How reliable is your PROM test?

The AmniSure® ROM Test adds to your clinical confidence – enabling better outcomes for your OB patients (1):

- 99% accurate to aid in diagnosis of ROM when used as part of the overall clinical assessment
- Results within 15 minutes
- More cost-effective than other diagnostic methods

Sample to Insight

QIAGEN

The right decision for mom and her baby starts with results you can trust

Only AmniSure employs a single, proven amniotic fluid protein marker to deliver highly specific results backed up by more than 10 peer-reviewed, independent studies. This means more confidence for you and better outcomes for your patients.

Research studies indicate that the amniotic fluid markers used in the ROM Plus® Rupture of Membranes Test are less-specific and more susceptible to interference by blood than the marker used in the AmniSure ROM Test (2,3).

- In samples with only a 15% admixture of maternal blood plasma, the ROM Plus Test had a 50% chance of giving a false positive result, while the AmniSure ROM Test had only a 7% chance of giving a false positive result (2).
- Among 151 women with vaginal bleeding as well as signs and symptoms indicative of PROM, the PAMG-1 marker used in the AmniSure ROM Test demonstrated 91.5% specificity for PROM diagnosis. In the same patient population, the IGFBP-1 marker used in the ROM Plus Test demonstrated only 75.0% specificity (3).

False positive results associated with lower test specificity may lead to more unnecessary treatment for moms and their babies, and, for preterm patients, the potential for lifelong complications (4).

Protect your patients and your practice

Include the

99%

accurate test – AmniSure – as part of your clinical assessment.

> *Our data showed better performance for the PAMG-1 compared with the IGFBP-1 detecting tests in all quality parameters evaluated (3).*

	AmniSure ROM Test (1)	ROM Plus Test (5)
Amniotic fluid biomarker(s) detected	PAMG-1	IGFBP-1 (PP12) & AFP
Overall sensitivity	98.9%	99.1%
Overall specificity	98.1%	75%
Number of independent, peer-reviewed clinical studies evaluating performance*	10 +	2
Correlation to ROM testing gold standard – Indigo Carmine	99% (6)	No data
Precautions & Warnings related to test use	Results should be used in conjunction with other clinical information.	The test may report positive results in patients with intact membranes (see specificity in the performance section) and therefore decisions to induce labor should not be based solely on the ROM Plus test results.
Time to results	Up to 12 minutes	Up to 21 minutes

***when used as indicated; May 2017**

Table 1. Comparison of AmniSure and ROM Plus.

Specificity matters in PROM diagnosis

Of 100 healthy women (no PROM), expected false positive results (1, 5):			
	At all stages of pregnancy		At late gestational stages
AmniSure	2	AmniSure (≥34 weeks gestation)	1
ROM Plus	25	ROM Plus (≥37 weeks gestation)	42

Table 2. Expected false-positive results with AmniSure or ROM Plus.

Reduce the costs of unnecessary hospital admissions with AmniSure

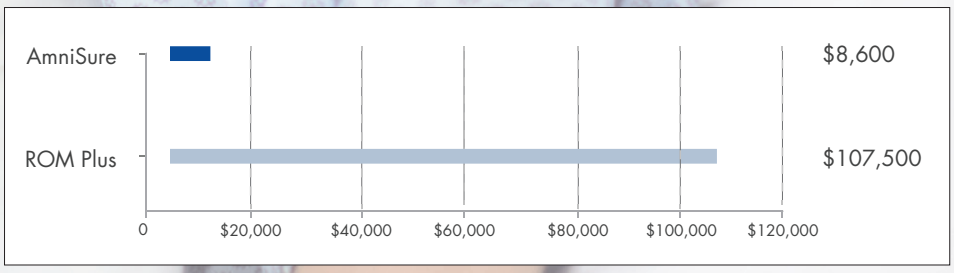

Figure 1. Reduce costs with AmniSure. *Cost hospital stay per 100 patients. Cost estimate at $4300 mean cost per maternal-neonatal hospital stay associated with a false positive test result (7).

To see how AmniSure can deliver better reliability and cost effectiveness compared to the ROM Plus test, visit **www.AmniSure.com**.

References

1. AmniSure ROM (Rupture of [fetal] Membranes) Test Instructions for Use. QIAGEN, 2015.
2. Sabio, E. (2013) The effect of maternal blood on the performance of the AmniSure ROM Test (PAMG-1) and the ROM Plus Test (AFP & IGFBP-1) for the diagnosis of premature rupture of the fetal membranes (PROM). Abstract submitted to the 2013 AACC Annual Meeting. Clin. Chem. **59**, A187.
3. Ramsauer, B. et al. (2015) Effect of blood on ROM diagnosis accuracy of PAMG-1 and IGFBP-1 detecting rapid tests. J. Perinat. Med. **43**, 417–422.
4. Park, J.S. and Norwitz E.R. (2005) Technical Innovations in Clinical Obstetrics. Contemporary OB/GYN **50**.
5. ROM plus Rupture of membranes test instructions for use. P/N 050-0642 REV E, 2016.
6. Sosa, C.G., Herrera, E., Restrepo, J.C., Strauss, A. and Alonso, J. (2014) Comparison of placental alpha microglobulin-1 in vaginal fluid with intraamniotic injection of indigo carmine for the diagnosis of rupture of membranes. J. Perinat. Med. **42**, **611–6**.
7. Moore, B., Levit, K. and Elixhauser, A. (2014) Costs per hospital stay in the United States, 2012. HCUP Statistical Brief #181. October 2014. Agency for Healthcare Research and Quality, Rockville, MD. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb181-Hospital-Costs-United-States-2012.pdf.

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