

NX Prenatal Announces New Clinical Study Published in AJOG

Provides Strong Evidence Supporting the Time-to-Prepare Test's Ability to Predict Pre-Term Birth in First Trimester Samples

BELLAIRE, TX, USA, June 20, 2024 /EINPresswire.com/ -- NX Prenatal, a leading women's healthcare company focused on the development of advanced prenatal diagnostic tests, is announcing a new clinical study that demonstrates the company's first trimester pre-term birth test's ability to predict the risk of spontaneous pre-term birth (sPTB) in nulliparous pregnant women. The study was published recently in the [American Journal of Obstetrics and Gynecology](#). The new data, which represents the largest clinical validation study to date for a PTB test, substantiated that women with a high-risk test result demonstrated a 20-fold higher risk of pre-term birth than women in the low-risk category. This data validates that NX Prenatal's sPTB test can be highly effective at stratifying first-trimester pregnancies into risk categories to assist physicians in guiding the appropriate prenatal care.

"The NX Prenatal technology focuses on identifying the women at highest risk for early preterm birth. These may be the most important cases to prevent as babies born preterm have the highest risk of long-term developmental challenges and long neonatal intensive care unit stays. These cases have a large impact on both families and the healthcare system," said Dr. David Haas, the Munsick Professor and Vice-Chair for Research for OB/GYN at Indiana University School of Medicine, who was the senior author on the paper. "By focusing on and identifying these high-risk women in the first trimester where clinical intervention may be possible, we would be able to set up appropriate triage to high-risk care pathways and specialists, with the goal of maximizing time in the womb."

The study, which evaluated 400 patients consisting of pre-term birth samples and healthy controls, determined the ability of the company's Time-to-Prepare test to predict sPTB. The data from the study demonstrated the ability of NX Prenatal's test to predict sPTB risk with high accuracy. Women in the study who were determined to be at high-risk had a 7.5% risk of having a sPTB prior to 35 weeks gestation compared to only 0.4% in the low-risk group, representing a 20x higher risk profile. In the study, 60% of the women in the high-risk category ended up having a sPTB event (birth <37 weeks gestation) demonstrating the strong ability of the company's test to predict risk. Importantly, the company's preterm test was developed to minimize false positive results, with only 9% being classified as high-risk. This allows for the effective allocation of resources to patients that most need it. NX Prenatal's Time-to-Prepare test is the only first-

trimester, pre-term birth test currently in development.

"NX Prenatal's PTB test has demonstrated in three peer-reviewed studies to stratify PTB risk," said Thomas F. McElrath M.D. PhD, Professor of Obstetrics, Gynecology and Reproductive Biology at Harvard Medical School. "NX Prenatal's proprietary exosome technology provides a potential early window into the biological processes associated with PTB which potentially offers opportunities for therapeutic intervention."

NX Prenatal is currently undergoing a second major clinical validation study consisting of approximately 600 patients to further validate its technology and is in the planning stages for a large prospective clinical validation and clinical utility study to further prove the ability of its technology to impact patient outcomes and healthcare costs.

"We strongly believe that we have the best solution for physicians and women to improve outcomes in this important area of unmet medical need. One in ten births in this country are pre-term with increasing incidence and a total cost of \$25.2 billion to the U.S. healthcare system according to a National Center for Biotechnology Information study," said Paul Kortschak, CEO of NX Prenatal. "We plan to commercialize this important product starting in 2025 with a goal of improving health outcomes for mothers and their babies while lowering healthcare costs."

About NX Prenatal:

NX Prenatal Inc. is a private, US-based molecular diagnostics company recognized for its innovative work developing new exosome-based liquid biopsy tests for the large maternal-fetal medicine market. The company's proprietary multiplexing and AI/ML-driven platform is being utilized to develop enabling, early warning systems for adverse pregnancy outcomes including preterm birth, preeclampsia and placenta accreta. For more information, please visit the company's website at www.nxprenatal.com.

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