



1copyTM Technical Specs

1copyTM COVID-19 qPCR Multi kit

A decorative grid of small, light blue dots arranged in a 10x10 pattern, covering the right side of the page. A single dot in the 4th row, 8th column is replaced by a small blue and red flame icon.

Global
Mobile
Healthcare
Leader
through
Innovative
Technology

1copy™

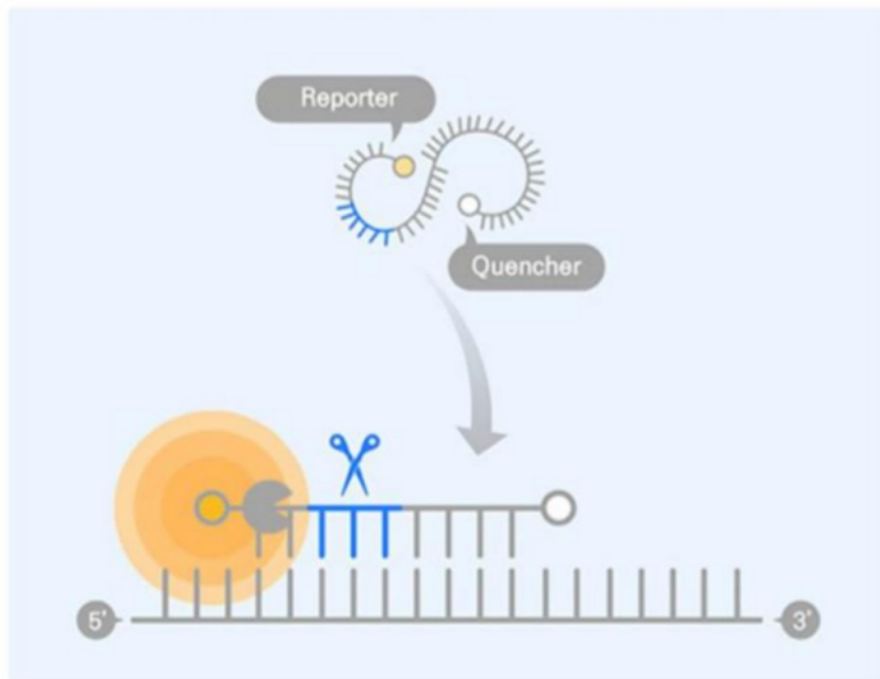
Molecular Diagnostics

1copy™ COVID-19 qPCR Multi kit



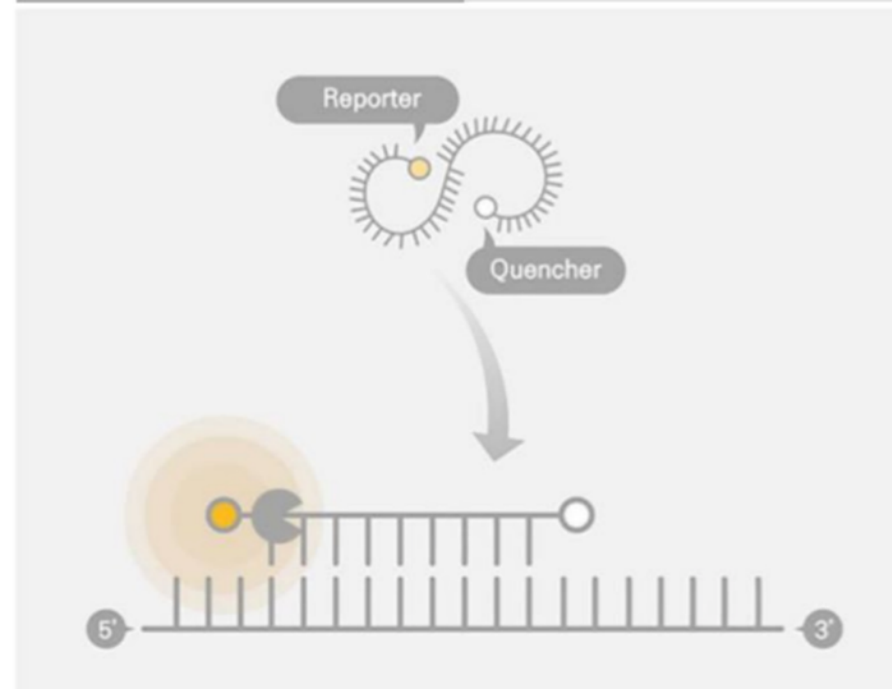
Catacleave(DNA-RNA-DNA Hybrid probe) + RNase(Thermo-stable, Hot-start)

