PartoSure™

Literature Summary

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Sample to Insight

Comparison with other commercially available biomarker tests

PartoSure is trusted worldwide

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

Wing, D.A., Haeri, S., Silber, A.C., et al (2017) Obstet Gynecol. 130, 1183.

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

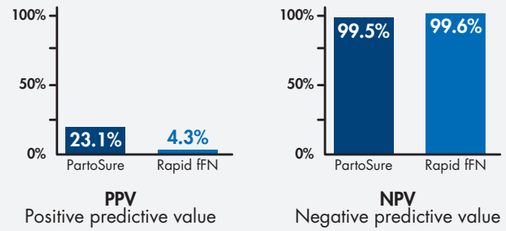
PartoSure Results:

≤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 (2)

Melchor, J.C., Navas, H., Marcos, M., et al. (2018) Ultrasound Obstet Gynecol. 51(5), 644.

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.

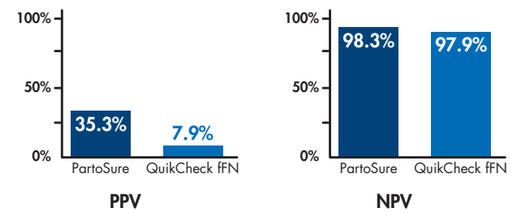
Study population: Number: 745, Range for GA: 24–34 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded.

PartoSure Results:

≤7 Days: PPV: 35.3% | NPV: 98.3%

≤14 Days: PPV: 41.2% | NPV: 97.1%

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



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 (3)

Ravi, M., Beljorie, M., El Masry, K. (2018) J Matern Fetal Neonatal Med. May 28, 1 [Epub ahead of print].

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: Number: 72; Range for GA: 23–34 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded.

PartoSure 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	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.

Accurately 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 (4)

Nikolova, T., Bayev, O., Nokolova, N., et al. (2015) J Perinat Med. 43, 395.

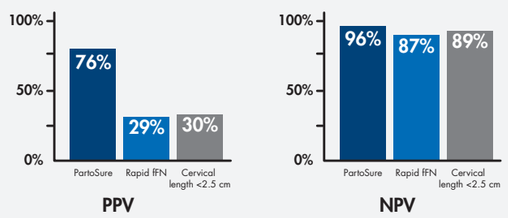
Objective: Prospective trial comparing PartoSure with detection of fFN and cervical length measurement to predict PTD within 7 and 14 days of testing in women presenting with symptoms of PTL. Additionally, the combination of each biomarker test with cervical length measurement was studied.

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

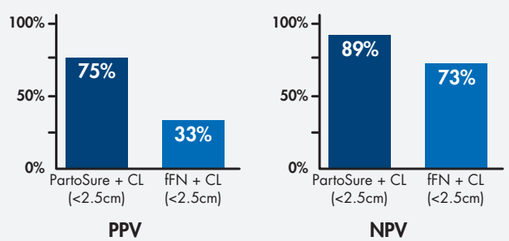
PartoSure Results:
≤7 Days: PPV: 76% | NPV: 96%
≤14 Days: PPV: 81% | NPV: 89%

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 (7).



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.



Comparison of the fetal fibronectin and placental alpha microglobulin-1 tests for predicting imminent spontaneous preterm birth (5)

Van Holsbeke, C., Dam, K., Staelens, A. et al. (2016) Ultrasound Obstet Gynecol. 48 (S1), 84.

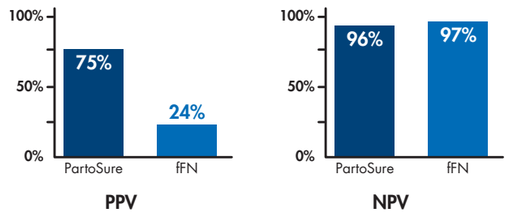
Objective: Interim analysis of a prospective trial that compared PartoSure or fFN testing alongside cervical length measurement to predict sPTD within 7 and 14 days of testing.

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

PartoSure 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.



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 (6)

Nikolova, T., Uotila, J., Nikolova, N., et al. (2018) Am J Obstet Gynecol. 219(6), 610.

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: Number: 403; Range for GA: 20–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded.

