

Test Report

Report No. : 기용2020-00590

Company : M monitor Inc.

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Address : Room No, 633 and 222, 62, Seongseogongdan-ro, 11-gil, Dalseo-gu, Daegu 42713, Republic of Korea

1. Product Name : Isopollo® COVID-19 detection kit (real-time)
- Type and Model : 100 Tests/Kit
2. Use of Report : For submission
3. Date of Receipt : 2020. 07. 07.
4. Date of Test : 2020. 07. 07. - 2020. 07. 10.
5. Testing Method : Presented standard by the client, M monitor Inc.
6. Test Results : Pass

Tested by : Han ji-hun

한지훈
(서명)

Approved by : KIM YONGTAE

김용태
(서명)

1. This report is based on the test and analysis performed with the sample(s) submitted by the client.
Therefore, the report does not guarantee the quality of entire products.
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It is only used for the purpose of the quality test.
3. The copy of this report is invalid for use.
4. This report is the English version of No. 기용2020-00590.

2020. 07. 10.



Korea Testing Certification

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1. Outline

This is the test result of the product 『Isopollo® COVID-19 detection kit (real-time)』 provided by the client.

2. Applicable or reference standard

Presented standard by the client, M monitor Inc.

3. Test sample

- (1) Isopollo® COVID-19 detection kit (real-time)
- (2) Lot No.: 522270939



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4. Test condition and method

Test item	Test condition and method	Criteria												
Detection time	<p>After mixing the component of the Isopollo[®] COVID-19 detection kit (real-time) and nucleic acid, detect RdRP and N genes within 30 minutes at (58 ± 3) °C from the start of nucleic acid isothermal amplification reaction.</p> <table border="1"> <thead> <tr> <th>Step</th> <th>Temperature</th> <th>Time</th> <th>cycle</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>(58 ± 3) °C</td> <td>30 sec</td> <td>40</td> </tr> <tr> <td>2</td> <td>(80 ± 3) °C</td> <td>2 min</td> <td>1</td> </tr> </tbody> </table>	Step	Temperature	Time	cycle	1	(58 ± 3) °C	30 sec	40	2	(80 ± 3) °C	2 min	1	Measured value
Step	Temperature	Time	cycle											
1	(58 ± 3) °C	30 sec	40											
2	(80 ± 3) °C	2 min	1											
Sensitivity	<p>Sensitivity check for RdRP and N genes -Target sensitivity should be less than (1 X 10²) copies/rxn (Concentration obtained by 95% or more positive)</p>	Measured value												
Specificity (Cross-reactivity)	<p>Specificity check for RdRP and N genes -Test the specific performance of each primer of RdRP and N genes. -The target cross-reactive microorganism should not be detected.</p>	Measured value												



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5. Test result

5.1 Detection time

Test item	Test condition and method	Unit	Test result													
Detection time	After mixing the component of the Isopollo® COVID-19 detection kit (real-time) and nucleic acid, detect RdRP and N genes within 30 minutes at 58±3°C from the start of nucleic acid isothermal amplification reaction.	-	Pass (Within 30 mins)													
	<table border="1"><thead><tr><th>Step</th><th>Temperature</th><th>Time</th><th>cycle</th></tr></thead><tbody><tr><td>1</td><td>(58 ± 3) °C</td><td>30 sec</td><td>40</td></tr><tr><td>2</td><td>(80 ± 3) °C</td><td>2 min</td><td>1</td></tr></tbody></table>			Step	Temperature	Time	cycle	1	(58 ± 3) °C	30 sec	40	2	(80 ± 3) °C	2 min	1	
	Step			Temperature	Time	cycle										
1	(58 ± 3) °C	30 sec	40													
2	(80 ± 3) °C	2 min	1													



