



## PerkinElmer and Women & Infants Hospital of Rhode Island Launch Trial to Evaluate Performance Characteristics for High-Volume Non-Invasive Prenatal Testing Platform

July 10, 2018

**International Conference on Prenatal Diagnosis and Therapy (ISPD), Booth #15, Antwerp, Belgium – July 10, 2018** – [PerkinElmer, Inc.](#), a global leader committed to innovating for a healthier world, today announced a collaboration with [Women & Infants Hospital \(WIH\) of Rhode Island](#), a Care New England hospital, to evaluate an innovative test method using the [Vanadis® NIPT system](#). PerkinElmer's Vanadis NIPT system is under development and not available for clinical use in the United States.

Non-invasive prenatal testing (NIPT) using cell-free DNA (cfDNA) has become the standard follow-up procedure for women classified as high risk following traditional prenatal screening and other national guidelines indicating risk for aneuploidy. Unlike existing NIPT technologies which require more complex platforms such as sequencing or microarrays, the Vanadis NIPT platform is the first of its kind designed to simplify screening for trisomies 21 (Down syndrome), 18 (Edwards syndrome) and 13 (Patau syndrome). This cost-effective, high-throughput scalable platform measures fetal chromosomal trisomies in maternal plasma by labeling and counting specific cfDNA fragments using imaging -- removing the costly and data-intensive steps required for sequencing or microarray solutions.

The VALUE (Validation of a Lower Cost Aneuploidy Screen) [study](#) is funded through a contract with Women & Infants Hospital, but the design, implementation, analyses and reporting is the sole responsibility of the study staff at Women & Infants. The research study aims to test samples from approximately 2,650 women, most from an average risk pregnancy population, with additional high-risk cases added to determine performance characteristics such as detection rates and false positive rates. Turnaround time, associated costs, fetal sex determination, and quality metrics will also be examined. Women & Infants will serve as the primary study center and laboratory site. Fourteen enrollment [sites](#) across North America are currently participating in the VALUE study.

"All pregnant women should have access to reliable, low-cost NIPT as a follow-up to aneuploidy screening, but this has not previously been possible, as the current approaches are complex, have limited capacity and require the expertise of specialized genetic laboratories," said Linh Hoang MD, PhD, Vice President, Reproductive Health, PerkinElmer. "By incorporating novel technology and analytics, the Vanadis assay has the potential to fundamentally change the cost structure and workflow for NIPT and give more women access to cfDNA screening. Our solution is designed to make it simpler for any laboratory to provide high-precision NIPT with a fully automated platform that they can integrate into their current screening programs and workflow."

"We believe that it is important that prenatal screening be under local laboratory control rather than concentrated in a few large commercial laboratories. The Vanadis technology requires less upfront investment as well as non-specialized laboratory space and technicians. It has the potential to be as efficient as current next generation sequencing offerings, yet could be cost-competitive with current serum-based screening," said Glenn Palomaki, PhD, associate director of the Division of Medical Screening and Special Testing at Women & Infants Hospital and professor in the Department of Pathology and Laboratory Medicine at The Warren Alpert Medical School of Brown University.

PerkinElmer obtained the proprietary NIPT technology through its [acquisition](#) of Vanadis Diagnostics, AB. A [research study](#), "Imaging Single DNA Molecules for High Precision NIPT," recently published Nature Scientific Reports described the Vanadis NIPT technology and presented data on the feasibility of applying the assay for detection of fetal trisomy 21 in maternal plasma.

"Our group at Women & Infants has been offering prenatal screening for more than 30 years and has been a leader in identifying new methodologies and subsequently introducing them into routine prenatal care practices. This study may provide a pathway to continuing to offer the best testing available to all pregnant women," said Geralyn Lambert-Messerlian, PhD, director of the [Division of Medical Screening and Special Testing](#) at Women & Infants and a professor in the Departments of Pathology and Laboratory Medicine and Obstetrics and Gynecology at The Warren Alpert Medical School of Brown University.

For more information on the Vanadis NIPT system, please visit [www.vanadisdx.com](http://www.vanadisdx.com), or stop in at PerkinElmer's booth #15 at ISPD, July 8-11, 2018.

### About PerkinElmer

PerkinElmer, Inc. is a global leader committed to innovating for a healthier world. Our dedicated team of about 11,000 employees worldwide is passionate about providing customers with an unmatched experience as they help solve critical issues especially impacting the diagnostics and discovery and analytical solutions markets. Our innovative detection, imaging, informatics, and service capabilities, combined with deep market knowledge and expertise, help customers gain earlier and more accurate insights to improve lives and the world around us. The Company reported revenue of approximately \$2.3 billion in 2017, serves customers in more than 150 countries, and is a component of the S&P 500 Index. Additional information is available through 1-877-PKI-NYSE, or at [www.perkinelmer.com](http://www.perkinelmer.com).

### About Women & Infants Hospital

Women & Infants Hospital of Rhode Island, a Care New England hospital, is one of the nation's leading specialty hospitals for women and newborns. A major teaching affiliate of The Warren Alpert Medical School of Brown University for obstetrics, gynecology and newborn pediatrics, as well as a number of specialized programs in women's medicine, Women & Infants is the ninth largest stand-alone obstetrical service in the country and the largest in New England with approximately 8,500 deliveries per year. A Designated Baby-Friendly® USA hospital, U.S. News & World Report 2014-15 Best Children's Hospital in Neonatology and a 2014 Leapfrog Top Hospital, in 2009 Women & Infants opened what was at the time the country's largest, single-family room neonatal intensive care unit.

Women & Infants and Brown offer fellowship programs in gynecologic oncology, maternal-fetal medicine, urogynecology and reconstructive pelvic surgery, neonatal-perinatal medicine, pediatric and perinatal pathology, gynecologic pathology and cytopathology, and reproductive endocrinology and infertility. It is home to the nation's first mother-baby perinatal psychiatric partial hospital, as well as the nation's only fellowship program in obstetric medicine.

Women & Infants has been designated as a Breast Imaging Center of Excellence by the American College of Radiography; a Center of Excellence in Minimally Invasive Gynecology; a Center of Biomedical Research Excellence by the National Institutes of Health (NIH); and a Neonatal Resource Services Center of Excellence. It is one of the largest and most prestigious research facilities in high risk and normal obstetrics, gynecology and newborn pediatrics in the nation, and is a member of the National Cancer Institute's Gynecologic Oncology Group and the Pelvic Floor Disorders Network.

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