Performance Report COVD SARS-CoV-2 Molecular

Test Event 2022_1 Results Deadline 2022-06-15

Participant

Centre de Recherche International Chantal Biya

ID

CMR1011AM

ACCEPTABLE	UNACCEPTABLE
100%	0%

Program

SARS-CoV-2 Molecular

Order Code: COVD435

Subscription ID: 222004

ACCEPTABLE	UNACCEPTABLE
100%	0%

Analytes

N gene Intepretation	5 ACCEPTABLE 0 UNACCEPTABLE	100%	0%
ORF1ab gene Interpretation	5 ACCEPTABLE 0 UNACCEPTABLE	100%	0%
SARS-CoV-2 Interpretation	5 ACCEPTABLE 0 UNACCEPTABLE	100%	0%

Please note that this summary excludes Not Evaluated results. Those results are available in the detailed section of this report.

Performance Report

2022/Jun/23
Final

Participant	CMR1011AM	Centre de Recherche International Chantal Biya
Subscription ID	222004	COVD435 SARS-CoV-2 Molecular
Results Deadline	2022/May/01	
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)	2022/May/10
Were the samples received in good condition?	Yes

Assay: Da An Gene RNA/DNA Purification Kit/Da An Gene Detection Kit for 2019 Novel Coro

N gene ct value

Sample	Run	Replicate 1 Result	Grade	SDI	Replicate 2 Result	Grade	SDI	Replicate 3 Result	Grade	SDI	Peer Group Statistics Participants (n)	Results (n)	Statistical (n)	Mean	SD	CV(%)
A	1	>45, Above Linear/Detection Limit														
B	1	29.762														
C	1	28.780														
D	1	>45, Above Linear/Detection Limit														
E	1	>45, Above Linear/Detection Limit														

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model

ORF1ab gene ct value

Grade: Acceptable | Unacceptable | Not evaluated

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

Participant CMR1011AM Centre de Recherche International Chantal Biya
Subscription ID 222004 COVD435 SARS-CoV-2 Molecular
Results Deadline 2022/May/01
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Assay Da An Gene RNA/DNA Purification Kit/Da An Gene Detection Kit for 2019 Novel Coro

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	>45, Above Linear/Detection Limit														
B	1	31.733														
C	1	30.770														
D	1	>45, Above Linear/Detection Limit														
E	1	>45, Above Linear/Detection Limit														

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model

Grade Acceptable Unacceptable Not evaluated

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Assay Da An Gene RNA/DNA Purification Kit/Da An Gene Detection Kit for 2019 Novel Coro

N gene Intepretation

Sample	Result	Grade	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	
A	Negative	✓	13	13	13	13	100	Negative
B	Positive	✓	13	13	13	13	100	Positive
C	Positive	✓	13	13	13	13	100	Positive
D	Negative	✓	13	13	13	13	100	Negative
E	Negative	✓	13	13	13	13	100	Negative

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
252858	AS3	Extraction	Da An Gene RNA/DNA Purification 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		

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 (%)	

Grade ✓ Acceptable ✗ Unacceptable ⊖ Not evaluated

Performance Report

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Subscription ID 222004 COVD435 SARS-CoV-2 Molecular
Results Deadline 2022/May/01
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Assay Da An Gene RNA/DNA Purification Kit/Da An Gene Detection Kit for 2019 Novel Coro

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	Negative	✓	13	13	13	13	100	Negative
B	Positive	✓	13	13	13	13	100	Positive
C	Positive	✓	13	13	13	13	100	Positive
D	Negative	✓	13	13	13	13	100	Negative
E	Negative	✓	13	13	13	13	100	Negative

Peer Group Description

PG ID	PG Code	Test Process	Kit	Technique	Instrument Model
252858	AS3	Extraction	Da An Gene RNA/DNA Purification 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

Participant CMR1011AM Centre de Recherche International Chantal Biya
Subscription ID 222004 COVD435 SARS-CoV-2 Molecular
Results Deadline 2022/May/01
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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	Negative	✓	516	525	525	518	99	Negative
B	Positive	✓	516	525	525	512	98	Positive
						3	1	Presumptive Positive
C	Positive	✓	516	525	525	518	99	Positive
						1	0.2	Presumptive Positive
D	Negative	✓	516	525	525	515	98	Negative
E	Negative	✓	516	525	525	515	98	Negative

Peer Group Description

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

Grade ✓ Acceptable ✗ Unacceptable ⊖ Not evaluated

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Performance Report

Participant	CMR1011AM	Centre de Recherche International Chantal Biya
Subscription ID	222004	COVD435 SARS-CoV-2 Molecular
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Note: COVD samples **B** (SARS-CoV-2 wild type) and **C** (SARS-CoV-2 Alpha variant - B.1.1.7) were positive for SARS-CoV-2, while samples **A, D and E** were negative for SARS-CoV-2.

