

# CERTIFICATE

Survey of 25 June 2021

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

## Virus Antigen Detection - SARS-CoV-2 (Ag) (410):

Validity 12 months:

SARS-CoV-2 antigen (Rapid Test)

## Virus Genome Detection - Coronaviruses incl. SARS CoV-2 (340):

Validity 12 months:

MERS coronavirus (RNA) - qualitative

SARS-CoV-2 (RNA) - qualitative

## Virus Genome Detection - SARS-CoV-2 (409):

Validity 12 months:

SARS-CoV-2 (RNA) - qualitative

(R) analysis is subject to the RiliBÄK

### Participant:

5577

Nat. Center of Infectious and Parasitic Diseases

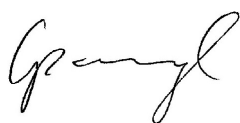
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Düsseldorf, 02 August 2021



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



Prof. Dr. rer. nat. Heinz Zeichhardt  
(Adviser)

# CERTIFICATE OF PARTICIPATION

Survey of 25 June 2021

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

## Virus Antigen Detection - SARS-CoV-2 (Ag) (410):

SARS-CoV-2 antigen (Rapid Test)

## Virus Detection (Genome/Antigen) - Respiratory Syncytial Virus (359):

RSV (RNA) - qualitative (R: B3)

## Virus Genome Detection - Coronaviruses incl. SARS CoV-2 (340):

MERS coronavirus (RNA) - qualitative

SARS-CoV-2 (RNA) - qualitative

Other human coronaviruses (RNA) - qualitative

## Virus Genome Detection - SARS-CoV-2 (409):

SARS-CoV-2 (RNA) - qualitative

(R) analysis is subject to the RiliBÄK

### Participant:

5577

Nat. Center of Infectious and Parasitic Diseases

Prof. Todor Kantardjiev

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1504 Sofia



Düsseldorf, 02 August 2021

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

Prof. Dr. rer. nat. Heinz Zeichhardt  
(Adviser)

### Survey of 25 June 2021

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**410**

### Virus Antigen Detection - SARS-CoV-2 (Ag)

**SARS-CoV-2 antigen (Rapid Test)** +

Name of test	Unit	Method	Manufacturer			
Novel Coronavirus Antigen Rapid Test Kit		Rapid Test (382)	JINWOFU BIOENGINEERING TECHNOLOGY (JIN)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	410006	positive (3)	positive (3)	SV		+
	410007	negative (1)				
	410008	negative (1)	negative (1)	SV		+
	410009	positive (3)	positive (3)	SV		+
	410010	negative (1)	negative (1)	SV		+

Sample not evaluated

**359**

### Virus Detection (Genome/Antigen) - Respiratory Syncytial Virus

**RSV (RNA) - qualitative**

Name of test	Unit	Method	Manufacturer			
		PCR / NAT (395)	IN-HOUSE PRODUCTION (ZX)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	359069	positive (3)	positive (3)	SV		+
	359070	positive (3)	positive (3)	SV		+
	359071	positive (3)	positive (3)	SV		+
	359072	positive (3)	below detection limit/negative (1)	SV		-

**340**

### Virus Genome Detection - Coronaviruses incl. SARS CoV-2

**MERS coronavirus (RNA) - qualitative** +

Name of test	Unit	Method	Manufacturer			
		PCR / NAT (395)	IN-HOUSE PRODUCTION (ZX)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	340082	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340083	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340084	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340085	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340086	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340087	positive (3)	positive (3)	SV		+

## Listing and evaluation of the results

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### Survey of 25 June 2021

#### Other human coronaviruses (RNA) - qualitative

Name of test	Unit	Method	Manufacturer			
		PCR / NAT (395)	IN-HOUSE PRODUCTION (ZX)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	340082	positive for HCoV NL63 (NL63)	positive for HCoV NL63 (NL63), positive for HCoV (for non differentiating HCoV tests) (Non)	SV		+
	340083	positive for HCoV NL63 (NL63)	below detection limit/negative (1)	SV		-
	340084	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340085	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340086	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340087	below detection limit/negative (1)	below detection limit/negative (1)	SV		+

