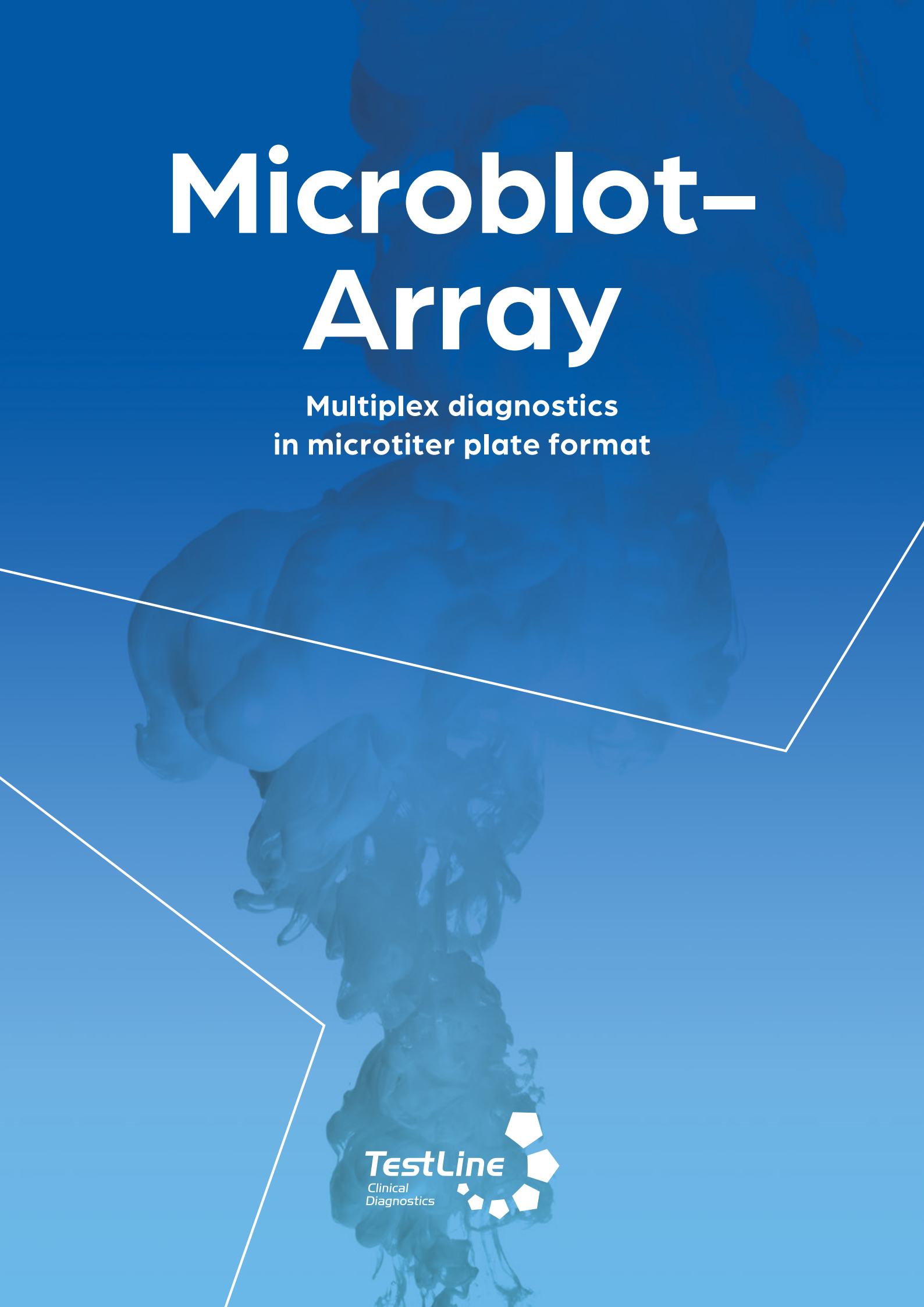
Microblot-Array

Multiplex diagnostics in microtiter plate format



TestLine Clinical Diagnostics

Definition of efficient multiplex diagnostics

Main clinical areas covered

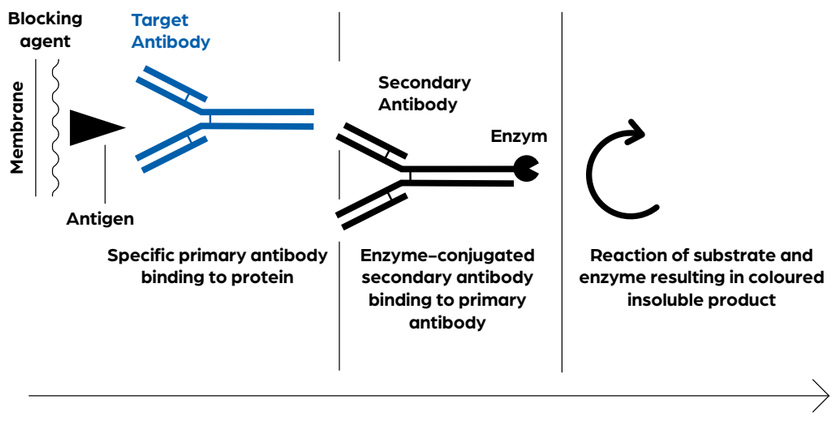
- Infectious serology
- Autoimunity

Microblot-Array is an immunoblot array in microtiter plate format designed for efficient multiplex diagnostics. The technology eliminates the bottleneck of traditional BLOT processing and capacity and opens up the way to high throughput testing and automation.

