Chembio Launches Commercial Distribution of Third-Party COVID-19 Antigen Assay

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HAUPPAUGE, N.Y., Aug. 27, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced its launch of commercial distribution of an FDA Emergency Use Authorized, patent pending, rapid point-of-care COVID-19 antigen test for use in decentralized and traditional testing settings. Product inventory is on-hand and immediately available for shipment to Chembio customers across the United States.

The SCoV-2 Ag *Detect* ™ Rapid Test, manufactured by InBios International, Inc., is a rapid immunoassay test authorized for use in laboratories with a CLIA waiver certification. It provides results in 20 minutes from a nasal swab and requires no instrumentation. The test can be used for both patients who are suspected of COVID-19 by their healthcare provider within 5 days of symptom onset and for asymptomatic serial testing.

"We are excited about the addition of this differentiated product to our menu of COVID-19 assays," said Charles Caso, Vice President of Sales and Marketing for Chembio. "We are now offering U.S. customers SCoV-2 Ag *Detect* ™, a test for COVID-19 antigens in both symptomatic and asymptomatic populations, as well as Status™ COVID-19/Flu A&B, a product that differentiates flu from COVID-19 using a single nasal swab sample. Our expanded commercial team can now offer testing solutions for CLIA waived settings and work and school settings."

"The SCoV-2 Ag *Detect*™ Rapid Test complements our internal development efforts on our DPP Respiratory Panel product and our DPP SARS CoV-2 Antigen assay," continued Mr. Caso. "We believe this product is an important addition to our portfolio at a time when testing volume is increasing as Delta variant infections are on the rise. The United States has seen a spike in 7-day average confirmed COVID-19 cases from a 2021 low of 11,651 on June 18, 2021 to 133,056 as of August 18, 2021, per the U.S. Centers for Disease Control and Prevention tracking data."

The SCoV-2 Ag *Detect*™ Rapid Test has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. Its emergency use is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

About Chembio Diagnostics
Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical 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.

DPP is Chembio's registered trademark, and the Chembio logo is Chembio's trademark. For convenience, these trademarks appear in this release without ® or ™ symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademark. SCoV-2 Ag Detect™ is a trademark of InBios International, Inc., and Status™ is a trademark of LifeSign LLC.

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