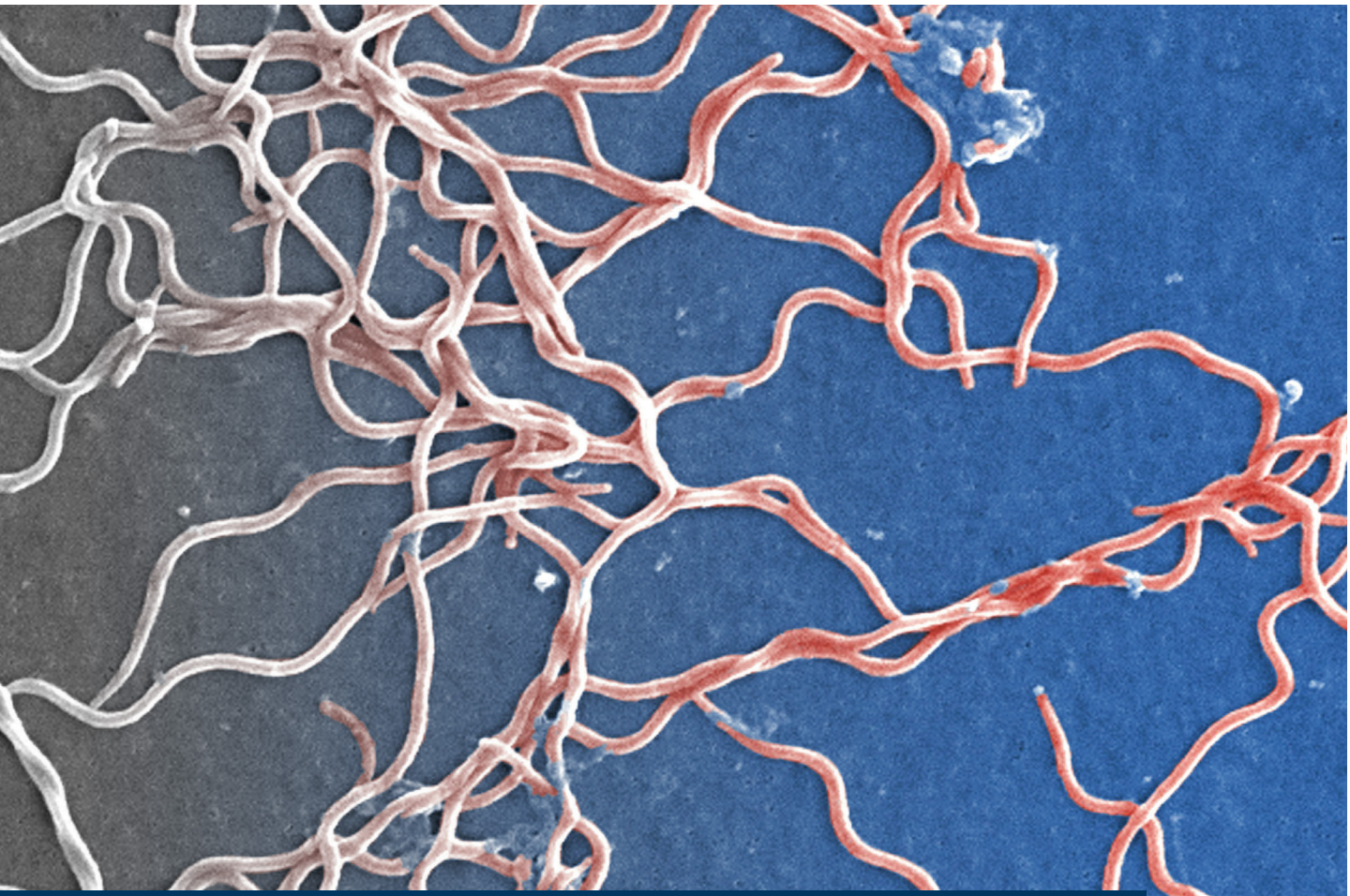


Lyme borreliosis and anaplasmosis

Enzyme immunoassays for the diagnosis of Lyme borreliosis and anaplasmosis

ELISA, **IMMUNOBLOT** and **MICROBLOT-ARRAY** kits are optimized and validated for detection of IgG and IgM antibodies in human serum, plasma, cerebrospinal or synovial fluid

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Lyme borreliosis is a multisystem infectious disease caused by spirochete *Borrelia burgdorferi*. The infection is transmitted by ticks of the genus Ixodes. Lyme borreliosis is characterized by early and late clinical symptoms.

Phases of lyme borreliosis

Early localised infection – lasts for days or weeks. It is characterized by erythema migrans (EM), which appears in only 50% of patients. Early symptoms of the disease may include "flu-like" symptoms, headache and lymphadenitis.

Early disseminated infection – lasts for weeks or months. Borrelia are disseminated by blood vessels and the lymphatic system (CNS, joints, heart, eye, skin – secondary EM). At this stage, the most frequently diagnosed symptoms are: neuroborreliosis, paresis neurofacialis, borrelial lymphocytoma (swollen earlobes, knucklebones, etc.) and Bannwarth syndrome.

Late disseminated infection – lasts for months or years. The most typically diagnosed immunopathological changes include Acrodermatitis chronica atrophicans (chronic skin lesions – ACA), chronic neuroborreliosis, and borrelial arthritis.

The results of extensive studies have demonstrated that all the genospecies may not only cause the development of erythema migrans (EM), but also have many other clinical manifestations. *Borrelia (B.) garinii* is associated with neurological symptoms, *B. afzelii* with chronic skin disorders (especially ACA), and *B. burgdorferi* sensu stricto is mainly related to joint injuries.

Human granulocytic anaplasmosis (HGA) is an illness caused by bacteria *Anaplasma phagocytophilum*. The vector in our country is castor bean tick – Ixodex ricinus. While the tick is sucking the blood the bacteria enters the cardiovascular system of the host where it attacks blood cells.

Clinical symptoms usually develop within one week of being attacked by the tick. The symptoms of the illness might manifest from asymptomatic forms to serious forms with respiratory, gastrointestinal, renal, neurological symptoms, etc.

First of all it manifests by feverish state after being bitten by a tick which lasts for at least 3 to 7 days.

Other symptoms can be skin changes (in about 20% of cases) and non-specific symptoms which resemble Lyme disease. Amongst them there are swollen glands, headaches, muscle pains, nausea, vomitting and abdominal problems, pareses are also frequent. Serious states and complications occur with immunodeficit patients, persons who have had a transplantation and patients without spleen.

