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## **ChemBio's DPP(R) HIV-Syphilis Multiplex Test Demonstrates 100% Sensitivity and Specificity in Evaluation by Mexico's Institute of Epidemiological Diagnosis and Reference**

MEDFORD, N.Y., May 14, 2013 (GLOBE NEWSWIRE) -- **ChemBio Diagnostics, Inc.** (Nasdaq:CEMI), a leader in point-of-care diagnostic tests for infectious diseases, announces receipt of an evaluation report from Mexico's Institute of Epidemiological Diagnosis and Reference (InDRE) regarding the Company's DPP<sup>®</sup> HIV-Syphilis multiplex test, which showed the Company's assay performed with 100% agreement for both markers on all 941 samples tested.

In evaluating the sensitivity and specificity of the ChemBio DPP<sup>®</sup> HIV-Syphilis product, 527 biological samples were tested on the HIV line, of which 158 were true negative and 369 were true positive, and 414 were tested on the Syphilis line, of which 108 were true negative and 306 were true positive. The ChemBio DPP<sup>®</sup> HIV-Syphilis test performed with 100% sensitivity and 100% specificity on all samples.

The ChemBio DPP<sup>®</sup> HIV-Syphilis Assay is a single-use immunochromatographic, rapid screening test for the detection of antibodies both to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) and to Syphilis *Treponema pallidum* in fingerstick whole blood, venous whole blood, serum or plasma samples. The ChemBio DPP<sup>®</sup> HIV-Syphilis Assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV and/or syphilis.

Commenting on today's announcement, Javan Esfandiari, ChemBio's Senior Vice President of Research and Development, said, "We are very pleased with the outstanding results of this evaluation, which is the first of a number of ongoing external studies, evaluations and registration submissions for this product. This multiplex test adds the syphilis marker to our recently FDA-approved DPP<sup>®</sup> HIV 1/2 test, and should greatly strengthen the prevention of mother-to-child transmission (PMTCT) of syphilis. We are seeing strong interest in this product from global health programs for the PMTCT of HIV, both because of its potential to reduce the adverse outcomes from untreated maternal syphilis and the potential to reduce the risk of mother-to-child HIV transmission."

Globally, far more pregnant women are estimated to have syphilis than HIV, and untreated maternal syphilis always results in an adverse pregnancy outcome such as fetal death, stillbirth, premature birth, low birth weight or congenital syphilis infection. A dual rapid test for HIV and syphilis could greatly strengthen PMTCT of syphilis, because programs for the PMTCT of HIV are much better financed and because they have stronger external and internal stakeholders. In addition, program costs and supply chains could be more effectively managed. Also syphilis commonly co-exists in patients with HIV (prevalence is 14—36%). Genital sores caused by syphilis make it easier to transmit and acquire HIV infection. The risk of acquiring HIV is estimated to be two- to-five-times higher if exposed to the virus when syphilis is present.

### **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<sup>®</sup> 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<sup>®</sup>) 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<sup>®</sup>. 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. For further information, visit our website at [www.chembio.com](http://www.chembio.com).

### **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 are estimates only. Such statements 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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