

CERTIFICATE

Survey of 14 March 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, 17 April 2025



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



Dr. rer. nat. Martin Blüthner
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 14 March 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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Dr. rer. nat. Martin Blüthner
(Adviser)

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 14 March 2025

Adviser:

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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	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	21	positive (1)	positive (1)	SV		+
	22	negative (0)				

Sample not evaluated

anti-DFS70 / LEDGF - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	OTHER MANUFACTURERS (ZY)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	21	negative (0)	negative (0)	SV		+
	22	negative (0)				

Sample not evaluated

Autoantibodies against dsDNA - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
(1)	21	negative (0)	negative (0), positive (1)	SV		+
	22	negative (0)				

Sample not evaluated

(1) Due to the fact that the criteria for testing the stability of the material were not satisfied, no evaluation of this sample is made.

Individual summary of results

10011570: TestLine Clinical Diagnostics s.r.o.

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Autoimmune Diseases 01 - Connective Tissue Diseases (ANA)

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

Sample 21

Collective	negative	positive	total
all methods	1	85 ●	86

Sample 22

Collective	negative	positive	total
all methods	31	55	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 = 140, Rate of success: 98,6%)

Sample 21

Collective	negative	positive	total
all methods	138 ●	1	139

Sample 22

Collective	negative	positive	total
all methods	138	0	138

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 = 116, Rate of success: 100%)

Sample 21

Collective	negative	positive	total
all methods	110 ●	6 ●	116

Sample 22

Collective	negative	positive	total
all methods	75	41	116

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