

CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - *Borrelia burgdorferi* Antibodies (332):

Validity 12 months:

AB against *Borrelia burgdorferi* IgG (qualitative) - Immunological test (CLIA) (R: B2)

AB against *Borrelia burgdorferi* IgG (qualitative) - Immunological test (ELISA) (R: B2)

AB against *Borrelia burgdorferi* IgG - Blot - Immunoblot (R: B2)

AB against *Borrelia burgdorferi* IgM - Blot - Immunoblot (R: B2)

(R) analysis is subject to the RiliBÄK

Customer:
10011570
TestLine Clinical Diagnostics s.r.o.
Krizikova 188/68
61200 Brno



Düsseldorf, 25 June 2025



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



Prof. Dr. med. K.-P. Hunfeld
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 06 June 2025

You have participated in the External Quality Assessment with the following analysis

Infection Serology - Borrelia burgdorferi Antibodies (332):

AB against Borrelia burgdorferi IgG (qualitative) - Immunological test (CLIA) (R: B2)

AB against Borrelia burgdorferi IgG (qualitative) - Immunological test (ELISA) (R: B2)

AB against Borrelia burgdorferi IgG (semiquantitative) - Immunological test (CLIA) (R: B2)

AB against Borrelia burgdorferi IgM (qualitative) - Immunological test (CLIA) (R: B2)

AB against Borrelia burgdorferi IgM (qualitative) - Immunological test (ELISA) (R: B2)

AB against Borrelia burgdorferi IgM (semiquantitative) - Immunological test (CLIA) (R: B2)

AB against Borrelia burgdorferi IgG - Blot - Immunoblot (R: B2)

AB against Borrelia burgdorferi IgM - Blot - Immunoblot (R: B2)

diagnostic comment

(R) analysis is subject to the RiliBÄK

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Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 06 June 2025

Adviser:

Prof. Dr. med. K.-P. Hunfeld

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Infection Serology - Borrelia burgdorferi Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Borrelia burgdorferi IgG (semiquantitative)	(1) 31		350								Sample not evaluated
	(1) 32		1.53								Sample not evaluated
AB against Borrelia burgdorferi IgM (semiquantitative)	(1) 31		27.1								Sample not evaluated
	(1) 32		8.03								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Borrelia burgdorferi IgG (semiquantitative)	31	U/ml	350	1.00	228	TT	ZY99	0200118407
	32		1.53	1.00				
AB against Borrelia burgdorferi IgM (semiquantitative)	31	U/ml	27.1	1.00	228	TT	ZY99	0200118468
	32		8.03	1.00				

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Borrelia burgdorferi IgG (qualitative)	31	190	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	228	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Borrelia burgdorferi IgM (qualitative)	31	190	TT	ZY99	positive (3)	negative, borderline (1,2)	gM	-
	32				negative (1)	negative (1)	gM	+
	31	228	TT	ZY99	positive (3)	negative, borderline (1,2)	gM	-
	32				negative (1)	negative (1)	gM	+
AB against Borrelia burgdorferi IgG - Blot	31	247	TT	ZY99	positive (3)	positive (3)	gM	+
	32				negative (1)	negative, borderline (1,2)	gM	+
AB against Borrelia burgdorferi IgM - Blot	31	247	TT	ZY99	borderline (2)	negative, borderline, positive (1,2,3)	gM	+
	32				negative (1)	negative (1)	gM	+
diagnostic comment	31				The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for an early stage of Lyme disease or serum scar, depending on the clinical context.	The serological result indicates recent or past infection with B. burgdorferi. The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	M	-
	32				No serological evidence for infection with Borrelia burgdorferi. Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	No serological evidence for infection with Borrelia burgdorferi. Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	M	+

(1) Semiquantitative results are collected for scientific reasons only and are therefore not certified.

Additional information on the evaluation is available for download in the RV-Online system in the column "Report".

