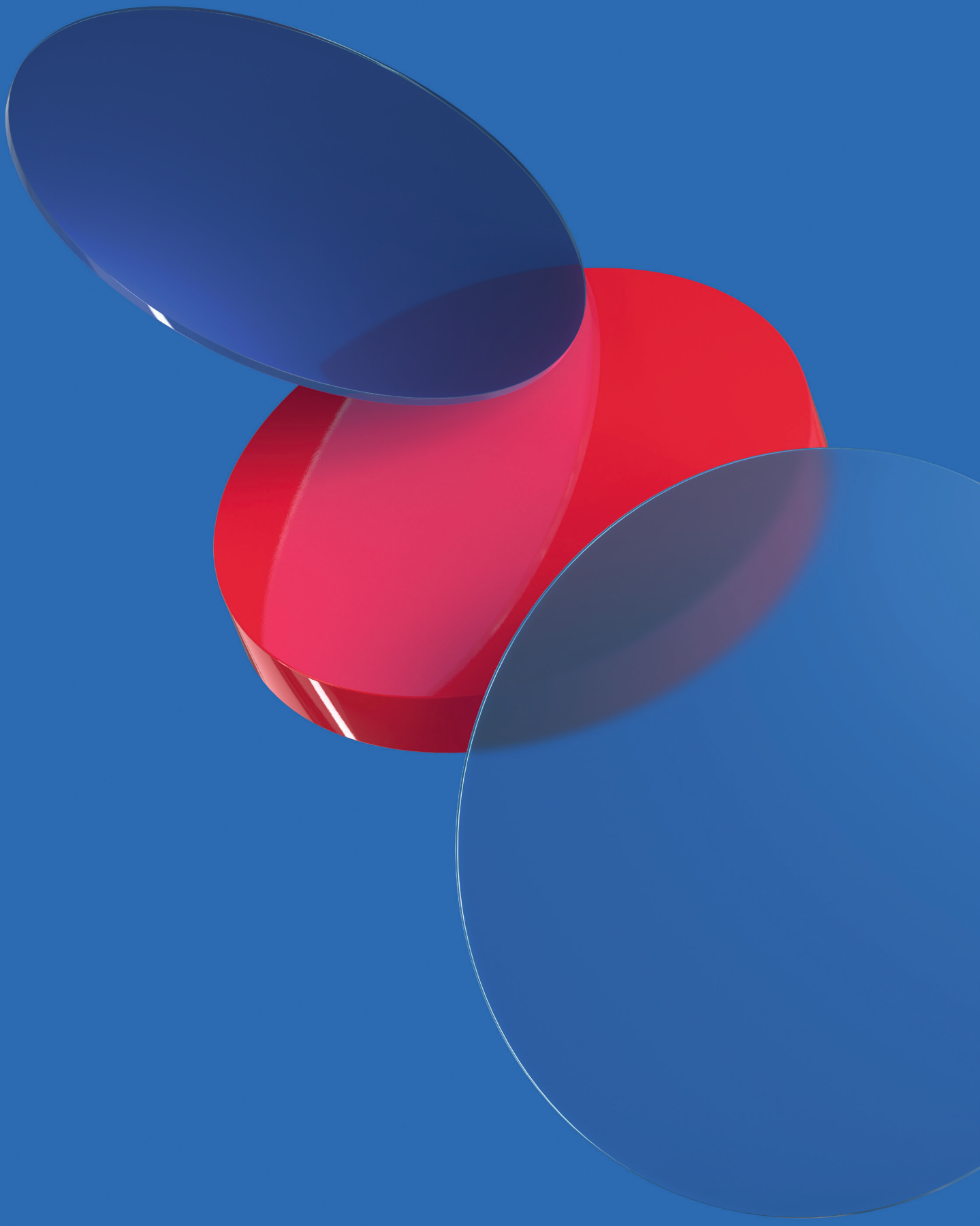
PartoSure®

Rapid, reliable prediction of spontaneous preterm birth

Literature review

Sample to Insight



Literature review summary

Accuracy of PAMG-1 immunoassay (PartoSure Test) to aid in prediction of spontaneous preterm birth

Study authors	Year	Number of women	PPV (%)	NPV (%)
Low risk (≤5%) or cervical length >3.0 cm				
Melchor JC, et al.	2018	367	35	98
Ravi M, et al.	2018	72	40	99
Wing DA, et al.	2017	635	23	100
Intermediate risk (5–15%) or cervical length 1.5–3.0 cm				
Konoplyannikov AG, et al.	2022	137	64	–
Nikolova T, et al.	2018	328	61	97
Bolotskikh V, et al.	2017	99	75	100
Lotfi G, et al.	2017	148	75	98
Fatkullin I, et al.	2016	45	60	100
Van Holsbeke C, et al.	2016	50	75	96
Haverhagen A, et al.	2015	64	100	94
High risk (≥15%) or cervical length <1.5 cm				
Nikolova T, et al.	2015	203	76	96
Chawanpaiboon S, et al.	2021	14	83	81

The table above includes performance metrics from published independent research involving the PartoSure Test used on patients presenting with suspicion of preterm labor and intact fetal membranes in accordance with the package insert. Study details follow.

