

CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - Chlamydia trachomatis Antibodies (312):

Validity 12 months:

AB against Chlamydia trachomatis IgG (qualitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgG (qualitative) - Immunological test (ELISA)
AB against Chlamydia trachomatis IgA (qualitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgA (qualitative) - Immunological test (ELISA)
AB against Chlamydia trachomatis IgM (qualitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgM (qualitative) - Immunological test (ELISA)
AB against Chlamydia trachomatis IgG - Immunoblot
AB against Chlamydia trachomatis IgA - Immunoblot
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 - Chlamydia trachomatis Antibodies (312):

AB against Chlamydia trachomatis IgG (qualitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgG (qualitative) - Immunological test (ELISA)
AB against Chlamydia trachomatis IgG (semiquantitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgA (qualitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgA (qualitative) - Immunological test (ELISA)
AB against Chlamydia trachomatis IgA (semiquantitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgM (qualitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgM (qualitative) - Immunological test (ELISA)
AB against Chlamydia trachomatis IgM (semiquantitative) - Immunological test (CLIA)
AB against Chlamydia trachomatis IgG - Immunoblot
AB against Chlamydia trachomatis IgA - Immunoblot
diagnostic comment

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(Adviser)

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 06 June 2025

Adviser:

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Infection Serology - Chlamydia trachomatis Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Chlamydia trachomatis IgG (semiquantitative)	(1) 31		0.120								Sample not evaluated
	(1) 32		41.4								Sample not evaluated
AB against Chlamydia trachomatis IgA (semiquantitative)	(1) 31		2.18								Sample not evaluated
	(1) 32		2.87								Sample not evaluated
AB against Chlamydia trachomatis IgM (semiquantitative)	(1) 31		1.45								Sample not evaluated
	(1) 32		1.68								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Chlamydia trachomatis IgG (semiquantitative)	31	U/ml	0.120	1.00	228	TT	ZY99	0200123407
	32	U/ml	41.4	1.00				
AB against Chlamydia trachomatis IgA (semiquantitative)	31	U/ml	2.18	1.00	228	TT	ZY99	0200123409
	32	U/ml	2.87	1.00				
AB against Chlamydia trachomatis IgM (semiquantitative)	31	U/ml	1.45	1.00	228	TT	ZY99	0200126078
	32	U/ml	1.68	1.00				

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Chlamydia trachomatis IgG (qualitative)	31	190	TT	ZY99	negative (1)	negative (1)	gM	+
	32				positive (3)	positive (3)	gM	+
	31	228	TT	ZY99	negative (1)	negative (1)	gM	+
	32				positive (3)	positive (3)	gM	+
AB against Chlamydia trachomatis IgA (qualitative)	31	190	TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	228	TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Chlamydia trachomatis IgM (qualitative)	31	190	TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
	31	228	TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
AB against Chlamydia trachomatis IgG - Immunoblot	31		TT	ZY99	negative (1)	negative (1)	gM	+
	32				positive (3)	positive (3)	gM	+
AB against Chlamydia trachomatis IgA - Immunoblot	31		TT	ZY99	negative (1)	negative (1)	gM	+
	32				negative (1)	negative (1)	gM	+
diagnostic comment	31				no serological evidence for an infection	no serological evidence for an infection	M	+
	32				serological evidence for a past infection	serological evidence for a past infection	M	+

** BRAVO **

(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.

Survey of 06 June 2025

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Infection Serology - Chlamydia trachomatis Antibodies

AB against Chlamydia trachomatis IgG (semiquantitative) (U/ml, N = 254)								
Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			155		
	32		Sample not evaluated			155		
CLIA	31		Sample not evaluated			93		
	32		Sample not evaluated			93		
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 Chlamydia trachomatis IgA (semiquantitative) (U/ml, N = 218)								
Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			140		
	32		Sample not evaluated			140		
CLIA	31		Sample not evaluated			77		
	32		Sample not evaluated			77		
other methods (1)	31		Sample not evaluated			2		
	32		Sample not evaluated			2		

(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 Chlamydia trachomatis IgM (semiquantitative) (U/ml, N = 39)								
Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	31		Sample not evaluated			29		
	32		Sample not evaluated			29		
CLIA	31		Sample not evaluated			9		
	32		Sample not evaluated			9		
other methods (1)	31		Sample not evaluated			1		
	32		Sample not evaluated			1		

