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# INSTAND

Summary of sample properties and  
target values of the  
External Quality Assessment Scheme  
Virus Genome Detection -  
Coronaviruses incl. SARS-CoV-2

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# INSTAND EQA schemes in virology

in cooperation with:

Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV)

Gesellschaft für Virologie e.V. (GfV)

Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (DGHM)

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# INSTAND External Quality Assessment Schemes – June/July 2020

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

Dear colleagues,

You have registered for the INSTAND external quality assessment (EQA) scheme Virus Genome Detection - Coronaviruses incl. SARS-CoV-2 of June/July 2020. Today you receive information on the provision of your participation documents and the provision of the *summary of sample properties and target values*.

Since the EQAS term September 2019, your participation documents are available only online. Paper based documents are not sent by mail anymore.

### 1. Participation documents

With the "EQAS (RV) Online system", you have direct access to your individual participation documents for the corresponding EQA scheme via the button "Evaluation" after login on the INSTAND website <https://rv-online.instandev.de/>.

For download are available:

- certificate (button "Certificate Download")
- certificate, certificate of participation, listing and evaluation of results (button "Evaluation Download")
- individual summary of results (button "General overview Download")

Regarding the results for SARS-CoV-2, please note:

*The qualitative results for SARS-CoV-2 are shown in the "individual summary of results" differentiated by test manufacturer and test name.*

*A more detailed listing of qualitative results for SARS-CoV-2 - differentiated by gene region, test manufacturer and test name - will be shown in the report.*

### 2. Summary of sample properties and target values

The "Summary of sample properties and target values" is available:

- by email with a link to the document "Summary of sample properties and target values" and
- on the INSTAND homepage under "EQAS Online / Service for EQA tests / EQA area (Virus genome detection)"  
in English language: <http://www.instand-ev.de/en/eqas-online/service-for-eqa-tests.html> and  
in German language: <http://www.instand-ev.de/ringversuche-online/ringversuche-service.html>.

Please see the following Table 1 for details on sample properties and the expected target values for this EQA scheme June/July 2020.

The report for this EQA scheme will be released on the INSTAND homepage immediately after completion. For details please see the INSTAND homepage under

"EQAS Online / Service for EQA tests / EQA area (Virus genome detection)"

in English language: <http://www.instand-ev.de/en/eqas-online/service-for-eqa-tests.html> and

in German language: <http://www.instand-ev.de/ringversuche-online/ringversuche-service.html>.

For the parameter "SARS-CoV-2 (RNA) – qualitative", the qualitative results will be shown in the report, differentiated by

- gene region,
- test manufacturer,
- test name.

## ACKNOWLEDGEMENT

We thank our cooperation partner at Charité – Universitätsmedizin Berlin:

- Charité - Universitätsmedizin Berlin, Institut für Virologie Nationales Konsiliarlaboratorium für Coronaviren, Helmut-Ruska-Haus, Prof. Dr. Christian Drosten, Dr. Victor M. Corman, Dr. Daniela Niemeyer

Furthermore, we thank the following INSTAND expert laboratories:

- Universitätsklinikum Frankfurt, Institut für Medizinische Virologie, Prof. Dr. Sandra Ciesek, Prof. Dr. Holger F. Rabenau, Prof. Dr. Annemarie Berger
- Medizinisches Infektiologiezentrum Berlin, Dr. Martin Obermeier, Dr. Robert Ehret
- Uniklinik Köln, Institut für Virologie, Nationales Referenzzentrum für Papillom- und Polyomaviren, Prof. Dr. Florian Klein, Prof. Dr. Ulrike Wieland, Dr. Steffi Silling, Dr. Rolf Kaiser, Dr. Eva Heger, Dr. Elena Knops
- LGC, UK National Measurement Laboratory for Chemical and Bio-Measurement, Teddington, UK Dr. Jim Huggett, Dr. Denise O'Sullivan
- Medizinische Hochschule Hannover, Institut für Virologie, Nationales Konsiliarlaboratorium für Adenoviren, Prof. Dr. Thomas Schulz, PD Dr. Albert Heim, Dr. Wolfram Puppe, Dr. Corinna Schmitt
- Robert Koch-Institut, Abt. Infektionskrankheiten, FG 17 Influenzaviren und weitere Viren des Respirationstraktes, Nationales Referenzzentrum für Influenza, Nationales Konsiliarlaboratorium für Respiratorische Syncytialviren (RSV), Parainfluenzaviren, Metapneumoviren, Berlin: Dr. Ralf Dürrwald, Dr. Barbara Biere, Dr. Janine Reiche
- Universitätsklinikum Bonn, Institut für Virologie, Prof. Dr. Anna-Maria Eis-Hübinger
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- Universitätsklinikum Freiburg, Institut für Virologie, Nationales Konsiliarlaboratorium für HSV und VZV, Prof. Dr. Hartmut Hengel, Dr. Daniela Huzly, Prof. Dr. Marcus Panning

For quantitative characterization of the SARS-CoV-2 positive samples by digital PCR (dPCR), we thank:

