NEWS RELEASE

New CDC Guidelines Endorse Opt-Out Screening for Two of the Most Common Sexually Transmitted Infections (STIs), Recommend Nucleic Acid Testing for Mycoplasma Genitalium

7/26/2021

With STIs reaching a new high for the sixth consecutive year, a more inclusive screening approach is considered for chlamydia and gonorrhea in women under 25

First CDC guidelines to recommend testing specific populations for Mycoplasma genitalium, which was previously listed as an emerging issue

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) commends the decision by the United States Centers for Disease Control and Prevention (CDC) to endorse an updated approach to screening for Chlamydiatrachomatis and Neisseriagonorrhoea, two of the most common sexually transmitted infections (STIs) in the country.1 The guidelines state that providers may now consider opt-out screening, sometimes referred to as universal screening, for these infections in adolescent and young adult women during routine clinical care.2 Studies support that opt-out STI testing can improve patient acceptance, result in cost savings, and substantially increase screening, especially among patients who do not disclose sexual behavior.2-5

Historically, the CDC has recommended that healthcare providers screen all sexually active women under the age of 25, as well as high-risk populations, on an annual basis. Many healthcare providers, however, report a reluctance on the part of their patients to discuss their sexual activity and/or a frequent lack of trust in the transparency of those discussions.2 In contrast, a universal screening strategy automatically notifies the patient that testing will be performed unless the patient declines, regardless of reported sexual activity.2 A universal screening strategy does not eliminate the need for a patient-provider conversation about sexual health, but instead makes STI testing part

of routine care, thereby removing barriers and associated stigma.

“Including opt-out screening for chlamydia and gonorrhea in the newly updated CDC guidelines represents significant recognition of the value of this strategy in reducing infections, especially among young women,” said Michelle Garsha, vice president of women’s health in Hologic’s Diagnostic Solutions Division. “Women bear most of the burden of undiagnosed and untreated sexually transmitted infections, and with STIs resurging in the U.S. as we move out of the COVID-19 pandemic, reducing barriers to screening is even more important.”

The CDC reports that there are 26 million new cases of STIs each year, with 50% occurring among adolescents and young adults ages 15-24 years old.6 In fact, the CDC noted that “reported rates of chlamydia and gonorrhea are highest among females during their adolescent and young adult years.”2 Many STIs are asymptomatic, meaning that regular screening is often the only way to know a patient’s status. However, because the COVID-19 pandemic impacted routine clinical care including STI testing, there is the potential for even more missed asymptomatic cases in the current environment.6-8 Left untreated in women, chlamydia infections can lead to the development of pelvic inflammatory disease (PID), ectopic pregnancy, tubal factor infertility, and the potential for neonatal complications.9 Gonorrhea infections have also been linked to PID and neonatal complications, as well as an increased risk of HIV infection.9,10

“As a practicing OB-GYN, I know that some teens and young women feel uncomfortable talking about their sexual activity and may feel there is a stigma associated with screening for STIs,” said Alison Cowan, MD and medical director, Diagnostic Solutions at Hologic. “By screening all young women, we can help normalize and destigmatize testing for STIs, allowing us to better serve our patients by identifying and treating more infections before they lead to serious complications like infertility.”

For the first time, CDC guidelines also defined specific populations (men with recurrent urethritis and women with recurrent cervicitis) to be tested for Mycoplasma genitalium and recommended nucleic-acid amplification testing (NAAT) for detection. The 2015 CDC guidelines included M. genitalium as an emerging issue, but no FDA-cleared NAATs were available at that time11. Hologic was first to market in 2019 with a NAAT for M. genitalium, and Hologic’s Aptima® Mycoplasma genitalium Assay is specifically noted in the current guidelines1. Before the introduction of NAAT testing for M. genitalium, diagnosis could only be suspected in men with recurrent urethritis and women with recurrent cervicitis because the bacterium cannot be grown effectively in culture. Anitibiotic resistance is a pressing issue with M. genitalium infections, with one study led by Hologic scientists demonstrating that approximately half the women who tested positive were infected with an antibiotic-resistant strain12. No FDA-cleared M. genitalium tests are available in the U.S. that detect antibiotic resistance, although Hologic is working to develop one.

Hologic developed and markets the widely used Aptima Combo® 2 Assay for detecting chlamydia and gonorrhea,

as well as the Aptima® Multitest Swab Specimen Collection Kit, which can be used to collect samples for detection of up to seven disease states and infections using Hologic's suite of Aptima sexual health assays, including Bacterial vaginosis, Candida species, Candida glabrata, trichomoniasis, chlamydia, gonorrhea and Mycoplasma genitalium. For more information on Hologic's sexual health and other diagnostic assays, visit **https://www.hologic.com/hologic-products/diagnostic-solutions**.

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**.

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Source: Hologic, Inc.

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