

CERTIFICATE

Survey of 29 August 2025

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

Autoimmune Diseases 03 - Connective Tissue Diseases (ENA) (255):

Validity 24 months:

anti-U1-snRNP - qualitative
anti-SmD - qualitative
anti-Sm - qualitative
anti-SS-A / Ro - qualitative
anti-SS-A / Ro (52 kD - proteins) - qualitative
anti-SS-A / Ro (60 kD - proteins) - qualitative
anti-SS-B / La - qualitative
anti-Topoisomerase-1 - qualitative
anti-PM / Scl - qualitative
anti-Jo 1 (Histidyl-tRNA-Synthetase) - 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 03 - Connective Tissue Diseases (ENA) (255):

anti-U1-snRNP - qualitative
anti-SmD - qualitative
anti-Sm - qualitative
anti-SS-A / Ro - qualitative
anti-SS-A / Ro (52 kD - proteins) - qualitative
anti-SS-A / Ro (60 kD - proteins) - qualitative
anti-SS-B / La - qualitative
anti-Topoisomerase-1 - qualitative
anti-PM / Scl - qualitative
anti-Jo 1 (Histidyl-tRNA-Synthetase) - qualitative

(R) analysis is subject to the RiliBÄK

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(Adviser)

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Autoimmune Diseases 03 - Connective Tissue Diseases (ENA)

anti-U1-snRNP - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	positive (1)	positive (1)	SV		+

anti-SmD - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-Sm - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-SS-A / Ro - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	positive (1)	positive (1)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-SS-A / Ro (52 kD - proteins) - qualitative

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	positive (1)	positive (1)	SV		+
	-02	negative (0)	negative (0)	SV		+

Listing and evaluation of the results

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anti-SS-A / Ro (60 kD - proteins) - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	positive (1)	positive (1)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-SS-B / La - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-Topoisomerase-1 - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-PM / Scl - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-250812	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	-01	negative (0)	negative (0)	SV		+
	-02	negative (0)	negative (0)	SV		+

anti-Jo 1 (Histidyl-tRNA-Synthetase) - qualitative

+

Name of test	Unit	Method	Manufacturer			
		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample 255A-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

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Autoimmune Diseases 03 - Connective Tissue Diseases (ENA)

anti-U1-snRNP - qualitative (N = 117, Rate of success: 91,5%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	117 ●	0	117

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	10	107 ●	117

anti-SmD - qualitative (N = 45, Rate of success: 100%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	45 ●	0	45

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	45 ●	0	45

anti-Sm - qualitative (N = 105, Rate of success: 96,2%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	104 ●	1	105

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	102 ●	3	105

anti-SS-A / Ro - qualitative (N = 68, Rate of success: 97,1%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	0	67 ●	67

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	67 ●	1	68

anti-SS-A / Ro (52 kD - proteins) - qualitative (N = 100, Rate of success: 53%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	2	98 ●	100

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	54 ●	46	100

anti-SS-A / Ro (60 kD - proteins) - qualitative (N = 87, Rate of success: 96,6%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	2	85 ●	87

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	86 ●	1	87

anti-SS-B / La - qualitative (N = 128, Rate of success: 100%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	128 ●	0	128

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	128 ●	0	128

anti-Topoisomerase-1 - qualitative (N = 95, Rate of success: 100%)

Sample 255A-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 255A-250812-02

Collective	negative	positive	total
all methods	95 ●	0	95

anti-PM / Scl - qualitative (N = 106, Rate of success: 99,1%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	106 ●	0	106

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	105 ●	1	106

anti-Jo 1 (Histidyl-tRNA-Synthetase) - qualitative (N = 129, Rate of success: 100%)

Sample 255A-250812-01

Collective	negative	positive	total
all methods	129 ●	0	129

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

Sample 255A-250812-02

Collective	negative	positive	total
all methods	129 ●	0	129