

CERTIFICATE

Survey of 01 November 2024

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

Infection Serology - Bordetella pertussis Antibodies (317):

Validity 24 months:

AB against Bordetella pertussis IgG (qualitative) - Immunological test (ELISA)

AB against Bordetella pertussis IgA (qualitative) - Immunological test (ELISA)

AB against Bordetella pertussis IgM (qualitative) - Immunological test (ELISA)

AB against Bordetella pertussis IgG - Immunoblot

AB against Bordetella pertussis IgM - Immunoblot

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 - Bordetella pertussis Antibodies (317):

AB against Bordetella pertussis IgG (qualitative) - Immunological test (ELISA)
AB against Bordetella pertussis IgG (semiquantitative) - Immunological test (ELISA)
AB against Bordetella pertussis IgA (qualitative) - Immunological test (ELISA)
AB against Bordetella pertussis IgM (qualitative) - Immunological test (ELISA)
AB against Bordetella pertussis IgG - Immunoblot
AB against Bordetella pertussis IgA - Immunoblot
AB against Bordetella pertussis IgM - Immunoblot
diagnostic comment

(R) analysis is subject to the RiliBÄK

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(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 - Bordetella pertussis Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Bordetella pertussis IgG (semiquantitative)	(1) 61		67.6								Sample not evaluated
	(1) 62		143								Sample not evaluated

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number	Antigen
AB against Bordetella pertussis IgG (semiquantitative)	61	IU/ml	67.6	1.00	190	TT	ZY99	0100111477	PT
	62		143	1.00					

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Bordetella pertussis IgG (qualitative)	61	190	TT	ZY99	borderline (2)	borderline, positive (2,3)	gM	+
	62				positive (3)	positive (3)	gM	+
AB against Bordetella pertussis IgA (qualitative)	61	190	TT	ZY99	borderline (2)	negative, borderline, positive (1,2,3)	gM	+
	62				negative (1)	negative (1)	gM	+
AB against Bordetella pertussis IgM (qualitative)	61	190	TT	ZY99	negative (1)	negative (1)	gM	+
	62				negative (1)	negative (1)	gM	+
AB against Bordetella pertussis IgG - Immunoblot	61		TT	ZY99	positive (3)	positive (3)	gM	+
	62				positive (3)	positive (3)	gM	+
AB against Bordetella pertussis IgA - Immunoblot	61		TT	ZY99	negative (1)	negative, borderline, positive (1,2,3)	gM	+
	62				borderline (2)	negative (1)	gM	-
AB against Bordetella pertussis IgM - Immunoblot	(2) 61		TT	ZY99	negative (1)	negative (1)	gM	+
	(2) 62				negative (1)	negative (1)	gM	+
diagnostic comment	61				serological evidence for an acute infection	serological evidence for a past infection (or immunisation), serological evidence for an acute infection	M	+
	62				serological evidence for a past infection (or immunisation)	serological evidence for a past infection (or immunisation), serological evidence for an acute infection	M	+

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

(2) In general, no certificate is issued for this parameter in this EQA scheme.

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 - Bordetella pertussis Antibodies

AB against Bordetella pertussis IgG (semiquantitative) (N = 199)

Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Antigen: Pertussis Toxin	61		Sample not evaluated			177		
	62		Sample not evaluated			177		
Antigen: PT plus FHA	61		Sample not evaluated			24		
	62		Sample not evaluated			24		
without Antigen indication (1)	61		Sample not evaluated			1		
	62		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

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Infection Serology - Bordetella pertussis Antibodies

AB against Bordetella pertussis IgG (qualitative) (N = 199, Rate of success: 95%)

Sample 61

Collective	positive (3)	borderline (2)	negative (1)	total
Pertussis Toxin, ELISA, Diasorin	4 ●	4 ●	0	8
Pertussis Toxin, ELISA, Euroimmun	42 ●	11 ●	2	55
Pertussis Toxin, ELISA, Orgentec	3 ●	0 ●	0	3
Pertussis Toxin, ELISA, Virion \ Serion	18 ●	18 ●	1	37
Pertussis Toxin, ELISA, Virotech	2 ●	3 ●	0	5
Pertussis Toxin, ELISA, other providers	9 ●	4 ●	1	14
Pertussis Toxin, other methods	24 ●	29 ●	1	54
PT plus FHA, ELISA, Virion \ Serion	9 ●	2 ●	0	11
PT plus FHA, ELISA, Virotech	6 ●	1 ●	0	7
PT plus FHA, ELISA, other providers	3 ●	0 ●	0	3
PT plus FHA, other methods	1 ●	1 ●	0	2

