

# When ROM is suspected, the clock is ticking.



Include AmniSure® for rapid, reliable results.



Sample to Insight

## Are mom and baby at risk?

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

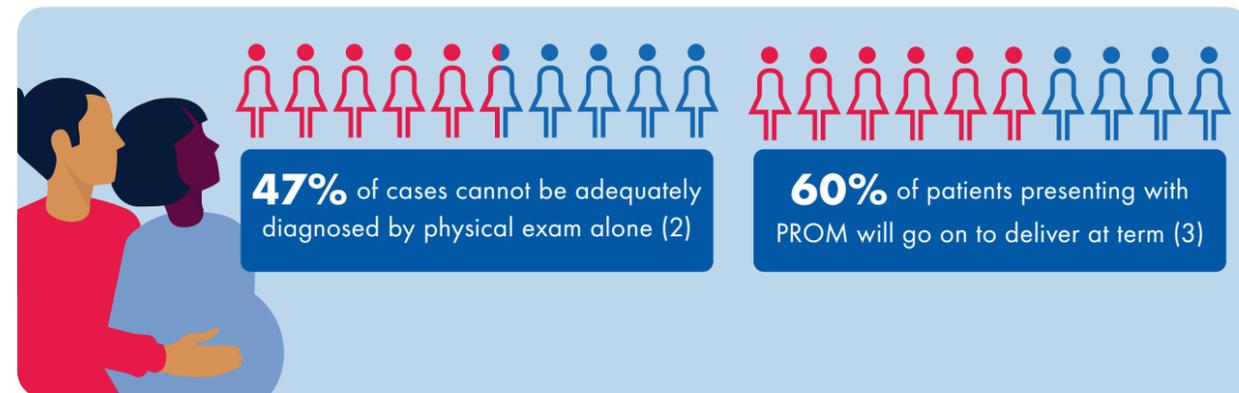
Early detection brings clarity and protects mother and child



## Finding the balance

When not addressed quickly and appropriately, premature ROM (PROM) can result in complications for both mother and baby. Traditional methods of ROM diagnosis, such as ferning or nitrazine, are likely to result in either false positives or false negatives and may lead to the respective over/undertreatment of vulnerable pregnant women (1).

A test that reliably identifies when expectant mothers are experiencing PROM 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.



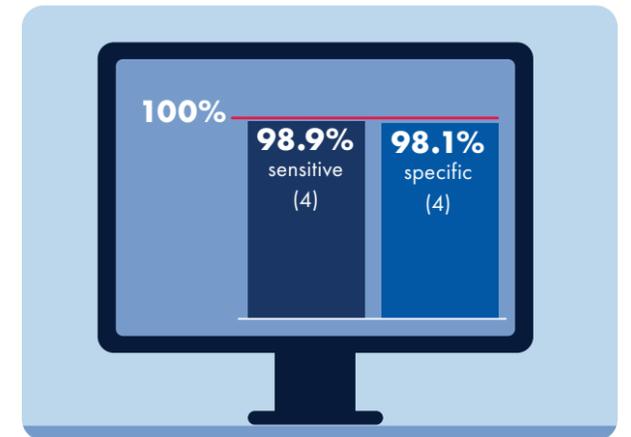
AmniSure is a rapid, qualitative test that accurately detects placental alpha microglobulin-1 (PAMG-1) in patients presenting with signs, symptoms, or complaints suggestive of ROM. Including AmniSure as part of the ROM assessment can provide additional insight to guide clinical decisions.

Feature	AmniSure
Cited in more than 30 publications	✓
~99% correlation to indigo carmine (3)	✓
Detects high-concentration of PAMG-1 (4)	✓
No gestational age limitation (4)	✓
No speculum required (4)	✓
Reliable in blood (5)	✓

## Results you can trust

AmniSure is highly sensitive and specific for assessment of ROM, routinely outperforming conventional methods of diagnosis (1,6,7).

Specifically, nitrazine and ferning are known to sometimes result in false positives and false negatives, largely due to interfering substances such as blood, urine, semen, and certain infections (7). AmniSure performance is unaffected by these substances, leading to reliable results that can help guide clinical decisions (5,7).



