



Global Mobile Healthcare Leader



Global
Mobile
Healthcare
Leader
through
Innovative
Technology

COVID-19 qPCR kit

1copy™

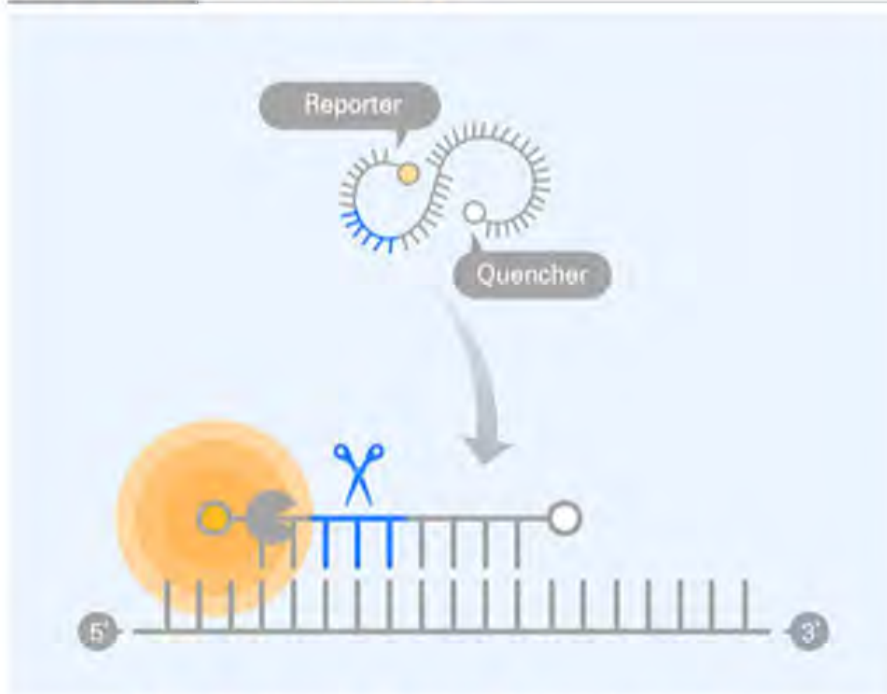
Molecular Diagnostics

1copy™ COVID-19 qPCR kit



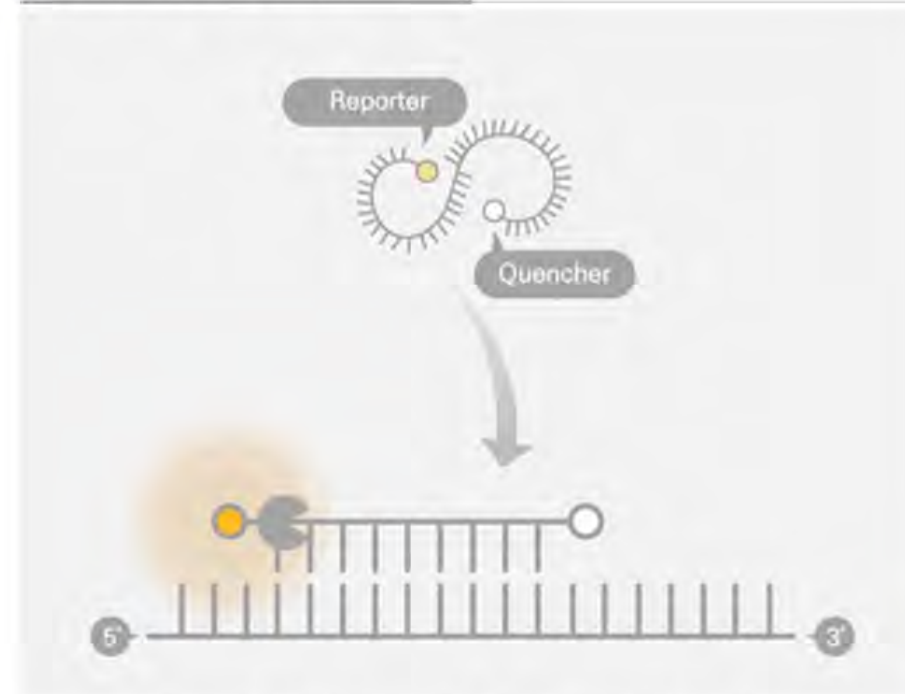
Catacleave(DNA-RNA-DNA Hybrid probe) + RNase(Thermo-stable, Hot-start)

1 copy™ Technology



More efficient probe degradation ↑
→ Higher fluorescence intensity ↑

Others (ex Taqman)