Sample 62

Collective	positive (3)	borderline (2)	total
Pertussis Toxin, ELISA, Diasorin	8 ●	0	8
Pertussis Toxin, ELISA, Euroimmun	55 ●	0	55
Pertussis Toxin, ELISA, Orgentec	3 ●	0	3
Pertussis Toxin, ELISA, Virion \ Serion	32 ●	5	37
Pertussis Toxin, ELISA, Virotech	5 ●	0	5
Pertussis Toxin, ELISA, other providers	14 ●	0	14
Pertussis Toxin, other methods	54 ●	0	54
PT plus FHA, ELISA, Virion \ Serion	11 ●	0	11
PT plus FHA, ELISA, Virotech	7 ●	0	7
PT plus FHA, ELISA, other providers	3 ●	0	3
PT plus FHA, other methods	2 ●	0	2

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

AB against Bordetella pertussis IgA (qualitative) (N = 177, Rate of success: 86,4%)

Sample 61

Collective	negative (1)	positive (3)	borderline (2)	total
Pertussis Toxin, ELISA, Diasorin	4 ●	0 ●	2 ●	6
Pertussis Toxin, ELISA, Euroimmun	22 ●	28 ●	4 ●	54
Pertussis Toxin, ELISA, Orgentec	0 ●	4 ●	0 ●	4
Pertussis Toxin, ELISA, Virion \ Serion	29 ●	1 ●	2 ●	32
Pertussis Toxin, ELISA, Virotech	3 ●	0 ●	1 ●	4
Pertussis Toxin, ELISA, other providers	3 ●	2 ●	5 ●	10
Pertussis Toxin, other methods	43 ●	3 ●	0 ●	46
PT plus FHA, ELISA, Virion \ Serion	3 ●	1 ●	6 ●	10
PT plus FHA, ELISA, Virotech	3 ●	0 ●	1 ●	4
PT plus FHA, ELISA, other providers	4 ●	1 ●	0 ●	5
Antigen: PT plus FHA	1 ●	0 ●	0 ●	1

Sample 62

Collective	negative (1)	positive (3)	borderline (2)	total
Pertussis Toxin, ELISA, Diasorin	4 ●	1	1	6
Pertussis Toxin, ELISA, Euroimmun	51 ●	1	2	54
Pertussis Toxin, ELISA, Orgentec	0 ●	4	0	4
Pertussis Toxin, ELISA, Virion \ Serion	30 ●	0	2	32
Pertussis Toxin, ELISA, Virotech	3 ●	0	1	4
Pertussis Toxin, ELISA, other providers	7 ●	3	0	10
Pertussis Toxin, other methods	45 ●	2	0	47
PT plus FHA, ELISA, Virion \ Serion	5 ●	0	5	10
PT plus FHA, ELISA, Virotech	4 ●	0	0	4
PT plus FHA, ELISA, other providers	4 ●	1	0	5
Antigen: PT plus FHA	1 ●	0	0	1

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

AB against Bordetella pertussis IgM (qualitative) (N = 32, Rate of success: 93,8%)

Sample 61

Collective	negative (1)	positive (3)	total
Euroimmun	13 ●	0	13
Virion \ Serion	10 ●	0	10
Virotech	1 ●	0	1
other Providers	7 ●	1	8

Sample 62

Collective	negative (1)	borderline (2)	total
Euroimmun	13 ●	0	13
Virion \ Serion	10 ●	0	10
Virotech	1 ●	0	1
other Providers	6 ●	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 Bordetella pertussis IgG - Immunoblot (N = 40, Rate of success: 100%)

Sample 61

Collective	positive (3)	total
Mikrogen	21 ●	21
Viramed	11 ●	11
other Providers	8 ●	8

Sample 62

Collective	positive (3)	total
Mikrogen	21 ●	21
Viramed	11 ●	11
other Providers	8 ●	8

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

AB against Bordetella pertussis IgA - Immunoblot (N = 35, Rate of success: 85,7%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
Mikrogen	15 ●	1 ●	1 ●	17
Viramed	9 ●	0 ●	1 ●	10
other Providers	4 ●	1 ●	3 ●	8

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
Mikrogen	17 ●	0	0	17
Viramed	9 ●	0	1	10
other Providers	4 ●	2	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 Bordetella pertussis IgM - Immunoblot (N = 2, Rate of success: 100%)

Sample 61

Collective	negative (1)	total
all providers	2 ●	2

Sample 62

Collective	negative (1)	total
all providers	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 = 180, Rate of success: 93,3%)

Sample 61

Collective	no serological evidence for an infection	serological evidence for a past infection (or immunisation)	serological evidence for an acute infection	total
all providers	8	127 ●	42 ●	177

Sample 62

Collective	no serological evidence for an infection	serological evidence for a past infection (or immunisation)	serological evidence for an acute infection	total
all providers	2	88 ●	90 ●	180

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