# PerkinElmer Receives CE-IVD Mark for Its Vanadis Fully Automated NIPT Platform

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***Innovative Cost-Effective Solution Provides Pregnant WomenWidespread Access to Non-Invasive Prenatal Testing***

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 26, 2018-- PerkinElmer, Inc. (NYSE: PKI), a global leader committed to innovating for a healthier world, today announced that its Vanadis® NIPT system has obtained CE-IVD mark for commercialization and distribution throughout Europe and other countries that accept CE marking. This non-invasive test provides screening results for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome). The Vanadis NIPT system has been validated in an external clinical study conducted in France. The blinded study analyzed 80 samples from pregnancies affected by trisomy 21 and 670 samples from unaffected pregnancies, classifying all cases correctly, with only one sample failing to generate a result. In addition to trisomy 21, PerkinElmer conducted clinical studies to demonstrate high sensitivity and specificity for trisomies 18 and 13.

Generally, non-invasive prenatal testing (NIPT) analyzes cell-free DNA (cfDNA) circulating in the maternal blood and has rapidly become the standard follow-up procedure for women classified as high risk following traditional prenatal screening. Measuring cfDNA from a standard blood draw to detect common chromosomal trisomies has been demonstrated with high sensitivity and specificity.

“NIPT has been previously limited by the complexity, cost and capacity of existing commercially available technologies, which prevented many laboratories and obstetricians from offering reliable, and cost-effective solutions for aneuploidy screening,” said Olle Ericsson, General Manager at Vanadis Diagnostics, a PerkinElmer company. “With our Vanadis platform, we are taking the technical complexity out of NIPT while breaking down the cost barriers. This will enable more women to gain access to NIPT and improve the level of prenatal care on a global level.”

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, 18 and 13. The Y chromosome can be measured as an optional marker. This cost-effective, high-throughput scalable platform measures fetal chromosomal trisomies in maternal plasma by targeted fluorescent labeling and counting specific cfDNA fragments—removing the costly and data-intensive steps required for gene sequencing or microarray solutions.

“The promising results we’ve seen lead us to believe that a broad range of women throughout Europe and around the world now stand to benefit significantly from being able to have NIPT as a key component of prenatal care,” said Jérémie Gautier, head of the project management team at CerbaXpert, which played a leading role in the evaluation study in France.

PerkinElmer is also currently collaborating with Women & Infants Hospital (WIH) of Rhode Island, a Care New England hospital, in a clinical validation study to evaluate an innovative test method using the VanadisNIPT system.* The VALUE (Validation of a Lower Cost Aneuploidy Screen) study aims to test samples from approximately 2,500 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.

“The Vanadis technology has the potential to bring cfDNA screening for common trisomies to the general pregnancy population who cannot readily access NIPT at this time due to the high cost of available tests,” said Glenn Palomaki, PhD, Associate Director of the Division of Medical Screening and Special Testing at WIH, and Professor, Department of Pathology and Laboratory Medicine at the Warren Alpert Medical School of Brown University. “This platform has the potential to be as efficient as current next generation sequencing offerings—yet could be cost-competitive with current first trimester combined screening.”

For more information on the Vanadis NIPT system, please visit: www.prenataltesting.perkinelmer.com/vanadis.

**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**.**

**PerkinElmer’s Vanadis NIPT system is not available for clinical use in the United States.*

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PerkinElmer, Inc.
Brian Willinsky, +1-781-663-5728
brian.willinsky@perkinelmer.com