



Aptima® HIV-1 Quant Dx Assay Receives Additional FDA Approval for Use as an Aid in the Diagnosis of HIV Infection

-- First FDA-Approved Assay for Both Qualitative Diagnosis and Quantitative Viral Load Monitoring --

MARLBOROUGH, Mass., *November 20, 2020 /Businesswire/* -- Hologic, Inc. (Nasdaq: HOLX) announced today that the U.S. Food and Drug Administration (FDA) has approved a diagnostic claim for its HIV-1 (human immunodeficiency virus type 1) viral load monitoring assay. The Aptima® HIV-1 Quant Dx assay is now the first dual-claim assay for both diagnosis and viral load monitoring in the United States.

The Aptima HIV-1 Quant Dx assay, which was approved in late 2016 for viral load monitoring, is a molecular diagnostic test that runs on the fully automated, sample-to-result Panther® system. The assay utilizes a dual target approach against highly conserved regions in the HIV genome that is designed to deliver reliable, consistent qualitative and quantitative results across HIV-1 groups and subtypes. The Aptima HIV-1 Quant Dx assay is also CE IVD-marked for both diagnostic and viral load monitoring claims.

“This is an exciting new claim for our highly sensitive and reliable HIV test because it has the potential to improve patient care,” said Kevin Thornal, president of Diagnostic Solutions at Hologic. “A simultaneous viral load measurement with diagnosis will allow healthcare providers to guide treatment choices for patients to begin therapy immediately. The dual claim will also benefit our clinical laboratory customers, who continuously seek to consolidate their testing as much as possible onto one automated platform.”

Starting treatment at the time of diagnosis is expected to reduce the risk of HIV transmission to others and to maximize prospects for long-term good health.

There are approximately 1.2 million people living in the US with HIV, with 38,000 new infections in 2018.¹

For more information about Hologic’s U.S. virology portfolio, please visit: <http://usaptimavirology.com>.

About the Panther and Panther Fusion Systems

The Panther molecular diagnostics system is a best-in-class, fully automated, sample-to-result platform that can be used in low-, medium- or high-throughput laboratories. With a small footprint, adaptable workflow options and consolidated testing menu, it combines women’s health, sexually transmitted infection and viral load testing, which can all be done simultaneously. The Panther Fusion system provides an expanded *in vitro* diagnostics menu, as well as Open Access™ functionality to run laboratory developed tests. Hologic’s Panther and Panther Fusion systems now offer 18 FDA-cleared assays and 20 CE-marked assays that detect more than 20 pathogens. More than 2,250 Panther systems have been installed in clinical diagnostic laboratories around the world.

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:

1. HIV.gov: U.S. Statistics. <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>. Accessed on 11/12/2020.

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