

Analysis Report

REPORT NO: LMMD/PCR/N/0005/21

DATE: 21-05-2021

Name of Test Kit	InfectID, Microbio-InfectID-COVID-19
Manufacturer	Microbio Pty Ltd, Australia
Number of kit Supplied	3kit/ (1*200 rxn)
Manufacture Date	02-2021
Expiry Date	05-2021
Lot Nos	INF-CVD-R0001/ INF-CVD-R0002/ INF-CVD-R0003 INF-CVD-D0001/ INF-CVD-D0002/ INF-CVD-D0003

1. Test details

1.1	Number of Tests Used for Evaluation	210
1.2	Total Number of Confirmed Positive Used for Evaluation	105
1.3	Total Number of Confirmed Negative Used for Evaluation	105



2. Observation: Parallel evaluation of both the D and R kits

Sample 1

Kit	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12
InfectiD COVID-R	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg
InfectiD COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg

Sample 2

Kit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12
InfectiD COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
InfectiD COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Pos	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg

Sample 3

Kit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12
InfectiD COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Pos	Neg	Neg	Neg	Neg
InfectiD COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg

Sample 4

Kit	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12
InfectiD COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Pos	Neg	Neg	Neg
InfectiD COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg	Neg



Sample 5

Kit	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg

Sample 6

Kit	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg

Sample 7

Kit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day1 0	Day1 1	Day1 2
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Pos	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg	Neg

Sample 8

Kit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day1 0	Day1 1	Day1 2
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg

Sample 9

Kit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day1 0	Day1 1	Day1 2
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Pos	Neg	Neg	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg



-CoV-2 rt-pcr Kit 1.0													
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Sample 10

Kit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg

Sample 11

Kit	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Pos	Neg	Neg	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Pos	Neg	Neg	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg	Neg

Sample 12

Kit	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12
InfectID COVID-R	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Pos	Neg	Neg
InfectID COVID-D	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Pos	Neg	Neg
RealStar [®] SARS-CoV-2 rt-pcr Kit 1.0	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Neg

Independent assessment of Kits

Microbio-InfectID-COVID-19 RT PCR ,InfectID-COVID-19-D

InfectID-COVID-19-D	RT-PCR test (RealStar [®] SARS-CoV-2 rt-pcr Kit)		Total
	Positive	Negative	
Positive	100 (TP)	0 (FP)	
Negative	5 (FN)	105 (TN)	
Total	105	105	210

TP- True positive TN-True negative FP- False positive FN- False Negative

➤ 2.1 Sensitivity: $TP / (TP + FN) = 100 / (100 + 5) = 95.23\%$

➤ 2.2 Specificity: $TN / (TN + FP) = 105 / (105 + 0) = 100\%$

➤ 2.3 Positive Predictive Value: $TP / (TP + FP) = 100 / (100 + 0) = 100\%$

➤ 2.4 Negative Predictive Value: $TN / (TN + FN) = 105 / (105 + 5) = 95.45\%$



Microbio-InfectID-COVID-19 RT PCR InfectID-COVID-19-R

InfectID-COVID-19-R	RT-PCR test (RealStar [®] SARS-CoV -2 rt-pcr Kit)		Total
	Positive	Negative	
Positive	97(TP)	5(FP)	
Negative	8(FN)	100 (TN)	
Total	105	105	210

TP- True positive TN-True negative FP- False positive FN- False Negative

- 2.5 Sensitivity: $TP / (TP + FN) = 97 / (97 + 8) = 92.38\%$
- 2.6 Specificity: $TN / (TN + FP) = 100 / (100 + 5) = 95.23\%$
- 2.7 Positive Predictive Value: $TP / (TP + FP) = 97 / (97 + 5) = 95.09\%$
- 2.8 Negative Predictive Value: $TN / (TN + FN) = 100 / (100 + 8) = 92.59\%$

3 Assay Descriptions

3.1 Objective: To evaluate the performance of InfectID, Microbio-InfectID-COVID-19 RT PCR (InfectID-COVID-19-R/ InfectID-COVID-19-D) by Microbio Pty Ltd, Australia in human swab specimen.

3.2 Purpose: The purpose of this procedure is to evaluate InfectID, Microbio-InfectID-COVID-19 RT PCR. This document applies to the evaluation of RT PCR kit manufactured by Microbio Pty Ltd Australia.

3.3 Responsibility: The RT-PCR kit should be able to produce results with high specificity and sensitivity with no cross reactivity

3.4 Quality Management: The kit was validated at Laboratory Medicine and Molecular Diagnostics (LMMD), Rajiv Gandhi Centre for Biotechnology under quality system procedure of NABL ISO 15189-2012 strictly adhering to ICMR protocols

4 Procedure

InfectID, Microbio-Sars-infectID-Covid-19 RT PCR (InfectID-COVID-19-R/ InfectID-COVID-19-D) validation was done using kit comparison procedure under NABL ISO 15189-2012 guidelines strictly adhering to ICMR protocols.

