



# Nixxi Developing Mass Spec Test Targeting Preterm Birth Space

Apr 30, 2020 | [Adam Bonislawski](#)

NEW YORK – Start-up Nixxi is developing a mass spectrometry-based test for identifying mothers at high risk of delivering prematurely.

In April, researchers affiliated with the Phoenix, Arizona-based firm published [a study](#) in *Human Reproduction Open* that found that maternal serum levels of 11-deoxycorticosterone (DOC) and 16-alpha-hydroxyprogesterone (16 $\alpha$ -OHP) could be used to predict an increased risk delivery prior to 32 weeks.

The company is now in the middle of a second study validating those results, said Avi Patil, Nixxi's founder and CEO. Additionally, the company is looking to expand its research to look directly at factors predictive of neonatal outcomes, he said.

Preterm birth is a relatively common issue in the US. According to numbers from the March of Dimes, around 1 in 10 babies are born prematurely with costs to the healthcare system totaling more than \$25 billion per year.

While interventions like vaginal progesterone or increased surveillance of cervical shortening can be used to improve management of women at risk of preterm delivery, tools for assessing women's risk levels have traditionally been lacking. One of the major predictors of preterm delivery is having previously given birth prematurely, which offers little help in the case of first-time mothers.

In recent years, however, several proteomics firms have set out to tackle this challenge. In 2017, Sera Prognostics [launched its PreTRM test](#) nationwide for assessing preterm birth risk through an agreement with Laboratory Corporation of America.

[NX Prenatal](#), meanwhile, is working with Thermo Fisher Scientific to develop exosome-based proteomic tests for preterm birth risk as well as monitoring fetal health *in utero* and predicting development of preeclampsia.

Nixxi is looking not at proteins but steroid hormone pathways as an indicator of preterm delivery risk.

"These are well defined pathways that have been studied over the last couple of decades that link changes in [these pathways] to increased risk of uterine contractility, preterm labor, etc.," Patil said.

In the *Human Reproduction Open* study, the researchers investigated links between spontaneous preterm birth and components of the progestogen, glucocorticoid and mineralocorticoid steroid pathways. They quantified levels of 11 steroid metabolites using targeted mass spec, analyzing samples from 93 women taken from the Building Blocks of Pregnancy Biobank at the Indiana University School of Medicine. Of the 93 subjects, 28 delivered prior to 32 weeks gestation, 40 delivered after 32 weeks but before 37 weeks, and 25 delivered at 37 weeks or later.

Their analysis found that the ratio of DOC to 16 $\alpha$ -OHP could identify women delivering before 32 weeks with a sensitivity of 89 percent and specificity of 59 percent and an area under the (AUC) curve of 81 percent.

By way of comparison, studies done by NX Prenatal researchers found that the company's assay identified first-time mothers who gave spontaneous preterm birth before the end of 35 weeks gestation with a sensitivity of 63 percent, a specificity of 86 percent and an area under the curve of .77.

Sera Prognostics' 5,501-subject Proteomic Assessment of Preterm Risk (PAPR) study found that its PreTRM test predicting delivery before 35 weeks with an AUC of .93 and before 37 weeks with an AUC of .75.

While's Sera's PreTRM test appears to offer superior performance for predicting delivery prior to 35 weeks than the Nixxi test does for prior to 32 weeks, Patil said the company hopes to set itself apart by focusing on the earlier time point.

He noted that while preterm delivery is defined as birth prior to 37 weeks, neonatal care has improved over the last decades to where many children born in the 32 to 37 week range will have good outcomes.

"We were really looking to address those pregnancies that would be delivered spontaneously... and which would be most likely to lead to long-term complications for the neonates from prematurity," he said, adding that this led to their focus on the 32-week timepoint.

Babies born prior to 32 weeks "have the greatest chance of long-term morbidities," he said. "That impacts families the most and it also raises the costs within the healthcare ecosystem. We know this is a major pain point for payors, and anything that can be done to reduce the rate of preterm birth at less than 32 weeks goes a long way to reducing [costs] because the cost of care associated with those births is disproportionate."

Patil, who remains a practicing maternal-fetal medicine specialist, as does Nixxi Chief Medical Officer Chad Grotegut, who is an associate professor of obstetrics and gynecology and a maternal-fetal medicine specialist at Duke University, added that he believed use of later time points could increase anxiety among women who tested as at-risk and increase unnecessary healthcare usage.

"If you predict that a woman is going to deliver preterm at less than 37 weeks, what does that mean?" he said. "Does that mean 36 weeks? Does that mean 26 weeks? There's a tremendous difference in terms of the implications. Am I just increasing their anxiety? That's a thought process that has been vocalized to us by clinicians in practice."

Patil said Nixxi currently plans to take the test to market on a mass spec platform. Sera's PreTRM test also runs on mass spec, and NX Prenatal is developing its test on mass spec, as well.

Patil said the company is currently in the middle of a study validating its initial results. It is also working on identifying markers that can measure neonatal outcomes more directly.

"One of the weaknesses in the obstetric field is that for as long as people have been trying to assess who is going to deliver preterm, everyone has realized that preterm birth is really a surrogate for how the baby does," he said. "So, that is on the horizon as well. How do we give a risk stratification for that? How do we inform moms and providers about that risk so they can implement mitigation strategies?"

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