Your answer can impact more than a life

Reduce hospital admissions by including AmniSure and PartoSure

Your answer can impact more than a life – Reduce hospital admissions by including AmniSure

The uncertainty of diagnosing PROM

20%

Estimated pregnancies present with suspicion of PROM (1)

40%

Patients presenting who will have no obvious leakage of fluid from the cervical os (3)

54%

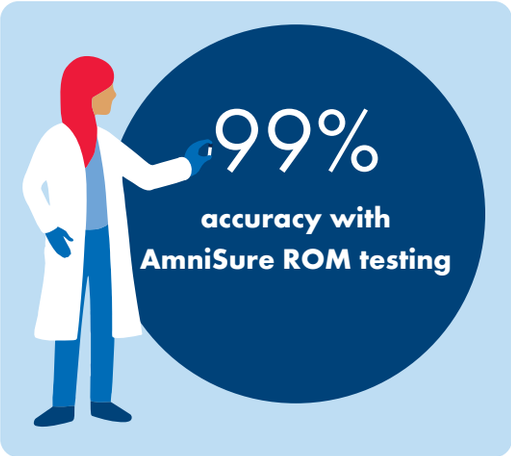
Negative predictive value for standard clinical assessments, even when used in combination (3)

47%

Cases that cannot be adequately diagnosed by physical exam alone (1)

When a patient presents with suspicion of premature rupture of membranes (PROM), in nearly half of all cases the diagnosis is uncertain based on physical examination alone (1). And traditional methods for diagnosis – pH/nitrazine, ferning, and pooling – may be unreliable (2–4).

According to the latest considerations for Labor and Delivery from the Society for Maternal-Fetal Medicine and the Society for Obstetric and Anesthesia and Perinatology, alternative methodologies for evaluation of rupture of membranes could be considered, given the potential exposure risks (like microscopy for ferning evaluation) for women with SARS-CoV-2 or patients under investigation (15).



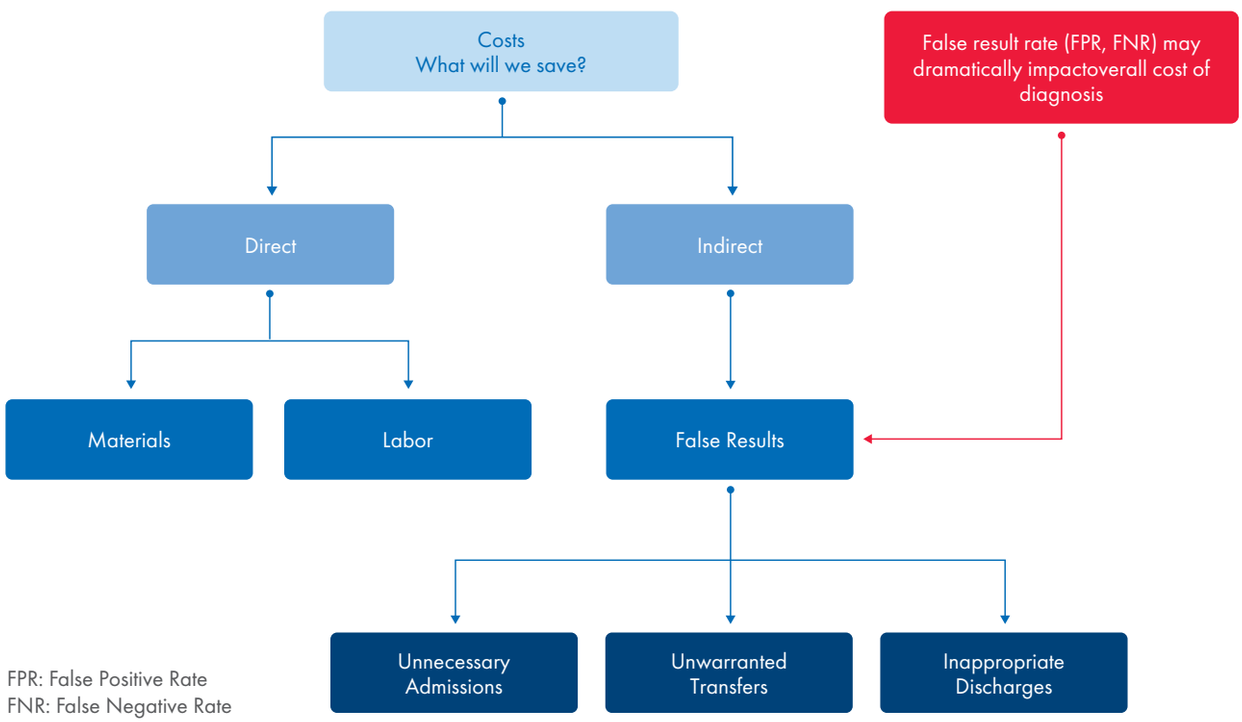
Avoid additional burden to healthcare professionals

