NEWS RELEASE

New Hologic Assay is First and Only FDA-Cleared Diagnostic Test to Detect Emerging Health Threat Mycoplasma genitalium

1/23/2019

-- FDA clearance makes clinically validated assay available for sexually-transmitted infection listed as emerging threat by the CDC --

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that the U.S. Food and Drug Administration (FDA) has granted clearance for its Aptima® Mycoplasma genitalium assay, the first and only FDA-cleared test to detect this under-recognized but increasingly common sexually transmitted infection (STI). This newest Aptima assay joins a growing suite of market-leading tests offered by Hologic to help combat the rise of STIs in the U.S.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20190123005868/en/

Aptima® Mycoplasma genitalium assay, the first and only FDA-cleared test to detect this under-recognized but increasingly common sexually transmitted infection (Photo: Business Wire)

Hologic's first-in-category assay, cleared through the FDA's De Novo request process, provides laboratories with a highly sensitive and specific molecular diagnostic method to identify infections and enable effective treatment.

First discovered in the early 1980s, Mycoplasma genitalium (M. genitalium) was listed as an emerging public health threat by the U.S. Centers for Disease Control and Prevention (CDC) in 2015.1,2 Current estimates indicate that M. genitalium may affect more than 15 percent of men and women in certain high-risk populations, and its prevalence is growing.3 Because of the lack of an FDA-cleared test until now, M. genitalium has often been misdiagnosed as

other STIs and, in some cases, treated with the wrong antibiotics. This often leaves the underlying infection untreated, which can lead to increased transmission and recurrent infections.

“Although Mycoplasma genitalium is typically more common than gonorrhea, there is very little public awareness of this rising sexually transmitted infection, which can cause serious and potentially devastating health problems,” said Damon Getman, Ph.D., senior principal research scientist and director of research at Hologic. “The introduction of the Aptima Mycoplasma genitalium assay gives healthcare professionals the opportunity to provide optimal care for their patients and reflects Hologic’s commitment to developing innovative solutions that address emerging public health threats.”

In men, M. genitalium symptoms may include urethritis, the swelling and inflammation of the urethra. In women, M. genitalium has been linked to cervicitis, the swelling and inflammation of the cervix.4,5 If left untreated, infections can lead to infertility in women and increased risk of HIV acquisition and transmission.2,6 Patients infected with M. genitalium may be asymptomatic or experience symptoms similar to those associated with a chlamydial infection, so accurate diagnostic tests are critical to help healthcare professionals and their laboratory partners identify these bacterial infections and treat them appropriately. Research has shown as many as 50 percent of women and 42 percent of men with M. genitalium may have an antibiotic-resistant strain, further emphasizing the importance of early detection and regular screening.3

“We are tremendously proud of the team of scientists and engineers who developed this assay,” said Tom West, Hologic’s division president, Diagnostic Solutions. “They exemplify Hologic’s dedication to help arm laboratories and healthcare professionals with superior diagnostic tools to identify harmful infections, and this FDA clearance represents another milestone in furthering that mission.”

In published research, Hologic’s ribosomal RNA-based M. genitalium assay displayed greater sensitivity than lab-developed or CE-marked DNA-based tests .7,8 Hologic introduced the first FDA-cleared diagnostic test kit for STIs in the 1990s using its innovative RNA-based technology. Since then, Hologic has expanded its Aptima STI portfolio to include assays for chlamydia, gonorrhea, human papillomavirus (HPV), herpes simplex viruses (HSV 1&2), trichomonas, and Zika* virus. The Aptima virology portfolio also includes quantitative assays for the human immunodeficiency virus (HIV) and hepatitis B and C (HBV and HCV). All are available on Hologic’s fully-automated Panther®system. In 2017, the Aptima assays helped an estimated 40 million patients obtain fast, high-quality test results.9

Including the first IVD for the detection of Mycoplasma genitalium, Hologic’s Panther and Panther Fusion® system now offers 14 FDA-cleared or approved assays that detect more than 20 pathogens, making it the only high-throughput molecular diagnostic platform in the United States to combine comprehensive sexual health, cervical health, viral load, respiratory testing and open channel10 functionality on a fully automated system.

For more information on the Aptima assays, visit **https://healthdxs.com/en/**.

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.

* The Aptima Zika Virus assay has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; this test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C.§ 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. For additional availability in other countries beyond the U.S., please contact your local sales representatives or distributor.

---

1 Tully JG, Taylor-Robinson D, Cole RM, et al. A newly discovered mycoplasma in the human urogenital tract. Lancet 1981;1: 1288–91.

2 CDC. 2015 Sexually Transmitted Diseases Treatment Guidelines. Emerging Issues. **https://www.cdc.gov/std/tg2015/emerging.htm**. Updated June 4, 2015. Accessed December 7, 2018.

3 Getman D, Jiang A, O'Donnell M, et al. Mycoplasma genitalium Prevalence, Coinfection, and Macrolide Antibiotic Resistance Frequency in a Multicenter Clinical Study Cohort in the United States. Journal of Clinical Microbiology. 2016; 54(9):2278-2283.

4 Horner P, Martin D. Mycoplasma genitalium infection in men. Journal of Infectious Diseases. 2017. 216 (Suppl 2), S396.

5 Wiesenfeld H, Manhart L. Mycoplasma genitalium in Women: Current knowledge and research priorities for this recently emerged pathogen. Journal of Infectious Diseases. 2017. 216 (Suppl 2), S389.

6 Gatski M, Martin DH, Theall K, et al. Mycoplasma genitalium infection among HIV-positive women: prevalence, risk factors and association with vaginal shedding. International Journal of STD & AIDS. 2011; 22: 155–159.

7 Unemo M, Salado-Rasmussen K, Hansen M, et al. Clinical and analytical evaluation of the new Aptima Mycoplasma genitalium assay, with data on M. genitalium prevalence and antimicrobial resistance in M. genitalium in Denmark, Norway and Sweden in 2016. Clinical Microbiology and Infection. 2018. 24, 533-539.

8 Le Roy C, Pereyre S, Henin N, et al. French Prospective Clinical Evaluation of the Aptima Mycoplasma genitalium CE-IVD Assay and Macrolide Resistance Detection Using Three Distinct Assays. Journal of Clinical Microbiology. 2017. 55, 3194-3200.

9 Hologic internal estimate.

10 Open channel functionality on the Panther system is a non-IVD function, which is not cleared or approved by the FDA.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20190123005868/en/**

Investor Contact:

Michael Watts
+1 858.410.8588
michael.watts@hologic.com

Media Contact:

Jane Mazur
+1 508.263.8764 (direct)
+1 585.355.5978 (mobile)
jane.mazur@hologic.com

Source: Hologic, Inc.