PartoSure 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	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 (7)

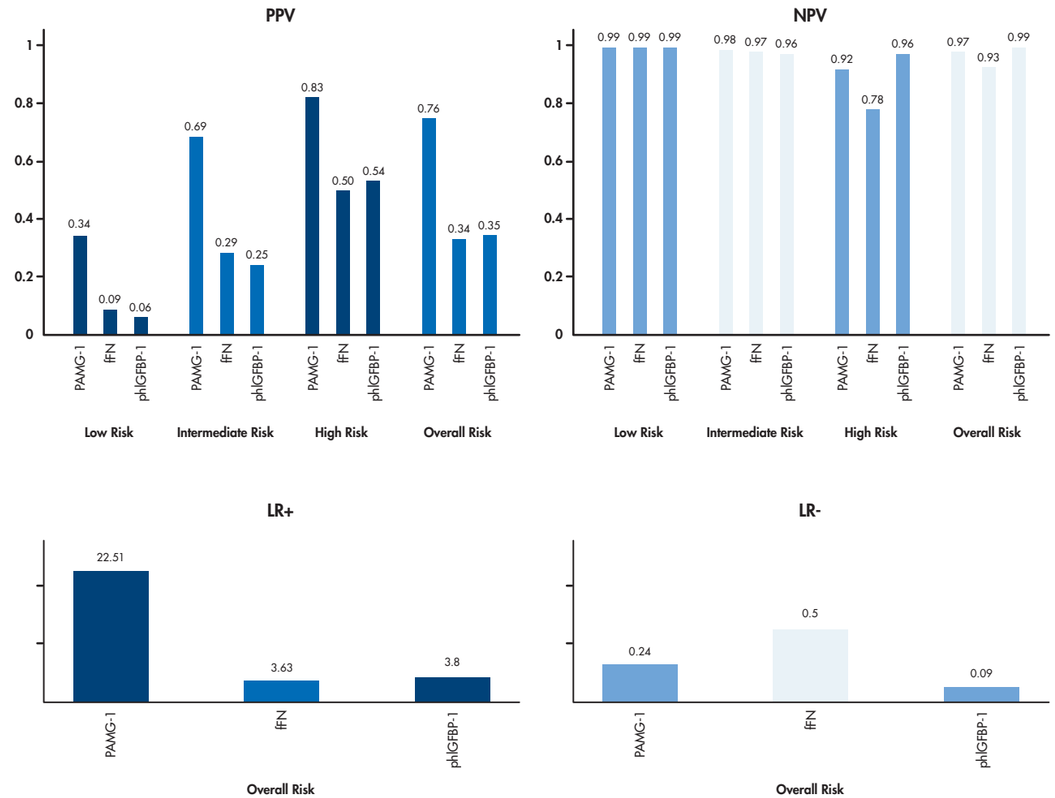
Melchor, J.C., Khalil, A., Wing, D., et al. (2018) Ultrasound Obstet Gynecol. 52, 442.

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.

PartoSure 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 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	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.

Accuracy compared with assessments that do not include biomarkers

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

Preterm labor: reproducibility of detection test of PAMG-1 before and after digital examination, and transvaginal cervical length (8)

Werlen, S., Raia, T., Di Bartolomeo A., et al. (2015) Gynecol Obstet Fertil. 43, 640.

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: Number: 41, Range of GA: 24–34 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded.

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 (9)

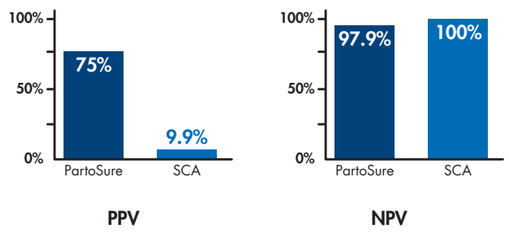
Lotfi, G., Faraz, S., Nasir, R., et al. (2017) J Matern Fetal Neonatal Med. Oct 26, 1.

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: Number: 132; Range of GA: 24–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded.

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

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



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.

