

CERTIFICATE

Survey of 29 August 2025

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

Autoimmune Diseases 11 - Gluten-Sensitive Enteropathies (271):

Validity 12 months:

anti-deamidated Gliadin IgG

anti-deamidated Gliadin IgA

anti-Transglutaminase IgA (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 11 - Gluten-Sensitive Enteropathies (271):

anti-Gliadin IgG
anti-Gliadin IgA
anti-deamidated Gliadin IgG
anti-deamidated Gliadin IgA
anti-Transglutaminase IgA (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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Autoimmune Diseases 11 - Gluten-Sensitive Enteropathies

anti-Gliadin IgG

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 271A- 250812	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	medium AB-concentration (3)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+
	-02	no AB-concentration (0)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		-

anti-Gliadin IgA

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 271A- 250812	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	positive borderline AB-concentration (1)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+
	-02	no AB-concentration (0)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		-

anti-deamidated Gliadin IgG

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 271A- 250812	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	medium AB-concentration (3)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+
	-02	high AB-concentration (4)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 29 August 2025

anti-deamidated Gliadin IgA

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 271A- 250812	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	positive borderline AB-concentration (1)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+
	-02	positive low AB-concentration (2)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+

anti-Transglutaminase IgA

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 271A- 250812	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	high AB-concentration (4)	positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+
	-02	medium AB-concentration (3)	positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+

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 11 - Gluten-Sensitive Enteropathies

anti-Gliadin IgG (N = 31, Rate of success: 90,3%)

Sample 271A-250812-01

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	1	3 ●	2 ●	19 ●	6 ●	31

Sample 271A-250812-02

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	2	1 ●	1 ●	9 ●	17 ●	30

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

anti-Gliadin IgA (N = 29, Rate of success: 58,6%)

Sample 271A-250812-01

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	10	5 ●	5 ●	6 ●	3 ●	29

Sample 271A-250812-02

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	3	9 ●	6 ●	7 ●	4 ●	29

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

anti-deamidated Gliadin IgG (N = 102, Rate of success: 98%)

Sample 271A-250812-01

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	0	4 ●	52 ●	39 ●	6 ●	101

Sample 271A-250812-02

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	1	2 ●	8 ●	49 ●	42 ●	102

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

anti-deamidated Gliadin IgA (N = 103, Rate of success: 95,1%)
Sample 271A-250812-01

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	1	12 ●	58 ●	26 ●	5 ●	102

Sample 271A-250812-02

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	3	13 ●	40 ●	32 ●	15 ●	103

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

anti-Transglutaminase IgA (N = 147, Rate of success: 97,3%)
Sample 271A-250812-01

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	0	1	1 ●	13 ●	131 ●	146

Sample 271A-250812-02

Collective	no AB-concentration (0)	positive borderline AB-concentration (1)	positive low AB-concentration (2)	medium AB-concentration (3)	high AB-concentration (4)	total
all methods	2	1	2 ●	63 ●	79 ●	147

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