

Performance Report COVID SARS-CoV-2 Molecular

Test Event 2021_2 Results Deadline 2021-07-28


Participant Centre de Recherche International Chantal Biya ID CM1016AI	ACCEPTABLE 100%	UNACCEPTABLE 0%	NOT EVALUATED 0%
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Program SARS-CoV-2 Molecular	ACCEPTABLE 100%	UNACCEPTABLE 0%	NOT EVALUATED 0%
Order Code COVID435			
Subscription ID 194627			

Analytes	ACCEPTABLE	UNACCEPTABLE	NOT EVALUATED
N gene Interpretation	5 ACCEPTABLE 0 UNACCEPTABLE 0 NOT EVALUATED.	100%	0%
ORF1ab gene Interpretation	5 ACCEPTABLE 0 UNACCEPTABLE 0 NOT EVALUATED.	100%	0%
RdRp/N gene Interpretation	5 ACCEPTABLE 0 UNACCEPTABLE 0 NOT EVALUATED.	100%	0%
SARS-CoV-2 Interpretation	5 ACCEPTABLE 0 UNACCEPTABLE 0 NOT EVALUATED.	100%	0%

Performance Report

1 / 8
2021/Sep/09
Final

Participant CM1016AI Centre de Recherche International Chantal Biya
Subscription ID 194627 COVD435 SARS-CoV-2 Molecular
Results Deadline 2021/Jul/14
Accreditation  Accredited by A2LA as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01.

Sample Condition

Date samples were received (YYYY/MMM/DD) 2021/Jul/06
 Were the samples received in good condition? Yes

Assay Abbott RealTime SARS-CoV-2

RdRp/N gene ct value

Sample	Run	Replicate 1			Replicate 2			Replicate 3			Peer Group Statistics					
		Result	Grade	SDI	Result	Grade	SDI	Result	Grade	SDI	Participants (n)	Results (n)	Statistical (n)	Mean	SD	CV(%)
A	1	19.45	⊖													
B	1	>37, Above Linear/Detection Limit	⊖													
C	1	19.73	⊖													
D	1	>37, Above Linear/Detection Limit	⊖													
E	1	20.09	⊖													

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model

Grade  Acceptable  Unacceptable  Not evaluated

Performance Report

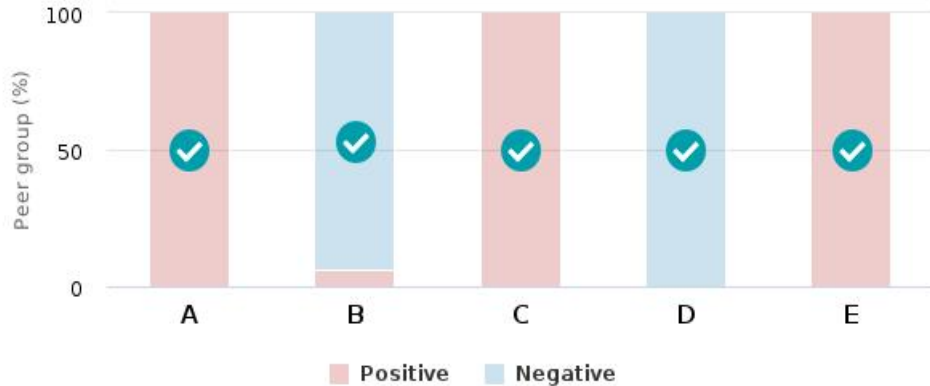
2 / 8
2021/Sep/09
Final

Participant	CM1016AI	Centre de Recherche International Chantal Biya
Subscription ID	194627	COVID435 SARS-CoV-2 Molecular
Results Deadline	2021/Jul/14	
Accreditation	Accredited by A2LA as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01.	

Assay Abbott RealTime SARS-CoV-2

RdRp/N gene Interpretation

Sample	Result	Grade	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	
A	Positive	✓	17	17	17	17	100	Positive
B	Negative	✓	17	17	17	16	94	Negative
C	Positive	✓	17	17	17	17	100	Positive
D	Negative	✓	17	17	17	17	100	Negative
E	Positive	✓	17	17	17	17	100	Positive




Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
250763	AS3	Extraction	Abbott mSample Preparation DNA Kit		
		Amplification	Abbott RealTime SARS-CoV-2 assay		

Grade Acceptable Unacceptable Not evaluated

Performance Report

3 / 8
2021/Sep/09
Final

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Assay Abbott RealTime SARS-CoV-2


Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
		Detection	Abbott RealTime SARS-CoV-2 assay		