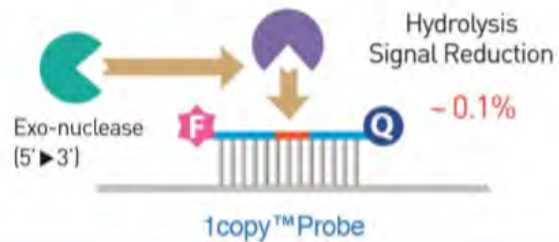
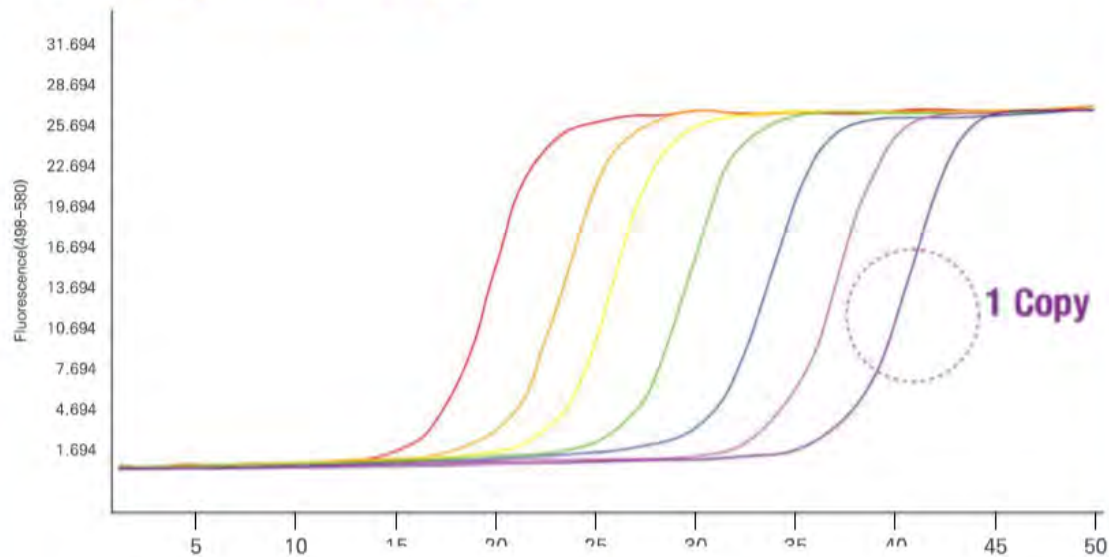


Less efficient probe degradation ↓
→ Lower fluorescence intensity ↓

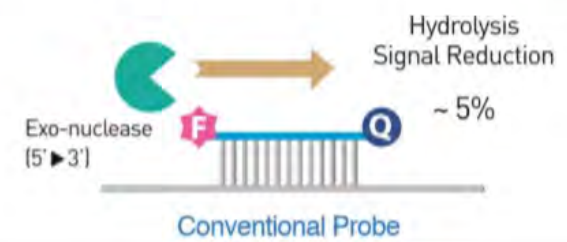
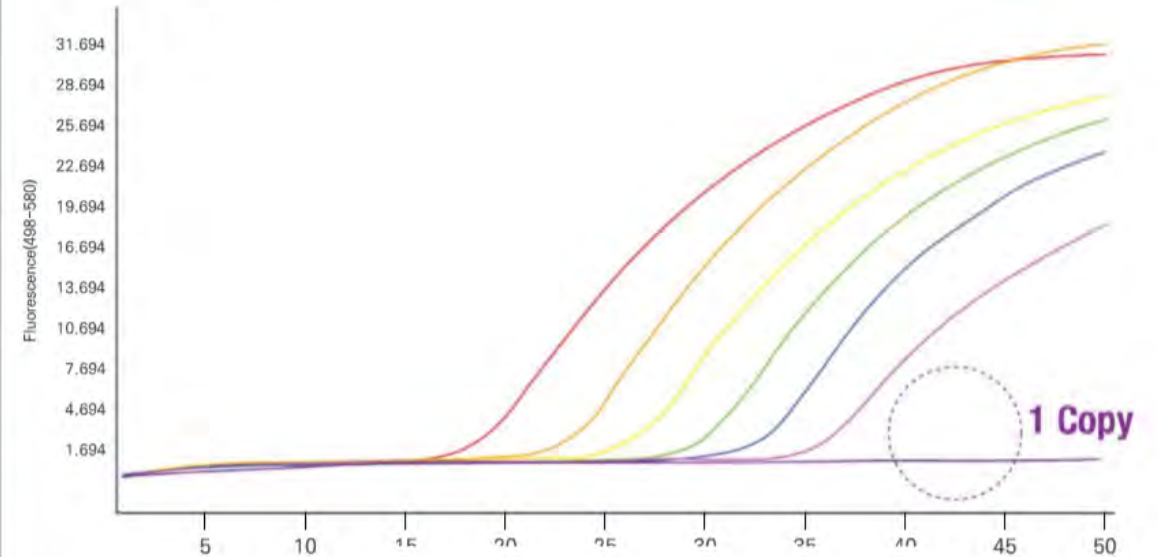
- DNA
- RNA
- DNA Polymerase
- ✂ RNase

