

COVID-19 detection, in vitro diagnostic medical device

# Real-Q 2019-nCoV Detection Kit

This product has obtained approval for emergency use from Korea Centers for Disease Control and Prevention (KCDC) and Ministry of Food and Drug Safety (MFDS).

## ● Overview of Real-Q 2019-nCoV Detection Kit

- Real-Q 2019-nCoV Detection Kit is an in vitro diagnostic medical device that qualitatively detects the COVID-19 gene in samples (sputum, oropharyngeal and nasopharyngeal specimens etc.) of patients with suspected respiratory infections using 1-step real-time RT-PCR(Reverse transcription polymerase chain reaction) system.
- It used the TaqMan probe for detection of COVID-19 RdRP gene and E gene and also IC TaqMan probe for amplification of human RNase P as internal control. The Internal control can be used to check for nucleic acid isolation and possible PCR inhibition.
- The target gene for detection and the fluorescent dye of the probe are shown in the table below.

| FAM                  | HEX/VIC          | Cy5           |
|----------------------|------------------|---------------|
| 2019 nCoV, RdRP gene | Beta CoV, E gene | human RNase P |

❖ RdRP, RNA dependent RNA polymerase gene; E, Envelope gene

- It is designed to detect TaqMan probe fluorescence signals in three different wavelength signals in a 1-tube.
- The Real-Q 2019-nCoV Detection Kit contains all reagents for real time PCR, such as PCR reaction mixture, RT-PCR enzyme, nCoV primer and probe mixture contained internal control primer and probe mixture, Positive control, and water. Also, this kit contains UNG (Uracil-N-glycosylase) in PCR reaction mixture to prevent carry over contamination

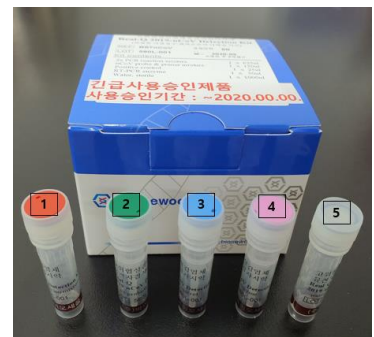
## ● How to use

- Applicable real time PCR instrument

| Manufacturer | Equipment name  |
|--------------|---|
| Bio-Rad      | CFX96 real-time PCR detection system                              |
| ThermoFisher | Applied Biosystems 7500/7500 fast Real-Time PCR Instrument System |

- Kit Components

| Cap color   | Component name                   |
|-------------|----------------------------------|
| Red cap ●   | 2X PCR reaction mixture          |
| Green cap ● | nCoV probe&primer mixture        |
| Blue cap ●  | Positive control                 |
| Pink cap ●  | RT-PCR enzyme                    |
| Colorless   | Water, sterile, DNase/RNase free |



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## ● Specimen

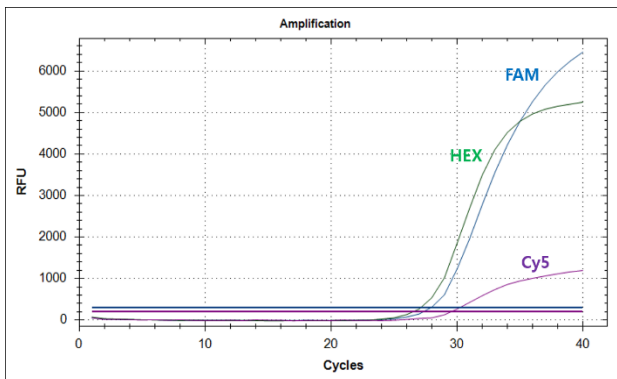
Nasopharyngeal (NP) swab, NP aspirates, oropharyngeal (throat) swab, sputum, endotracheal aspirates, endobronchial aspirates, bronchoalveolar lavage (BAL)

## ● Real time PCR condition

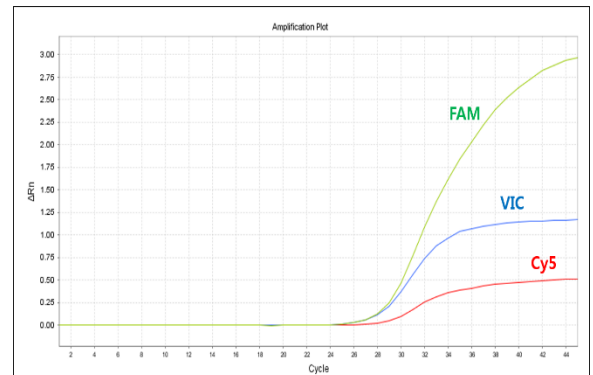
| Step | Temperature | Time   | Cycle | Signal Acquisition                      |
|------|-------------|--------|-------|---|
| 1    | 50 °C       | 30 min | 1     |   |
| 2    | 95 °C       | 15 min | 1     |   |
| 3    | 95 °C       | 15 sec | 40    | Acquiring FAM, HEX(VIC), and Cy5 signal |
|      | 62 °C       | 45 sec |       |   |

❖ Running time: 1hr 50min.

## ● Amplification curve



❖ CFX 96 real-time PCR detection system



❖ AB 7500 real-time PCR detection system

## ● Contact

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