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INSTAND

Report on Extra External Quality Assessment Scheme Group No. 340 Virus Genome Detection – SARS-CoV-2

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INSTAND EQA schemes in virology

in cooperation with:

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

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for their outstanding support in the introduction of this EQA scheme.

Important comment:
Only 4 of the 7 samples, examined in this extra EQA scheme, will be considered for obtaining a certificate of successful participation

While this extra EQA scheme was still running, i.e. before the end of the extended submission deadline on 28 April 2020, INSTAND e.V. received urgent inquiries from home and abroad to uncover the properties of the samples to be examined, so that laboratories could improve their test method at short notice in the event of any incorrect measurements.

In coordination with the "Gemeinsame Diagnostikkommussion" (Joint Diagnostic Council) of the “Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten” (DVV e.V.) and the “Gesellschaft für Virologie” (GfV e.V.), INSTAND e.V. therefore decided to uncover the sample properties of 3 out of the 7 samples during the still running EQA scheme. An interim evaluation report has been published based on the results of 112 laboratories as of April 14, 2020, 1:57 p.m. Berlin time under:
https://www.instand-ev.de/fileadmin/uploads/user_upload/Dokumente/Virologie/20200417g_EN_EQAS_340_SARS-CoV-2_interim_evaluation.pdf

Sample with results already uncovered in the interim evaluation
Samples 340059, 340060 and 340064:
All submitted results for these 3 “uncovered” samples are only shown in this report, but are not taken into account when issuing the certificate of successful participation.

Samples whose properties are only revealed with this comment:
Samples 340061, 340062, 340063 and 340065:
The results for these four samples submitted by the extended submission deadline on April 28, 2020 are taken into account when issuing the certificate of successful participation.

Presentation of results:
The following report shows the results for all 7 samples examined in this EQA scheme differentiated with regard to the targeted gene regions of SARS-CoV-2.

Outline of the report

1 Notes to the evaluation

1.1 Guidelines of the German Medical Association (RiliBÄK)

The INSTAND External Quality Assessment (EQA) scheme "Virus Genome Detection - Coronaviruses" (340) is not listed in the Guidelines of the German Medical Association on quality assurance in medical laboratory testing (Bundesärztekammer/ RiliBÄK = Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen). However, it is performed by INSTAND e.V. in accordance to the requirements of the specified RiliBÄK Section B 3 "Direct detection and characterisation of infectious agents".

Please note:

• According to the decision of the Board of the German Medical Association from 18 October 2019, new Guidelines of the German Medical Association on quality assurance in medical laboratory testing (RiliBÄK 2019) have been released on 23 December 2019 in the "Deutsches Ärzteblatt" (DOI: 10.3238/arztebl.2019.rili_baek_QS_Labor20192312, English version will follow). The following additional EQA schemes are now subject to the RiliBÄK: Immunological EQA schemes (see Table B2-2) Measles virus, antibodies against Mumps virus, antibodies against Varicella zoster virus, antibodies against EQA schemes for direct detection and characterization of infectious agents (see Table B3-2) Hepatitis E virus, genome detection Measles virus, genome detection Mumps virus, genome detection Norovirus, genome detection Rubella virus, genome detection West Nile virus, genome detection	PDF
• The following report for the EQA term April 2020 will still refer to the previous RiliBÄK version in accordance with the decision of the Executive Board from 11 April 2014 and 20 June 2014 (published in German language: Deutsches Ärzteblatt, Jg. 111, Heft 38, 19. November/December 2014, A 1583 - A 1618). The RiliBÄK version of 2014 will expire on 22 December 2021 after the end of the transition period for the recently released RiliBÄK 2019.	PDF

1.2 Release of reports of EQA schemes in virus diagnostics

Each participant of this EQA scheme receives an email with a table allowing to directly open and/or save the report of the corresponding EQA scheme by clicking the respective download button.

Furthermore, each report of a defined EQA scheme will be released on the INSTAND homepage immediately after completion as PDF file 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).

1.3 Participation documents

For this Extra EQA scheme (340) "Virus Genome Detection – SARS-CoV-2" April 2020, the following participation documents are available online in EQAS Online (https://rv-online.instandev.de/index.shtml?lang=en):

- certificate,
- certificate of participation,
- listing and evaluation of the results,
- individual summary of results.

The " listing and evaluation of the results" lists the respective tests/analytes, assigned to defined parameters, for which the requirements of the EQA scheme are met. Each parameter is individually evaluated for the "certificate" and separately listed in all participation and evaluation documents.

The EQA scheme "Virus Genome Detection – SARS-CoV-2" (340) comprises the following parameters:

Parameters

(70) SARS-CoV-2 (RNA) – qualitative

(60) SARS-CoV-2 (RNA) – quantitative

1.3.1 Receiving a certificate of successful participation

The INSTAND Extra EQA scheme "Virus Genome Detection – SARS-CoV-2" (340) is not listed in the RiliBÄK, however, it is performed by INSTAND e.V. in accordance to the requirements of the specified RiliBÄK Section B 3 from November 2014. The evaluation criteria for the results of EQA schemes for the detection of virus genome follow the Guidelines of the German Medical Association, RiliBÄK section E 3 "Special requirements for round robin testing of medical laboratory detection and characterisation of infectious agents" under (3) Analyzing the round robin test results, sentence 1:
"Analysis is performed using the target results. The assessment criteria must be fulfilled for every sample."
This means for the 4 samples (taken into account when issuing a certificate of successful participation) that 100% correct results must be achieved according to the target values.

Example - Program "Virus Genome Detection – SARS-CoV-2*" (340):*
All 4 samples 3400061, 340062, 340063 and 340065 of the sample set (taken into account when issuing a certificate of successful participation) have to be tested correctly with the same method in parameter 70 "SARS-CoV-2 (RNA) – qualitative". The same applies for parameter 60 of this EQA scheme.
Please see page 4: “Important comment".

Please note for the evaluation of the quantitative results of this EQA scheme that the evaluation criterion for stating a result as "correct" is based on an interval of -1.0 $\log_{10}$ to +1.0 $\log_{10}$ of the target value (based on the results of all methods).

For orientation, the quantitative results are depicted in an interval of -0.8 $\log_{10}$ to +0.8 $\log_{10}$ as well as in an interval of -0.25 $\log_{10}$ to +0.25 $\log_{10}$ of the target value (based on the results of all methods).

1.3.2 Validity of the certificates

The INSTAND Extra EQA scheme "Virus Genome Detection – SARS-CoV-2" (340) is not listed in the RiliBÄK, however, it is performed by INSTAND e.V. in accordance to the requirements of the specified RiliBÄK Section B 3.
As practiced for EQA schemes regulated in the Specified RiliBÄK Section B 3, the validity period for the Extra EQA scheme "Virus Genome Detection – SARS-CoV-2" (340) is 12 months. The validity of the certificates starts with the closing date of the EQA scheme (deadline for the receipt of data). This date is printed on top of the certificates.

1.3.3 Next INSTAND EQA schemes for virus genome detection of coronaviruses incl. SARS-CoV-2 in 2020

EQA term June/July 2020		**EQA term November 2020**	
New Dates		**Dates**	
Deadline for registration:	11 June 2020	Deadline for registration:	25 September 2020
Shipment date:	22 June 2020	Shipment date:	09 November 2020
Deadline for receipt of data:	22 July 2020	Deadline for receipt of data:	27 November 2020

While the Extra INSTAND EQA scheme April 2020 focused on the virus genome detection of SARS-CoV-2, the upcoming EQA schemes in June/July 2020 and November 2020 will offer the possibility of differentiating between SARS-CoV-2, MERS-CoV and other human CoV.
Please note: Laboratories with different test spectra can take part in the EQA schemes in June/July and November 2020: (i) laboratories that carry out genome detection of only SARS-CoV-2 and (ii) laboratories which additionally differentiate between different CoVs.

1.4 Listing and evaluation of the results and individual summary of results

For this Extra EQA scheme "Virus Genome Detection – SARS-CoV-2 (RNA)" (340), a "listing and evaluation of the results" together with the "certificate", "certificate of participation" and an "individual summary of results" are available online in EQAS Online (https://rv-online.instandev.de/index.shtml?lang=en).

The "listing and evaluation of the results" summarizes for each qualitative test, assigned to defined parameters, the "correct result" with the target value as "correct specification(s)". For quantitative tests/analytes, the target value and additionally the target range ("lower limit" and "upper limit") is stated on the "listing and evaluation of the results". The reported result of the laboratory is stated as "your specification(s)" (qualitative statements) and "your value" (quantitative statements), respectively.
This information is given line by line for each sample analyzed. Correct results are marked with a "+" in each line for the corresponding sample (column "meets criteria").

In addition, a "+"-symbol on the right side of parameter title indicates that a certificate is issued for a given parameter if the laboratory reached **100% correct results** for all samples according to the target values.

The "individual summary of results" lists for each qualitative and/or quantitative parameter performed by the laboratory, the frequency of a given statement differentiated according to sample number, manufacturer and test name. In addition, an orange colored bar (in the corresponding line) marks the test system (manufacturer and test name) applied by the laboratory.
Furthermore, the matching qualitative statement is also highlighted by an orange colored bar in the corresponding column. Qualitative results evaluated as "correct" are marked by a dot.

1.5 Overview of results of all participants and their evaluation

A summary of results is given for each of the samples in a table with a specification by parameters. A success rate is depicted for each of the samples reflecting the portion of "correct" results (expressed as "percent" correct results and as "number of correct results per number of total results reported"). In addition, an overall success rate - based on the results for the 4 evaluated samples of the sample set - is given for each of the parameters.

See Table 3 in section 2: Annotation by the EQAS advisor.

1.6 Deployed EQA samples

Coronavirus positive samples deployed in this Extra EQA scheme "Virus Genome Detection – SARS-CoV-2" (340) derive from lysates of cells which have been infected with coronavirus (SARS-CoV-2, HCoV OC43 or HCoV 229E). Samples positive for **SARS-CoV-2** contain **heat inactivated virus**.
Negative samples derive from lysates of non-infected cells

The samples are lyophilized and should be reconstituted in 1.1 ml aqua bidest. (sterile, pyrogen-free, PCR-grade) directly before testing.

1.7 Target values

The evaluation of this EQA scheme is based on the determination of target values for each of the samples analyzed.
Please note: Reference measurement methods for the determination of target values are not applicable for virus diagnostics.

The target value of a given EQA scheme sample - preset by the EQA scheme adviser - is confirmed by the INSTAND Expert Laboratories prior to the distribution of the samples to the participants of this EQA scheme. The above mentioned INSTAND Expert Laboratories test the samples for a second time during the course of the EQA scheme as regular participants. The **final target value for a given sample** is derived from the consensus value from all qualitative results and quantitative results (based on the robust average according to algorithm A/DIN ISO 13528/Annex C), respectively, reported by the participants including the results reported by the INSTAND Expert Laboratories during the EQA scheme.

Accepted statements of results according to the respective sample property

- **Quantitative results** - statements as "genome equivalents/ml = copies/ml" and "below detection limit", respectively
  For the statement "below detection limit", it should be proceeded as follows:
  In case of a test system with a detection limit of e.g. 50 copies/ml, the result "< 50" should be entered under "Result (quant)" for the corresponding sample.
- **Qualitative results** - "positive" or "below detection limit/negative" or " indeterminate"
  (nominal characteristics)

In case the results of a given EQA scheme deviate from the present target value, it will be investigated whether the deviating results are due to the test performance in the laboratory or to test immanent problems of commercial or in-house-tests. This investigation is performed together with the INSTAND Expert Laboratories under the auspices of the EQA scheme adviser and in cooperation with the Joint Diagnostic Council of DVV and GfV.