The comprehensive evaluation of Microblot-Array testing is ensured by using the Microblot-Array Software in combination with the BioVendor Microblot-Array Reader, enabling complex image analysis including results evaluation and connectivity to LIS.

Microblot-Array principle

Specific recombinant proteins/antigens spotted onto a nitrocellulose membrane



Microblot-Array

- Antigens spotted in triplicate – minimizing statistical variation
- Controls in each well
- 4 calibration spots to create a calibration curve
- Evaluation based on combination of positive antigen spots: qualitative, quantitative (U/ml) or semiquantitative (IP)

Microblot-Array Software

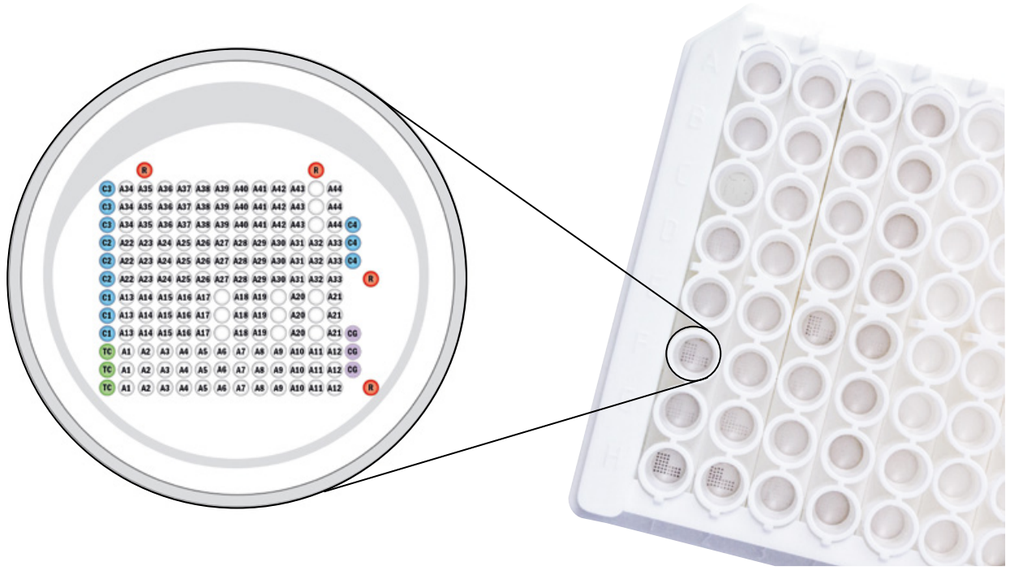
- Automated test identification
- Intuitive and user-friendly guiding throughout the results evaluation
- Complex image analysis
- Optional manual control of spot localization
- Detailed results comparison within single wells and spots
- Evaluation of the validity test through control spots
- Export of results in various formats
- LIS connectivity

Microblot-Array Reader

- Fast high-quality scanning and evaluation: 5 min. per full plate
- Scanning of selected wells/strips
- Automated spot localization and image analysis
- Optimized for a 96-well microtiter plates format

Protocol Summary

Step No.		Test steps
1		Pipette Universal Solution – 150 µl
2		Wells soaking at room temperature for 10 min
3		Aspirate off
4		Dilute samples serum/plasma 1:51 (10 µl + 500 µl) cerebrospinal fluid 1:3 (50 µl + 100 µl) synovial fluid 1:17.5 (10 µl + 165 µl)
5		Pipette control and diluted samples – 100 µl
6		Incubate at room temperature for 30 min
7		Quick wash using the Universal Solution
8		Aspirate and wash 3 × 5 min with 150 µl of Universal Solution
9		Pipette Conjugate – 100 µl
10		Incubate at room temperature for 30 min
11		Quick wash using the Universal Solution
12		Aspirate and wash 3 × 5 min with 150 µl of Universal Solution
13		Pipette Substrate Solution (BCIP/NBT) – 100 µl
14		Incubate at room temperature for 15 min
15		Quick wash using the distilled water
16		Aspirate and wash 2 × 5 min with 200 µl of distilled water
17		Dry and evaluate strips