Accuracy predict preterm labor with PartoSure and cervical length measurement

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

Nikolova T, et al. *J Perinat Med.* 2015;43(4):395–402.

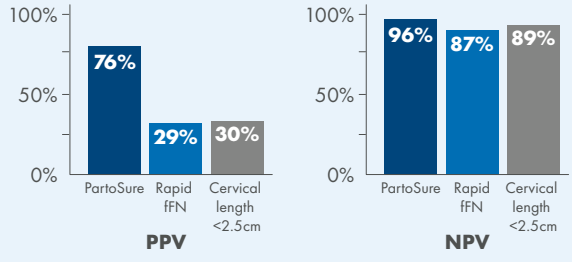
Objective: Prospective trial comparing PartoSure with detection of fFN and cervical length measurement to predict PTD within 7 and 14 days of testing in women presenting with symptoms of PTL. Additionally, the combination of each biomarker test with cervical length measurement was studied.

Study population: Range of GA: 20–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=203).

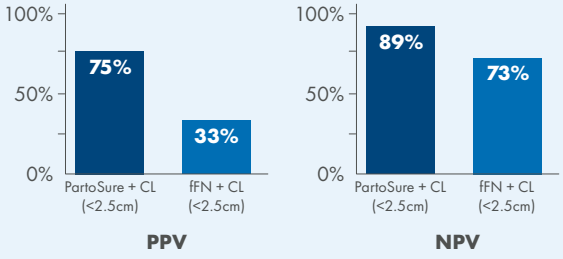
Results: ≤7 Days: PPV: 76% | NPV: 96%
≤14 Days: PPV: 81% | NPV: 89%

Findings: Among the three methods investigated, PartoSure showed the highest sensitivity, specificity, PPV and NPV. When cervical length measurement was least accurate in predicting PTL (e.g., between 1.5–3.0 cm), the PPV and NPV were highest when PartoSure testing was combined with cervical length measurement.

Comparison of positive predictive value and negative predictive value for delivery within 7 days based on results of the PartoSure test, fFN assay (QuikCheck™ fFN Test), or cervical length <2.5 cm.



Prediction of spontaneous preterm delivery ≤7 days among singleton women exhibiting symptoms of preterm labor when the biomarker test was combined with cervical length measurement of <2.5 cm.



Combined value of placental alpha macroglobulin-1 detection and cervical length via transvaginal ultrasound in the diagnosis of preterm labor in symptomatic patients

Bolotskikh V, Borisova V. *J Obstet Gynaecol Res.* 2017;43(8):1263–1269.

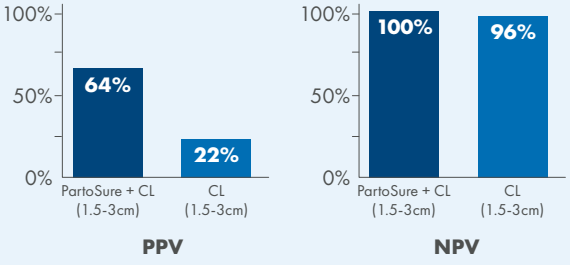
Objective: Prospective trial to assess the performance of PartoSure in combination with cervical length measurement via transvaginal ultrasound for predicting delivery within 7 and 14 days of testing in women with symptoms of PTL.

Study population: Range for GA: 22–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=99).

Results:
≤7 Days: PPV: 75% | NPV: 100%
≤14 Days: PPV: 88% | NPV: 100%

Findings: When used in combination with a cervical length of 1.5–3.0 cm, PartoSure is highly predictive of imminent sPTD in women presenting with threatened PTL. As a combined assessment, PartoSure and cervical length can accurately identify women at high risk of delivery, helping to reduce unnecessary admissions and treatments.

Prediction of spontaneous preterm delivery ≤7 days among singleton women with symptoms of preterm labor tested with PartoSure and/or cervical length measurement.



Placental alpha microglobulin-1 in cervicovaginal fluid and cervical length to predict preterm birth by Thai women with symptoms of labor

Chawanpaiboon S, et al. *Asian Biomed.* 2021;15(3):119–127.

Objective: To assess whether consideration of cervical length can improve the accuracy of PAMG-1 testing to predict preterm birth.

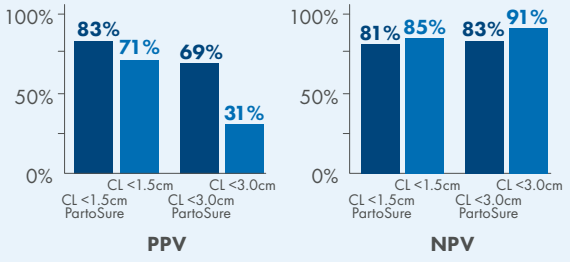
Study design: Prospective observational study

Study population: Pregnant women at 20–37 weeks gestational age with signs of preterm labor, cervical dilatation <3cm and effacement <80% (n=161).

