INSTAND

CERTIFICATE

Survey of 30 August 2024

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

Autoimmune Diseases 12 - Rheumatoid Arthritis (273):

Validity 12 months:

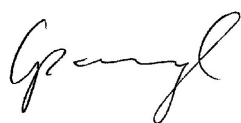**anti-CCP (cyclic citrulline peptide)**
Rheumatoid Factor (IgM) (R: B2)
Rheumatoid Factor (IgG) (R: B2)
Rheumatoid Factor (IgA) (R: B2)

(R) analysis is subject to the RiliBÄK

Customer:
10011570
TestLine Clinical Diagnostics s.r.o.
Krizikova 188/68
61200 Brno

DAkkS
Deutsche
Akkreditierungsstelle
D-EP-15027-02-00

INSTAND
Qualitätskontrolle
und Ringversuch
DÜSSELDORF
Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V.

Düsseldorf, 23 October 2024

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

Dr. rer. nat. Martin Blüthner
(Adviser)

INSTAND
Gesellschaft zur Förderung der Qualitätssicherung
in medizinischen Laboratorien e.V.
Ubierstr. 20 | 40223 Düsseldorf

10011570

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CERTIFICATE OF PARTICIPATION

Survey of 30 August 2024

You have participated in the External Quality Assessment with the following analysis

Autoimmune Diseases 12 - Rheumatoid Arthritis (273):

anti-CCP (cyclic citrulline peptide)
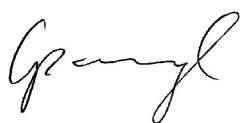Rheumatoid Factor (IgM) (R: B2)
Rheumatoid Factor (IgG) (R: B2)
Rheumatoid Factor (IgA) (R: B2)

(R) analysis is subject to the RiliBÄK

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Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 30 August 2024

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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	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
	51	high AB-concentration (4)	positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET	+
	52	medium AB-concentration (3)	positive borderline AB-concentration (1), positive low AB-concentration (2), 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	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
	51	high AB-concentration (4)	positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET	+
	52	high AB-concentration (4)	positive low AB-concentration (2), medium AB-concentration (3), high AB-concentration (4)	ET	+

Rheumatoid Factor (IgG)   +

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

Survey of 30 August 2024

Rheumatoid Factor (IgA) +

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

Survey of 30 August 2024

273	Autoimmune Diseases 12 - Rheumatoid Arthritis

anti-CCP (cyclic citrulline peptide) (N = 181, Rate of success: 96,7%)

Sample 51

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	5 ●	19 ●	153 ●	181

Sample 52

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	15 ●	72 ●	75 ●	16 ●	181

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 = 53, Rate of success: 100%)

Sample 51

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	6 ●	20 ●	27 ●	53

Sample 52

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	10 ●	26 ●	17 ●	53

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 = 38, Rate of success: 76,3%)

Sample 51

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	6	7 ●	12 ●	12 ●	1 ●	38

Sample 52

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	7	10 ●	11 ●	9 ●	1 ●	38

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 = 49, Rate of success: 95,9%)

Sample 51

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	1	3 ●	12 ●	32 ●	49

Sample 52

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	12 ●	10 ●	12 ●	15 ●	49

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