It is an illness which is mostly acute, some more complicated cases which were not cured in time change into chronic state and might even be life threatening to the patient. Men are more prone to become ill with this illness than women (4:1).

Diagnosis of infection

The diagnosis of the disease is based on anamnesis, clinical picture, and the results of laboratory tests. At present, the diagnostic methods of choice are screening of specific IgG and IgM class antibodies by means of ELISA, and subsequent confirmation of the antibodies to specific antigens by means of immunoblot. Direct cultivation or electron microscopy is not applicable in a routine use.

Serological diagnosis of borreliosis is difficult regarding to the large genetic diversity of the species *Borrelia burgdorferi* s.l., possible cross reactivity with unrelated antigens of other microorganisms, and borrelia richness to heat shock proteins. Diagnosis is also complicated as well by different individual serological reactivity. The production of antibodies can be extremely slow in the early phase of the disease. On the other hand, the IgG and IgM antibodies can persists for more than ten years.

The diagnosis of HGA only on the basis of clinical manifestation is very difficult. That is why it is necessary to evaluate both the clinical manifestations and the laboratory findings. The characteristic laboratory findings are leukopenia, thrombocytopenia and increase in liver transaminases.

Specific antibodies are produced within the first 2 weeks since the onset of the disease. However, only 30 – 60 % of patients are seropositive during the acute phase and 70 – 90 % of patients are positive during the convalescence.

Two-Level Antibody Detection

The IgM and IgG class antibodies are detected in two levels with two types of tests. First, the samples are divided by ELISA method into two groups according to their positive or negative test results. Provided that the test result is negative and the symptoms of infection persist, the second (control) collection is performed in 2-3 weeks. The positive and borderline results are recommended to be confirmed by immunoblot. The result of the test does not indicate the diagnosis, but it may support it.

The number of disagreements between immunoblot (2nd level testing) and ELISA results (1st level) is reduced when the ELISA method is based on recombinant antigens as are the TestLine assays.

1st level: Entry test for IgM and IgG antibody class using ELISA method

Positive or borderline test result

Negative test result

2nd level: Confirmation using immunoblot
in IgM and IgG antibody classes

Positive test result

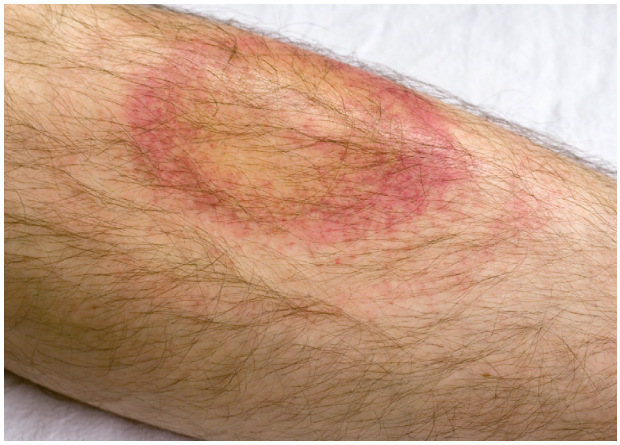
Borderline test result

Negative test result

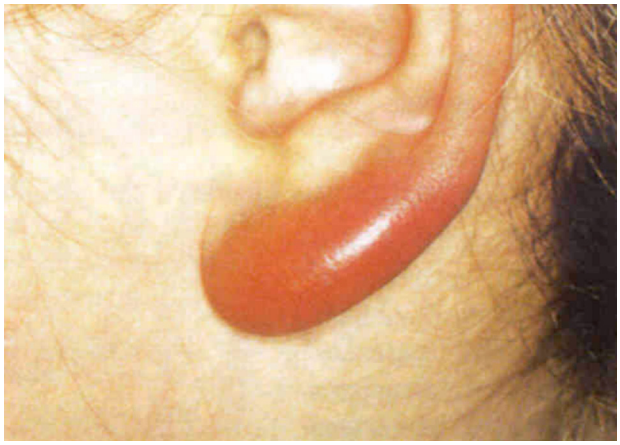
- Antibodies are not detected in the tested sample.
- If the symptoms persist, repeat sample collection 2-3 weeks later.

The clinical diagnosis of the disease status is based on a **comprehensive clinical picture** of the patient, not only on the serological result of the tested sample.

Two-level antibody detection (adapted from MiQ 12 2000 Lyme borreliosis, B. Wilske et al.)



Erythema migrans



Borrelial lymphocytoma

Sensitivity for Various Stages of Lyme Borreliosis

Lyme Borreliosis Form	Diagnosis	Sensitivity by MiQ
Localized early	Erythema migrans	20–50%
Disseminated early	Borrelial lymphocytoma Erythema migrans multiple Neuroborreliosis Lyme arthritis and carditis	70–90%
Disseminated late	Acrodermatitis chronica atrophicans Late neuroborreliosis	90–100%

Specific Borrelia antigens

Antigens	Description
VlsE Ba VlsE Bg VlsE Bs	Variable major protein-like sequence, expressed | Species specific antigen | Main antigen of early and late antibody response to LB | Significantly increases test sensitivity (approx. 90% of samples of positive sera and CSF react in this antigen band)
p83	Main extracellular protein (product of p100 degradation) | Late antibody response antigen | Highly immunoreactive antigen, typical of neuroborreliosis
p58	OppA-2 (Oligopeptide permease 2) - membrane transporter | Considered as a marker of disseminated stage of Lyme disease
p41 Ba p41 Bs	Inner part of flagellin | Highly specific antigen of early antibody response
p39	BmpA (glycosaminopeptide receptor) | Antigen of late antibody response | Significant antigen for advanced disseminated form of LB, often associated with Lyme arthritis
OspB	Outer surface protein B | Antigen of late antibody response
OspA Ba OspA Bg OspA Bs	Outer surface protein A | Antigen of late antibody response, typical for neuroborreliosis
OspC Ba OspC Bg OspC Bs OspC Bsp	Outer surface protein C | Antigen of early antibody response | Immunodominant marker of IgM antibody response
OspE	Outer surface protein E
NapA	Neutrophil activating protein A | Strong immunogen, main marker of Lyme arthritis pathogenesis
p17	DbpA (Decorin-Binding protein A) | Antigen of early and late antibody response, typical of neuroborreliosis

Ba – B. afzelii, Bg – B. garinii, Bs – B. burgdorferi sensu stricto, Bsp – B. spielmanii