Benefits

Efficiency

- Analysis of up to 96 patient samples per plate
- Low sample consumption – only 10 µl
- Parallel testing of multiple markers simultaneously – time and cost saving diagnostics

Flexibility

- One parameter × various parameters
- One strip × high number of samples
- Manual processing × automated processing

Automation

- Possibility of automated processing using an ELISA instrument*
- Intuitive software for test evaluation
- Evaluation of individual antigens and their association with pathogen species or disease type

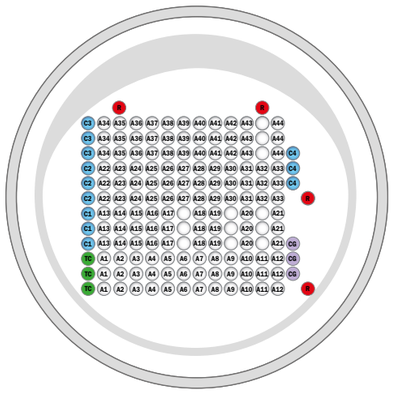
User comfort

- Ready-to-use components
- Identical assay procedure (30–30–15 min.)
- Remote troubleshooting

**In the case of automated processing, an additional universal solution is required because of the dead volumes of the instruments. We recommend 2 extra bottles/kit (when running one plate per week). Please contact our sales representatives for more information.*

Microblot-Array for the diagnostics of systemic autoimmune diseases

The main benefit of Microblot-Array ANA kits is the high number of antigens which can be simultaneously detected in one sample. The kits are primarily intended for confirmation of ELISA or other screening method. However, they also enable identification of specific antibody and thus differentiation of systemic autoimmune diseases, such as myositis, scleroderma, systemic lupus and others. The kits are optimized and validated for detection of specific IgG in human serum or plasma.



R – Reference
TC – Test control
CG – Conjugate control IgG
C1 – Calibration 1
C2 – Calibration 2
C3 – Calibration 3
C4 – Calibration 4

Test characteristic

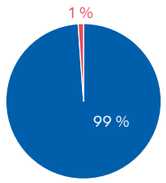
Parameters of the Microblot-Array ANA kit

	Diagnostic Sensitivity	Diagnostic Specificity
ANA	95.2% (n = 398)	95.3% (n = 148)

Comparative study – Correlation of results

Myopathy

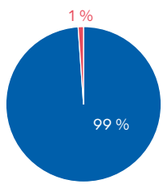
n = 80	Microblot-Array	BLOT
positive	70	69
negative	0	0
total conformity	98.6 %	



BLOT vs. Microblot-Array

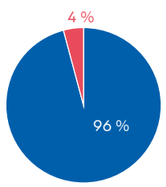
Systemic sclerosis

n = 124	Microblot-Array	BLOT
positive	107	106
negative	0	0
total conformity	99.1 %	



BLOT vs. Microblot-Array

n = 204	Microblot-Array	ELISA
positive	194	186
negative	7	6
total conformity	95.5 %	



ELISA vs. Microblot-Array

conformity disagreement

Microblot-Array Multiplex diagnostics in microtiter plate format

Spot No.	Antigen	Description	Probable association with disease (Evaluation of association with disease by SW)			
			ANA	Myositis	Scleroderma	SLE and other connective tissue diseases
A1	Jo-1	Hystidyl tRNA synthetase	●	●		
A2	PL-7	Threonyl tRNA synthetase	●	●		
A3	PL-12	Alanyl tRNA synthetase	●	●		
A4	EJ	Glycyl tRNA Synthetase	●	●		
A5	OJ	Isoleucyl tRNA synthetase	●	●		
A6	KS	Asparaginyl tRNA synthetase	●	●		
A7	YARS	Tyrosyl tRNA synthetase (Ha)	●	●		
A8	ZoA	Phenylalanyl tRNA synthetase	●	●		
A9	ZoB		●	●		
A10	HMGCR*	3-hydroxy-3methylglutaryl-coenzyme A reductase	●	●		
A11	SAE-1	Small ubiquitin-like modifier activating enzyme	●	●		
A12	SAE-2		●	●		
A13	SRP54	Signal recognition particle	●	●		
A14	Mi-2	Helicase protein-nuclear transcription	●	●		
A15	TIF1γ	Transcription Intermediary Factor 1	●	●		
A16	MDA5	Melanoma differentiation associated protein 5 (CADM-140)	●	●		
A17	NXP2	Nuclear matrix protein 2 (p140, MJ)	●	●		
A18	PMScl 100	Human exosome complex	●	●	●	
A19	PMScl 75		●	●	●	
A20	Scl70	DNA-topoisomerase I	●		●	
A21	CENP A	Centromere A	●		●	
A22	CENP B	Centromere B	●		●	
A23	POLR3A	RNA polymerase III	●		●	
A24	NOR90	Nucleolar transcription factor 1 (Ubtf1)	●		●	●
A25	Th/To	Ribonuclease P protein subunit 25 (Rpp25)	●		●	
A26	PDGFR-β	Platelet-derived growth factor receptor beta	●		●	
A27	Fibrillarin	U3 RNP – fibrillarin	●		●	
A28	Ro52	TRIM21	●	●	●	●
A29	Ro60	Sjögren's-syndrome-related antigen A (SS-A)	●			●
A30	La	Sjögren's-syndrome-related antigen B (SS-B)	●			●
A31	RNP A	U1 small nuclear ribonucleoprotein A	●		●	●
A32	RNP 68/70	U1 small nuclear ribonucleoprotein 68/70 kDa	●		●	●
A33	RNP C	U1 small nuclear ribonucleoprotein C	●		●	●
A34	SmB	Smith antigen B	●			●
A35	SmD	Smith antigen D	●			●
A36	PCNA	Proliferating cell nuclear antigen	●			●
A37	P0	Ribosomal protein P0	●			●
A38	Ku	Ku (p70/p80)	●	●	●	●
A39	Nucleolin	Nucleolin	●			●
A40	Histons	Histone	●			●
A41	Nucleosome	Nucleosome	●			●
A42	dsDNA	Double-stranded DNA	●			●
A43	M2	Mitochondrial M2 (AMA-M2)	●		●	
A44	DFS70	Dense fine speckled 70 antigen	●			

