



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

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

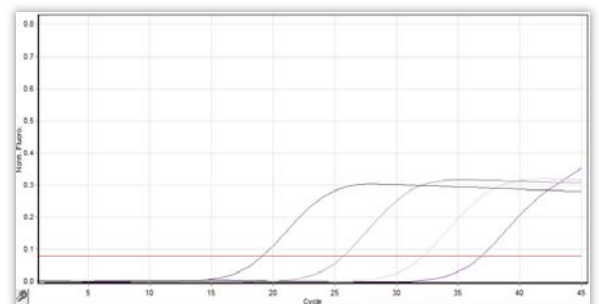


INTENDED USE

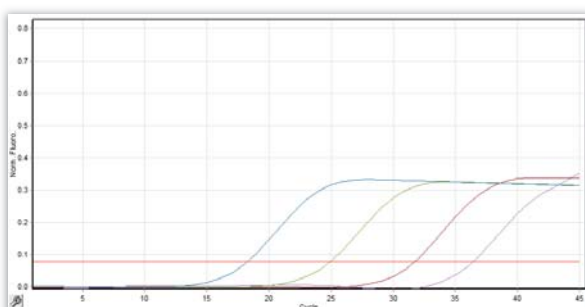
The GB SARS-CoV-2 Real-Time RT-PCR is an in vitro nucleic acid amplification test (NAT) for the qualitative detection of novel coronavirus (SARS-CoV-2) in the respiratory tract specimens (i.e., sputum), serum or plasma, utilizing Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and TaqMan probe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

PERFORMANCE

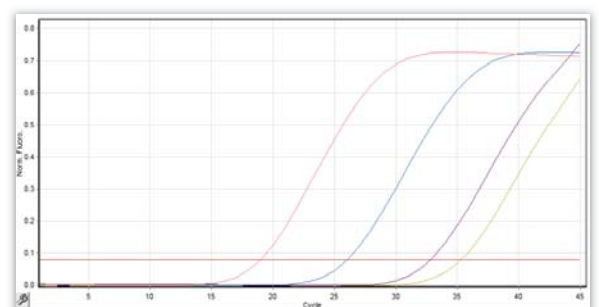
- Limit of Detection (LoD) : 1×10^2 copies/ml
- All serial dilutions of in-vitro transcription RNA of the target gene can be detected. (10^2 , 10^4 , 10^6 , 10^8 copies/ml < 37 Ct)
- Including IC (internal control) as an indicator of the RT-PCR performance, which can reduce the results of false-negative.



E gene



ORF1ab gene



N gene

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	<ul style="list-style-type: none"> Respiratory specimens (e.g. sputum, nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, and tracheal aspirates) Serum, plasma
Instrument Required	<ul style="list-style-type: none"> Extraction system & Extraction kit Real-time PCR instrument with FAM and VIC detection channel
Kit Storage	-20°C, avoid repeated freezing and thawing of kit contents
Biosafety Precautions	<p>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:</p> <ul style="list-style-type: none"> Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCov) Biosafety in Microbiological and Biomedical Laboratories 5th edition

REAGENTS SUPPLIED

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

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

ORDERING INFORMATION

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

2020.Apr.

