III |
|---|---|---|
| Days to Weeks | | |
| Weeks to Months | | |
| Months to Years | | |
| Erythema migrans<br>Fever<br>Headache<br>Joint pain | Neuroborreliosis<br>Arthralgia<br>Myalgia<br>Lyme carditis | Chronic polyarthritis<br>Acrodermatitis atrophicans<br>Encephalomyelitis<br>Paresis<br>Chronic pain |

## Test principle

The Optiplex Borrelia IgG or IgM assay is a consumer-friendly multiplex test, which allows the simultaneous detection of human IgG or IgM antibodies directed against various Borrelia antigens. No wash steps are required. The test is based on spectrally distinguishable bead populations coated with different recombinant Borrelia antigens on their surface. A mixture of these coated beads (Bead Mix) is incubated with patient samples allowing Borrelia-specific IgG or IgM to bind to the antigens on the bead surface. Bound IgG or IgM is then detected by addition of a fluorescence-conjugated anti-human IgG or IgM secondary antibody (Conjugate). The quantitative analysis of all analytes is performed under chemical equilibrium conditions by measuring bead-associated fluorescence signals using the Luminex® analyzer. The Optiplex Borrelia IgG and IgM tests provide high analytical sensitivity and specificity as well as a broad dynamic range. These results are superior to the combined results for conventional ELISA and Western Blot procedures, and provide direct quantification of antibody-antigen complexes under chemical equilibrium conditions.



## Advantages of Optiplex Borrelia IgG and IgM tests

- Minimal sample volume (5 µl)
- No wash steps
- Short incubation time
- Fully automated analysis
- Broad dynamic range
- Simultaneous detection of antibodies against different Borrelia antigens

## Components of Optiplex Borrelia IgG and IgM tests

- Bead-Mix
- Conjugate
- Reference control
- Positive and negative control
- Assay buffer
- Microtiter plate
- Instruction sheet

Contents of the test kit are sufficient for 96 determinations.

## Test procedure

25 µl diluted Sample or Control
25 µl Bead-Mix

▼ **Incubation 1 h, 37°C**

50 µl Conjugate

▼ **Incubation 1 h, 37°C**

Analysis and evaluation
using the Luminex® analyzer

| Antigens in Borrelia IgG test | Antigens in Borrelia IgM test |
|---|---|
| p 100 afz. | p 100 afz. |
| p 41/I afz. | p 41/I afz. |
| p 58 gar. | p 39 afz. |
| p 39 afz. | Osp C gar. |
| Osp A afz. | Osp C afz. |
| Osp C afz. | Osp A afz. |
| p 18 afz. | p 18 afz. |
| VlsE-C6-Peptide | VlsE-C6-Peptide |
| Lysate ZQ1 gar. | Lysate MMS afz. |

**Ordering information**

| Cat. No. | Content | |
|---|---|---|
| IN0503 | Optiplex Borrelia IgM test | 96 tests |
| IN0504 | Optiplex Borrelia IgG test | 96 tests |



Further information see package insert

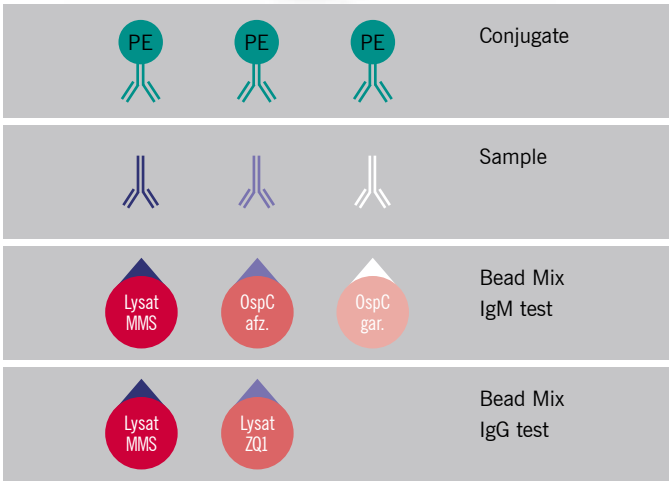
# Optiplex Borrelia Screening IgG and IgM

## Bead-based Immunoassays for Detection of IgM or IgG Antibodies against Borrelia Antigens in Human Serum and Cerebrospinal Fluid

In serum IgM antibodies are usually not detectable until week 3 after infection. Approximately three weeks later IgG antibodies are detectable. The high sensitivity of the Optiplex Borrelia Screening IgG and IgM tests allows the diagnosis of borreliosis at an early stage of infection.


### Test principle

The Optiplex Borrelia IgG or IgM test is a consumer-friendly multiplex test, which allows for the simultaneous detection of human IgG or IgM antibodies directed against various Borrelia antigens. No wash steps are required. The test is based on spectrally distinguishable bead populations coated with different recombinant Borrelia antigens. A mixture of these coated beads (Bead Mix) is incubated with a patient sample allowing Borrelia-specific IgG or IgM to bind to the antigens on the bead surface. Bound IgG or IgM are then detected by addition of a fluorescence-conjugated anti-human IgG or IgM secondary antibody (conjugate). The quantitative analysis is performed by measuring bead-associated fluorescence signals using the Luminex® analyzer. The Optiplex Borrelia IgG and IgM tests provide high analytical sensitivity and specificity as well as a broad dynamic range.




