PartoSure™

Literature Summary

Sample to Insight

New clinical data from the US

Placental alpha microglobulin-1 compared with fetal fibronectin to predict preterm delivery in symptomatic women (1)

Wing et al. (2017) Obstet Gynecol. 130, 1183-91.

Objective: A prospective U.S. multi-center trial conducted at 15 university and community hospitals comparing PartoSure and the Rapid fFN test* for the prediction of imminent spontaneous preterm delivery (sPTD) within 7 and 14 days from time of testing.

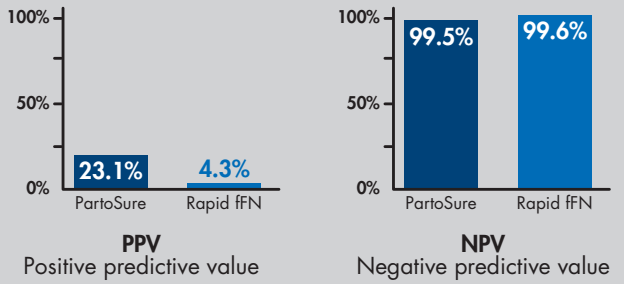
Study population: N: 635, GA: 24-34$^{6/7}$ weeks

PartoSure Results:

≤ 7 Days: PPV: 23.1% | NPV: 99.5%

≤ 14 Days: PPV: 30.8% | NPV: 98.6%

Prediction of sPTD ≤ 7 days among singleton patients exhibiting symptoms of PTL



Findings: In women with symptoms of preterm labor (PTL), the PPV for preterm delivery within 7 days was shown to be 5-fold higher for PartoSure compared to the detection of fFN.

Trusted results in Europe

Predictive performance of PAMG-1 vs fFN test for risk of spontaneous preterm birth in symptomatic women attending an emergency obstetric unit: retrospective cohort study (2)

Melchor et al. Ultrasound Obstet Gynecol. (2017) 18892.

Objective: Retrospective audit of two time periods, calendar years 2012 and 2016, to determine the effectiveness of the PartoSure vs the detection of QuikCheck fFN** in patients presenting to the hospital with signs and symptoms of PTL for prediction of delivery within 7 or 14 days from time of testing.

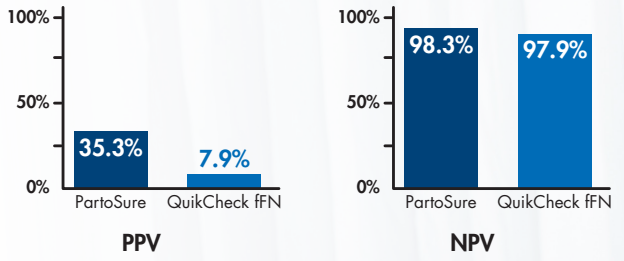
Study population: N: 745, GA: 24-34$^{6/7}$ weeks

PartoSure Results:

≤ 7 Days: PPV: 35.3% | NPV: 98.3%

≤ 14 Days: PPV: 41.2% | NPV: 97.1%

Prediction of sPTD ≤ 7 days among singleton patients exhibiting symptoms of PTL



Findings: PartoSure was found to be over 4 times more reliable in predicting sPTD than using fFN detection. With fewer false positives PartoSure maybe be valuable in improved classification of patients requiring intervention, allowing for a potential reduction in unnecessary admissions, avoidable treatments and hospital resources.

*FDA-approved. **CE-marked.

Preterm labor and birth management: recommendations from the European Association of Perinatal Medicine (3)

Di Renzo et al. (2017) J Matern Fetal Neonatal Med. 30, 2011-30.

Objective: The European Association of Perinatal Medicine (EAPM) developed these guidelines based on recent evidence as adapted to a European perspective of the challenge of PTL and birth management.