- The kits used for validation was CE IVD certified kits. Kit used for nucleic acid extraction were Qiagen[™] viral RNA Nucleic acid extraction.
- SARS-CoV-2 real time PCR was performed for extracted RNAs using RealStar[®]SARS-CoV -2 rt-pcr Kit 1.0



- 105 SARS CoV 2 positive samples and 105 SARS CoV 2 Negative samples were taken for the experiment.

5. **Testing Protocol:** The manufacturer's instructions included in the kit were strictly followed.

6. **Interpretation:** Results were Interpreted as instructed by kit manufacturer.

7. **Disclaimer:**

- Positive samples used in the study were collected from hospitalized RT PCR positive COVID patients.
- Report is valid only for the lots submitted by the company.
- RGCBC does not guarantee that the RT PCR kit will continue to meet the above-represented standards. Validation has been performed on one or few representative lots and it's the responsibility of the manufacturer to maintain the kit quality of the subsequent lots
- The report is generated for the above-mentioned product only, and cannot be extended to other related or non-related products.
- The report does not endorse the procurement of the kits from the supplier mentioned.

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Observations/Run File

InfectID, Microbio-InfectID-COVID-19 RT PCR (InfectID-COVID-19-D)



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Melt Report

Experiment Information

Run Name	Run 2021-05-08 (1)
Run Start	08-05-2021 11:15:51
Run Finish	08-05-2021 12:36:05
Operator	sanu
Notes	micro bio
Run On Software Version	Rotor-Gene Q Software 2.3.1.49
Run Signature	The Run Signature is valid.
Gain Green	5.33
Machine Serial No.	0714111

Melt Information

Digital Filter	Light
Imported Analysis Settings	
Sample Page	Page 1
Temp. Threshold	77°C

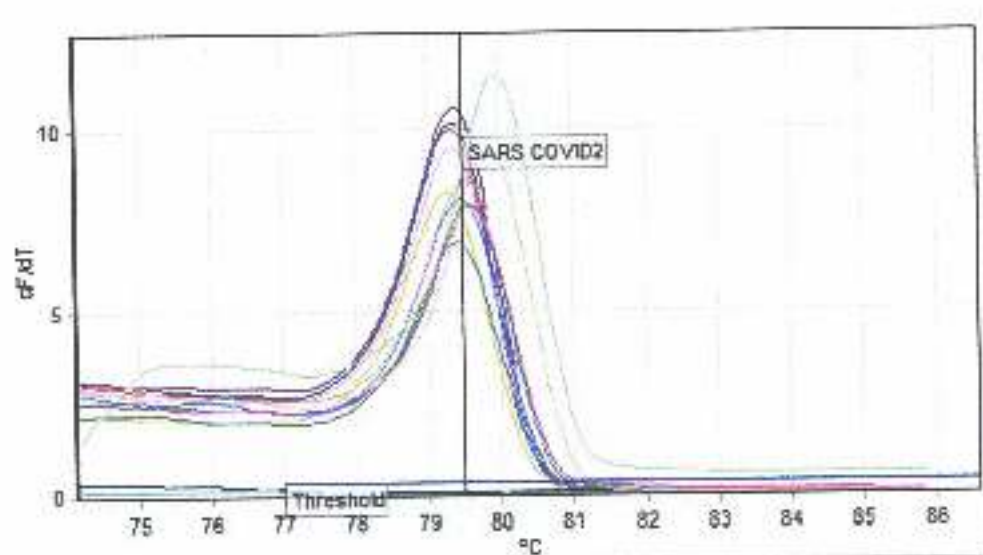


Threshold	0.3
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Profile

Cycle	Cycle Point
Hold 1	Hold @ 48°C, 20min 0s
Hold 2	Hold @ 94°C, 3min 0s
Cycling (40 repeats)	Step 1: Hold @ 94°C, 2s
	Step 2: Hold @ 46°C, 2s
	Step 3: Hold @ 72°C, 5s, acquiring to Cycling A([Green][1][1])
Melt	Ramp from 74°C to 86°C
	Hold for 90s on the 1st step
	Hold for 5s on next steps, Melt A([Green][1][1])

Melt data for Melt A.Green



No.	Color	Name	Genotype	Peak
1	Red	SAMPLE 1		79.31 (SARS COVID2)
2	Yellow	SAMPLE 2		79.25 (SARS COVID2)
3	Blue	SAMPLE 3		79.34 (SARS COVID2)
4	Purple	SAMPLE 4		79.40 (SARS COVID2)
5	Pink	SAMPLE 5		79.34 (SARS COVID2)
6	Blue	SAMPLE 6		79.46 (SARS COVID2)
7	Teal	SAMPLE 7		79.40 (SARS COVID2)
8	Red	SAMPLE 8		79.55 (SARS COVID2)
9	Green	SAMPLE 9		79.55 (SARS COVID2)
10	Pink	SAMPLE 10		79.61 (SARS COVID2)
11	Black	ntc		
12	Blue	ntc		
13	Yellow	pc		79.85 (SARS COVID2)
14	Green	pc		79.94 (SARS COVID2)