1 copy™ Technology



More efficient probe degradation ↑
→ Higher fluorescence intensity ↑

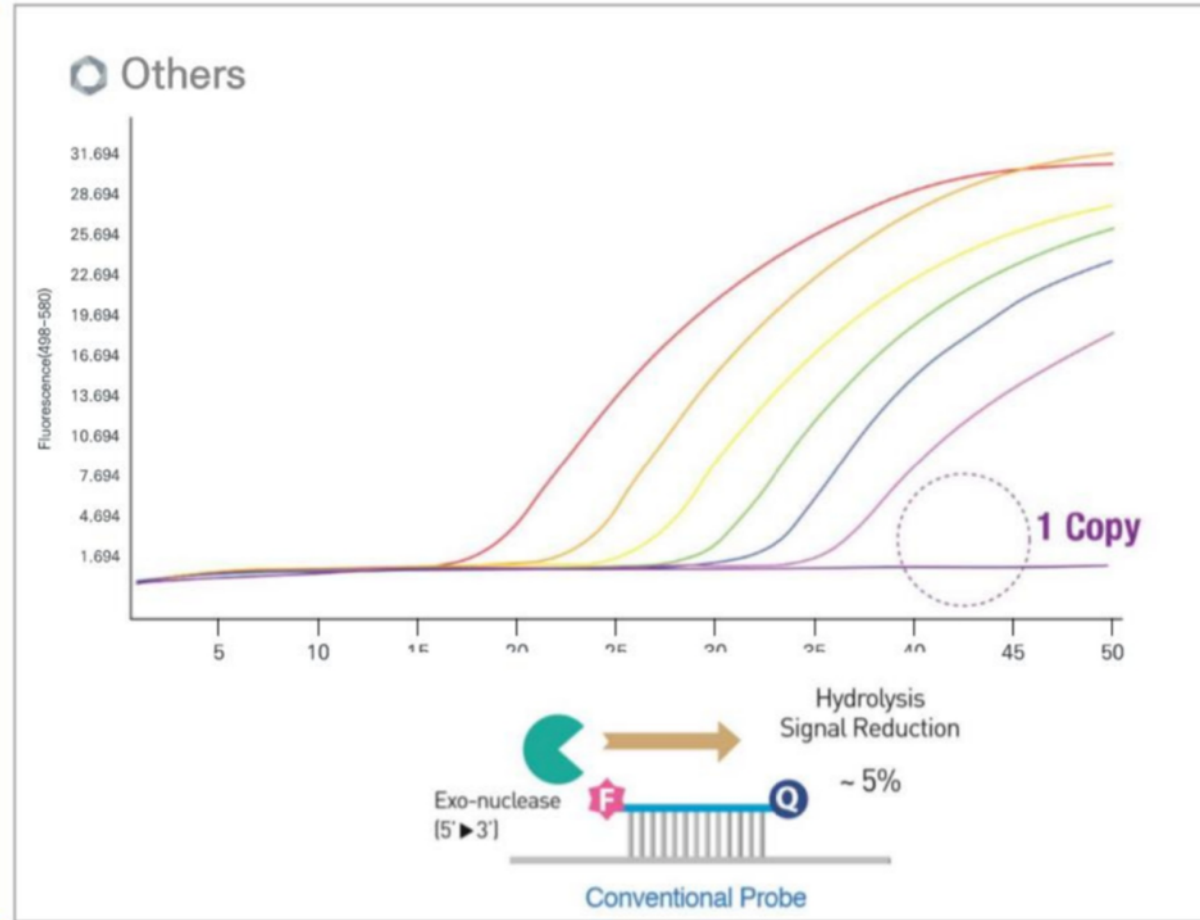
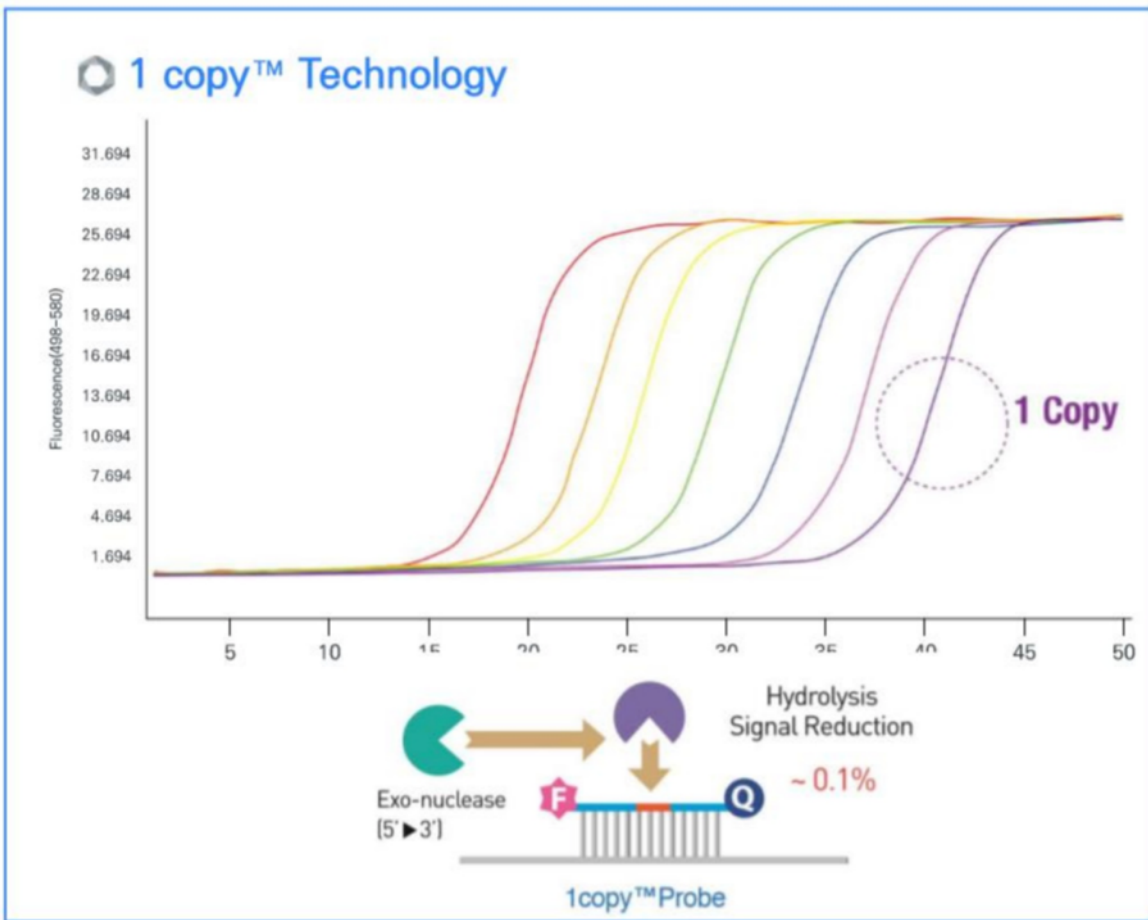
Others (ex Taqman)



