Landmark Study Finds PreTRM® Blood Test Reduces Earliest Preterm Births and Newborn Complications

Published in the journal PREGNANCY, the PRIME Study demonstrates significant improvements in neonatal outcomes with early risk screening and targeted interventions.

SALT LAKE CITY, Jan. 7, 2026 /PRNewswire/ -- A randomized controlled trial of 5,018 women has found that a simple blood test, when paired with targeted interventions, can significantly reduce the risk of preterm birth and improve outcomes for newborns. The findings, published in PREGNANCY, the peer-reviewed journal of the Society for Maternal-Fetal Medicine, highlight the effectiveness of the PreTRM Test in identifying women at higher risk for spontaneous preterm birth and guiding preventive care.

Key findings from the PRIME Study include:

- 56% and 32% fewer babies were born before 32 and 35 weeks, respectively
- 20% fewer babies admitted to the NICU
- Fewer health complications for newborns (20% reduction in odds of neonatal morbidity)
- A NICU day was saved for every 4.2 patients screened

The PreTRM Test is a first-of-its-kind, personalized, non-invasive blood test that predicts the risk of spontaneous preterm birth in asymptomatic women carrying a single baby. In the study, women identified by the PreTRM Test as higher risk for preterm birth received daily vaginal progesterone, low-dose aspirin, and nurse-led care management, while lower-risk women and the control group received standard prenatal care.

"The PreTRM Test represents a meaningful step forward in how we identify and manage risk for preterm birth," said Dr. Brian Iriye, principal investigator for the PRIME study. "Today, many women who ultimately deliver prematurely would be considered 'low risk' by traditional criteria, and that gap is not acceptable. By quantifying a woman's biologic risk early in pregnancy, the PreTRM Test allows us to move beyond guesswork and implement a straightforward, low-burden, evidence-based care plan that supports her, protects her baby, and improves outcomes for the families we serve—while reducing the downstream cost and complications of being born too soon."

"These findings not only reinforce the strong results from the AVERT PRETERM Trial but also enhance our ability to build a robust, differentiated body of clinical evidence for the PreTRM test-and-treat strategy," said Zhenya Lindgardt, President and CEO of Sera Prognostics. "With preterm birth still impacting 1 in 10 infants in the U.S., our commitment extends beyond innovative technologies like the PreTRM Test to driving education, awareness, and equitable access to prenatal care. Looking ahead, we see a significant opportunity to transform maternal and neonatal health outcomes, setting a new commercial and clinical standard that delivers measurable value for patients, providers, and health systems."

Dr. Brian Iriye, principal investigator for the PRIME study, Zhenya Lindgardt, President and CEO of Sera and Dr.Tiffany Inglis, Chief Medical Officer of Sera, will be participating in a Jefferies fireside chat to discuss the full results of the PRIME study. The call will take place on Friday, January 9, 2026, at 8:30 a.m. Eastern Time. Interested parties may reach out to their Jefferies sales representative for details.

The PreTRM Test and targeted interventions demonstrated a more effective and efficient strategy in reducing NICU admissions and length of stay than current standard care. When using the PreTRM Test and targeted interventions, the number needed to screen to prevent a single NICU admission was approximately 39 – as compared to 150 when using current standard care. Further, only about 4 women need to be screened with PreTRM and treated to prevent one day in the NICU. As PRIME excluded women with prior spontaneous preterm birth or premature cervical shortening at the time of enrollment, the study results illustrate the value of the test for patients at otherwise low overall risk of preterm birth and therefore not identified by current screening approaches.

The PRIME study included a diverse population with no significant differences in patient demographics in the control vs treatment arm. With birth complications and preterm birth disproportionately impacting certain populations, the PreTRM Test and targeted interventions offer a solution to improve outcomes for historically disadvantaged groups.

About Preterm Birth
Preterm birth—any birth before 37 weeks' gestation—is the leading cause of illness and death in newborns. In the United States, more than one in ten infants is born prematurely each year, with significant long-term health and economic consequences.

About The PreTRM® Test

The PreTRM Test is the only broadly validated, commercially available blood-based biomarker test that provides an early, accurate and individualized risk prediction for spontaneous preterm birth in asymptomatic singleton pregnancies. The PreTRM Test measures and analyzes proteins in the blood that are highly predictive of preterm birth. The PreTRM Test permits physicians to identify, during the weeks 18 through 20 of pregnancy, which women are at increased risk for preterm birth and its complications, enabling more informed, personalized clinical decisions based on each woman's individual risk. The PreTRM Test is ordered by a medical professional.

About Sera Prognostics, Inc.
Sera Prognostics is a health diagnostics company dedicated to improving the lives of women and babies through precision pregnancy care. The company's PreTRM® Test is the only broadly validated, commercially available blood-based biomarker test for early, individualized risk prediction of spontaneous preterm birth. Sera Prognostics is headquartered in Salt Lake City, Utah.

Safe Harbor Statement
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to building a robust, differentiated body of clinical evidence for the PreTRM® test-and-treat strategy; driving education, awareness, and equitable access to prenatal care; transforming maternal and neonatal health outcomes; setting a new commercial and clinical standard that delivers measurable value for patients, providers, and health systems; the Company's participation in a Jefferies fireside chat to discuss the full results of the PRIME study; and the company's strategic directives under the caption "About Sera Prognostics, Inc." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by forward-looking statements. These risks and uncertainties include, but are not limited to: net losses, cash generation, and the potential need to raise more capital; revenues from the PreTRM Test representing substantially all Company revenues to date; the need for broad scientific and market acceptance of the PreTRM Test; a concentrated number of material customers; our ability to introduce new products; potential competition; our proprietary biobank; critical suppliers; the COVID-19 pandemic and its potential lingering impact on our operations, as well as the business or operations of third parties with whom we conduct business; estimates of total addressable market opportunity and forecasts of market growth; potential third-party payer coverage and reimbursement; new reimbursement methodologies applicable to the PreTRM Test, including new CPT codes and payment rates for those codes; changes in FDA regulation of laboratory-developed tests; the intellectual property rights protecting our tests and market position; and other factors discussed under the heading "Risk Factors" contained in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

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