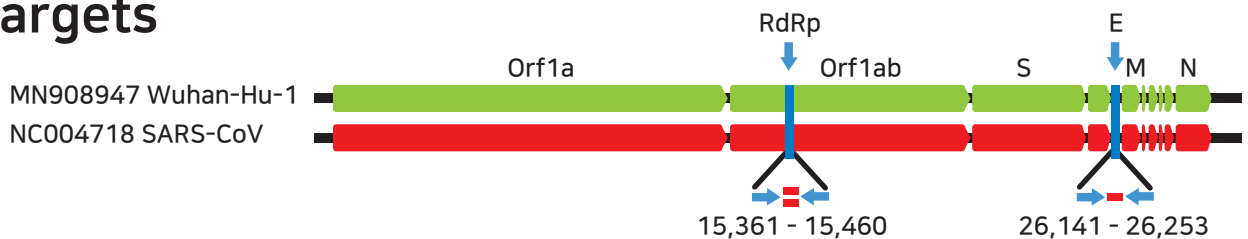


ExAmplar

COVID-19 real-time PCR kit (L)

- Fully Lyophilized, real-time RT PCR kit
- Ambient temperature shipping (no dry ice)
- 2-8°C storage for 12 months
- Ready-to-use : add extracted RNA and buffer

Test targets



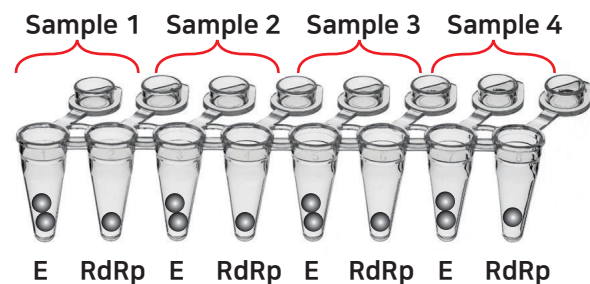
Designed according to Berlin, Germany protocol

https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2

Test Procedure

- 1 Add 15 µL of resuspension buffer to each well.
- 2 Add 5 µL RNA to 2 wells(2 beads and 1 bead) for each extract.
- 3 Centrifuge lightly
- 4 -1. Using **ExAmplar**
 - : Select 'Q test' → 'SARS-CoV-2' →
 - Assign all tubes as 'SP' → Run
- 2. Using conventional PCRs with following condition

| Temp.(°C) | Time (min:sec) | # of Cycles |
|-----------|----------------|-------------|
| 54 | 15:00 | 1 |
| 95 | 05:00 | 1 |
| 95 | 00:15 | 45 |
| 60 | 00:40 | |



Real-time PCRs

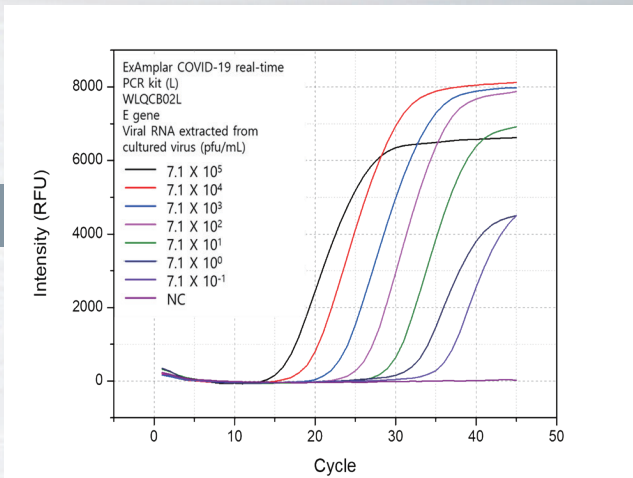
ExAmplar



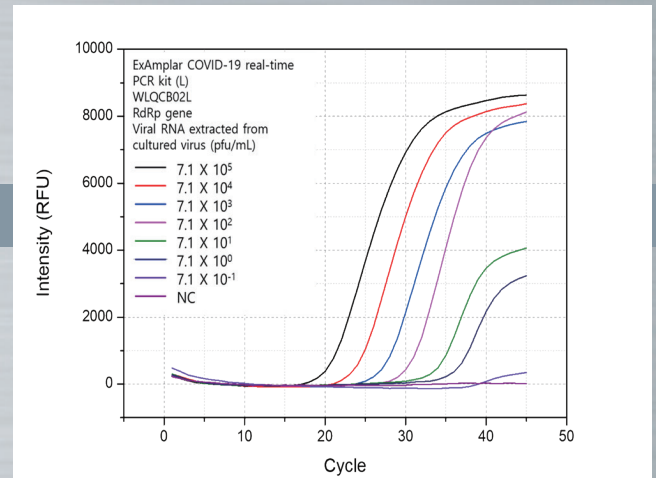
1. Performance Data

Analytical Sensitivity

E gene Assay: betacorona



RdRp gene Assay: SARS-CoV-2



| | Limit of Detection | 95% confidence interval (CI) |
|-----------|----------------------|------------------------------|
| E gene | 5.2 copies/ μ L | 4.2 ~ 7.2 copies/ μ L |
| RdRp gene | 15.1 copies/ μ L | 12.5 ~ 19.6 copies/ μ L |

Analytical Specificity

No cross reactivity with known respiratory viruses

2. Stability

Shipping : ambient temp (under 45°C)

Storage : 12 months at 2-8°C

3. Certification

CE-IVD

Kit components

| Components | Quantity |
|--|-----------------------------|
| ExAmplar COVID-19 reaction tube (lyophilized) : separate packaging, 4 tests/tube (48 tests/kit) | 12 tubes |
| Resuspension Buffer | 2 vials (1.5 mL \times 2) |
| Positive control (IVT RNA) (lyophilized) | 1 vial |
| Negative control | 1 vial (150 μ L) |