Findings: In symptomatic women, biomarker measurement in cervicovaginal secretions is one proposed method of increasing the accuracy of cervical length (CL) measurement alone. Publications have observed that when used in combination, the diagnosis of PTL and prediction of spontaneous preterm delivery is improved.

In asymptomatic women, when the CL is between 15-30 mm, CL has the lowest predictive value. In these cases, the EAPM recommends combining the measurement with the biomarker test exhibiting the highest NPV and PPV which can be given shortly after a vaginal examination. In Europe, according to published data, this would be PartoSure.

Clinical symptoms alone are not enough to predict imminent spontaneous delivery in symptomatic women

The combined value of PAMG-1 detection and cervical length via transvaginal ultrasound in the diagnosis of preterm labor in symptomatic patients (4)

Bolotskikh et al. (2017) J Obstet Gynaecol Res. 43, 1263-69.

Objective: Prospective trial to assess the performance of PartoSure in combination with CL measurement via transvaginal ultrasound for prediction of delivery within 7 and 14 days of testing patients presenting with symptoms of PTL.

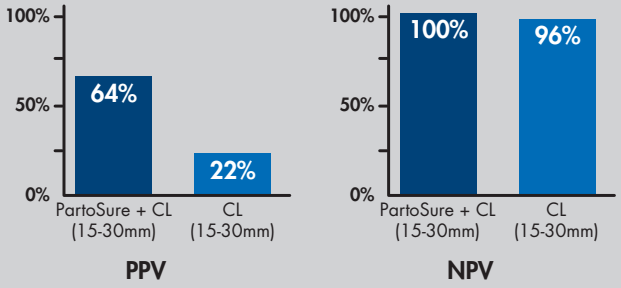
Study population: N: 99, GA: 22-36$^{6/7}$ weeks

PartoSure Results:

≤ 7 Days: PPV: 75% | NPV: 100%

≤ 14 Days: PPV: 88% | NPV: 100%

Prediction of sPTD ≤ 7 days among singleton patients exhibiting symptoms of PTL



Findings: When used in combination with CL of 15-30 mm, PartoSure is highly predictive of imminent sPTD in women presenting with threatened PTL. As a combined assessment, PartoSure and CL was a more accurate identification of those at high risk of delivery, reducing unnecessary admissions and treatments.

Comparison of the effectiveness of a PAMG-1 test and standard clinical assessment in the prediction of preterm birth and reduction of unnecessary hospital admissions (5)

Lotfi et al. (2017) J Matern Fetal Neonatal Med.

Objective: Prospective trial to assess the performance of PartoSure vs standard clinical assessment (SCA) for the risk assessment of sPTD within 7 and 14 days of testing patients who present with symptoms of PTL.

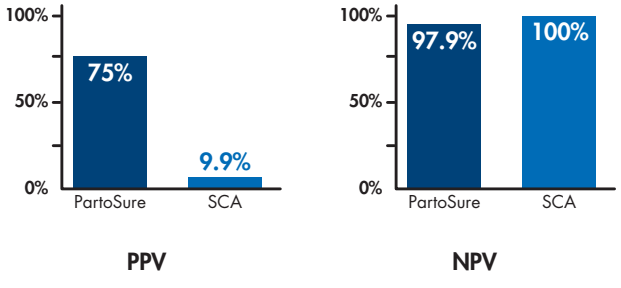
Study population: N: 132, GA: 24-36$^{6/7}$ weeks

PartoSure Results:

≤ 7 Days: PPV: 75% | NPV: 97.9%

≤ 14 Days: PPV: 87.5% | NPV: 95.7%

Prediction of sPTD ≤ 7 days among singleton patients exhibiting symptoms of PTL



Findings: Study results show in the prediction of sPTD within 7 and 14 days PartoSure had a higher PPV than SCA alone (≤14 data for SCA not shown here). Based on data presented, 91% of admissions could have been avoided if the PartoSure results had been used in combination with clinical assessment.