Less efficient probe degradation ↓
→ Lower fluorescence intensity ↓

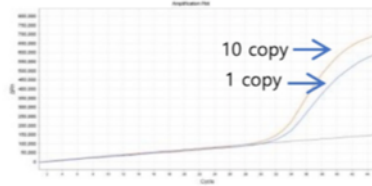
- DNA
- RNA
- DNA Polymerase
- ✂ RNase

Single Molecule RNA Detection

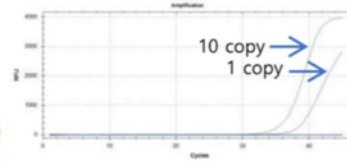


High compatibility with commercial PCR machines

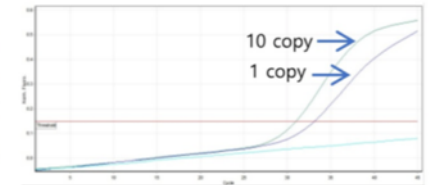
ABI7500 (ABI)



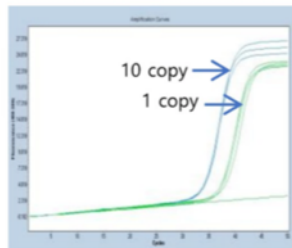
CFX96 (Bio-Rad)



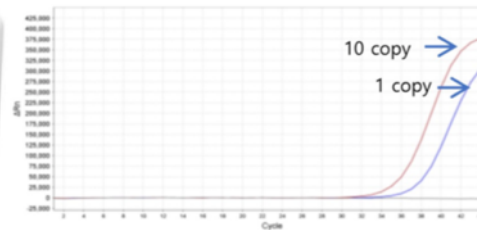
Rotor gene Q (Qiagen)



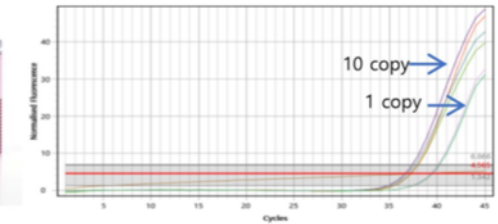
LC480 (Roche)



Quantstudio5 (ABI)



Mic qPCR cycler (BMS)