Results:
≤7 Days: PPV 83% (CL <15 mm) | NPV 81% (CL < 15mm)
≤14 Days: PPV 83% (CL <15 mm) | NPV 74% (CL < 15mm)

Findings: PartoSure in combination with cervical length of 1.5–3.0 cm was highly accurate in predicting spontaneous preterm birth within 7 days compared to PartoSure or cervical length measurement alone.

Comparison of positive predictive value and negative predictive value of spontaneous preterm birth within 7 days based on results of cervical length <1.5 cm or <3.0 cm, or PartoSure in combination with cervical length <1.5 cm or <3.0 cm.



Combination of the placental alpha-1 microglobulin test and ultrasonic cervical length measurement to predict the time of preterm birth

Konoplyannikov AG, et al. *J Matern Fetal Neonatal Med.* 2022;35(3):541–545.

Objective: To compare the effectiveness of PAMG-1 testing in combination with cervical length measurement versus cervical length measurement alone in predicting the time of labor onset.

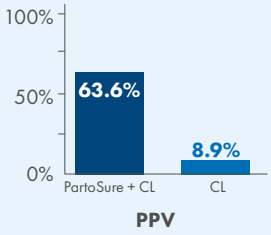
Study design: Prospective observational study.

Study population: Pregnant women at 22–37 weeks gestational age with signs of preterm labor and ultrasound cervical length measurement between 15–30 mm (n=137).

Results: PartoSure combined with cervical length 15–30 mm has a PPV for pre-term birth within 7–14 days of 63.6%.

Findings: PartoSure in combination with cervical length measurement showed a >7-fold higher PPV for spontaneous preterm birth within 7–14 days compared to cervical length measurement alone.

Prediction of spontaneous preterm birth within 7–14 days among women with signs of preterm labor and cervical length 15–30 mm with or without PartoSure.



PartoSure accuracy compared with assessments that do not include biomarkers

Preterm labor: reproducibility of detection test of PAMG-1 before and after digital examination, and transvaginal cervical length

Werlen, S. et al. *Gynecol Obstet Fertil.* 2015;43:640–645.

Objective: Prospective, observational study to assess if PartoSure could be used with similar accuracy after digital vaginal examination or cervical length measurement via transvaginal ultrasound.

Study population: Range of GA: 24–34 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=41).

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

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

Lotfi, G. et al. *J. Matern Fetal Neonatal Med.* 2017;32,793–797.

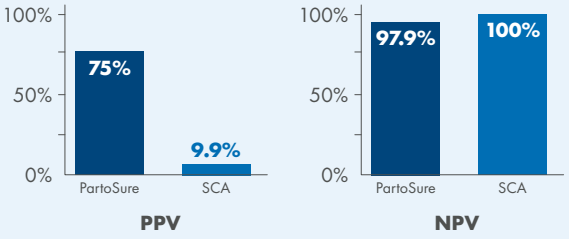
Objective: Prospective trial to assess the performance of PartoSure compared with standard clinical assessment for the risk assessment of PTD within 7 and 14 days of testing in women who present with symptoms of PTL.

Study population: Range of GA: 24–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=132).

Results:
≤7 Days: PPV: 75% | NPV: 97.9%
≤14 Days: PPV: 87.5% | NPV: 95.7%

Findings: PartoSure had a higher PPV than standard clinical assessment alone for predicting sPTD within 7 and 14 days. Based on data presented, up to 91% of all admissions could have been avoided if PartoSure had been used in combination with clinical assessment.

Prediction of spontaneous preterm delivery ≤7 days among singleton women with symptoms of preterm labor tested with PartoSure or standard clinical assessment.



Comparison with other commercially available biomarker tests

Comparison of the fetal fibronectin and placental alpha microglobulin-1 tests for predicting imminent spontaneous preterm birth

Van Holsbeke, C. et al. *Ultrasound Obstet Gynecol.* 2016;48(S1):84.

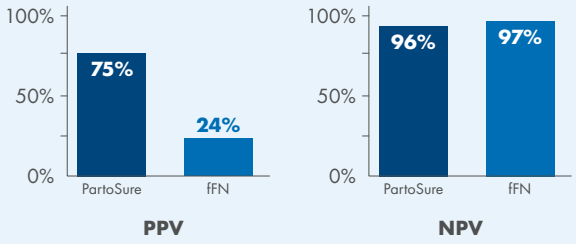
Objective: Interim analysis of a prospective trial that compared PartoSure or fFN testing alongside cervical length measurement to predict sPTD within 7 and 14 days of testing.

Study population: Range of GA: 22–34 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=50).

