Twist Bioscience and Biotia Receive U.S. FDA Emergency Use Authorization for First Hybridization Capture-Based Next-Generation Sequencing SARS-CoV-2 Assay

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- Ability to sequence and surveil evolution of virus mutations over time and geography -

- Enables batch analysis of up to 96 samples at once; higher-plex assay development ongoing -

SOUTH SAN FRANCISCO, Calif. & NEW YORK--(BUSINESS WIRE)--Mar. 24, 2021-- Twist Bioscience Corporation (NASDAQ: TWST), a company enabling customers to succeed through its offering of high-quality synthetic DNA using its silicon platform, and Biotia, Inc., a company that uses proprietary analytical software for infectious disease diagnostics, today received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the SARS-CoV-2 Next-Generation Sequencing (NGS) Assay.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210324005311/en/

The SARS-CoV-2 NGS Assay is an *in vitro* diagnostic test, a highly sensitive nucleic acid hybridization capture-based assay, intended for the detection of SARS-CoV-2 RNA.

The SARS-CoV-2 NGS Assay has the ability to analyze the entire RNA viral sequence, to determine the presence or absence of the virus. Furthermore, in an optional research-use only (RUO) report the software analyzes the RNA sequence to detect genetic variants and lineages of SARS-CoV-2.[1] The hybridzation capture-based approach utilized in this assay maximizes the number of genetic variants identified, where other sequencing methods may miss mutations in certain regions.

New mutations in the SARS-CoV-2 virus continue to accumulate and circulate around the world, creating genetic variants of concern that may alter transmissability or vaccine efficacy, including the most recent B.1.1.7, B.1.351, and P.1 lineages initially found in the U.K., South Africa, and Brazil respectively. Especially given these emerging variants, this capture-based method is an important new tool for the identification, sequencing, and surveillance of COVID-19.

According to the World Health Organization's Genome Sequencing for SARS-CoV-2, published January 8, 2021, "One advantage of using a capture-based approach over a PCR amplicon-based approach is that capture-based approaches can tolerate sequence differences from the probe sequences of 10–20%. This is higher than the mismatch tolerated by PCR, where such a divergence from the primer sequences would result in a high risk of amplicon failure. Capture-based approaches can therefore be used to enrich successfully for relatively divergent SARS-CoV-2 sequences."

"While there are many available high-throughput diagnostic tests available for COVID-19, our solution enables clinicians and researchers the ability to sequence and surveil the evolution of mutations in the virus over time and geography. This is especially significant at the moment as more variants are identified that are more contagious," said Emily M. Leproust, Ph.D., CEO and co-founder of Twist Bioscience. "Importantly, while many labs are conducting individual sequencing runs for each patient sample, this assay and the accompanying software provide a way to batch about 100 samples together, providing actionable information that can then be used to inform public health and clinical decisions."

The assay utilizes Twist Bioscience's unique ability to rapidly develop virus-specific panels through DNA synthesis and Biotia's comprehensive data analysis software and reporting capabilities. The SARS-CoV-2 NGS Assay was validated on a NextSeq® 550 Sequencing System. Because the assay analyzes the full sequence data, the test reduces the likelihood of a false-negative result. In contrast, a majority of SARS-CoV-2 tests based on polymerase chain reaction (PCR) only identify limited genetic markers of the virus.

In the separate and free RUO report, the full sequence of the virus is profiled, enabling improved understanding of mutations, genetic variability, and the evolution of the virus as it's transmitted. A recent pre-print on MedRxiv and submitted for peer review details results of the NGS SARS-CoV-2 Assay with the COVID-DX Solution to detect the virus and its genetic variants.

"As SARS-CoV-2 continues to evolve, the need for insightful research tools leveraging NGS and evolutionary principles has become starkly clear," commented Niamh O'Hara, Ph.D., CEO and co-founder of Biotia. "This assay also greatly expands testing options in the clinical space, bringing new technology to patients."

