

AMERICAN MEDICAL ASSOCIATION (AMA) GRANTS SERA PROGNOSTICS A CPT® PLA CODE FOR PreTRM®, THE ONLY BROADLY VALIDATED BLOOD TEST TO ASSESS RISK OF PRETERM BIRTH

– Receipt of dedicated CPT® code marks important commercialization milestone to pursue reimbursement for the PreTRM® Test –

Salt Lake City – February 3, 2021 – [Sera Prognostics, Inc.](https://www.seraprognostics.com), The Pregnancy Company™, focused on improving maternal and neonatal health through innovative precision biomarker approaches, announced today that the American Medical Association (AMA) has assigned a new, dedicated Current Procedural Terminology (CPT®) Proprietary Laboratory Analysis (PLA) code to facilitate billing and payment for the PreTRM® Test, the company's proprietary proteomic blood test for measuring a woman's risk of spontaneous preterm birth to enable timely intervention. The establishment of the new code, 0247U, is a result of the AMA's PLA program, which enables labs with distinct, single-source Laboratory Developed Tests (LDT) to apply for a dedicated code that can be utilized to bill payors in order to receive reimbursement. This code is included in the revised set of PLA codes the AMA released on December 30, 2020, with an effective date of April 1, 2021.

The new code, 0247U, is associated with an official Descriptor that states, "Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth." As such, it is specific to the PreTRM® Test.

"The receipt of this dedicated CPT® PLA code is an important milestone in our commercial strategy to establish coding, coverage and payment for our proprietary PreTRM® Test," said Gregory C. Critchfield, MD, MS, chairman and chief executive officer of Sera Prognostics. "We believe that the PreTRM® Test has an important role to play to improve risk identification that allows earlier proactive interventions designed to decrease adverse outcomes and thereby reduce healthcare costs. We are committed to making the test broadly accessible. This CPT® PLA code is a step in our ongoing efforts to secure reimbursement from individual employer-sponsored, commercial and Medicaid health plans, an essential component of our business and market access strategies."

Preterm birth is a leading cause of illness and death in newborns. The PreTRM® Test provides an early and individual risk prediction for spontaneous preterm birth in asymptomatic, singleton pregnancies. Identifying higher risk pregnancies by PreTRM® enables resources to be more efficiently focused on pregnancies that are at the greatest risk of adverse neonatal outcomes.

About Sera Prognostics, Inc.

Sera Prognostics is a leading proteomic and bioinformatics company dedicated to improving the lives of women and babies through precision biomarker-based tests designed to enhance pregnancy care. Sera's vision is to deliver pivotal information in early pregnancy to physicians, to help them to improve the health of their patients and reduce costs of healthcare delivery. Sera's PreTRM® Test reports to a physician the individualized risk of a pregnant woman to deliver prematurely, enabling earlier proactive interventions in patients with higher risk. Sera is also developing a robust pipeline of innovative tests focused on other complications of pregnancy. Sera Prognostics is located in Salt Lake City, Utah. For more information, please visit the company's website at www.seraprognostics.com.

About Preterm Birth

Preterm birth is defined as any birth before 37 weeks gestation and is a leading cause of illness and death in newborns. The 2020 March of Dimes Report Card shows that of nearly 4 million babies born annually in the U.S., more than one in ten is born prematurely.¹ 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, vision and hearing loss, and can generate significant costs throughout the lives of affected children. The annual U.S. health care costs to manage complications of prematurity were estimated at \$31.5B for 2015.²

About the PreTRM® Test

The PreTRM® Test is the only broadly clinically validated, commercially available blood test that provides an early individual 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, as early as 19 weeks of pregnancy, which women are at increased risk for premature delivery, enabling more informed clinical decisions based on each woman's individual risk, so that her care can be personalized to address her risk. The PreTRM® Test is ordered by a medical professional. For more information, please

visit www.PreTRM.com and the PreTRM® Test YouTube Channel. You can also join the conversation on Facebook and @PreTRM on Twitter.

About Sera's Science

Using its advanced proprietary mass spectrometry and bioinformatics platform technologies, Sera detects biologically important protein expression differences to build high performing predictions of risk for adverse pregnancy outcomes (including preterm birth, preeclampsia, gestational diabetes, growth restriction, and others). Rigorous clinical validation of PreTRM® Test performance (accuracy of predicting premature delivery) was reported in the *American Journal of Obstetrics & Gynecology* in 2016 in a U.S. cohort of 5,501 patients across 11 centers. Sera's biomarker predictions have been studied with leading scientific collaborators in patient cohorts from the U.S., Europe, Asia and Africa.

About Clinical Outcomes Studies

Sera's validated PreTRM® predictions have been taken into prospective intervention studies, where populations of pregnant women have been screened by the Sera test. Women found to be at higher preterm delivery risk and not otherwise readily identifiable receive proactive interventions, and important outcomes are examined in comparison to pregnancies in control groups where the test is not available.

Topline results showing the benefit of the PreTRM® strategy in a recently completed randomized controlled prospective intervention study ([PREVENT PTB Study, NCT03530332](#)) became available [online for the Late Breaking Poster Session of the March 2020 Annual Meeting of the Society of Reproductive Investigation](#), in Vancouver, Canada.

1 <http://www.marchofdimes.org/mission/prematurity-reportcard.aspx>

2 Caughey *et al.*, *Am J Perinatol Rep* 2016;6:e407-e416.A

<https://investors.seraprognostics.com/AMERICAN-MEDICAL-ASSOCIATION-AMA-GRANTS-SERA-PROGNOSTICS-A-CPT-R-PLA-CODE-FOR-PreTRM-R-, -THE-ONLY-BROADLY-VALIDATED-BLOOD-TEST-TO-ASSESS-RISK-OF-PRETERM-BIRTH>