DIAGNOSTICS OF LYME BORRELIOSIS

BIOMEDICA

Global Technology.
Local **Solutions.**

DIAGNOSTICS OF LYME BORRE

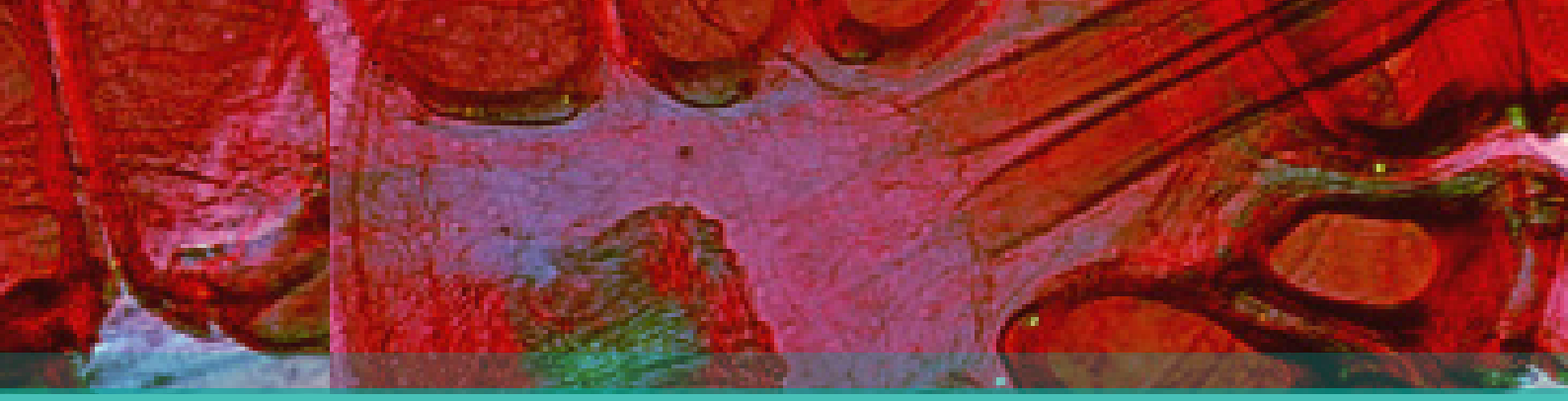
BIOMEDICA – YOUR PARTNER IN LYME BORRELIOSIS DIAGNOSTICS

BIOMEDICA has been on the forefront as a distributor of in vitro diagnostics for **more than 35 years**. BIOMEDICA has established **13 local offices**, distributed **across Central Eastern Europe (CEE)**, employing a **team of 250 professionals**. The reliability of BIOMEDICA's business performance and quality of products are evidenced in our daily work and our daily efforts with and for our customers.

We supply customers in the fields of health care and research with **flexible solutions, quality products, technical services and ongoing support.**

The **ISO 9001:2008 certification** throughout the entire group of companies ensures constant improvement in quality of products and services.

Map showing BIOMEDICA local offices.



LIOSIS

DIAGNOSTICS OF LYME DISEASE

Lyme Borreliosis (LB, Lyme disease) is the most commonly reported tick-borne infection in Europe and North America. It is caused by a gram-negative spirochaete, named Borrelia (first isolation of Borrelia burgdorferi from Ixodes scapularis, deer tick). The pathogens are transmitted by the bite of various tick species, in Europe mostly by Ixodes ricinus (sheep tick). The incubation period varies from 3 to 30 days.

The disease is a multi-system disorder which can affect a complex range of tissues including the skin, heart, nervous system, and to a lesser extent the eyes, kidneys and liver.

Lyme disease has been known in Europe under a variety of names (including erythema migrans, neuroborreliosis, acrodermatitis chronica atrophicans, Bannwarth´s syndrome).

Clinical presentations can generally be divided into three stages but progress from an early to later stage is not inevitable, even if the infection is untreated:

Stage 1: early dermatitis – appearing days or weeks after the infection.
Clinical: erythema migrans.

Stage 2: early disseminated infection – appearing weeks or months after infection.
Clinical: lymphocytic meningoradiculitis (Bannwarth´s syndrome), neuroborreliosis.

Stage 3: late disseminated infection – occuring up to years after infection.
Clinical: chronic progressive encephalomyelitis, acrodermatitis chronica atrophicans, chronic arthritis.

