NEWS RELEASE

New Study Shows Increased Fetal Fibronectin (fFN) Testing in Pregnant Women Could Help Guide Better Patient Care

10/4/2017

-- Increased fFN testing could improve care management by preventing more women with symptoms of preterm labor from being discharged from the hospital too soon --

MARLBOROUGH, Mass., October 4, 2017 – A new study found that women with symptoms of preterm labor who were discharged from the hospital without a fetal fibronectin (fFN) test were more likely to deliver their baby prematurely within three days compared to women who were discharged with an fFN test, Hologic, Inc. announced today. The **study**1, published this week in the journal ClinicoEconomics and Outcomes Research, is one of the largest to evaluate interventions and outcomes in women presenting with symptoms of preterm labor.

"One in 10 infants born in the U.S. will be delivered prematurely, which has serious implications for the health of both the mother and the baby. In fact, preterm delivery is a leading cause of infant morbidity. Unfortunately, the rate of preterm births has been increasing again in the past two years," said James Byrne, MD, chairman of the Department of Obstetrics and Gynecology at Santa Clara Valley Medical Center and a contributing author of the paper. "In our study, one in five women discharged went on to deliver their baby prematurely within three days, and only 4 percent of these women received an fFN test. This indicates a significant missed opportunity for healthcare providers to better understand patients' risk for preterm labor and improve care management with the use of screening tools such as fFN testing."

- Study Details: The retrospective study is one of the first to assess the use of fFN screening through medical claims data drawn from the Inovalon Medical Outcomes Research for Effectiveness and Economics Registry (MORE2 Registry®), a national multi-payer claims database that includes members enrolled in commercial plans and managed Medicaid or Medicare Advantage plans. Researchers investigated healthcare and delivery timing patterns from June 2012 through November 2015 among more than 23,000 women nationwide who

went to the hospital displaying symptoms of preterm labor.

- Key Results: The study found that only 12 percent of pregnant women with symptoms of preterm labor received fFN screening. Furthermore, of those who were discharged from the emergency room, one in five went on to deliver within three days, and almost 96 percent of this group was not screened for the presence of fFN. Conversely, of the women who were admitted to the hospital, 9 percent did not deliver during their stay, and over 80 percent of these patients did not receive fFN screening.

  The study also evaluated the outcomes of women who received transvaginal ultrasounds (TVUS), both with and without a corresponding fFN test. The percentage of women who delivered within three days of being discharged was lower for those who received fFN testing only versus those who had a TVUS only, suggesting that the use of fFN testing may have added valuable information to inform patient care. The percentage of women who delivered within three days of being discharged was lowest among patients who had both an fFN test and a TVUS**. Specifically, 1 percent of women who received both tests went on to deliver within three days compared to 3 percent of those who underwent fFN testing alone and 18 percent of those who received TVUS alone.**

  "The numbers show that the need to increase fFN testing is two-fold," said Edward Evantash, MD, medical director and vice president of medical affairs for Hologic. "Not only will we be able to screen women at risk for preterm delivery more accurately and provide better care for her and her unborn baby, but we can also decrease unnecessary interventions and hospital admissions for those not at risk, ultimately lowering medical costs. All mothers deserve the best possible perinatal care, and the fFN test is a useful tool that should be used for those who are experiencing symptoms of preterm labor."

The fFN test is a safe, reliable and non-invasive assay that detects the presence of fetal fibronectin in vaginal secretions. It can help healthcare providers determine if a woman is at risk for preterm delivery through a clinically proven predictive value. In line with Hologic's commitment to improving women's health and well-being, the Company continues to develop a quantitative fFN test to further optimize perinatal care for women and their unborn babies. A quantitative fFN test is CE-marked and commercially available in Europe but is not yet available for sale for diagnostic use in the U.S. To learn more about the fFN test, visit **www.ffntest.com**.

Hologic was a sponsor of the MORE2 Registry® study. Initial results were presented at the Society for Maternal-Fetal Medicine's 37th Annual Pregnancy Meeting in Las Vegas in January 2017.

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.

###

Hologic Investor Contact

Michael Watts

Vice President, Investor Relations and Corporate Communications

(858) 410-8588

michael.watts@hologic.com

Hologic Media Contact

Jane Mazur

Senior Director, Divisional Communications

(508) 263-8764

jane.mazur@hologic.com

References

Blackwell, Sean C, et al. “Utilization of Fetal Fibronectin Testing and Pregnancy Outcomes among Women with Symptoms of Preterm Labor.” ClinicoEconomics and Outcomes Research, Volume 9, 2017, pp. 585–594., doi:10.2147/ceor.s141061.