QIAGEN

Strength in your decision with PartoSure®

Your aid in assessing the risk of spontaneous preterm birth

Sample to Insight

Preterm birth: A major diagnostic challenge

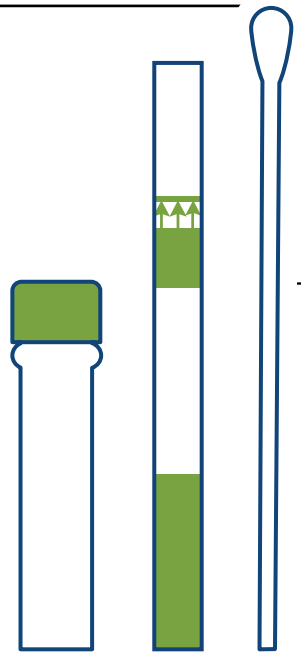
Accurately assessing the risk of preterm birth is a difficult diagnosis with significant implications. Clinical evaluation alone is limited in its ability to predict imminent delivery among patients with signs of threatened preterm labor (PTL).

Additionally, according to ACOG guidelines traditional biomarker tests, such as those based on the detection of fetal fibronectin (fFN), have been reported to have poor positive predictive values (PPV) for imminent delivery (1). The increased chance of false positives, indicated by a lower PPV, can lead to unnecessary admissions and interventions.

- 28% of patients presenting with signs and symptoms of threatened preterm labor may be admitted to the hospital (2).
- Studies show 7 to 20% of patients admitted deliver within 7 days (3,4,5).
- Unnecessary admissions cost $20.3K/case on average (6).

Simple steps, rapid results

PartoSure is a rapid, qualitative test for detecting the presence of placental alpha microglobulin-1 (PAMG-1) in cervicovaginal secretions in pregnant women with signs and symptoms of early preterm labor (7).



PartoSure

Assess the risk of spontaneous preterm birth

- Results in **5 MINUTES**
- Recent intercourse* **DOES NOT INTERFERE**

- Speculum examination **NOT REQUIRED**
- External reader **NOT REQUIRED**

* If lubricants, antiseptics or disinfectants are present, delay testing 24 hours.

PAMG-1 is a placental protein found in high concentrations in the amniotic cavity. Due to the low concentration of PAMG-1 in normal vaginal discharge, studies have demonstrated a strong correlation between a positive PAMG-1 test and imminent delivery in patients presenting with threatened PTL and intact membranes (8).

Improved confidence for your assessment of spontaneous preterm birth

A prospective U.S. multi-center trial conducted at 15 university and community hospitals compared PartoSure to conventional methods used to assess the risk of spontaneous preterm delivery ≤ 7 days of testing. Performance was studied in symptomatic pregnant women with a singleton gestation, intact amniotic membranes and cervical dilation <3 cm. (9)

The study reported, for the prediction of spontaneous preterm delivery ≤ 7 days among singletons in the US study population, the PartoSure test had the highest positive predictive value and comparable negative predictive value, when compared to each conventional method alone.

Performance of PartoSure and Clinical Risk Factors in Prediction of Spontaneous Preterm Delivery ≤ 7 Days Among Singleton Gestations

Test method	PPV	NPV
PartoSure	23.1	99.5
Rapid fFN™	4.3	99.6
Uterine Activity (≥4 contractions/hr)	1.5	99.2
Cervical Dilation (>1 cm and <3cm)	11.1	99.4
Vaginal Bleeding (any bleeding)	3.5	99.3

PPV: positive predictive value, NPV: negative predictive value

A published study reported a 67% decrease in false positive test results after switching to PartoSure

A European maternity hospital retrospectively reviewed the medical records of women presenting to the emergency obstetrical unit with threatened PTL and their findings support the US clinical trial results. The investigators examined medical records from a year in which the hospital used the detection of fFN (QuikCheck fFN™) as its standard biomarker test and a separate year in which PartoSure was used as its standard biomarker test (10).

	PartoSure Test Period	QuikCheck fFN Test Period
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	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)
PPV	35.3%	7.9%
NPV	98.3%	97.9%

SD: standard deviation, GA: estimated gestational age at testing, sPTD: spontaneous preterm delivery, PPV: positive predictive value, NPV: negative predictive value, fFN: fetal fibronectin

Reducing unnecessary interventions may lead to decreased costs

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

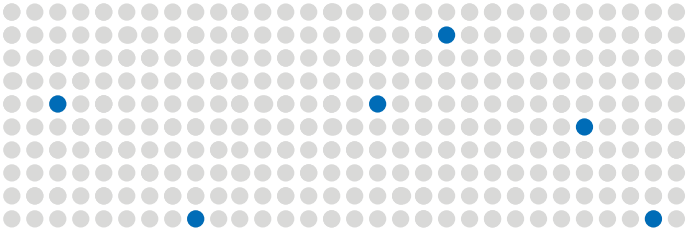
- Decreasing unnecessary admissions and acute interventions
- Reducing the length of stay of high risk patients
- Minimizing unnecessary patient transfers

85%

of patients admitted to the hospital for threatened preterm labor do not deliver within the next seven days (4).