Single Molecule RNA Detection

1 copy™ Technology

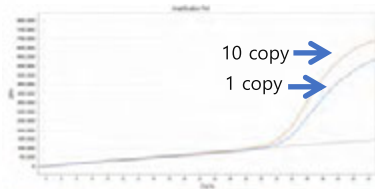


Others

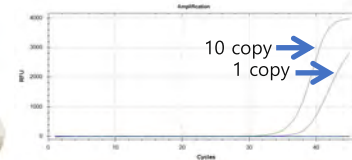


High compatibility with commercial PCR machine

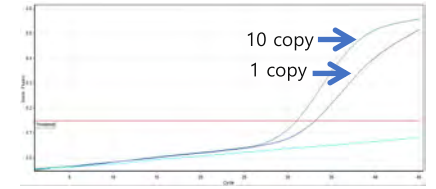
ABI7500 (ABI)



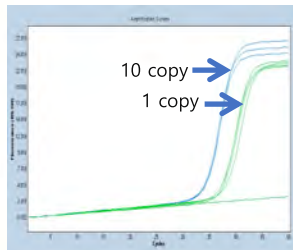
CFX96 (Bio-Rad)



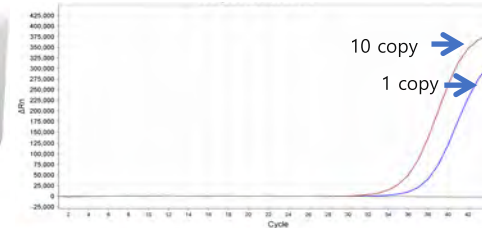
Rotor gene Q (Qiagen)



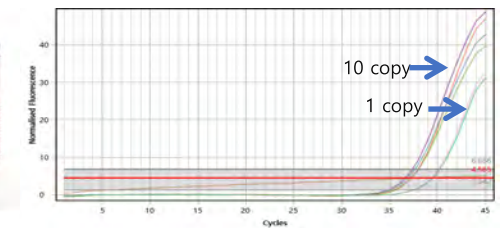
LC480 (Roche)



Quantstudio5 (ABI)



Mic qPCR cycler (BMS)



		2019	2020				2021			
		4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
CML	BCR-ABL	●								
AML	PML-RARA	●		●						
	RUNX1-RUNX1T1		●		●					
	CBFB-MYH11						●		●	
	ETV6-RUNX1						●		●	
	NPM1						●		●	
	WT1							●		●
	BAALC							●		●
Cancer	JAK2			●		●				
	BRAF			●		●				
	EGFR				●		●			
Virus	COVID-19★		●							
	HBV				●		●			
	HCV					●		●		
	HIV						●		●	

