

Your Answer Can Impact a Life.

Evaluate PROM Confidently by
Including AmniSure[®] as Part
of Your Clinical Assessment

Sample to Insight





Should you admit her or send her home?

The uncertainty of diagnosing PROM

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).

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)

47%

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

54%

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

She is counting on you for accurate, reliable results

AmniSure is 99% accurate in aiding a diagnosis of PROM as part of the overall clinical assessment and has a proven 99% correlation with the current gold standard, indigo carmine. The AmniSure ROM Test is a rapid immunoassay supplied as a single, cost-effective test for in vitro diagnostics. The 4-step test procedure detects placental alpha microglobulin-1 (PAMG-1) protein that is found in high concentrations in amniotic fluid and low concentrations in cervicovaginal fluid (5).

- Saves time and costs of additional PROM diagnostic methods
- Consistent performance across all gestational ages when used as part of the overall clinical assessment
- 99% correlation with gold standard – indigo carmine dye infusion
- Sensitive (98.9%) and specific (98.1%), to support diagnostic accuracy of negative and positive PROM results when used as part of the overall clinical assessment

99%
Accuracy
of the AmniSure ROM Test



Science that makes sense

The AmniSure ROM Test detects placental alpha microglobulin-1 (PAMG-1) in the vaginal discharge of pregnant patients presenting with signs, symptoms or complaints suggestive of PROM. Regardless of gestational age, high concentrations of PAMG-1 exist in amniotic fluid (2000–25,000 ng/ml), but low concentrations are found in the background vaginal discharge (0.05–0.22 ng/ml; see references 2 and 3). Clinically significant leakage of amniotic fluid due to PROM increases the concentration of PAMG-1 by at least 2 orders of magnitude (3). Therefore, AmniSure was designed to detect the presence of PAMG-1 in vaginal discharge from 5 ng/ml and above (5).

Published data show the high accuracy of the AmniSure ROM Test

Publications on the AmniSure ROM Test

| Reference | Authors and year | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|-----------|---------------------------|-----------------|-----------------|---------|---------|
| 2. | Cousins et al. (2005) | 98.9 | 100 | 100 | 99.1 |
| 3. | Lee et al. (2007) | 98.7 | 87.5 | 98.1 | 91.3 |
| 6. | Grizzel et al. (2008) | 100 | 100 | 100 | 100 |
| 7. | Silva and Martinez (2009) | 100 | 100 | 100 | 100 |
| 8. | Tagore and Kwek (2010) | 92.7 | 100 | 100 | 95.2 |
| 9. | Albayrak et al. (2011) | 94.3 | 97.5 | 97.6 | 93.9 |
| 10. | Birkenmaier et al. (2012) | 94.4 | 98.6 | 96.2 | 98.0 |
| 11. | Ramsauer et al. (2013) | 96.0 | 98.9 | N/A | N/A |
| 12. | Sosa et al. (2014) | 100 | 99.1 | 96.3 | 100 |
| 13. | Ramsauer et al. (2015) | 97.8 | 91.5 | 94.6 | 96.4 |

PPV: positive predictive value.

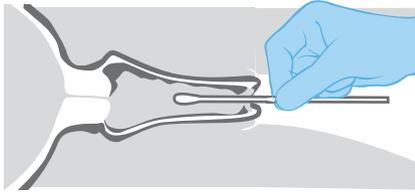
NPV: negative predictive value.

N/A: not available.



AmniSure 4-Step Testing Procedure*

1

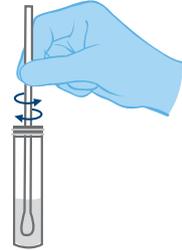


Collect sample

1 minute - collection.

Collect sample of vaginal discharge with sterile collection swab (no speculum required).

2



Transfer to solvent

1 minute - dilution.