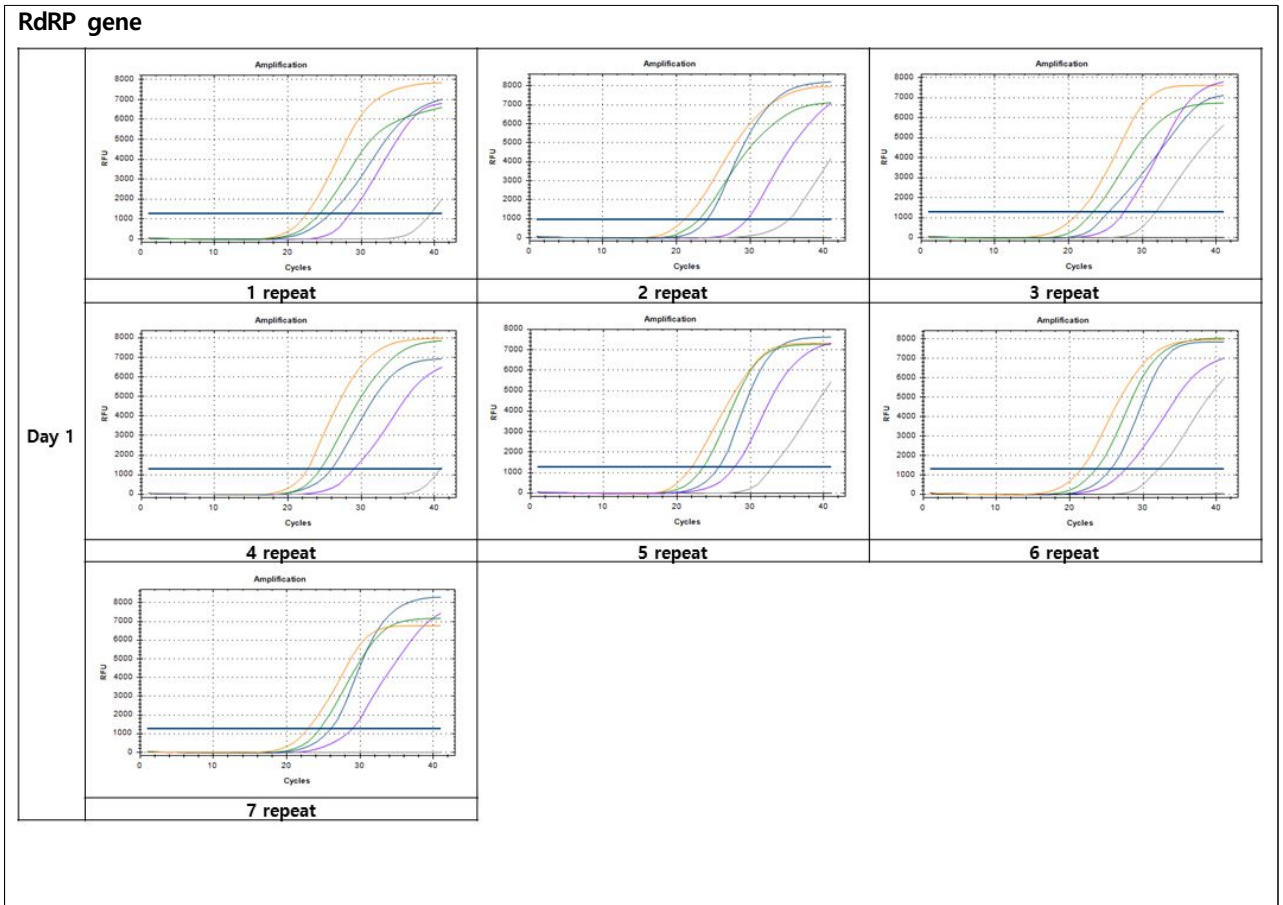
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5.2 Sensitivity

Test item	Test condition and method	Unit	Test result
Sensitivity	Sensitivity check for RdRP and N gene -Target sensitivity should be less than (1×10^2) copies/rxn (Concentration obtained by 95% or more positive)	%	100