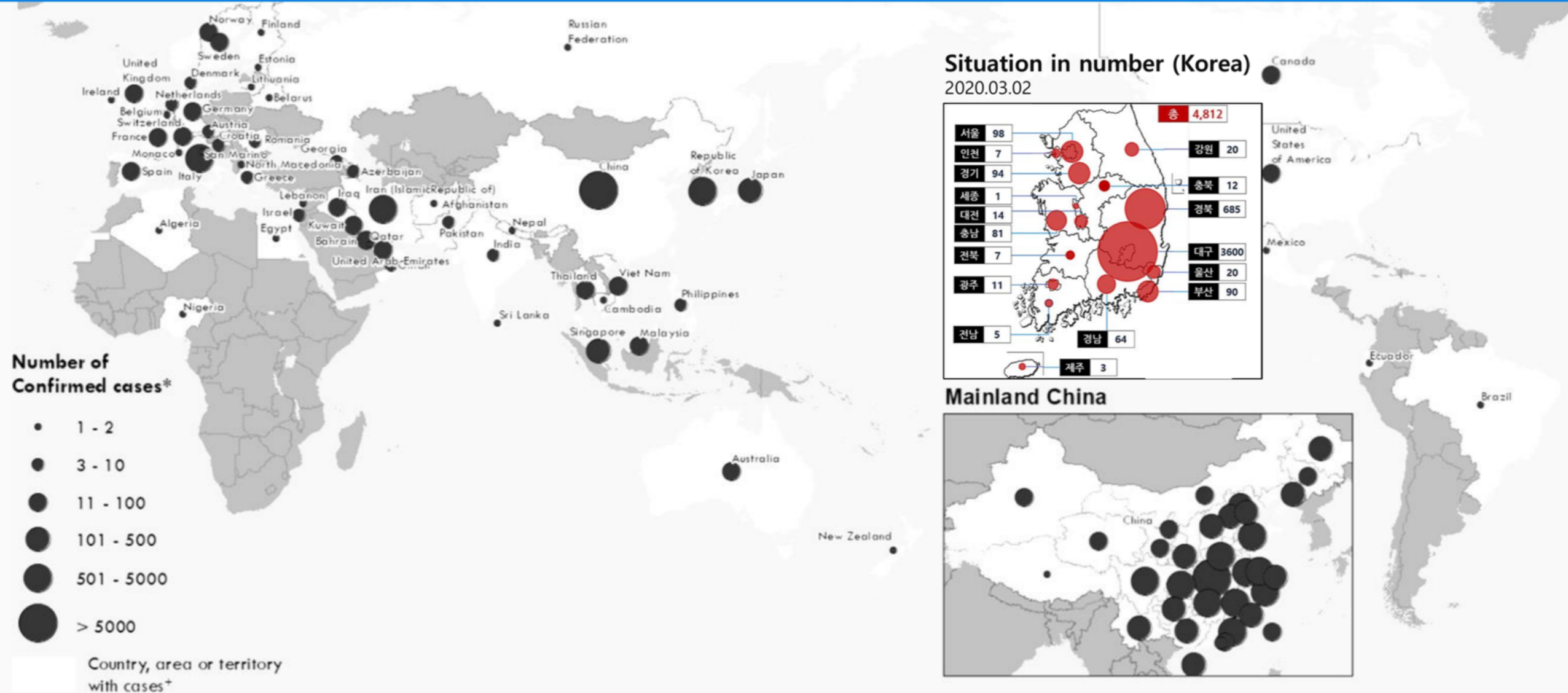


| | | 2019 | 2020 | | | | 2021 | | | |
|--------------|---------------|------|------|----|----|----|------|----|----|----|
| | | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
| CML | BCR-ABL | ● | | | | | | | | |
| AML | PML-RARA | ● | | ● | | | | | | |
| | RUNX1-RUNX1T1 | | ● | | ● | | | | | |
| | CBFB-MYH11 | | | | | | ● | | ● | |
| | 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 an infectious disease caused by the most recently discovered coronavirus.
- 2020.03.01 Situation in number(worldwide) 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)

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

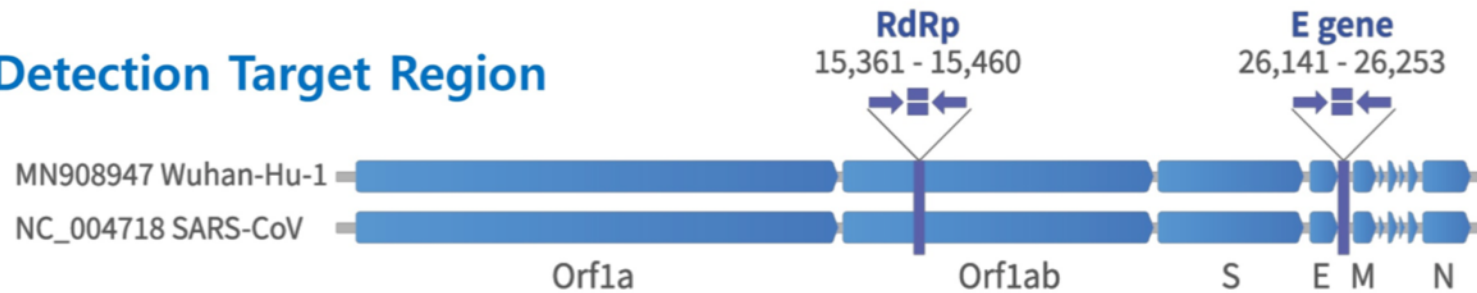
| Country | Institute | Gene targets |
|-----------|---|---|
| China | China CDC | ORF1ab and N |
| Germany | Charité | RdRP, E, N |
| Hong Kong | HKU | ORF1b-nsp14, N |
| Japan | National Institute of Infectious Diseases, Department of Virology III | Pancorona and multiple targets, Spike protein |
|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