(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 Chlamydia trachomatis IgG (qualitative) (N = 285, Rate of success: 89,5%)

Sample 31

Collective	negative (1)	borderline (2)	total
ELISA, DiaSorin	14 ●	0	14
ELISA, Euroimmun	81 ●	0	81
ELISA, Mikrogen	9 ●	0	9
ELISA, Orgentec	20 ●	0	20
ELISA, Savayon	5 ●	0	5
ELISA, Vircell	6 ●	0	6
ELISA, Virion \ Serion	31 ●	0	31
ELISA, other provider	18 ●	1	19
CLIA, DiaSorin	81 ●	0	81
CLIA, Vircell	8 ●	0	8
CLIA, other provider	5 ●	0	5
other methods	6 ●	0	6

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, DiaSorin	0	0	14 ●	14
ELISA, Euroimmun	4	19	58 ●	81
ELISA, Mikrogen	0	0	9 ●	9
ELISA, Orgentec	0	0	20 ●	20
ELISA, Savayon	0	0	5 ●	5
ELISA, Vircell	0	0	6 ●	6
ELISA, Virion \ Serion	1	0	30 ●	31
ELISA, other provider	3	2	14 ●	19
CLIA, DiaSorin	1	0	80 ●	81
CLIA, Vircell	0	0	8 ●	8
CLIA, other provider	0	0	5 ●	5
other methods	0	0	6 ●	6

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

AB against Chlamydia trachomatis IgA (qualitative) (N = 254, Rate of success: 98%)

Sample 31

Collective	negative (1)	total
ELISA, DiaSorin	12 ●	12
ELISA, Euroimmun	77 ●	77
ELISA, Mikrogen	9 ●	9
ELISA, Orgentec	16 ●	16
ELISA, Virion \ Serion	29 ●	29
ELISA, other provider	26 ●	26
CLIA, Diasorin	68 ●	68
CLIA, other provider	9 ●	9
other methods	8 ●	8

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, DiaSorin	12 ●	0	0	12
ELISA, Euroimmun	76 ●	1	0	77
ELISA, Mikrogen	9 ●	0	0	9
ELISA, Orgentec	16 ●	0	0	16
ELISA, Virion \ Serion	28 ●	0	1	29
ELISA, other provider	26 ●	0	0	26
CLIA, Diasorin	67 ●	0	1	68
CLIA, other provider	9 ●	0	0	9
other methods	6 ●	0	2	8

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

AB against Chlamydia trachomatis IgM (qualitative) (N = 53, Rate of success: 86,8%)

Sample 31

Collective	negative (1)	borderline (2)	total
ELISA, Euroimmun	11 ●	2	13
ELISA, Orgentec	9 ●	0	9
ELISA, Virion \ Serion	7 ●	0	7
ELISA, other provider	13 ●	0	13
CLIA, all providers	7 ●	0	7
other methods	4 ●	0	4

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	13 ●	0	0	13
ELISA, Orgentec	9 ●	0	0	9
ELISA, Virion \ Serion	6 ●	1	0	7
ELISA, other provider	11 ●	1	1	13
CLIA, all providers	5 ●	2	0	7
other methods	4 ●	0	0	4

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

AB against Chlamydia trachomatis IgG - Immunoblot (N = 32, Rate of success: 96,9%)

Sample 31

Collective	negative (1)	total
Mikrogen	29 ●	29
other providers	3 ●	3

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

Sample 32

Collective	negative (1)	positive (3)	total
Mikrogen	1	28 ●	29
other providers	0	3 ●	3

AB against Chlamydia trachomatis IgA - Immunoblot (N = 25, Rate of success: 100%)

Sample 31

Collective	negative (1)	total
Mikrogen	23 ●	23
other providers	2 ●	2

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

Sample 32

Collective	negative (1)	total
Mikrogen	23 ●	23
other providers	2 ●	2

diagnostic comment (N = 213, Rate of success: 92%)

Sample 31

Collective	no serological evidence for an infection	serological evidence for a past infection	total
all methods	212 ●	1	213

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

Sample 32

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for a present infection	total
all methods	6	205 ●	10	221