NEWS RELEASE

# Newly Published Research Shows that Hologic's Molecular Assays for Diagnosing Vaginitis are More Effective than Traditional Methods

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– More sensitive and specific assays for vaginitis reduce the "incorrect, misguided or prolonged treatment" that can result from older, subjective testing methods –

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Clinical evidence demonstrating the effectiveness of new FDA-cleared assays for the detection of vaginitis has been published online in the Journal of Clinical Microbiology. The prospective, multi-center clinical study is the first in the United States to formally validate the performance of the Aptima® BV and Aptima® CV/TV assays, available from Hologic, Inc. (Nasdaq: HOLX) on its fully automated Panther® system.

Vaginitis, a condition that affects millions of women every year, is responsible for up to half of all gynecologic visits in the United States, as well as significant expense to the healthcare system.1

"As leaders in women's health, we delivered on the need for new, molecular assays for vaginitis that have higher sensitivity and specificity than traditional methods," said Kevin Thornal, Hologic's division president, Diagnostic Solutions. "This study demonstrates that our assays are better at diagnosing infection than previously available options, which ultimately will ensure women receive the right treatment sooner."

The study notes that women suffering from vaginitis "are often underserved by the current paradigm of inaccurate or incomplete diagnosis guiding inadequate or inappropriate treatment." Prior to the introduction of molecular assays, clinicians had no choice but to analyze fresh vaginal discharge samples using a combination of older, subjective methods – pH, a potassium hydroxide (KOH) "whiff" test and Gram-stained microscopic examination – to identify the underlying cause.

The new Aptima molecular tests circumvent barriers to accurate diagnosis associated with the use of these traditional methods, including absence of proper equipment, lack of training, and access to microscopy in the clinic. These and other barriers can result in many women being misdiagnosed, which the study says can lead to "incorrect, misguided or prolonged treatment."1 In fact, separate research shows that when treatment is based on diagnosis with these traditional methods, more than half of women with vaginitis experience recurring symptoms.2

"Many women try to self-diagnose and self-treat before eventually visiting a healthcare provider, assuming that abnormal vaginal discharge, itching or irritation is due to a simple yeast infection," said the study's corresponding author, Dr. Jane R. Schwebke, professor of medicine at the University of Alabama at Birmingham. "But BV or TV left untreated or improperly treated can put women at risk for a variety of complications, including an increased chance of getting sexually transmitted infections (STIs) such as chlamydia or HIV, pelvic inflammatory disease, and pregnancy-related risks including premature delivery, low birth weight and infertility."2,4 These objective and comprehensive diagnostic tests will mitigate such risks and allow clinicians to feel more confident that they're properly treating women."

BV (bacterial vaginosis) is the most common vaginal infection in the U.S., affecting an estimated 21 million women a year.3 Together with CV (vulvovaginal candidiasis) – commonly known as yeast infections – and TV (trichomonas vaginalis), individually or in combination, these three vaginal infections cause about 90 percent of vaginitis infections.2,4 Each cause of vaginitis has its own characteristics, consequences and treatment recommendations, which vary between BV, CV and TV, further reinforcing the need for accurate diagnoses.

## Study Details

Subjects in the multi-center, cross-sectional diagnostic accuracy study for the Aptima BV and Aptima CV/TV assays were at least 14 years old with symptoms of vaginitis such as abnormal vaginal discharge, vaginal odor, genital itching or irritation, pain or discomfort during sexual intercourse or urination, edema or erythema. They were enrolled at 21 U.S. sites, including clinical research centers and emergency medicine, family planning, public health, STI and family medicine/obstetric-gynecologic (OB-GYN) facilities between June and October 2018.

Patient- and clinician-collected vaginal swab samples obtained from women with symptoms of vaginitis were tested with the Aptima BV and Aptima CV/TV assays. The prevalence of infection was similar for clinician- and patient-collected samples: 49 percent for BV, 29 percent for CV due to the Candida species group, 4 percent for CV due to C.glabrata, and 10 percent for TV. Sensitivity and specificity estimates for the tests in clinician-collected samples were, respectively, 95.0 percent and 89.6 percent for BV, 91.7 percent and 94.9 percent for the Candida species group, 84.7 percent and 99.1 percent for C. glabrata, and 96.5 percent and 95.1 percent for TV. Sensitivity and specificity were similar in patient-collected samples.

Hologic offers 16 FDA-cleared assays on the Panther system that detect more than 20 pathogens, offering the only high-throughput molecular diagnostic platform in the U.S. to combine comprehensive sexual health, cervical health, viral load, respiratory testing and open channel functionality on a fully automated system.

For more information on the Aptima BV and Aptima CV/TV assays, visit **www.hologic.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**.

## Hologic 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.



Source: Hologic, Inc.

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1. Clinical validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: results from a prospective multi-center clinical study. J Clin Microbiol. 2019.
2. Hologic. Aptima BV Assay Package Insert. **https://www.hologic.com/package-inserts/diagnostic-products?portfolio=136**.
3. Koumans EH, Sternberg M, Bruce C, McQuillan G, Kendrick J, Sutton M, Markowitz LE. The prevalence of bacterial vaginosis in the United States, 2001-2004; associations with symptoms, sexual behaviors, and reproductive health. External. Sex Transm Dis. 2007 Nov;34(11):864-9.

4. Hologic. Aptima CV/TV Assay Package Insert. **https://www.hologic.com/package-inserts/diagnostic-products?portfolio=136**.

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