Chembio Diagnostics Submits FDA De Novo/510(k) Request for DPP SARS-CoV-2 Antigen Test System

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HAUPPAUGE, N.Y., Dec. 06, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced that it has submitted a De Novo/510(k) Request to the U.S. Food and Drug Administration (FDA) for the DPP SARS-CoV-2 Antigen test system.

Chembio received an award from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, to support development of a COVID-19 point-of-care antigen test system using Chembio's proprietary Dual Path Platform (DPP) technology. BARDA support included funding for the completion of clinical studies and preparation of a De Novo/510(k) submission for the rapid DPP SARS-CoV-2 Antigen test system.

The DPP SARS-CoV-2 Antigen test system is designed to detect SARS-CoV-2 antigens in only 20 minutes, using a minimally invasive nasal swab and read with a DPP Micro Reader or DPP Micro Reader 2 optical analyzer.

"The De Novo/510(k) Request for the DPP SARS-CoV-2 Antigen test system reflects our long-term strategy and commitment to deliver rapid, decentralized COVID testing solutions and broaden our portfolio of products in other disease categories that require rapid results for the U.S. market," said Richard Eberly, Chembio's President and Chief Executive Officer. "We would like to thank BARDA for their collaborative efforts in the development of both our COVID-19 tests and the respective regulatory submissions. We are hopeful for a straightforward review process with the FDA in order to offer healthcare providers additional testing solutions to support the evolving needs of the pandemic."

About the DPP Rapid Test Platform
Chembio's proprietary DPP technology platform provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, delivering greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

Chembio's portfolio of DPP-based point-of-care tests with FDA regulatory approvals include the DPP HIV-Syphilis System (PMA approved), DPP HIV 1/2 Assay (PMA approved and CLIA waived), DPP Zika IgM System (510(k)), and DPP Ebola Antigen System (EUA). Additionally, DPP-based tests have received regulatory approvals from the World Health Organization, CE-Mark, ANVISA, and other global organizations, where they aid in the detection and diagnosis of several other critical diseases and conditions.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

About Chembio Diagnostics
Chembio is a leading diagnostics company focused on developing and commercializing point-of-care tests used for the rapid detection and diagnosis of infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers. Learn more at www.chembio.com.

About the Project
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