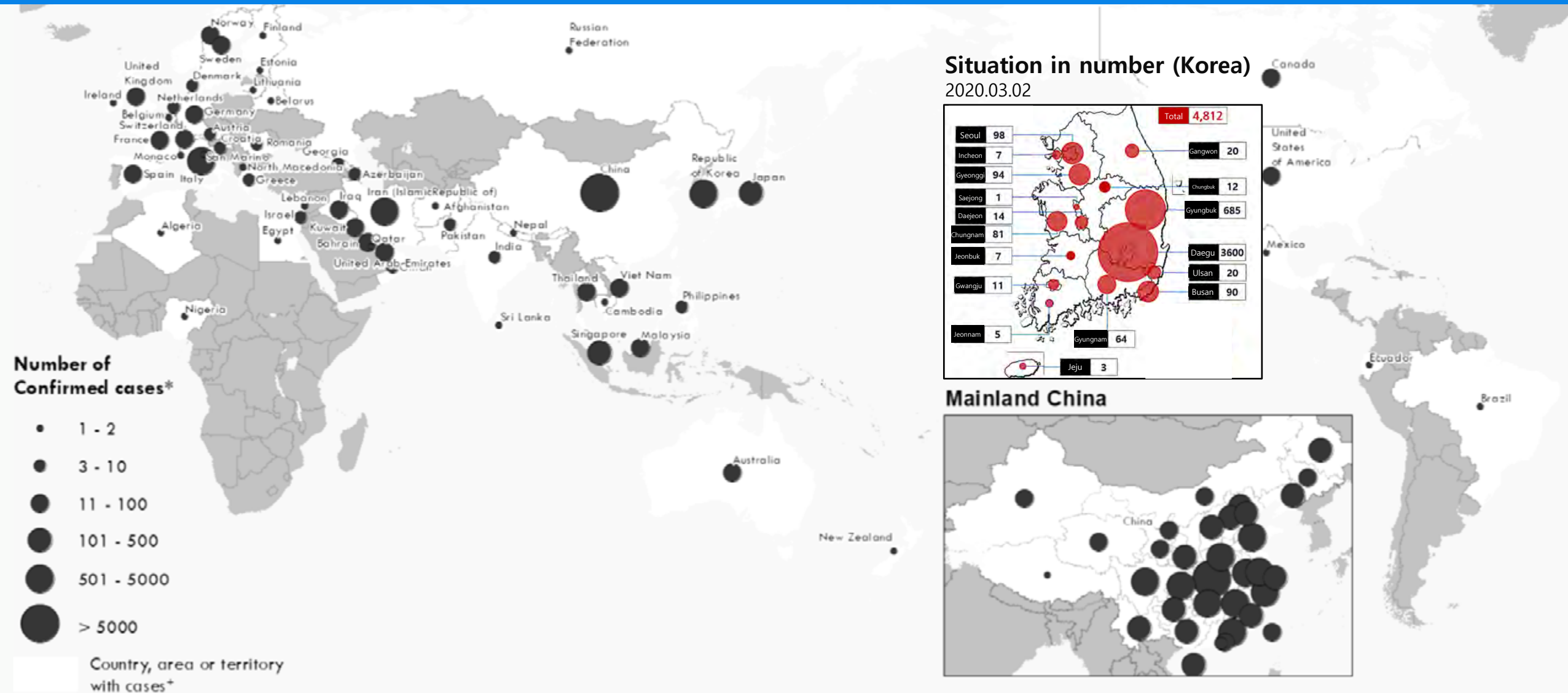
● Now available

● R&D/RUO

● CE/MFDS

Distribution of COVID-19 cases as of 01 March 2020

- **COVID-19** is the infectious disease caused by the most recently discovered coronavirus.
- **2020.03.01** Situation in number(world wide) **87,137 confirmed / 2,977 death**



Referring to German's WHO guidance for COVID-19

- WHO guidelines recommend using real-time PCR for COVID-19 molecular diagnostics.
- The Korea CDC guidance refers to the German's WHO guidance for COVID-19.

(Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR – Charité, Berlin Germany, 17 January 2020)


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Coronavirus disease (COVID-19) technical guidance: Laboratory testing for 2019-nCoV in humans

3. Molecular assays to diagnose 2019-nCoV

Several assays that detect the 2019-nCoV have been and are currently under development, both *in-house* and commercially. Some assays may detect only the novel virus and some may also detect other strains (e.g. SARS-CoV) that are genetically similar.

In-house developed molecular assays

Some groups shared their protocols which can be accessed below (Summary table and link to the protocols). In some cases, the groups will be willing to send reagents or reagent mixes prepared in their laboratories, with or without associated fees. It is strongly recommended to contact the developer if you need further assistance. The list is not exhaustive and is being updated regularly.

Summary table of available protocols

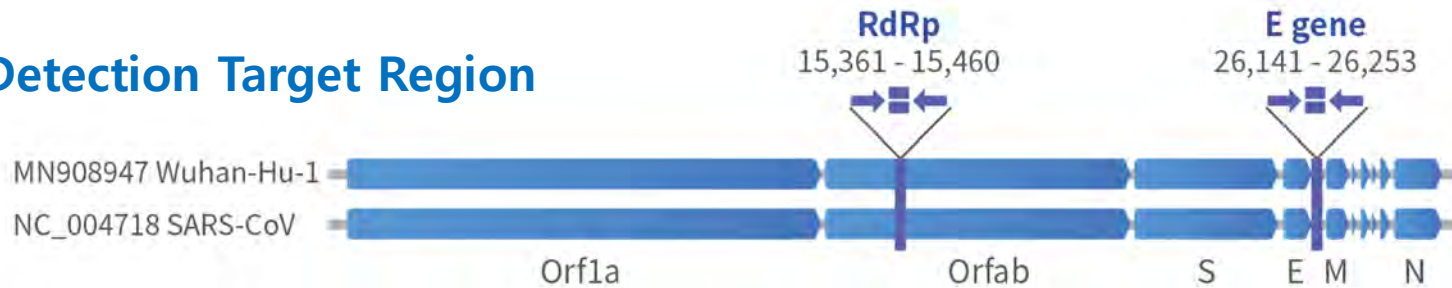
Country	Institute	Gene targets
China	China CDC	ORF1ab and N
Germany	Charité	RdRP, E, N
Hong Kong	HKU	ORF1b-nsp14, N
Japan	National Institute of Infectious Diseases, Department of Virology III	Pancorona and multiple targets, Spike protein
Thailand	National Institute of Health	N
US	US CDC	Three targets in N gene