Combined value of placental alpha macroglobulin-1 detection and cervical length via transvaginal ultrasound in the diagnosis of preterm labor in symptomatic patients (10)

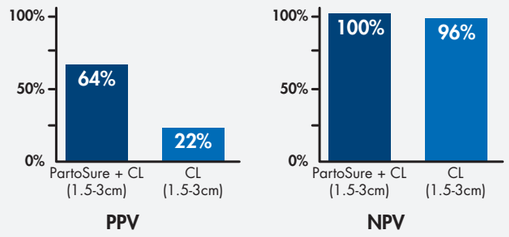
Bolotskikh, V., Borisova V. (2017) J Obstet Gynaecol Res. 43, 1263.

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: Number: 99; Range for GA: 22–36 and 6/7 weeks. Women with ruptured membranes or cervical dilation ≥3.0 cm were excluded.

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

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



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.

Guidelines and recommendations on biomarker assessments

Preterm labor and birth management: recommendations from the European Association of Perinatal Medicine (11)

Di Renzo, G. C., Cabero Roura L., Facchinetti F., et al. (2017) J Matern Fetal Neonatal Med. 30, 2011.

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 (12, 13, 14, 15)

Spanish, Italian, Danish and Czech guidelines and recommendations.

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

National guidance and recommendations for PartoSure.

Organisation	Recommendation regarding PartoSure
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"
Società Italiana di Ginecologia e Ostetricia (SIGO)	"A reasonable algorithm for the diagnosis of preterm birth is (…), if cervical length is <30mm, use fFN or PAMG-1"
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."
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"

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 (16)

Heverhagen, A. (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: Number: 31; Range of GA: 24–37 and 6/7 weeks.

PartoSure 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 (17)

Fatkullin, I., Akhmetgaliev A., Matveeva, E., 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 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: Number: 45; Range of GA: 24–34 and 6/7 weeks.

PartoSure 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 (18)

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.

PartoSure 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	phlGFBP-1*	Cost difference: phlGFBP-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	phlGFBP-1*	Cost difference: phlGFBP-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 phlGFBP-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 phlGFBP-1. These savings would be realised in both tertiary and non-tertiary UK hospitals.

Publication Summary Table

The following table summarises the published studies that examined the predictive performance of PartoSure testing in women presenting with signs and symptoms of PTL. Studies are further classified based on the prevalence of sPTD within 7 days. Higher risk groups were classified due to the lower risk patients being screened out by initial cervical length measurement.

Study	Population	Year	N	PPV	NPV
Low Risk (≤5%)					
Wing et al.[1]	US	2017	635	23%	99%
Melchor et al.[2]	Europe	2017	745	35%	98%
Ravi et al.[10]	Middle East	2017	72	40%	99%
Intermediate Risk (5-15%)					
Nikolova et al.[11]	Europe	2018	403	61%	98%
Lotfi et al.[5]	Middle East	2017	148	75%	98%
Hadzi-Lega et al.[21]	Europe	2017	57	50%	98%
Bolotskikh et al.[4]	Europe	2017	99	75%	100%
Fatkullin et al.* [10]	Europe	2016	45	60%	100%
Lou et al.* [22]	Europe	2016	65	100%	100%
Van Holsbeke et al.* [8]	Europe	2016	50	75%	96%
Konoplyannikov et al.* [23]	Europe	2016	71	55%	97%
Heverhagen, A.* [9]	Europe	2015	64	100%	94%
High Risk (≥15%)					
Nikolova et al.[7]	Europe	2015	203	76%	96%
Nikolova et al.[24]	Europe	2014	101	78%	97%

*PartoSure test in combination with cervical length measurement

Notes

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

References:

1. Wing D.A., Haeri, S., Silber, A.C., et al (2017) Obstet Gynecol. 130, 1183.
2. Melchor, J.C., Navas, H., Marcos, M., et al. (2018) Ultrasound Obstet Gynecol. 51(5), 644.
3. Ravi, M., Beljorie, M., El Masry, K. (2018) J Matern Fetal Neonatal Med. May 28, 1 [Epub ahead of print].
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5. Van Holsbeke, C., Dam, K., Staelens, A., et al. (2016) Ultrasound Obstet Gynecol. 48(S1), 84.
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7. Melchor, J.C., Khalil, A., Wing, D., et al. (2018) Ultrasound Obstet Gynecol. 52, 442.
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