

CERTIFICATE

Survey of 06 June 2025

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

Infection Serology - Tetanus Toxoid Antibodies (310):

Validity 12 months:

AB against Tetanus toxoid (qualitative) - Immunological test (ELISA)

AB against Tetanus toxoid (semiquantitative) - Immunological test (CLIA)

AB against Tetanus toxoid (semiquantitative) - 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 - Tetanus Toxoid Antibodies (310):

AB against Tetanus toxoid (qualitative) - Immunological test (ELISA)

AB against Tetanus toxoid (semiquantitative) - Immunological test (CLIA)

AB against Tetanus toxoid (semiquantitative) - Immunological test (ELISA)

diagnostic comment

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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

Adviser:

Prof. Dr. med. K.-P. Hunfeld

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Infection Serology - Tetanus Toxoid Antibodies

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
AB against Tetanus toxoid (semiquantitative)	31	IU/ml	0.920	1.20	tSV	0.510	1.90	-23.3%	-0.743	+	
	32		2.46	3.35	tSV	1.20	5.50	-26.6%	-1.24	+	
	31	IU/ml	1.09	1.20	tSV	0.510	1.90	-9.2%	-0.292	+	
	32		2.03	3.35	tSV	1.20	5.50	-39.4%	-1.84	+	

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Lot number
AB against Tetanus toxoid (semiquantitative)	31		0.920	1.00	228	ZY	ZY99	0200119317
	32		2.46	1.00				
	31		1.09	1.00	190	ZY	ZY99	0100125300
	32		2.03	1.00				

Analyte	Sam- ple	Method	Manu- facturer	Device	Your specification(s)	Correct specification(s)	TV- Type	Meets criteria
AB against Tetanus toxoid (qualitative)	31	190	ZY	ZY99	positive (3)	positive (3)	gM	+
	32				positive (3)	positive (3)	gM	+
diagnostic comment	31				> 0.5 - 1.1 IU/ml; protective active immunity, booster vaccination in 2-5 years suggested	> 0.5 - 1.1 IU/ml; protective active immunity, booster vaccination in 2-5 years suggested, > 1.1 - 5.0 IU/ml; protective active immunity, booster vaccination in 5-10 years suggested	M	+
	32				> 1.1 - 5.0 IU/ml; protective active immunity, booster vaccination in 5-10 years suggested	> 1.1 - 5.0 IU/ml; protective active immunity, booster vaccination in 5-10 years suggested, > 5.0 IU/ml; protective active immunity, booster vaccination in 10 years suggested	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.

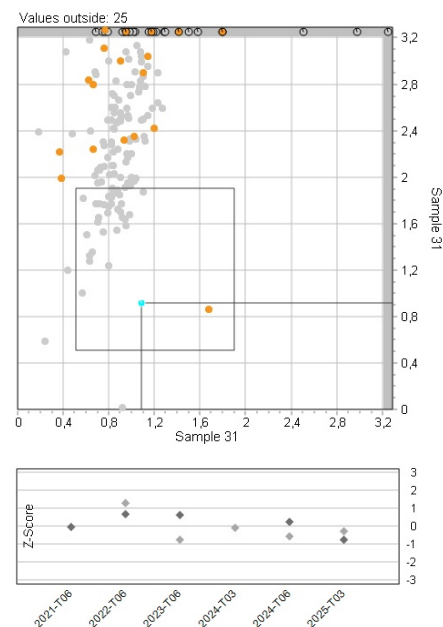
Survey of 06 June 2025

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Infection Serology - Tetanus Toxoid Antibodies

AB against Tetanus toxoid (semiquantitative) (IU/ml, N = 168)										
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.		total	
The Binding Site	31	1.20	0.510 - 1.90	0.816	46.3	9	77.8		77.8	
	32	3.35	1.20 - 5.50	2.60	19.8	9	100			
Euroimmun	31	1.20	0.510 - 1.90	0.982	13.3	54	96.3		96.3	
	32	3.35	1.20 - 5.50	2.34	26.3	54	100			
Vircell	31	1.20	0.510 - 1.90	0.910	24.0	21	95.2		75.0	
	32	3.35	1.20 - 5.50	4.35	58.6	21	71.4			
Virion \ Serion	31	1.20	0.510 - 1.90	0.805	17.4	54	94.4		90.7	
	32	3.35	1.20 - 5.50	2.22	30.8	54	94.4			
Sekisui Virotech	31	1.20	0.510 - 1.90	1.10	21.4	10	100		100	
	32	3.35	1.20 - 5.50	2.78	29.5	10	100			
other providers	31	1.20	0.510 - 1.90	0.997	37.8	22	90.9		85.7	
	32	3.35	1.20 - 5.50	2.84	25.2	22	95.5			

Rate of success: 89,9%



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Infection Serology - Tetanus Toxoid Antibodies

AB against Tetanus toxoid (qualitative) (N = 131, Rate of success: 97,7%)

Sample 31

Collective	negative (1)	positive (3)	total
The Binding Site	0	5 ●	5
Euroimmun	2	40 ●	42
Vircell	0	12 ●	12
Virion \ Serion	0	47 ●	47
Sekisui Virotech	0	10 ●	10
other providers	0	15 ●	15

Sample 32

Collective	negative (1)	positive (3)	total
The Binding Site	0	5 ●	5
Euroimmun	0	42 ●	42
Vircell	1	11 ●	12
Virion \ Serion	0	47 ●	47
Sekisui Virotech	0	10 ●	10
other providers	0	15 ●	15

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

diagnostic comment (N = 162, Rate of success: 94,4%)

Sample 31

Collective	0.1 - 0.5 IU/ml; existing protective immunity, booster vaccination provides long term immunity	> 0.5 - 1.1 IU/ml; protective active immunity, booster vaccination in 2-5 years suggested	> 1.1 - 5.0 IU/ml; protective active immunity, booster vaccination in 5-10 years suggested	total
all providers	6	127 ●	29 ●	162

Sample 32

Collective	< 0.1 IU/ml; no protective active immunity, immunisation suggested	> 0.5 - 1.1 IU/ml; protective active immunity, booster vaccination in 2-5 years suggested	> 1.1 - 5.0 IU/ml; protective active immunity, booster vaccination in 5-10 years suggested	> 5.0 IU/ml; protective active immunity, booster vaccination in 10 years suggested	total
all providers	1	3	147 ●	11 ●	162

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