1.8 Determination of evaluation intervals

The evaluation interval for each SARS-CoV-2 positive sample corresponds to a target value interval, which is based on an interval of -1.0 log10 to +1.0 log10 of the target value (based on all results of the evaluated methods).
The **final target value of each positive sample** is determined as the consensus value deriving from all quantitative results (see Section "Target values").

2 Annotation by the EQAS Adviser

Dear colleagues,

Below please find a detailed comment on this Extra EQA scheme (340) "Virus Genome Detection – SARS-CoV-2" April 2020 with:

- Information about parameters, statement of results and evaluation criteria,
- Information about sample properties,
- Summary of sample properties, target values, results and success rates as well as
- Annex with detailed description of all reported qualitative and quantitative results including a differentiation according to
  gene region,
  manufacturer,
  test name,
  median from Ct/Cp/Cq/CN values,
  lowest reported Ct/Cp/Cq/CN value and
  highest reported Ct/Cp/Cq/CN value

We report the results submitted by **463 laboratories**
out of **488 laboratories having registered from 36 countries**
(25 laboratories did not return results)

2.1 Parameters, statement of results and evaluation criteria for this EQA scheme

The following statements of results differentiated by the targeted gene region of SARS-CoV-2 were requested for each of the parameters in this EQA scheme which were the basis for evaluation (see Table 1):

Table 1: Parameters, statement of results and evaluation criteria

Parameters	**Statement of results** the following statements of results were requested	**Evaluation criteria** no. of correctly determined samples for receiving a "certificate"
(70) SARS-CoV-2 (RNA) – qualitative	**positive** or **below detection limit/negative** or **indeterminate**	4 of the 4 samples evaluated in this Extra EQA scheme[$]
(60) SARS-CoV-2 (RNA) – quantitativ	**genome equivalents/ml = copies/ml** or **below detection limit**	4 of the 4 samples evaluated in this Extra EQA scheme[$]

[$] In the interim evaluation of 17 April 2020, all participants in the Extra INSTAND EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020 were informed of the sample properties of samples 340059, 340060 and 340064. The results of these 3 samples are not taken into account when issuing a certificate of successful participation.

However, the results submitted for samples 340061, 340062, 340063 and 340065 are considered for the evaluation when issuing a certificate of successful participation.

2.2 Sample properties

For the Extra EQA scheme (340) "Virus Genome Detection – SARS-CoV-2" April 2020
7 samples were provided:

Table 2: Sample properties

Sample No.	Sample source	Dilution	Sample considered for issuing a certificate of successful participation
340059*,$	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 1 000*,$	nein$
340060$	**SARS-CoV-2 negative**, lysate of HCoV OC43 infected cells as specificity control	1 : 2 500$	nein$
340061*	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 1 000 000*	ja
340062	**SARS-CoV-2 negative**, lysate of non-infected cells (MRC-5 cells) as specificity control	----	ja
340063*	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 10 000*	ja
340064*,$	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 100 000*,$	nein$
340065	**SARS-CoV-2 negative**, lysate of HCoV 229E infected cells as specificity control	1 : 2 500	ja

* The positive samples 340059, 304061, 340063 and 340064 represent different dilution steps of a dilution series of al lysate of cells infected with SARS-CoV-2.

$ In the interim evaluation of 17 April 2020, all participants in the Extra INSTAND EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020 were informed of the sample properties of samples 340059, 340060 and 340064. The results of these 3 samples are not taken into account when issuing a certificate of successful participation.

However, the results submitted for samples 340061, 340062, 340063 and 340065 are considered for the evaluation when issuing a certificate of successful participation.

** Strain: BetaCoV/Munich/ChVir984/2020

2.3 Summary of sample properties, target values, results and success rates

**Table 3: Qualitative results –
Summary of sample properties, target values, results, success rates,
medians of Ct/Cp/Cq/CN values as well as the reported minimum Ct/Cp/Cq/CN value and
reported maximum Ct/Cp/Cq/CN value – differentiated according to the targeted gene region**

A Sample no.	B Sample properties	C Expected qualitative result for SARS-CoV-2	D Gene region	E Correct results per reported results differentiated by gene region	F Reported Ct/Cp/Cq/CN-results differentiated by gene region median (min – max)
Sample 340059[$,*]	**SARS-CoV-2 1 : 1 000 diluted** **sample not evaluated[$]**	**positive**	E	373/373 (100%)	22.6 (16.8-34.0)
			N	165/167 (98.8%)	23.6 (17.9-34.9)
			ORF1a	45/46 (97.8%)	22.2 (20.8-28.7)
			ORF1ab	48/48 (100%)	21.8 (10.9-29.1)
			RdRP	185/185 (100%)	23.8 (10.0-34.5)
			S	100/100 (100%)	21.8 (17.5-27.8)
			n.s.[§]	64/64 (100%)	22.6 (9.4-33.0)
		total		**980/983 (99.7%)[$]**	**22.8**
Sample 340060[$]	**HCoV OC43 1 : 2 500 diluted specificity control** **sample not evaluated[$]**	**negative**	E	368/373 (98.7%)	-
			N	162/166 (97.6%)	-
			ORF1a	45/46 (97.8%)	-
			ORF1ab	45/48 (93.8%)	-
			RdRP	178/181 (98.3%)	-
			S	99/100 (99.0%)	-
			n.s.[§]	64/64 (100%)	-
		total		**961/983 (97.8%)[$]**	**-**
Sample 340061*	**SARS-CoV-2 1 : 1 000 000 diluted**	**positive**	E	364/373 (97.6%)	32.1 (15.0-40.0)
			N	153/167 (91.6%)	33.3 (20.0-40.7)
			ORF1a	44/46 (95.7%)	31.7 (30.6-36.0)
			ORF1ab	42/48 (87.5%)	31.5 (20.0-39.3)
			RdRP	158/185 (85.4%)	33.5 (19.5-42.8)
			S	97/100 (97.0%)	31.5 (20.0-39.0)
			n.s.[§]	56/64 (87.5%)	31.9 (19.3-37.5)
		total		**914/983 (93.0%)**	**32.4**
Sample 340062	**CoV negative specificity control**	**negative**	E	371/373 (99.5%)	-
			N	164/167 (98.2%)	-
			ORF1a	46/46 (100%)	-
			ORF1ab	47/48 (97.9%)	-
			RdRP	178/182 (97.8%)	-
			S	99/100 (99.0%)	-
			n.s.[§]	64/64 (100%)	-
		total		**969/983 (98.6%)**	-

**Table 3 (continued): Qualitative results –
Summary of sample properties, target values, results, success rates, medians of Ct/Cp/Cq/CN values as well as the reported minimum Ct/Cp/Cq/CN value and reported maximum Ct/Cp/Cq/CN value – differentiated according to the targeted gene region**

A Sample no.	B Sample properties	C Expected qualitative result for SARS-CoV-2	D Gene region	E Correct results per reported results differentiated by gene region	*E-1* *Correct results per reported results differentiated by gene region* *[reduced by the no. of incorrect result assignments (mix-ups) for samples 340064 and 340065]*	F Reported Ct/Cp/Cq/CN-results differentiated by gene region median (min – max)
Sample 340063*	**SARS-CoV-2 1 : 10 000 diluted**	**positive**	E	368/371 (99.2%)	n.a.	25.7 (19.8-35.3)
			N	165/167 (98.8%)		26.9 (20.0-39.6)
			ORF1a	45/46 (97.8%)		25.5 (24.0-31.5)
			ORF1ab	45/47 (95.7%)		24.7 (14.5-33.4)
			RdRP	184/184 (100%)		27.2 (13.4-38.3)
			S	100/100 (100%)		25.0 (18.0-30.0)
			n.s.§	64/64 (100%)		25.7 (12.8-35.9)
		total		**971/983 (98.8%)**		**26.0**
Sample 340064$,*	**SARS-CoV-2 1 : 100 000 diluted** **sample not evaluated$**	**positive**	E	356/373 (95.4%)	356/359 (99.2%)	29.2 (17.7-36.0)
			N	146/166 (88.0%)	145/147 (98.6%)	30.2 (20.0-41.5)
			ORF1a	44/46 (95.7%)	44/45 (97.8%)	28.8 (27.3-34.0)
			ORF1ab	41/48 (85.4%)	41/42 (97.6%)	28.8 (18.4-37.0)
			RdRP	168/185 (90.8%)	168/171 (98.2%)	30.5 (16.0-41.4)
			S	97/100 (97.0%)	97/97 (100%)	28.6 (20.0-34.2)
			n.s.§	64/64 (100%)	64/64 (100%)	29.0 (16.5-40.0)
		total		**916/983 (93.2%)$**	**915/925 (98.9%)$**	**29.5**
Sample 340065	**HCoV 229E 1 : 2 500 diluted specificity control**	**negative**	E	355/373 (95.2%)	355/359 (98.9%)	-
			N	146/166 (88.0%)	145/147 (98.6%)	-
			ORF1a	44/46 (95.7%)	44/45 (97.8%)	-
			ORF1ab	41/48 (85.4%)	41/42 (97.6%)	-
			RdRP	165/182 (90.7%)	165/168 (98.2%)	-
			S	93/100 (93.0%)	93/97 (95.9%)	-
			n.s.§	64/64 (100%)	64/64 (100%)	-
		total		**908/983 (92.4%)**	**907/925 (98.1%)**	-
Success rate for all 4 evaluated samples&					**428/461 (92.8%)&**	
Success rate for all 4 evaluated samples (updated)&&					**428/437 (97.9%)&&**	

Legend to Table 3:

* The positive samples 340059, 340061, 340063 and 340064 are consecutive dilution steps of a dilution series of one and the same lysate of cells which were infected with SAR-CoV-2 virus. The samples containing SARS-CoV-2 are inactivated.

$ In the interim evaluation of 17 April 2020, all participants in the Extra INSTAND EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020 were informed of the sample properties of samples 340059, 340060 and 340064. The results of these 3 samples are not taken into account when issuing a certificate of successful participation.

However, the results submitted for samples 340061, 340062, 340063 and 340065 are considered for the evaluation when issuing a certificate of successful participation.

§ n.s. = not stated = gene region was not specified by the participant

& The success rate for all 4 evaluated samples in parameter 70 refer to the number of participating laboratories. Laboratories having reported results obtained by several methods are recorded only once in the corresponding parameter.

&& The updated success rate for all 4 evaluated samples in parameter 70 refers to the number of participating laboratories, reduced by the number of laboratories (24 laboratories) with incorrect result assignments (mix-ups) for samples 340064 and 340065.
Laboratories having reported results obtained by several methods are recorded only once in the corresponding parameter.

