

CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - Chlamydia pneumoniae (Chlamydophila) Antibodies (314):

Validity 12 months:

AB against Chlamydia pneumoniae IgA (qualitative) - Immunological test (CLIA)

AB against Chlamydia pneumoniae IgA (qualitative) - Immunological test (ELISA)

AB against Chlamydia pneumoniae IgM (qualitative) - Immunological test (CLIA)

AB against Chlamydia pneumoniae IgM (qualitative) - Immunological test (ELISA)

AB against Chlamydia pneumoniae IgG - Immunoblot

(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 pneumoniae (Chlamydophila) Antibodies (314):

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

(R) analysis is subject to the RiliBÄK

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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

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314

Infection Serology - Chlamydia pneumoniae (Chlamydomphila) Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Chlamydia pneumoniae IgG (semiquantitative)	(1) 31		140								Sample not evaluated
	(1) 32		188								Sample not evaluated
AB against Chlamydia pneumoniae IgA (semiquantitative)	(1) 31		5.50								Sample not evaluated
	(1) 32		11.3								Sample not evaluated
AB against Chlamydia pneumoniae IgM (semiquantitative)	(1) 31		7.54								Sample not evaluated
	(1) 32		7.97								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Chlamydia pneumoniae IgG (semiquantitative)	31	U/ml	140	1.00	228	TT	ZY99	0200123420
	32	U/ml	188	1.00				
AB against Chlamydia pneumoniae IgA (semiquantitative)	31	U/ml	5.50	1.00	228	TT	ZY99	CL100467
	32	U/ml	11.3	1.00				
AB against Chlamydia pneumoniae IgM (semiquantitative)	31	U/ml	7.54	1.00	228	TT	ZY99	CL100468
	32	U/ml	7.97	1.00				

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

Survey of 06 June 2025

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Infection Serology - Chlamydia pneumoniae (Chlamydophila) Antibodies

AB against Chlamydia pneumoniae IgG (semiquantitative) (U/ml, N = 183)							
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)
				AVG	CV	Num.	Sam. total
ELISA	31		Sample not evaluated			163	
	32		Sample not evaluated			163	
other methods	31		Sample not evaluated			21	
	32		Sample not evaluated			21	

Graphical representation
not useful

AB against Chlamydia pneumoniae IgA (semiquantitative) (U/ml, N = 153)							
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)
				AVG	CV	Num.	Sam. total
ELISA	31		Sample not evaluated			138	
	32		Sample not evaluated			138	
CLIA	31		Sample not evaluated			13	
	32		Sample not evaluated			13	
other methods (1)	31		Sample not evaluated			3	
	32		Sample not evaluated			3	

Graphical representation
not useful

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

AB against Chlamydia pneumoniae IgM (semiquantitative) (U/ml, N = 114)							
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)
				AVG	CV	Num.	Sam. total
ELISA	31		Sample not evaluated			96	
	32		Sample not evaluated			96	
CLIA	31		Sample not evaluated			15	
	32		Sample not evaluated			15	
other methods (1)	31		Sample not evaluated			3	
	32		Sample not evaluated			3	

Graphical representation
not useful

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

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Infection Serology - Chlamydia pneumoniae (Chlamydophila) Antibodies

AB against Chlamydia pneumoniae IgG (qualitative) (N = 197, Rate of success: 89,8%)

Sample 31				
Collective	negative (1)	positive (3)	borderline (2)	total
ELISA, Euroimmun	70 ●	2	0	72
ELISA, Mikrogen	11 ●	0	0	11
ELISA, Orgentec	22 ●	0	0	22
ELISA, Savayon	6 ●	0	0	6
ELISA, Vircell	5 ●	1	0	6
ELISA, Virion \ Serion	39 ●	0	0	39
ELISA, other provider	7 ●	9	3	19
Immunological test (CLIA)	15 ●	3	0	18
other methods	4 ●	0	0	4

Sample 32				
Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	1	0	71 ●	72
ELISA, Mikrogen	0	0	11 ●	11
ELISA, Orgentec	0	0	22 ●	22
ELISA, Savayon	0	0	6 ●	6
ELISA, Vircell	0	0	6 ●	6
ELISA, Virion \ Serion	0	1	38 ●	39
ELISA, other provider	1	0	18 ●	19
Immunological test (CLIA)	0	0	18 ●	18
other methods	0	0	4 ●	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 pneumoniae IgA (qualitative) (N = 168, Rate of success: 85,7%)

Sample 31

Collective	negative (1)	total
ELISA, Euroimmun	68 ●	68
ELISA, Mikrogen	8 ●	8
ELISA, Orgentec	15 ●	15
ELISA, Savayon	6 ●	6
ELISA, Virion \ Serion	35 ●	35
ELISA, other provider	19 ●	19
Immunological test (CLIA)	10 ●	10
other methods	7 ●	7

Sample 32

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	67 ●	1	0	68
ELISA, Mikrogen	8 ●	0	0	8
ELISA, Orgentec	15 ●	0	0	15
ELISA, Savayon	2 ●	2	2	6
ELISA, Virion \ Serion	34 ●	1	0	35
ELISA, other provider	12 ●	2	5	19
Immunological test (CLIA)	2 ●	0	8	10
other methods	4 ●	0	3	7

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

AB against Chlamydia pneumoniae IgM (qualitative) (N = 131, Rate of success: 98,5%)

Sample 31

Collective	negative (1)	borderline (2)	total
ELISA, Euroimmun	43 ●	0	43
ELISA, Mikrogen	7 ●	0	7
ELISA, Orgentec	15 ●	0	15
ELISA, Vircell	5 ●	0	5
ELISA, Virion / Serion	26 ●	0	26
ELISA, other provider	19 ●	1	20
CLIA, all providers	12 ●	0	12
other methods	3 ●	0	3

Sample 32

Collective	negative (1)	positive (3)	total
ELISA, Euroimmun	43 ●	0	43
ELISA, Mikrogen	7 ●	0	7
ELISA, Orgentec	15 ●	0	15
ELISA, Vircell	5 ●	0	5
ELISA, Virion / Serion	26 ●	0	26
ELISA, other provider	20 ●	0	20
CLIA, all providers	12 ●	0	12
other methods	2 ●	1	3

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

AB against Chlamydia pneumoniae IgG - Immunoblot (N = 30, Rate of success: 93,3%)

Sample 31

Collective	negative (1)	total
Mikrogen	28 ●	28
other providers	2 ●	2

Sample 32

Collective	negative (1)	positive (3)	total
Mikrogen	2	26 ●	28
other providers	0	2 ●	2

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

AB against Chlamydia pneumoniae IgA - Immunoblot (N = 28, Rate of success: 85,7%)

Sample 31

Collective	negative (1)	total
Mikrogen	26 ●	26
other providers	2 ●	2

Sample 32

Collective	negative (1)	positive (3)	total
Mikrogen	23 ●	3	26
other providers	1 ●	1	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 = 181, Rate of success: 79,6%)

Sample 31

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for a present infection	total
all methods	167 ●	13	1	181

Sample 32

Collective	no serological evidence for an infection	serological evidence for a past infection	serological evidence for a present infection	total
all methods	5	161 ●	23	189

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