Many features of later infection are not specific to Lyme Borreliosis and occur in other conditions.

The diagnosis of Lyme Borreliosis should be made only after careful evaluation of the patient´s clinical history, physical findings, laboratory evidence and exposure risk evaluation.

TWO-STAGE DIAGNOSTICS FOR LYME DISEASE

For the serological diagnosis of anti-borrelia antibodies, the German Association for Hygiene and Microbiology (DGHM), the Robert Koch Institute (RKI) and the Center for Disease Control (CDC) call for a two-stage strategy:

In the first step a preferably sensitive screening by ELISA is performed, e.g. by BIOMEDICA Borrelia recombinant IgG / IgM ELISA, which also detects antibodies against the Borrelia major antigen VlsE. During the early stage of borreliosis, the test result may still be negative. A second analysis should therefore be carried out after one to two weeks if borreliosis is indicated. In suspected cases of neuroborreliosis Borrelia-specific antibodies are investigated simultaneously in CSF and serum.

If the screening test result is positive or borderline, it should be followed up by immunoblot, e.g. MIKROGEN recomLine Borrelia IgG / IgM, which provide a secure and highly sensitive differentiation between Borrelia-specific and non-specific reactions.

SCREENING

Borrelia recombinant IgG ELISA CE
Borrelia recombinant IgM ELISA CE

BIOMEDICA

12x8 breakable microtiter-well strips ELISA for the quantitative and qualitative determination of IgG- and IgM-antibodies in human serum, plasma, and CSF, for screening purposes.

Antibodies in the human sample bind to the antigens coated on the microtiter plate. Unbound immunoglobulins are removed by washing processes. The enzyme conjugate attaches to bound antibody. Unbound conjugate is removed by washing processes. After adding the substrate solution (TMB), a blue dye is produced by the bound enzyme (peroxidase). By adding stop solution the colour changes to yellow and can be detected with a normal colorimetric ELISA reader (filter 450nm).

To improve the diagnostic specificity, the BIOMEDICA microtiter-well strips are coated with the following recombinant antigens for IgG and / or IgM detection:

- p21 = OspC (outer surface protein C – B. sensu strictu, B. afzellii, B. garinii)
- p18 (B. afzelii)
- p100 (B. afzelii)
- VIsE (fusion protein of different genospecies)
- p41i (inner part of flagellin of B. garinii)

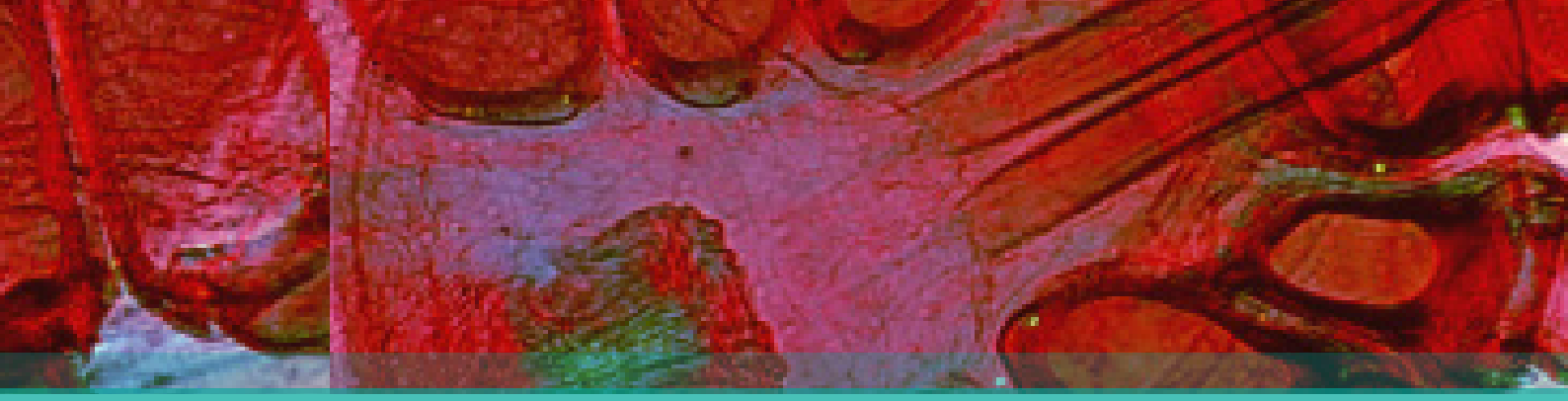
Sample dilution for IgG detection:
- Serum or plasma: 1+100 with sample dilution, e.g. 10 µl sample + 1 ml sample diluent, mix well
- CSF: 1+2 with sample diluent, e.g. 100 µl sample + 200 µl sample diluent, mix well