Published data on digital examination and PartoSure

Preterm labor: Reproducibility of detection test of PAMG-1 before and after digital examination, and transvaginal cervical length (6)

Werlen et al. (2015) Gynecol Obstet Fertil. 43, 640-5.

Objective: Prospective, observational study to assess if PartoSure could be used after vaginal examinations, such as digital examination and cervical length measurement via transvaginal ultrasound.

Study population: N: 41, GA: 24-34 weeks

Findings: 100% of test results remain negative or positive after digital examination and 95.1% after transvaginal ultrasound. These findings indicate the performance of a digital examination prior to specimen collection does not affect PartoSure test results.*

PartoSure vs detection of fFN

Comparison of a novel test for placental alpha microglobulin-1 with fetal fibronectin and cervical length measurement for the prediction of imminent spontaneous preterm delivery in patients with threatened preterm labor (7)

Nikolova et al. (2015) J Perinat Med. 43, 395-402.

Objective: Prospective trial comparing PartoSure to both detection of fFN and cervical length measurement for the prediction of delivery within 7 and 14 days of testing patients presenting with symptoms of PTL. Additionally, the combination of each biomarker test alongside CL measurement was studied.

Study population: N: 203 (fFN 66), GA: 20-36$^{6/7}$ weeks

PartoSure Results:

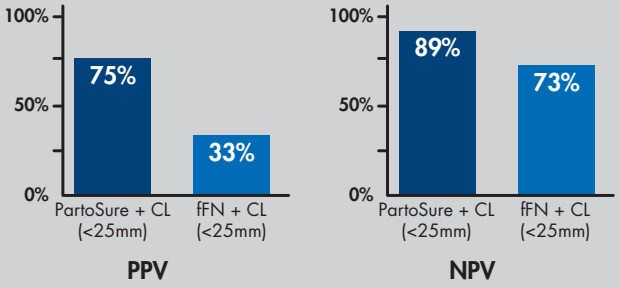
≤ 7 Days: PPV: 76% | NPV: 96%

≤ 14 Days: PPV: 81% | NPV: 89%

Performance of testing methods for sPTD ≤ 7 Days in singleton patients

Testing method	SN	SP	PPV	NPV
PartoSure	80	95	76	96
QuikCheck fFN	50	72	29	87
CL (<25 mm)	57	73	30	89

Prediction of sPTD ≤ 7 days among singleton patients exhibiting symptoms of PTL



Findings: Study results found that among these three methods PartoSure shows the highest sensitivity, specificity, PPV and NPV. When CL is least accurate (between 15-30 mm), the PPV and NPV were the highest when the combination of PartoSure and CL measurement was utilized.

*The FDA-approved PartoSure product requires collection prior to digital examination.

Reducing unnecessary interventions may lead to decreased costs

Placental Alpha Microglobulin-1 in combination with transvaginal ultrasound for prediction of preterm birth (8)

Heverhagen et al. (2015) Perinat Med 43 (S1), 240

Objective: Prospective trial to assess the performance of PartoSure in combination with cervical length measurement via transvaginal ultrasound for prediction of sPTD.

Study population: N: 64, GA: 24-37$^{6/7}$ weeks

PartoSure Results:

≤ 7 Days: PPV: 100% | NPV: 94%

9% of symptomatic patients delivered within 7 days

83% were hospitalized

75% received corticosteroids

59% received tocolytic therapy

Findings: When used alongside CL measurement (N: 31) the PartoSure test had a PPV of 100% and NPV of 97%. Additionally, the investigators found a high rate of unnecessary use of corticosteroids, tocolytics and hospitalization. Utilizing a method with a high PPV may reduce costs and improve patient safety and this study proposed one opportunity could be the combined use of CL measurement and PartoSure.

Utilization of a novel biomarker test (PartoSure PAMG-1) to reduce the length of stay in patients with threatened preterm labor and a short cervix (9)

Fatkullin et al. (2016) Am J Obstet Gynecol 29 (S1), 283.