Table 4: Quantitative results - Summary of sample properties, target values, results and success rates

Sample No.	340059*,$	340060$	340061*	340062	340063*	340064*,$	340065	Success rate For all 4 evaluated samples&
Sample properties	SARS-CoV-2 positive	SARS-CoV-2 negative HCoV OC43	SARS-CoV-2 positive	SARS-CoV-2 negative	SARS-CoV-2 positive	SARS-CoV-2 positive	SARS-CoV-2 negative HCoV 229E	
Dilution	1 : 1 000*	1 : 2 500	1 : 1 000 000*	---	1 : 10 000*	1 : 100 000*	1 : 2 500	
SARS-CoV-2 (RNA) - quantitative in copies/ml – parameter 60 (basis for receiving a „certificate“)								
Target values for all methods#	17 071 604$	0$	25 978	0	2 198 982	220 046$	0	
Target range Interval +/-1.0 log_{10} of the target value#	1 707 160 – 170 716 040	0 – 0	2 598 – 259 780	0 – 0	219 898 – 21 989 820	22 005 – 2 200 460	0 – 0	
Considered as "correct" results for this interval	**76.5%**$ (26/34)	**97.1%**$ (33/34)	**73.5%** (25/34)	**97.1%** (33/34)	**73.5%** (25/34)	**70.6%**$ (24/34)	**94.1%** (32/34)	**71.4%**& (15/21)&
Additional intervals for orientation								
Interval +/-0.8 log_{10} of the target value#	2 705 667 – 107 714 539	0 – 0	4 117 – 163 910	0 – 0	348 515 – 13 874 638	34 875 – 1 388 396	0 – 0	
Results for this interval	**67.6%**$ (23/34)	**97.1%**$ (33/34)	**55.9%** (19/34)	**97.1%** (33/34)	**64.7%** (22/34)	**58.8%**$ (20/34)	**94.1%** (32/34)	**66.7%**& (14/21)&
Interval +/-0.25 log_{10} of the target value #	9 600 068 – 30 358 082	0 – 0	14 609 – 46 196	0 – 0	1 236 578 – 3 910 404	123 741 – 391 303	0 – 0	
Results for this interval	**17.6%**$ (6/34)	**97.1%**$ (33/34)	**14.7%** (5/34)	**97.1%** (33/34)	**14.7%** (5/34)	**8.8%**$ (3/34)	**94.1%** (32/34)	**14.3%**& (3/21)&

* The positive samples 340059, 340061, 340063 and 340064 are consecutive dilution steps of a dilution series of one and the same lysate of cells which were infected with SAR-CoV-2 virus. The samples containing SARS-CoV-2 are inactivated.

& The success rate for all 4 evaluated samples in parameter 60 refer to the number of participating laboratories. Laboratories having reported results obtained by several methods are recorded only once in the corresponding parameter.

Target values for all methods: determined for each positive sample from quantitative results of all participants (see section "Target values")

$ In the interim evaluation of 17 April 2020, all participants in the Extra INSTAND EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020 were informed of the sample properties of samples 340059, 340060 and 340064. The results of these 3 samples are not taken into account when issuing a certificate of successful participation. However, the results submitted for samples 340061, 340062, 340063 and 340065 are considered for the evaluation when issuing a certificate of successful participation.

Table 5: Quantitative results - SARS-CoV-2 (RNA) – Reported results of 21 laboratories in copies/ml – parameter 60

Sample No.		340059*,$	340060$	340061*	340062	340063*	340064*,$	340065
Sample properties		SARS-CoV-2 positive	SARS-CoV-2 negative HCoV OC43	SARS-CoV-2 positive	SARS-CoV-2 negative	SARS-CoV-2 positive	SARS-CoV-2 positive	SARS-CoV-2 negative HCoV 229E
Dilution		1 : 1 000*	1 : 2 500	1 : 1 000 000*	---	1 : 10 000*	1 : 100 000*	1 : 2 500
Method / gene region	Participant No.	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml
dPCR / E gene	4233	6 944 589	0**	9 814	0**	700 308	64 947	0**
	68050	3 884 734	< 50	3 992	< 50	378 938	38 201	< 50
dPCR / N gene	47761	11 000 000	0**	10 000	0**	880 000	94 000	0**
	68050	4 191 358	< 50	5 104	< 50	452 521	48 712	< 50
	68050	5 598 288	< 50	5 163	< 50	394 515	44 245	< 50
	68050	5 901 430	< 50	5 436	< 50	508 297	53 478	< 50
dPCR / ORF1b	68050	2 474 836	< 50	2 346	< 50	209 502	22 689	< 50
dPCR / RdRP gene	4233	361 975	0**	377	0**	46 224	4 620	0**

Table 5 (continued): Quantitative results - SARS-CoV-2 (RNA) – Reported results of 21 laboratories in copies/ml – parameter 60

Sample No.		340059*,$	340060$	340061*	340062	340063*	340064*,$	340065
Sample properties		SARS-CoV-2 positive	SARS-CoV-2 negative HCoV OC43	SARS-CoV-2 positive	SARS-CoV-2 negative	SARS-CoV-2 positive	SARS-CoV-2 positive	SARS-CoV-2 negative HCoV 229E
Dilution		1 : 1 000*	1 : 2 500	1 : 1 000 000*	---	1 : 10 000*	1 : 100 000*	1 : 2 500
Method / gene region	Participant No.	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml
qPCR / other	2005	97 000 000	0**	71 000	0**	8 700 000	810 000	0**
	2362	24 000 000	0**	24 000	0**	4 300 000	500 000	0**
	4297	14 301 540	0**	7 360	0**	1 928 160	63 540	0**
	5329	92 800 000	0**	201 000	0**	12 400 000	1 400 000	0**
	5329	62 700 000	0**	87 800	0**	8 060 000	797 000	0**
	5329	57 000 000	0**	89 900	0**	6 560 000	656 000	0**
	8705	2 000 000	0**	200 000	0**	800 000	400 000	0**
qPCR / E gene	1056	31 643 000	0**	18 000	0**	2 893 000	231 000	0**
	1296	1 500 000	< 100	1 100	< 100	110 000	4 000	< 100
	5329	42 800 000	0**	88 900	0**	4 860 000	480 000	0**
	41443	7 740 000	0**	12 800	0**	834 000	70 800	0**
	67790	284 662 884	n.s.	219 433	n.s.	28 853 675	2 041 466	n.s.
	67995	11 768 560	< 10	20 680	< 10	2 340 710	238 120	< 10
	68021	10 000 000	0**	10 000	0**	1 000 000	100 000	0**

Table 5 (continued): Quantitative results - SARS-CoV-2 (RNA) – Reported results of 21 laboratories in copies/ml – parameter 60

Sample No.		340059*,$	340060$	340061*	340062	340063*	340064*,$	340065
Sample properties		SARS-CoV-2 positive	SARS-CoV-2 negative HCoV OC43	SARS-CoV-2 positive	SARS-CoV-2 negative	SARS-CoV-2 positive	SARS-CoV-2 positive	SARS-CoV-2 negative HCoV 229E
Dilution		1 : 1 000*	1 : 2 500	1 : 1 000 000*	---	1 : 10 000*	1 : 100 000*	1 : 2 500
Method / gene region	Participant No.	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml	copies/ml
qPCR / N gene	1467	23 217 000	0**	36 470	0**	2 921 300	338 420	0**
	4973	3 811 423	< 85	2 687	< 85	319 616	22 553	< 85
	4973	78 599 453	< 85	52 326	< 85	7 248 930	450 806	< 85
	40839	644 900	0**	665	0**	67 540	4 857	0**
	58803	450 276	0**	478	0**	64 325	4 288	0**
	67794	57 428 571	0**	108 514	0**	6 857 143	819 429	0**
qPCR / ORF1ab	4973	3 330 633	< 85	1 857	< 85	285 607	18 621	< 85
qPCR / RdRP gene	5329	211 000	0**	0**	0**	37 100	5 580	0**
	40839	1 580 000	0**	2 140	0**	188 000	17 400	0**
	42366	1 083 470	0**	1 110	0**	61 900	5 730	0**
qPCR / S gene	752	5 217 100	< 1 000	17 700	< 1 000	2 567 200	< 1 000	148 900
	4973	2 300 899	< 85	2 884	< 85	243 910	21 412	< 85

** The statement "0" represents results reported as "below detection limit" and "negative", respectively. n.s. = not stated

* The positive samples 340059, 340061, 340063 and 340064 are consecutive dilution steps of a dilution series of one and the same lysate of cells which were infected with SAR-CoV-2 virus. The samples containing SARS-CoV-2 are inactivated.

$ In the interim evaluation of 17 April 2020, all participants in the Extra INSTAND EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020 were informed of the sample properties of samples 340059, 340060 and 340064. The results of these 3 samples are not taken into account when issuing a certificate of successful participation. However, the results submitted for samples 340061, 340062, 340063 and 340065 are considered for the evaluation when issuing a certificate of successful participation.

2.4 Summary and discussion of results

In the Extra INSTAND EQA scheme Virus Genome Detection - SARS-CoV-2 - April 2020, the focus for the participating laboratories was to check their analytics for SARS-CoV-2 detection with regard to test sensitivity and test specificity. The present evaluation focuses primarily on the qualitative results regarding the correct analyses of (i) 4 differently concentrated samples with SARS-CoV-2, (ii) 2 samples with other human coronaviruses (HCoV OC43 and 229E), (iii) and one sample with uninfected control cells (MRC-5 cells).

The qualitative results are supplemented by the reported results for Ct/Cp/Cq/CN values as well as quantitative results in copies/ml. For the quantitative results, see section 2.4.1.3.

In the present report, all results are taken into account for each method, without showing the influence of the extraction efficiency on the amplification used. This differentiation will follow in a subsequent publication.

Please note:
Pre-analytical factors that have a significant impact on test sensitivity (e.g. collection of nasopharyngeal swabs) could not be considered for this interlaboratory comparison.

2.4.1 Results for the four SARS-CoV-2 positive samples

The SARS-CoV-2 positive samples derive from a serial dilution series with SARS-CoV-2:
Sample 340059 (1 : 1 000 diluted),
Sample 340063 (1 : 10 000 diluted),
Sample 340064 (1 : 100 000 diluted) and
Sample 340061 (1 : 1 000 000 diluted).

Please note in section 3 the detailed description of all qualitative results differentiated by
- gene region,
- manufacturer,
- test name,
- median from Ct/Cp/Cq/CN values,
- lowest reported Ct/Cp/Cq/CN value and
- highest reported Ct/Cp/Cq/CN value.

2.4.1.1 Qualitative results differentiated by applied test and gene region

(see Table 3 und Annex/Section 3.1)

Regardless of the gene region tested, the genome detection tests for SARS-CoV-2 generally revealed correct positive results for the three SARS-CoV-2 positive samples 340059, 340063 and 340064 in the dilution range between 1 : 1 000 and 1 : 100 000 (98.9% - 99.7% correct results for each gene region). These high success rates represent very good proficiency of the participating laboratories with their applied test formats.

With the highest diluted sample 340061 (SARS-CoV-2 positive, diluted 1: 1 000 000; target value of 25 978 copies/ml; see Table 4), the qualitative results show differences in sensitivity between the individual tests. Some of the applied tests, differentiating between several gene regions, are differently sensitive to the detection of the respective gene regions.

The highest diluted sample 340061 (SARS-CoV-2 positive, diluted 1: 1 000 000) was used as an *educational sample* in this extra INSTAND EQA scheme for genome detection of SARS-CoV-2. For this reason, a false negative result exclusively for sample 340061 was not considered for the certificate for those laboratories that have not correctly recognized this sample as positive.

Please note for Table 3/columns E and E-1):
Column E: For sample 340064 (SARS-CoV-2 positive, diluted 1: 100 000), the reduced success rate of only 93.2% is essentially due to incorrect assignment of results ("mix-ups") for sample 340064 and sample 340065 (negative for SARS-CoV-2 and positive for HCoV 229E).