**Check availability in your country.*
● *– supplementary antigens. SLE – Systemic lupus erythematosus*

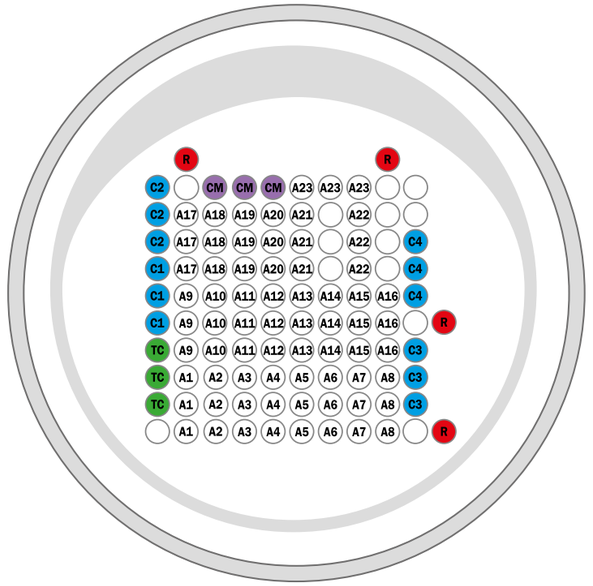
Microblot-Array for the diagnostics of *Borrelia* species and *Anaplasma phagocytophilum*

The kits are optimized for the detection of specific IgG and IgM antibodies to recombinant antigens of *Borrelia* species and *Anaplasma phagocytophilum* (HGA) in human serum, plasma, cerebrospinal or synovial fluid.

Serological diagnostics of borreliosis is difficult due to the large genetic diversity of the species *Borrelia burgdorferi s.l.,* possible cross reactivity with unrelated antigens of other microorganisms (p44, OmpA, TpN17 and VCA-p18), and borrelia richness to heat shock proteins. Diagnostics is also complicated due to various 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 persist for more than ten years. The Microblot-Array Borrelia kits help to refine the diagnostics thanks to the high number of antigens present in one single test.

Spot No.	Antigen	Description	Kit
A1	VlsE Ba	Expressed part of variable major protein-like sequence, significant for IgG antibody response, species-specific antigen	Microblot-Array Borrelia IgG, Microblot-Array Borrelia IgM
A2	VlsE Bg		
A3	VlsE Bs		
A4	p83	Main extracellular protein (product of p100 degradation)	
A5	p58	OppA-2 (Oligopeptide permease 2) – membrane transporter, is considered a marker of disseminated stage of Lyme disease	
A6	p41 Ba	Internal flagellin, highly specific antigen of early antibody response	
A7	p41 Bs		
A8	p39	BmpA (glycosaminopeptide receptor) – marker of late IgG antibody response	
A9	OspB	Outer surface protein B, marker of late stage of infection, considered a marker of Lyme arthritis	
A10	OspA Ba	Outer surface protein A, highly specific marker of *Borrelia* infection in IgG class	
A11	OspA Bg		
A12	OspA Bs		
A13	OspC Ba	Outer surface protein C – main antigen of early antibody response, immunodominant marker of IgM antibody response	
A14	OspC Bg		
A15	OspC Bs		
A16	OspC Bsp		
A17	OspE	Outer surface protein E	
A18	NapA	Neutrophil activating protein A – strong immunogen, main marker of Lyme arthritis pathogenesis	
A19	p17	DbpA (decorin-binding protein A) – outer membrane protein	
A20	p44	*Anaplasma phagocytophilum* – main marker of HGA antibody response	
A21	OmpA	Outer membrane protein A of *Anaplasma phagocytophilum*; peptidoglycan-associated lipoprotein, significant virulence marker	
A22	Asp62	Surface protein – membrane transporter	
A23	TpN17	Highly specific membrane protein of *Treponema pallidum*	Microblot-Array Borrelia IgG
	VCA-p18	Viral Capsid Antigen p18 – important marker of EBV infection	Microblot-Array Borrelia IgM