Results: ≤7 Days: PPV: 75% | NPV: 96%

Findings: When PartoSure or fFN tests were used alongside cervical length measurement, PartoSure was more accurate, with respect to PPV, than the fFN test at predicting PTD in symptomatic women. Data suggest unnecessary admissions and drug administration may be reduced by up to 71% with PartoSure and cervical length measurement.

Performance of PartoSure and fFN testing combined with cervical length measurement for spontaneous preterm delivery ≤7 days in singleton women. with cervical length measurement of <2.5 cm.



Placental alpha macroglobulin-1 compared with fetal fibronectin to predict preterm delivery in symptomatic women

Wing DA, et al. *Obstet Gynecol.* 2017;130(6):1183–1191

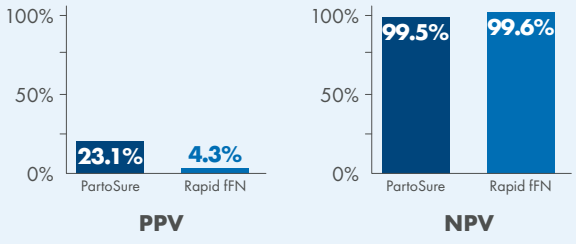
Objective: A prospective U.S. multi-center trial conducted at 15 university and community hospitals comparing PartoSure with detection of fetal fibronectin (fFN) at a cut-off of 50 ng/mL for the prediction of imminent spontaneous preterm delivery (sPTD) within 7 and 14 days from time of testing.

Study population: Range for gestational age (GA): 24–34 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=635).

Results:
≤7 Days: PPV: 23.1% | NPV: 99.5%
≤14 Days: PPV: 30.8% | NPV: 98.6%

Findings: The PPV for preterm delivery (PTD) within 7 days was over 5-fold higher with PartoSure compared with fFN testing.

Prediction of spontaneous preterm birth ≤7 days among women with symptoms of preterm labor tested with PartoSure or fFN testing (Rapid fFN test).



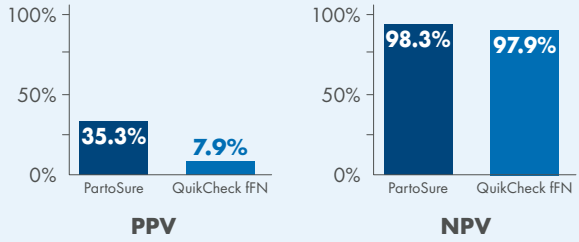
Predictive performance of PAMG-1 vs fFN test for risk of spontaneous preterm birth in symptomatic women attending an emergency obstetrical unit: retrospective cohort study

Melchor, J.C. et al. *Ultrasound Obstet Gynecol.* 2018;51(5):644–649.

Objective: Retrospective audit of data from 2016 and 2012 to predict PTD within 7 or 14 days of testing in women presenting at hospital with signs and symptoms of PTL. Testing in 2016 utilized PartoSure while testing in 2012 was performed using the QuikCheck fFN Test and a cut-off of 50 ng/mL.

Study population: Range for GA: 24–34 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=745).

Prediction of spontaneous preterm birth ≤7 days among women with symptoms of preterm labor tested with PartoSure or QuikCheck fFN Test.



Results:

≤7 Days: PPV: 35.3% | NPV: 98.3%

≤14 Days: PPV: 41.2% | NPV: 97.1%

Retrospective European study comparing PartoSure and the QuikCheck fFN Test on predicting preterm labor

	PartoSure test	QuikCheck fFN test
Calendar year evaluated	2016	2012
Evaluable subjects	367	378
GA at testing-weeks (mean±SD)	30.52±2.98	30.41±2.88
Prevalence of sPTD ≤7 days, % (n)	3.3 (12/367)	2.6 (10/378)
Positive test % (n)	4.6 (17/367)	10.1 (38/378)
False positive test % (n)	3.1 (11/355)	9.5 (35/368)

Findings: PartoSure was found to be over 4 times more reliable in predicting sPTD than fFN detection. With fewer false positive results, PartoSure was better able to identify women requiring intervention, allowing for potential reductions in unnecessary admissions, avoidable treatments and use of hospital resources.

Evaluation of the quantitative fetal fibronectin test and PAMG-1 test for the prediction of spontaneous preterm birth in patients with signs and symptoms suggestive of preterm labor

Ravi M, et al. *J Matern Fetal Neonatal Med.* 2018;32(23):3909–3914.

Objective: Comparison of qualitative fFN testing at a range of different threshold concentrations with the PartoSure Test in ability to assess risk of imminent sPTD in women with symptoms of PTL in the United Arab Emirates.

Study population: Range for GA: 23–34 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=72).

