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ASIA EDITION

BGI Genomics receives EUA from FDA for SARS-CoV-2 detection kit

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Kits are currently being distributed to more than 70 countries and regions worldwide

China based BGI Genomics. Co. Ltd. and its US subsidiary BGI Americas Corp. have announced that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for its RT-PCR kit for detecting SARS-CoV-2.

BGI's highly sensitive test can return results within three hours. It is intended for the qualitative detection of SARS-CoV-2, the virus that causes COVID-19 disease, in bronchoalveolar lavage fluid (BALF) and throat swabs.

"The authorization of our diagnostic test for COVID-19 in the US will provide high-quality, high-volume testing capabilities to the US, and enable medical professionals to respond quickly to diagnose patients, preventing further spread of infection," said Ye Yin, CEO of BGI Genomics.

Advantages of BGI's test include:

- High sensitivity– Limit of Detection at 100 copies/mL in BALF and 150 copies/mL in throat swabs
- High specificity – No cross-reactivity with 54 human respiratory pathogens
- Fast TAT – Sample to result in 3 hours
- Ease of use – All inclusive with pre-mixed reaction reagents
- Easy interpretation – Analysis of one target with well-defined controls