Chembio Announces the Receipt of CLIA Waiver for its DPP HIV-Syphilis System

MEDFORD, N.Y., Feb. 24, 2023 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today announced receipt of a Clinical Laboratory Improvement Amendments (CLIA) waiver from the U.S. Food and Drug Administration (FDA) for the DPP HIV-Syphilis System.

“The DPP HIV-Syphilis System represents an exciting advancement in rapid testing for sexually transmitted infections. We are excited that the 200,000+ CLIA waived point-of-care testing sites in the U.S. now have access to the DPP HIV-Syphilis System where its use can help save lives and minimize the spread of both HIV and syphilis,” said Richard L. Eberly, Chembio’s President and Chief Executive Officer. “Rapid HIV and syphilis combination testing is now even more important to community health as the U.S. Centers for Disease Control and Prevention’s (CDC) most recent sexually transmitted disease (STD) surveillance data reports that STDs in the U.S. have reached all-time highs for the sixth consecutive year. Most importantly, the DPP HIV-Syphilis System offers actionable information to better manage two of the most critical threats posed by syphilis infections: the potentially lethal mother to child transmission and the increased risk of contracting HIV.”

Mr. Eberly continued, “We would like to thank the FDA for their efforts in granting the CLIA waiver for the first point-of-care test to aid in the diagnosis of both HIV and syphilis from a single patient sample. We believe this is a significant step forward in the management of HIV and syphilis infections.”

Russell Rooms, DNP, APRN-C of Diversity Family Health, a private practice clinic specializing in the care of the LGBTQ+ community, further added, “The Chembio DPP HIV-Syphilis test has provided us with the ability to quickly screen patients for HIV and syphilis and allows us to be able to start treatment faster and differentiate between other disease processes. This means that we can better prevent the spread of these infections.”

Co-infection rates of HIV and syphilis are on the rise and, according to the CDC, individuals with an active syphilis infection have an estimated two- to five-fold increased risk of contracting HIV if exposed to that virus. The CDC has also reported that untreated syphilis in pregnant women who acquired the disease during the four years before delivery can lead to infection of the fetus in up to 80% of cases and may result in stillbirth or infant death in up to 40% of cases. Congenital syphilis is a preventable disease that could be significantly reduced through effective prenatal testing of women of childbearing age and treatment of infected pregnant women.

According to the U.S. Department of Health & Human Services, one in eight people living with HIV in the United States are unaware of their infection. Improving access to HIV testing can help more people learn their status so they can be connected to care and treatment. The CDC recommends that individuals at higher risk of HIV infection be tested at least annually.

Chembio’s DPP HIV-Syphilis System assists clinicians in diagnosing both HIV and syphilis while patients are still under care at the testing location. The DPP HIV-Syphilis System is a multiplex, single-use, 15-minute test that is designed, in combination with Chembio’s Micro Reader analyzer, to simultaneously detect antibodies to HIV types 1 and 2 and *Treponema pallidum*, the bacteria that causes syphilis. The test uses a small, 10-microliter sample of fingerstick whole blood, venous whole blood, or plasma. The DPP HIV-Syphilis System is highly sensitive and specific, has a built-in procedural control, can be stored at room temperature, and has a 24-month shelf life.

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, enabling 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 to detect and diagnose 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 (-> www.globenewswire.com).

Forward-Looking Statements
Certain statements contained in this press release are not historical facts and may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to the distribution and sale of Chembio's DPP HIV-Syphilis System, and the availability, timing, functionality and continued regulatory approval of the test system. Such statements, which are expectations only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events or performance may differ materially from 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 following: the ability of Chembio to timely maintain regulatory approvals for such test system, which approvals are subject to processes that can change recurringly without notice. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's periodic public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2021, its Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2022, June 30, 2022 and September 30, 2022, and in subsequent filings, particularly under the heading "Risk Factors."

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