Specific anaplasma antigens

Antigens	Description
p44	Main antigen of antibody response to HGA
OmpA	Outer membrane protein A of Anaplasma phagocytophilum, peptidoglycan-associated lipoprotein, significant virulence marker
Asp62	Membrane transporter surface protein

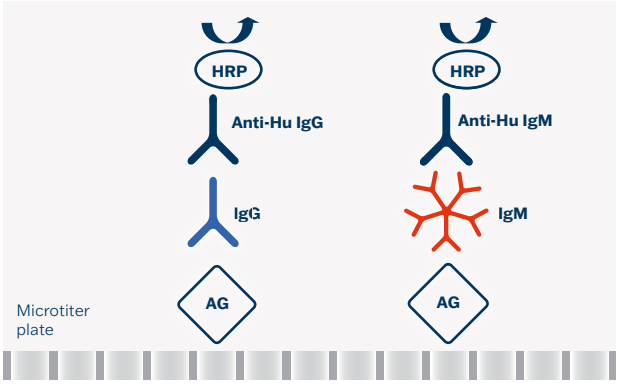
Cross-reacting antigens

Antigens	Description
TpN17	Highly specific membrane protein of *Treponema pallidum* (IgG)
VCA-p18	Viral Capsid Antigen – important marker of EBV infection (IgM)

ELISA

Test Principle

The assays are based on a sandwich type of ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml) – cerebrospinal fluids 1:2 (110 µl + 110 µl) – synovial fluids 1:21 (20 µl + 400 µl), 1:41 (10 µl + 400 µl)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 4 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 15 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF included
- Semiquantitative evaluation of results (Index of Positivity)

Advantages

- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- High conformity with Immunoblot results
- Elimination of cross-reactivity with antibodies to *Treponema pallidum*
- Identical assay procedure
- Total screening time 1.5 hours
- Long shelf life: 15 months from the production date
- Ready for automation
- Customer support

Clinical application

- Screening for antibodies against *Borrelia burgdorferi* in human serum, plasma and cerebrospinal or synovial fluid
- Detection of intrathecal synthesis of specific antibodies (diagnosis of neuroborreliosis)

Antigens

EIA Borrelia recombinant IgG
Recombinant fragments of specific antigens *Borrelia burgdorferi* sensu lato VlsE (Ba, Bg, Bs), p83, p58, p41i (internal flagelin), p39, OspA (Ba, Bg), OspB, OspC (Ba, Bg), OspE, p17, NapA

EIA Borrelia recombinant IgM
OspC (Ba, Bg, Bs, Bsp), VlsE, p41i (internal flagelin), p39, p17, OspE

EIA Borrelia afzelii VlsE IgG, EIA Borrelia afzelii IgM
Sonicated whole-cell antigen of the *Borrelia afzelii* strain, rich in p83, p41 (flagelin), p39, OspA, OspC, p19, enriched in VlsE antigen in IgG antibody class

EIA Borrelia garinii VlsE IgG, EIA Borrelia garinii IgM
Sonicated whole-cell antigen of *Borrelia garinii* , rich in p83, p41 (flagelin), p39, OspA, OspC, p18 a p14, enriched in VlsE antigen in IgG antibody class

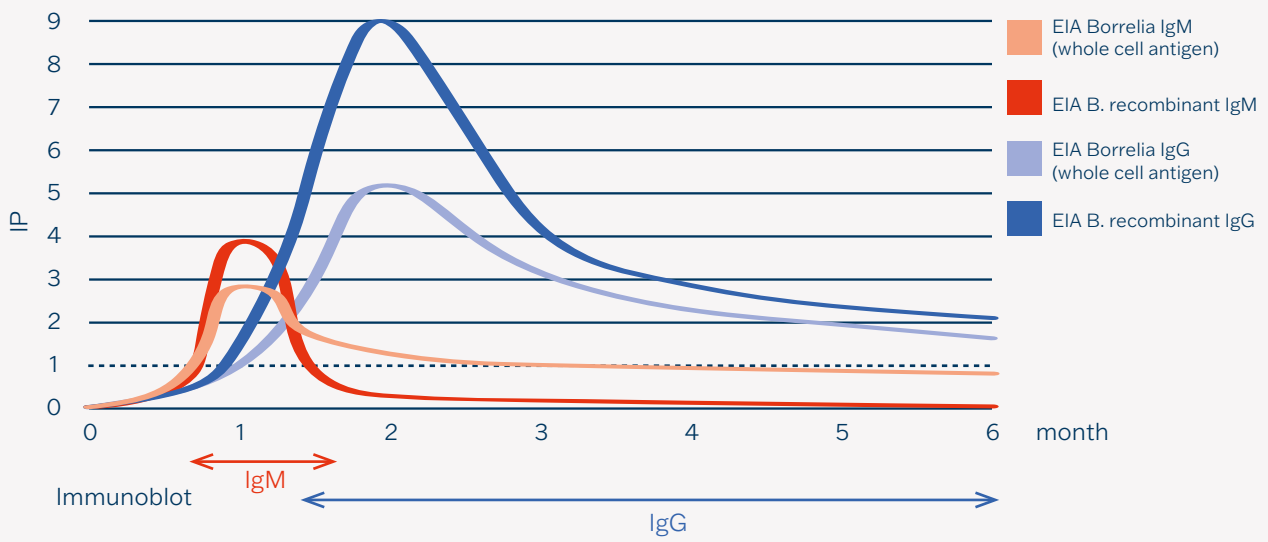
EIA Borrelia b. sensu stricto VlsE IgG, EIA Borrelia b. sensu stricto IgM
Sonicated whole-cell antigen of *Borrelia burgdorferi* sensu stricto strain, rich in p83, p41 (flagelin), p39, OspA, OspB, OspC, p21 a p18, enriched in VlsE antigen in IgG ntibody class

EIA Borrelia VlsE IgG, EIA Borrelia IgM
Sonicated whole-cell antigens of all the main pathogenic strains of Borrelia (*B. garinii*, *B. afzelii* and *B. burgdorferi* sensu stricto), enriched in VlsE antigen in IgG antibody class