- Reduce hospital admissions for suspected PROM
- Maximize your accuracy in ROM testing by including AmniSure
- Focus on the pregnancies at risk, offer your help and capacities to those confidently diagnosed

Incorrect results dramatically impact the overall cost of diagnosis

A **false positive** can result in unnecessary medications, transfers, hospital admission and induction (5–9).

A **false negative** can lead to an unwarranted discharge, which could cause lifelong complications and potential litigation (5–9).



FPR: False Positive Rate
FNR: False Negative Rate

Your answer can impact more than a life – Reduce hospital admissions by including PartoSure

Clinical evaluation alone, including the measurement of cervical length (CL) and dilatation, is not sufficiently predictive of imminent delivery in women with signs of threatened preterm labor (PTL). Accurately assessing this risk can be difficult and not diagnosing PTL can have significant implications for the well-being of the patient and her unborn child.

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 (10). The increased chance of false positives, indicated by a lower PPV, with these tests can lead to unnecessary admissions and interventions.

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 designed as an aid to rapidly assess the risk of preterm delivery in ≤7 or ≤14 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 20 weeks, 0 days and 36 weeks, 6 days gestation.

A more accurate assessment of patients with signs and symptoms of PTL is urgently needed to identify women truly at risk:

- Reduce hospital admissions for preterm labor
- Reduce use of tocolytics and antenatal corticosteroids
- 85% of pregnant women admitted to the hospital for threatened PTL do not deliver within the next 7 days (17)

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

According to the latest considerations for Labor and Delivery from the Society for Maternal Fetal Medicine and the Society for Obstetric and Anesthesia and Perinatology, prolonged exposure to high-dose steroids has been associated with worsening SARS-CoV-2 patient outcomes in the general population. How this applies to antenatal corticosteroids (ANCS) is unknown. Until evidence is available, practices could consider adjusting protocols, balancing theoretical maternal risks against the magnitude of known fetal benefits in each clinical circumstance (15).

Strengthen your decision with PartoSure

Predictive accuracy for spontaneous preterm birth in symptomatic women within 7 days of testing (AUC from receiveroperating characteristics curves) and positivity rate for PartoSure, fFN testing 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

Published data indicate PartoSure can also be used in combination with CL in women with a CL of 1.5 to 3.0 cm to identify those at highest risk of PTL (6). In addition, as shown by Werlen et al., PartoSure provides reliable results even when used 30 minutes after digital examination or transvaginal ultrasound, providing confidence that this test can be administered without loss of accuracy (16).

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The AmniSure ROM Test (Rupture of [fetal] Membranes test) is intended for in vitro diagnostic use.

The PartoSure Test is intended for in vitro diagnostic use.

Ordering Information

Product	Contents	Cat. no.
AmniSure		
AmniSure ROM Test (25)	Box of 25 test kits	FMRT-1-10-ML-RT
AmniSure ROM Test (10)	Box of 10 test kits	FMRT-1-10-ML-RT
PartoSure		
PartoSure Test (20)	Box of 20 test kits	TTDT-1-20-OUS

For more information, visit **www.herQIAGEN.com/AmniSure**
or **www.herQIAGEN.com/PartoSure**

Ordering	**www.qiagen.com/shop**
Technical Support	**www.support.qiagen.com**
Website	**www.qiagen.com**