Results:
≤7 Days: PPV: 40.0% | NPV: 98.5%
≤14 Days: PPV: 40.0% | NPV: 96.3%

Accuracy of PartoSure versus fFN testing at different threshold values in women presenting with signs and symptoms of preterm labor

	PartoSure test	fFN test*			
		10 ng/mL	50 ng/mL	200 ng/mL	500 ng/mL
Sensitivity, % (95% CI)	66.67 (9.43–99.16)	66.67 (9.43–99.16)	66.67 (9.43–99.16)	33.33 (0.84–90.57)	0.00 (0.00–0.76)
Specificity, % (95% CI)	95.65 (87.82–99.09)	57.97 (45.48–69.76)	76.81 (65.09–86.13)	92.75 (83.80–97.61)	97.10 (89.92–99.65)
PPV, % (95% CI)	40.00 (5.27–85.34)	6.45 (0.79–21.42)	11.11 (1.38–34.71)	16.67 (0.42–64.12)	0.00 (0.00–84.19)
NPV, % (95% CI)	98.51 (91.96–99.96)	97.56 (87.14–99.94)	98.15 (90.11–99.95)	96.97 (89.48–99.63)	95.71 (87.98–99.11)
Positive likelihood ratio	15.33 (3.91–60.08)	1.59 (0.68–3.70)	2.87 (1.16–7.13)	4.60 (0.75–28.09)	Not available
Negative likelihood ratio	0.35 (0.07–1.73)	0.58 (0.11–2.88)	0.43 (0.09–2.16)	0.72 (0.32–1.60)	1.03 (0.99–1.07)

Values highlighted in blue indicate a statistically significant difference ($p<0.05$) in predicting spontaneous birth within 7 days of testing for PartoSure compared with fFN testing.
* fFN test not specified

Findings: PartoSure can be used to more accurately predict PTL than fFN even when different concentrations of fFN are used as the cut-off for a positive test. Use of PartoSure rather than fFN could lead to a reduction in the number of false positive results and hence unnecessary admissions, transfers or treatments like tocolysis or induction of lung maturation.

Prediction of spontaneous preterm delivery in women presenting with premature labor: a comparison of placenta alpha microglobulin-1, phosphorylated insulin-like growth factor binding protein-1, and cervical length

Nikolova T, et al. *Am J Obstet Gynecol.* 2018;219(6):610.e1–610.e9.

Objective: PartoSure was compared with a phosphorylated insulin-like growth factor-binding protein-1 (phIGFBP-1) test (Actim Partus) alone or in combination with transvaginal cervical length measurement in women presenting with signs and symptoms of PTL in tertiary care settings in Finland, Republic of Macedonia, and Russia.

Study population: Range for GA: 20–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded (n=403).

Results: ≤7 Days*: PPV: 60.9% | NPV: 97.7%
≤14 Days*: PPV: 70.0% | NPV: 94.9%
*when cervical length<2.5 cm

Table 4: Accuracy of PartoSure versus Actim Partus phIGFBP-1 testing in women presenting with signs and symptoms of preterm labor and a cervical length of 1.5–3.0 cm

	PartoSure test	Actim Partus phIGFBP-1 test
Sensitivity, % (95% CI)	73.7 (48.8–90.9)	84.2 (60.4–96.6)
Specificity, % (95% CI)	94.9 (90.6–97.7)	76.8 (69.9–82.8)
PPV, % (95% CI)	60.9 (43.8–75.6)	28.1 (21.9–35.2)
NPV, % (95% CI)	97.1 (94.1–98.6)	97.8 (94.1–99.2)
Positive likelihood ratio	14.5 (7.3–28.9)	3.6 (2.6–5.1)
Negative likelihood ratio	0.3 (0.1–0.6)	0.2 (0.1–0.6)

Values highlighted in blue indicate a statistically significant difference ($p<0.05$) in predicting spontaneous preterm birth ≤7 days of testing for PartoSure compared with Actim Partus testing.

Findings: The PPV for PartoSure was 3.2 times that of Actim Partus while maintaining a similar NPV in women with a cervical length of 1.5–3.0 cm and hence at highest risk of PTL. PartoSure is therefore a better predictor of imminent spontaneous PTD than Actim Partus, either alone or in combination with cervical length measurement.

Prediction of preterm delivery in symptomatic women using PAMG-1, fetal fibronectin and phIGFBP-1 tests: systematic review and meta-analysis

Melchor, J.C. et al. *Ultrasound Obstet Gynecol.* 2018;52:442–451.