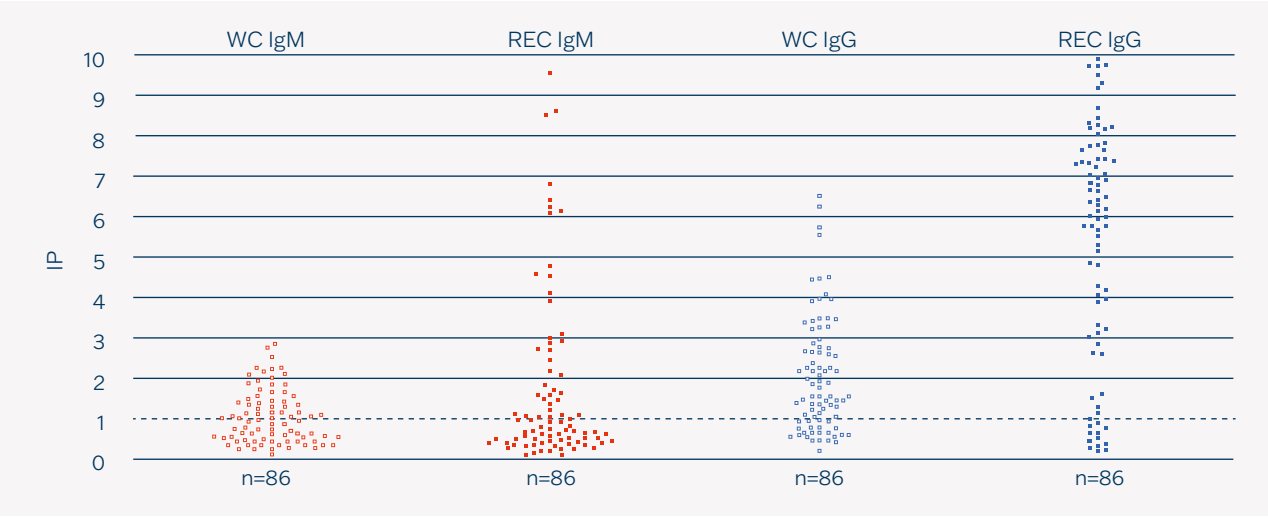
Test Characteristics

ELISA	Diagnostic sensitivity	Diagnostic specificity
EIA Borrelia recombinant IgG	98.3%	98.1%
EIA Borrelia recombinant IgM	99.1%	97.3%
EIA Borrelia afzelii VlsE IgG	98.9%	98.9%
EIA Borrelia afzelii IgM	95.6%	99.0%
EIA Borrelia b. sensu stricto VlsE IgG	98.9%	98.9%
EIA Borrelia b. sensu stricto IgM	97.5%	98.9%
EIA Borrelia garinii VlsE IgG	98.9%	99.0%
EIA Borrelia garinii IgM	95.7%	98.9%
EIA Borrelia VlsE IgG	98.9%	99.0%
EIA Borrelia IgM	97.5%	98.9%

Antibody Response



High Dynamic of Antibody Response of Recombinant Antigens



Comparison – Index of Positivity (IP) of ELISA test with whole cell (WC) antigen in EIA Borrelia garinii IgM and IgG with ELISA test with recombinant (REC) antigens in EIA Borrelia recombinant IgM and IgG in the serum of 86 patients with Lyme neuroborreliosis. (Data prepared for publication.)

Neuroborreliosis and intrathecal synthesis of specific antibodies

Antibody Index Software enables the evaluation of the antibody index (AI), i.e. the ratio of specific antibodies in the cerebrospinal fluid and serum in relation to the state of the blood cerebrospinal fluid barrier and the concentration of total immunoglobulins in CSF and serum.

According to the international recommendation of the European Union Concerted Action on Lyme Borreliosis (EUCALB), evidence of intrathecal antibody production is necessary for diagnosis of early and late neuroborreliosis (i.e. specific antibodies to Borrelia sp. produced in the cerebrospinal fluid (CSF) must be detected).

The antibody level in the CSF depends on the following parameters:

- Antibodies present in blood serum
- Permeability of blood-CSF barrier
- Intrathecal production of antibodies

The presence of specific antibodies as such (in the serum and/or CSF) cannot be deemed sufficient evidence.

Intrathecal synthesis - Borrelia IgG & IgM (Antibody index)

Probe

Patient	Nowak George	Serum No.	101S
Native No.	1122331234	CSF No.	101C
Ward		Sample collection	27.05.2022

Clinical chemistry

	Albumin	IgG	IgM	Unit
Serum	54,70	12,45	1,42	g/l
CSF	264,00	45,90	1,75	mg/l

Blood-brain barrier	
QAlb	4,83

QAlb Value	Blood-brain barrier classification
< 5	Normal function
5 - 10	Mild disfunction
10 - 15	Moderate disfunction
> 15	Severe disfunction

Specific antibodies

	Extinction		Arbitrary units	
	IgG	IgM	IgG	IgM
Serum	1,544	1,923	100,00	93,66
CSF	0,750	0,454	43,58	17,28

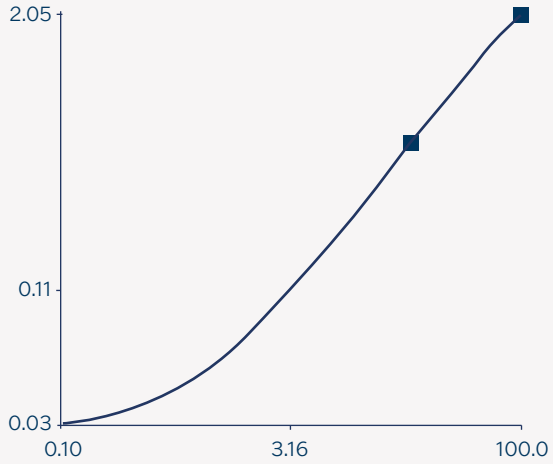
Results

			Intrathecal synthesis
Antibody index	AI (IgG)	2,589	POSITIVE result
	AI (IgM)	3,971	POSITIVE result

Notes

Advantages

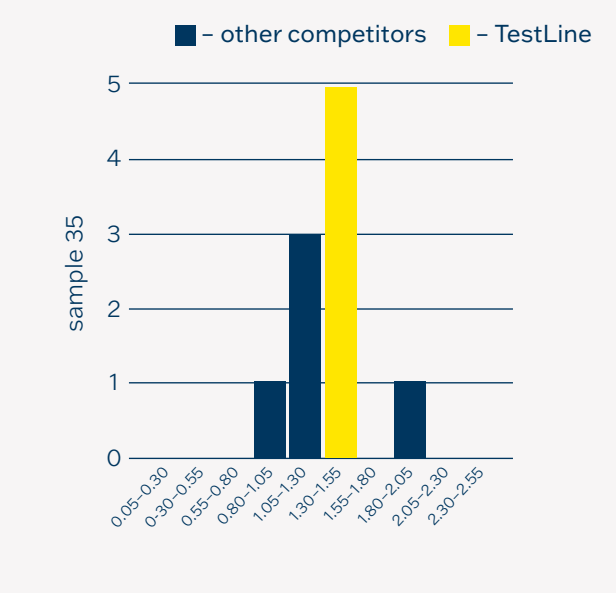
- Small amount of CSF sample needed to determine AI (approx. 0.15 ml)
- Possibility of Antibody Index determination within routine EIA test
- Quick and easy evaluation with Antibody Index Software



The calibration curve is included in the SW and is available from Positive Control and CUT-OFF values provided for the EIA Borrelia garinii IgG, IgM and EIA Borrelia recombinant IgG, IgM kits.