COVID-19 Detection system

Spicemen type

- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

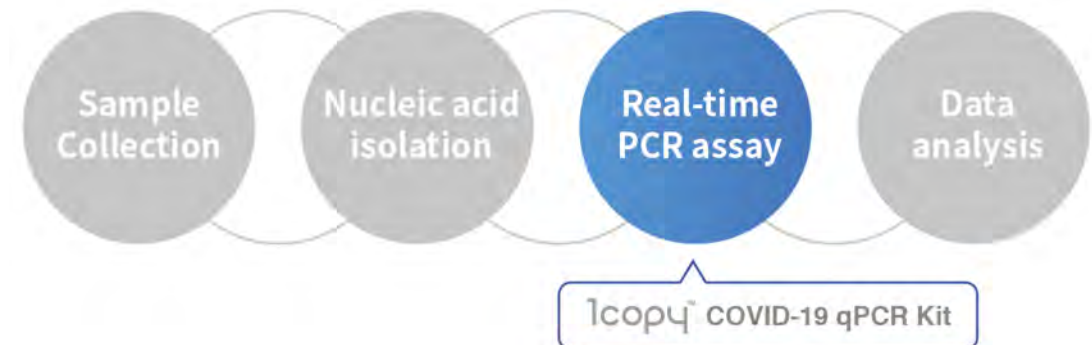
Detection Target Region



Real-time PCR instruments

- Roche Light Cycler® 480
- Qiagen Rotor-Gene® Q 5plex HRM
- Applied Biosystems® Quantstudio5
- Applied Biosystems® 7500 Real-Time PCR system
- Bio-RAD CFX96™ Real-Time PCR Detection system

Process



Importance of LoD in COVID-19 detection

Issue of false negative

KBS WORLD RADIO News Topics Entertainment Programs

Domestic

Patient Released from Hospital Rediagnosed with COVID-19

Write: 2020-02-29 18:47:33 Update: 2020-02-29 15:27:18

A South Korean woman, in her 70s, who had fully recovered from the coronavirus has been re-diagnosed with the disease just six days after she was discharged from the hospital.

Lim Byeong-taek, the mayor of Siheung city in Gyeonggi Province, shared this development on his Facebook page on Friday.

He said the 73-year-old woman was the first case of COVID-19 in Siheung and the 25th patient nationwide, adding that symptoms have returned and she is diagnosed with the virus once again.

The mayor said she left the hospital last Saturday after testing negative twice, but she then went on to develop minor symptoms and alerted a public health center on Thursday. She was then confirmed with the infection on Friday.

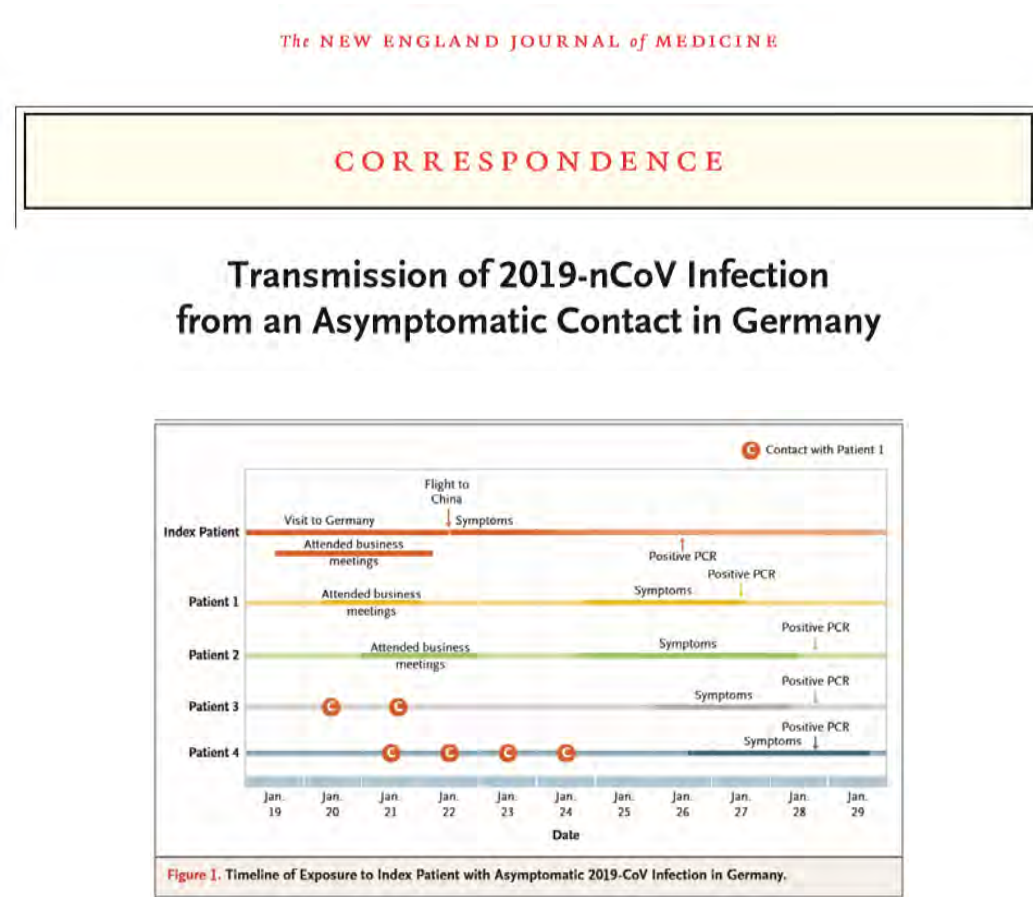
The patient said she only stayed at home since being released from the hospital.