Bin Name	Temperature	Sample No.	Sample Name	Peak
SARS COVID2	79.50	1	1	79.3
		2	2	79.3
		3	3	79.3
		4	4	79.4
		5	5	79.3



Run Name	Temperature	Sample No.	Sample Name	Peak
		6	6	79.5
		7	7	79.4
		8	8	79.6
		9	9	79.6
		10	10	79.6
		13	pc	79.9
		14	pc	79.9
			Mean	79.50
			Std. Dev	0.21





Melt Report

Experiment Information

Run Name	Run 2021-05-15 (2)
Run Start	15-05-2021 16:54:07
Run Finish	15-05-2021 18:08:29
Operator	sanu
Notes	micro bio r
Run On Software Version	Rotor-Gene Q Software 2.3.1.49
Run Signature	The Run Signature is valid.
Gain Green	5.33
Machine Serial No.	0714111

Melt Information

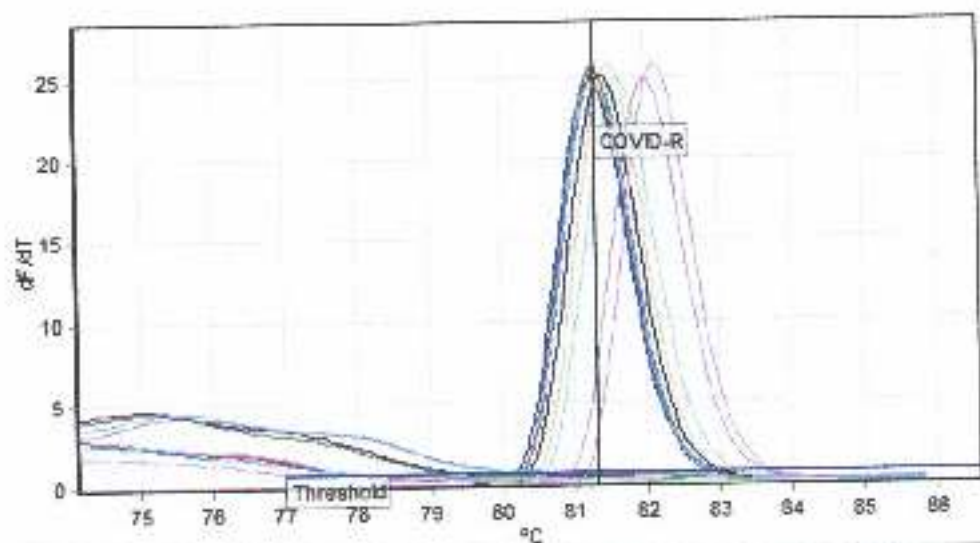
Digital Filter	Light
Imported Analysis Settings	Covid-R
Sample Page	Page 1
Temp. Threshold	77°C
Threshold	0.67

Profile



Cycle	Cycle Point
Hold 1	Hold @ 48°C, 20min 0s
Hold 2	Hold @ 94°C, 3min 0s
Cycling (40 repeats)	Step 1: Hold @ 94°C, 2s
	Step 2: Hold @ 52°C, 2s
	Step 3: Hold @ 72°C, 5s, acquiring to Cycling A[[Green]][1][1]]
Melt	Ramp from 74°C to 86°C
	Hold for 90s on the 1st step
	Hold for 5s on next steps, Melt A[[Green]][1][1]]

Melt data for Melt A.Green



No	Color	Name	Genotype	Peak 1
1	Red	Day 11		
2	Yellow	Day 7		81.29 (COVID-R)
3	Blue	Day 6		81.28 (COVID-R)



No.	Color	Name	Genotype	Peak 1
4	■	Day 12		
5	■	Day 10		
6	■	Day 5		81.35 (COVID-R)
7	■	Day 8		81.29 (COVID-R)
8	■	Day 4		81.35 (COVID-R)
9	■	Day 9		
10	■	Day 11		
11	■	Day 5		81.41 (COVID-R)
12	■	Day 8		
13	■	Day 7		81.50 (COVID-R)
14	■	Day 12		
15	■	Day 11		81.65
16	■	ntc		
17	■	ntc		
18	■	pc		82.01
19	■	pc		82.18

Bin Name	Temperature	Sample No.	Sample Name	Peak
COVID-R	81.32	2	Day 7	81.3
		3	Day 6	81.3



Bin Name	Temperature	Sample No.	Sample Name	Peak
		6	Day 5	81.4
		7	Day 8	81.3
		8	Day 4	81.4
		11	Day 5	81.4
		13	Day 7	81.5
			Mean	81.35
			Std. Dev.	0.08