- LGC, UK National Measurement Laboratory for Chemical and Bio-Measurement, Teddington, UK Dr. Jim Huggett, Dr. Denise O'Sullivan
- Physikalisch-Technische Bundesanstalt, AG 8.32 Zell- und molekularbiologische Messverfahren Prof. Dr. Rainer Macdonald, Dr. Andreas Kummrow, Dr. Annabell Plauth, Dr. Samreen Falak
- National Institute of Standards and Technology, Applied Genetics Group, Gaithersburg, U.S.A. Dr. Peter Vallone, Dr. Megan Cleveland

Surplus samples of the current Extra EQA scheme June/July 2020 and previous EQA schemes in virus diagnostics are available for test assessment of your virus diagnostics. Please contact INSTAND e.V. for details.

Thank you for your kind cooperation.

Prof. Dr. Heinz Zeichhardt

Dr. Martin Kammel

**Table 1: EQA Scheme Virus Genome Detection -  
Coronaviruses incl. SARS-CoV-2 June/July 2020 -  
Summary of sample properties and target values**

Program	Group	RiliBÄK	Sample	Sample properties			Target value of all methods copies/ml § robust mean calculated from EQAS data  (* via dPCR assigned quantitative value)
				qualitative	virus	dilution	
Corona- viruses (RNA)  ¹tissue culture supernatant  ²cell lysate	340	conform to B 3	340066*. <sup>1</sup>	positive* not evaluated	SARS-CoV-2 <sup>1</sup> (inactivated)	(a) 1 : 5 000 000	2 943 <sup>§,*</sup>  (1 570 ± 360)*
			340067 <sup>1</sup>	positive	MERS-CoV <sup>1</sup> (inactivated)	1 : 1 000	26 646 636 <sup>§</sup>
			340068 <sup>1</sup>	positive	HCoV 229E <sup>1</sup>	1 : 1 000	----#
			340069 <sup>1</sup>	positive	SARS-CoV-2 <sup>1</sup> (inactivated)	(a) 1 : 50 000	268 471 <sup>§</sup>
			340070 <sup>2</sup>	negative	MRC-5-cells <sup>2</sup> as negative control	1 : 6	0
			340071**. <sup>1</sup>	weak positive** not evaluated (educative sample)	SARS-CoV-2 <sup>1</sup> (inactivated)	(a) 1 : 50 000 000	not evaluated**
			340072 <sup>1</sup>	positive	HCoV NL63 <sup>1</sup>	1 : 1 000	----#
			340073 <sup>1</sup>	positive	SARS-CoV-2 <sup>1</sup> (inactivated)	(a) 1 : 500 000	25 002 <sup>§</sup>
			340074 <sup>1</sup>	positive	HCoV OC43 <sup>1</sup>	1 : 1 000	----#

Non-marked samples derive from independent preparations.

a: For the SARS-CoV-2 positive samples diluted in consecutive steps was used:

Strain: BetaCoV/Munich/ChVir984/2020, inactivated, provided by Nationales Konsiliarlaboratorium für Coronaviren, Charité – Universitätsmedizin Berlin, Institut für Virologie, Prof. Dr. Christian Drosten, Dr. Victor M. Corman, Dr. Daniela Niemeyer

\* Sample 340066:

The results of this sample are not taken into account in any parameter when issuing a certificate of successful participation (not evaluated).

This sample has an assigned value of 1 570 ± 360 copies/ml by means of digital RT PCR (dPCR) and has been provided to the EQAS participants with revealed properties for orientation already during the EQA scheme.

This dPCR assigned value of 1 570 ± 360 copies/ml is a preliminary value combining the measurements from three National Measurement Institutes:

- National Measurement Laboratory for Chemical and Bio-Measurement, LGC, Teddington, UK
- Physikalisch-Technische Bundesanstalt, AG 8.32 Zell- und molekularbiologische Messverfahren, Berlin, Germany
- National Institute of Standards and Technology, Applied Genetics Group, Gaithersburg, U.S.A..

The value of 2943 copies/ml represents the consensus value of all reported quantitative results in the EQA scheme (robust average according to algorithm A/DIN ISO 13528/Annex C).

\*\* Sample 340071:

This sample is weak positive for SARS-CoV-2 and with a dilution of 1 : 50 000 000 this sample was conceived as an educative sample. For this reason, the results of this sample are not taken into account in the following parameters when issuing a certificate of successful participation (not evaluated):

- Coronavirus (RNA) – qualitative without differentiation
- SARS-CoV-2 (RNA) – quantitative
- SARS-CoV-2 (RNA) – qualitative
- Interpretation of Results

§ The quantitative target value for a given sample is derived from the consensus value from all quantitative results (based on the robust average according to algorithm A/DIN ISO 13528/Annex C)

# A target value has not been assigned due to the limited number of quantitative analyses. An evaluation interval has instead been set for each of the corresponding positive samples by the EQA scheme adviser (ET), considering the results of the INSTAND Expert Laboratories. The evaluation interval is shown in "listing and evaluation of the results" and in the report.