



Include PartoSure® for rapid, reliable results.



When preterm labor threatens,
decide next steps with confidence.

Sample to Insight



Results you can trust

Accurately accessing the risk of imminent delivery in women with signs of threatened preterm labor (PTL) is challenging.

Measurement of cervical length and dilation are not sufficiently predictive. Plus traditional biomarker tests, such as those based on the detection of fetal fibronectin (fFN) and phosphorylated insulin-like growth factor-binding protein-1 (pIIGFBP-1), have

been reported to have poor positive predictive values (PPV) for imminent delivery (1).

The increased chance of false positives with these tests, indicated by a lower PPV, can lead to unnecessary admissions and interventions. PartoSure performance is marked by a higher PPV, providing reliable results that can help guide clinical decisions (1).

The value of PAMG-1 as a marker of imminent delivery

Regardless of gestational age, high concentrations of placental alpha microglobulin-1 (PAMG-1) exist in amniotic fluid, but low concentrations are found in normal vaginal discharge. Therefore, positive detection of PAMG-1 in vaginal discharge is a strong indicator of imminent delivery in women presenting with threatened PTL and intact membranes (2).

Other available immunoassays measure the concentration of alternative biomarkers. However, IFU data of commercially available PTL biomarker tests reveal that the presence of relevant PAMG-1 is a more accurate measure of likelihood of delivery in ≤ 7 days, as indicated by a higher PPV. A high negative predictive value (NPV) is maintained, ruling out risk of imminent delivery when test results are negative (3–5).

	PartoSure Test (3)	Rapid fFN® (4)	Actim® Partus (5)
Amniotic fluid biomarker detected	PAMG-1	fFN	pIIGFBP-1
PPV	76%	13%	50%
NPV	96%	99%	96%

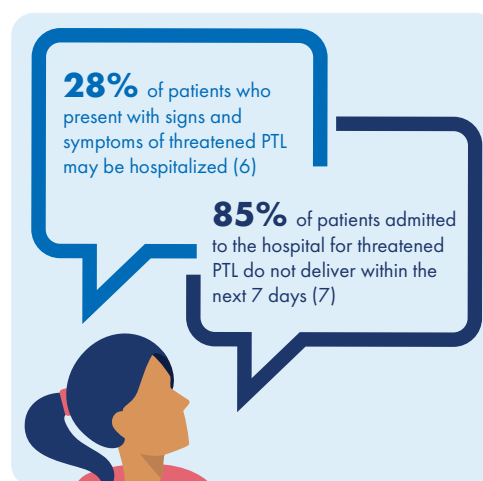
When PTL threatens, PartoSure provides accurate and reliable results to aid in clinical decision making and should be used as part of your overall

clinical assessment to determine the next course of action for patients presenting with signs and symptoms and minimal cervical dilatation (≤ 3 cm).

Are mom and baby at risk?

When an expectant mother presents with symptoms of PTL, she is counting on you to know what comes next. Do you have the right diagnostic tools you need to make the right decision for her and the baby?

A test that reliably identifies when expectant mothers are imminently likely to deliver can reduce missed cases that go on to deliver prematurely, while also limiting the number of women that are admitted unnecessarily due to a false positive.



PartoSure Test features

✓ High PPV and NPV	✓ Results in 5 minutes
✓ Applicable shortly after vaginal examination	✓ No special equipment or training needed
✓ No speculum examination required	✓ Wide gestational age range from 20 weeks +0 days to 36 weeks + 6 days

Reducing unnecessary interventions decreases cost

Published studies suggest a lower rate of false positive test results and associated higher PPVs, such as those seen in the PartoSure test, may contribute to:

- Reducing the length of stay for high risk patients
- Decreasing unnecessary admissions and use of acute interventions
- Minimizing unnecessary patient transfers

The York Health Economics Consortium (YHEC) determined that cost savings are possible with PartoSure in both tertiary and non-tertiary UK hospitals (8).

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
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
Total	83,018	197,948	-114,929	183,706	-100,687

* Cost savings are shown in the blue cells. Findings are based on data that assumed fFN testing was with Rapid fFN Q10 and phIGFBP-1 testing was with Actim Partus. Additional assumptions are addressed in the published study.

Ready and reliable

PartoSure is accurate, is ready to use as packaged with no additional tools necessary, can be administered bedside or in the lab by qualified staff, has a wide gestational range, and is not affected by blood, urine or semen – enabling a fast and effective response to almost any situation where PTL threatens (3).

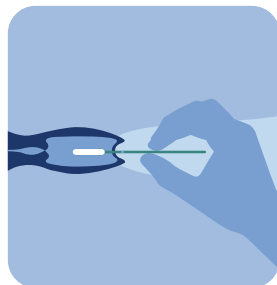
The PartoSure 4-step test procedure

1

Collect sample

30 second collection.

Hold the sterile swab by the middle of its shaft and insert into the vagina until fingers contact the skin (no more than 5-7cm deep). Withdraw after 30 seconds.

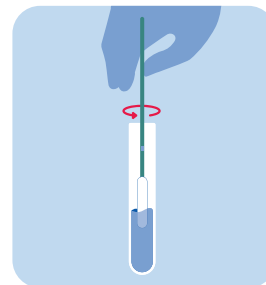


2

Transfer to solvent

30 second dilution.

Immediately place the swab in the provided solvent vial and rinse by rotating the swab for 30 seconds. Discard swab.



3

Insert test strip

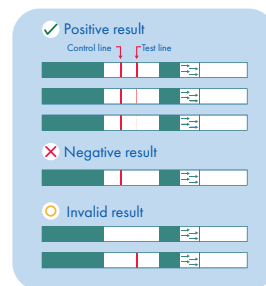
Insert the white end of the test strip (marked with arrows facing downward) into the vial with solvent.



4

Read results

Remove the test strip from the vial if two lines are clearly visible in the test region or after 5 minutes. Do not read strip after 10 minutes have passed since inserting test strip into the vial.



Positive: Two lines	Negative: One control line	Invalid: No lines or test line only
Imminent delivery within ≤ 7 or ≤ 14 days is highly likely	Imminent delivery within ≤ 7 or ≤ 14 days is highly unlikely	Results not valid; retest

References:

- Melchor, J.C., et al. (2018) Ultrasound Obstet. Gynecol. 52:442-51.
- Lee, S.M., et al. (2012) J. Matern. Fetal. Neonatal. Med. 25:1690-8.
- PartoSure Test Instructions for Use (IFU), QIAGEN 2019. IFUs are available on www.qiagen.com.
- Rapid fFN IFU <https://www.hologic.com/package-inserts/diagnostic-products/ffn-test>
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- Grobman, W.A., et al. (2004) Am. J. Obstet. Gynecol. 191:235-40.
- Nikolova, T., et al. (2015) J. Perinat. Med. 43:395-402.
- York Health Economics Consortium (YHEC). Economic evaluation case study: PartoSure. July 2018.



Include PartoSure in your PTL clinical assessment for results you can trust.
Talk to a PartoSure specialist or visit **www.qiagen.com** today to get started.

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