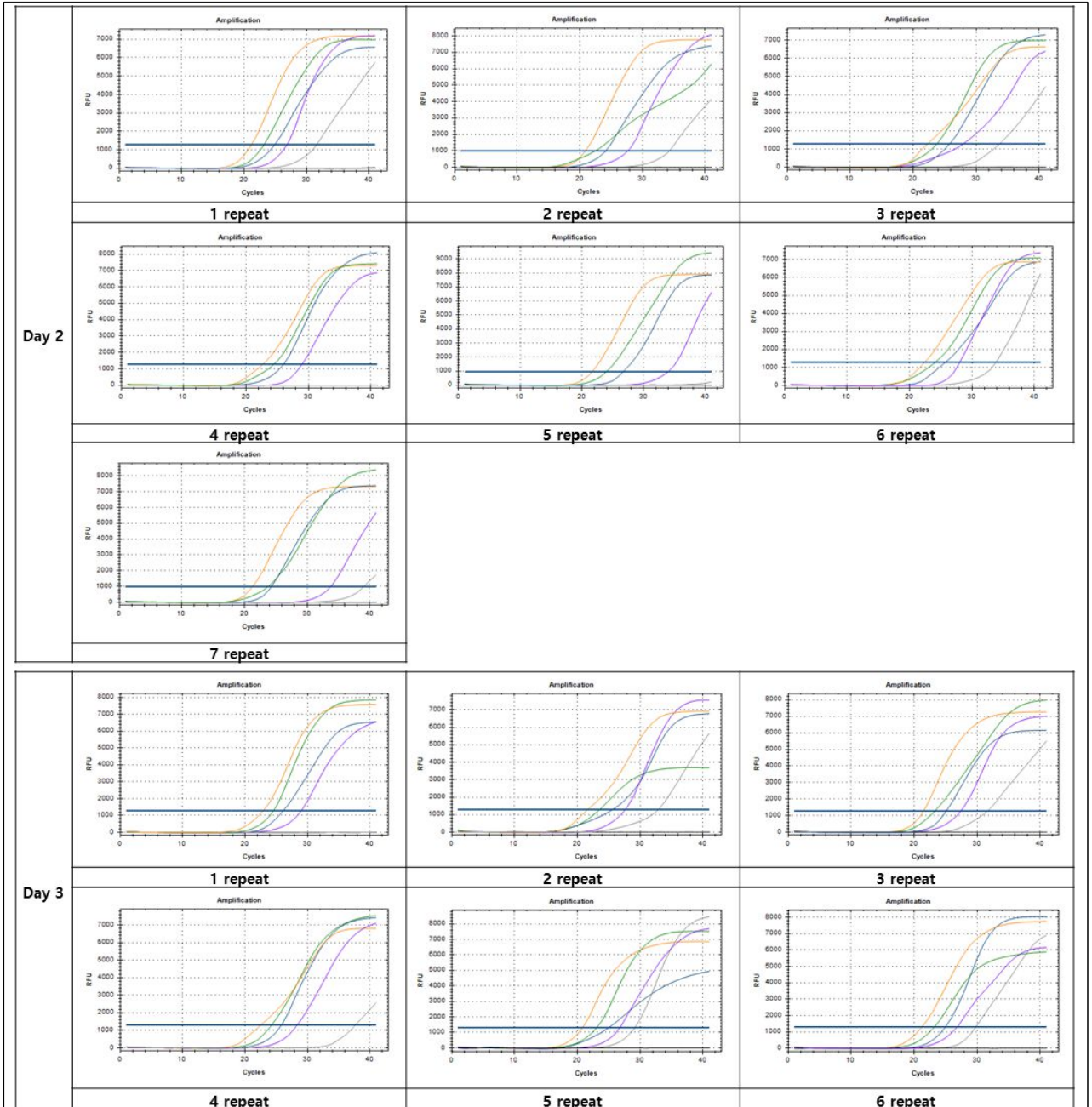
CFX96™ Dx System (Bio-Rad Laboratories, Inc., USA. 12007917) was used for the LAMP (Loop-mediated isothermal amplification) reaction. The concentration of DNA was determined as Limit of Detection (LoD) is determined for concentrations obtained more than 95% or more positive based on CLSI EP17 criteria. SARS-CoV-2 Standard is serially diluted by 5×10^1 copies/ μl , 4×10^1 copies/ μl , 2×10^1 copies/ μl , 1×10^1 copies/ μl , 5×10^0 copies/ μl . The tests were repeated 20 times (20 sample replicates) totally for 3 days (1 day and 2 day: 7 replicates per day, last day: 6 replicates per day).



