

SERA PROGNOSTICS ANNOUNCES PUBLICATION OF DATA DEMONSTRATING IMPROVED PERFORMANCE OF ITS PRETRM® TEST WITH MORE PRECISE GESTATIONAL AGE

Results show that the validated proteomics predictor has even greater predictive performance to determine risk of spontaneous preterm birth

SALT LAKE CITY, May 19, 2022 /PRNewswire/ -- **Sera Prognostics** Inc., The Pregnancy Company® (NASDAQ: [SERA](#)), focused on improving maternal and neonatal health by providing innovative pregnancy biomarker information to doctors and patients, today announced the publication of improved PreTRM® test performance using women from the Proteomic Assessment of Preterm Risk (PAPR) clinical study whose pregnancy outcomes are aligned with updated ACOG gestational age dating guidelines. The newly published article reports:

- A greater observed sensitivity of 88% at 75% specificity, which represent increases of 17% and 1%, respectively, relative to all subjects
- An improved performance was also demonstrated over an expanded 18-20 weeks' gestational age time interval for performing PreTRM testing, consistent with the timeframe of routine obstetric visits during pregnancy
- A negative predictive value of 99% for the test, at its validated threshold

"Beyond increased performance, these data show that the PreTRM® test can also be offered more conveniently to women over a broader time interval during pregnancy, typically months before preterm delivery occurs," said Michael Foley, MD, Sera's Chief Medical Officer. "A PreTRM® test higher risk result reflects a similar risk as is revealed by traditional assessment techniques, but the PreTRM® test identifies far more patients who are at risk of premature delivery. Furthermore, the reported 99% negative predictive value of the PreTRM® test means that women not found to be at higher risk of preterm delivery can have very high confidence of not delivering a premature infant."

"These new data demonstrate substantially improved PreTRM® test predictive performance over an expanded blood draw window when gestational age is known with more accuracy, as the first and only broadly validated commercially available blood test for prematurity risk is made even more available to physicians and their patients," said Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "Sera's pioneering work in the pregnancy space highlights the power of our proteomics and bioinformatics approach to provide valuable information to women and their physicians to enable proactive care in a greater number of pregnancies that are truly at higher risk of preterm delivery."

The PreTRM® test was developed and validated for prediction of spontaneous preterm birth broadly in the U.S. in the Proteomic Assessment of Preterm Risk (PAPR) study. In a subsequent large prospective U.S. study, the Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor (TREETOP), the biomarkers were demonstrated to be predictive of very early preterm birth of any cause, length of neonatal hospital stay, and neonatal morbidity and mortality. The new data reported here, "Better Estimation of Spontaneous Preterm Birth Prediction Performance Through Improved Gestational Age Dating" (<https://www.mdpi.com/2077-0383/11/10/2885/htm>), were published as a peer-reviewed article in the *Journal of Clinical Medicine*, showing that the PreTRM® test provides highly accurate predictions that are confirmed when outcomes are known more reliably.

About Sera Prognostics, Inc.

Sera Prognostics is a leading health diagnostics company dedicated to improving the lives of women and babies through precision pregnancy care. Sera's mission is to deliver early, pivotal information in pregnancy to physicians, enabling them to improve the health of their patients, resulting in reductions in the costs of healthcare delivery. Sera has a robust pipeline of innovative diagnostic tests focused on the early prediction of preterm birth risk and other complications of pregnancy. Sera's precision medicine PreTRM® Test reports to a physician the individualized risk of spontaneous premature delivery in a pregnancy, enabling earlier proactive interventions in women with higher risk. Sera Prognostics is located in Salt Lake City, Utah.

About Preterm Birth

Preterm birth is defined as any birth before 37 weeks' gestation and is the leading cause of illness and death in newborns. The 2021 March of Dimes Report Card shows that more than one in ten infants is born prematurely. Prematurity is associated with a significantly increased risk of major long-term medical complications, including

learning disabilities, cerebral palsy, chronic respiratory illness, intellectual disability, seizures, and vision and hearing loss, and can generate significant costs throughout the lives of affected children. The annual health care costs to manage short- and long-term complications of prematurity in the United States were estimated to be approximately \$25 billion for 2016.

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 19th or 20th week of pregnancy, which women are at increased risk for preterm birth, enabling more informed, personalized clinical decisions based on each woman's individual risk. The PreTRM® test is ordered by a medical professional.

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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 women not found to be at higher risk of preterm delivery by the PreTRM® test having extremely high confidence of not delivering a premature infant; 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 ongoing COVID-19 pandemic and its 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 Final Prospectus on Form S-1, which was filed with the Securities and Exchange Commission on July 14, 2021, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, or Current Reports on Form 8-K. 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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<https://investors.seraprognostics.com/2022-05-19-sera-prognostics-announces-publication-of-data-demonstrating-improved-performance-of-its-pretrm-test-with-more-precise-gestational-age>