Sample dilution for IgM detection:
- Serum or plasma: 1+100 with sample dilution, e.g. 10 µl sample + 1 ml sample diluent, mix well
- CSF: 1+1 with sample diluent, e.g. 100 µl sample + 100 µl sample diluent, mix well
- No additional RFS stripping necessary

Product advantages
- Recombinant antigens lead to better standardization and lot-to-lot consistency
- High sensitivity and specificity confirmed by clinical samples
- Controls included: positive / cut-off / negative
- Colour-coded strips and reagents
- Easy test procedure for manual and instrument use
- Total incubation time <2 hours
- Standardised CSF-serum-analysis available
- Free SW (based on Reiber's formula) to calculate CSF levels
- CE label meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
- Constant quality checks and confirmation by external INSTAND Ringversuch

Ordering Information:
BI-21032 Borrelia recombinant IgG ELISA, 12x8 tests
BI-21042 Borrelia recombinant IgM ELISA, 12x8 tests

Related product:
BI-3501 RFS Rheumatoid Factor Removal Stripper Solution, 40 tests



CONFIRMATION

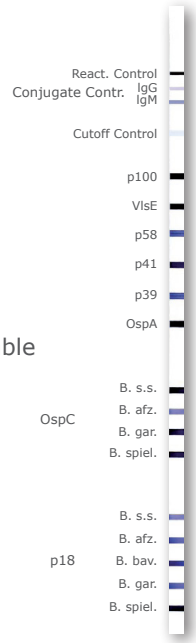
recomLine Borrelia IgG CE
recomLine Borrelia IgM CE

MIKROGEN DIAGNOSTIK

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG or IgM antibodies against Borrelia burgdorferi in human serum, plasma or CSF.

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 five of the so far known as immunopathogenic genospecies (B. burgdorferi sensu stricto, B. garinii, B. afzelii, Borrelia spielmanii and B. bavariensis) on one single test strip:

- VlsE from different genospecies
- OspC from all genospecies
- p18 (Decorin binding protein A = DbpA) from all genospecies



Product advantages

- Recombinant antigens
- 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 five genospecies: B. burgdorferi sensu stricto, B. garinii, B. afzelii, B. spielmanii and B. bavariensis
- 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 CSF-serum-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 BIOMEDICA Borrelia ELISA
- Conform with MiQ Lyme Borreliosis[1] and DIN 58969-44[2]

Ordering information

MG-4272/MG-4276 recomLine Borrelia IgG 20/200 tests
MG-4273/MG-4277 recomLine Borrelia IgM 20/200 tests

LITERATURE

[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*

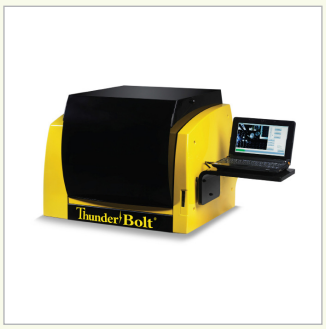
[2)] DIN 58969-44: Medizinische Mikrobiologie - Serologische und molekularbiologische Diagnostik von Infektionskrankheiten - Teil 44: Immunoblot (IB); Spezielle Anforderungen für den Nachweis von Antikörpern gegen Borrelia burgdorferi

Antigen	Strain
p100	*B.afzelii*
VlsE	*different Borrelia-genospecies*
p58	*B.garinii*
p41	*B. burgdorferi sensu stricto*
p39	*B.afzelii*
OspA	*B.afzelii*
OspC	*B. burgdorferi sensu stricto, B.afzelii, B.garinii, B. Spielmanii*
p18	*B. burgdorferi sensu stricto, B.afzelii, B.garinii, B. Spielmanii, B. bavariensis*

AUTOMATION OF ELISA AND S

With the tests kits, the instruments for ELISA and strip processing and the strip evaluation software recomScan, BIOMEDICA offers a suitable master plan for the automation of your diagnostic laboratory.