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5.2 Sensitivity (continued)



Lane information

- (2.5×10^2) copies/rxn (orange), 2. (2.0×10^2) copies/rxn (green), 3. (1.0×10^2) copies/rxn (blue)
- (5.0×10^1) copies/rxn (purple), 5. (2.5×10^1) copies/rxn (gray), NC: Negative Control (black)



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5.2 Sensitivity (continued)

RdRP gene

Ratio		1	2	3	4	5	NC
Day 1	1 repeat	22.60	24.41	25.86	28.55	39.52	Negative (-)
	2 repeat	21.13	23.12	24.20	29.61	35.31	Negative (-)
	3 repeat	21.52	23.34	25.44	27.53	31.82	Negative (-)
	4 repeat	22.69	24.44	25.99	29.01	Negative (-)	Negative (-)
	5 repeat	22.07	23.61	25.74	27.87	33.01	Negative (-)
	6 repeat	21.53	23.56	25.56	27.58	32.10	Negative (-)
	7 repeat	22.94	24.57	26.09	29.04	Negative (-)	Negative (-)
Day 2	1 repeat	21.22	23.23	24.96	26.93	31.67	Negative (-)
	2 repeat	20.85	22.38	24.10	27.60	34.24	Negative (-)
	3 repeat	22.35	23.79	25.80	28.01	33.73	Negative (-)
	4 repeat	22.73	24.50	26.07	29.02	Negative (-)	Negative (-)
	5 repeat	21.69	24.02	26.73	34.04	Negative (-)	Negative (-)
	6 repeat	22.47	24.18	25.81	28.08	33.89	Negative (-)
	7 repeat	21.24	23.70	24.25	33.71	39.00	Negative (-)
Day 3	1 repeat	22.94	24.57	26.16	29.05	Negative (-)	Negative (-)
	2 repeat	21.68	23.57	25.63	27.62	32.94	Negative (-)
	3 repeat	21.51	23.33	25.12	27.43	31.67	Negative (-)
	4 repeat	22.51	24.23	25.82	28.33	37.66	Negative (-)
	5 repeat	20.80	23.06	24.94	26.74	29.13	Negative (-)
	6 repeat	21.22	23.20	24.96	26.83	29.78	Negative (-)
Lane information	Lane information 1. (2.5 X 10 ²) copies/rxn (orange), 2. (2.0 X 10 ²) copies/rxn (green) 3. (1.0 X 10 ²) copies/rxn (blue), 4. (5.0 X 10 ¹) copies/rxn (purple) 5. (2.5 X 10 ¹) copies/rxn (gray), NC: Negative Control (black)						
Interpretation of Result	Ct Value: within 40 means positive (+), no detection means negative (-)						