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



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

Test characteristics

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

	Diagnostic Sensitivity	Diagnostic Specificity
Borrelia IgG	97.3% (n = 74)	98.0% (n = 100)
Anaplasma IgG	92.0% (n = 25)	100.0% (n = 30)
Treponema	98.3% (n = 59)	100.0% (n = 30)

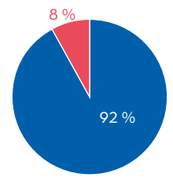
Parameters of Microblot-Array Borrelia IgM (tested on sera)

	Diagnostic Sensitivity	Diagnostic Specificity
Borrelia IgM	94.6% (n = 56)	95.8% (n = 95)
Anaplasma IgM	95.0% (n = 20)	100.0% (n = 38)
EBV	100.0% (n = 39)	98.0% (n = 51)

Comparative study

Correlation of results IgG

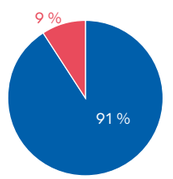
n = 77	Microblot-Array	ELISA
positive	38	41
negative	33	36
total conformity	92.2 %	



ELISA vs. Microblot-Array

Correlation of results IgM

n = 68	Microblot-Array	ELISA
positive	19	21
negative	40	44
total conformity	90.7 %	



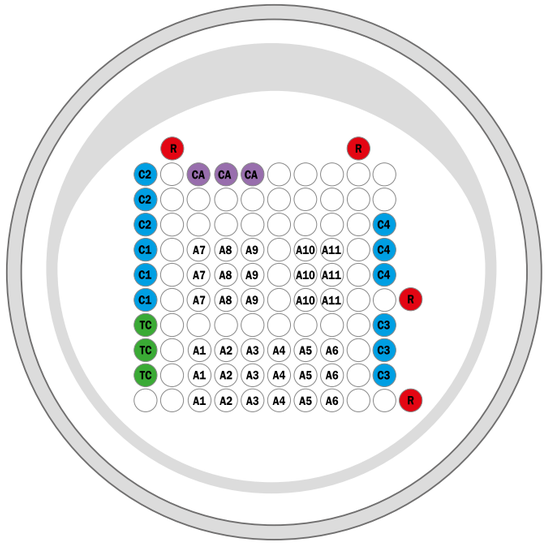
ELISA vs. Microblot-Array

conformity disagreement

Microblot–Array for the diagnostics of *Chlamydia* species

Microblot–Array *Chlamydia* are kits designed for the confirmation of positive or cut–off results of samples which were previously screened by ELISA or other serological methods. They serve for the detection of specific IgA and IgG antibodies to recombinant antigens of *Chlamydia* species in human serum or plasma. Thanks to the complex antigen composition they can be used for determination of particular species.

Spot No.	Antigen	Description	Species association
A1	MOMP Cp	Dominant major outer membrane protein (species specific) – structural protein; metabolic function	*Chlamydia pneumoniae*
A2	MOMP1	MOMP isoform, produced by posttranslational modification	
A3	OMP2 Cp	Outer membrane protein (species specific) – structural protein of *Chlamydia* outer membrane complex	
A4	OMP4	Outer membrane protein	
A5	OMP5	Outer membrane protein	
A6	P54	Immunodominant outer antigen, highly specific to *Ch. pneumoniae* – sensitive marker for diagnosis of acute infection	
A7	MOMP Ct	Dominant major outer membrane protein (species specific) – structural protein; metabolic function	*Chlamydia trachomatis*
A8	OMP2 Ct	Outer membrane protein (species specific) – structural protein of *Chlamydia* outer membrane complex	
A9	HSP60	Heat shock protein (GroEL); marker of chronic infection	
A10	MOMP Cps	Dominant major outer membrane protein (species specific) – structural protein; metabolic function	*Chlamydia psittaci*
A11	OMP2 Cps	Outer membrane protein (species specific) – structural protein of *Chlamydia* outer membrane complex	



R – Reference
TC – Test control
CA – Conjugate control IgA
CG – Conjugate control IgG
C1 – Calibration 1
C2 – Calibration 2
C3 – Calibration 3
C4 – Calibration 4

Test characteristic

Parameters of Microblot–Array Chlamydia IgA

	Diagnostic Sensitivity	Diagnostic Specificity
Ch. pneumoniae	94.4% (n = 54)	94.3% (n = 53)
Ch. trachomatis	94.1% (n = 68)	94.6% (n = 50)