Grade  Acceptable  Unacceptable  Not evaluated

Performance Report

4 / 8
2021/Sep/09
Final

Participant CM1016AI Centre de Recherche International Chantal Biya
Subscription ID 194627 COVID435 SARS-CoV-2 Molecular
Results Deadline 2021/Jul/14
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Assay Qiagen QIAamp Viral RNA Mini Kit/Da An Gene Detection Kit for 2019 Novel Coronav

ORF1ab gene ct value

Sample	Run	Replicate 1			Replicate 2			Replicate 3			Peer Group Statistics					
		Result	Grade	SDI	Result	Grade	SDI	Result	Grade	SDI	Participants (n)	Results (n)	Statistical (n)	Mean	SD	CV(%)
A	1	31.988	⊖													
B	1	>45, Above Linear/Detection Limit	⊖													
C	1	31.623	⊖													
D	1	>45, Above Linear/Detection Limit	⊖													
E	1	31.514	⊖													

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model


N gene ct value

Sample	Run	Replicate 1			Replicate 2			Replicate 3			Peer Group Statistics					
		Result	Grade	SDI	Result	Grade	SDI	Result	Grade	SDI	Participants (n)	Results (n)	Statistical (n)	Mean	SD	CV(%)
A	1	30.237	⊖													
B	1	>45, Above Linear/Detection Limit	⊖													
C	1	30.614	⊖													
D	1	>45, Above Linear/Detection Limit	⊖													
E	1	30.813	⊖													

Grade  Acceptable  Unacceptable  Not evaluated

Performance Report

5 / 8
2021/Sep/09
Final

Participant	CM1016AI	Centre de Recherche International Chantal Biya
Subscription ID	194627	COVD435 SARS-CoV-2 Molecular
Results Deadline	2021/Jul/14	
Accreditation	 Accredited by A2LA as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01.	

Assay: Qiagen QIAamp Viral RNA Mini Kit/Da An Gene Detection Kit for 2019 Novel Coronav


Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model

Grade  Acceptable  Unacceptable  Not evaluated

Performance Report

6 / 8
2021/Sep/09
Final

Participant CM1016AI Centre de Recherche International Chantal Biya
Subscription ID 194627 COVID435 SARS-CoV-2 Molecular
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Assay Qiagen QIAamp Viral RNA Mini Kit/Da An Gene Detection Kit for 2019 Novel Coronav

ORF1ab gene Interpretation

Sample	Result	Grade	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	
A	Positive	✓	3	3	3	3	100	Positive
B	Negative	✓	3	3	3	3	100	Negative
C	Positive	✓	3	3	3	3	100	Positive
						0	0	Equivocal/Grey Zone
D	Negative	✓	3	3	3	3	100	Negative
E	Positive	✓	3	3	3	3	100	Positive
						0	0	Presumptive Positive
						0	0	Equivocal/Grey Zone

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
253078	AS3	Extraction	Qiagen QIAamp Viral RNA Mini Kit		
		Amplification	Da An Gene Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA		
		Detection	Da An Gene Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA		


N gene Interpretation

Sample	Result	Grade	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	

Grade  Acceptable  Unacceptable  Not evaluated

Performance Report

7 / 8
2021/Sep/09
Final

Participant CM1016AI Centre de Recherche International Chantal Biya
Subscription ID 194627 COVID435 SARS-CoV-2 Molecular
Results Deadline 2021/Jul/14
Accreditation  Accredited by A2LA as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01.

Assay Qiagen QIAamp Viral RNA Mini Kit/Da An Gene Detection Kit for 2019 Novel Coronav

N gene Interpretation

Sample	Result	Grade	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	
A	Positive	✓	3	3	3	3	100	Positive
						0	0	Equivocal/Grey Zone
B	Negative	✓	3	3	3	3	100	Negative
C	Positive	✓	3	3	3	3	100	Positive
D	Negative	✓	3	3	3	3	100	Negative
E	Positive	✓	3	3	3	3	100	Positive
						0	0	Presumptive Positive


Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
253078	AS3	Extraction	Qiagen QIAamp Viral RNA Mini Kit		
		Amplification	Da An Gene Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA		
		Detection	Da An Gene Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA		

Grade  Acceptable  Unacceptable  Not evaluated

Performance Report

8 / 8
2021/Sep/09
Final

Participant CM1016AI Centre de Recherche International Chantal Biya
Subscription ID 194627 COVD435 SARS-CoV-2 Molecular
Results Deadline 2021/Jul/14
Accreditation  Accredited by A2LA as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01.

