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Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2

For Emergency Use Authorization Only | For in vitro diagnostic use | Rx Only

Product Description

On April 24, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) amendment for BGI's Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2. The amendment expands the previously issued EUA label to further include the optional use of automated sample preparation system, additional viral RNA extraction kit and PCR systems for testing a broader range of clinical samples. Hospitals and reference laboratories can run the highly sensitive test with automation and receive results for 192 samples in 4 hours.

Features

- Taqman Reverse Transcription PCR
- ORF1ab gene as domain target
- Human β–actin as internal control
- Manufacturing in ISO 13485 compliant and high-volume production facility
- Stringent QC with positive and no-template controls

Benefits

- Highly sensitive – Detect as low as 100 viral copies/mL for BALF samples
- Highly specific – No cross-reactivity with 54 human respiratory pathogens
- High-throughput – Ramp up labs for large-scale, community-based testing
- Fast TAT – Sample to result in 4 hours with automated sample preparation system
- Ease of use – All inclusive with pre-mixed reaction reagents
- Easy interpretation – Analysis of one target with well-defined controls

Product Specifications

No of reactions per kit	50
Acceptable samples	Collected from throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage fluid (BALF)
Acceptable real-time PCR machines	– Applied Biosystems 7500 Fast Real-Time PCR System, Software v2.0.6 – Applied Biosystems 7500 Real-Time PCR System, Software v2.0.5 – Applied Biosystems QuantStudio 5 Real-Time PCR System, 96-Well, Software v1.5.1 – Roche LightCycler 480 Instrument II, 96-Well, Software v1.5.0
Acceptable viral RNA extraction kits	– MGIEasy Nucleic Acid Extraction Kit, 96 or 1728 preps – QIAamp Viral RNA Mini Kit, 50 or 250 preps
Automation (Optional)	MGISP-960RS Automated Sample Preparation System, Software v1.2
Limit of detection	– BALF samples: 100 viral copies/mL – Throat swab samples: 150 viral copies/mL
Reagent stability	Under dark for 5 days at 2-8°C or 12 months at -18°C

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Key Components

Component	Volume	Quantity	Description
SARS-CoV-2 Reaction Mix	1mL/vial	1 vial	Reagents for amplification, probes, primers for virus target and internal reference
SARS-CoV-2 Enzyme Mix	80μL/vial	1 vial	Taq polymerase, reverse transcriptase and uracil-DNA glycosylase (UDG)
SARS-CoV-2 Positive Control	750μL/vial	1 vial	Mix solution of pseudo-virus with target virus genes and internal reference
SARS-CoV-2 Blank Control	750μL/vial	1 vial	DNase/RNase free water

Request for Information or Quotation

Contact your BGI account representative for more information including product pricing.
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In the United States:
– This test has not been FDA cleared or approved;
– This test has been authorized by FDA under an EUA for use by authorized laboratories;
– This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
– This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner.

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