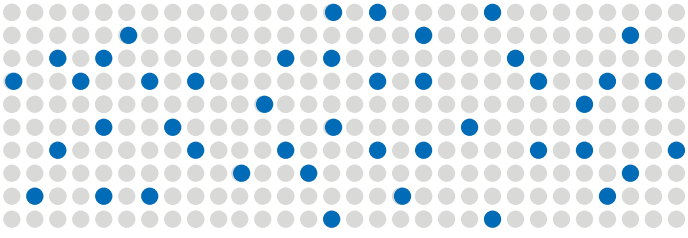
The average US birthing hospital has approximately 1,200 births annually and PTL tests may be used on up to 300 of these patients (11)

PartoSure may produce 6 positives



False positives within this group: 5

Traditional biomarker tests may produce 44 Positives

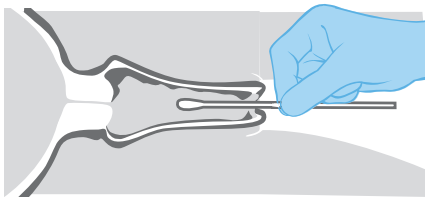


False positives within this group: 42

Up to 37 patients may avoid unnecessary intervention annually, which could result in savings of ~$750K USD (6, 9)

PartoSure 4-Step Testing Procedure

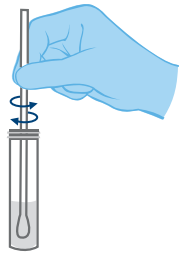
1



Collect sample

Collect sample of vaginal discharge with sterile collection swab for 30 secs (no active rotation or speculum required).

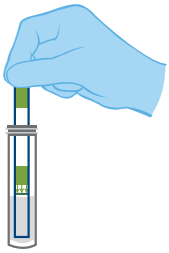
2



Transfer to solvent

Rinse specimen swab in solvent vial for 30 seconds. Discard swab.

3

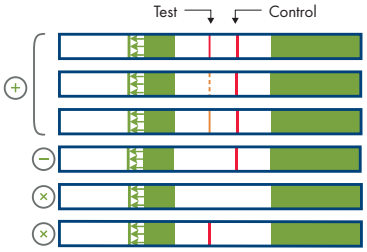


Insert test strip

Insert test strip into vial. Positive as soon as two lines are visible on strip. 5 minutes to call negative result.

Note: Please refer to package insert for complete instructions for use.

4



Read result

A positive result is indicated by two lines in the test region, while a negative result is indicated by a single control line in the test region. Do not read or interpret the result after 10 minutes have passed since inserting the test strip into the vial.

Note: A faint or broken test line should always be read as positive.

The PartoSure test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of placental alpha microglobulin-1 (PAMG-1) in vaginal secretions of pregnant women. The device is intended for use by healthcare professionals as an aid in assessing the risk of spontaneous preterm delivery in ≤ 7 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes, and minimal cervical dilatation (< 3 cm), sampled between 24 weeks, 0 days and 34 weeks, 6 days gestation in women with a singleton gestation.

Ordering information

Product	Contents	Product code
PartoSure Test (20)	Box of 20 test kits	TTDT-1-20-US

Reimbursement information

CPT® code for PAMG-1	The CPT code for Placental Alpha Microglobulin-1 (cervicovaginal secretions) is 84112
ICD-9 codes for labor and delivery	644: Early or threatened labor 644.0: Threatened labor 644.1: Early onset of delivery

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

References:

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7. PartoSure Test Instructions for Use. QIAGEN, 2018.
8. Lee et al. (2012) The clinical significance of a positive Amnisure test in women with preterm labor and intact membranes. J Matern Fetal Neonatal Med. **25**, 1690-8.
9. Wing et al. (2017) Placental Alpha Microglobulin-1 compared with fetal fibronectin to predict preterm delivery in symptomatic women. Obstet Gynecol. 130, 1183-91.
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11. American Hospital Association (AHA). US Birthing Hospital Data, 2016.