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Positive Data From Independent Study of Chembio Diagnostics' Rapid, Point-of-Care Syphilis Test Published in Clinical Infectious Diseases

Test Accurately Detects Both Nontreponemal and Treponemal Antibodies

MEDFORD, N.Y., Dec. 6, 2012 (GLOBE NEWSWIRE) -- **Chembio Diagnostics, Inc.** (Nasdaq:CEMI), a leader in point-of-care diagnostic tests for infectious diseases, reported today that data from a study evaluating performance characteristics (sensitivity and specificity) of the Company's patented Dual Path Platform (DPP®) rapid point-of-care (POC) test for syphilis was recently published online in *Clinical Infectious Diseases* and is expected to be published in the upcoming print edition. DPP® Syphilis Screen and Confirm is the first dual non-treponemal (screen for infection) and treponemal (confirms an active syphilis infection if non-treponemal is reactive) POC syphilis test that permits the simultaneous yet separate detection of both markers at the POC. The study authors concluded that DPP® Syphilis Screen and Confirm demonstrated good sensitivity and specificity in detecting treponemal and non-treponemal antibodies in three kinds of blood specimens. The complete article, *"A dual point-of-care test shows good performance in simultaneously detecting nontreponemal and treponemal antibodies in patients with syphilis — A multi-site evaluation study in China,"* can be accessed online at http://cid.oxfordjournals.org/content/early/2012/10/29/cid.cis928.abstract .

The study was supported by a grant from the Rapid Syphilis Test Introduction Project (UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases A70577 through a grant from the Bill & Melinda Gates Foundation).

Lawrence Siebert, Chembio's Chief Executive Officer, noted, "These data independently confirm the high sensitivity and specificity of our DPP® Syphilis Screen and Confirm rapid assay in patients with syphilis. The simultaneous detection of treponemal and non-treponemal antibodies offers the opportunity to increase coverage of syphilis screening and treatment. Currently, there is no single FDA-approved point-of-care test for syphilis that differentiates between active and past, or previously treated cases, and there continues to be a substantial interest in this product by public health groups in the United States and abroad."

According to the U.S. Centers for Disease Control and Prevention (CDC), "The use of only one type of serologic test is insufficient for diagnosis because each type of test has limitations, including the possibility of false-positive test results in persons without syphilis. False-positive *nontreponemal* test results can be associated with various medical conditions unrelated to syphilis, including autoimmune conditions, older age and injection-drug use; therefore, persons with a reactive *nontreponemal* test should receive a *treponemal* test to confirm the diagnosis of syphilis."

Mr. Siebert added, "We believe these positive data will be helpful in supporting our U.S. regulatory filing for DPP Syphilis Screen and Confirm, for which we are pursuing a *de novo* 510(k) regulatory pathway with the U.S. Food and Drug Administration (FDA). We are in discussion with the FDA to review these and other data and then to re-initiate clinical trials and submit our application by the middle of 2013."

According to the CDC, syphilis is a sexually transmitted disease caused by the bacterium *Treponema pallidum*. Syphilis can cause long-term complications and/or death if not adequately treated. In 2010 there were 45,834 new cases of syphilis in the U.S., of which, 13,774 were primary and secondary syphilis, the earliest and most transmissible stages of syphilis. The World Health Organization estimated that 11 million new cases of syphilis occurred in adults in 2005, the majority of them in developing countries.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $10 billion point-of-care testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by Alere, Inc. (formerly, Inverness Medical Innovations, Inc.). Chembio markets its HIV STAT-PAK® line of rapid HIV tests internationally to government and donor-funded programs directly and through distributors. Chembio has developed a patented point-of-care test platform technology, the Dual Path Platform (DPP®) technology, which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the

development and manufacture of new products based on DPP®. Headquartered in Medford, NY, with approximately 170 employees, Chembio is licensed by the U.S. Food and Drug Administration (FDA) as well as the U. S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13.485.

Forward-Looking Statements

Statements contained herein that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements, which are estimates 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 the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain additional financing and to obtain regulatory approvals in a timely manner, as well as the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

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