

CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - Yersinia Antibodies (315):

Validity 24 months:

AB against Yersinia IgG (qualitative) - Immunoblot

AB against Yersinia IgA (qualitative) - Immunoblot

AB against Yersinia IgA (qualitative) - Immunological test (ELISA)

AB against Yersinia IgM (qualitative) - Immunological test (ELISA)

diagnostic comment

(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 - Yersinia Antibodies (315):

AB against Yersinia IgG (qualitative) - Immunoblot
AB against Yersinia IgG (qualitative) - Immunological test (ELISA)
AB against Yersinia IgA (qualitative) - Immunoblot
AB against Yersinia IgA (qualitative) - Immunological test (ELISA)
AB against Yersinia IgM (qualitative) - Immunological test (ELISA)
diagnostic comment

(R) analysis is subject to the RiliBÄK

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(Head of Reference Institution)



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

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

Zentralinstitut für Labormedizin, Mikrobiologie &
Krankenhaushygiene
Krankenhaus Nordwest
Steinbacher Hohl 2-26
60488 Frankfurt am Main

Tel.: +49 69 7601 4349

Fax: +49 69 7601 3907

Mail: hunfeld.klaus-peter@khnw.de

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Infection Serology - Yersinia Antibodies

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Yersinia IgG (qualitative)	31	190	ZY	ZY99	negative (1)	borderline, positive (2,3)	gM	-
	32				negative (1)	negative, borderline (1,2)	gM	+
	31	247	ZY	ZY99	positive (3)	borderline, positive (2,3)	gM	+
	32				negative (1)	negative, borderline (1,2)	gM	+
AB against Yersinia IgA (qualitative)	31	190	ZY	ZY99	negative (1)	negative, borderline (1,2)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	247	ZY	ZY99	negative (1)	negative, borderline (1,2)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Yersinia IgM (qualitative)	31	190	ZY	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
diagnostic comment	31				serological evidence for a past infection	serological evidence for a past infection, serological evidence for an associated sequelae, serological evidence for a past infection + serological evidence for an associated sequelae	M	+
	32				no serological evidence for an infection	no serological evidence for an infection, serological evidence for a past infection	M	+

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.

Survey of 06 June 2025

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Infection Serology - Yersinia Antibodies

AB against Yersinia IgG (qualitative) (N = 252, Rate of success: 73,8%)

Sample 31

Collective	positive (3)	negative (1)	borderline (2)	total
ELISA, Euroimmun	0 ●	37	0 ●	37
ELISA, Mikrogen	15 ●	0	0 ●	15
ELISA, Orgentec	15 ●	2	0 ●	17
ELISA, Virion / Serion	31 ●	2	0 ●	33
ELISA, Virotech	0 ●	0	4 ●	4
ELISA, other provider	0 ●	3	0 ●	3
Immunoblot, Euroimmun	26 ●	1	0 ●	27
Immunoblot, Mikrogen	48 ●	1	0 ●	49
Immunoblot, Viramed	46 ●	0	0 ●	46
Immunoblot, Virotech	6 ●	0	0 ●	6
Immunoblot, other provider	6 ●	0	0 ●	6
other methods	8 ●	1	0 ●	9

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	35 ●	2 ●	0	37
ELISA, Mikrogen	15 ●	0 ●	0	15
ELISA, Orgentec	17 ●	0 ●	0	17
ELISA, Virion / Serion	33 ●	0 ●	0	33
ELISA, Virotech	4 ●	0 ●	0	4
ELISA, other provider	3 ●	0 ●	0	3
Immunoblot, Euroimmun	13 ●	0 ●	14	27
Immunoblot, Mikrogen	19 ●	27 ●	3	49
Immunoblot, Viramed	46 ●	0 ●	0	46
Immunoblot, Virotech	3 ●	1 ●	2	6
Immunoblot, other provider	6 ●	0 ●	0	6
other methods	8 ●	0 ●	1	9

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

AB against Yersinia IgA (qualitative) (N = 266, Rate of success: 88,7%)

Sample 31

Collective	negative (1)	positive (3)	borderline (2)	total
ELISA, Euroimmun	37 ●	1	0 ●	38
ELISA, Mikrogen	15 ●	1	0 ●	16
ELISA, Orgentec	20 ●	0	0 ●	20
ELISA, Virion / Serion	33 ●	0	0 ●	33
ELISA, Virotech	4 ●	0	0 ●	4
ELISA, other provider	3 ●	0	0 ●	3
Immunoblot, Euroimmun	14 ●	14	0 ●	28
Immunoblot, Mikrogen	46 ●	6	0 ●	52
Immunoblot, Viramed	40 ●	8	2 ●	50
Immunoblot, Virotech	7 ●	0	0 ●	7
Immunoblot, other provider	7 ●	0	0 ●	7
other methods	7 ●	0	0 ●	7

Sample 32

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	37 ●	1	38
ELISA, Mikrogen	16 ●	0	16
ELISA, Orgentec	20 ●	0	20
ELISA, Virion / Serion	33 ●	0	33
ELISA, Virotech	4 ●	0	4
ELISA, other provider	3 ●	0	3
Immunoblot, Euroimmun	22 ●	5	27
Immunoblot, Mikrogen	52 ●	0	52
Immunoblot, Viramed	50 ●	0	50
Immunoblot, Virotech	7 ●	0	7
Immunoblot, other provider	7 ●	0	7
other methods	8 ●	0	8

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

AB against Yersinia IgM (qualitative) (N = 51, Rate of success: 100%)

Sample 31

Collective	negative (1)	total
ELISA, Mikrogen	10 ●	10
ELISA, Virion / Serion	12 ●	12
ELISA, other provider	6 ●	6
Immunoblot, Mikrogen	17 ●	17
Immunoblot, other provider	4 ●	4
other methods	2 ●	2

Sample 32

Collective	negative (1)	total
ELISA, Mikrogen	10 ●	10
ELISA, Virion / Serion	12 ●	12
ELISA, other provider	6 ●	6
Immunoblot, Mikrogen	17 ●	17
Immunoblot, other provider	4 ●	4
other methods	2 ●	2

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

diagnostic comment (N = 198, Rate of success: 78,3%)

Sample 31

Collective	serological evidence for a past infection	no serological evidence for an infection	serological evidence for a past infection, serological evidence for an associated sequelae	serological evidence for an acute infection	others	total
all methods	139 ●	28	11 ●	7	13 ●	198

Sample 32

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for an associated sequelae	serological evidence for an acute infection	total
all methods	165 ●	34 ●	3	1	203

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