The patient was first confirmed with the virus earlier this month while living with her son and daughter-in-law, who have been to China's Guangdong Province.

A Siheung city official said further examination is needed, but it appears to be South Korea's first case of a COVID-19 relapse.

http://world.kbs.co.kr/service/news_view.htm?lang=e&Seq_Code=151690

Issue of small number of viral load

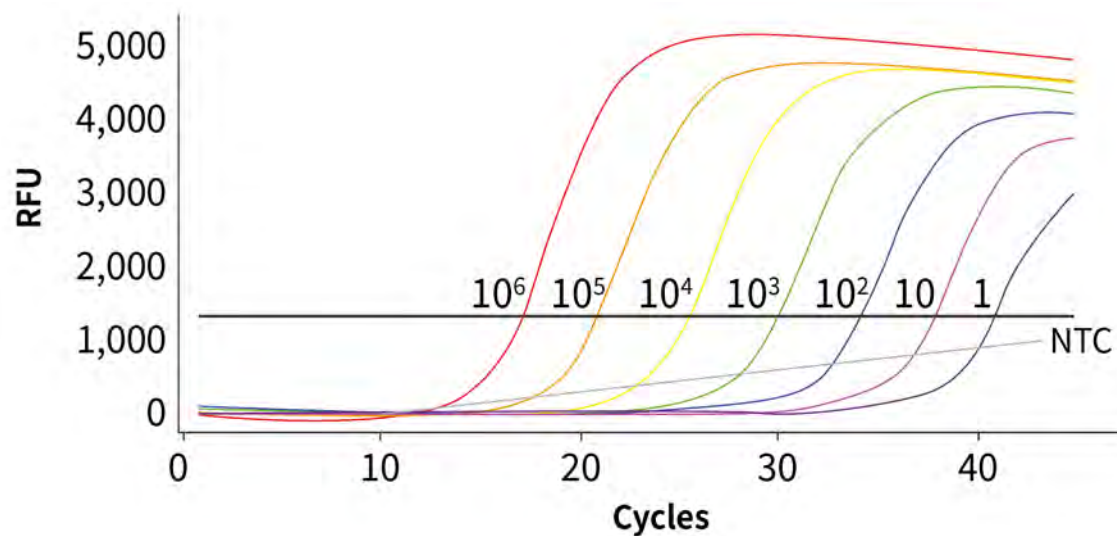


Rothe C et al. Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany. N Engl J Med. 2020 Jan 30.

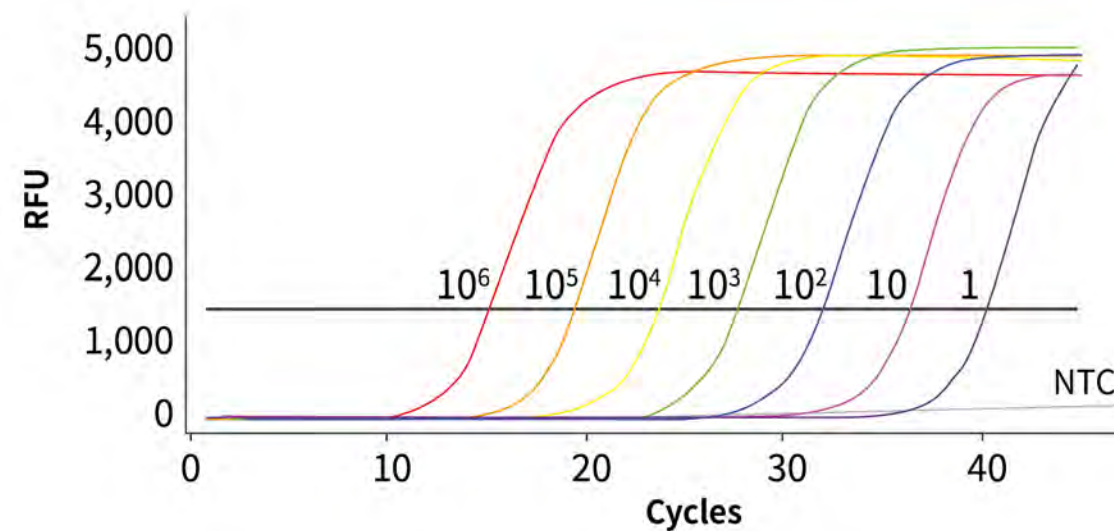
COVID-19 qPCR detect single molecule of RNA