External Quality Assessment

The Antibody Index calculation was confirmed as correct by a quality assessment test performed by an external scientific company (Instand e.V.) for detection of intrathecal antibody production according to Reiber in May 2021.



INSTAND

CERTIFICATE

Survey of 21 May 2021

You have fulfilled the requirements of the External Quality Assessment with the following analysis

Cerebrospinal Fluid Analysis 05 - Neuroborreliosis (465):

Validity 12 months:

Borrelia IgG Antibody Index

(R) analysis is subject to the RiliBÄK

Participant:

TestLine s.r.o.
Clinical Diagnostics s.r.o.
Krizikova 68
61200 Brno

DAkkS Deutsche Akkreditierungsstelle D-EP-15027-02-00

INSTAND Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V. Düsseldorf

Düsseldorf, 07 June 2021

Prof. Dr. med. Michael Spannagl
(Head of Reference Institution)

Dr. rer. nat. Thomas Zimmermann
(Adviser)

INSTAND
Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V.
Ubierstr. 20 | 40223 Düsseldorf

1570

1 / 6

Serology of CSF and serum related to intrathecal antibody synthesis and Antibody Index determination

Serum	CSF	Intrathecal antibody synthesis	AI determination according to Reiber
–	+	Positive	YES v positivity confirmed (EUCALB recommendation)
+	+	Usually positive, but a passive transfer of antibodies via a disturbed blood-CSF barrier is possible	YES – necessary for detection of intrathecal synthesis
+	–	Possibly positive (provided that the measured absorbance values in the CSF and serum are close to absorbance of the CUT-OFF control)	YES – necessary for detection of intrathecal synthesis
–	–		

IMMUNOBLOT

User Comfort

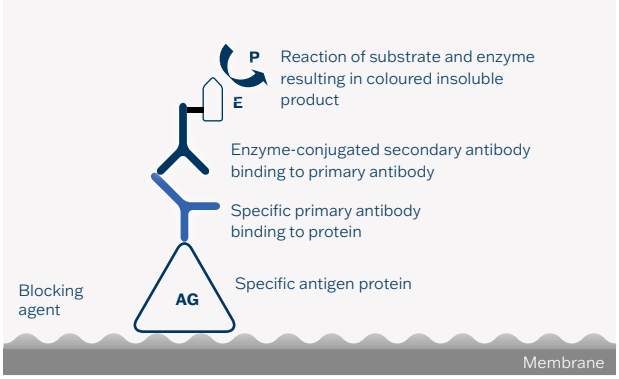
- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Positive and Negative controls
- Control line on the strip
- Easy assay procedure

Advantages

- Immunodominant antigens from individual Borrelia species – *B. afzelii*, *B. garinii*, *B. burgdorferi* sensu stricto
- Recombinant antigen p44 – useful for differential diagnosis of HGA
- Recombinant antigen TpN17 for exclusion of crossreactivity with *Treponema pallidum*
- Possible to detect Borrelia antibodies in cerebrospinal fluid
- Easy interpretation and reproducibility of results
- High sensitivity and specificity
- Compatibility with all commercial immunoblot processing systems
- Customer support

Test Principle

Antigens are transferred to a nitrocellulose membrane using a micro-dispensing method.



Summary Protocol

Step		Test steps
	1.	Pipette Universal solution 2 ml
	2.	Strips soaking 10 min. at room temperature – Shaker
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (30 µl + 1.5 ml) – cerebrospinal fluids 1:2 (0,75 ml + 0.75 ml) – synovial fluids 1:17,5 (90 µl + 1.5 ml)
	5.	Pipette Controls and diluted samples 1.5 ml
	6.	Incubate 30 min. at room temperature – Shaker
	7.	Aspirate samples and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	8.	Pipette Conjugate 1.5 ml
	9.	Incubate 30 min. at room temperature – Shaker
	10.	Aspirate Conjugate and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	11.	Pipette Substrate solution (BCIP/NBT) 1.5 ml
	12.	Incubate 15 min. at room temperature – Shaker
	13.	Aspirate Substrate solution and wash strips with 2 ml of distilled water 2-times for 5 min. – Shaker
	14.	Sticking and evaluation of strips

BLOT-LINE

Antigens

BLOT-LINE Borrelia/HGA IgG,
BLOT-LINE Borrelia/HGA IgM
– recombinant antigens: VlsE, p83, p41, p39, OspB, OspA, OspC, p17, p44, TpN17

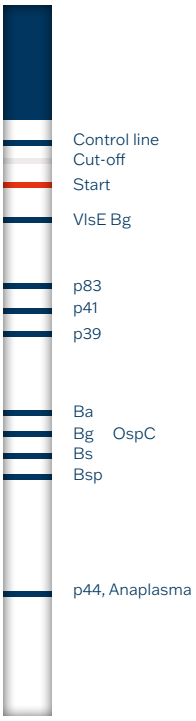
BLOT-LINE Borrelia afzelii IgG
BLOT-LINE Borrelia garinii IgG
– recombinant antigens: VlsE, p83, p41, p39 (BmpA), OspA, OspC, p17 (DbpA)

BLOT-LINE Borrelia b. sensu stricto IgG
– recombinant antigens: VlsE, p83, p41, p39 (BmpA), OspB, OspA, OspC, p18 (OspE)

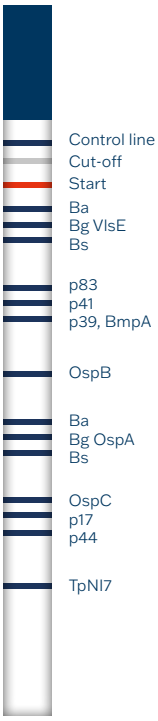
BLOT-LINE Borrelia afzelii IgM
BLOT-LINE Borrelia garinii IgM
BLOT-LINE Borrelia b. sensu stricto IgM
– recombinant antigens: VlsE, p83, p41, p39 (BmpA), OspC