COVID-19 Detection system

● Specimen type

- Nasopharyngeal swab
- Oropharyngeal swab

● Detection Target Region

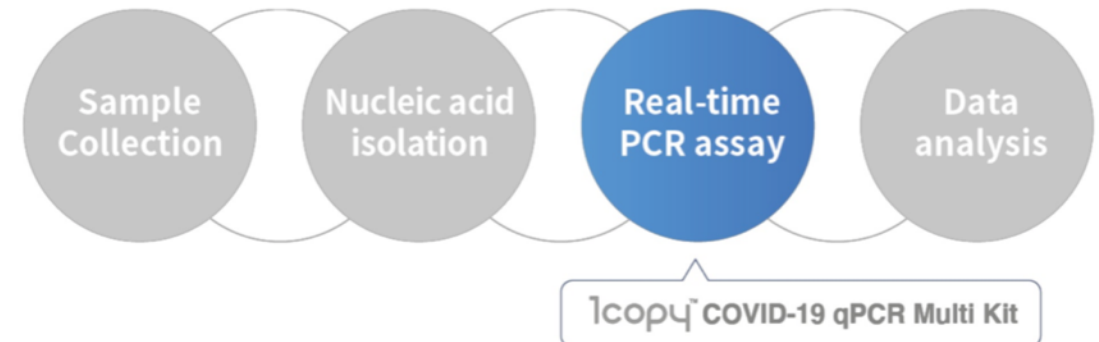


*Internal Positive Control is included.

● 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

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Patient Released from Hospital Rediagnosed with COVID-19

Write: 2020-02-29 14:47:33 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.

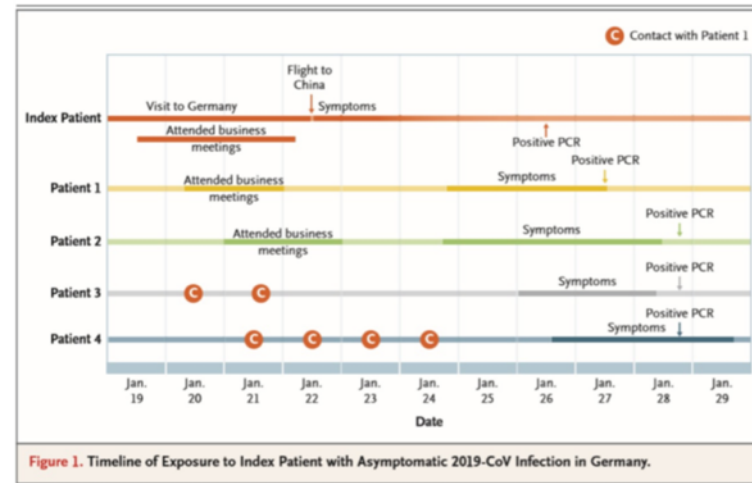
http://world.kbs.co.kr/service/news_view.htm?lang=e&Seq_Code=151690