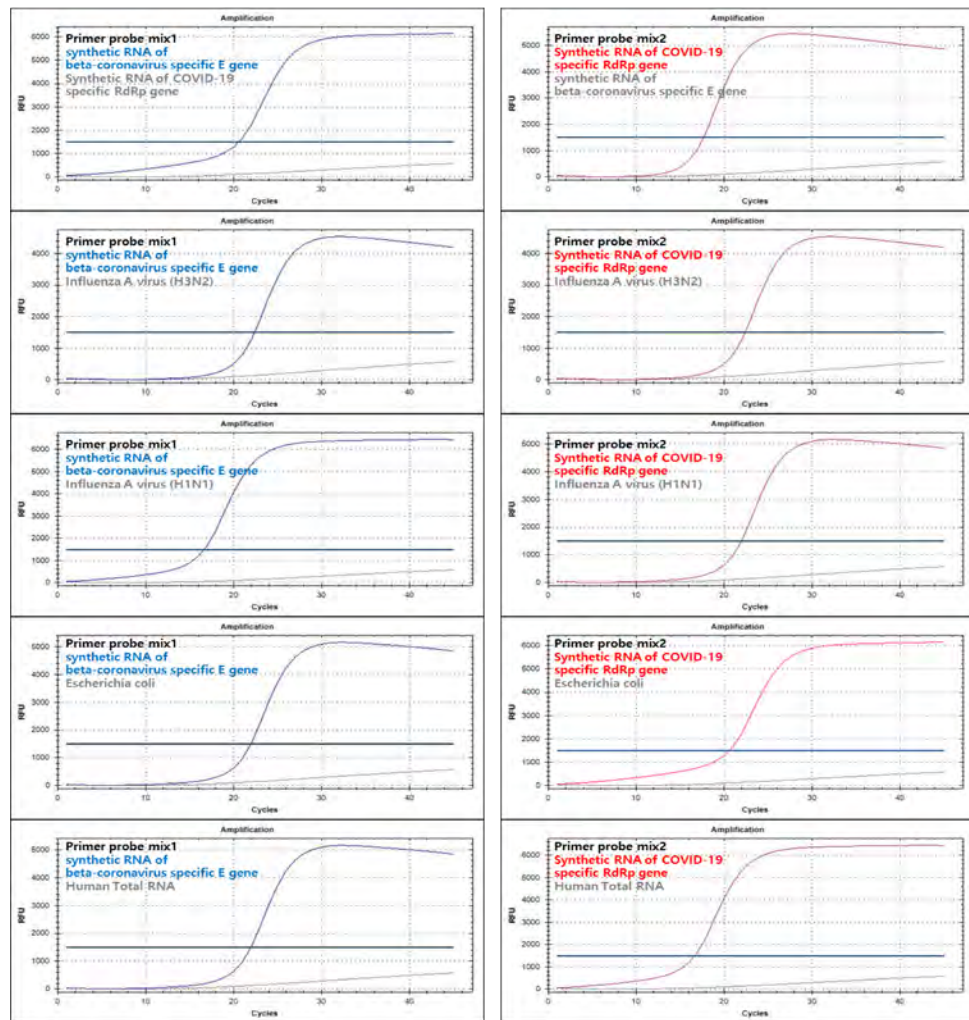
Copy/reaction	10 ³ copies	10 ² copies	10 copies	8 copies	4 copies	2 copies	1 copy	0 copy
RdRp gene Detection rate	100%	100%	100%	100%	98%	90%	78%	0%
E gene Detection rate	100%	100%	100%	100%	97%	87%	64%	0%

Synthetic RNA of COVID-19 specific RdRp gene



Synthetic RNA of beta-coronavirus specific E gene



[illegible]

10¹copy™ COVID-19 qPCR Specification



Specification		Contents (100 Test/Kit)
Steps	Single step	● Master mix : 2ea
LoD	0.2copy/ μ l (4copies/reaction)	● Primer/Probe mix (E gene) : 1ea
Target	ReRp, E gene	● Primer/Probe mix (RdRp gene) : 1ea
Turn-around time	1hour 30minutes	● Control 1 (E gene) : 1ea
		● Control 2 (RdRp gene) : 1ea
		⊙ DEPC Water



THANK YOU!

