

CERTIFICATE

Survey of 29 August 2025

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

Autoimmune Diseases 01 - Connective Tissue Diseases (ANA) (251):

Validity 12 months:

Collagenosis Screening (ANA) - qualitative (R: B2)

anti-DFS70 / LEDGF - qualitative

Autoantibodies against dsDNA - qualitative (R: B2)

(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 01 - Connective Tissue Diseases (ANA) (251):

Collagenosis Screening (ANA) - qualitative (R: B2)

anti-DFS70 / LEDGF - qualitative

Autoantibodies against dsDNA - qualitative (R: B2)

(R) analysis is subject to the RiliBÄK

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



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:

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251

Autoimmune Diseases 01 - Connective Tissue Diseases (ANA)

Collagenosis Screening (ANA) - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 251A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	positive (1)	positive (1)	SV		+
	-02	positive (1)	negative (0), positive (1)	SV		+

anti-DFS70 / LEDGF - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	OTHER MANUFACTURERS (ZY)			
Result (qual)	Sample 251A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

Autoantibodies against dsDNA - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 251A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	positive (1)	negative (0), positive (1)	SV		+
	-02	negative (0)	negative (0), positive (1)	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.

Survey of 29 August 2025

251

Autoimmune Diseases 01 - Connective Tissue Diseases (ANA)

Collagenosis Screening (ANA) - qualitative (N = 86, Rate of success: 98,8%)

Sample 251A-250812-01

Collective	negative	positive	total
all methods	1	85 ●	86

Sample 251A-250812-02

Collective	negative	positive	total
all methods	36 ●	50 ●	86

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

anti-DFS70 / LEDGF - qualitative (N = 148, Rate of success: 98,6%)

Sample 251A-250812-01

Collective	negative	positive	total
all methods	146 ●	2	148

Sample 251A-250812-02

Collective	negative	positive	total
all methods	148 ●	0	148

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

Autoantibodies against dsDNA - qualitative (N = 109, Rate of success: 99,1%)

Sample 251A-250812-01

Collective	negative	positive	total
all methods	26 ●	83 ●	109

Sample 251A-250812-02

Collective	negative	positive	total
all methods	33 ●	75 ●	108

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