Issue of small number of viral load

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany



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

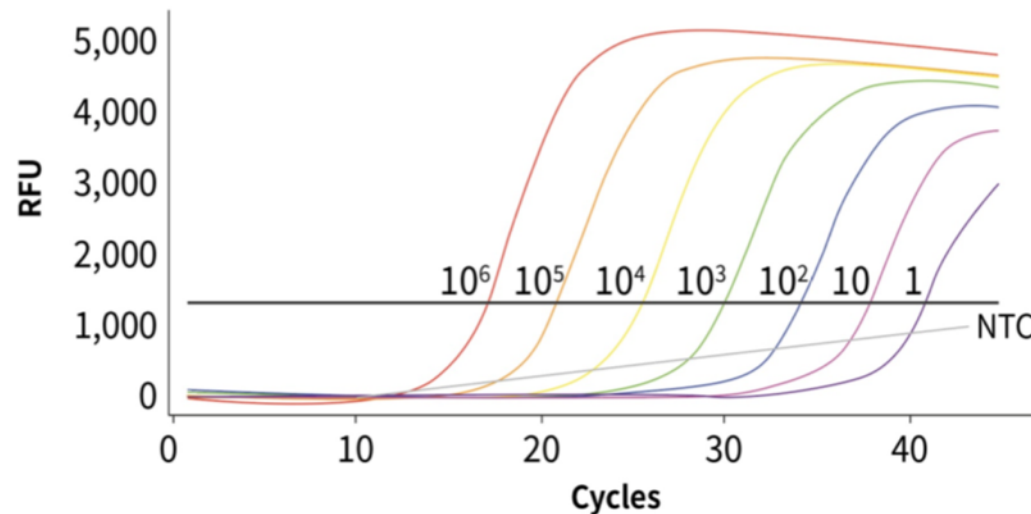
COVID-19 qPCR detect single molecule of RNA

| 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% |

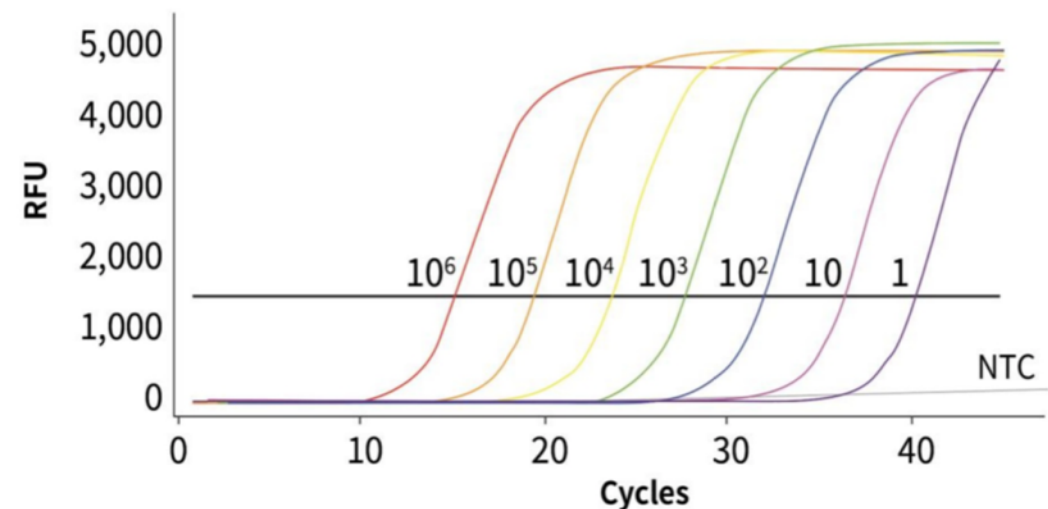
Because the sensitivity of 1copy™ COVID-19 Multi Kit is very high, good laboratory techniques should be followed.

- ✓ Testing is limited to laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.
- ✓ There is a risk of false positive values resulting from cross-contamination.
- ✓ Only use aerosol barrier pipette tips and change tips between liquid transfers.
- ✓ False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.