The "mix-ups" for samples 340064 and 340065 concern 24 laboratories with a total of 58 results per sample. See also section 2.4.2.1.

Column E-1: For sample 340064 (SARS-CoV-2 positive diluted 1 : 100 000), the updated success rate is 98.9% correct results (915 correct analyzes out of 925 analyzes in total). The results shown in column E-1 do not take into account the data of the above mentioned 24 laboratories with a total of 58 results.

2.4.1.2 Reported Ct/Cp/Cq/CN values differentiated by gene region

(see Table 3 und Annex/Section 3.1)

For each of the four SARS-CoV-2 positive samples, the medians of the Ct/Cp/Cq/CN values are close to each other, regardless of the gene region tested

Sample 340059: SARS-CoV-2 positive, **1 : 1 000 diluted**	Ct/Cp/Cq/CN medians between 21.8 and 23.8
Sample 340063: SARS-CoV-2 positive, **1 : 10 000 diluted**	Ct/Cp/Cq/CN medians between 24.7 and 27.2
Sample 340064: SARS-CoV-2 positive, **1 : 100 000 diluted**	Ct/Cp/Cq/CN medians between 28.6 and 30.5
Sample 340061: SARS-CoV-2 positive, **1 : 1 000 000 diluted**	Ct/Cp/Cq/CN medians between 31.5 and 33.5

Taking into account the dilution factor of 10 between the four above mentioned samples, the medians of the reported Ct/Cp/Cq/CN values show the expected gradation of the virus concentration.

With regard to the different gene regions, the high variability of the reported Ct/Cp/Cq/CN values is noticeable for all four SARS-CoV-2 positive samples (see min - max statements, Table 3). This variability affects the tests of different manufacturers to different degrees. Please see the Annex/Section 3.1 for an evaluation with a differentiation of the results by gene region, manufacturer, test name, median of the Ct/Cp/Cq/CN values, lowest reported Ct/Cp/Cq/CN value and highest reported Ct/Cp/Cq/CN value.
In order to clarify the observed variability of the Ct/Cp/Cq/CN values in the individual test systems, a separate evaluation will follow to show to what extent the fluctuations are caused by different extraction efficiencies in the individual tests.

Please note: The extraction methods used by the laboratories are not taken into account in this report.

2.4.1.3 Quantitative results

(see Tables 4 and 5):

A total of 21 participants reported quantitative results for each of the four SARS-CoV-2 positive samples (34 quantitative analyzes per sample). The statements in Table 5 summarize the results for conventional qPCR/NAT and digital PCR (dPCR).

Taking into account the dilution factor of 10 between the four SARS-CoV-2 positive samples, the robust average (determined according to algorithm A / DIN ISO 13528 / Appendix C) show the expected gradation of the virus concentrations.
The evaluation interval for each SARS-CoV-2 positive sample corresponds to a target value interval, which is based on an interval of -1.0 log10 to +1.0 log10 of the target value (based on all results of the evaluated methods).

2.4.1.3.1 Quantitative results determined by digital PCR (dPCR)

(see Table 5)

A total of three EQA participants reported quantitative results, determined by digital PCR, for each of the four SARS-CoV-2 positive samples (8 quantitative analyzes per sample).

Taken together the quantitative results obtained by dPCR for the gene regions E gene, N gene and ORF1b, the intervals for copies/ml are as follows:

Sample 340059: SARS-CoV-2 positive, **1 : 1 000 diluted**	copies/ml between	2 474 836 and 11 000 000
Sample 340063: SARS-CoV-2 positive, **1 : 10 000 diluted**	copies /ml between	209 502 and 880 000
Sample 340064: SARS-CoV-2 positive, **1 : 100 000 diluted**	copies /ml between	22 689 and 94 000
Sample 340061: SARS-CoV-2 positive, **1 : 1 000 000 diluted**	copies /ml between	2 346 and 10 000

For the RdRP gene region, the following statements in copies/ml were given by dPCR:

Sample 340059: SARS-CoV-2 positive, **1 : 1 000 diluted**	copies /ml	361 975
Sample 340063: SARS-CoV-2 positive, **1 : 10 000 diluted**	copies /ml	46 224
Sample 340064: SARS-CoV-2 positive, **1 : 100 000 diluted**	copies /ml	4 620
Sample 340061: SARS-CoV-2 positive, **1 : 1 000 000 diluted**	copies/ml	377

Taking into account the dilution factor of 10 between the four SARS-CoV-2 positive samples, the dPCR results show the expected concentration gradations very well (see Table 5).
In addition, the dPCR statements revealed only slight variations for the quantitative results for the gene regions E gene, N gene and ORF1b.

With regard to the RdRP gene region, the results in copies/ml for each of the four SARS-CoV-2 positive samples were lower than for the gene regions E gene, N gene and ORF1b. The Gemeinsame Diagnostikkommission der DVV und GfV (Joint diagnostic Council of the DVV and GfV) together with the National Consultant Laboratory for Coronaviruses will consider the observation of deviating results.

2.4.2 Results for the three SARS-CoV-2 negative samples deployed as specificity controls of the applied SARS-CoV-2 tests

For specificity control, the following samples were used in the Extra EQA scheme for virus genome detection SARS-CoV-2 - April 2020:

Sample 340060	negative for SARS-CoV-2 positive for HCoV OC43 (1 : 2 500 diluted)	Ct value of HCoV OC43 specific PCR: 25.8
Sample 340065	negative for SARS-CoV-2 positive for HCoV 229E (1 : 2 500 diluted)	Ct value of HCoV 229E specific PCR: 28.4
Sample 340062	negative for SARS-CoV-2 MRC-5 cell lysate	

Please see section 3 for a detailed differentiation of the qualitative results by
- gene region,
- manufacturer,
- test name,

2.4.2.1 Qualitative results of the three SARS-CoV-2 negative samples differentiated by the applied test and gene region

For the three SARS-CoV-2-negative samples 340060, 340062 und 340065, the tests for genome detection of SARS-CoV-2 mostly gave correct negative results (97.8% to 98.6% correct qualitative results) regardless of the gene region examined. These high success rates represent very good proficiency of the participating laboratories with their applied test formats.

In addition, some results for the SARS-CoV-2 negative control samples 340060, 340062 and 340065 indicate specificity problems that are independent of mix-ups for the samples 340064 und 340065. It is to be clarified whether these false positive results are due to a specificity problem of the applied tests or to a carryover of SARS-CoV-2 or to mix-ups with other samples of this EQA scheme's panel during the test performance in the respective laboratories.

Please note for Table 3/columns E and E-1:
Column E: For sample 340065 (negative for SARS-CoV-2 and positive for HCoV 229E), the reduced success rate of only 92.4% is essentially due to incorrect assignment of results ("mix-ups") for sample 340065 and sample 340064 (SARS-CoV-2 positive, diluted 1 : 100 000).
The "mix-ups" for samples 340065 and 340064 concern 24 laboratories with a total of 58 results per sample.
See also section 2.4.1.1.

Column E-1: For sample 340065 (negative for SARS-CoV-2 and positive for HCoV 229E), the updated success rate is 98.1% correct results (907 correct analyzes out of 925 analyzes in total). The results shown in column E-1 do not take into account the data of the above mentioned 24 laboratories with a total of 58 results.

3 Annex with tables

3.1 Qualitative genome detection of SARS-CoV-2

(parameters 70)

4 Acknowledgements

We thank our cooperation partner at Charité – University Medicine Berlin and the following INSTAND expert laboratories for their support in the introduction of this extra EQA scheme:

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

Surplus samples of the current 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 very much for your kind cooperation.

Sincerely yours,

H. Zeichhardt

Prof. Dr. Heinz Zeichhardt
EQAS Adviser

M. Kammel

Dr. Martin Kammel
Assistant EQAS Adviser

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

3 Annex with tables

3.1 Qualitative genome detection of SARS-CoV-2

SARS-CoV-2 (RNA) – qualitative

Differentiation by
- *gene region,*
- *manufacturer,*
- *test name,*
- *median from Ct/Cp/Cq/CN values,*
- *lowest reported Ct/Cp/Cq/CN value and*
- *highest reported Ct/Cp/Cq/CN value*

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

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70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340059 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=2)	intermediate (N=1)	positive (N=980)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
E-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	0	0	48		21.7	18.6	27.6
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	0	0	4		21.5	20.6	29.3
OTHER MANUFACTURERS		10	0	0	10		24.1	22.7	27.0
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2				
CEPHEID	Xpert Xpress SARS-CoV-2	11	0	0	11		21.5	21.0	24.3
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		47	0	0	47		22.5	16.8	34.0
ELITech	GeneFinder COVID-19 Plus	8	0	0	8		21.1	18.4	26.8
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1		23.9	23.9	23.9
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	0	0	1		28.2	28.2	28.2
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1		23.2	23.2	23.2
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5		23.0	22.4	24.0
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	0	0	5		24.4	22.5	25.4
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	0	0	3		21.6	17.0	22.0
LUMINEX	NxTAG CoV	1	0	0	1				
MIKROGEN	ampliCube Coronavirus Panel	1	0	0	1		23.0	23.0	23.0
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	0	0	3		22.8	20.6	25.0
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	0	0	4		20.7	19.1	22.2
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	0	0	3		23.6	18.4	26.7
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	0	0	55		23.2	17.7	26.2
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	39	0	0	39		22.8	21.1	29.4
SEEGENE	Allplex 2019 n-CoV Assay	51	0	0	51		21.3	18.0	28.7
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	68	0	0	68		22.9	19.2	29.5
TIB MOLBIOL	LightMix Sarbeco E-gene	1	0	0	1		23.4	23.4	23.4
		373	**0**	**0**	**373**		**22.6**	**16.8**	**34.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

