LUMINEX® xMAP® TECHNOLOGY

A milestone in immunodiagnostics – ideally suited for high sample throughput.

recomBead
PRODUCT PORTFOLIO

Article-No.        Article-No.
4254 recomBead Borrelia IgG 2.0    5754 recomBead Bordetella pertussis IgG 2.0
                    Reagents for 96 determinations (quantitative results in IU/ml)
4255 recomBead Borrelia IgM 2.0    5755 recomBead Bordetella pertussis IgA 2.0
                    Reagents for 96 determinations (quantitative results in IU/ml)
4554 recomBead EBV IgG 2.0        5154 recomBead Treponema IgG 2.0
                    Reagents for 96 determinations
4555 recomBead EBV IgM 2.0        5155 recomBead Treponema IgM 2.0
                    Reagents for 96 determinations
4654 recomBead Yersinia IgG 2.0   31049 recomQuant
                    Reagents for 96 determinations
4655 recomBead Yersinia IgA [IgM]* 2.0 recomBead analysis Software
                    Reagents for 96 determinations
* [] optional available as additional reagent

recomBead CXCL13
Each recomBead CXCL13 kit consists of two packing units
PART A CXCL13 and PART B CXCL13. Please always order both
units simultaneously in equal amounts.

7754 PART A CXCL13
                    Reagents for 96 determinations
27702 PART B CXCL13
                    Reagents for 96 determinations

LUMINEX® MULTIPLEX-TECHNOLOGY – PRODUCT BENEFITS

- High-throughput assay
  Ideally suited for high sample throughput
- Automation
  Fully automated processing and analysis possible; integration into an existing
  laboratory information system possible
- All in one
  Combines the advantages of ELISA and confirmatory test, detection of antibodies
  for individual antigens
- Flexible
  Flexible combination of different test systems and conjugate classes on one plate possible –
  same incubation time
- Safe
  Integrated controls: Incubation control, conjugate control, negative control
- Precise
  Very high accuracy and reproducibility of test results
- Fast
  20 minutes sample incubation, 20 minutes conjugate incubation –
  analysis result in less than 3 hours
- Small sample volume
  10 µl sample volume sufficient
The technology is based on microscopic polystyrene beads, so called microspheres. One hundred different bead populations exist. The populations can be distinguished from each other by their specific colour code.

Each bead can be coated with a selection of specific antigens or antibodies, thus allowing analysis of up to 100 parameters in one single sample simultaneously. Besides the classical MicroPlex beads, a second generation of polystyrol beads using a para-magnetic layer (MagPlex®) has been developed. These can be fixed magnetically to simplify processing.

The technology is extremely user friendly and ideal for various applications in medical diagnostics.

1. Detection of antibodies using recomBead tests
   The Mikrogen multi-analyte assays include defined combinations of bead populations coated with different antigens. Antigens used are immunodominant and serologically relevant proteins of the pathogen. The detection of antibodies present in a patient sample takes place on the surface of these microspheres. Once the patient sample has been added, each microsphere population will bind its specific target molecule (antibody).

2. CXCL13 Sandwich technology
   Anti-hCXCL13 is covalently bound to the surface of magnetic colour-coded microscopic beads. The quantification of the target antigen CXCL13 in the CSF sample is done via a sandwich assay using anti-hCXCL13 antibodies and a biotin streptavidin reporter system, followed by fluorescent measurement.
LUMINEX® SYSTEMS

Analyzer

The xMAP® technology, developed by the Luminex® corporation, provides an innovative platform for the analysis of multiplex assay systems. The analysis system comprises a workstation (e.g. Luminex® 200™ or MAGPIX®), an automated fluidic system, a computer, a monitor and software.

Luminex® 200™ system
The method used is based on flow cytometry. The microspheres are separated when injected into the measuring cell. Two lasers are focused on the particle beam in the measuring cell. A red laser identifies the colour code of the bead while the quantitative analysis is carried out by a second green laser. Classical MicroPlex beads as well as the new magnetic MagPlex® beads can be used.

MAGPIX® System
Magnetic beads (MagPlex®) are used in the MAGPIX® system allowing a straight forward automation. A CCD camera detects the two-dimensional magnetically fixed beads in the red and green light spectrum. MAGPIX® is a compact and robust system with short start-up and shut-down protocols.

