CLIA: 46D2064326
Director: Salil Bhowmik, PhD, NRCC(CC)

Sera Prognostics, Inc
2749 East Parleys Way Suite 200, Salt Lake City, UT 84109

PreTRM.com
801-990-6600

PreTRM® TEST RESULTS

REPORT:

28789

STATUS:

Final

PATIENT INFORMATION:

NAME	Kiki Sera [wb another]	GENDER	Female
DOB	September 09, 1999	HEIGHT	65 in | 5' 5"
DUE DATE	August 20, 2026	PRE-PREGNANCY WEIGHT	125 lbs
MEDICAL RECORD NUMBER		BMI	20.8

PROVIDER INFORMATION:

NAME	Matthew Bullock
ADDRESS	123 Street, Suite 222 Orem, UT 84663
PHONE	(123) 123-1233
FAX	

PATIENT CLINICAL INFORMATION & CLINICAL USE:

- ✓ Pre-Existing Diabetes (Either Type 1 or 2)
- ✓ Prior Live Birth
- ✓ Prior Preterm Birth (<37 Weeks)
- ✓ Chronic Hypertension Prior to Pregnancy
- ✓ Prior Preeclampsia

Sera ID:
A26086-50004 (2428)

Sample Type:
Whole Blood

Received:
March 27, 2026 3:07 pm MT

Reference ID:
SA00000000001424

Collected:
March 27, 2026 3:07 pm

Reported:
March 30, 2026 3:50 pm MT

PreTRM Test Result: Risk of Singleton Spontaneous Preterm Birth

HIGHER RISK

ACTION RECOMMENDED
Clinical studies suggest patients with higher-risk results from the PreTRM Test may benefit from additional care and interventions. Contact your healthcare provider to discuss if these options are right for you.

INTERPRETATION OF RESULTS

The PreTRM Test is reported as 'Higher Risk' or 'Not Higher Risk' based upon the individualized risk of spontaneous preterm birth (sPTB) with a decision threshold. A 'Higher Risk' result is assigned to patients whose individualized risk of sPTB is approximately 2.3 times the average risk of sPTB before 37 weeks in the U.S. population of singleton pregnancies as measured by positive predictive value. A 'Not Higher Risk' result is assigned to patients whose individualized risk of sPTB is lower than this threshold. The clinical validation of the PreTRM Test was conducted in asymptomatic (no signs or symptoms of preterm labor with intact membranes) pregnant patients according to Saade et al.[3] If a patient differs clinically from the reported validation study patients, interpretation of the reported risk may differ. Interpretation of all PreTRM Test results must always be based upon best clinical judgement.

Questions about your results? We're here for you.
Email **support@pretrm.com** or call us at **801-990-6600**

PreTRM®
Test for Risk Management

SEE PAGE 2 FOR IMPORTANT CLINICAL INFORMATION AND TECHNICAL SPECIFICATIONS

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PreTRM® TEST RESULTS

REPORT:	SERA ID:	STATUS:
28789	A26086-50004 (2428)	Final

PreTRM® Test for Risk Management

INTENDED USE AND INDICATIONS FOR USE

The PreTRM Test predicts the risk of spontaneous preterm birth (before 37 weeks) in asymptomatic women (no signs or symptoms of preterm labor with intact membranes) ≥18 years old with a singleton pregnancy. The PreTRM Test is performed via a single blood draw between 18wk - 20wk/6d (126 - 146 days) gestation. It is not intended for use in women who have a multiple pregnancy, have a known or suspected fetal anomaly, or are on any form of progesterone therapy after the first trimester. If the PreTRM Test was ordered for a patient outside of intended use for this test, caution should be exercised when interpreting the personalized risk results.

PURPOSE OF THE TEST

Spontaneous preterm birth (sPTB) includes births at <37 weeks gestational age following preterm labor or preterm spontaneous rupture of membranes, but it does not include medically indicated preterm delivery for maternal and/or fetal conditions. Approximately 10% of all singleton births are preterm, with approximately 75% of these described as spontaneous. This results in a population prevalence of 7.3% sPTB in singletons.[1,2] The strongest clinical risk predictor for preterm birth is a prior sPTB. Other identified risk factors associated with sPTB include: 1) short cervical length, 2) young or advanced maternal age, 3) race and ethnicity, 4) behavioral and socioeconomic factors, and 5) infections and/or other comorbidities during the pregnancy.[3,4] Comprehensive assessment of a patient's birth history and risk factors provides limited insight, predicting only approximately 20% of subsequent sPTBs.[3] The PreTRM test result may be useful for providers when considering potential clinical management of patients at increased risk of sPTB.

