Chembio Announces Launch of DPP COVID-19 Serological Point-of-Care Test

April 1, 2020

IgM/IgG Antibody Results in 15 Minutes from a Simple Finger Stick

HAUPPAUGE, N.Y., March 31, 2020 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced the U.S. launch of the rapid DPP COVID-19 serological point-of-care test for the detection of IgM and IgG antibodies. These results can be obtained within 15 minutes from a simple finger stick utilizing Chembio's MicroReader 1 and MicroReader 2 analyzers which are produced by Chembio Germany. The ability of the DPP platform to provide numerical results can aid clinicians in determining current or past exposure to the COVID-19 virus and monitoring infection progression, while avoiding the human interpretation errors associated with visual readings.

The DPP COVID-19 test detects antibodies in the blood that are produced by the body in response to a novel coronavirus infection. Numerical readings of the IgM and IgG antibodies have the ability to assist clinicians in determining patients who have been exposed to the novel coronavirus, even among patients who exhibit mild to no symptoms. Detection of an acute infection phase, as determined by the level of IgM antibodies, helps determine if a patient may still be infectious and could possibility transmit the infection to another person. Further along in the infection progression, the body typically starts to produce IgG antibodies, which increase while IgM levels decrease until eventually only IgG antibodies are present, demonstrating prior infection without the ability to transmit the virus.

"The results and data from our DPP COVID-19 test can help improve clinical outcomes through the management of individual patients by enabling clinicians to understand the likelihood of past and present infection and to manage populations as a whole as a surveillance test," stated Richard Eberly, Chief Executive Officer of Chembio. "Our measured approach has positioned us to offer a viable and sustainable long-term solution for clinicians. We expect to begin shipping product in April 2020, and we will continue to work with our partner LumiraDx to provide DPP COVID-19 tests with the ability to scale based upon market demand."

"We are excited that, through diligent collaboration with the FDA, our test will be distributed as authorized by the FDA Notification process under the public health emergency guidance issued on March 16, 2020," stated Gail S. Page, Chembio director. "This is another example of Chembio's ability to respond in an expeditious manner to global pandemics with differentiated solutions, as demonstrated previously with Zika and Ebola."

About Chembio Diagnostics
Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in approximately 15 minutes. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease, a number of which applications are under active development with collaboration partners. 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.

Forward-Looking Statements
The first, third and fourth paragraphs of this press release contain statements concerning the intent, belief and current expectations of Chembio and its management that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements reflect management's current views based on certain assumptions, and they involve risks and uncertainties. Actual results, events, or performance may differ materially from the forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to: the success of Chembio's research, development and commercialization efforts; Chembio's ability to maintain existing, and timely obtain additional, regulatory approvals; the potential development of competing diagnostic tests for COVID-19; the unpredictability associated with the COVID-19 pandemic; Chembio's retention of key personnel; and other changes in U.S. trade policy; and other risks described in public reports filed by Chembio with the Securities and Exchange Commission, including under the caption "Risk Factors" in Chembio's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Chembio undertakes no obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

DPP is Chembio's registered trademark. For convenience, this trademark appears in this release without ® symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademark.

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