Rinse specimen swab in solvent vial. **Discard swab.**

3

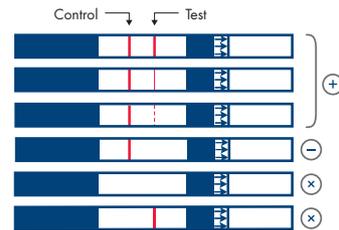


Insert test strip

10 minutes - removal of test strip.

Insert test strip into vial to initiate PAMG-1 detection. Remove the test strip after 10 minutes and then read the test results within 5 minutes.

4



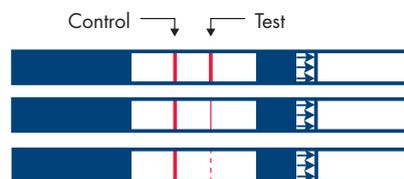
Read results

Remove test strip from vial, observe and record results. Do not read after 15 minutes have passed since inserting the strip into the vial. **Note: Faint or broken lines should always be read as positive.**

Reading results

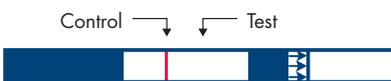
Positive result:

Two Lines



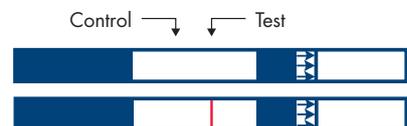
Negative result:

One Control Line



Invalid result:

No Lines or Test Line only

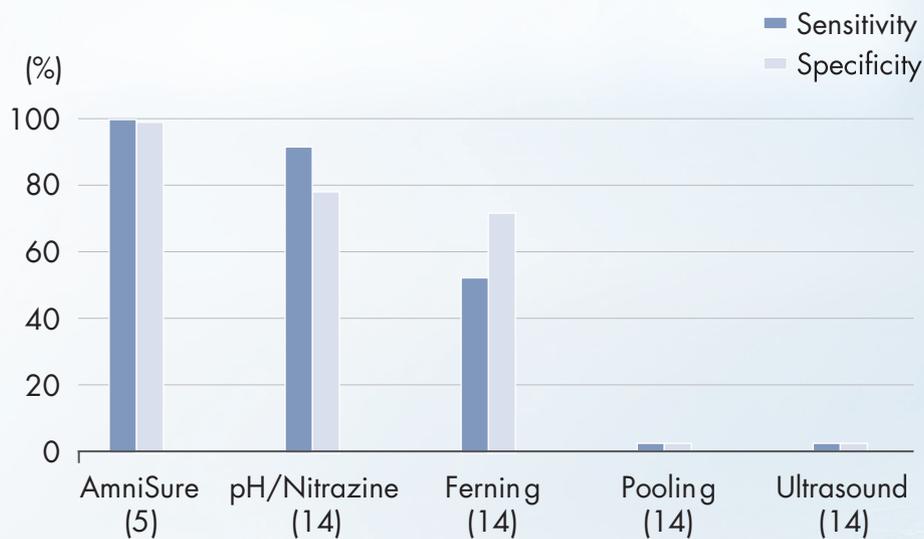


* Please refer to package insert for complete instructions for use.