Individual summary of results

10011570: TestLine Clinical Diagnostics s.r.o.

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Infection Serology - Borrelia burgdorferi Antibodies

AB against Borrelia burgdorferi IgG (semiquantitative) (U/ml, N = 386)								
Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			187		
	32		Sample not evaluated			187		
CLIA	31		Sample not evaluated			196		
	32		Sample not evaluated			196		
other methods (1)	31		Sample not evaluated			7		
	32		Sample not evaluated			7		

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Graphical representation
not useful

AB against Borrelia burgdorferi IgM (semiquantitative) (U/ml, N = 369)								
Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			180		
	32		Sample not evaluated			180		
CLIA	31		Sample not evaluated			180		
	32		Sample not evaluated			180		
other methods	31		Sample not evaluated			12		
	32		Sample not evaluated			12		

Graphical representation
not useful

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Infection Serology - Borrelia burgdorferi Antibodies

AB against Borrelia burgdorferi IgG (qualitative) (N = 407, Rate of success: 90,2%)

Sample 31			
Collective	negative (1)	positive (3)	total
ELISA, BioMerieux	0	9 ●	9
ELISA, Euroimmun	0	109 ●	109
ELISA, Mikrogen	0	18 ●	18
ELISA, Orgentec	0	14 ●	14
ELISA, Virion \ Serion	1	27 ●	28
ELISA, Virotech	0	9 ●	9
ELISA, other provider	1	19 ●	20
CLIA, DiaSorin	0	174 ●	174
CLIA, other provider	1	18 ●	19
other methods	0	7 ●	7

Sample 32				
Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, BioMerieux	9 ●	0	0	9
ELISA, Euroimmun	101 ●	5	3	109
ELISA, Mikrogen	15 ●	2	1	18
ELISA, Orgentec	14 ●	0	0	14
ELISA, Virion \ Serion	28 ●	0	0	28
ELISA, Virotech	9 ●	0	0	9
ELISA, other provider	17 ●	1	2	20
CLIA, DiaSorin	152 ●	20	2	174
CLIA, other provider	18 ●	0	1	19
other methods	6 ●	0	1	7

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against *Borrelia burgdorferi* IgM (qualitative) (N = 408, Rate of success: 81,4%)

Sample 31

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, BioMerieux	9 ●	0 ●	0	9
ELISA, Euroimmun	13 ●	52 ●	45	110
ELISA, Mikrogen	18 ●	0 ●	1	19
ELISA, Orgentec	13 ●	0 ●	1	14
ELISA, Virion \ Serion	26 ●	1 ●	1	28
ELISA, Virotech	9 ●	0 ●	0	9
ELISA, other provider	12 ●	3 ●	5	20
CLIA, DiaSorin	152 ●	19 ●	5	176
CLIA, other provider	11 ●	2 ●	4	17
other methods	5 ●	0 ●	1	6

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, BioMerieux	9 ●	0	0	9
ELISA, Euroimmun	93 ●	15	2	110
ELISA, Mikrogen	13 ●	0	6	19
ELISA, Orgentec	14 ●	0	0	14
ELISA, Virion \ Serion	28 ●	0	0	28
ELISA, Virotech	9 ●	0	0	9
ELISA, other provider	16 ●	2	2	20
CLIA, DiaSorin	176 ●	0	0	176
CLIA, other provider	16 ●	0	1	17
other methods	5 ●	0	1	6

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against *Borrelia burgdorferi* IgG - Blot (N = 350, Rate of success: 84,6%)

Sample 31

Collective	positive (3)	total
Immuno- and Westernblot, Euroimmun	65 ●	65
Immuno- and Westernblot, Mikrogen	28 ●	28
Immuno- and Westernblot, Viramed	67 ●	67
Immuno- and Westernblot, Virotech	6 ●	6
Immuno- and Westernblot, other provider	16 ●	16
Line Blot, Euroimmun	54 ●	54
Line Blot, Mikrogen	64 ●	64
Line Blot, Viramed	4 ●	4
Line Blot, Virotech	17 ●	17
Line Blot, other provider	4 ●	4
other methods	23 ●	23