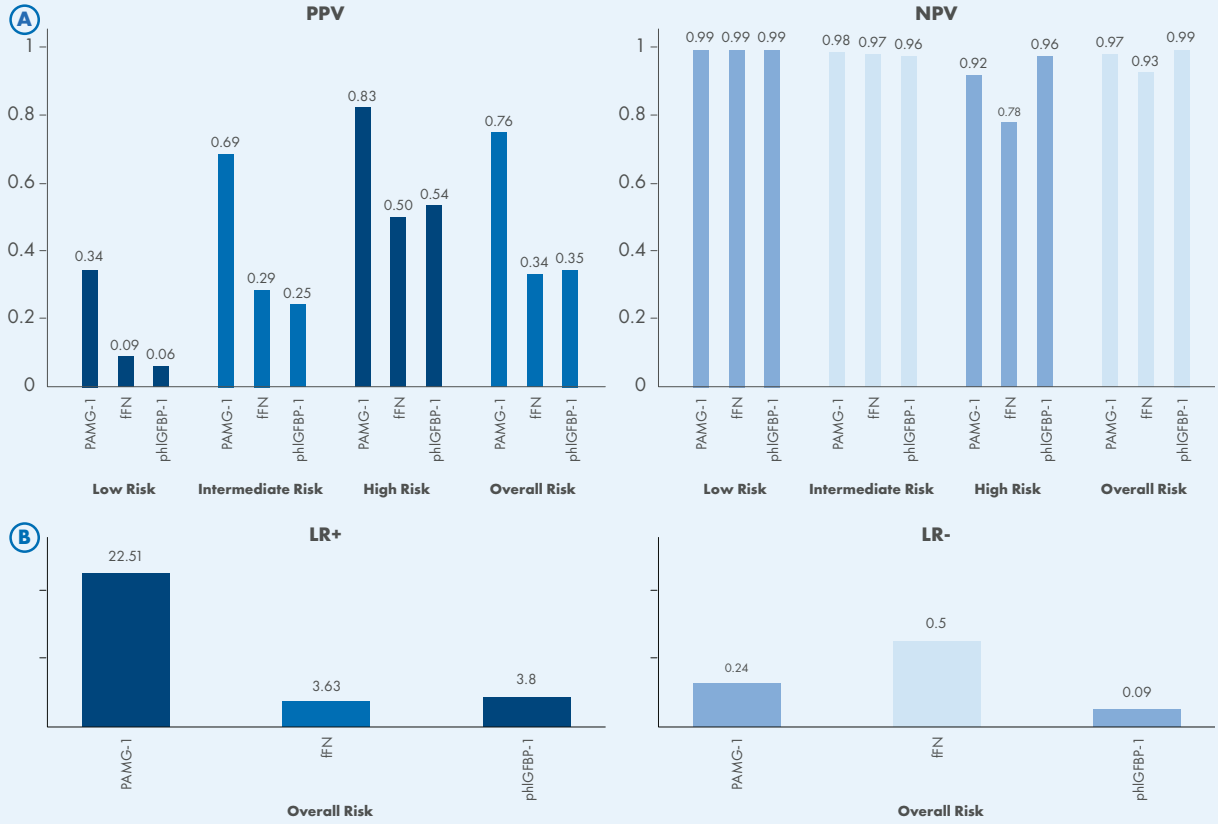
Objective: Systematic review, meta-analysis and database search of published records from inception until October 2017 for the prediction of PTD within 7 days of testing in women with symptoms of PTL.

Study population: Data were extracted from 65 articles, which included 14 for PartoSure, 40 for fFN and 22 for phIGFBP-1 testing.

Results: ≤7 Days: PPV*: 76.0% | NPV: 97.0%

* PPV overall and not categorised for risk based on cervical length measurement

Summary estimates for prediction of preterm birth within 7 days of testing using PartoSure, fetal fibronectin (fFN) and phosphorylated insulin-like growth factor-binding protein-1 (phIGFBP-1) biomarker tests according to risk group. (A) Positive and negative predictive values; (B) Likelihood ratio (LR) for positive and negative test.



Predictive accuracy for spontaneous preterm delivery in symptomatic women within 7 days of testing (AUC from receiver-operating characteristics curves) and positivity rate for PartoSure, fFN and phIGFBP-1 tests

	PartoSure test	fFN test	phIGFBP-1 test
Area under the curve (AUC)	0.961	0.874	0.801
Positivity rate, %	7.9	23.0	29.7

Findings: This search of published records until October 2017 indicated the PPV for PartoSure was significantly higher than that of fFN or phIGFBP-1 testing. This was also true for other diagnostic accuracy measures such as NPV, positive likelihood ratio (LR+) and negative likelihood ratio (LR–). The sensitivity to specificity ratio was also higher with PartoSure compared with fFN or phIGFBP-1 tests.

Evidence from additional publications

While the meta-analysis performed by Melchor et al is particularly valuable for its comparison of PAMG-1 with other biomarkers, there are additional meta-analyses that review PAMG-1 performance across multiple studies and provide further support for its use as an accurate predictor of preterm birth.

Methods of detection and prevention of preterm labour and the PAMG-1 detection test: a review

Dochez V, et al. *J Perinat Med.* 2020;49(2): 119–126.

Conclusion

Based on review of 10 independent published studies, PAMG-1 is concluded to be a biomarker that may help identify those women with signs of preterm labor and shortened cervical length who are imminently likely to deliver, enabling adaptive management of antenatal corticosteroid therapy.

Placental alpha microglobulin-1 (PartoSure) test for the prediction of preterm birth: a systematic review and meta-analysis

Pirjani R, et al. *J Matern Fetal Neonatal Med.* 2021;34(20):3445–3457.

