GENERAL BIOLOGICALS CORPORATION since 1984

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# GB SARS-CoV-2 Real-Time RT-PCR Kit

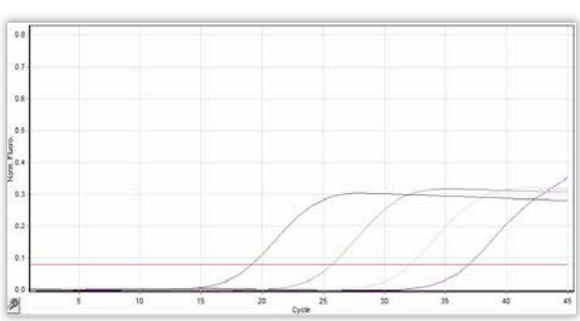
## For in-vitro Qualitative Detection of 2019-Novel Coronavirus in Human Respiratory Specimens and Sera


## INTENDED USE

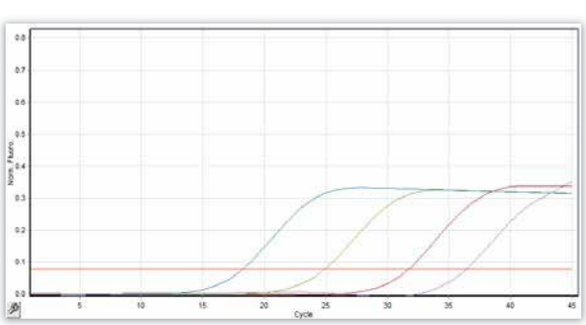
The GB SARS-CoV-2 Real-Time RT-PCR is an in vitro nucleic acid amplification test (NAT) for the qualitative detection of novel coronavirus (SARS-CoV-2) in the respiratory tract specimens (i.e., sputum), serum or plasma, utilizing Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and TaqMan probe technology.

## PERFORMANCE

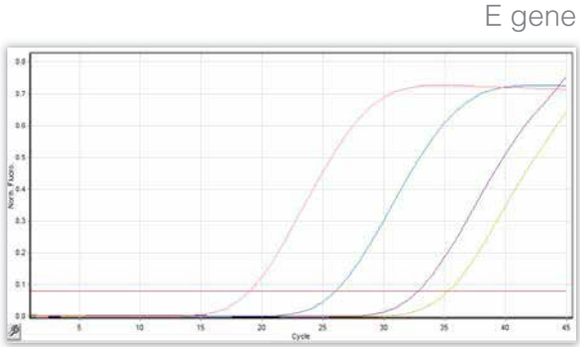
- Limit of Detection (LoD)：$1\times10^2$ copies/ml
- All serial dilutions of in-vitro transcription RNA of the target gene can be detected. ($10^2$, $10^4$, $10^6$, $10^8$ copies/ml < 37 Ct)
- Including IC (internal control) as an indicator of the RT-PCR performance, which can reduce the results of false-negative.




E gene




ORF1ab gene




N gene

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## PRODUCT INFORMATION

| | |
|---|---|
| Test Principle | One-step real-time RT-PCR (TaqMan®-based detection) |
| Targets | E gene, N gene and ORF1ab region of SARS-CoV-2 (COVID-19) |
| Number of Tests | 100T / Kit |
| Time to Results | 1.5 hr ~ 2 hr |
| Specimen Type | • Respiratory specimens (e.g. sputum, nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, and tracheal aspirates)<br>• Serum, plasma |
| Instrument Required | • Extraction system & Extraction kit<br>• Real-time PCR instrument with FAM and VIC detection channel |
| Kit Storage | -20°C, avoid repeated freezing and thawing of kit contents |
| Biosafety Precautions | Laboratory personnel are required to wear appropriate personal protective equipment when handling clinical specimens and should be trained in using the real-time PCR instrument. Processing should be performed in a certified class II biological safety cabinet following biosafety level 2 or higher guidelines. For more information, refer to:<br>• Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCov)<br>• Biosafety in Microbiological and Biomedical Laboratories 5th edition |

## REAGENTS SUPPLIED

Each kit provides reagents sufficient for performing 100 tests and consists of the following:

1. GB one-step Real-time RT-PCR reagent
2. Ready-to-use primer and probe mixture for E gene, N gene and ORF1ab region / E gene, ORF1ab region of SARS-CoV-2.
3. Nuclease-free water
4. Positive Controls

### ORDERING INFORMATION

| Catalog No. | Description | Package |
|---|---|---|
| 4PCO002E | GB SARS-CoV-2 Real-Time RT-PCR (E / N / ORF1ab) | 100 tests |
| 4PCO042E | GB SARS-CoV-2 Real-Time RT-PCR (E / ORF1ab) | 100 tests |


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**Innvolution Healthcare Pvt Ltd is sole importer and distributors of RT PCR and RNA Extraction Kits from GBC Taiwan.**