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Hologic Obtains European CE Mark for Aptima® Assay to Detect Herpes Simplex Virus 1 & 2

--Highly Accurate HSV Test Now Available Alongside Women's Health Menu on the Fully Automated Panther System--

MARLBOROUGH, Mass. (November 15, 2016) – Hologic, Inc. (Nasdaq: HOLX) announced today that it has obtained a CE Mark for the Company's Herpes Simplex Virus (HSV) assay, enabling the test to be marketed in the European Union. The Aptima® HSV 1 & 2 assay is a nucleic acid amplification test for the qualitative detection of HSV RNA in clinician-collected swab specimens from skin lesions.

The assay can be used to aid in the diagnosis of HSV-1 and/or HSV-2 infections in symptomatic male and female patients. The assay distinguishes between HSV 1 and 2, which is recommended in all patients with first-episode genital herpes.1 Patients with HSV-2 are at increased risk for contracting and transmitting HIV-1 (human immunodeficiency virus).2

"Nucleic acid testing is the gold standard for detection of infectious agents," said Joao Malagueira, VP Sales Diagnostics, International. "Providing physicians with accurate diagnoses -- specifically distinguishing between HSV 1 and 2 -- is critical to choosing effective treatment regimens and advising patients of their additional risks."

The Aptima HSV 1 & 2 assay runs on Hologic's Panther® system, a market-leading, integrated platform that fully automates all aspects of molecular testing, from sample to result. The system substantially reduces hands-on time for laboratories by providing random and continuous access with rapid turnaround time. Lesion samples can be collected using either the Aptima Multitest Swab Collection Kit or a commercially available Viral Transport Medium collection kit.

The Aptima HSV 1 & 2 assay joins a growing list of CE-Marked assays available on the Panther system, which includes a virology menu (HIV-1, Hepatitis C Virus, Hepatitis B Virus) and tests for Sexually Transmitted Infections (chlamydia/gonorrhea, Trichomonas and M. genitalium).

"Labs increasingly are looking to consolidate testing onto a single platform, and by expanding the number of tests available on Panther, we are helping these customers become more efficient," said Malagueira.

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

The HSV assay is not intended for use with cerebrospinal fluid or for prenatal screening. The Aptima HSV 1 & 2, HIV-1, HBV, HCV, and M. genitalium assays are not currently available for sale in the United States.

About Hologic

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.

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.

1Patel 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.

2Freeman 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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