Conclusion

Based on review of 15 independent published studies, positive likelihood ratio (LR+) and negative (LR-) for PAMG-1 were calculated to be 15.26 and 0.31 respectively for prediction of delivery by symptomatic women within 7 days. Based on review of 10 independent published studies, LR+ and LR- were calculated to be 16.72 and 0.42 respectively for prediction of delivery within 14 days. The authors concluded that PAMG-1 (PartoSure) is highly accurate at predicting preterm birth within 7–14 days in symptomatic women.

A diagnostic profile on the PartoSure test

Rouholamin S, et al. *Expert Rev Mol Diagn.* 2020;20(12):1163–1170.

Conclusion

Building on the analysis of Pirjani et al, based on review of 21 independent published studies, LR+ and LR- for PAMG-1 were calculated to be 12.64 and 0.35 respectively for prediction of delivery by symptomatic women within 7 days. Based on review of 13 independent published studies, LR+ and LR- were calculated to be 11.71 and 0.45 respectively for prediction of delivery within 14 days. The authors concluded that PartoSure shows higher accuracy over other methods at predicting preterm birth within 7–14 days in symptomatic women, and should be part of the clinical evaluation.

Impact on antenatal corticosteroid administration

The use of PAMG-1 testing in patients with preterm labor, intact membranes and a short sonographic cervix reduces the rate of unnecessary antenatal glucocorticoid administration

Kehl S, et al. *J Perinat Med.* 2021;49(9):1135–1140.

Objective: To evaluate the rate of antenatal corticosteroid (ACS) treatment administered with and without the use of PAMG-1 testing.

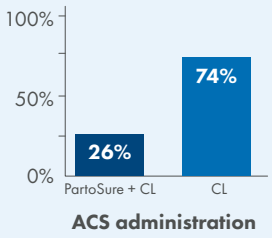
Study design: Retrospective analysis

Study population: Pregnant women with and without signs of preterm labor and sonographical cervical length measurement between 1.5–2.4 cm and divided into 2 groups according to addition of PAMG-1 testing or not (n=130).

Findings:

- In the PAMG-1 group ACS administration was performed less frequently (26% v 74%, p<0.0001), the rate of delivery within 7 days did not differ (3% v 6.5%, p=0.42), time to delivery was longer (61.5 v 43 days, p=0.01) and NICU admission occurred less often (38% v 60%, p=0.03).
- Adding PAMG-1 testing to clinical examination reduces unnecessary interventions in women with shortened cervical length.

Comparison of antenatal corticosteroid administration with the PartoSure test plus cervical length versus cervical length alone.



Evaluate preterm labor confidently by including PartoSure as part of your clinical assessment.

Cost-benefit analysis of biomarker tests

Reducing unnecessary interventions may lead to decreased costs

Placental alpha microglobulin-1 in combination with transvaginal ultrasound for prediction of preterm birth

Haverhagen, *A. Perinat Med.* 2015;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: Range of GA: 24–37 and 6/7 weeks (n=31).

Results: ≤7 Days: PPV: 100% | NPV: 94%

Findings: In women with symptoms of PTL, only 9% of women delivered within 7 days of testing while 83% were hospitalized, 75% were given corticosteroids, and 59% tocolytic therapy as a precaution. PartoSure, when used with cervical length measurement of 1.5 to 3.0 cm, had a PPV of 100% and a NPV of 97% for predicting delivery within 7 days. The investigators found a high rate of unnecessary use of corticosteroids, tocolytics and hospitalization in women in this study. Utilizing a method with a high PPV such as PartoSure in combination with cervical length measurement may reduce costs and unnecessary risks to patients.

Utilization of a novel biomarker test to reduce the length of stay in patients with threatened preterm labor and a short cervix

Fatkullin, I. et al. *Am J Obstet Gynecol.* 2016;29:283.

Objective: Prospective, observational trial to evaluate PartoSure as a tool to decrease length of hospitalization in women presenting with a short cervix and signs and symptoms of sPTD. Admission and treatment were performed according to local guidelines based on cervical length ≥2.5 cm.

Study population: Range of GA: 24–34 and 6/7 weeks (n=45).

Results: ≤7 Days: PPV: 60% | NPV: 100%

Findings: In women with symptoms of PTL, no women delivered within 7 days of testing but 53% were hospitalized, 70% of those admitted were given corticosteroids, and all received tocolytic therapy as a precaution. Based on the PPV and NPV, 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.

Economic evaluation case study: PartoSure

York Health Economics Consortium (YHEC). Economic evaluation case study: PartoSure. July 2018.

Objective: Economic model and cost analysis that aimed to estimate the economic impact of using PartoSure compared with other available tests for PTD in the UK.