## The value of PAMG-1 as a ROM biomarker

Regardless of gestational age, high concentrations of 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 that fetal membranes have ruptured (6).

Other available ROM immunoassays measure the concentration of alternative biomarkers. However, IFU data of commercially available ROM biomarker tests reveal that the presence of relevant PAMG-1 is a more accurate measure of ROM status (4,8,9).

	AmniSure ROM Test (4)	ROM Plus® test (8)	Actim® PROM (9)
Amniotic fluid biomarker(s) detected	PAMG-1	IGFBP-1 (PP12) & AFP	IGFBP-1
Overall specificity	98.1% without speculum	75.0% without speculum	91.0% without speculum 86.4% with speculum
Overall sensitivity	98.9% without speculum	99.1% without speculum	90.1% without speculum 95.5% with speculum

When ROM is suspected, AmniSure 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.

## Ready and reliable

AmniSure is 98% accurate, is ready to use as packaged with no additional tools necessary, can be administered bedside or in the lab by qualified staff, has no gestational age limitation, and is not affected by blood – enabling a fast and effective response in almost any situation when ROM is suspected (4).

### The AmniSure 4-step test procedure

1

#### Collect sample

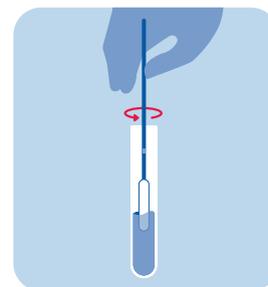
1 minute collection.  
Collect sample of vaginal discharge with sterile collection swab (no speculum required).



2

#### Transfer to solvent

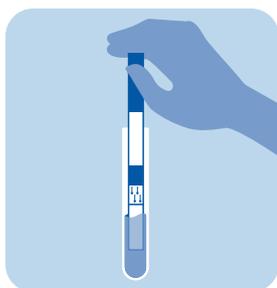
1 minute dilution.  
Rinse specimen swab in solvent vial.  
Discard swab.



3

#### Insert test strip

Insert test strip into vial to initiate PAMG-1 detection process.  
After 10 minutes, remove the test strip, and read the results within 5 minutes.

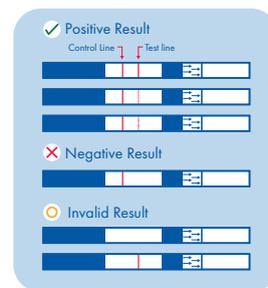


4

#### Read results

Remove test strip from vial, observe and record results. Do not read strip after 15 mins have passed since dripping strip into vial.

Note: Faint or broken lines should always be read as positive.



#### References:

1. Abdelazim, I.A. and Makhlof, H.H. (2012) Arch. Gynecol. Obstet. 285, 985-989.
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3. Silva, E. and Martinez, J.C. (2009) Diagnosing ROM: a comparison of the gold standard, indigo carmine amnioinfusion, to the rapid immunoassay, the AmniSure ROM test. J. Perinat. Med. 37, 956.
4. AmniSure IFU <https://www.qiagen.com/de/resources/resourcedetail?id=d91f71db-e3bc-4c16-b654-1831d2fe322c&lang=en>
5. Ramsauer, B., Duwe, W., Shlehe, B., et al. (2015) Effect of blood on ROM diagnosis accuracy of PAMG-1 and IGFBP-1 detecting rapid tests. J. Perinat. Med. 43(4), 417
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8. ROM Plus IFU <https://www.laborie.com/wp-content/uploads/2021/07/OB-MAN-001-EN-ART0087REV02-ROM-Plus-IFU.pdf>
9. Actim PROM IFU <https://www.coopersurgical.com/wp-content/uploads/Actim-PROM-Test-Kit-Instructions-for-Use.pdf>



Include AmniSure in your ROM clinical assessment for results you can trust.

Talk to an AmniSure specialist or visit [www.qiagen.com](http://www.qiagen.com) today to get started.

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