BLOT-LINE Anaplasma IgG,
BLOT-LINE Anaplasma IgM
– recombinant antigens: p44, Asp62, OmpA

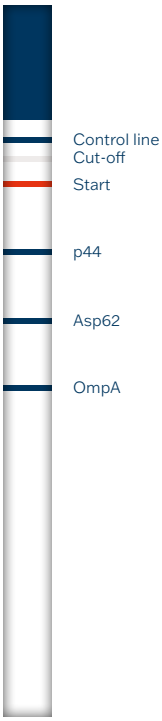
BLOT-LINE Borrelia/HGA IgM



BLOT-LINE Borrelia/HGA IgG



BLOT-LINE Anaplasma IgG

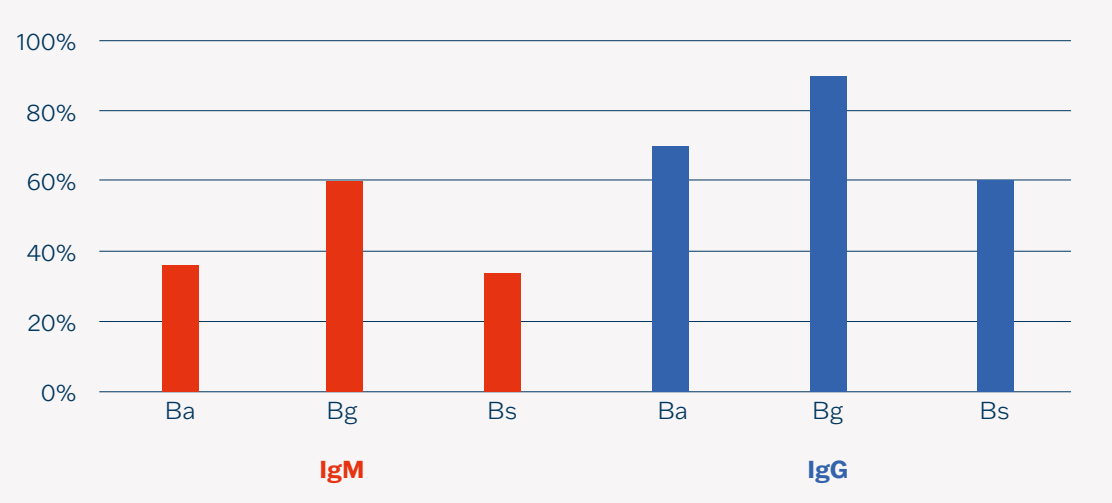


Test Characteristics

	Borrelia		Anaplasma	
Immunoblot	**Diagnostic sensitivity**	**Diagnostic specificity**	**Diagnostic sensitivity**	**Diagnostic specificity**
BLOT-LINE Anaplasma IgG	–	–	92.0%	94.0%
BLOT-LINE Anaplasma IgM	–	–	91.4%	99.0%
BLOT-LINE Borrelia/HGA IgG	96.8%	98.5%	92.9%	96.3%
BLOT-LINE Borrelia/HGA IgM	97.1%	96.4%	94.7%	97.1%
BLOT-LINE Borrelia afzelii IgG	97.3%	96.9%	–	–
BLOT-LINE Borrelia afzelii IgM	96.6%	95.9%	–	–
BLOT-LINE Borrelia garinii IgG	97.1%	96.2%	–	–
BLOT-LINE Borrelia garinii IgM	95.2%	97.0%	–	–
BLOT-LINE Borrelia b. sensu stricto IgG	96.8%	96.9%	–	–
BLOT-LINE Borrelia b. sensu stricto IgM	96.2%	96.8%	–	–

Reactivity of Different Types of Tests in a Group of Patients with Neuroborreliosis (n=60)

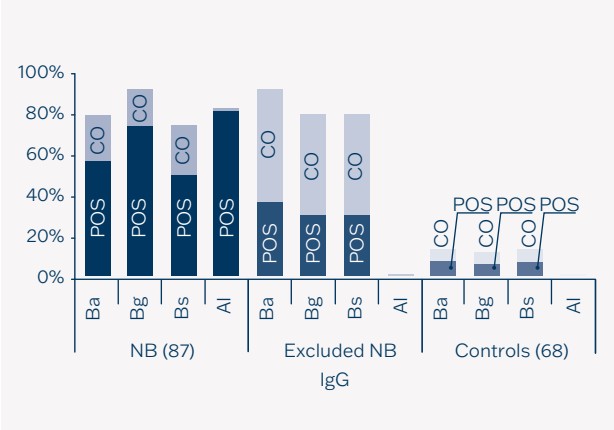
(BLOT-LINE B. afzelii – Ba, BLOT-LINE B. garinii – Bg, BLOT-LINE B. b. sensu stricto – Bs)



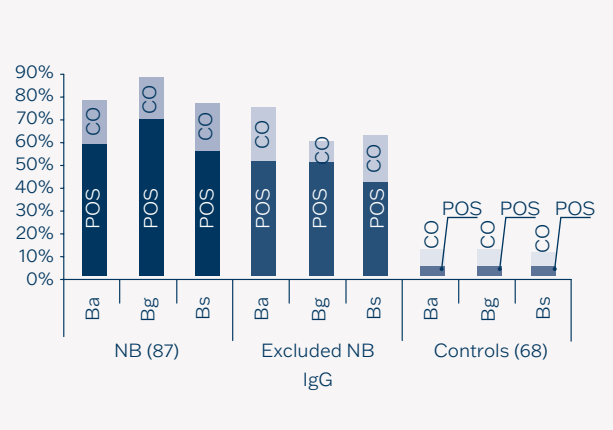
BLOT-LINE Borrelia garinii kit shows more than 20 percent higher reactivity in the group of patients with neuroborreliosis compared to BLOT-LINE Borrelia afzelii and BLOT-LINE Borrelia b. sensu stricto.

Incidence of IgG Antibodies against VlsE in Neuroborreliosis (NB)

Serum



Liquor



BlueBLOT-LINE

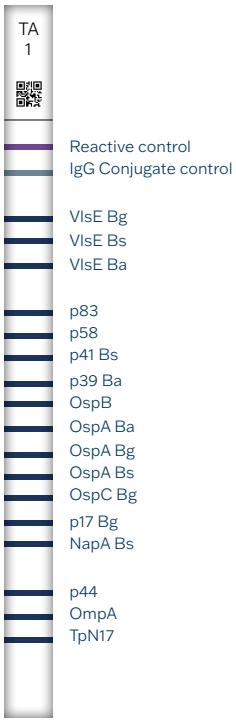
BlueDiver Instrument, Immunoblot Software and BlueBLOT-LINE Borrelia kits - a complete solution for simple, rapid and accurate immunoblot analysis, including the evaluation.