Results:

Table 6: Economic impact and cost-comparison analysis of PartoSure compared with other assessments for preterm labor in the UK

Tertiary UK hospital with 500 patients presenting with symptoms of preterm labor per year

Cost breakdown, £	PartoSure	phIGFBP-1*	Cost difference: phIGFBP-1* minus PartoSure	fFN* 50 ng/mL	Cost difference: fFN* 50 ng/mL minus PartoSure
Cost of test†	37,665	26,249	11,417	45,000	-7,335
Cost of treating patients eligible for test	89,232	202,804	-113,571	165,156	-75,924
Cost of treating patients not eligible for test	0	66,250	-66,250	66,250	-66,250
Total	126,897	295,302	-168,405	276,406	-149,509

Non-tertiary UK hospital with 300 patients presenting with symptoms of preterm labor per year

Cost breakdown, £	PartoSure	phIGFBP-1*	Cost difference: phIGFBP-1* minus PartoSure	fFN* 50 ng/mL	Cost difference: fFN* 50 ng/mL minus PartoSure
Cost of test†	22,599	15,749	6,850	27,000	-4,401
Cost of treating patients eligible for test	60,419	137,324	-76,905	111,831	-51,412
Cost of treating patients not eligible for test	0	44,874	-44,874	44,874	-44,874
Total	83,018	197,948	-114,929	183,706	-100,687

Cost savings are shown in blue. These scenarios are based on the assumption that all patients are eligible for PartoSure and 90% are eligible for the comparator tests and there is an intermediate risk of preterm labor (PTL). In addition, in tertiary centers it is assumed 500 patients will present with symptoms of PTL out of 5,000 births and in non-tertiary centers this will be 300 patients out of 3,000 births and that any non-tertiary hospital would transfer a patient via in-utero transfer to a tertiary hospital if the patient presents with suspected PTL before 28 weeks' gestation.

* Findings based on data that assumed fFN testing was with Rapid fFN Q10 and phIGFBP-1 testing was with ActimPartus.

† Including staff time.

Findings: Considerable annual cost savings are possible with PartoSure, as determined by a cost comparison analysis by the York Health Economics Consortium (YHEC). This ranged from £100,687 for 300 women with symptoms of PTL treated in a non-teritary UK hospital and tested with fFN to £168,405 for 500 women with symptoms of PTL treated in a teritary UK hospital and tested with phIGFBP-1. These savings would be realised in both tertiary and non-tertiary UK hospitals.

Guidelines and recommendations on biomarker assessments

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

Di Renzo, G.C. et al. *J Matern Fetal Neonatal Med.* 2017;30:2011–2030.

The European Association of Perinatal Medicine (EAPM) developed guidelines based on recent evidence adapted to account for European clinical practice.

Recommendations: In symptomatic women, biomarker measurement in cervicovaginal secretions combined with cervical length measurement has been shown to increase the accuracy of predicting sPTD. To identify asymptomatic women at risk of PTD, the EAPM recommends combining cervical length measurement with a biomarker test that can be used shortly after a vaginal examination. According to recent literature summarized by Di Renzo et al., PartoSure is the test that exhibits the highest NPV and PPV and is therefore recommended in women with a cervical length between 1.5 and 3.0 cm.

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

Country-specific guidelines for preterm labor diagnosis and management

National guidelines from Germany, Austria, Switzerland, Spain, Italy, Denmark and the Czech Republic assess the use of PartoSure in diagnosing PTD. Their recommendations are summarized below.

National guidance and recommendations for PartoSure.

Organization	Recommendation regarding PartoSure
German Society for Gynecology and Obstetrics (DGGG), Austrian Society for Gynecology and Obstetrics (OEGGG), Swiss Society for Gynecology and Obstetrics (SGGG)	"Patients with preterm contractions and a cervical length of >30 mm or 15–30 mm measured by transvaginal ultrasound and who have additionally tested negative for fibronectin, phIGFBP-1 or PAMG-1 should not be administered antenatal steroids only because of contractions as there is only a small risk (<5%) of preterm birth occurring in the next 7 days." (1) "If asymptomatic patients with a cervical length of 5–15 mm who have tested negative for fibronectin, phIGFBP-1 or PAMG-1 have no additional risk factors for preterm birth, they should not be administered antenatal steroids because of the very low probability (<1%) that they will give birth within 7 days." (1)
Sociedad Española de Ginecología y Obstetricia (SEGO)	"Although the PPV and the sensitivity of [PartoSure] are the highest, the main utility of this test, as is the measurement of cervical length, is its high negative predictive value; its prognostic capacity increases in populations with high prevalence of prematurity" (2)
Società Italiana di Ginecologia e Ostetricia (SIGO)	"A reasonable algorithm for the diagnosis of preterm birth is (...), if cervical length is <30 mm, use fFN or PAMG-1" (3)
Dansk Selskab for Obstetrik og Gynækologi (DSOG)	"[PartoSure] has the highest NPV of 96%, 87% for fFN and 89% for cervical length measurement. PAMG-1 also has the highest PPV of 76% compared to fFN and cervical length measurement." (4)
Ceska Gynekologicko porodnicka spolecnost (CGPS)	"PAMG-1 in cervicovaginal secretions has a NPV comparable to fFN and phIGFBP-1, and an even higher positive predictive value for birth within 7 days" (5)

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