Twist Bioscience and Biotia Receive Expanded Emergency Use Authorization to Report Genetic Variants of SARS-CoV-2

August 2, 2022

- FDA EUA Variant Calling Assay Allows for Sequencing to Inform Patient Treatment -

SOUTH SAN FRANCISCO, Calif. & NEW YORK--(BUSINESS WIRE)--Aug. 2, 2022-- 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 expanded Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the SARS-CoV-2 Next-Generation Sequencing (NGS) Assay for the qualitative detection, identification and differentiation of SARS-CoV-2 lineages and identification of specific genomic mutations. The Assay was developed in 2020, and this expanded authorization builds on the initial EUA that was received in March 2021 for the qualitative detection of the SARS-CoV-2 virus.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220802005390/en/

The hybridization capture-based SARS-CoV-2 NGS Assay has the ability to analyze the entire RNA viral sequence, and to determine the presence or absence of the virus. With the expanded authorization, the reporting of the identified and differentiated SARS-CoV-2 genetic mutations and viral lineages (e.g. Delta, Omicron) to clinicians is now authorized, potentially aiding them to direct appropriate clinical management based upon the specific lineage of virus, when clinically indicated.

The authorization also allows for the reporting of individual mutations in patient samples, information that is important to track as the virus evolves and new variants emerge. The hybridization capture-based approach utilized in this assay maximizes the number of genetic variants and mutations that may be 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 transmissibility or vaccine efficacy, including the most recent Omicron (BA.2.12.1, BA.4 and BA.5) variants. The virus will continue to evolve, and we expect that this capture-based assay will serve as an important new tool for viral identification, sequencing, and surveillance. With this expanded EUA, we anticipate that these data will, for the first time, now enable the appropriate treatment of COVID-19.

“We developed this assay in the early days of the pandemic and, while useful for detecting the presence or absence of the virus, the true value lies in receiving a comprehensive sequencing report with all identified mutations that is now available under the expanded EUA,” said Emily M. Leproust, Ph.D., CEO and co-founder of Twist Bioscience. “We believe this assay will continue to be critical to monitor the sequence evolution of SARS-CoV-2 and is another example of our commitment to provide tools to fight the pandemic, even when it becomes endemic.”

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 a separate report available to clinicians for professional interpretation, previously for research use only but now authorized under the expanded EUA, the full sequence of the virus is identified, and mutations and variant differentiation are reported. The expanded EUA comes at an important time during the pandemic, as we see evidence of the failure of specific monoclonal antibody therapies against Omicron variants. Variant identification, when used in conjunction with patient history and other diagnostic findings, may now aid in selecting appropriate therapeutics. A paper published in Microbiology Spectrum details results of the NGS SARS-CoV-2 Assay with the COVID-DX Solution to detect the virus and its genetic variants.

“Researchers have been tracking SARS-CoV-2 variants and mutations, using this analytical software, since the outset of the pandemic. This expanded FDA authorization marks an important step forward, enabling improved COVID-19 patient care,” commented Niamh O’Hara, Ph.D., CEO and co-founder of Biotia. “Outside of COVID, this signals a shift in the infectious disease field for the future, bringing new cutting-edge genomics technology into the clinic.”

About the Test and Interface

The SARS-CoV-2 NGS Assay is an *in vitro* diagnostic test intended for the qualitative detection of the SARS-CoV-2 nucleic acid, the identification and differentiation of SARS-CoV-2 Phylogenetic Assignment of Named Global Outbreak (PANGO) lineages and specific SARS-CoV-2 genomic mutations 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, covers the entire virus’ genome and identifies specific mutations and PANGO lineages of SARS-CoV-2 in samples.

The complementary Biotia COVID-DX software provides a clinically-oriented report including the presence or absence of the SARS-CoV-2 virus, the genomic mutations and PANGO lineages. FASTQ files (sequencing output) can be generated in certified clinical laboratories and submitted to Biotia COVID-DX (v1), a cloud-based software, to generate clinical reports. Access to the Biotia COVID-DX software is 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 and the clinical reports have not been approved by the FDA and are only for use by specified personnel under the FDA's EUA. Twist and Biotia also offer a research use only (RUO) version of the SARS-CoV-2 NGS Assay, for non-clinical labs. 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.

Follow us on Twitter | Facebook | LinkedIn

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.

Follow us on Twitter | Facebook | LinkedIn | YouTube

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 Quarterly Report Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220802005390/en/

Twist Bioscience:
Angela Bitting
925- 202-6211
abitting@twistbioscience.com

Biotia:
Steve Capoccia
617-372-1539
spc@spcoms.com

Source: Twist Bioscience Corporation