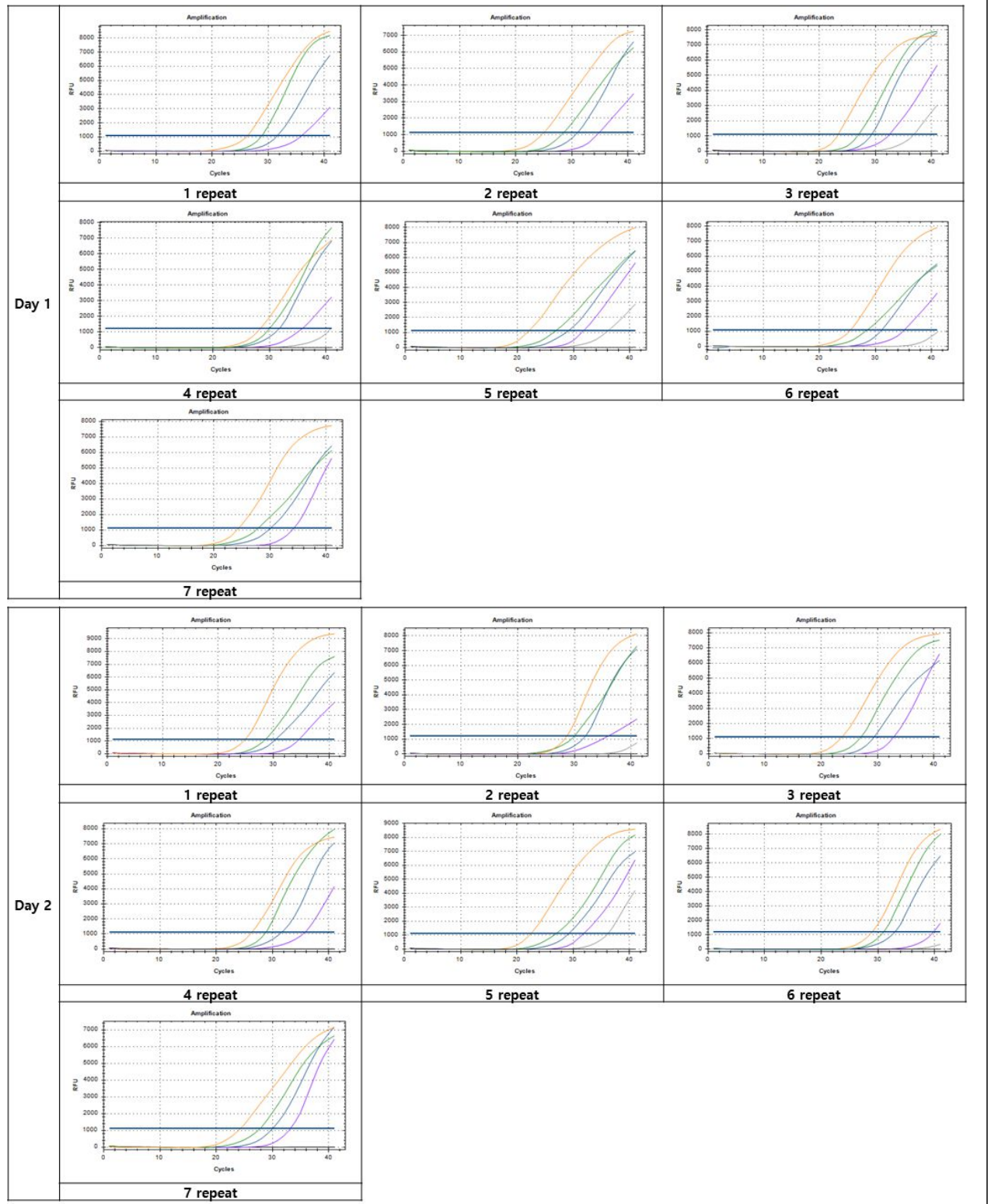


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5.2 Sensitivity (continued)