Antigens

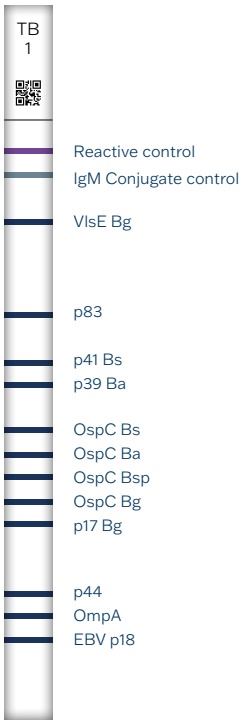
BlueBLOT-LINE Borrelia IgG,
BlueBLOT-LINE Borrelia IgM

– recombinant antigens: VlsE, p83, p58, p41, p39, OspB, OspA, OspC, p17, NapA, p44, OmpA, TpN17, p18

BlueBLOT-LINE Borrelia IgG



BlueBLOT-LINE Borrelia IgM



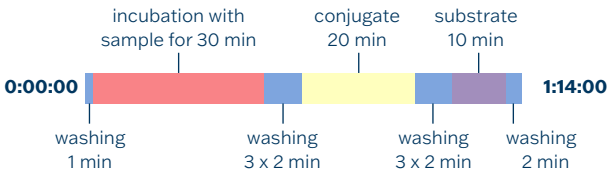
Unique feature and advantages

- Space-saving
- No risk of contamination
- High flexibility
- Easy to use and short hands on time
- High reliability
- Extremely short analysis time

Protocol summary

- Inserting holders with strips and reagents into the instrument
- Automatic batch and expiry control using the integrated barcode reader
- Samples pipetting
- Automated incubation and washing
- Strips drying

Total assay time:



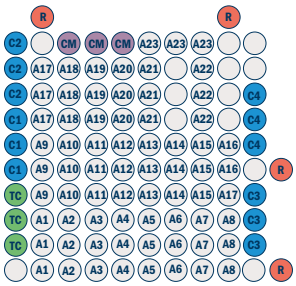
Test Characteristics

Immunoblot	Borrelia		Anaplasma	
	Diagnostic sensitivity	Diagnostic specificity	Diagnostic sensitivity	Diagnostic specificity
BlueBLOT-LINE Borrelia IgG	97.4%	99.0%	83.0%	99.0%
BlueBLOT-LINE Borrelia IgM	98.3%	99.0%	92.0%	96.0%

MICROBLOT-ARRAY

Specific recombinant proteins (antigens) are applied to a nitrocellulose membrane, which is adapted to the format of a well of a microtitre plate, in the form of spots. The principle of applying antigens is similar to that of BLOT-LINE kits. Thanks to the possibility of processing with ELISA devices, the new multiplex technology brings significant efficiency in the processing of these confirmation tests.

Distribution of Antigens and Control Spots



Reference spots

- **R** – Reference
- **TC** – Test control
- **CM** – Conjugate control IgM
- **CG** – Conjugate control IgG
- **C1** – Calibration 1
- **C2** – Calibration 2
- **C3** – Calibration 3
- **C4** – Calibration 4
- **A1–A23** – Antigens

User comfort

- Low sample consumption
- Reagents in working dilution
- Antigens spotted in triplicate – minimizing statistical variation
- Fully automatic assay processing and results evaluation
- Parallel testing of multiple markers simultaneously
- High sensitivity
- Evaluation with the help of highly sophisticated SW
- Automated validity check via control spots

Summary Protocol

Step		Test steps
	1.	Pipette Universal solution 150 µl
	2.	Strips soaking 10 min. at room temperature
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (10 µl + 500 µl) – cerebrospinal fluids 1:3 (50 µl + 100 µl) – synovial fluids 1:17,5 (10 µl + 165 µl)
	5.	Pipette Controls and diluted samples 100 µl
	6.	Incubate 30 min. at room temperature
	7.	Quick wash with Universal solution*
	8.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
	9.	Pipette Conjugate 100 µl
	10.	Incubate 30 min. at room temperature
	11.	Quick wash with Universal solution*
	12.	Aspirate samples and wash strips with 150 µl of Universal solution 3-times for 5 min.
	13.	Pipette Substrate solution (BCIP/NBT) 100 µl
	14.	Incubate 15 min. at room temperature
	15.	Quick wash with distilled water*
	16.	Aspirate Substrate solution and wash strips with 200 µl of distilled water 2-times for 5 min.
	17.	Dry and evaluate strips

*If automatic washer is used, fill the wells up to their edges and when the last well is filled, aspirate them off immediately.

Antigens

Patogens	Antigens
Borrelia burgdorferi	VlsE Ba, VlsE Bg, VlsE Bs, p83, p58, p41 Ba, p41 Bs, p39, OspB, OspA Ba, OspA Bg, OspA Bs, OspC Ba, OspC Bg, OspC Bs, OspC Bsp, OspE, NapA, p17
Anaplasma phagocytophilum	p44, OmpA, Asp62
Treponema pallidum (IgG)	TpN17
EBV (IgM)	VCA-p18

Test Characteristics

Parameters of Microblot-Array Borrelia IgG
(tested on sera)

	Diagnostic Sensitivity	Diagnostic Specificity
Borrelia IgG	98.7% (n = 74)	98.9% (n = 100)
Anaplasma IgG	92.0% (n = 25)	99.9% (n = 30)
Treponema IgG	98.3% (n = 59)	99.9% (n = 30)

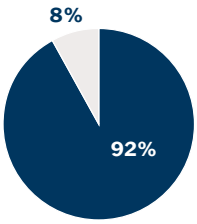
Parameters of Microblot-Array Borrelia IgM
(tested on sera)

	Diagnostic Sensitivity	Diagnostic Specificity
Borrelia IgM	98.5% (n = 56)	99.9% (n = 95)
Anaplasma IgM	95.0% (n = 20)	99.9% (n = 38)
EBV IgM	99.9% (n = 39)	99.9% (n = 51)

Comparative Study

Correlation of results IgG

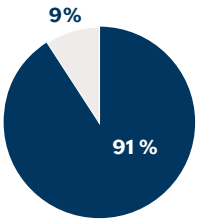
n = 77	Microblot-Array	ELISA
positive	38	41
negative	33	36
agreement	**92.2%**	