SARS-CoV-2 Interpretation

Sample	Result	Grade	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	
A	Positive	✓	220	220	220	214	97	Positive
B	Negative	✓	220	220	220	213	97	Negative
						2	1	Invalid
C	Positive	✓	220	220	220	211	96	Positive
D	Negative	✓	220	220	220	217	99	Negative
E	Positive	✓	220	220	220	210	95	Positive
						1	0.5	Presumptive Positive
						1	0.5	Equivocal/Grey Zone

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
0	AR	All Results			

Grade  Acceptable  Unacceptable  Not evaluated



Test Event Summary

SARS-CoV-2 Molecular

COVD435

Status: Final

Issue Date: 2021-09-09

Version #:1.0

Published Results Deadline Date: 2021-07-14
Actual Results Deadline Date: 2021-08-11

Report prepared and authorized by the ASPIRE unit of Oneworld Accuracy.

Oneworld Accuracy

Oneworld Accuracy is a social enterprise group headquartered in Vancouver, British Columbia, Canada. We are guided by the conviction that accurate medical tests are a fundamental human right for all people in all countries as they enable doctors to make proper decisions so patients receive proper care.

Our Mission: To achieve universal testing accuracy for improved healthcare for all people.

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Confidentiality Commitment

The identity of participants in EQA programs shall be confidential and known only to persons involved in the operation of the programs, unless the participant waives confidentiality.

All information supplied by a participant to Oneworld Accuracy shall be treated as confidential.

When an interested party requires the test results to be directly provided by Oneworld Accuracy Inc, the participants shall be made aware of the arrangement in advance of participation.

Activities Subcontracted

Oneworld Accuracy subcontracts the following activities for all EQA programs: manufacturing of EQA samples, testing samples for homogeneity and stability and delivery of EQA samples to participants.

All Oneworld Accuracy subcontractors are thoroughly reviewed and evaluated on a regular basis. Oneworld Accuracy seeks ISO certification from all subcontractors wherever possible.

About the EQA Program

The SARS-CoV-2 Molecular - COVID435 program includes 5 sample(s) consisting of FLOQSwab® distributed in 3 shipment(s) for the 3 test event(s) in the year. The current event opened on 2021-06-23 and had a published results deadline of 2021-07-14 (actual results deadline 2021-08-11).

If storage was necessary, samples were stored at 2-30°C | 35-86°F from the time of receipt until dispatching to the participants. All shipments were packed with the appropriate amount of stabilizers, if necessary, to ensure the required temperature was maintained throughout the regular delivery time. Any exceptions were recorded and results reviewed at the time of evaluation.

Statistical Analysis

For quantitatively reported analytes Oneworld Accuracy applies certain sections from **ISO 13528:2015 - Statistical methods for use in proficiency testing by interlaboratory comparison** for calculating the robust mean and standard deviation for our evaluations. For qualitatively reported analytes, evaluation is based on consensus between participants and/or concordance between reported results and reference values as provided by the manufacturer, consultants, or consultant laboratories. If the analyte is reported quantitatively, then one of the following evaluation methods would apply:

1. If the assigned value is derived from the peer group mean -

The evaluation criteria may be peer group mean +/- SD, percentage (%), or an absolute value. Peer group mean is the robust mean of the results included in a statistically valid peer group created with like instruments, reagents, or methods, once statistical outliers are removed. The upper and lower limits of the acceptable range are determined from that described in the evaluation criteria as shown in the performance report.

The peer groups are shown in the performance report. The different peer groups and their associated statistics are shown in the Participation Statistics for the program and available for download from the Oneworld Accuracy website.

2. If the assigned value is derived from a reference method -

The evaluation criteria would be Reference value +/- percentage (%). Reference values can be traceable values as provided by accredited reference laboratories using reference methods, or be gravimetrically 'weighted-in'. The upper and lower limits of the acceptable range are determined from that described in the evaluation criteria as shown in the performance report.

Some programs apply Multiple Assessment Criteria (MAC) as the grading system. Depending on the percentage difference between the reference value and the reported result, results can be graded as Unacceptable, Minimal, Desirable, and Optimal.

[Click here for an interpretation guide for our performance reports, as well as a troubleshooting guide for EQA results](#)

Comments and Observations

For the test event (results deadline 2021-07-14, actual results deadline 2021-08-11), there were 3395 expected results. There were 3393 results submitted providing a participation rate of 99.94% collaboration wide.

Evaluation can be conducted with additional data from a different program format, thus the participation counts mentioned here might be different than those seen on performance reports and participation statistics reports.

Participants submitted results online using OASYS with a unique identifier assigned for each participant.