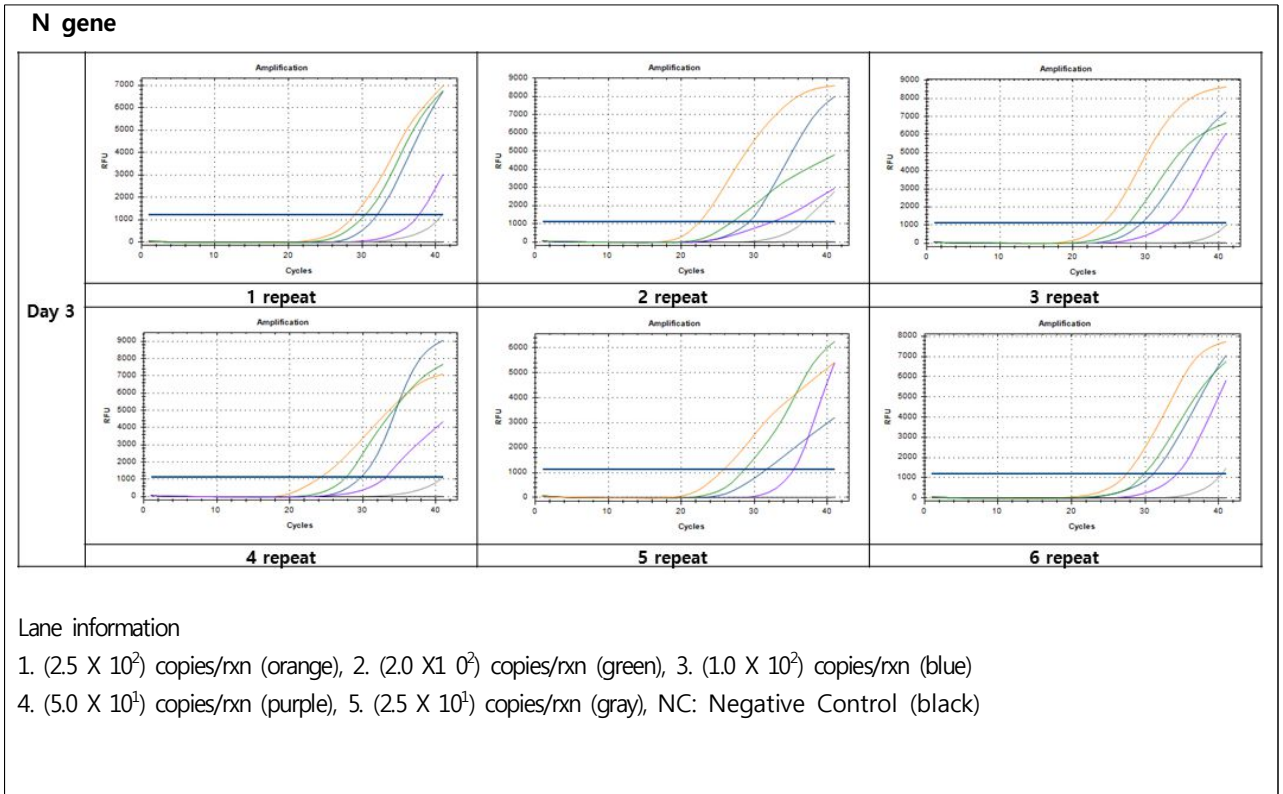
N gene



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5.2 Sensitivity (continued)



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5.2 Sensitivity (continued)

N gene

Ratio		1	2	3	4	5	NC
Day 1	1 repeat	26.36	28.96	31.67	36.02	Negative (-)	Negative (-)
	2 repeat	25.01	28.52	31.02	34.84	Negative (-)	Negative (-)
	3 repeat	23.38	27.05	29.35	32.51	36.91	Negative (-)
	4 repeat	28.39	30.01	31.73	35.80	Negative (-)	Negative (-)
	5 repeat	22.05	26.83	29.09	31.76	36.13	Negative (-)
	6 repeat	25.61	28.60	31.17	35.21	Negative (-)	Negative (-)
	7 repeat	24.41	27.89	30.08	34.25	Negative (-)	Negative (-)
Day 2	1 repeat	24.87	28.51	30.36	34.59	Negative (-)	Negative (-)
	2 repeat	28.67	30.04	31.98	35.99	Negative (-)	Negative (-)
	3 repeat	23.67	27.08	29.39	32.89	Negative (-)	Negative (-)
	4 repeat	26.34	28.85	31.65	35.80	Negative (-)	Negative (-)
	5 repeat	22.49	27.00	29.22	31.86	36.20	Negative (-)
	6 repeat	29.03	31.06	33.04	39.84	Negative (-)	Negative (-)
	7 repeat	24.32	27.82	30.05	33.20	Negative (-)	Negative (-)
Day 3	1 repeat	28.98	30.41	32.06	37.71	Negative (-)	Negative (-)
	2 repeat	23.16	27.01	29.28	32.50	36.70	Negative (-)
	3 repeat	24.14	27.62	29.43	33.11	Negative (-)	Negative (-)
	4 repeat	24.19	27.68	29.71	33.14	Negative (-)	Negative (-)
	5 repeat	25.78	28.63	31.61	35.36	Negative (-)	Negative (-)
	6 repeat	27.53	29.92	31.18	34.38	Negative (-)	Negative (-)
Lane information	Lane information 1. (2.5 X 10 ²) copies/rxn (orange), 2. (2.0 X 10 ²) copies/rxn (green) 3. (1.0 X 10 ²) copies/rxn (blue), 4. (5.0 X 10 ¹) copies/rxn (purple) 5. (2.5 X 10 ¹) copies/rxn (gray), NC: Negative Control (black)						
Interpretation of Result	Ct Value: within 40 means positive (+), no detection means negative (-)						

