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Hologic Announces FDA Clearance of Aptima® Assay to Detect Herpes Simplex Virus 1 & 2

-- Aptima HSV 1 & 2 Assay Now Available Alongside Women's Health, Virology Menu on the Fully Automated Panther System --

MARLBOROUGH, Mass. , June 20, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that it has obtained FDA clearance to market the Aptima® Herpes Simplex Virus (HSV) 1 & 2 molecular assay on the fully automated Panther® system. The test will be commercially available in the 50 United States, U.S. territories and Puerto Rico. According to the U.S. Centers for Disease Control and Prevention, infections with HSV-2, the herpes strain with more serious health implications, affect more than 24 million Americans.[1]

The Aptima HSV 1 & 2 assay can be used to qualitatively detect, and differentiate between, HSV-1 and HSV-2. Specimens collected in a broad range of transport media, including the Aptima specimen transport medium, can be tested with the assay.

"Helping our clinical lab customers consolidate testing on the Panther system enables them to be more efficient and productive," said Tom West, president of the Diagnostic Solutions Division at Hologic. "By partnering with our customers, we'll be better able to offer more people high-quality and faster testing results and improve detection of STIs like herpes. This new product clearance reflects our commitment to providing healthcare professionals and patients with greater certainty and peace of mind."

The HSV assay joins a growing list of molecular tests available on Hologic's Panther system, a market-leading, integrated platform that fully automates molecular testing for laboratories. The Panther system substantially reduces hands-on time for laboratories by providing random and continuous access with rapid turnaround time. Many U.S.-based laboratories today conduct HSV testing via live culture, which is both time-consuming, with additional manual steps, and slow, delivering results in days rather than hours. In addition, studies show that HSV molecular diagnostic tests are three to five times more sensitive than live culture samples.[2]

Hologic estimates that tests run on the Panther system benefit more than 40 million people worldwide annually.[3] These include assays for other sexually transmitted infections (such as Human papillomavirus, Chlamydia trachomatis/Neisseria gonorrhea, Trichomonas vaginalis) and a virology menu (including HIV-1 and Hepatitis C Viruses).

How the new assay works

The Aptima HSV 1 & 2 assay is a nucleic acid amplification test for the qualitative detection and differentiation of HSV types 1 and 2 in clinician-collected swab specimens from anogenital skin lesions. These samples can be collected using either the new Aptima Multitest Swab Specimen Collection Kit or commercially available viral transport media. The Aptima Multitest Swab Specimen Collection Kit offers healthcare providers greater versatility in sample collection.

The assay can be used to aid in the diagnosis of HSV-1 and/or HSV-2 infections in symptomatic women and men. It distinguishes between HSV 1 and 2, which is recommended in all patients with first-episode genital herpes.[4] Patients with HSV-2 are at increased risk for contracting and transmitting HIV-1 (human immunodeficiency virus).[5] Pregnant women infected with HSV-2 are at risk of transmitting the virus to their babies during birth, which can cause neurological complications.

To learn more about the Aptima HSV 1 & 2 assay, please visit http://www.hologic.com/products/clinical-diagnostics/assays-and-tests/aptima-hsv-1-2-assay

About Hologic Inc.

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.

[1]https://www.cdc.gov/std/stats/sti-estimates-fact-sheet-feb-2013.pdf

[2]Hook EW. A new look at genital herpes: the critical role of the laboratory in diagnosis and management. MLO Med Lab Obs. 2012;44(7):8.

[3]Internal Hologic estimates

[4]Patel R, et al. 2010 European Guideline for the Management of Genital Herpes. IUSTI/WHO European STD Guidelines Editorial Board. http://www.iusti.org/regions/europe/pdf/2010/Euro_Guideline_2010_herpes.pdf. Published 2010. Accessed August 30, 2016.

[5]Freeman EE, et al. Herpes simplex virus 2 infection increases HIV acquisition in men and women: systematic review and meta-analysis of longitudinal studies. *AIDS.* 2006;20(1):73-83.

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