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# Chembio's DPP(R) HIV 1/2 Assay Receives CLIA Waiver From FDA

## Waiver Significantly Expands U.S. Market to Include CLIA-Waived Sites

MEDFORD, N.Y., Oct. 30, 2014 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq:CEMI), a leader in point-of-care (POC) diagnostic tests and technology, today announced that the U.S. Food and Drug Administration (FDA) granted a CLIA Waiver for the Company's DPP® HIV 1/2 Assay. Chembio's DPP® HIV 1/2 Assay was FDA-approved previously, and the CLIA Waiver will allow Chembio to expand into important new channels that are closest to patient care including physician-office-lab (POL) facilities, clinics and other community healthcare providers.

Chembio's DPP® HIV 1/2 Assay detects HIV antibodies in oral fluid or blood and uses the Company's patented Dual Path Platform (DPP®) technology, which offers excellent sensitivity and specificity. The product's unique SampleTainer® specimen collection bottle is a safe, closed system for collecting potentially infectious samples. The DPP® HIV 1/2 Assay is one of only two FDA approved, CLIA-waived oral fluid HIV 1/2 rapid tests available in the U.S.

"Accurate diagnostic testing is an important tool in the battle against HIV/AIDS," stated John Sperzel, CEO of Chembio. "Our DPP® HIV 1/2 Assay combines excellent sensitivity and specificity, simple and safe oral fluid sample collection, and exceptional ease of use. We believe this combination will lead to more testing, which will result in increased detection, earlier treatment and lower exposure rates. We recently signed agreements with several major U.S. distributors for the DPP® HIV 1/2 and HIV 1/2 STAT-PAK® Assays and, with receipt of this latest waiver, we will expand our U.S. sales and marketing effort as planned."

The U.S. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 to establish standards for all laboratory testing and amended it in 2008 to establish more stringent guidelines for *in-vitro* diagnostics. CLIA standards require that only accurate and easy-to-use tests are performed in the physician's office. The FDA determines whether a device is CLIA-waived based on extensive evaluations conducted in a CLIA-waived environment by intended users such as physicians, nurses and medical assistants.

Chembio's DPP® HIV 1/2 and HIV 1/2 STAT-PAK® Assays are both manufactured in the U.S. by Chembio. For more information on any of the Chembio-branded products please contact our customer service team at 1.844.CHEMBIO or visit us at: www.chembio.com.

**About Chembio Diagnostics**

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing $8.0 billion point-of-care testing market. Chembio markets its DPP® HIV 1/2 Assay and HIV 1/2 STAT-PAK® Assay in the U.S. and internationally. The Company's SURE CHECK® HIV 1/2 Assay is marketed exclusively in the U.S. as Clearview® Complete. Outside the U.S., Chembio markets its SURE CHECK® HIV 1/2 Assays 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.

Headquartered in Medford, NY, 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 13485. Chembio Diagnostic Systems, Inc. is a wholly-owned subsidiary of Chembio Diagnostics, Inc. For more information, please visit: 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, 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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