



ValidationInstitute

2021 Validation Report

Review for: Sera Prognostics
Valid through March 2022



Company Profile



Category:	Obstetrics
Website:	www.seraprognostics.com
Public or Private:	Private
Year Established:	2008
CEO:	Gregory Critchfield MD
Company contact:	Darron Segall

Description:

Sera Prognostics delivers pivotal information in early pregnancy to physicians and expectant mothers, designed to enable them to improve maternal and neonatal health and reduce healthcare costs. Sera's precision medicine PreTRM® test reports to a physician the individualized risk of premature delivery in a pregnancy, enabling earlier proactive interventions in women with higher risk. For more information, please visit the company's website at www.seraprognostics.com.

Preterm birth is defined as any birth before 37 weeks' gestation and is the leading cause of illness and death in newborns. The 2020 March of Dimes





Report Card shows that of approximately 3.8 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, and vision and hearing loss, and can generate significant costs throughout the lives of affected children. The annual US health care costs to manage complications of prematurity were estimated to be approximately \$25 billion for 2016 [2].

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 about the PreTRM® test, please visit www.PreTRM.com and the PreTRM® Test YouTube Channel. You can also join the conversation on Facebook and @PreTRM.





Claim Assertion for Validation

Over 50% of preterm births occurs in women who have no identifiable risk factors [3]. Traditional screening methods are capturing about 17% of women who will go on to deliver early [4][5].

The PreTRM® Test, in addition to traditional screening methods, can identify up to 4 to 5 times more pregnancies at higher risk for preterm birth [6]. Early data, via a published abstract at the Society for Reproductive Investigation (SRI) meeting, examined the benefit of identifying higher risk pregnancies coupled with earlier proactive interventions vs. current standard practice [7]. Data from this and other studies indicate a meaningful benefit of the PreTRM® strategy with respect to outcomes of clinical importance.

Sera Prognostics is willing to go at risk in contracting with self-funded companies with over 5000 employees who sign a deal with Sera in 2021 to offer the PreTRM® test as a benefit to employees. Sera will charge 53% up front (\$400) and collect the 47% balance of \$345 once a 10% reduction or greater in neonatal days is achieved over the course of a single year. Achieving that reduction for a single year triggers the collection for the previous three years.*

The total number of neonatal days/1000 births over a period of 1-3 years prior to the PreTRM® test implementation is the baseline.

A standard one-year pay-as-you-go contract is also available.*

*Detailed contract terms and conditions will be negotiated between Sera Prognostics and self-funded entities





Methodology/ Examples

An abstract was accepted at a leading global conference for health economics and outcomes research, ISPOR conference and will be published in early May.⁸ The manuscript was submitted to the American Journal of Managed Care and is currently under review for publication. The manuscript details a model, using real-world outcomes and cost data from >40,000 births to estimate the cost-effectiveness of a test-and-treat strategy using PreTRM[®]. Screening otherwise low-risk pregnant women with the PreTRM test, followed by standard treatment with progesterone and high-intensity case management could lower total healthcare costs and prevent preterm births. Sensitivity analyses confirmed the strategy was dominant across varied parameters (costs of treatment, cost of preterm infant care, cost of test, test performance, compliance, treatment effectiveness).



References

1. Martin JA, et al. Births: Final Data for 2019. National Vital Statistics Reports; vol 70 no 2. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: <https://dx.doi.org/10.15620/cdc:100472>
2. Waitzman NJ, et al. Preterm birth lifetime costs in the United States in 2016: An update. *Semin Perinatol.* 2021 Jan 24:151390. doi: 10.1016/j.semperi.2021.151390. Epub ahead of print. PMID: 33541716.
3. Iams, J.D. Prevention of preterm parturition. *N Engl J Med.* 2014;370:254-61.
4. Petrini JR, Callaghan WM, Klebanoff M, et al. Estimated effect of 17 alpha-hydroxyprogesterone caproate on preterm birth in the United States. *Obstet Gynecol.* 2005;105:267-72.
5. Hassan SS, Romero R, Vidyadhari D, et al. Vaginal progesterone reduces the rate of preterm birth in women with a sonographic short cervix: a multicenter, randomized, double-blind, placebo-controlled trial. *Ultrasound Obstet Gynecol.* 2011;38:18-31.
6. 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;214:633.e1-24.
7. Late Breaking Poster Session presentation at Society for Reproductive Investigation March 14, 2020. <https://www.abstractsonline.com/pp8/#!/9037/presentation/1155>
8. Michael Grabner, et al. Cost-effectiveness of a proteomic test for preterm birth prediction abstract accepted and scheduled to be published April 21, 2021 by ISPOR 2021 Conference - a leading global conference for health economics and outcomes research (HEOR)



Validation and Credibility Guarantee

Sera Prognostics has achieved a level 3 – Contractual Integrity Validation. Validation Institute is confident that **Sera Prognostics** performs as they state they are willing to provide up to a \$10,000 guarantee as part of their Credibility Guarantee Program*.

Level 1 - Savings

Can produce a reduction of health care spend including the cost of the provider. Product/solution has produced, and replicated a lower cost for healthcare overall or a specific component of healthcare

Level 2 - Outcomes

Product/solution has measurably “moved the needle” on an outcome (risk, hba1c, events, employee retention, etc.) of importance.

Level 3 - Contractual Integrity

No outcomes or savings has been shown, but vendor is willing to put a part of their fees “at risk” as a guarantee

Level 4 - Metrics

Claim is made with sourced, overridable assumptions linked to peer-reviewed or government sources





Validation Expiration: March 2022

CERTIFICATE OF VALIDATION

Applicant:

Sera Prognostics

2749 East Parleys Way, Suite 200

Salt Lake City, UT 84109

Claim:

Sera will show a reduction of 10% or higher of neonatal days

Validation Achieved:

Level 3 - Contractual Integrity Validation

Al Lewis

Senior Advisor

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Benny DiCecca

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Validation Institute





About Validation Institute

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of healthcare.

To strengthen our offering and provide additional credibility around our service, the **Validation Institute** recently announced a Credibility Guarantee* that offers customers of validated solution providers up to a \$25,000 guarantee. This guarantee confirms that a validated solution provider will, achieve what the validation language on a marketing claim says it will achieve.

