Chembio Diagnostics Submits EUA Application for New DPP SARS-CoV-2 Antigen Test

November 16, 2021

HAUPPAUGE, N.Y., Nov. 16, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced the submission of an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for the new DPP SARS-CoV-2 Antigen test.

Previously, 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 assist in developing a COVID-19 point-of-care antigen test system using Chembio's proprietary DPP technology and requesting FDA EUA for the test system. The DPP SARS-CoV-2 Antigen test system has been designed to detect SARS-CoV-2 antigens in only 20 minutes. The DPP SARS-CoV-2 Antigen test system is now designed to use a minimally invasive nasal swab and be read visually or with a DPP Micro Reader or DPP Micro Reader 2 optical analyzer.

"We are steadfast in our commitment to leveraging our proprietary DPP technology to address COVID-19 testing needs, while offering a broad portfolio of testing solutions for a variety of healthcare customers. Rapid point-of-care testing has proved to be one of the best tools for mitigating the spread of the virus as rapid results enable healthcare workers to initiate on-site patient management," said Richard Eberly, Chembio's President and Chief Executive Officer. "We are pleased to have completed the submission which we view as a testament to our team's dedication and technical expertise. Again, we would like to extend our gratitude to BARDA for their continued guidance and support throughout this process. We look forward to working closely with BARDA and the FDA to bring patients and health care workers the benefits of the DPP SARS-CoV-2 Antigen test system."

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
This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50120C00138.

Contact:
Philip Taylor
Gilmartin Group
415-937-5406
investor@chembio.com

Source: Chembio Diagnostics, Inc.