NEWS RELEASE

Clinical Study Published in Prenatal Diagnosis Further Validates PerkinElmer's Vanadis Fully Automated NIPT Platform

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CE-Marked Solution Gives Pregnant Women Widespread Access to Non-Invasive Prenatal Testing

WALTHAM, Mass. – August 21, 2019 – **PerkinElmer, Inc.**, a global leader committed to innovating for a healthier world, today announced that its **Vanadis**® fully automated non-invasive prenatal testing (NIPT) system has been validated in an external clinical study, titled "Clinical Validation of a Novel Automated Cell-Free DNA (cfDNA) Screening Assay for Trisomy 21, 13 and 18 in Maternal Plasma." The study **was published by** Prenatal Diagnosis on August 19.

Maternal plasma samples from 1,200 singleton pregnancies, which included 158 fetal aneuploidies, were analyzed using the Vanadis NIPT system's non-sequencing cfDNA method. It found that the new cfDNA assay has high sensitivity and specificity for trisomies 21 (Down syndrome), 18 (Edwards syndrome) and 13 (Patau syndrome), and accurately determines fetal sex, while maintaining a low failure rate.

The study demonstrated that cfDNA testing with the highly automated Vanadis NIPT system does not require specialized personnel for screening. The Vanadis system is also designed to help reduce cost and allow wider population-based screening.

“We continue to be encouraged by clinical studies that further validate our Vanadis platform as a reliable, cost-effective solution for laboratories and obstetricians to offer aneuploidy screening,” said Masoud Toloue, Ph.D., vice president and general manager, Diagnostics, PerkinElmer. “Our Vanadis platform eliminates the technical complexity of NIPT, giving more women access to cfDNA screening for common trisomies and further improving prenatal care on a global scale.”

PerkinElmer’s Vanadis NIPT system, which **received CE-IVD mark** for commercialization and distribution throughout Europe and other countries that accept CE marking, had previously been validated in a separate 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. PerkinElmer conducted clinical studies to demonstrate high sensitivity and specificity for trisomies 18 and 13, as well.

In the U.S., PerkinElmer is collaborating with Women & Infants Hospital (WIH) of Rhode Island, a Care New England hospital, in a **clinical validation study**, testing samples from approximately 2,500 women.* Most samples are from an average risk pregnancy population, with additional high-risk cases added to determine performance characteristics such as detection rates and false positive rates.

For more information, please visit: **https://prenataltesting.perkinelmer.com/**.

*PerkinElmer’s Vanadis NIPT system is not available for clinical use in the U.S. Products may not be licensed in accordance with the laws in all countries, such as the U.S. and Canada. Please check with your local representative for availability.

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About PerkinElmer
PerkinElmer enables scientists, researchers and clinicians to address their most critical challenges across science and healthcare. With a mission focused on innovating for a healthier world, we deliver unique solutions to serve the diagnostics, life sciences, food and applied markets. We strategically partner with customers to enable earlier and more accurate insights supported by deep market knowledge and technical expertise. Our dedicated team of about 13,000 employees worldwide is passionate about helping customers work to create healthier families, improve the quality of life, and sustain the wellbeing and longevity of people globally. The Company reported revenue of approximately $2.8 billion in 2018, serves customers in more than 180 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**.

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