### Advantages of Optiplex Borrelia Screening IgG and IgM tests

- Minimal sample volume (5 µl)
- No wash steps
- Short incubation time
- Fully automated analysis
- Broad dynamic range
- Simultaneous detection of antibodies against different Borrelia antigens

### Components of Optiplex Borrelia Screening IgG and IgM tests

- Bead-Mix
- Conjugate
- Reference control
- Positive and negative control
- Assay buffer
- Microtiter plate
- Instruction sheet

Contents of the test kit are sufficient for 96 determinations.

**The test procedure is identical to Optiplex Borrelia tests.**

| Antigens in Borrelia Screening IgG test | Antigens in Borrelia Screening IgM test |
|---|---|
| Lysat Borrelia garinii (Strain ZQ1) | Lysat Borrelia afzelii (Strain MMS) |
| Lysat Borrelia afzelii (Strain MMS) | OspC afzelii |
| | OspC garinii |

### Ordering information

| Cat. No. | Content | |
|---|---|---|
| IN0501 | Optiplex Borrelia Screening IgM test | 96 tests |
| IN0502 | Optiplex Borrelia Screening IgG test | 96 tests |

Further information see package insert

# Optiplex HPV Genotyping Kit

NEW: now CE marked


## Fluorescent Bead Assay (FBA) on 24 Human Papillomaviruses (HPV) in Polymerase Chain Reaction (PCR) amplified samples

The Optiplex HPV Genotyping Kit is a qualitative and sensitive high-throughput procedure for the identification of multiple high- and low-risk genital HPV genotypes in a single reaction.

### Intended use

More than 100 HPV of the Alphapapillomavirus genus are known. 24 of the most common types have been divided into three groups based on their association to cancer: 15 high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82), 3 putative high-risk types (26, 53, and 66), and 6 low-risk types primarily found in genital warts and low-grade cervical lesions (6, 11, 42, 43, 44, and 70) (MUNOZ et al. 2003).

The Optiplex HPV Genotyping Kit is an in vitro diagnostic test kit for detection of infections and coinfections of Human Papillomavirus genotypes 6, 11, 16, 18, 26, 31, 33, 35, 39, 42, 43, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73 and 82 in PCR-amplified samples of genomic DNA isolated from cervical smears.

The kit was produced in cooperation with the German Cancer Research Center (DKFZ) according to the method published by Schmitt et al. 2006 and 2008. It constitutes a qualitatively superior research tool for epidemiological studies, cancer-screening programmes, the characterization of study populations in HPV trials and the evaluation of the efficacy of HPV vaccine trials.

References: MUNOZ, N. et al., 2003, N. Engl. J. Med. 348:518-527; SCHMITT, M. et al., 2006, J. Clin. Microbiol. 44:504-512; SCHMITT, M. et al., 2008, J. Clin. Microbiol., 46:1050-1059

### Test principle

The Optiplex HPV Genotyping Kit allows the simultaneous detection of 24 HPV types in a PCR-amplified sample.

The sample DNA, extracted from cervical scrapings, is subjected to PCR amplification, using sets of biotinylated broad range primers contained in the kit. Optionally, a pair of primers for the amplification of a ß-globin gene fragment can be added to the PCR in order to verify the quality of the human sample DNA.

PCR products are added to the bead mix containing 26 distinct bead populations coupled to 24 HPV, one ß-globin and one hybridization control specific oligonucleotide probe. After thermal denaturation of the double stranded PCR products, the target sequences are hybridized to HPV type-specific bead-bound probes.

After a wash step the hybridized PCR products are labelled by binding of R-phycoerythrin marked streptavidin.

An additional wash step eliminates the non-bound fluorescent marker.

After resuspending the beads, the read-out in the Luminex® analyzer is performed. HPV types are discerned according to the unique bead signature, whereas the presence of PCR products is determined by phycoerythrin fluorescence.

An analytical sensitivity cut-off is calculated based on the negative control.

### Advantages of the Optiplex HPV Genotyping Kit

- Simultaneous detection of 24 human Papillomaviruses
- Minimal sample volume
- High specificity and sensitivity
- Short incubation times
- Saves time and money
- incl. 2 validity controls (sample material/PCR, hybridization)

Further information see package insert

# HPV Genotyping Kit

## Components of Optiplex HPV Genotyping Kit

- Bead-Mix
- Conjugate
- PCR Primer Set 1
- PCR Primer Set 2
- Hybridization Control
- Wash Buffer
- Staining Buffer
- 96 Well Hybridization Plate
- 96 Well Filtration Plate
- 96 Lock-Well Plate
- Seal Foil

Content is sufficient for 96 determinations.

### Ordering information

| Cat. No. | Content |
|---|---|
| IN0601 | Optiplex HPV Genotyping Kit 96 Tests<br>Bead-based assay for the detection of 24 human papillomaviruses in PCR amplified samples |

## Test procedure

Amplification (PCR)

▼

Denaturation

▼

Hybridization to bead-bound probes

▼

Wash & labeling

▼

Wash & read-out of the plate using Luminex® analyzer

**Human Papillomavirus Types:**

High-risk types:
16, 18, 31, 33, 35,39, 45, 51, 52, 56, 58, 59, 68, 73, 82

Putative high-risk types:
26, 53, 66

Low risk-types:
6, 11, 42, 43, 44, 70

Further information see package insert

DiaMex GmbH

Highend diagnostic products

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