



NEWS RELEASE

Aptima® HIV-1 Quant Dx Assay Awarded World Health Organization Prequalification

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MARLBOROUGH, Mass., January 15, 2018 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that its CE-marked Aptima® HIV-1 Quant Dx assay has been awarded World Health Organization (WHO) prequalification for in vitro diagnostics.

The Aptima HIV-1 Quant Dx assay, employing Hologic's proprietary real-time transcription-mediated amplification (TMA) technology, is the first HIV-1 viral load assay with a dual claim for both diagnosis and treatment monitoring. The assay runs on Hologic's Panther® system, a market-leading, integrated platform that fully automates testing, from sample to result. The system substantially reduces hands-on time for laboratories by providing random and continuous access with rapid turnaround time.

The WHO prequalification means that the Aptima HIV-1 Quant Dx assay meets WHO standards of quality, safety, performance and reliability, and allows global health organizations to consider the Aptima HIV-1 Quant Dx assay for public sector procurement in resource-limited countries.

"This milestone highlights Hologic's commitment to, and progress toward, advancing the fight against HIV in highly affected regions of the world," said Tom West, President, Diagnostic Solutions Division at Hologic. "Access to advanced HIV testing platforms is crucial to managing care and mitigating the spread of the disease in low- and middle- income countries."

There are 36.7 million people living with HIV globally, with East and Southern Africa bearing the largest number of infected individuals - 19.4 million. Sub-Saharan Africa accounts for 64% of all new HIV infections.^{1,2}

"Hologic has an impressive legacy in the virology space that started two decades ago with the development of

nucleic acid tests to screen the blood supply, and qualitative assays for HIV and HCV in the early 2000's," said West. "We leveraged this expertise to develop an innovative and fully automated HIV viral load assay on our Panther instrument that is well suited for laboratories in resource-limited settings. Hologic looks forward to joining the battle to reduce the burden of this global epidemic. "

About the Aptima HIV-1 Quant Dx Assay

The Hologic Aptima HIV-1 Quant Dx assay is designed to meet today's demands for HIV diagnosis and treatment monitoring. The new assay uses a dual target approach against highly conserved regions in the HIV-1 genome, a sophisticated primer design, and redundancy of oligonucleotides for protection against mutations, thereby helping ensure accurate detection and quantitation of HIV-1. The assay is designed to deliver both sensitivity and precision across a broad set of HIV-1 groups and subtypes. Laboratories can now have greater confidence in assay performance, despite drug selection pressures and growing genetic diversity.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's diagnostic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

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References

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