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70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340059 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=2)	intermediate (N=1)	positive (N=980)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
N-Gene									
ABBOTT	RealTime SARS-CoV-2	3	0	0	3				
OTHER MANUFACTURERS		10	0	0	10		24.6	20.1	34.9
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		20.0	17.9	20.5
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2		20.0	18.4	21.6
CEPHEID	Xpert Xpress SARS-CoV-2	12	0	0	12		23.7	22.8	26.9
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	0	0	4		23.2	21.0	25.7
CLONIT	quanty COVID-19 Kit	4	1	0	3		21.0	19.3	22.6
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		33	0	0	33		24.5	19.9	31.8
ELITech	GeneFinder COVID-19 Plus	9	0	0	9		22.2	18.7	27.9
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1		21.3	21.3	21.3
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4		23.5	22.0	25.9
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1		23.3	23.3	23.3
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	0	0	3		23.4	23.3	24.8
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	1	0	2		20.4	18.0	22.8
LUMINEX	NxTAG CoV	1	0	0	1				
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	0	0	3		19.9	19.3	20.4
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	0	0	3		23.6	20.7	24.2
SEEGENE	Allplex 2019 n-CoV Assay	52	0	0	52		23.2	20.0	31.0
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	13	0	0	13		29.4	27.4	34.5
VITASSAY	Vitassay qPCR SARSCoV-2	1	0	0	1		24.6	24.6	24.6
		167	**2**	**0**	**165**		**23.6**	**17.9**	**34.9**
ORF1a									
OTHER MANUFACTURERS		1	0	0	1		24.4	24.4	24.4
MIKROGEN	ampliCube Coronavirus Panel	3	0	1	2		23.3	21.7	24.1
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	0	0	10		22.1	20.8	25.3
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	0	0	32		22.2	21.7	28.7
		46	**0**	**1**	**45**		**22.2**	**20.8**	**28.7**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340059 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=2)	intermediate (N=1)	positive (N=980)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
ORF1ab									
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	0	0	5		22.3	19.7	27.5
OTHER MANUFACTURERS		9	0	0	9		23.1	10.9	29.1
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		20.0	19.5	20.9
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2		18.8	16.8	20.8
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	0	0	4				
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	0	0	7		21.5	18.8	26.2
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4		19.3	19.1	19.8
IN HOUSE		6	0	0	6		25.2	21.4	28.4
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	0	0	3		23.0	18.0	23.0
LUMINEX	NxTAG CoV	1	0	0	1				
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	0	0	1		21.8	21.8	21.8
VITASSAY	Vitassay qPCR SARSCoV-2	2	0	0	2		22.7	22.4	23.0
		48	**0**	**0**	**48**		**21.8**	**10.9**	**29.1**
RdRP-Gene									
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	0	0	1				
ABBOTT	RealTime SARS-CoV-2	6	0	0	6		10.6	10.0	14.5
OTHER MANUFACTURERS		10	0	0	10		23.6	21.8	32.1
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		42	0	0	42		25.1	19.6	34.5
ELITech	GeneFinder COVID-19 Plus	9	0	0	9		23.2	21.0	28.2
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	0	0	1				
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4		25.1	23.0	28.6
GENESIG	Coronavirus COVID-19	5	0	0	5		25.4	23.5	30.1
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5		25.8	25.2	27.9
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	0	0	4		24.6	21.7	27.8
SEEGENE	Allplex 2019 n-CoV Assay	57	0	0	57		23.0	20.7	30.2
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	40	0	0	40		27.1	21.5	34.4
		185	**0**	**0**	**185**		**23.8**	**10.0**	**34.5**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340059 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=2)	intermediate (N=1)	positive (N=980)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
S-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	0	0	61		21.3	17.5	24.4
OTHER MANUFACTURERS		1	0	0	1				
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		20.0	18.6	21.1
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2		19.4	18.4	20.4
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	0	0	26		24.8	23.2	26.1
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4		19.3	18.7	19.9
IN HOUSE		1	0	0	1		22.2	22.2	22.2
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	0	0	1		27.8	27.8	27.8
		100	**0**	**0**	**100**		**21.8**	**17.5**	**27.8**
gene region not specified by participants									
ABBOTT	RealTime SARS-CoV-2	9	0	0	9		11.6	9.9	13.9
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	0	0	1		24.0	24.0	24.0
OTHER MANUFACTURERS		14	0	0	14		22.5	9.4	26.0
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	0	0	3		25.3	21.2	27.5
ANICON	Kylt SARS-CoV-2 Screening RTU	1	0	0	1		25.4	25.4	25.4
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	0	0	1		21.1	21.1	21.1
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2				
IN HOUSE		3	0	0	3		22.7	22.0	25.1
EURO IMMUN	EURORealTime SARS-CoV-2	4	0	0	4		23.9	22.7	27.4
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	0	0	4		22.4	20.7	24.5
GENESIG	Coronavirus COVID-19	6	0	0	6		27.7	25.4	33.0
GERBION	virellaSARS-CoV-2 seqc	2	0	0	2		23.7	22.7	24.7
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	0	0	11		22.0	18.7	27.2
SEEGENE	Allplex 2019 n-CoV Assay	3	0	0	3		20.8	20.0	23.9
		64	**0**	**0**	**64**		**22.6**	**9.4**	**33.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340060 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV OC43 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=961)	intermediate (N=9)	positive (N=8)	Sample not evaluated
E-Gene						
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	48	0	0	
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	3	0	1	
OTHER MANUFACTURERS		10	10	0	0	
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	2	0	0	
CEPHEID	Xpert Xpress SARS-CoV-2	11	11	0	0	
IN HOUSE (dPCR)		1	1	0	0	
IN HOUSE		47	47	0	0	
ELITech	GeneFinder COVID-19 Plus	8	7	1	0	
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	0	0	
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	1	0	0	
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	1	0	0	
GERBION	virellaSARS-CoV-2 seqc	5	5	0	0	
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	5	0	0	
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	3	0	0	
LUMINEX	NxTAG CoV	1	1	0	0	
MIKROGEN	ampliCube Coronavirus Panel	1	1	0	0	
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	3	0	0	
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	4	0	0	
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	3	0	0	
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	54	0	1	
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	39	39	0	0	
SEEGENE	Allplex 2019 n-CoV Assay	51	51	0	0	
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	68	66	1	1	
TIB MOLBIOL	LightMix Sarbeco E-gene	1	1	0	0	
		373	**368**	**2**	**3**	

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample: 340060 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV OC43 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=961)	intermediate (N=9)	positive (N=8)	Sample not evaluated
N-Gene						
ABBOTT	RealTime SARS-CoV-2	3	3	0	0	
OTHER MANUFACTURERS		10	10	0	0	
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	2	0	0	
CEPHEID	Xpert Xpress SARS-CoV-2	12	12	0	0	
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	4	0	0	
CLONIT	quanty COVID-19 Kit	4	4	0	0	
IN HOUSE (dPCR)		1	1	0	0	
IN HOUSE		33	33	0	0	
ELITech	GeneFinder COVID-19 Plus	9	8	1	0	
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	0	0	
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	4	0	0	
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	1	0	0	
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	3	0	0	
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	3	0	0	
LUMINEX	NxTAG CoV	1	1	0	0	
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	3	0	0	
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	3	0	0	
SEEGENE	Allplex 2019 n-CoV Assay	52	50	0	2	
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	12	12	0	0	
VITASSAY	Vitassay qPCR SARSCoV-2	1	1	0	0	
		166	**162**	**2**	**2**	
ORF1a						
OTHER MANUFACTURERS		1	1	0	0	
MIKROGEN	ampliCube Coronavirus Panel	3	3	0	0	
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	9	0	1	
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	32	0	0	
		46	**45**	**0**	**1**	

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

340 70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340060 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV OC43 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=961)	intermediate (N=9)	positive (N=8)	Sample not evaluated
ORF1ab						
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	4	0	1	
OTHER MANUFACTURERS		9	9	0	0	
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	2	0	0	
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	3	0	1	
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	7	0	0	
DIASORIN	Simplexa COVID-19 Direct Kit	4	4	0	0	
IN HOUSE		6	6	0	0	
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	3	0	0	
LUMINEX	NxTAG CoV	1	1	0	0	
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	1	0	0	
VITASSAY	Vitassay qPCR SARSCoV-2	2	2	0	0	
		48	**45**	**1**	**2**	
RdRP-Gene						
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	1	0	0	
ABBOTT	RealTime SARS-CoV-2	6	6	0	0	
OTHER MANUFACTURERS		10	9	1	0	
IN HOUSE (dPCR)		1	1	0	0	
IN HOUSE		41	40	1	0	
ELITech	GeneFinder COVID-19 Plus	9	8	1	0	
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	1	0	0	
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	4	0	0	
GENESIG	Coronavirus COVID-19	5	5	0	0	
GERBION	virellaSARS-CoV-2 seqc	5	5	0	0	
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	4	0	0	
SEEGENE	Allplex 2019 n-CoV Assay	57	57	0	0	
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	37	37	0	0	
		181	**178**	**3**	**0**	

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340 70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340060 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV OC43 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=961)	intermediate (N=9)	positive (N=8)	Sample not evaluated
S-Gene						
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	61	0	0	
OTHER MANUFACTURERS		1	1	0	0	
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	2	0	0	
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	26	0	0	
DIASORIN	Simplexa COVID-19 Direct Kit	4	4	0	0	
IN HOUSE		1	1	0	0	
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	1	0	0	
		100	**99**	**1**	**0**	
gene region not specified by participants						
ABBOTT	RealTime SARS-CoV-2	9	9	0	0	
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	1	0	0	
OTHER MANUFACTURERS		14	14	0	0	
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	3	0	0	
ANICON	Kylt SARS-CoV-2 Screening RTU	1	1	0	0	
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	0	0	
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	2	0	0	
IN HOUSE		3	3	0	0	
EURO IMMUN	EURORealTime SARS-CoV-2	4	4	0	0	
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	4	0	0	
GENESIG	Coronavirus COVID-19	6	6	0	0	
GERBION	virellaSARS-CoV-2 seqc	2	2	0	0	
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	11	0	0	
SEEGENE	Allplex 2019 n-CoV Assay	3	3	0	0	
		64	**64**	**0**	**0**	