ELISA PROCESSOR



GD-TBE100-00 THUNDERBOLT® AUTOMATED ELISA PROCESSING

The ThunderBolt® offers automation features previously reserved for instruments many times the price and size. Streamline your workflow with easy loading, and fully automated processing, reading and reporting of results. Experience the difference ThunderBolt® walk-away automation will bring to your laboratory. The The ThunderBolt® processes up to 2x96 tests.

STRIP PROCESSORS, READERS AND SCANNERS

ZZ-MAB3000-6 MEDTEC'S AUTOBLOT 3000

Benchtop Western Blot processor for accurate and highly reproducible results, processes up to 20 strips

MG-31050 MIKROGEN'S DYNABLOT PLUS

For the automatic processing of all MIKROGEN's strip assays, processes up to 40 strips

TQ-16059028 TECAN'S PROFIBLOT 48

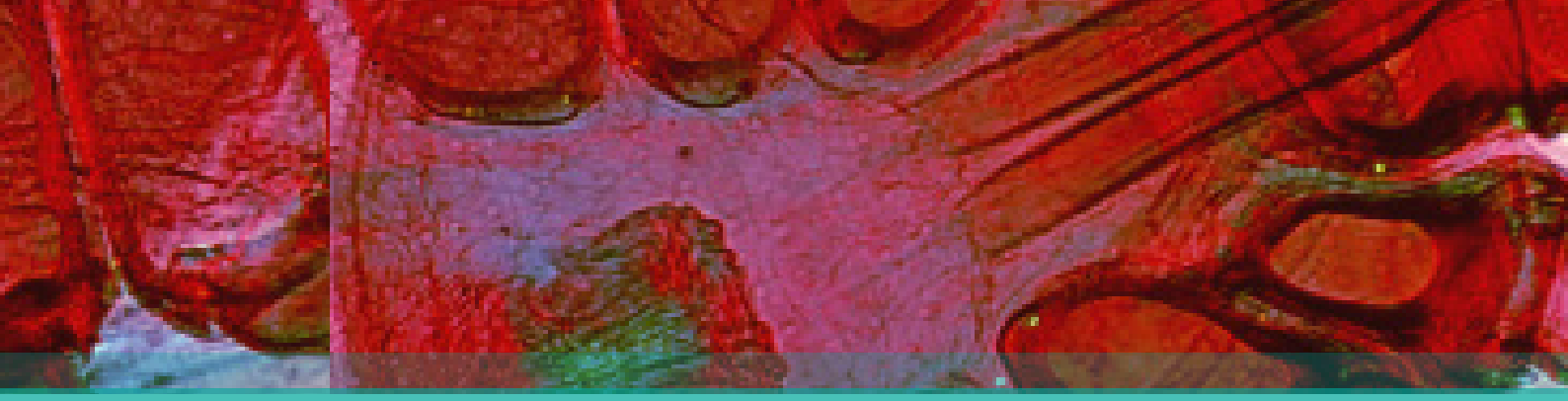
Fully automated Western Blot analysis, processes up to 48 strips

MG-31009 BLOTRIX READER

Scan test strips directly from the black incubation trays.

MG-31010 FLATBED SCANNER OPTICPRO S28

Scan test strips from black evaluation sheets.



TRIP ASSAYS

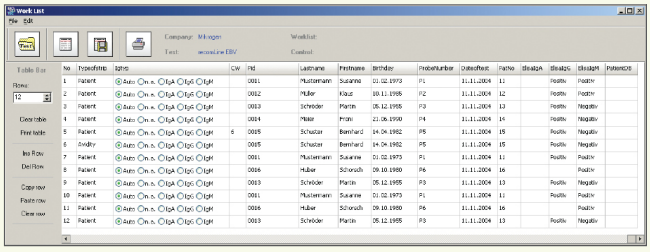
STRIP EVALUATION SOFTWARE

MG-31006 RECOMSCAN SOFTWARE

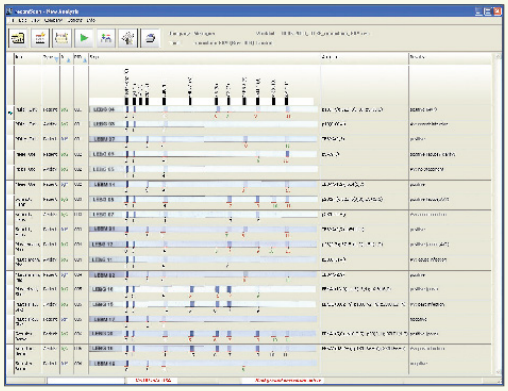
Automatic detection and interpretation of MIKROGEN's recomBlot and recomLine assays. Easy to connect to the laboratory EDP (electronic data processing).

