NEWS RELEASE

FDA Approval of ThinPrep® Integrated Imager Expands Automated Imaging for Pap Testing to More Labs

4/25/2018

MARLBOROUGH, Mass., April 25, 2018 /**PRNewswire**/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that the United States Food and Drug Administration (FDA) has granted premarket approval (PMA) for the ThinPrep® Integrated Imager, which will make automated imaging of Pap tests more broadly available to laboratories and cytologists in the United States. Studies have shown that automated, assisted imaging can increase the sensitivity of detecting suspicious cells compared to manual slide review.1-4

Most ThinPrep Pap tests are currently run in high-volume reference laboratories that employ automated imaging via the Hologic ThinPrep Imaging System. The ThinPrep Integrated Imager combines the power of ThinPrep computer-assisted imaging and the ease of dual slide review into a single, automated microscope, bringing increased sensitivity for cervical disease detection to laboratories of all sizes.

"Approval of the ThinPrep Integrated Imager brings the benefits of ThinPrep automated Pap imaging to small- and mid-sized laboratories in the United States, and of course to their patients," said Tom West, president, Diagnostic Solutions division at Hologic. "Development of this newest ThinPrep product confirms Hologic's commitment to women's health and specifically to robust and accessible screening strategies for cervical cancer."

Over the last 40 years, the number of cervical cancer cases has been cut in half thanks largely to regular testing, which can identify abnormalities before they become cervical cancer.5

The ThinPrep Integrated Imager guides cytology technicians to areas showing potential abnormal cells, and images slides in approximately 90 seconds. It combines an imaging station and review scope into a single desktop system offering high-quality optics and an easy-to-use interface to enable a convenient, flexible workflow. Also able to be

used as a conventional microscope, the ThinPrep Integrated Imager consolidates the needs of the cytotechnologist into one device.

In conjunction with the ThinPrep Integrated Imager, Hologic is also launching the Compass Stainer in the US. Already available internationally, the Compass Stainer is a smaller footprint automated stainer that can perform both routine and special staining protocols. The Compass Stainer is an affordable solution for lower volume laboratories that do not have the space for a larger, more expensive automated stainer.

To learn more about ThinPrep Pap testing products available in the United States, please visit **https://healthdxs.com/en/thinprep/**.

About Cervical Cancer and Pap+HPV Together

Hologic is the market-leading supplier in the United States of Pap tests (ThinPrep) and HPV tests (Aptima®), frequently used together on the same sample to screen for cervical pre-cancer and cancer (an approach known as Pap+HPV Together or co-testing). According to guidelines from the American College of Obstetricians and Gynecologists, women under the age of 30 should get regular Pap testing, with co-testing being the preferred approach for women 30 to 65.6

Before introduction of the Pap test, cervical cancer was the leading cause of cancer related deaths for women in the U.S., but now ranks 14th in frequency.7 About eight out of 10 women will contract HPV, the virus that causes cervical cancer, at some point in their lives, but most of the time the virus goes away. In some cases, however, it can remain and promote development of cervical cancer. For women between 30 and 65, the preferred screening approach, Pap+HPV Together, detects 95 percent of cervical cancer cases.8 Screening with both tests also prevents more cases of pre-cancer than either test used alone.8 In fact, the largest retrospective study of cervical cancer testing strategies found that one out of five cases of cervical cancer was missed when the HPV test was used alone.8

More information about the value of co-testing is available at **PapPlusHPV.com**.

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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Blatt et al. Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. Cancer Cytopathology. 2015;123(5):282-288 [Study included ThinPrep®, SurePath®, Hybrid Capture® 2 assay].

SOURCE Hologic, Inc.