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340061 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=58)	intermediate (N=11)	positive (N=914)	Quota (93%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
E-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	0	0	48	100,00%	31.7	28.7	36.0
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	1	0	3	75,00%	29.4	28.5	30.2
OTHER MANUFACTURERS		10	0	0	10	100,00%	33.0	32.4	36.5
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2	100,00%			
CEPHEID	Xpert Xpress SARS-CoV-2	11	0	0	11	100,00%	31.1	30.5	35.1
IN HOUSE (dPCR)		1	0	0	1	100,00%			
IN HOUSE		47	1	0	46	97,87%	32.9	25.7	37.5
ELITech	GeneFinder COVID-19 Plus	8	2	0	6	75,00%	31.2	30.4	35.5
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1	100,00%	33.7	33.7	33.7
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	0	0	1	100,00%	35.5	35.5	35.5
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1	100,00%	32.2	32.2	32.2
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5	100,00%	33.0	31.8	33.0
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	1	0	4	80,00%	33.5	31.4	37.9
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	0	0	3	100,00%	30.0	27.0	30.5
LUMINEX	NxTAG CoV	1	0	0	1	100,00%			
MIKROGEN	ampliCube Coronavirus Panel	1	0	0	1	100,00%	32.0	32.0	32.0
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	0	0	3	100,00%	31.4	30.8	35.3
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	0	0	4	100,00%	29.9	28.0	32.2
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	0	0	3	100,00%	33.6	28.1	38.6
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	1	0	54	98,18%	33.3	15.0	37.1
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	39	0	0	39	100,00%	32.4	30.5	34.9
SEEGENE	Allplex 2019 n-CoV Assay	51	0	1	50	98,04%	31.1	19.2	36.3
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	68	2	0	66	97,06%	32.7	29.6	40.0
TIB MOLBIOL	LightMix Sarbeco E-gene	1	0	0	1	100,00%	32.0	32.0	32.0
		373	**8**	**1**	**364**	**97,59%**	**32.1**	**15.0**	**40.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340061 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=58)	intermediate (N=11)	positive (N=914)	Quota (93%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
N-Gene									
ABBOTT	RealTime SARS-CoV-2	3	0	0	3	100,00%			
OTHER MANUFACTURERS		10	1	1	8	80,00%	33.2	29.3	38.4
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4	100,00%	27.9	20.0	30.0
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2	100,00%	30.4	29.2	31.5
CEPHEID	Xpert Xpress SARS-CoV-2	12	0	0	12	100,00%	33.8	33.1	38.2
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	0	0	4	100,00%	32.6	31.0	36.4
CLONIT	quanty COVID-19 Kit	4	1	0	3	75,00%	31.8	29.6	34.0
IN HOUSE (dPCR)		1	0	0	1	100,00%			
IN HOUSE		33	3	0	30	90,91%	33.5	30.1	40.7
ELITech	GeneFinder COVID-19 Plus	9	0	0	9	100,00%	32.1	28.8	37.5
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1	100,00%	30.7	30.7	30.7
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4	100,00%	34.5	33.0	37.9
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1	100,00%	33.5	33.5	33.5
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	0	0	3	100,00%	33.3	32.9	34.6
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1	33,33%	32.6	32.6	32.6
LUMINEX	NxTAG CoV	1	0	0	1	100,00%			
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	0	0	3	100,00%	29.7	29.5	29.9
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	0	0	3	100,00%	33.1	30.2	33.6
SEEGENE	Allplex 2019 n-CoV Assay	52	1	1	50	96,15%	33.1	21.5	37.1
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	13	3	1	9	69,23%	38.2	35.9	40.0
VITASSAY	Vitassay qPCR SARSCoV-2	1	0	0	1	100,00%	33.5	33.5	33.5
		167	**11**	**3**	**153**	**91,62%**	**33.3**	**20.0**	**40.7**
ORF1a									
OTHER MANUFACTURERS		1	0	0	1	100,00%	34.2	34.2	34.2
MIKROGEN	ampliCube Coronavirus Panel	3	0	1	2	66,67%	34.5	31.9	34.7
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	1	0	9	90,00%	31.9	30.6	34.1
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	0	0	32	100,00%	31.7	31.1	36.0
		46	**1**	**1**	**44**	**95,65%**	**31.7**	**30.6**	**36.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340061 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=58)	intermediate (N=11)	positive (N=914)	Quota (93%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
ORF1ab									
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	1	0	4	80,00%	31.3	26.3	31.6
OTHER MANUFACTURERS		9	0	2	7	77,78%	32.8	21.7	39.3
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4	100,00%	29.8	20.0	30.8
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2	100,00%	29.6	28.7	30.4
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	1	0	3	75,00%			
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	1	0	6	85,71%	31.3	30.2	36.3
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4	100,00%	29.2	29.0	29.7
IN HOUSE		6	1	0	5	83,33%	35.2	31.4	36.9
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	0	0	3	100,00%	32.0	32.0	32.1
LUMINEX	NxTAG CoV	1	0	0	1	100,00%			
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	0	0	1	100,00%	31.3	31.3	31.3
VITASSAY	Vitassay qPCR SARSCoV-2	2	0	0	2	100,00%	32.4	32.0	32.8
		48	**4**	**2**	**42**	**87,50%**	**31.5**	**20.0**	**39.3**
RdRP-Gene									
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	0	0	1	100,00%			
ABBOTT	RealTime SARS-CoV-2	6	0	0	6	100,00%	20.5	19.5	23.7
OTHER MANUFACTURERS		1	0	0	1	90,00%	32.1	31.0	39.3
IN HOUSE (dPCR)		10	1	0	9	100,00%			
IN HOUSE		42	3	0	39	92,86%	34.2	29.9	42.8
ELITech	GeneFinder COVID-19 Plus	9	4	1	4	44,44%	35.2	35.0	35.4
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	0	0	1	100,00%			
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	1	0	3	75,00%	35.4	34.0	40.3
GENESIG	Coronavirus COVID-19	5	0	1	4	80,00%	35.4	33.0	38.3
GERBION	virellaSARS-CoV-2 seqc	5	3	0	2	40,00%	36.1	35.9	36.3
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	2	0	2	50,00%	34.0	31.7	36.3
SEEGENE	Allplex 2019 n-CoV Assay	57	1	1	55	96,49%	33.0	20.8	38.6
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	40	8	1	31	77,50%	35.6	31.5	40.2
		185	**23**	**4**	**158**	**85,41%**	**33.5**	**19.5**	**42.8**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340061 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=58)	intermediate (N=11)	positive (N=914)	Quota (93%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
S-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	0	0	61	100,00%	31.0	27.5	34.6
OTHER MANUFACTURERS		1	0	0	1	100,00%			
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	1	0	3	75,00%	28.3	20.0	30.7
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2	100,00%	26.1	22.6	29.6
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	2	0	24	92,31%	34.7	32.2	39.0
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4	100,00%	29.2	28.4	30.2
IN HOUSE		1	0	0	1	100,00%	32.0	32.0	32.0
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	0	0	1	100,00%	36.3	36.3	36.3
		100	**3**	**0**	**97**	**97,00%**	**31.5**	**20.0**	**39.0**
gene region not specified by participants									
ABBOTT	RealTime SARS-CoV-2	9	0	0	9	100,00%	21.6	19.7	23.8
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	0	0	1	100,00%	34.0	34.0	34.0
OTHER MANUFACTURERS		14	1	0	13	92,86%	32.2	19.3	36.0
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	1	0	2	66,67%	33.1	31.3	34.8
ANICON	Kylt SARS-CoV-2 Screening RTU	1	1	0	0	0,00%			
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	0	0	1	100,00%	32.2	32.2	32.2
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	1	0	1	50,00%			
IN HOUSE		3	0	0	3	100,00%	33.2	31.9	35.0
EURO IMMUN	EURORealTime SARS-CoV-2	4	0	0	4	100,00%	34.1	32.3	37.4
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	0	0	4	100,00%	32.4	30.1	34.5
GENESIG	Coronavirus COVID-19	6	3	0	3	50,00%	34.3	21.2	37.1
GERBION	virellaSARS-CoV-2 seqc	2	0	0	2	100,00%	34.6	31.6	37.5
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	1	0	10	90,91%	31.3	29.2	32.4
SEEGENE	Allplex 2019 n-CoV Assay	3	0	0	3	100,00%	33.4	30.0	34.4
		64	**8**	**0**	**56**	**87,50%**	**31.9**	**19.3**	**37.5**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

340 70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340062 (Result (qual)) - SARS-CoV-2 negative, lysate of non-infected cells

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=969)	intermediate (N=4)	positive (N=7)	Quota (98.6%)
E-Gene						
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	48	0	0	100,00%
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	4	0	0	100,00%
OTHER MANUFACTURERS		10	10	0	0	100,00%
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	2	0	0	100,00%
CEPHEID	Xpert Xpress SARS-CoV-2	11	11	0	0	100,00%
IN HOUSE (dPCR)		1	1	0	0	100,00%
IN HOUSE		47	47	0	0	100,00%
ELITech	GeneFinder COVID-19 Plus	8	8	0	0	100,00%
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	0	0	100,00%
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	1	0	0	100,00%
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	1	0	0	100,00%
GERBION	virellaSARS-CoV-2 seqc	5	5	0	0	100,00%
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	5	0	0	100,00%
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	3	0	0	100,00%
LUMINEX	NxTAG CoV	1	1	0	0	100,00%
MIKROGEN	ampliCube Coronavirus Panel	1	1	0	0	100,00%
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	3	0	0	100,00%
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	4	0	0	100,00%
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	3	0	0	100,00%
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	55	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	39	39	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	51	50	0	1	98,04%
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	68	67	0	1	98,53%
TIB MOLBIOL	LightMix Sarbeco E-gene	1	1	0	0	100,00%
		373	**371**	**0**	**2**	**99,46%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340062 (Result (qual)) - SARS-CoV-2 negative, lysate of non-infected cells

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=969)	intermediate (N=4)	positive (N=7)	Quota (98.6%)
N-Gene						
ABBOTT	RealTime SARS-CoV-2	3	3	0	0	100,00%
OTHER MANUFACTURERS		10	10	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	75,00%
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	2	0	0	100,00%
CEPHEID	Xpert Xpress SARS-CoV-2	12	12	0	0	100,00%
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	4	0	0	100,00%
CLONIT	quanty COVID-19 Kit	4	3	0	1	75,00%
IN HOUSE (dPCR)		1	1	0	0	100,00%
IN HOUSE		33	33	0	0	100,00%
ELITech	GeneFinder COVID-19 Plus	9	9	0	0	100,00%
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	0	0	100,00%
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	4	0	0	100,00%
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	1	0	0	100,00%
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	3	0	0	100,00%
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	3	0	0	100,00%
LUMINEX	NxTAG CoV	1	1	0	0	100,00%
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	3	0	0	100,00%
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	3	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	52	51	0	1	98,08%
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	13	13	0	0	100,00%
VITASSAY	Vitassay qPCR SARSCoV-2	1	1	0	0	100,00%
		167	**164**	**1**	**2**	**98,20%**
ORF1a						
OTHER MANUFACTURERS		1	1	0	0	100,00%
MIKROGEN	ampliCube Coronavirus Panel	3	3	0	0	100,00%
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	10	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	32	0	0	100,00%
		46	**46**	**0**	**0**	**100,00%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340062 (Result (qual)) - SARS-CoV-2 negative, lysate of non-infected cells

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=969)	intermediate (N=4)	positive (N=7)	Quota (98.6%)
ORF1ab						
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	5	0	0	100,00%
OTHER MANUFACTURERS		9	9	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	75,00%
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	2	0	0	100,00%
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	4	0	0	100,00%
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	7	0	0	100,00%
DIASORIN	Simplexa COVID-19 Direct Kit	4	4	0	0	100,00%
IN HOUSE		6	6	0	0	100,00%
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	3	0	0	100,00%
LUMINEX	NxTAG CoV	1	1	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	1	0	0	100,00%
VITASSAY	Vitassay qPCR SARSCoV-2	2	2	0	0	100,00%
		48	**47**	**1**	**0**	**97,92%**
RdRP-Gene						
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	1	0	0	100,00%
ABBOTT	RealTime SARS-CoV-2	6	6	0	0	100,00%
OTHER MANUFACTURERS		10	9	0	1	90,00%
IN HOUSE (dPCR)		1	1	0	0	100,00%
IN HOUSE		41	40	1	0	97,56%
ELITech	GeneFinder COVID-19 Plus	9	9	0	0	100,00%
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	1	0	0	100,00%
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	4	0	0	100,00%
GENESIG	Coronavirus COVID-19	5	5	0	0	100,00%
GERBION	virellaSARS-CoV-2 seqc	5	5	0	0	100,00%
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	4	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	57	55	0	2	96,49%
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	38	38	0	0	100,00%
		182	**178**	**1**	**3**	**97,80%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340062 (Result (qual)) - SARS-CoV-2 negative, lysate of non-infected cells