Objective: Prospective, observational trial to evaluate PartoSure as a tool to decrease length of hospitalization for patients presenting with a short cervix and signs and symptoms of sPTD. Admission and treatment were done according to local guidelines based on CL ≥ 25 mm.

Study population: N: 45, GA: 24-34$^{6/7}$ weeks

PartoSure Results:

≤ 7 Days: PPV: 60% | NPV: 100%

The average length of stay was **8.4 days**

53% of the patients were admitted

70% of admitted patients received corticosteroid therapy

100% received tocolytic therapy

8% received antibiotics

None of them delivered within 7 days

Findings: A negative PartoSure test in combination with clinical assessment can decrease unnecessary admissions and acute interventions, reduce the length of stay and minimize unnecessary treatment.

Publication Summary Table

Publication summary for studies that examined the predictive performance of PartoSure for sPTD within 7 days in patients with signs and symptoms of PTL. Studies are further classified based on the prevalence of sPTD within 7 days. Higher risk groups were classified as such due to the lower risk patients being screened out by initial procedural CL measurement.

Study	Population	Year	N	Prevalence of sPTD	PPV	NPV
Low Risk (≤5%)						
Wing et al.[1]	US	2017	635	2%	23%	99%
Melchor et al.[2]	Europe	2017	745	3%	35%	98%
Ravi et al.[10]	Middle East	2017	72	4%†	40%	99%
Intermediate Risk (5-15%)						
Fatkullin et al.*[9]	Europe	2016	45	7%	60%	100%
Nikolova et al.[11]	Europe	2017	328	8%	60%	98%
Lotfi et al.[5]	Middle East	2017	148	9%	75%	98%
Heverhagen, A.*[8]	Europe	2015	64	9%	100%	94%
Lou et al.[13]	Europe	2016	65	9%	100%	100%
Konoplyannikov et al.*[13]	Europe	2016	71	11%	55%	97%
Hadzi-Lega et al.[14]	Europe	2017	57	11%	50%	98%
Bolotskikh et al.[4]	Europe	2017	99	12%	75%	100%
High Risk (≥15%)						
Nikolova et al.[7]	Europe	2015	203	17%	76%	96%
Nikolova et al.[15]	Europe	2014	101	20%	78%	97%

*PartoSure test taken alongside CL measurement

Notes

The PartoSure Test is intended for *in vitro* diagnostic use.

References:

1. Wing et al. (2017) Placental Alpha Microglobulin-1 compared with fetal fibronectin to predict preterm delivery in symptomatic women. Obstet Gynecol. 130, 1183-91.
2. Melchor et al. (2017) Predictive performance of PAMG-1 vs fFN test for risk of spontaneous preterm birth in symptomatic women attending an emergency obstetric unit: retrospective cohort study. Ultrasound Obstet Gynecol. doi: 10.1002/uog.18892. [Epub ahead of print].
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13. Konoplyannikov, A., Lysyuk, I., Sokolyan, N., Pipia, N., Apresyan, S., Karasova, A. (2016) PAMG-1 biomarker test (PARTOSURE) in combination with transvaginal ultrasound for improved assessment of spontaneous preterm birth in patients with threatened preterm labor. J Matern Fetal Neonatal Med. 29(S1), 278.
14. Hadzi-Lega, M., Maier, J.T., Helmer, H., Hellmeyer, L., Markova, A.D., Poposka, A. (2017) Comparison of PAMG-1 and phIGFBP-1 tests for the prediction of preterm delivery in patients with preterm labor. Open Journal of Obstetrics and Gynecology. 7, 358-68.
15. Nikolova, T., Bayev, O., Nikolova, N., Di Renzo, G.C. (2014) Evaluation of a novel placental alpha microglobulin-1 (PAMG-1) test to predict spontaneous preterm delivery. J Perinat Med. 42, 473-7.

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