Hologic Announces FDA Clearance of the Panther Fusion® GBS Assay

System's Latest Assay Increases Lab Efficiency and Flexibility
With Highly Sensitive and Specific Detection

MARLBOROUGH, Mass., August 2, 2018 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that it has received FDA clearance for its Group B *Streptococcus* (GBS) assay on the Panther Fusion® system.

GBS is a bacterium naturally carried by some women. If passed from a mother to her baby during labor, it can lead to serious health consequences for the newborn and even death from illnesses including meningitis, blood poisoning or pneumonia.[1] The approval follows Group B Strep Awareness Month, the July initiative to promote awareness and prevention of GBS during pregnancy through early infancy.

The new Panther Fusion GBS assay brings excellent performance and automation to detecting this bacterium.[2] In fact, clinical research showed the Panther Fusion GBS assay exhibited 100 percent sensitivity compared to culture-based testing methods.[2] The assay will also increase testing options for healthcare providers, as it is validated for the two enrichment broths that make up 95 percent of the samples used on the market. The assay also has less stringent requirements for clinical sample storage and transport than culture-based tests.[3]

"A nucleic acid amplification test is the most sensitive and reliable screening method available today for identifying pregnant women who are carriers of this serious bacterium," said Tom West, president of the Diagnostic Solutions Division at Hologic. "As a leader in diagnostics for women, our commitment to providing high quality, life-saving solutions now extends to newborns, who can be fatally impacted by GBS infection."

Guidelines Recommend All Pregnant Women Be Tested
If a pregnant woman carries the GBS bacterium – *Streptococcus agalactiae* – it can spread to the amniotic fluid after the onset of labor, ultimately transmitting to the baby during childbirth.[3] While common and not harmful to healthy adults, the bacterium can cause serious health consequences or even death if passed to an infant.[3] An estimated 18 percent of women in the U.S. are carriers, making universal screening imperative so that perinatal transmission to the baby can be prevented.[4]

Since the first screening guidelines were put in place in the 1990s, the rate of early-onset GBS has decreased almost 86 percent[1], and today the Centers for Disease Control and Prevention recommend that all pregnant women at 35-37 weeks' gestation be tested for GBS. This recommendation is endorsed by the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Nurse-Midwives, the American College of Obstetricians and Gynecologists, and the American Society for Microbiology.[4]

Panther Fusion: Enhanced Value through an Expanded Menu
The Panther Fusion module can be added to existing Panther® systems to extend testing capabilities. The Panther Fusion system adds the capacity to run polymerase chain reaction (PCR) assays to the transcription-mediated amplification (TMA) assays that are performed on the base Panther system. As a result, labs will retain all the key benefits of the Panther platform – including full sample-to-result automation, the ability to

run multiple tests from a single sample, random and continuous access, sample processing with rapid turnaround time and STAT capabilities – while simultaneously streamlining and refining specimen processing to maximize efficiency.

The Panther Fusion GBS assay joins the Panther Fusion Flu A/B/RSV, Panther Fusion Paraflu, and Panther Fusion AdV/hMPV/RV assays, all of which received FDA clearance in 2017. The GBS assay has also been CE-marked for diagnostic use and is commercially available in Europe.

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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