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=969)	intermediate (N=4)	positive (N=7)	Quota (98.6%)
S-Gene						
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	60	1	0	98,36%
OTHER MANUFACTURERS		1	1	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	4	0	0	100,00%
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	2	0	0	100,00%
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	26	0	0	100,00%
DIASORIN	Simplexa COVID-19 Direct Kit	4	4	0	0	100,00%
IN HOUSE		1	1	0	0	100,00%
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	1	0	0	100,00%
		100	**99**	**1**	**0**	**99,00%**
gene region not specified by participants						
ABBOTT	RealTime SARS-CoV-2	9	9	0	0	100,00%
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	1	0	0	100,00%
OTHER MANUFACTURERS		14	14	0	0	100,00%
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	3	0	0	100,00%
ANICON	Kylt SARS-CoV-2 Screening RTU	1	1	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	0	0	100,00%
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	2	0	0	100,00%
IN HOUSE		3	3	0	0	100,00%
EURO IMMUN	EURORealTime SARS-CoV-2	4	4	0	0	100,00%
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	4	0	0	100,00%
GENESIG	Coronavirus COVID-19	6	6	0	0	100,00%
GERBION	virellaSARS-CoV-2 seqc	2	2	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	11	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	3	3	0	0	100,00%
		64	**64**	**0**	**0**	**100,00%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340063 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 10 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=6)	intermediate (N=2)	positive (N=971)	Quota (98.8%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
E-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	0	0	48	100,00%	25.0	22.0	30.3
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	1	0	3	75,00%	26.8	23.3	29.1
OTHER MANUFACTURERS		10	0	0	10	100,00%	26.7	25.4	29.1
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2	100,00%			
CEPHEID	Xpert Xpress SARS-CoV-2	11	0	0	11	100,00%	24.8	24.1	27.3
IN HOUSE (dPCR)		1	0	0	1	100,00%			
IN HOUSE		47	0	0	47	100,00%	26.0	19.8	33.0
ELITech	GeneFinder COVID-19 Plus	8	0	0	8	100,00%	25.5	23.8	31.0
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1	100,00%	27.3	27.3	27.3
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	0	0	1	100,00%	29.9	29.9	29.9
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1	100,00%	25.0	25.0	25.0
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5	100,00%	26.6	26.0	28.0
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	0	0	5	100,00%	27.4	24.9	29.2
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	1	0	2	66,67%	22.8	21.0	24.6
LUMINEX	NxTAG CoV	1	0	0	1	100,00%			
MIKROGEN	ampliCube Coronavirus Panel	1	0	0	1	100,00%	26.0	26.0	26.0
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	0	0	3	100,00%	24.2	23.9	28.1
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	0	0	4	100,00%	23.8	22.4	25.6
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	0	0	3	100,00%	26.7	22.2	30.4
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	0	0	55	100,00%	26.5	20.6	30.1
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	38	0	0	38	100,00%	26.0	23.8	28.7
SEEGENE	Allplex 2019 n-CoV Assay	51	0	0	51	100,00%	24.7	22.0	29.0
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	67	0	1	66	98,51%	26.0	22.8	35.3
TIB MOLBIOL	LightMix Sarbeco E-gene	1	0	0	1	100,00%	25.9	25.9	25.9
		371	**2**	**1**	**368**	**99,19%**	**25.7**	**19.8**	**35.3**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340063 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 10 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=6)	intermediate (N=2)	positive (N=971)	Quota (98.8%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
N-Gene									
ABBOTT	RealTime SARS-CoV-2	3	0	0	3	100,00%			
OTHER MANUFACTURERS		10	0	0	10	100,00%	28.4	23.3	39.6
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4	100,00%	21.4	20.0	24.4
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2	100,00%	22.7	20.4	24.9
CEPHEID	Xpert Xpress SARS-CoV-2	12	0	0	12	100,00%	26.6	26.3	29.8
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	0	0	4	100,00%	26.4	24.4	29.6
CLONIT	quanty COVID-19 Kit	4	1	0	3	75,00%	25.4	23.1	27.6
IN HOUSE (dPCR)		1	0	0	1	100,00%			
IN HOUSE		33	0	0	33	100,00%	27.8	23.2	38.3
ELITech	GeneFinder COVID-19 Plus	9	0	0	9	100,00%	25.2	23.4	31.0
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1	100,00%	24.7	24.7	24.7
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4	100,00%	27.3	26.0	29.7
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1	100,00%	26.1	26.1	26.1
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	0	0	3	100,00%	28.1	26.9	29.0
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	1	0	2	66,67%	24.1	22.0	26.2
LUMINEX	NxTAG CoV	1	0	0	1	100,00%			
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	0	0	3	100,00%	23.5	23.1	23.8
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	0	0	3	100,00%	27.6	23.5	27.7
SEEGENE	Allplex 2019 n-CoV Assay	52	0	0	52	100,00%	26.8	20.2	29.2
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	13	0	0	13	100,00%	32.7	30.8	37.2
VITASSAY	Vitassay qPCR SARSCoV-2	1	0	0	1	100,00%	27.4	27.4	27.4
		167	**2**	**0**	**165**	**98,80%**	**26.9**	**20.0**	**39.6**
ORF1a									
OTHER MANUFACTURERS		1	0	0	1	100,00%	27.1	27.1	27.1
MIKROGEN	ampliCube Coronavirus Panel	3	0	1	2	66,67%	27.1	25.0	27.4
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	0	0	10	100,00%	25.2	24.0	27.5
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	0	0	32	100,00%	25.5	24.8	31.5
		46	**0**	**1**	**45**	**97,83%**	**25.5**	**24.0**	**31.5**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340063 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 10 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=6)	intermediate (N=2)	positive (N=971)	Quota (98.8%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
ORF1ab									
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	1	0	4	80,00%	25.0	24.5	29.5
OTHER MANUFACTURERS		9	0	0	9	100,00%	25.6	14.5	33.4
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4	100,00%	22.6	20.0	24.4
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2	100,00%	20.3	16.4	24.1
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	0	0	4	100,00%			
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	0	0	7	100,00%	24.3	22.3	30.7
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4	100,00%	22.4	22.2	22.9
IN HOUSE		6	0	0	6	100,00%	28.7	25.0	30.3
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	1	0	2	66,67%	24.3	22.0	26.6
LUMINEX	NxTAG CoV	1	0	0	1	100,00%			
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test								
VITASSAY	Vitassay qPCR SARSCoV-2	2	0	0	2	100,00%	26.2	26.0	26.4
		47	**2**	**0**	**45**	**95,74%**	**24.7**	**14.5**	**33.4**
RdRP-Gene									
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	0	0	1	100,00%			
ABBOTT	RealTime SARS-CoV-2	6	0	0	6	100,00%	14.1	13.4	17.5
OTHER MANUFACTURERS		10	0	0	10	100,00%	25.9	25.2	35.1
IN HOUSE (dPCR)		1	0	0	1	100,00%			
IN HOUSE		42	0	0	42	100,00%	28.1	23.0	36.1
ELITech	GeneFinder COVID-19 Plus	9	0	0	9	100,00%	27.2	24.8	32.8
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	0	0	1	100,00%			
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4	100,00%	28.7	27.0	32.9
GENESIG	Coronavirus COVID-19	5	0	0	5	100,00%	28.8	27.0	32.5
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5	100,00%	29.5	29.0	31.6
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	0	0	4	100,00%	28.1	25.0	31.0
SEEGENE	Allplex 2019 n-CoV Assay	57	0	0	57	100,00%	26.2	24.0	33.2
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	39	0	0	39	100,00%	30.5	24.7	38.3
		184	**0**	**0**	**184**	**100,00%**	**27.2**	**13.4**	**38.3**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340063 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 10 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=6)	intermediate (N=2)	positive (N=971)	Quota (98.8%)	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
S-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	0	0	61	100,00%	24.7	21.0	28.1
OTHER MANUFACTURERS		1	0	0	1	100,00%			
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4	100,00%	21.9	20.0	24.6
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2	100,00%	20.6	18.0	23.1
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	0	0	26	100,00%	27.7	25.9	30.0
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4	100,00%	22.8	22.2	22.9
IN HOUSE		1	0	0	1	100,00%	25.6	25.6	25.6
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	0	0	1	100,00%	29.9	29.9	29.9
		100	**0**	**0**	**100**	**100,00%**	**25.0**	**18.0**	**30.0**
gene region not specified by participants									
ABBOTT	RealTime SARS-CoV-2	9	0	0	9	100,00%	15.4	13.5	16.7
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	0	0	1	100,00%	28.0	28.0	28.0
OTHER MANUFACTURERS		14	0	0	14	100,00%	25.8	12.8	29.0
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	0	0	3	100,00%	27.0	25.2	30.5
ANICON	Kylt SARS-CoV-2 Screening RTU	1	0	0	1	100,00%	27.9	27.9	27.9
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	0	0	1	100,00%	25.0	25.0	25.0
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2	100,00%			
IN HOUSE		3	0	0	3	100,00%	25.7	24.6	28.3
EURO IMMUN	EURORealTime SARS-CoV-2	4	0	0	4	100,00%	27.1	25.6	31.1
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	0	0	4	100,00%	25.6	23.7	27.7
GENESIG	Coronavirus COVID-19	6	0	0	6	100,00%	31.4	26.7	35.9
GERBION	virellaSARS-CoV-2 seqc	2	0	0	2	100,00%	26.5	25.7	27.3
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	0	0	11	100,00%	25.3	24.6	30.8
SEEGENE	Allplex 2019 n-CoV Assay	3	0	0	3	100,00%	25.4	25.0	27.6
		64	**0**	**0**	**64**	**100,00%**	**25.7**	**12.8**	**35.9**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340064 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 100 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=64)	intermediate (N=2)	positive (N=916)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
E-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	0	0	48		28.7	25.4	33.9
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	2	0	2		25.2	20.5	29.8
OTHER MANUFACTURERS		10	0	0	10		30.0	28.7	33.3
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2				
CEPHEID	Xpert Xpress SARS-CoV-2	11	1	0	10		28.2	27.6	30.5
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		47	2	0	45		29.4	22.9	34.0
ELITech	GeneFinder COVID-19 Plus	8	1	0	7		28.7	26.9	34.1
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1		30.2	30.2	30.2
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	0	0	1		33.1	33.1	33.1
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1		29.5	29.5	29.5
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5		30.0	29.5	30.0
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	0	0	5		30.7	28.9	32.0
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1		27.6	27.6	27.6
LUMINEX	NxTAG CoV	1	0	0	1				
MIKROGEN	ampliCube Coronavirus Panel	1	0	0	1		29.0	29.0	29.0
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	0	0	3		28.4	27.9	31.6
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	0	0	4		27.1	25.5	29.5
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	0	0	3		30.2	25.3	33.5
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	0	0	55		30.0	17.7	33.8
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	39	0	0	39		29.1	27.8	32.0
SEEGENE	Allplex 2019 n-CoV Assay	51	7	0	44		28.1	25.4	33.7
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	68	2	0	66		29.7	26.9	36.0
TIB MOLBIOL	LightMix Sarbeco E-gene	1	0	0	1		29.5	29.5	29.5
		373	**17**	**0**	**356**		**29.2**	**17.7**	**36.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340064 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 100 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=64)	intermediate (N=2)	positive (N=916)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
N-Gene									
ABBOTT	RealTime SARS-CoV-2	3	0	0	3				
OTHER MANUFACTURERS		10	0	0	10		31.7	26.2	41.0
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		26.3	20.0	27.6
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	1	0	1		21.9	21.9	21.9
CEPHEID	Xpert Xpress SARS-CoV-2	12	1	0	11		30.3	29.8	32.9
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	0	0	4		29.8	27.3	31.8
CLONIT	quanty COVID-19 Kit	4	3	0	1				
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		33	1	0	32		31.3	27.2	38.5
ELITech	GeneFinder COVID-19 Plus	9	1	0	8		28.5	26.2	33.7
EURO IMMUN	EURORealTime SARS-CoV-2	1	0	0	1		27.8	27.8	27.8
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	4	0	0				
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	0	0	1		29.8	29.8	29.8
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	0	0	3		30.6	30.0	31.3
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1		29.2	29.2	29.2
LUMINEX	NxTAG CoV	1	0	0	1				
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	0	0	3		26.6	26.5	26.7
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	0	0	3		30.6	27.5	31.4
SEEGENE	Allplex 2019 n-CoV Assay	52	7	0	45		30.0	25.0	41.5
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	12	0	0	12		35.3	33.3	37.5
VITASSAY	Vitassay qPCR SARSCoV-2	1	0	0	1		30.2	30.2	30.2
		166	**20**	**0**	**146**		**30.2**	**20.0**	**41.5**
ORF1a									
OTHER MANUFACTURERS		1	0	0	1		30.5	30.5	30.5
MIKROGEN	ampliCube Coronavirus Panel	3	0	1	2		31.1	27.7	31.2
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	0	0	10		28.9	27.3	34.0
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	1	0	31		28.7	28.0	33.2
		46	**1**	**1**	**44**		**28.8**	**27.3**	**34.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340064 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 100 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=64)	intermediate (N=2)	positive (N=916)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
ORF1ab									
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	2	0	3		28.8	27.8	32.4
OTHER MANUFACTURERS		9	0	0	9		29.4	18.4	35.6
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		26.2	20.0	29.6
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	1	0	1		22.5	22.5	22.5
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	0	0	4				
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	0	0	7		27.9	25.8	34.5
DIASORIN	Simplexa COVID-19 Direct Kit	4	2	0	2		26.7	26.3	27.1
IN HOUSE		6	0	0	6		32.4	28.4	33.9
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1		33.1	29.2	37.0
LUMINEX	NxTAG CoV	1	0	0	1				
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	0	0	1		28.4	28.4	28.4
VITASSAY	Vitassay qPCR SARSCoV-2	2	0	0	2		29.4	28.7	30.1
		48	**7**	**0**	**41**		**28.8**	**18.4**	**37.0**
RdRP-Gene									
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	0	0	1				
ABBOTT	RealTime SARS-CoV-2	6	0	0	6		17.6	16.0	21.1
OTHER MANUFACTURERS		10	0	0	10		29.0	27.0	38.5
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		42	3	0	39		31.3	26.7	39.8
ELITech	GeneFinder COVID-19 Plus	9	1	0	8		30.0	28.1	36.5
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	0	0	1				
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	4	0	0				
GENESIG	Coronavirus COVID-19	5	0	0	5		32.3	30.0	36.6
GERBION	virellaSARS-CoV-2 seqc	5	0	0	5		32.8	31.9	34.9
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	1	0	3		28.6	28.5	34.2
SEEGENE	Allplex 2019 n-CoV Assay	57	7	0	50		29.7	27.6	32.8
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	40	0	1	39		33.9	28.0	41.4
		185	**16**	**1**	**168**		**30.5**	**16.0**	**41.4**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340064 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 100 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=64)	intermediate (N=2)	positive (N=916)	Sample not evaluated	Ct/Cp/ Ct/CN Median	Ct/Cp/ Cq/CN Min	Ct/Cp/ Cq/CN Max
S-Gene									
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	0	0	61		28.0	24.5	31.5
OTHER MANUFACTURERS		1	0	0	1				
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		26.9	20.0	28.0
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	1	0	1		21.5	21.5	21.5
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	0	0	26		31.1	29.3	32.7
DIASORIN	Simplexa COVID-19 Direct Kit	4	2	0	2		26.6	26.5	26.6
IN HOUSE		1	0	0	1		29.6	29.6	29.6
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	0	0	1		34.2	34.2	34.2
		100	**3**	**0**	**97**		**28.6**	**20.0**	**34.2**
gene region not specified by participants									
ABBOTT	RealTime SARS-CoV-2	9	0	0	9		18.5	16.8	20.3
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	0	0	1		31.0	31.0	31.0
OTHER MANUFACTURERS		14	0	0	14		29.4	16.5	36.5
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	0	0	3		30.5	28.5	34.7
ANICON	Kylt SARS-CoV-2 Screening RTU	1	0	0	1		32.1	32.1	32.1
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	0	0	1		28.5	28.5	28.5
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	0	0	2				
IN HOUSE		3	0	0	3		30.9	27.7	31.8
EURO IMMUN	EURORealTime SARS-CoV-2	4	0	0	4		30.8	28.9	34.1
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	0	0	4		28.9	27.4	30.5
GENESIG	Coronavirus COVID-19	6	0	0	6		34.6	30.8	40.0
GERBION	virellaSARS-CoV-2 seqc	2	0	0	2		29.7	28.6	30.8
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	0	0	11		28.8	28.0	33.9
SEEGENE	Allplex 2019 n-CoV Assay	3	0	0	3		28.2	28.0	31.1
		64	**0**	**0**	**64**		**29.0**	**16.5**	**40.0**