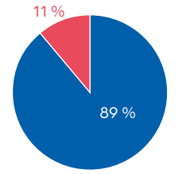
Parameters of Microblot–Array Chlamydia IgG

	Diagnostic Sensitivity	Diagnostic Specificity
Ch. pneumoniae	94.6% (n = 111)	96.0% (n = 25)
Ch. trachomatis	98.3% (n = 41)	92.7% (n = 60)

Comparative study

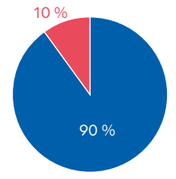
Correlation of results IgG

Ch. pneumoniae		
n = 52	**Microblot–Array**	**ELISA**
positive	31	32
negative	15	20
total conformity	88.5 %	



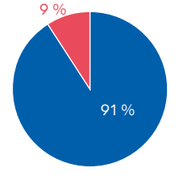
ELISA vs. Microblot–Array

Ch. pneumoniae		
n = 89	**Microblot–Array**	**BLOT**
positive	73	81
negative	7	8
total conformity	89.9 %	



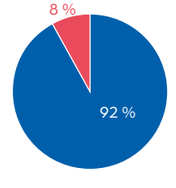
BLOT vs. Microblot–Array

Ch. trachomatis		
n = 70	**Microblot–Array**	**ELISA**
positive	17	20
negative	47	50
total conformity	91.4%	



ELISA vs. Microblot–Array

Ch. trachomatis		
n = 39	**Microblot–Array**	**BLOT**
positive	17	20
negative	19	19
total conformity	92.3 %	

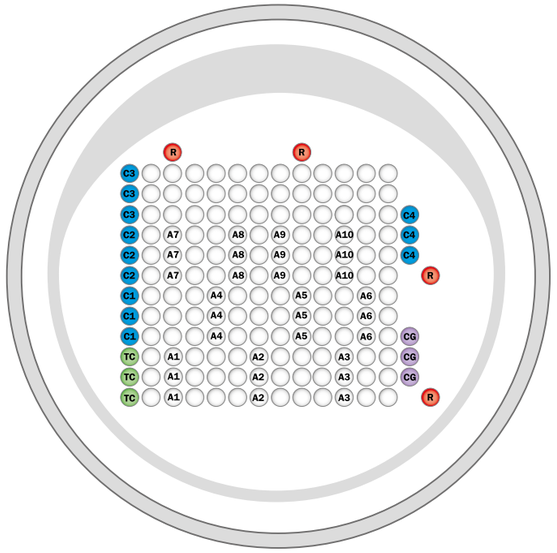


BLOT vs. Microblot–Array

conformity disagreement

Microblot–Array for the diagnostics of SARS–CoV–2 and other coronaviruses

Microblot–Array COVID–19 kits enable simultaneous detection of multiple SARS–CoV–2 markers (NP, RBD, Spike S2, E, ACE2, and PLPro). The kits also contain antigens to exclude cross–reactivities with other endemic coronaviruses (MERS–CoV, SARS–CoV, etc.). The kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum or plasma. They can be used for confirmatory testing, screening, epidemiological studies, identification of donors for convalescent plasma therapy, and other IVD and research applications related to the novel coronavirus.



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CA – Conjugate control IgA
CG – Conjugate control IgG
CM – Conjugate control IgM
C1 – Calibration 1
C2 – Calibration 2
C3 – Calibration 3
C4 – Calibration 4

Spot No.	Antigen	Description	Association
A1	Nucleocapsid NCP	A potent immunodominant coronavirus antigen that contains diagnostically important epitopes for the diagnosis of SARS–CoV–2	SARS–CoV–2
		Sensitive detection of anti–SARS–CoV–2 IgG antibodies	
A2	RBD	Receptor–binding domain of the S1 subunit of the spike (S) protein of SARS–CoV–2	
		Anti–RBD SARS–CoV–2 antibodies are highly subtype specific and protective	
		The presence of anti–RBD antibodies significantly correlates with the formation of neutralizing antibodies	
		IgA – for monitoring the immune response after a positive PCR reaction; indicator of the onset of the immune response IgM, IgG – detection of antibodies from 2 to 4 weeks after infection	
A3	Spike S2	S2 subunit of the spike protein SARS–CoV–2	
		Plays an important role in the fusion of the virus with the cell membrane	
A4	Envelope protein (E)	The smallest major structural protein	
		Important for different stages of viral infection and replication, important role in the life cycle of the virus	
A5	ACE2	Angiotensin Converting Enzyme (transmembrane glycoprotein)	SARS–CoV–2
		A key component of the renin–angiotensin system	
		Expressed in vascular endothelial cells in the heart, kidneys, but also the testes, liver, intestines, lungs and also the brain	
		Involved in the regulation of cardiovascular and renal function	
A6	PLpro	Papain–like protease	
		One of the basic SARS–CoV–2 proteins, essential for virus replication; deubiquitination activity	
		Necessary for proteolysis of the viral polyprotein	
A7	MERS–CoV S1	Middle East Respiratory Syndrome Coronavirus S1 protein	Other endemic coronaviruses
A8	SARS–CoV Np	Severe Acute Respiratory Syndrome Coronavirus Nucleocapsid protein	
A9	HCoV 229E Np	Human coronavirus 229E Nucleocapsid protein	
A10	HCoV NL63 Np	Human coronavirus NL63 Nucleocapsid protein	

