

CERTIFICATE

Survey of 22 November 2024

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

Virus Immunology - SARS-CoV-2 (Ab) (416):

Validity 12 months:

Anti-SARS-CoV-2 IgG

Anti-SARS-CoV-2 IgA

(R) analysis is subject to the RiliBÄK

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

Düsseldorf, 19 December 2024



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



Dr. med. Martin Obermeier
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 22 November 2024

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

Virus Immunology - SARS-CoV-2 (Ab) (416):

Anti-SARS-CoV-2 IgG

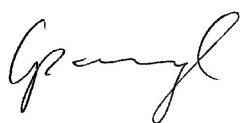
Anti-SARS-CoV-2 IgA

Anti-SARS-CoV-2 IgM

(R) analysis is subject to the RiliBÄK

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Dr. med. Martin Obermeier
(Adviser)

Adviser:
Dr. med. Martin Obermeier

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416

Virus Immunology - SARS-CoV-2 (Ab)

Anti-SARS-CoV-2 IgG

+

Name of test	Unit	Method	Manufacturer			
EIA COVID-19 RBD IgG		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	positive (3)	positive (3)	SV		+
Name of test	Unit	Method	Manufacturer			
EIA COVID-19 NP IgG		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
(1)	416A-241105-03	borderline (2)	negative (1)	SV		
(1)	416A-241105-04	borderline (2)	negative (1)	SV		
Name of test	Unit	Method	Manufacturer			
CLIA COVID-19 RBD IgG		Immunological test (CLIA) (228)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	positive (3)	positive (3)	SV		+
Name of test	Unit	Method	Manufacturer			
CLIA COVID-19 NP IgG		Immunological test (CLIA) (228)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	negative (1)	negative (1)	SV		+
Name of test	Unit	Method	Manufacturer			
Microblot-Array COVID-19 IgG		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	positive (3)	positive (3)	SV		+

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 22 November 2024

Anti-SARS-CoV-2 IgA

+

Name of test	Unit	Method	Manufacturer			
EIA COVID-19 RBD IgA		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	negative (1)	negative (1)	SV		+
Name of test	Unit	Method	Manufacturer			
EIA COVID-19 NP IgA		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	negative (1)				
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	negative (1)	negative (1)	SV		+
Name of test	Unit	Method	Manufacturer			
Microblot-Array COVID-19 IgA		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	positive (3)	positive (3)	SV		+
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	negative (1)	negative (1)	SV		+
Name of test	Unit	Method	Manufacturer			
CLIA COVID-19 NP IgA		Immunological test (CLIA) (228)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)	negative (1)	SV		+
	416A-241105-02	negative (1)				
	416A-241105-03	negative (1)	negative (1)	SV		+
	416A-241105-04	negative (1)	negative (1)	SV		+

Sample not evaluated

Sample not evaluated

Anti-SARS-CoV-2 IgM

Name of test	Unit	Method	Manufacturer			
EIA COVID-19 RBD IgM		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)				
	416A-241105-02	negative (1)				
	416A-241105-03	negative (1)				
	416A-241105-04	negative (1)				
Name of test	Unit	Method	Manufacturer			
EIA COVID-19 NP IgM		Immunological test (ELISA) (190)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	416A-241105-01	negative (1)				
	416A-241105-02	negative (1)				
	416A-241105-03	negative (1)				
	416A-241105-04	negative (1)				

Sample not evaluated
Sample not evaluated
Sample not evaluated
Sample not evaluated

Sample not evaluated
Sample not evaluated
Sample not evaluated
Sample not evaluated

Listing and evaluation of the results

10011570: TestLine Clinical Diagnostics s.r.o.

Survey of 22 November 2024

Anti-SARS-CoV-2 IgM

Name of test	Unit	Method	Manufacturer			
CLIA COVID-19 NP IgM		Immunological test (CLIA) (228)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	416A-241105-01	negative (1)				
	416A-241105-02	negative (1)				
	416A-241105-03	negative (1)				
	416A-241105-04	negative (1)				
Name of test	Unit	Method	Manufacturer			
Microblot-Array COVID-19 IgM		Immunoblot (247)	TEST-LINE (TT)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV- Type		Meets criteria
	416A-241105-01	negative (1)				
	416A-241105-02	negative (1)				
	416A-241105-03	negative (1)				
	416A-241105-04	negative (1)				

Sample not evaluated
Sample not evaluated
Sample not evaluated
Sample not evaluated

Sample not evaluated
Sample not evaluated
Sample not evaluated
Sample not evaluated

(1) This result is not considered for the certificate, because results of further tests / for further gene regions are evaluated as "correct" for all evaluated samples.