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

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

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

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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