Test characteristic

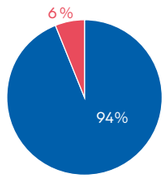
Parameters of Microblot–Array COVID19 kits

	Diagnostic Sensitivity	Diagnostic Specificity
COVID–19 IgA	98.3% (n = 233)	96.2% (n = 593)
COVID–19 IgG	98.7% (n = 309)	99.3% (n = 600)
COVID–19 IgM	97.7% (n = 219)	99.3% (n = 598)

Comparative study

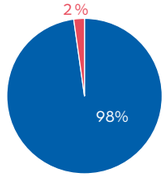
Correlation of results IgG

n = 102	Microblot–Array	BLOT
positive	87	91
negative	4	11
total conformity	93.5 %	



BLOT vs. Microblot–Array

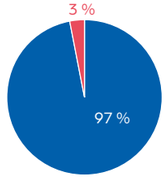
n = 247	Microblot–Array	ELISA
positive	237	236
negative	10	7
total conformity	98.4 %	



ELISA vs. Microblot–Array

Correlation of results IgM

n = 228	Microblot–Array	ELISA
positive	193	193
negative	35	27
total conformity	96.5 %	



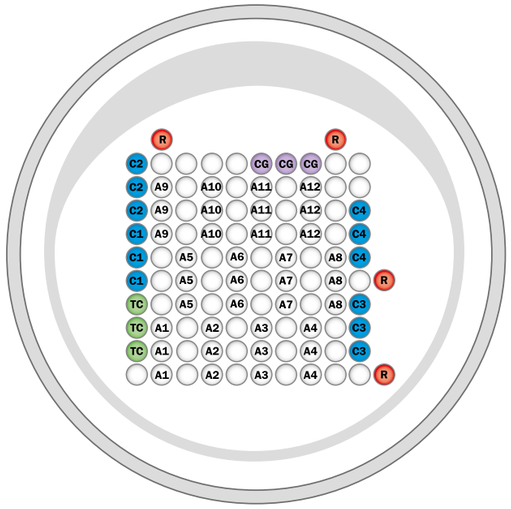
ELISA vs. Microblot–Array

conformity disagreement

Microblot–Array Multiplex diagnostics in microtiter plate format

Microblot–Array for the diagnostics of Epstein–Barr virus

Microblot–Array EBV kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum or plasma. The kits are intended for confirmatory determination of specific antibodies in samples that have been identified mainly as positive or borderline by ELISA or other serological tests. Determination of specific class antibodies against EBV antigens is a useful tool for identifying a stage of EBV infection (primary infection, latent chronic infection or reactivation).



R – Reference
TC – Test control
CA – Conjugate control IgA
CG – Conjugate control IgG
CM – Conjugate control IgM
C1 – Calibration 1
C2 – Calibration 2
C3 – Calibration 3
C4 – Calibration 4

Spot No.	Antigen	Description
A1	EBNA–1	Epstein–Barr nuclear antigen 1 IgG: an important diagnostic marker of the late phase or reactivation of the infection IgM: the antibodies are detectable 2–4 months after primary EBV infection, they may also appear during reactivation
A2	EBNA–2	Epstein–Barr nuclear antigen 2 IgG: high antibody titres are present during chronic infection or in the post–acute phase The absence of IgG anti–EBNA–2 antibodies and the presence of anti–EBNA–1 antibodies rules out primary infection
A3	VCA p18	Viral Capsid Antigen p18; IgA: marker of primary infection; high titres persist in patients with nasopharyngeal carcinoma IgM: marker of primary infection; they may also be present during infection reactivation IgG: an important marker of the late phase of the infection, antibodies do not occur in primary infections
A4	VCA p23	Viral Capsid Antigen p23 Antibodies against this antigen can be detected during all phases of the infection (both IgG and IgM), they persist in the body for a long time
A5	EA–D p54	Early Antigen Diffuse p54; BMRF1 IgA: produced during primary infection; high titres during reactivation; high titres persist in patients with nasopharyngeal carcinoma An additional marker of acute EBV infection, detectable even in the latent phase of primary infection (both IgG and IgM)
A6	EA–D p138	Early Antigen Diffuse p138 IgA: produced during primary infection; high titres during reactivation; high titres persist in patients with nasopharyngeal carcinoma An additional marker of acute EBV infection, detectable even in the latent phase of primary infection (both IgG and IgM)
A7	EA–R	Early Antigen Restricted protein p85; IgG: antibodies usually occur at a later stage; they are practically absent during the acute phase except in children; high levels in patients with reactivation or in immunocompromised patients

