

CERTIFICATE

Survey of 29 August 2025

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

Autoimmune Diseases 04 - Vasculitis / Glomerulopathies (257):

Validity 12 months:

anti-PR3 - qualitative (R: B2)

anti-MPO - qualitative (R: B2)

anti-glomerular basement membrane (GBM) - qualitative

(R) analysis is subject to the RiliBÄK

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



Düsseldorf, 20 October 2025



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



Dr. rer. nat. Martin Blüthner
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 29 August 2025

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

Autoimmune Diseases 04 - Vasculitis / Glomerulopathies (257):

anti-PR3 - qualitative (R: B2)

anti-MPO - qualitative (R: B2)

anti-glomerular basement membrane (GBM) - qualitative

(R) analysis is subject to the RiliBÄK

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Düsseldorf, 20 October 2025



Prof. Dr. med. Michael Spannagl
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Dr. rer. nat. Martin Blüthner
(Adviser)

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 29 August 2025

Adviser:

Dr. rer. nat. Martin Blüthner
 MVZ Labor PD Dr. Volkmann & Kollegen
 Kriegsstraße 99
 76133 Karlsruhe

Tel.: +49 721 85000 225
 Fax: +49 721 85000 115
 Mail: bluethner@laborvolkmann.de

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Autoimmune Diseases 04 - Vasculitis / Glomerulopathies

anti-PR3 - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 257A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	positive (1)	positive (1)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-MPO - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 257A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	positive (1)	positive (1)	SV		+

anti-glomerular basement membrane (GBM) - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 257A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

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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Autoimmune Diseases 04 - Vasculitis / Glomerulopathies

anti-PR3 - qualitative (N = 95, Rate of success: 94,7%)

Sample 257A-250812-01

Collective	negative	positive	total
all methods	5	90 ●	95

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

Sample 257A-250812-02

Collective	negative	positive	total
all methods	94 ●	1	95

anti-MPO - qualitative (N = 95, Rate of success: 98,9%)

Sample 257A-250812-01

Collective	negative	positive	total
all methods	95 ●	0	95

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

Sample 257A-250812-02

Collective	negative	positive	total
all methods	1	94 ●	95

anti-glomerular basement membrane (GBM) - qualitative (N = 42, Rate of success: 97,6%)

Sample 257A-250812-01

Collective	negative	positive	total
all methods	41 ●	1	42

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

Sample 257A-250812-02

Collective	negative	positive	total
all methods	42 ●	0	42