"This test opens the door to a new diagnostic method and can also guide vaccine research, since it captures viral variants so well," noted Christopher Mason, Ph.D., co-founder of Biotia, "We are elated to get an FDA EUA for our test, which brings needed tools into the fight against COVID-19, as well as pioneering these capture methods for tracking other pathogens in the future."

About the Test and Interface

The SARS-CoV-2 NGS Assay is an *in vitro* diagnostic test intended for the qualitative identification of the SARS-CoV-2 virus from nasopharyngeal (NP), oropharyngeal (OP), anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirates, nasal wash/aspirates as well as from bronchoalveolar lavage (BAL) specimens from individuals suspected of having COVID-19 by their healthcare provider. The SARS-CoV-2 NGS Assay, which includes Twist Bioscience's SARS-CoV-2 synthetic RNA controls, along with the Biotia COVID-DX software which generates a clinical report and RUO report, covers the entire virus genome and identifies all strains of SARS-CoV-2 in samples with as few as 800 viral copies per milliliter.

The complementary Biotia COVID-DX software provides a clinically-oriented report including the presence or absence of the SARS-CoV-2 virus. FASTQ files (sequencing output) can be generated in certified clinical laboratories and submitted to Biotia COVID-DX (v1.0), a cloud-based software, to generate clinical reports. Access to the Biotia COVID-DX software will be provided through a unique order number emailed to a clinician or researcher that includes credits for each kit purchased.

The SARS-CoV-2 NGS Assay and Biotia COVID-DX software are limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. The SARS-CoV-2 NGS Assay is intended for use by ***qualified and trained clinical laboratory personnel specifically instructed and trained in the use of the Illumina NextSeq 500/550/550Dx Sequencing System, NGS workflows, and in vitro diagnostic procedures***. The SARS-CoV-2 NGS Assay is only for use under the Food and Drug Administration's Emergency Use Authorization. This test will become available for purchase in the coming weeks. For more information, click here.

About Biotia

Biotia is a health tech company located in New York, NY, that leverages sequencing-based technology and proprietary AI-powered software to rapidly and accurately identify microorganisms and antimicrobial resistance. Their mission is to fight infectious diseases by deploying the leading reference library of microbes worldwide. Biotia, a spinout company of Jacobs Technion-Cornell Institute at Cornell Tech, has a New York State CLIA lab for COVID-19 testing affiliated with SUNY Downstate Health Sciences University.

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About Twist Bioscience Corporation

Twist Bioscience is a leading and rapidly growing synthetic biology and genomics company that has developed a disruptive DNA synthesis platform to industrialize the engineering of biology. The core of the platform is a proprietary technology that pioneers a new method of manufacturing synthetic DNA by "writing" DNA on a silicon chip. Twist is leveraging its unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next-generation sequencing (NGS) preparation, and antibody libraries for drug discovery and development. Twist is also pursuing longer-term opportunities in digital data storage in DNA and biologics drug discovery. Twist makes products for use across many industries, including healthcare, industrial chemicals, agriculture, and academic research.

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Legal Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including without limitation, the ability of the SARS-CoV-2 NGS Assay to successfully provide actionable information that can then be used to inform public health and clinical decisions, reduce the likelihood of a false positive or a false negative result, enable improved understanding of mutations, genetic variability, and the evolution of SARS-CoV-2 as it is transmitted and to advance COVID-19 research and control, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Twist Bioscience's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties of the ability to attract new customers and retain and grow sales from existing customers; risks and uncertainties of rapidly changing technologies and extensive competition in synthetic biology could make the products Twist Bioscience is developing obsolete or non-competitive; uncertainties of the retention of a significant customer; risks of third-party claims alleging infringement of patents and proprietary rights or seeking to invalidate Twist Bioscience's patents or proprietary rights; and the risk that Twist Bioscience's proprietary rights may be insufficient to protect its technologies. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Twist Bioscience's business in general, see Twist Bioscience's risk factors set forth in Twist Bioscience's Annual Report Form 10-K filed with the Securities and Exchange Commission on November 27, 2020 and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Twist Bioscience specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

[1]Variant detection and identification performance have not been evaluated by the FDA and these claims are not authorized under FDA's Emergency Use Authorization.

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