Of the results that were submitted, the percentage of results that were Acceptable (ACC) was 95.82%, Unacceptable (UNACC) 2.94% and Not-Evaluated (NE) 1.24%.

The percentage of Acceptable (ACC), Unacceptable (UNACC) and Not-Evaluated (NE) results by sample and analyte is shown below.

For samples with high NE (Not Evaluated) rates, it could be due to lack of peer group statistics or an evaluation decision being applied. Please review the participation statistics report or the performance report for additional information or commentary.

Table A: Performance by Analyte

Analyte	Sample	% ACC	% UNACC	% NE
ORF1ab gene Interpretation	A	93.00	6.00	1.00
	B	99.00	0.00	1.00
	C	94.00	5.00	1.00
	D	97.00	2.00	1.00
	E	97.00	2.00	1.00
SARS-CoV-2 Interpretation	A	97.27	2.73	0.00
	B	97.73	2.27	0.00
	C	95.91	4.09	0.00
	D	98.64	1.36	0.00
	E	96.36	3.64	0.00
N gene Intepretation	A	93.41	6.59	0.00
	B	96.70	3.30	0.00
	C	92.31	7.69	0.00
	D	97.80	2.20	0.00
	E	93.41	6.59	0.00
S gene Interpretation	A	100.00	0.00	0.00
	B	100.00	0.00	0.00
	C	95.45	4.55	0.00
	D	95.45	4.55	0.00
	E	95.45	4.55	0.00
RdRp gene Interpretation	A	100.00	0.00	0.00
	B	100.00	0.00	0.00
	C	87.50	12.50	0.00
	D	100.00	0.00	0.00
	E	95.83	4.17	0.00
E gene Interpretation	A	98.25	1.75	0.00
	B	99.13	0.87	0.00
	C	95.65	4.35	0.00
	D	99.13	0.00	0.87
	E	95.65	4.35	0.00
N2 gene Interpretation	A	98.63	1.37	0.00
	B	100.00	0.00	0.00
	C	98.65	1.35	0.00
	D	100.00	0.00	0.00
	E	97.30	2.70	0.00
N1 gene Interpretation	A	83.33	16.67	0.00
	B	100.00	0.00	0.00
	C	100.00	0.00	0.00
	D	100.00	0.00	0.00

Table A: Performance by Analyte

Analyte	Sample	% ACC	% UNACC	% NE
N1 gene Interpretation	E	83.33	16.67	0.00
RdRp/N gene Interpretation	A	100.00	0.00	0.00
	B	94.74	5.26	0.00
	C	100.00	0.00	0.00
	D	100.00	0.00	0.00
	E	100.00	0.00	0.00
ORF1ab gene Reactivity	A	81.82	9.09	9.09
	B	90.91	0.00	9.09
	C	90.91	0.00	9.09
	D	90.91	0.00	9.09
	E	90.91	0.00	9.09
ORF8 gene Interpretation	A	40.00	20.00	40.00
	C	40.00	20.00	40.00
	E	60.00	0.00	40.00
ORF8 gene Reactivity	A	40.00	20.00	40.00
	C	40.00	20.00	40.00
	E	60.00	0.00	40.00
RdRp/S gene Interpretation	A	100.00	0.00	0.00
	B	100.00	0.00	0.00
	C	100.00	0.00	0.00
	D	100.00	0.00	0.00
	E	100.00	0.00	0.00
E / N gene Interpretation	A	100.00	0.00	0.00
	B	100.00	0.00	0.00
	C	100.00	0.00	0.00
	D	100.00	0.00	0.00
	E	100.00	0.00	0.00

Note – Samples and/or analytes that are not evaluated are not displayed. Reasons can include lack of peer group statistics for evaluation and evaluation decisions such as lack of consensus between results. Refer to participation statistics reports and/or performance reports for additional information/commentary. Samples and/or analytes in which there are no submitted results are also not displayed.

Analytical problem(s) were submitted by participants who were unable to perform testing, or to get a result for a particular analyte or sample. The percentage of submitted results that had an analytical problem entered was 0.91%, and they were not evaluated (NE). The breakdown of analytical problem(s) submitted is shown below.

Table B: Analytical Problem(s)

Analytical Phase	Analytical Problem	%
Other	Not Measured	0.88
	Not Determinable	0.03

If possible and applicable, before each test event, participants should ensure they have appropriate reagents/consumables and instruments that are up-to-date with maintenance procedures, to prevent entry of a pre-analytical AP code. AP codes regarding linear/detection limits can indicate analytical issues concerning validity of a method’s measurement range, or samples that have analyte concentrations exceeding a method’s detection ranges.