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
Immuno- and Westernblot, Euroimmun	45 ●	1 ●	17	63
Immuno- and Westernblot, Mikrogen	12 ●	16 ●	0	28
Immuno- and Westernblot, Viramed	61 ●	2 ●	2	65
Immuno- and Westernblot, Virotech	6 ●	0 ●	0	6
Immuno- and Westernblot, other provider	13 ●	0 ●	1	14
Line Blot, Euroimmun	35 ●	0 ●	18	53
Line Blot, Mikrogen	11 ●	48 ●	0	59
Line Blot, Viramed	4 ●	0 ●	0	4
Line Blot, Virotech	15 ●	0 ●	0	15
Line Blot, other provider	4 ●	0 ●	0	4
other methods	24 ●	0 ●	0	24

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

AB against *Borrelia burgdorferi* IgM - Blot (N = 338, Rate of success: 94,1%)

Sample 31

Collective	positive (3)	negative (1)	borderline (2)	total
Immuno- and Westernblot, Euroimmun	46 ●	7 ●	8 ●	61
Immuno- and Westernblot, Mikrogen	1 ●	27 ●	0 ●	28
Immuno- and Westernblot, Viramed	58 ●	7 ●	1 ●	66
Immuno- and Westernblot, Virotech	0 ●	6 ●	0 ●	6
Immuno- and Westernblot, other provider	1 ●	12 ●	1 ●	14

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
Immuno- and Westernblot, Euroimmun	56 ●	3	1	60
Immuno- and Westernblot, Mikrogen	28 ●	0	0	28
Immuno- and Westernblot, Viramed	57 ●	2	5	64
Immuno- and Westernblot, Virotech	6 ●	0	0	6
Immuno- and Westernblot, other provider	14 ●	0	0	14

Collective	positive (3)	negative (1)	borderline (2)	total
Line Blot, Euroimmun	44 ●	4 ●	5 ●	53
Line Blot, Mikrogen	2 ●	59 ●	0 ●	61
Line Blot, Viramed	4 ●	0 ●	0 ●	4
Line Blot, Virotech	0 ●	16 ●	0 ●	16
Line Blot, other provider	1 ●	3 ●	1 ●	5
other methods	13 ●	11 ●	0 ●	24

Collective	negative (1)	borderline (2)	positive (3)	total
Line Blot, Euroimmun	53 ●	0	0	53
Line Blot, Mikrogen	58 ●	0	0	58
Line Blot, Viramed	4 ●	0	0	4
Line Blot, Virotech	14 ●	1	0	15
Line Blot, other provider	5 ●	0	0	5
other methods	23 ●	1	0	24

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

diagnostic comment (N = 336, Rate of success: 76,8%)

Sample 31

Collective	No serological evidence for infection with <i>Borrelia burgdorferi</i> . Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	The serological result indicates recent or past infection with <i>B. burgdorferi</i> . The test result provides evidence for an early stage of Lyme disease or serum scar, depending on the clinical context.	The serological result indicates recent or past infection with <i>B. burgdorferi</i> . The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	total
all methods	2	43	287 ●	332

Sample 32

Collective	No serological evidence for infection with <i>Borrelia burgdorferi</i> . Early infection however can not be excluded. In case of clinical suspicion control examination after 2-3 weeks is recommended.	The serological result indicates recent or past infection with <i>B. burgdorferi</i> . The test result provides evidence for an early stage of Lyme disease or serum scar, depending on the clinical context.	The serological result indicates recent or past infection with <i>B. burgdorferi</i> . The test result provides evidence for a late stage of Lyme disease or serum scar, depending on the clinical context.	total
all methods	297 ●	20	19	336

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