<table>
<thead>
<tr>
<th></th>
<th>Luminex® 200™</th>
<th>MAGPIX</th>
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<tbody>
<tr>
<td><strong>Optics</strong></td>
<td>Laser/APD/PMT</td>
<td>LED/CCD camera</td>
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<tr>
<td><strong>Hardware</strong></td>
<td>Flow cytometry</td>
<td>Fluorescence</td>
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<td><strong>Bead compatibility</strong></td>
<td>MicroPlex, MagPlex®</td>
<td>MagPlex®</td>
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<tr>
<td><strong>Dynamic range</strong></td>
<td>3,5 Log</td>
<td></td>
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<td><strong>Microtiter plate</strong></td>
<td>96 Well</td>
<td></td>
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<tr>
<td><strong>Footprint (incl. PC)</strong></td>
<td>132 cm (W) x 32 cm (H) x 64 cm (D)</td>
<td>83 cm (W) x 43 cm (H) x 63 cm (D)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>49 kg</td>
<td>17,5 kg</td>
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<tr>
<td><strong>Software</strong></td>
<td>xPonent</td>
<td></td>
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Software

The evaluation of the test recomBead systems takes place in two steps:
1) measuring of the beads by MAGPIX® or Luminex® 200™ system with the Luminex® xPONENT software and
2) test specific interpretation of the measurement with the Mikrogen recomQuant software

xPONENT

The Luminex® xPONENT software is a modular and flexible software package for the control of the MAGPIX® and Luminex® 200™ systems. The software’s graphical user interface follows the typical assay workflow. Navigation wizards and automated routine operations such as startup, shutdown, calibration and performance verification, further enhance system usability and result in increased walk-away time. Different access levels enable the user to acquire samples, perform analysis, run system maintenance routines or to administrate the system.

recomQuant

The Mikrogen specific test evaluation is done with the recomQuant software which accesses the raw data of the xPONENT software. recomQuant offers a high level of security: Lot data can be imported via download or barcode and contain, among other information, the shelf life of the test kits. The conjugate classes used are automatically detected and assigned. Data import and export is simple and intuitive, the results are presented clearly. A fast CSF analysis on the level of single antigens is available for recomBead Borrelia.
WORKFLOW

Processing of samples

Instrument
- Set up instrument
- Import work list
- Instrument prepares dilutions
- Instrument pipettes reagents

Manually
- Prepare work list
- Prepare dilutions
- Pipette reagents

Sample incubation
- 20 min

Conjugate incubation
- 20 min

Separate protocol for CSF analysis (Borrelia Antibody Index and CXCL13) available.

Measuring in analyzer

< 90 min*

*up to 90 min in case of complete plate (96 samples)

Evaluation with recomQuant

- Import raw data from xPONENT software, import lot data
- Evaluation and export/printout of results

Analysis results in less than 3 hours
Dynex DSX

The DSX is an open, fully automated analyzer for the complete sample preparation and processing of microtiter plate tests. It is controlled by a user-friendly Windows software, that allows the user to program different assays. Due to the high flexibility and usability, the DSX supports daily routine work, sample preparation can be carried out directly in a deep well plate. The device can process up to four microtiter plates simultaneously and be continuously reloaded during the run. For processing of MagPlex® beads, the DSX can be equipped with a magnetic plate for MagPlex® beads.

**Software**
- Revelation Software

**Tests per plate**
- 96 samples/plate. Up to 12 different assays

**Time management**
- Time table

**Barcode**
- Optional

**Number of plates**
- 4

**Plate incubators**
- 4 separate incubator modules

**Temperature ranging**
- +7 to +50°C

**Sample capacities**
- 96 samples

**Samples tubes**
- 96 (2 racks per 48)

**Controls and/or standards**
- 33

**Reagents**
- 24

**Loading**
- continuously (samples, plates, reagents)

**Wash buffer containers**
- 4 x 2 liters (level sensor)

**Waste container**
- 1 x 8 liters (level sensor)

**Pipetting tips capacities:**
- 4 racks (per 108 Spitzen / 300 µl), 1 Rack (41 Spitzen / 1300 µl)

**Min-Max-Volumina**
- Samples 5-250 µl (single shot mode), resp. 25 - 100 µl (multi shot mode), reagent 25 - 1000 µl