● Synthetic RNA of COVID-19 specific RdRp gene



● Synthetic RNA of beta-coronavirus specific E gene

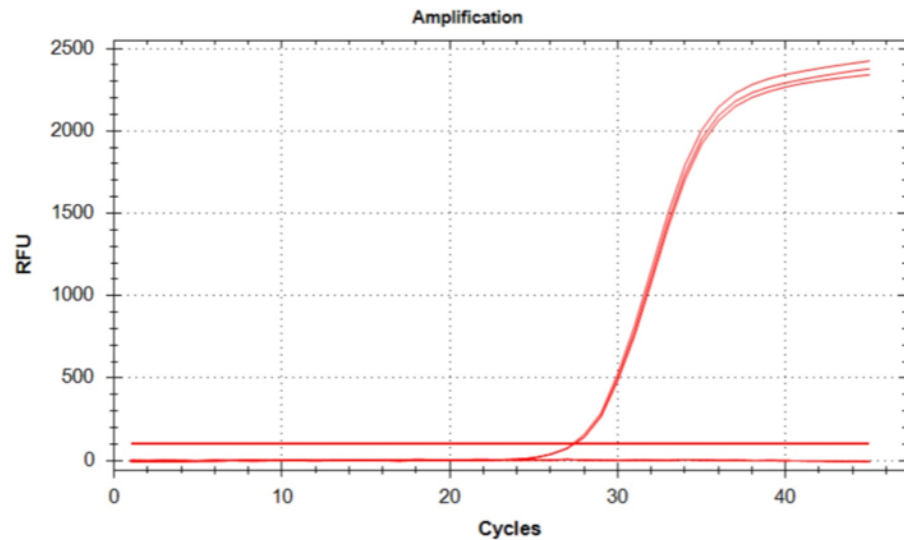


1copy™ COVID-19 Internal Positive Control(IPC)

- IPC originated from specimens is used as an extraction control and internal control.
- The IPC is needed to evaluate, whether the extraction and amplification procedure is valid or not.

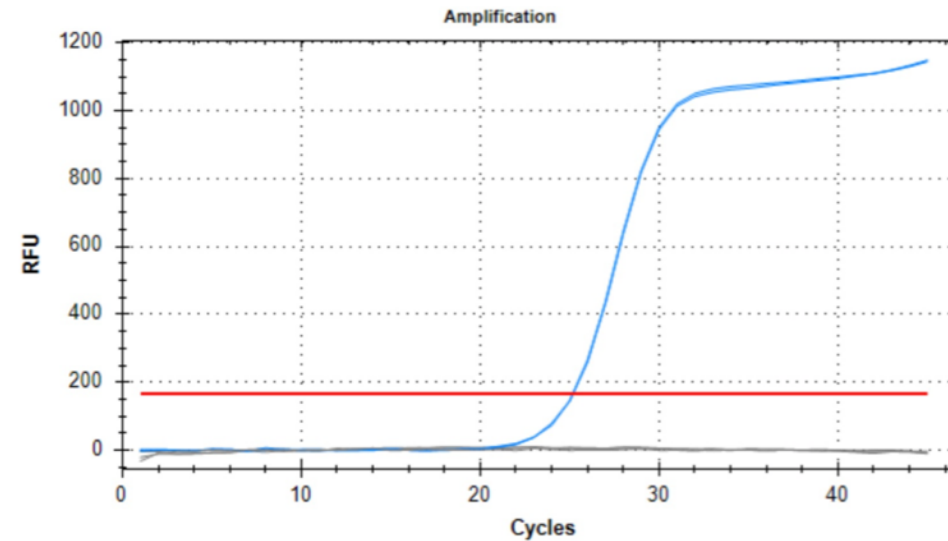
Measurement method : RT-qPCR / Target gene : Human GAPDH

● K-562 : 100pg/reaction



| Raw data(Ct) | |
|--------------|-------|
| 27.46 | 27.35 |
| 27.52 | 26.98 |
| 27.28 | 27.37 |
| 27.23 | 27.3 |
| 27.3 | 27.39 |
| average | 27.32 |

● Extraction RNA(from nasopharyngeal swab) : sample 4ul/reaction



| Raw data(Ct) | |
|--------------|-------|
| 24.93 | 25.35 |
| 25.49 | 25.17 |
| 25.51 | 25.39 |
| 25.23 | 25 |
| 25.38 | 25.18 |
| average | 25.26 |

| Specification | | Contents (100 Test/Kit) |
|------------------|--|--------------------------------------|
| Steps | Single step | ● Master mix : 2ea |
| LoD | 0.2copy/ μl (4copies/reaction) | ● Primer/Probe mix (E gene) : 1ea |
| Target | RdRp, 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 |



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 | - |

Thank
you!



Let's Connect



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