Plug-Ins for database, import/export, patient report separately available.
recomScan calibration card separately available.

CREATE WORK LIST:

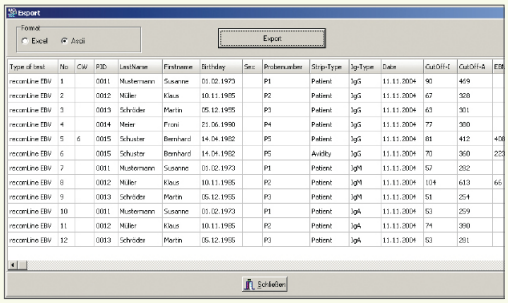


EVALUATION:



LIST REPORT:

EXPORT RESULTS TO LIS (LABORATORY INFORMATION SYSTEM):



BIOMEDICA OFFICES

Albania

Biomedica Sh.p.k
Zona 4, Godina 1, Kati 1, Ap. 6, Selite
1001 Tirana, Albania
T +355 4 481 8759
F +355 4 481 8759
office@bmgrp.al
www.bmgrp.al

Austria

Biomedica Medizinprodukte GmbH
Divischgasse 4
1210 Wien, Österreich
T +43 1 291 07 0
F +43 1 290 14 29
office@bmgrp.at
www.bmgrp.at

Bosnia & Herzegovina

Biomedica d.o.o.
Tvornička 3
71210 Ilidža, Sarajevo,
Bosnia and Herzegovina
T +387 33 262 725
F +387 33 262 726
office@bmgrp.ba
www.bmgrp.ba

Bulgaria

Biomedica Bulgaria Ltd.
2E ''Akad. Ivan E. Geshov'' blvd.
Business center "Serdika"
build. 2, floor 2, office 203
Sofia 1330, Bulgaria
T +359 2 447 2833
F +359 2 447 2831
office@bmgrp.bg
www.bmgrp.bg

Croatia

Biomedica dijagnostika d.o.o.
Strojarska 20/X
10000 Zagreb, Croatia
T +385 1 888 5727
F +385 1 888 5728
office@bmgrp.hr
www.bmgrp.hr

Czech Republic

Biomedica ČS, s.r.o.
Radlická 740/113d
158 00 Praha 5 - Jinonice, Czech Republic
T +420 2 839 33 605
F +420 2 839 32 507
office@bmgrp.cz
www.bmgrp.cz

Hungary

Biomedica Hungària Kft.
Ganz utca 16
1027 Budapest, Hungary
T +36 1 225 38 50
F +36 1 201 26 84
office@bmgrp.hu
www.bmgrp.hu

Macedonia

Biomedica dijagnostika Ltd
Ilindenska 103, local 2 and 3
1000 Skopje, Macedonia
T +389 2 3222 404
F +389 2 3222 404
office@bmgrp.mk
www.bmgrp.mk

Poland

Biomedica Poland Sp. z o.o.
Raszyńska 13
05-500 Piaseczno, Poland
T +48 22 737 5996
F +48 22 737 5994
office@bmgrp.pl
www.bmgrp.pl

Romania

Biomedica Medizinprodukte Romania SRL
Strada Siriului nr. 42 – 46, Et. 2, Sector 1
014354 Bucharest, Romania
T +40 37 276 68 44
F +40 21 232 22 04
office@bmgrp.ro
www.bmgrp.ro

Serbia

Biomedica MP d.o.o.
Lazara Mamuzića 26a
11186 Zemun, Serbia
T +381 11 630 1882
F +381 11 630 1883
office@bmgrp.rs
www.bmgrp.rs

Slovakia

Biomedica Slovakia s.r.o.
Drobného 27
841 01 Bratislava, Slovakia
T +421 2 693 099 01
F +421 2 693 099 08
office@bmgrp.sk
www.bmgrp.sk

Slovenia

Biomedis M.B. d.o.o.
Jurančičeva ulica 11
2000 Maribor, Slovenia
T +386 2 471 63 01
F +386 2 471 63 04
office@bmgrp.si
www.bmgrp.si

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