ELISA vs.
Microblot-Array

Correlation of results IgM

n = 68	Microblot-Array	ELISA
positive	19	21
negative	40	44
agreement	**90.7%**	



ELISA vs.
Microblot-Array

agreement disagreement

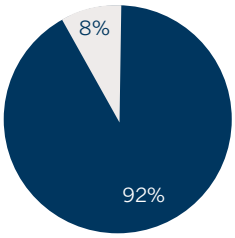
Comparative Study

Correlation of results IgM

		Microblot-Array		
		positive	borderline	negative
ELISA rec.	positive	48	2	3
	borderline	1	1	2
	negative	3	10	24

ELISA rec. Microblot Array

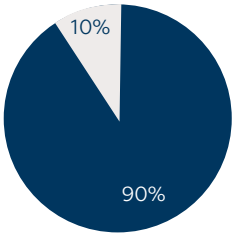
agreement
disagreement



		Microblot-Array		
		positive	borderline	negative
Western blot rec.	positive	41	3	0
	borderline	6	1	4
	negative	5	2	2

WB rec. Microblot Array

agreement
disagreement

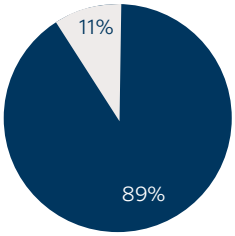


Correlation of results IgG

		Microblot-Array		
		positive	borderline	negative
ELISA rec.	positive	44	5	2
	borderline	0	1	0
	negative	6	11	24

ELISA rec. Microblot Array

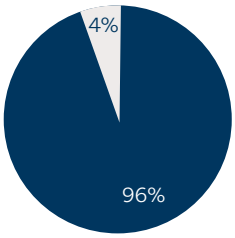
agreement
disagreement



		Microblot-Array		
		positive	borderline	negative
Western blot rec.	positive	42	4	1
	borderline	7	5	1
	negative	1	2	1

WB rec. Microblot Array

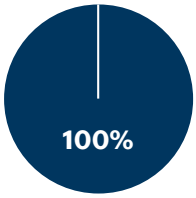
agreement
disagreement



Results in External Quality Assesments

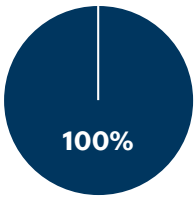
LABQUALITY – 02. 2021

EIA



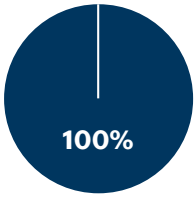
Category	Sample specification	TestLine result	Meets criteria
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	positive	positive	+

Immunoblot



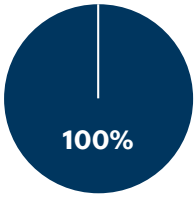
Category	Sample specification	TestLine result	Meets criteria
IgG*	positive	borderline	-
IgG	positive	positive	+
IgM	positive	positive	+
IgM	positive	positive	+

Microblot-Array



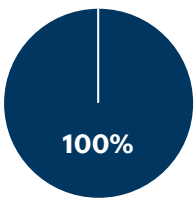
Category	Sample specification	TestLine result	Meets criteria
IgG	positive	positive	+
IgG	positive	positive	+
IgM	positive	positive	+
IgM	positive	positive	+

Clinical evaluation



Category	Sample specification	TestLine result	Meets criteria
Interpretation	infection confirmed	infection confirmed	+
Interpretation	infection confirmed	infection confirmed	+

Antibody Index Software



Category	Sample specification	TestLine result	Meets criteria
IgG	negative, borderline, positive	negative	+

Ordering information

ELISA

Cat. No.	Product	No. of Tests
BGV096	EIA Borrelia VlsE IgG	96
BM0096	EIA Borrelia IgM	96
BrG192	EIA Borrelia recombinant IgG (192)	192
BrM192	EIA Borrelia recombinant IgM (192)	192
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	192
BaM192	EIA Borrelia afzelii IgM (192)	192
BsGV96	EIA Borrelia b. sensu stricto VlsE IgG	96
BsM096	EIA Borrelia b. sensu stricto IgM	96
BgGVD2	EIA Borrelia garinii VlsE IgG (192)	192
BgM192	EIA Borrelia garinii IgM (192)	192
SK-BGV096	SmartEIA Borrelia VlsE IgG	96
SK-BM0096	SmartEIA Borrelia IgM	96
SK-BrG096	SmartEIA Borrelia recombinant IgG	96
SK-BrM096	SmartEIA Borrelia recombinant IgM	96
SK-BaGV96	SmartEIA Borrelia afzelii VlsE IgG	96
SK-BaM192	SmartEIA Borrelia afzelii IgM	96
SK-BsGV96	SmartEIA Borrelia b. sensu stricto VlsE IgG	96
SK-BsM096	SmartEIA Borrelia b. sensu stricto IgM	96
SK-BgGV96	SmartEIA Borrelia garinii VlsE IgG	96
SK-BgM096	SmartEIA Borrelia garinii IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyzer.

IMMUNOBLOT

Cat. No.	Product	No. of Tests
ApGL10	BLOT-LINE Anaplasma IgG	10
ApML10	BLOT-LINE Anaplasma IgM	10
BGL020	BLOT-LINE Borrelia/HGA IgG	20
BML020	BLOT-LINE Borrelia/HGA IgM	20
BaGL20	BLOT-LINE Borrelia afzelii IgG	20
BaML20	BLOT-LINE Borrelia afzelii IgM	20
BgGL20	BLOT-LINE Borrelia garinii IgG	20
BgML20	BLOT-LINE Borrelia garinii IgM	20
BsGL20	BLOT-LINE Borrelia b. sensu stricto IgG	20
BsML20	BLOT-LINE Borrelia b. sensu stricto IgM	20
BD-BGL024	BlueBLOT-LINE Borrelia IgG	24
BD-BML024	BlueBLOT-LINE Borrelia IgM	24
SwIm03	Immunoblot Software	1 pc

The BlueBLOT-LINE kits are designed for automatic processing using BlueDiver® analyzer.

MICROBLOT-ARRAY

Cat. No.	Product	No. of Tests
BGMA096	Microblot-Array Borrelia IgG	96
BMMA096	Microblot-Array Borrelia IgM	96

TestLine Clinical Diagnostics Ltd.
Krizikova 68, 612 00 Brno, Czech Republic
+420 549 121 203
sales@testlinecd.com
www.testlinecd.com

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

V08/2022