



A Trusted Total Lab Solution for COVID-19 Pandemic

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

To ramp up large-scale, community-based COVID-19 testing, BGI and MGI have teamed up to provide a one-stop, total lab solution as a result of the authorization from the FDA to expand BGI's SARS-CoV-2 RT-PCR Test solutions under emergency use authorization (EUA). The EUA label expansion includes the RNA extraction kit and automated liquid handling system manufactured by MGI, as well as the inclusion of additional PCR systems and sample types, thus allowing us to introduce a high-throughput testing workflow with broader clinical adaptability. The unprecedented kit manufacturing capacity is another way that enables the total lab solution to address major bottlenecks in COVID-19 testing.

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

- ORF1ab gene as domain target
- 50 reactions per kit
- Compatible real-time PCR systems
 - Applied Biosystems 7500, Software v2.0.5
 - Applied Biosystems 7500 Fast, Software v2.0.6
 - Applied Biosystems QuantStudio 5, 96-Well, Software v1.5.1
 - Roche LightCycler 480 Instrument II, 96-Well, Software v1.5.0
- Manufacturing capacity of 2 million reactions per day

MGIEasy Nucleic Acid Extraction Kit

- Compatible with throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage fluid (BALF)
- Available in 96-reaction and 1728-reaction packs
- Manufacturing capacity of 1 million reactions per day
- Abundant supply in US

MGISP-960RS Automation System

- Automated workstation with 96-channel pipette
- Battle tested for high throughput routine extractions
- Sample processing in batches: 192 samples in 80 min; 32 to 96 samples in 60 min
- Customizable protocols for both MGI and Qiagen RNA extraction kits

Total Advantages

Giving users the confidence and peace of mind for reliable SARS-CoV-2 testing and final test results, all key components of the total lab solution are manufactured in ISO 13485 compliant facilities.

1) Superior Performance

- RT-PCR assay detects as little as 100 viral copies/mL from bronchoalveolar lavage fluid samples
- Thoroughly tested automated RNA extraction protocol for high throughput operation
- Fine pipetting precision enabled by automation system
- Reduction in user operating errors resulting in higher reproducibility

3) Broad Compatibility

- Compatible with a variety of real-time PCR instruments commonly found in labs
- Viral RNA extracted from samples collected by throat swab, nasopharyngeal swab and more
- Applicable with viral RNA extraction kits manufactured by MGI or Qiagen

2) Highly Efficient

- Fast TAT: sample to result in 4 hours
- High throughput: MGISP-960RS processes 192 samples in 80 minutes
- Easy operations: one person can operate three automation systems simultaneously
- Economic: truly walk-away system and sample processing in batches
- Efficient RNA extraction through optimized chemistry

4) Integrated Process

- One-stop shop for the majority of components required in an end-to-end workflow
- Pre-mixed RT-PCR reaction reagents, extraction buffers and magnetic beads included
- Sample processing designed with safety in mind with UV lamp, laminar flow hood (ISO5) and protective door

Request for Information or Quotation

Contact your BGI account representative for RT-PCR kit and your MGI account representative for viral RNA extraction kit and MGISP-960RS automation system.

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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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