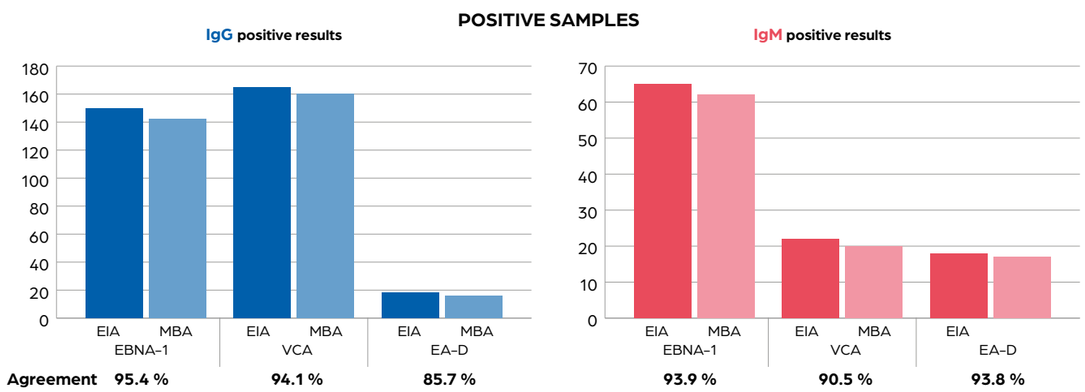
Spot No.	Antigen	Description
A8	Rta	Replication and transcription Activator (BRLF1); A very early antigen IgG: a potential diagnostic marker of a nasopharyngeal carcinoma
A9	ZEBRA	Z Epstein–Barr replication activator protein; Trans–activator protein BZLF1 IgM: it is a very early indicator of an acute infection IgG: it is an early stage marker but it is also detectable during the late stages of the infection Serological marker of EBV reactivation, marker of EBV–associated diseases
A10	gp85	Probable membrane antigen gp85 (BDLF3);
A11	gp350	Epstein–Barr virus envelope glycoprotein gp350 (BLLF1); IgM: high titres in patients with infectious mononucleosis IgG: the titre increases only a few months after the primary infection Specific immune response for EBV–associated diseases
A12	LMP1	Latent membrane protein 1 Frequent in latent infections Linked to EBV–associated malignancies (nasopharyngeal carcinoma)

Test characteristic

Parameters of Microblot–Array EBV kits

	Diagnostic Sensitivity	Diagnostic Specificity
EBV IgA	98.9% (n = 167)	96.7% (n = 70)
EBV IgG	98.8% (n = 167)	96.9% (n = 70)
EBV IgM	96.4% (n = 61)	89.3% (n = 60)

Comparative study



Ordering information

Kits

Autoimmunity

Code	Products	No. of tests per kit
ANAMA96	Microblot-Array ANA	96
ANApMA96	Microblot-Array ANA plus*	96

**Check availability in your country.*

Infectious serology

Code	Products	No. of tests per kit
BGMA096	Microblot-Array Borrelia IgG	96
BMMA096	Microblot-Array Borrelia IgM	96
BaGMA96	Microblot-Array Borrelia afzelii IgG	96
BaMMA96	Microblot-Array Borrelia afzelii IgM	96
BsGMA96	Microblot-Array Borrelia b. sensu stricto IgG	96
BsMMA96	Microblot-Array Borrelia b. sensu stricto IgM	96
BgGMA96	Microblot-Array Borrelia garinii IgG	96
BgMMA96	Microblot-Array Borrelia garinii IgM	96
CAMA096	Microblot-Array Chlamydia IgA	96
CGMA096	Microblot-Array Chlamydia IgG	96
CoVAMA96	Microblot-Array COVID-19 IgA	96
CoVGMA96	Microblot-Array COVID-19 IgG	96
CoVMMA96	Microblot-Array COVID-19 IgM	96
EBAMA96	Microblot-Array EBV IgA	96
EBGMA96	Microblot-Array EBV IgG	96
EBMMA96	Microblot-Array EBV IgM	96

Hardware & Software

Code	Products
ARCXIX096	Microblot-Array Reader (Array Reader C-series) + Software

Components

Code	Products
000009114	Universal Solution (300 ml)*

**In the case of automated processing, an additional universal solution is required because of the dead volumes of the instruments. We recommend 2 extra bottles/kit (when running one plate per week). Please contact our sales representatives for more information.*

IVD CE *All kits are CE and IVD certified.*

TestLine Clinical Diagnostics

www.testlinecd.com

Contact Information

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

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