

CERTIFICATE

Survey of 01 November 2024

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

Infection Serology - Mycoplasma pneumoniae Antibodies (324):

Validity 24 months:

AB against Mycoplasma pneumoniae IgG (qualitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgG (qualitative) - Immunological test (ELISA)
AB against Mycoplasma pneumoniae IgG (qualitative) - other method
AB against Mycoplasma pneumoniae IgA (qualitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgA (qualitative) - Immunological test (ELISA)
AB against Mycoplasma pneumoniae IgA (qualitative) - other method
AB against Mycoplasma pneumoniae IgM (qualitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgM (qualitative) - Immunological test (ELISA)
AB against Mycoplasma pneumoniae IgM (qualitative) - other method
diagnostic comment

(R) analysis is subject to the RiliBÄK

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



Düsseldorf, 03 December 2024

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

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

CERTIFICATE OF PARTICIPATION

Survey of 01 November 2024

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

Infection Serology - Mycoplasma pneumoniae Antibodies (324):

AB against Mycoplasma pneumoniae IgG (qualitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgG (qualitative) - Immunological test (ELISA)
AB against Mycoplasma pneumoniae IgG (qualitative) - other method
AB against Mycoplasma pneumoniae IgG (semiquantitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgA (qualitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgA (qualitative) - Immunological test (ELISA)
AB against Mycoplasma pneumoniae IgA (qualitative) - other method
AB against Mycoplasma pneumoniae IgM (qualitative) - Immunological test (CLIA)
AB against Mycoplasma pneumoniae IgM (qualitative) - Immunological test (ELISA)
AB against Mycoplasma pneumoniae IgM (qualitative) - other method
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 01 November 2024

Adviser:

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Infection Serology - Mycoplasma pneumoniae Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Mycoplasma pneumoniae IgG (semiquantitative)	(1) 61		12.2								Sample not evaluated
	(1) 62		16.6								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Mycoplasma pneumoniae IgG (semiquantitative)	61	U/ml	12.2	1.00	228	TT	ZY99	0200117950
	62		16.6	1.00				

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Mycoplasma pneumoniae IgG (qualitative)	61	190	TT	ZY99	negative (1)	negative, borderline, positive (1,2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
	61	9999	TT	ZY99	negative (1)	negative, borderline, positive (1,2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
	61	228	TT	ZY99	negative (1)	negative, borderline, positive (1,2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
AB against Mycoplasma pneumoniae IgA (qualitative)	61	190	TT	ZY99	negative (1)	negative (1)	gM	+
	62				negative (1)	negative (1)	gM	+
	61	9999	TT	ZY99	negative (1)	negative (1)	gM	+
	62				negative (1)	negative (1)	gM	+
	61	228	TT	ZY99	negative (1)	negative (1)	gM	+
	62				negative (1)	negative (1)	gM	+
AB against Mycoplasma pneumoniae IgM (qualitative)	61	190	TT	ZY99	positive (3)	borderline, positive (2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
	61	9999	TT	ZY99	positive (3)	borderline, positive (2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
	61	228	TT	ZY99	positive (3)	borderline, positive (2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
diagnostic comment	61				serological evidence for an acute infection	serological evidence for an acute infection	M	+
	62				no serological evidence for an infection	no serological evidence for an 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 01 November 2024

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Infection Serology - Mycoplasma pneumoniae Antibodies

AB against Mycoplasma pneumoniae IgG (semiquantitative) (U/ml, N = 243)								
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
ELISA	61		Sample not evaluated			148		
	62		Sample not evaluated			148		
CLIA	61		Sample not evaluated			92		
	62		Sample not evaluated			92		
other methods (1)	61		Sample not evaluated			3		
	62		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 - Mycoplasma pneumoniae Antibodies

AB against Mycoplasma pneumoniae IgG (qualitative) (N = 269, Rate of success: 82,2%)

Sample 61					Sample 62				
Collective	negative (1)	borderline (2)	positive (3)	total	Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	0 ●	0 ●	56 ●	56	ELISA, Euroimmun	25 ●	22	9	56
ELISA, Orgentec	16 ●	0 ●	0 ●	16	ELISA, Orgentec	15 ●	1	0	16
ELISA, Virion \ Serion	47 ●	6 ●	1 ●	54	ELISA, Virion \ Serion	52 ●	2	0	54
ELISA, Virotech	5 ●	1 ●	2 ●	8	ELISA, Virotech	7 ●	1	0	8
ELISA	27 ●	1 ●	3 ●	31	ELISA	24 ●	4	3	31
CLIA, Diasorin	80 ●	2 ●	4 ●	86	CLIA, Diasorin	85 ●	0	1	86
CLIA, other providers	15 ●	0 ●	0 ●	15	CLIA, other providers	10 ●	4	1	15
other methods	3 ●	0 ●	0 ●	3	other methods	3 ●	0	0	3

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

AB against Mycoplasma pneumoniae IgA (qualitative) (N = 136, Rate of success: 86,8%)

Sample 61					Sample 62		
Collective	negative (1)	borderline (2)	positive (3)	total	Collective	negative (1)	total
Euroimmun	42 ●	5	0	47	Euroimmun	47 ●	47
Orgentec	10 ●	1	0	11	Orgentec	11 ●	11
Virion \ Serion	45 ●	1	1	47	Virion \ Serion	47 ●	47
Virotech	1 ●	1	6	8	Virotech	8 ●	8
other providers	20 ●	0	3	23	other providers	23 ●	23

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

AB against Mycoplasma pneumoniae IgM (qualitative) (N = 294, Rate of success: 87,1%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	5	6 ●	46 ●	57
ELISA, Orgentec	0	0 ●	18 ●	18
ELISA, Virion \ Serion	4	34 ●	21 ●	59
ELISA, Virotech	0	0 ●	8 ●	8
ELISA, other providers	12	0 ●	26 ●	38
CLIA, Diasorin	2	0 ●	93 ●	95
CLIA, Vircel	0	0 ●	10 ●	10
CLIA, other providers	0	0 ●	5 ●	5
other methods	1	0 ●	3 ●	4

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

diagnostic comment (N = 242, Rate of success: 68,6%)

Sample 61

Collective	no serological evidence for an infection	serological evidence for an acute infection	serological evidence for a past infection	total
all providers	26	199 ●	16	241

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

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
ELISA, Euroimmun	57 ●	0	0	57
ELISA, Orgentec	18 ●	0	0	18
ELISA, Virion \ Serion	46 ●	10	3	59
ELISA, Virotech	8 ●	0	0	8
ELISA, other providers	38 ●	0	0	38
CLIA, Diasorin	94 ●	0	1	95
CLIA, Vircel	10 ●	0	0	10
CLIA, other providers	5 ●	0	0	5
other methods	3 ●	1	0	4

Sample 62

Collective	no serological evidence for an infection	serological evidence for an acute infection	serological evidence for a past infection	total
all providers	204 ●	8	28	240