Grade Acceptable Unacceptable Not evaluated

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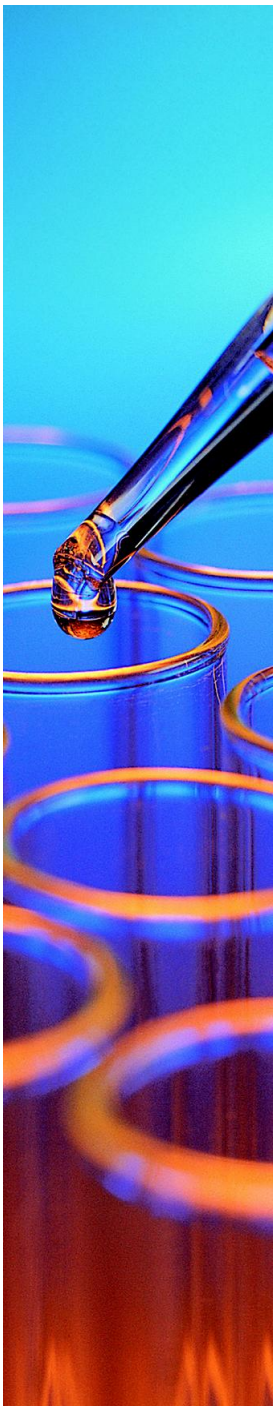

Test Event Summary

SARS-CoV-2 Molecular

COVD435

Status: Final Version #:1.0	Issue Date: 2022-06-22 Published Results Deadline Date: 2022-05-01 Actual Results Deadline Date: 2022-06-15

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.

Copyright

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 - COVD435 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 2022-03-30 and had a published results deadline of 2022-05-01 (actual results deadline 2022-06-15).

If storage was necessary, samples were stored at 4°C | 39°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

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Comments and Observations

For the test event (results deadline 2022-05-01, actual results deadline 2022-06-15), there were 8455 expected results. There were 8445 results submitted providing a participation rate of 99.88% 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 97.02%, Unacceptable (UNACC) 2.22% and Not-Evaluated (NE) 0.76%.

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 Reactivity	A	92.86	0.00	7.14
	B	93.10	0.00	6.90
	C	93.10	0.00	6.90
	D	93.10	0.00	6.90
	E	89.66	3.45	6.90
RdRp gene Reactivity	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	92.31	7.69	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
E gene Interpretation	A	97.52	1.86	0.62
	B	97.52	1.86	0.62
	C	98.14	1.24	0.62
	D	97.52	1.86	0.62
	E	98.14	1.24	0.62
N gene Intepretation	A	95.67	2.76	1.57
	B	95.28	3.15	1.57
	C	95.67	2.76	1.57
	D	95.67	2.76	1.57
	E	94.88	3.15	1.97
N1 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
N2 gene Interpretation	A	98.79	1.21	0.00
	B	100.00	0.00	0.00
	C	98.79	1.21	0.00
	D	100.00	0.00	0.00
	E	99.39	0.61	0.00
ORF1ab gene Interpretation	A	97.16	1.42	1.42
	B	95.26	3.32	1.42
	C	95.73	2.84	1.42
	D	94.31	4.27	1.42

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Table A: Performance by Analyte

Analyte	Sample	% ACC	% UNACC	% NE
ORF1ab gene Interpretation	E	94.79	3.79	1.42
RdRp gene Interpretation	A	95.96	4.04	0.00
	B	96.97	3.03	0.00
	C	100.00	0.00	0.00
	D	96.97	3.03	0.00
	E	96.97	3.03	0.00
RdRp/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
S gene Interpretation	A	95.18	3.61	1.20
	B	91.57	7.23	1.20
	C	73.49	25.30	1.20
	D	97.59	1.20	1.20
	E	96.39	2.41	1.20
SARS-CoV-2 Interpretation	A	98.48	1.33	0.19
	B	97.91	1.90	0.19
	C	98.67	1.14	0.19
	D	97.91	1.90	0.19
	E	97.91	1.90	0.19
ORF3a gene Intepretation	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 0.78%, 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	%
Pre-Analytical	Analyzer Out of Service	0.18
Other	Not Measured	0.53
	Internal Control Inhibited	0.06
	Not Determinable	0.01

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.

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