Please note:

- The number of analyses considered for the columns „Ct/Cp/Cq/CN Median“, „Ct/Cp/Cq/CN Min“ and „Ct/Cp/Cq/CN Max“ can be lower than the number of analyses stated in column „Total“ if laboratories have not stated their Ct/Cp/Cq/CN values.
- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340065 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV 229E 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=908)	intermediate (N=4)	positive (N=67)	Quota (92.4%)
E-Gene						
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	48	48	0	0	100,00%
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	4	2	0	2	50,00%
OTHER MANUFACTURERS		10	10	0	0	100,00%
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	2	0	0	100,00%
CEPHEID	Xpert Xpress SARS-CoV-2	11	10	0	1	90,91%
IN HOUSE (dPCR)		1	1	0	0	100,00%
IN HOUSE		47	45	0	2	95,74%
ELITech	GeneFinder COVID-19 Plus	8	7	0	1	87,50%
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	0	0	100,00%
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Screen	1	1	0	0	100,00%
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	1	0	0	100,00%
GERBION	virellaSARS-CoV-2 seqc	5	5	0	0	100,00%
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	5	5	0	0	100,00%
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1	66,67%
LUMINEX	NxTAG CoV	1	1	0	0	100,00%
MIKROGEN	ampliCube Coronavirus Panel	1	1	0	0	100,00%
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	3	3	0	0	100,00%
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	4	4	0	0	100,00%
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	3	3	0	0	100,00%
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	55	54	0	1	98,18%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	39	39	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	51	44	0	7	86,27%
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	68	65	0	3	95,59%
TIB MOLBIOL	LightMix Sarbeco E-gene	1	1	0	0	100,00%
		373	**355**	**0**	**18**	**95,17%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340065 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV 229E 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=908)	intermediate (N=4)	positive (N=67)	Quota (92.4%)
N-Gene						
ABBOTT	RealTime SARS-CoV-2	3	3	0	0	100,00%
OTHER MANUFACTURERS		10	10	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	75,00%
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	1	0	1	50,00%
CEPHEID	Xpert Xpress SARS-CoV-2	12	11	0	1	91,67%
CERTEST BIOTEC	VIASURE SARS-CoV-2	4	4	0	0	100,00%
CLONIT	quanty COVID-19 Kit	4	1	0	3	25,00%
IN HOUSE (dPCR)		1	1	0	0	100,00%
IN HOUSE		33	32	0	1	96,97%
ELITech	GeneFinder COVID-19 Plus	9	8	0	1	88,89%
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	0	0	100,00%
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4	0,00%
GENETIC SIGNATURES	EasyScreen SARS-CoV-2 Detection Kit	1	1	0	0	100,00%
INGENETIX	ViroReal SARS-CoV-2 & SARS	3	3	0	0	100,00%
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1	66,67%
LUMINEX	NxTAG CoV	1	1	0	0	100,00%
NEUMODX	NeuMoDx SARS-CoV-2 Assay	3	3	0	0	100,00%
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	3	3	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	52	45	0	7	86,54%
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	12	12	0	0	100,00%
VITASSAY	Vitassay qPCR SARSCoV-2	1	1	0	0	100,00%
		166	**146**	**1**	**19**	**87,95%**
ORF1a						
OTHER MANUFACTURERS		1	1	0	0	100,00%
MIKROGEN	ampliCube Coronavirus Panel	3	3	0	0	100,00%
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	10	10	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	32	30	0	2	93,75%
		46	**44**	**0**	**2**	**95,65%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340065 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV 229E 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=908)	intermediate (N=4)	positive (N=67)	Quota (92.4%)
ORF1ab						
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	3	0	2	60,00%
OTHER MANUFACTURERS		9	9	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	75,00%
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	1	0	1	50,00%
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	4	0	0	100,00%
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	7	0	0	100,00%
DIASORIN	Simplexa COVID-19 Direct Kit	4	2	0	2	50,00%
IN HOUSE		6	6	0	0	100,00%
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	2	0	1	66,67%
LUMINEX	NxTAG CoV	1	1	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	1	0	0	100,00%
VITASSAY	Vitassay qPCR SARSCoV-2	2	2	0	0	100,00%
		48	**41**	**1**	**6**	**85,42%**
RdRP-Gene						
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	1	0	0	100,00%
ABBOTT	RealTime SARS-CoV-2	6	6	0	0	100,00%
OTHER MANUFACTURERS		10	10	0	0	100,00%
IN HOUSE (dPCR)		1	1	0	0	100,00%
IN HOUSE		41	37	1	3	90,24%
ELITech	GeneFinder COVID-19 Plus	9	8	0	1	88,89%
EUROFINS TECHNOLOGIES	VirSeek SARS-CoV-2 Ident	1	1	0	0	100,00%
GENEMATRIX	NeoPlex COVID-19 Detection Kit	4	0	0	4	0,00%
GENESIG	Coronavirus COVID-19	5	5	0	0	100,00%
GERBION	virellaSARS-CoV-2 seqc	5	5	0	0	100,00%
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	4	4	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	57	50	0	7	87,72%
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	38	37	0	1	97,37%
		182	**165**	**1**	**16**	**90,66%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340

70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative

Sample 340065 (Result (qual)) - SARS-CoV-2 negative, positive for HCoV 229E 1 : 2 500 diluted, specificity control

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=908)	intermediate (N=4)	positive (N=67)	Quota (92.4%)
S-Gene						
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	61	58	0	3	95,08%
OTHER MANUFACTURERS		1	1	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	3	1	0	75,00%
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	1	0	1	50,00%
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	26	26	0	0	100,00%
DIASORIN	Simplexa COVID-19 Direct Kit	4	2	0	2	50,00%
IN HOUSE		1	1	0	0	100,00%
IMMUNDIAGNOSTIK	MutaPLEX Coronavirus	1	1	0	0	100,00%
		100	**93**	**1**	**6**	**93,00%**
gene region not specified by participants						
ABBOTT	RealTime SARS-CoV-2	9	9	0	0	100,00%
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	1	0	0	100,00%
OTHER MANUFACTURERS		14	14	0	0	100,00%
ANICON	Kylt SARS-CoV-2 Confirmation RTU	3	3	0	0	100,00%
ANICON	Kylt SARS-CoV-2 Screening RTU	1	1	0	0	100,00%
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	0	0	100,00%
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	2	2	0	0	100,00%
IN HOUSE		3	3	0	0	100,00%
EURO IMMUN	EURORealTime SARS-CoV-2	4	4	0	0	100,00%
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	4	4	0	0	100,00%
GENESIG	Coronavirus COVID-19	6	6	0	0	100,00%
GERBION	virellaSARS-CoV-2 seqc	2	2	0	0	100,00%
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	11	11	0	0	100,00%
SEEGENE	Allplex 2019 n-CoV Assay	3	3	0	0	100,00%
		64	**64**	**0**	**0**	**100,00%**

Please note:

- If success rates are shown in the tables, the respective success rate also takes into account missing and therefore incorrect results from laboratories. This occurs when the laboratories have not stated any result for an individual sample of the sample set.