

Hologic Enters the Viral Load Market with CE Mark Certification for the Aptima HIV-1 Viral Load Test

The new assay is certified for both diagnosis and viral load monitoring on the Panther system

Bedford, Mass., Dec. 1, 2014 -- Hologic, Inc. (NASDAQ: HOLX), today announced CE mark certification for its new Aptima HIV-1 Quant Dx assay for use on the Company's Panther system. The Aptima HIV-1 Quant Dx assay, employing Hologic proprietary real-time transcription-mediated amplification (Real-time TMA) technology, is the first HIV viral load assay with a dual claim for both diagnosis and treatment monitoring. This milestone marks Hologic's entry into the viral load market.

"The Aptima HIV-1 Quant Dx assay combines exceptional performance with the Panther system's full automation, and extends our commitment to give customers more freedom and control over workflow in viral load testing," said Tom West, Division President, Diagnostic Solutions. "The availability of this new assay on the Panther system eases the burden of laborious manual sample preparation, frees laboratories from batching restrictions required by older systems, and helps low- to high-volume laboratories streamline workflow. The Aptima HIV-1 Quant Dx assay sets a new benchmark for manufacturers of viral load assays and is the first in a line of viral load offerings that the Company expects to introduce including assays for Hepatitis C and Hepatitis B."

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 genome, a sophisticated primer design, and redundancy of oligonucleotides for protection against mutations, thereby helping to 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 confidence in assay performance, despite drug selection pressures and growing genetic diversity.

The Aptima HIV-1 Quant Dx assay is not currently approved for use in the U.S.

For more information about Hologic's molecular diagnostic products, please visit www.hologic.com.

About Hologic, Inc.:

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products. The Company's core business units focus on diagnostics, breast health, GYN surgical, and skeletal health. With a unified suite of technologies and a robust research and development program, Hologic is dedicated to The Science of Sure. For more information on Hologic, visit www.hologic.com.

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Forward-looking Statement Disclaimer:

This News Release may contain forward-looking information that involves risks and uncertainties, including statements about the use of the Hologic Aptima HIV-1 Quant Dx assay and Panther system. There can be no assurance these products will achieve the benefits described herein and that such benefits will be replicated in any particular manner with respect to an individual patient as 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. 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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