In conclusion, the tests were repeated 20 times totally for 3 days (day 1 and day 2: 7 replicates and 6 replicates for day 3) about SARS-CoV-2 RdRP gene and N gene using 1 Lot. Based on CLSI EP17, LoD of SARS-CoV-2 RdRP gene showing a detection rate $\geq 95\%$ was measured as less than (1.0 X 10²) copies/rxn. And also LoD of SARS-CoV-2 N gene showing a detection rate $\geq 95\%$ was measured as less than (1.0 X 10²) copies/rxn.



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5.3 Specificity

Test item	Test condition and method	Unit	Test result
Specificity (Cross-reactivity)	Specificity check for RdRP and N genes -Test the specific performance of each primer of RdRP and N genes. -The target cross-reactive microorganism should not be detected.	-	No detection

The cross-reactivity of the analysis specificity is to evaluate whether other microorganisms (bacteria, virus and etc.) which occur similar symptoms comparing with new coronavirus produce positive reaction or not. The cross-reactivity of Isopollo[®] COVID-19 detection kit (real-time) was carried out using test organisms presented in cross-reactivity test material based on MFDS (Korea Authority) Guideline: Influenza virus and hepatitis A virus guideline at page 54.

※ Test Microorganism

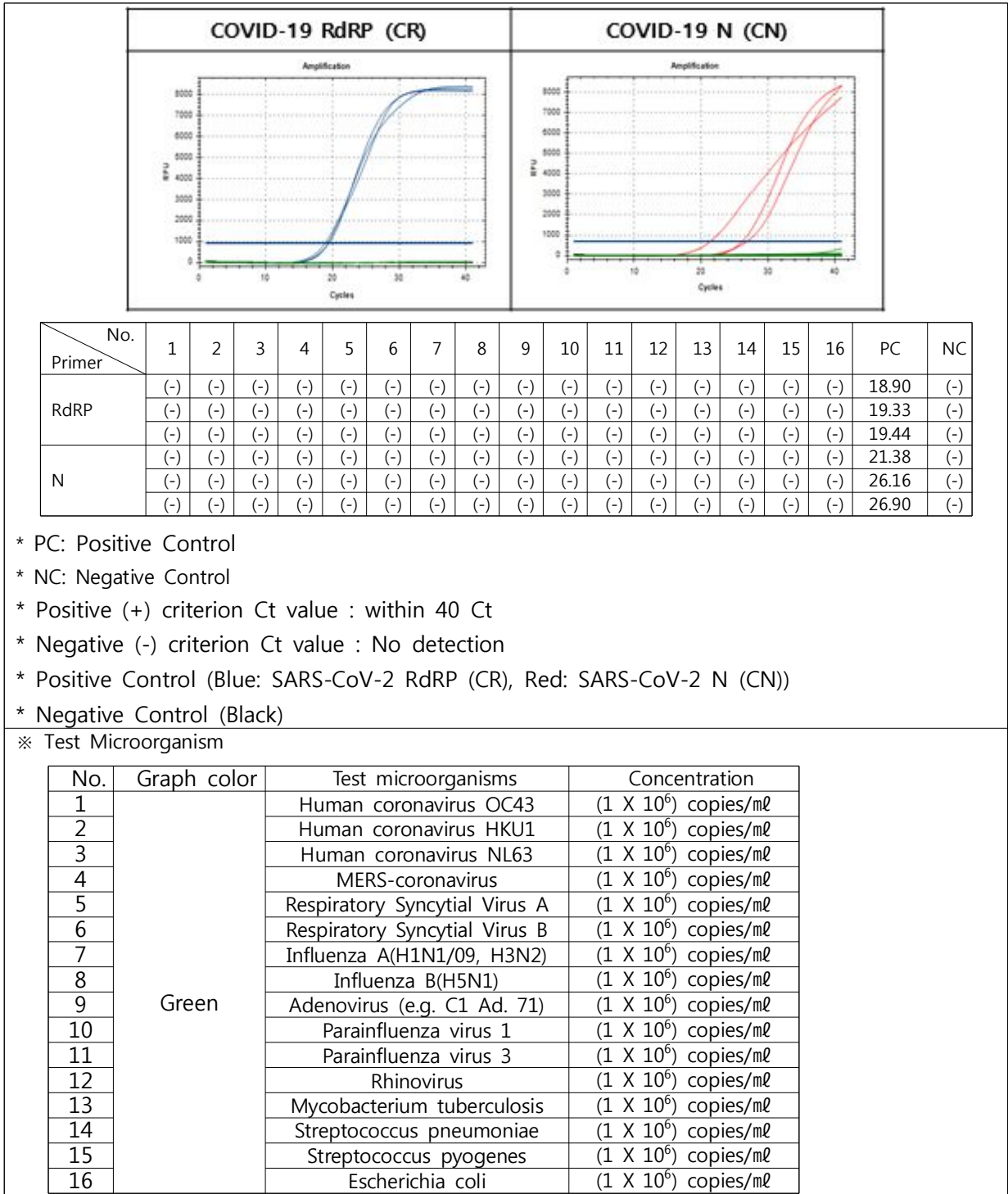
- 1 : Human coronavirus OC43
- 2 : Human coronavirus HKU1
- 3 : Human coronavirus NL63
- 4 : MERS-coronavirus
