PreTRM®
Test for Risk Management

Sera Prognostics, Inc
2749 East Parleys Way Suite 200, Salt Lake City, UT 84109
PreTRM.com / 801-990-6600

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

Predict Early

Report #: 4945

Patient: Hannah SeraTest 01

Final

Provider:

David Bennight Seratest
Address: 123 take it easy
orem, UT 84663
Phone: 1231231233 **Fax:**

DOB: December 24, 1988
Gender: F
Medical Record #:
Due Date: March 03, 2025
Height: 62in || 5' 2"
Pre-Pregnancy Weight: 130 lbs
Pre-Pregnancy BMI: 23.8

Sera ID: A24290-50000 (8573)
Reference ID: SA00000000001108
Sample Type: Whole Blood
Date/Time Collected: October 16, 2024 11:11 am
Date Received: October 16, 2024 3:33 pm MT
Date Reported: October 18, 2024 12:29 pm MT

PreTRM Test Result: Risk of Singleton Spontaneous Preterm Birth

NOT HIGHER RISK

Individual risk of spontaneous preterm birth is less than 2X general population risk

Interpretation of Results

The PreTRM test result is reported as 'Higher Risk' or 'Not Higher Risk' based upon the individualized percentage risk of spontaneous preterm birth (sPTB), calculated as a positive predictive value. A 'Higher Risk' result is assigned to patients whose individualized percentage risk of sPTB is ≥15%, approximately 2 times the average risk (7.3%) of sPTB before 37 weeks in the U.S. population of singleton pregnancies. A 'Not Higher Risk' result is assigned to patients whose individualized percentage risk of sPTB is <15%. This patient's individualized percentage risk of sPTB is ≤7.3%. 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.[Ref 3] If a patient differs clincally 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: Do you have any questions about your personal results? We are here for you.
Email us at **Support@pretrm.com** or call us at **801-990-6600**.

See Page 2 for Important Clinical Information and Technical Specifications

Sera Prognostics, Inc
2749 East Parleys Way Suite 200, Salt Lake City, UT 84109
PreTRM.com / 801-990-6600

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

Predict Early

Report #: 4945 **Sera ID:** A24290-50000 (8573) **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. [Ref 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. [Ref 3,4] Comprehensive assessment of a patient's birth history and risk factors provides limited insight, predicting only approximately 20% of subsequent sPTBs. [Ref 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

Clinical performance of the PreTRM test was validated in a blinded analysis of independent samples from a subset of patients from the Proteomic Assessment of Preterm Risk (PAPR) study (NCT01371019). [Ref 2] PAPR, a prospective clinical study that included 5,501 pregnant women broadly representative of the U.S. population, was conducted to identify proteins in maternal serum that may be predictive of preterm birth. Validated performance of the PreTRM test was achieved for unrestricted body mass index (BMI) levels, and increased predictive performance was also validated for restricted BMI in the range of >22 and ≤37. The PreTRM biomarker test result corresponding to the interpreted risk threshold of ≥15% was validated in the ACCORDANT study. [Ref 5] ACCORDANT (Clinical Validation of a Proteomic Biomarker Threshold for Increased Risk of Spontaneous Preterm Birth) utilizes subject data from the PAPR study and the TREETOP study (A Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor (TREETOP), NCT02787213). [Ref 6] The ACCORDANT analysis showed that the PreTRM biomarker threshold identified as significant in the PAPR study was also significant in the independent TREETOP cohort. A subsequent assessment of test performance at the validated threshold was performed in accordance with ACOG guidance on gestational age dating to obtain a more accurate estimate. [Ref 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. [Ref 2,8,9,10]

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 https://www.pretrm.com/news-resources/resources/, describes the analysis, test method and performance characteristics.

REFERENCES:

1. Martin JA, Hamilton BE, Osterman MJK, Curtin SC, Matthews TJ. Births: final data for 2013. Natl Vital Stat Rep. 2015;64(1):1-65. **2.** 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. **3.** Goldenberg RL, Iams JD, Mercer BM, et al. The preterm prediction study: the value of new vs standard risk factors in predicting early and all spontaneous preterm births. NICHD MFMU Network . Am J Public Health. 1998;88(2):233-238. **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- 1106. **5.** 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. **6.** 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. **7.** Burchard J, Saade GR, Boggess KA, et al. Better Estimation of Spontaneous Preterm Birth Prediction Performance through Improved Gestational Age Dating . J. Clin. Med. 2022, 11, 2885. https:// doi.org/10.3390/jcm11102885 **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.

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.

Approval Signature / Date

Salil Bhowmik, PhD, NRCC(CC) **Oct 16, 2024 13:16**