

CERTIFICATE

Survey of 29 August 2025

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

Autoimmune Diseases 12 - Rheumatoid Arthritis (273):

Validity 12 months:

anti-CCP (cyclic citrulline peptide)

Validity 6 months:

Rheumatoid Factor (IgM) (R: B2)

Rheumatoid Factor (IgG) (R: B2)

Rheumatoid Factor (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 12 - Rheumatoid Arthritis (273):

anti-CCP (cyclic citrulline peptide)

Rheumatoid Factor (IgM) (R: B2)

Rheumatoid Factor (IgG) (R: B2)

Rheumatoid Factor (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)

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

273

Autoimmune Diseases 12 - Rheumatoid Arthritis

anti-CCP (cyclic citrulline peptide)

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 273A- 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	high AB-concentration (4)	medium AB-concentration (3), high AB-concentration (4)	ET		+

Rheumatoid Factor (IgM)

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 273A- 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	no AB-concentration (0)	no AB-concentration (0), positive borderline AB-concentration (1)	ET		+

Rheumatoid Factor (IgG)

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 273A- 250812	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	-01	positive low AB-concentration (2)	positive borderline AB-concentration (1), positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET		+
	-02	no AB-concentration (0)	no AB-concentration (0), positive borderline AB-concentration (1)	ET		+

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 29 August 2025

Rheumatoid Factor (IgA)

+

Name of test	Unit	Method	Manufacturer			
		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Rating category	Sample 273A- 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	no AB-concentration (0)	no AB-concentration (0), positive borderline AB-concentration (1)	ET		+

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

273

Autoimmune Diseases 12 - Rheumatoid Arthritis

anti-CCP (cyclic citrulline peptide) (N = 176, Rate of success: 100%)

Sample 273A-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	0	1 ●	16 ●	159 ●	176

Sample 273A-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	0	0	0	5 ●	171 ●	176

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

Rheumatoid Factor (IgM) (N = 59, Rate of success: 96,6%)

Sample 273A-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	0	8 ●	27 ●	24 ●	59

Sample 273A-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	52 ●	5 ●	2	0	0	59

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

Rheumatoid Factor (IgG) (N = 45, Rate of success: 73,3%)

Sample 273A-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	11	6 ●	16 ●	10 ●	2 ●	45

Sample 273A-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	43 ●	1 ●	0	1	0	45

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

Rheumatoid Factor (IgA) (N = 54, Rate of success: 100%)

Sample 273A-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	0	2 •	18 •	34 •	54

Sample 273A-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	52 •	2 •	0	0	0	54

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