- 5 : Respiratory Syncytial Virus A
- 6 : Respiratory Syncytial Virus B
- 7 : Influenza A(H1N1/09, H3N2)
- 8 : Influenza B(H5N1)
- 9 : Adenovirus (e.g. C1 Ad. 71)
- 10 : Parainfluenza virus 1
- 11 : Parainfluenza virus 3
- 12 : Rhinovirus
- 13 : Mycobacterium tuberculosis
- 14 : Streptococcus pneumoniae
- 15 : Streptococcus pyogenes
- 16 : Escherichia coli



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5.3 Specificity (continued)



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5.3 Specificity (continued)

※ Cross-reactivity

No.	Graph color	Test microorganisms	Cross-reactivity
1	Green	Human coronavirus OC43	None
2		Human coronavirus HKU1	
3		Human coronavirus NL63	
4		MERS-coronavirus	
5		Respiratory Syncytial Virus A	
6		Respiratory Syncytial Virus B	
7		Influenza A(H1N1/09, H3N2)	
8		Influenza B(H5N1)	
9		Adenovirus (e.g. C1 Ad. 71)	
10		Parainfluenza virus 1	
11		Parainfluenza virus 3	
12		Rhinovirus	
13		Mycobacterium tuberculosis	
14		Streptococcus pneumoniae	
15		Streptococcus pyogenes	
16		Escherichia coli	

16 test microorganisms listed in the MFDS Guideline: Influenza virus and hepatitis A virus guideline at page 54 were tested for cross-reactivity. None of the 16 test microorganisms demonstrated cross-reactivity with SARS-CoV-2.



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6. Remark

※ This test was conducted with the specifications, environment and samples suggested by the client.

End.