#### SARS-CoV-2 (RNA) - qualitative

+

Name of test	Unit	Method	Manufacturer			
TaqPath COVID-19 RT-PCR Kit		PCR / NAT (395)	THERMO FISHER SCIENTIFIC (TFS)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	340082	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340083	positive (3)	positive (3)	SV		+
	340084	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340085	positive (3)	positive (3)	SV		+
	340086	positive (3)	positive (3)	SV		+
	340087	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
Primer / Gene region	Sample	Your value				
	340082	ORF1ab				
	340083	ORF1ab				
	340084	ORF1ab				
	340085	ORF1ab				
	340086	ORF1ab				
	340087	ORF1ab				

## Listing and evaluation of the results

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### Survey of 25 June 2021

Name of test	Unit	Method	Manufacturer			
TaqPath COVID-19 RT-PCR Kit		PCR / NAT (395)	THERMO FISHER SCIENTIFIC (TFS)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	340082	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340083	positive (3)	positive (3)	SV		+
	340084	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340085	positive (3)	positive (3)	SV		+
	340086	positive (3)	positive (3)	SV		+
	340087	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
Primer / Gene region	Sample	Your value				
	340082	N gene				
	340083	N gene				
	340084	N gene				
	340085	N gene				
	340086	N gene				
	340087	N gene				
Name of test	Unit	Method	Manufacturer			
TaqPath COVID-19 RT-PCR Kit		PCR / NAT (395)	THERMO FISHER SCIENTIFIC (TFS)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	340082	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340083	positive (3)	positive (3)	SV		+
	340084	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
	340085	positive (3)	positive (3)	SV		+
	(1) 340086	below detection limit/negative (1)	positive (3)	SV		
	340087	below detection limit/negative (1)	below detection limit/negative (1)	SV		+
Primer / Gene region	Sample	Your value				
	340082	S gene				
	340083	S gene				
	340084	S gene				
	340085	S gene				
	340086	S gene				
	340087	S gene				

(1) This result was not taken into account for the granting of the certificate.

### Survey of 25 June 2021

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## Virus Genome Detection - SARS-CoV-2

### SARS-CoV-2 (RNA) - qualitative +

Name of test	Unit	Method	Manufacturer		
TaqPath COVID-19 RT-PCR Kit		PCR / NAT (395)	THERMO FISHER SCIENTIFIC (TFS)		
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
	409006	positive (3)	positive (3)	SV	+
	409007	below detection limit/negative (1)	below detection limit/negative (1)	SV	+
	409008	positive (3)	positive (3)	SV	+
	409009	positive (3)	positive (3)	SV	+
	409010	below detection limit/negative (1)	below detection limit/negative (1)	SV	+
Primer / Gene region	Sample	Your value			
	409006	ORF1ab			
	409007	ORF1ab			
	409008	ORF1ab			
	409009	ORF1ab			
	409010	ORF1ab			
Name of test	Unit	Method	Manufacturer		
TaqPath COVID-19 RT-PCR Kit		PCR / NAT (395)	THERMO FISHER SCIENTIFIC (TFS)		
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
	409006	positive (3)	positive (3)	SV	+
	409007	below detection limit/negative (1)	below detection limit/negative (1)	SV	+
	409008	positive (3)	positive (3)	SV	+
	409009	positive (3)	positive (3)	SV	+
	409010	below detection limit/negative (1)	below detection limit/negative (1)	SV	+
Primer / Gene region	Sample	Your value			
	409006	N gene			
	409007	N gene			
	409008	N gene			
	409009	N gene			
	409010	N gene			
Name of test	Unit	Method	Manufacturer		
TaqPath COVID-19 RT-PCR Kit		PCR / NAT (395)	THERMO FISHER SCIENTIFIC (TFS)		
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
	(1) 409006	below detection limit/negative (1)	positive (3)	SV	
	409007	below detection limit/negative (1)	below detection limit/negative (1)	SV	+
	409008	positive (3)	positive (3)	SV	+
	409009	positive (3)	positive (3)	SV	+
	409010	below detection limit/negative (1)	below detection limit/negative (1)	SV	+
Primer / Gene region	Sample	Your value			
	409006	S gene			
	409007	S gene			
	409008	S gene			
	409009	S gene			
	409010	S gene			



## Listing and evaluation of the results

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Prof. Todor Kantardjiev

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### Survey of 25 June 2021

(1) This result was not taken into account for the granting of the certificate.