Appendix : 1copy™ COVID-19 qPCR Specification : Limit of Detection_Raw data

E gene

Copy /reaction	8copy	4copy	2copy	1copy	0.5copy	0copy
1	38.06	41.03	40.89	41.24	42.21	-
2	39.51	40.08	41.79	-	-	-
3	38.65	42.07	41.39	42.16	-	-
4	39.24	40.42	43.12	-	40.48	-
5	38.09	40.80	42.21	39.87	-	-
6	39.32	39.58	42.73	39.83	42.55	-
7	40.47	41.03	40.89	40.23	42.21	-
8	39.47	40.08	41.79	40.14	-	-
9	38.5	42.07	41.39	39.79	-	-
10	38.98	40.42	43.12	38.45	40.48	-
11	38.62	40.80	42.21	38.72	-	-
12	40.94	39.58	42.73	41.44	42.55	-
13	40.33	38.64	-	-	41.05	-
14	40.6	-	-	-	-	-
15	40.12	36.99	40.38	-	39.66	-
16	38.21	38.72	40.21	-	41.05	-
17	39.46	39.05	-	-	41.29	-
18	38.63	38.69	39.07	-	-	-
19	39.65	38.64	40.85	-	41.33	-
20	40.1	37.75	41.27	40.98	-	-
21	40.6	36.99	40.76	42.1	-	-
22	40.58	38.72	40.26	40.08	40.96	-
23	38.83	39.05	40.21	38.72	-	-
24	39.28	38.69	-	41.32	-	-
25	40.38	40.11	38.68	-	41.16	-
26	39.76	40.29	40.33	-	-	-
27	39.81	39.9	39.35	-	40.41	-
28	40.96	39.61	40.52	-	-	-
29	38.44	39.98	39.59	-	-	-
30	39.39	40.51	38.39	-	-	-
Detection Rate	100%	97%	87%	64%	50%	0%
Ct average	39.50	39.67	40.93	40.34	41.24	-

RdRp gene

Copy /reaction	10copy	8copy	4copy	2copy	1copy	0copy
1	40.71	40.68	42.46	41.12	41.89	-
2	40.72	39.85	42.13	42.83	-	-
3	40.45	39.85	41.70	42.55	-	-
4	40.72	39.83	41.63	43.16	-	-
5	40.95	39.62	42.48	42.77	-	-
6	40.09	41.98	-	42.05	41.42	-
7	41.30	39.82	41.81	43.71	42.37	-
8	41.39	39.95	41.07	43.71	42.62	-
9	40.12	39.66	43.42	42.02	40.79	-
10	39.68	39.35	42.62	-	-	-
11	40.82	40.29	41.65	43.05	42.32	-
12	40.23	38.99	41.57	41.93	-	-
13	-	39.06	40.99	42.41	41.47	-
14	-	41.52	42.98	43.05	40.88	-
15	-	39.94	41.11	43.95	40.38	-
16	-	42.86	41.20	42.53	41.89	-
17	-	39.33	41.25	43.21	-	-
18	-	39.45	41.92	40.84	-	-
19	-	38.77	40.96	43.81	43.73	-
20	-	40.49	42.23	41.28	41.47	-
21	-	39.76	40.19	41.76	39.19	-
22	-	39.64	41.07	41.32	39.74	-
23	-	38.88	40.95	42.79	43.09	-
24	-	40.00	42.06	42.30	40.15	-
25	-	40.23	39.86	41.06	40.91	-
26	-	39.64	40.03	42.07	43.10	-
27	-	38.87	40.03	41.68	41.45	-
28	-	39.41	40.26	-	41.72	-
29	-	40.13	41.31	40.64	41.38	-
30	-	39.31	40.15	42.57	39.98	-

Copy /reaction	10copy	8copy	4copy	2copy	1copy	0copy
31	-	41.05	42.06	41.30	41.19	-
32	-	39.55	40.61	41.35	39.49	-
33	-	39.25	39.98	42.09	39.27	-
34	-	39.57	40.25	40.21	41.14	-
35	-	40.30	44.94	43.53	39.19	-
36	-	40.51	39.77	40.32	40.18	-
37	-	39.55	37.84	39.20	-	-
38	-	39.55	38.26	40.79	-	-
39	-	39.60	38.39	39.20	-	-
40	-	39.42	38.00	38.47	-	-
41	-	40.73	38.33	39.39	-	-
42	-	39.51	39.22	40.14	-	-
43	-	39.98	38.21	39.91	-	-
44	-	39.71	39.12	39.95	-	-
45	-	40.00	38.03	39.96	-	-
46	-	39.97	39.19	39.82	-	-
47	-	40.15	37.89	39.98	-	-
48	-	39.12	38.90	39.80	-	-
49	-	39.43	-	39.36	-	-
50	-	39.06	-	40.26	-	-
51	-	40.16	-	39.56	-	-
52	-	40.39	-	39.82	-	-
53	-	39.77	-	39.54	-	-
54	-	39.36	-	41.06	-	-
55	-	39.35	-	-	-	-
56	-	39.63	-	-	-	-
57	-	43.75	-	-	-	-
58	-	39.18	-	-	-	-
59	-	39.11	-	-	-	-
60	-	39.34	-	-	-	-
Detection Rate	100%	100%	98%	90%	78%	0%
Ct average	40.60	39.89	40.64	41.37	41.16	-