

Test Report Update

For the PreTRM Test / Update Effective 10/29/2024


Simplified Risk Level Summary:

The new report will feature a more straightforward summary of the preterm birth risk category, making it easier to communicate key findings to patients.

- The PreTRM test result is reported as “Higher Risk” or “Not Higher Risk” based upon the individualized percentage risk of spontaneous preterm birth, calculated as a positive predictive value.
- A red “Higher Risk” result is assigned to patients whose individualized percentage risk of spontaneous preterm birth is $\geq 15\%$, approximately 2 times the average risk (7.3%) of spontaneous preterm birth before 37 weeks in the U.S. population of singleton pregnancies.
- A gray “Not Higher Risk” result is assigned to patients whose individualized percentage risk of spontaneous preterm birth is $< 15\%$.

Individual Percentage Risk: The patient’s individualized percentage risk of spontaneous preterm birth will be located in the interpretation of results section.

Action Recommended for Higher Risk Results: Reports with a Higher Risk result will include an action-recommended callout encouraging patients to contact their healthcare provider to discuss their options.

 **PreTRM**[®]
Test for Risk Management

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Predict Early

Report #: 332 **Patient:** Ambient Sample Seratest

FINAL


Provider:

L SeraTest
Address: 123 Anystreet Blvd
Anytown, AK 12345
Phone: 555-555-5555 Fax: 555-555-5555

DOB: February 03, 2000
Gender: F
Medical Record #: 000000-000
Due Date: September 06, 2024
Height: 66 in. / 5' 6"
Pre-Pregnancy Weight: 146 lbs.
Pre-Pregnancy BMI: 23.6


Sera ID: A23136-50005 (1834) **Sample Type:** Serum - Ambient **Date Received:** April 5, 2023 11:11 am MT
Reference ID: 444 **Date/Time Collected:** April 5, 2023 11:11 am **Date Reported:** May 16, 2023 5:00 pm MT

PreTRM Test Result: Risk of Singleton Spontaneous Preterm Birth

 **HIGHER RISK** Individual risk of spontaneous preterm birth is greater than or equal to 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 $\geq 15\%$, 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 45%. 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.

 **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.

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
This document contains private and confidential health information protected by state and federal law. Page 1 of 2

For questions or additional support, please contact us at support@pretrm.com or 801-990-6600.