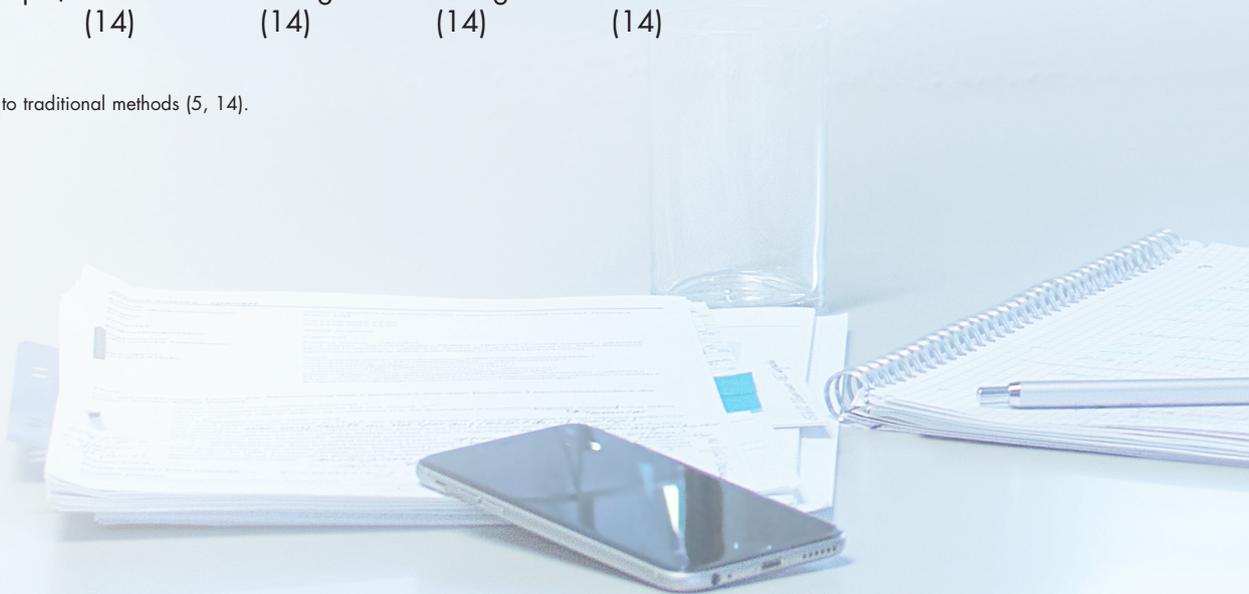
How does AmniSure compare to other PROM diagnostics?

AmniSure provides reliable results in the presence of common interfering substances (5), including:

- Urine
- Semen
- Trace blood
- Vaginal infections



Performance compared to traditional methods (5, 14).



PROM carries the risk
of neonatal sepsis
if not diagnosed within

24 h

of onset

Of patients
presenting with PROM,

60%

will go on to deliver
at term (17)

How many cases are you missing?

The cost of false negatives can result in failure to treat patients in a timely manner. Two independent risk factors of pre- and post-natal complications are incorrect and untimely PROM diagnoses (5).

- Incorrectly diagnosing PROM can lead to inappropriate or unnecessary interventions, such as hospitalization or induction of labor.
- If the patient is inappropriately discharged, or if PROM goes untreated, she could develop an intrauterine infection, resulting in costly complications.
- Poor fetal outcome can result if a patient is sent home and has PROM. Untimely diagnosis can potentially result in sepsis, cord prolapse or fetal demise.

How many cases are you over-treating?

The cost of false positives can result in unnecessary patient transfer, admission, and administration of antibiotics, corticosteroids, and tocolytics, which lead to a negative impact on both mom and the neonate (14).

- Using various combinations of traditional methodologies, 2–22% of cases can be falsely diagnosed (15).
- Current PROM protocols require patient admission from time of diagnosis to delivery, which can average \$1000 per day on an antepartum unit (16).

The cost of uncertainty

Approximately \$26 billion is spent annually in the United States for the initial medical care of premature infants and their mothers (15, 18). PROM is assessed in more than 30% of pregnant women, but preterm PROM (pPROM) still accounts for 25–30% of premature births (19).



