

Combat the spread of infectious disease

The past few months has shown that a team's rapid response to expediting an assay globally, dedicated to the detection of SARS-CoV-2, is possible. **BioGX**, in a long-term partnership with Becton, Dickinson and Company, has submitted a test to the FDA for emergency use authorisation (EUA) in the US, in parallel to CE-IVD approval. In these challenging times, laboratories around the world have an urgent need for an easy-to-use, reliable test to detect SARS-CoV-2 to determine if patients have contracted COVID-19. Authorisation to use these tests worldwide would increase access to highly reliable results.

In response to the recent coronavirus (COVID-19) outbreak, BioGX rapidly developed and launched a real-time PCR-based agnostic test kit for SARS-CoV-2 for immediate FDA emergency use authorisation (EUA) and CE-IVD approval. In a truly platform-agnostic manner, BioGX made this easy-to-use and highly reliable test available not only for an automated sample-to-answer platform but also conventional open PCR platforms in order to enable widespread adoption. "The foundation of BioGX stands firmly on its team's ability to listen and address customers' needs with speed. The world needed a test to detect SARS-CoV-2 fast and our team delivered," said Shazi Iqbal, CEO of BioGX.

As a global company, BioGX's products are available in over 100 countries and are even used in space. The company applies its US-based parent company's proprietary Sample-Ready reagent technology to rapidly develop room-temperature stable diagnostic kits for infectious diseases. In 2019, BioGX received CE-IVD marking for their new Flu A, Flu B, RSV A/B automated test. The new test greatly enhances the strain coverage and detection sensitivity, and offers testing for a greater variety of specimen types compared with the initially released test. The company has an expanding line of CE-IVD marked tests that presently includes 24 multiplex tests for infectious disease testing.

Due to urgent requests from BioGX's global partners, and the needs of public health agencies and healthcare providers worldwide, BioGX reacted to the current COVID-19 threat by expediting within two weeks, the development, production and manufacture of platform-agnostic real-time

PCR-based molecular test kits in their Sample-Ready lyophilised format. These tests are formatted for use on multiple instrument platforms, including automated sample-to-answer platforms. The kits can be shipped anywhere in the world with no refrigeration required.

Sample-Ready and platform-agnostic reagents

The concept of Sample-Ready technology is simple; all chemical and biological components formulated for identifying a gene signature-based test are combined into a single lyophilised reagent, packaged as a complete test in a tube or cartridge. The test is then ready to receive a purified DNA or RNA sample by just adding water. BioGX Sample-Ready technology enables the widespread application of the test on multiple real-time PCR platforms (platform agnostic) with a variety of starting specimen types. BioGX pioneered an approach that enabled unparalleled ease of use and reliability for molecular testing in the far reaches of the earth and even in space.

A truly global presence that reaches into space

BioGX is the first company to put real-time PCR technology in space, recently launching reagents to the International Space Station (ISS) aboard a SpaceX *Falcon 9* rocket as the supplier to NASA of reagents for the WetLab-2 programme. On earth, Sample-Ready technology enables running multiplexed molecular tests in locations where there is a lack of skilled expertise and environmental controls.

According to NASA, real-time PCR-based gene expression analysis is a powerful tool

for examining the molecular and cellular processes underlying spaceflight-induced conditions such as decreased immunity, loss of muscle and bone, cell stress, changes in the cell cycle, and changes in growth and development. Knowledge gained on the ISS using this technology will not only assist in developing ways to improve human health during long space flights, but also may contribute to our understanding of how to prevent and treat diseases here on Earth.

Michael Vickery, CSO and EVP of BioGX, says, "It is a privilege to be selected as the provider of the core molecular chemistry used in the WetLab-2 programme. We consider the selection of our technology for use in space travel to be further validation that assays developed in our Sample-Ready format are robust, reliable and durable for use under the most challenging conditions. We are excited to have the opportunity to test the limits of our technology while supporting the long-range goals of NASA."

Expanding product reach

BioGX has over 100 molecular tests that are distributed globally in over 100 countries. All products are developed and manufactured entirely in-house at its world-class ISO 13485-certified facilities.

BioGX does not develop or manufacture any instrument or platforms, and instead partners with platform providers to offer tests menu expansion on partners' platforms. BioGX's mission is to become a leading provider of open system reagents (OSRs) components enabling the most comprehensive sample-to-answer molecular menu expansion globally. ●

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