TEST METHOD AND SAMPLE

The PreTRM test identifies biomarkers in maternal serum or whole blood that have been clinically validated to be predictive of sPTB. Samples are analyzed via chromatographic separation followed by Multiple Reaction Monitoring (MRM) multiplex mass spectrometry. An algorithm combines the resulting biomarker relative abundances with individual clinical parameters to calculate the individualized patient risk prediction for sPTB.

PRETRM® TEST PERFORMANCE

The PreTRM test was originally developed using two large studies representative of the U.S. population: The Proteomic Assessment of Preterm Risk study (PAPR, NCT01371019) [1] and A Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor study (TREETOP, NCT02787213).[5] The PreTRM biomarkers were combined with clinical risk factors using machine learning to enhance qualitative performance on a subset of the PAPR study dataset ; this enhancement was then validated and optimized on an independent PAPR study subset with a decision threshold at approximately 2.3 times average risk.[6] The PreTRM Test algorithm uses clinical factors in its calculation. If clinical factors are missing, mean imputation may be used to account for the missing values. Clinical performance varies with different combinations of missing clinical factors. The range of performance for the PreTRM Test is 60%-62% sensitivity and 76%-78% pecificity for the intended use population. For blood drawn within 136-146 days of gestation and BMI ≥ 21 the range of clinical performance is 77% sensitivity and 73%-75% specificity. [7] The PreTRM test has been validated for frozen serum samples shipped on dry ice, and dried serum and dried whole blood shipped under ambient transport conditions. [1,8 ,9 , 10] Please contact Sera Prognostics Clinical Laboratory Support at 801-990-6600 if you have any questions or need additional information. The Technical Specifications summary, available at pretrm.com/news-resources/resources describes the analysis, test method and performance characteristics.

REFERENCES:

1. Saade GR, Boggess KA, Sullivan SA, et al. Development and validation of a spontaneous preterm delivery predictor in asymptomatic women. Am J Obstet Gynecol. 2016;214(5): 633.e1-633.e24. **2.** Martin JA, Hamilton BE, Osterman MJK, Curtin SC, Matthews TJ. Births: final data for 2013. Natl Vital Stat Rep. 2015;64(1):1-65. **3.** Institute of Medicine Committee on Understanding Premature Birth, and Assuring Healthy Outcomes. The National Academies Collection: Reports funded by National Institutes of Health. In: Behrman RE, Butler AS, eds. Preterm Birth: Causes, Consequences, and Prevention. Washington (DC): National Academies Press(US); 2007. **4.** Iams JD, Johnson FF, Sonek J, Sachs L, Gebauer C, Samuels P. Cervical competence as a continuum: a study of ultrasonographic cervical length and obstetric performance. Am J Obstet Gynecol. 1995;172(4 Pt 1):1097-1 106. **5.** Markenson GR, Saade GR, Laurent LC, et al. Performance of a proteomic preterm delivery predictor in a large independent prospective cohort. Am J Obstet Gynecol. MFM. 2020;2(3):100140. **6.** Burchard J, Polpitiya AD, Fox AC, et al. Clinical validation of a proteomic biomarker threshold for increased risk of spontaneous preterm birth. 2021 https://doi.org/10.1101/2021.01.23.21249902 **7.** Polpitiya A, Cox C, Butler H, et al. Integrating clinical factors and parity-specific models with molecular biomarkers to better predict the risk of preterm birth in asymptomatic women. medRxiv 2026:2026.03.13.26348357. DOI: 10.64898/2026.03.13.26348357. **8.** Data on file at Sera Prognostics, Inc. 1-VV-2092, Ambient Sample Transport for PreTRM - Validation Report, Salt Lake City, UT. **9.** Data on file at Sera Prognostics, Inc. 1-VV-2176 Affinity Capture Mass Spectrometry for PreTRM Validation Report, Salt Lake City, UT. **10.** Data on file at Sera Prognostics, Inc. 1-VV-2180, ACMS PreTRM Ambient Whole Blood - Verification Report, Salt Lake City, UT.

APPROVAL SIGNATURE
SALIL BHOWMIK, PHD, NRCC(CC)

DATE
MAR 27, 2026 15:46

The PreTRM® Test was developed and validated, and its performance characteristics determined by the Sera Prognostics Clinical Laboratory, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) to perform high complexity testing. This test has not been cleared or approved by the U.S. FDA.

Questions about your results? We're here for you.
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