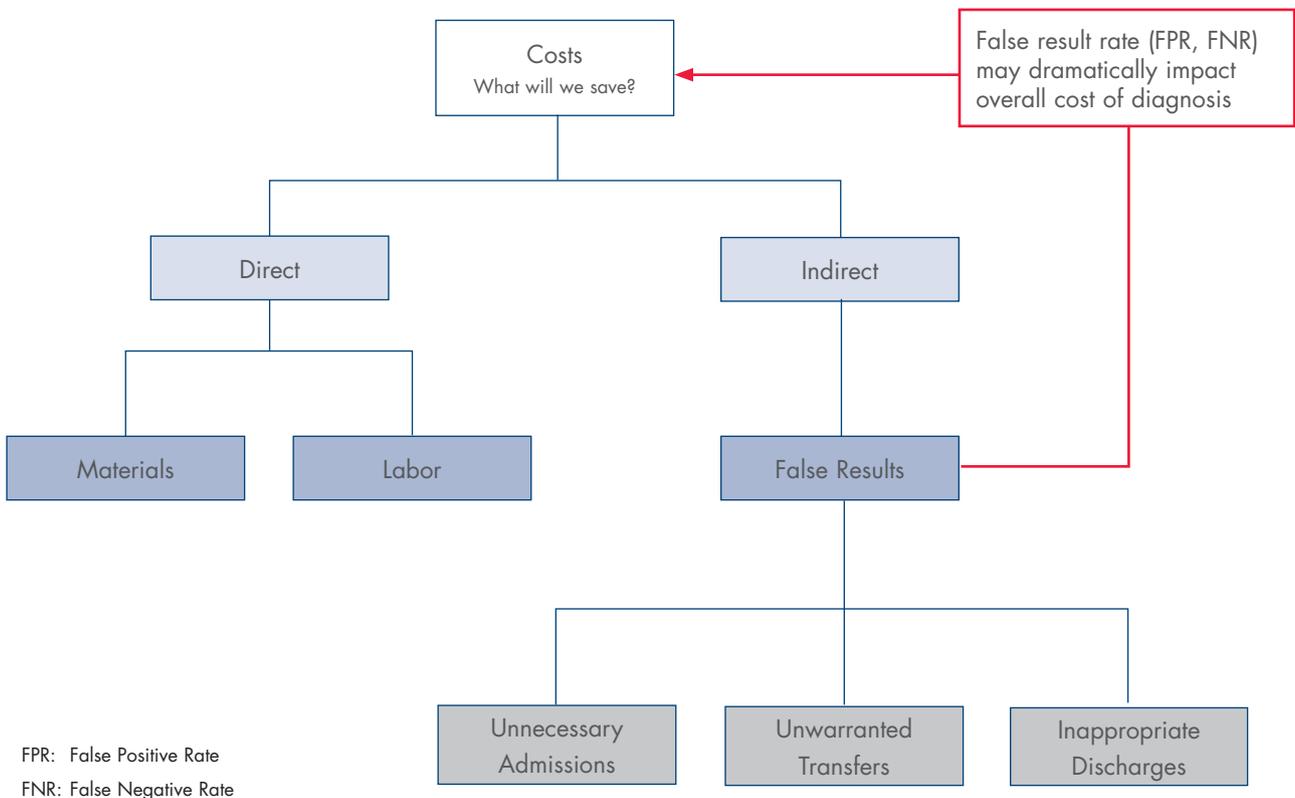


⊕ A **false positive** can result in unnecessary medications, transfers, hospital admission, and induction (10, 20–23).

⊖ A **false negative** can lead to an unwarranted discharge, which could cause lifelong complications and potential litigation (10, 20–23).

There is a significant financial advantage gained by adding the PAMG-1 test to the overall clinical assessment (15), primarily due to reductions in:

- Costs associated with false diagnoses using traditional methods
- Current spending on PROM diagnosis in non-obvious cases using traditional methods



Clinical evidence supports diagnostic accuracy alongside appropriate clinical judgment.

Start with AmniSure.



Use AmniSure as an aid in PROM diagnosis as part of the clinical assessment to avoid unnecessary expense, confidently send the patient home, or provide appropriate treatment without delays.

AmniSure is:

- Cost effective compared to testing and re-testing with traditional methods, especially in uncertain and equivocal cases (24)
- The only PROM diagnostic found to correlate 99% with indigo carmine intra-amniotic injection, recognized by ACOG as the PROM testing gold standard (7)

Contact us to learn how AmniSure can make an impact at your hospital!

Ordering Information

| Product | Contents | Cat. no. |
|---------------------------|---------------------|----------|
| AmniSure ROM Test (25) | Box of 25 test kits | Inquire |
| AmniSure ROM Test (10) | Box of 10 test kits | Inquire |
| AmniSure Test Starter Kit | Starter kit | Inquire |

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

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