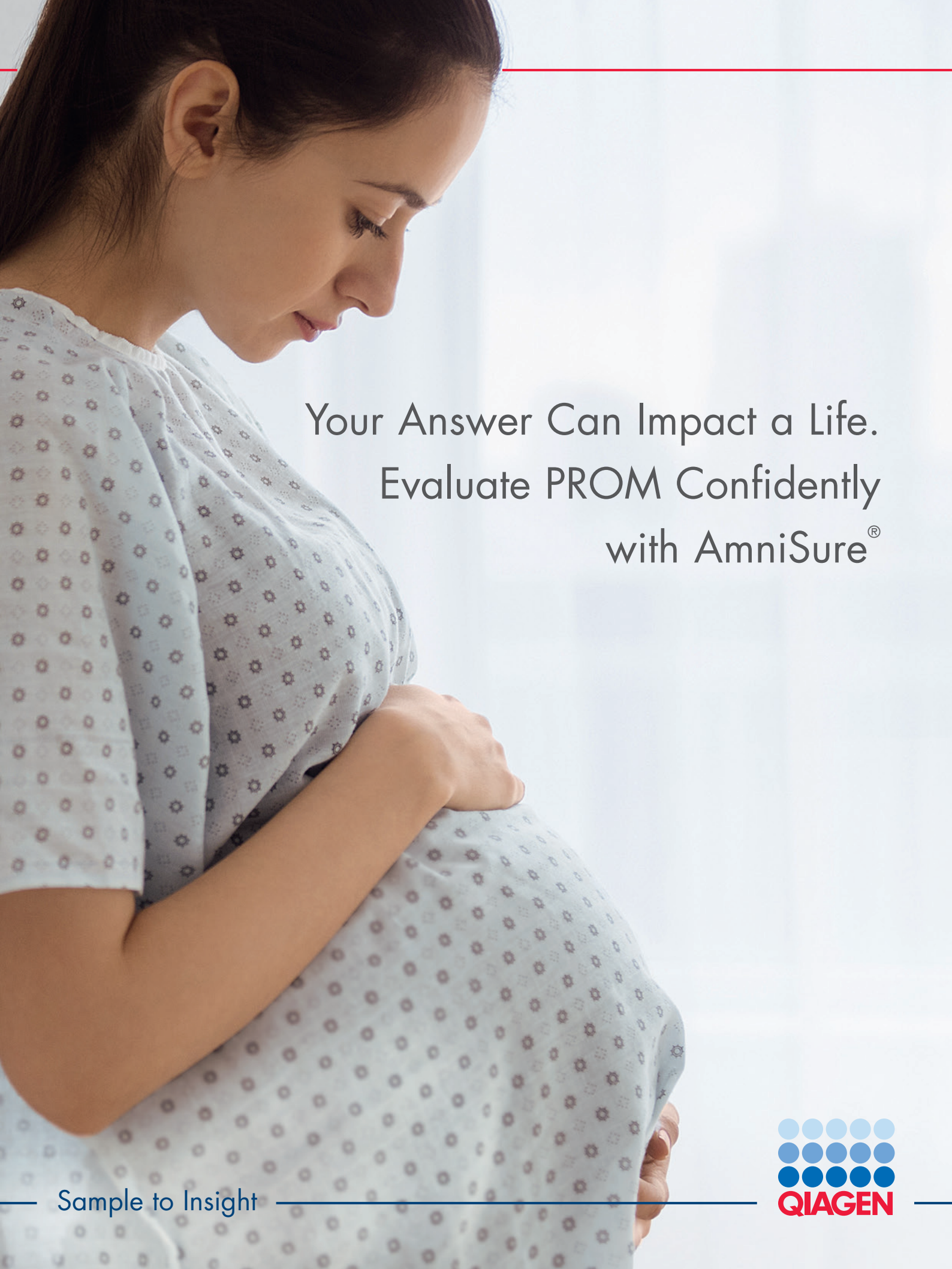


Your Answer Can Impact a Life. Evaluate PROM Confidently with AmniSure®

Sample to Insight

QIAGEN

Should you admit her or send her home?

The uncertainty of diagnosing PROM

When a patient presents with suspicion of 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 and is the only ROM test with proven correlation to 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).

- No confirmatory test required for a positive ROM result
- Saves time and costs of additional ROM diagnostic methods
- Consistent performance across all gestational ages
- 99% correlation with gold standard – indigo carmine dye infusion
- Sensitive (99%) and specific (98%), to support diagnostic accuracy of negative and positive ROM results

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 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).

Clinical evidence consistently validates the high accuracy of the AmniSure ROM Test

Clinical studies investigating efficacy of 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

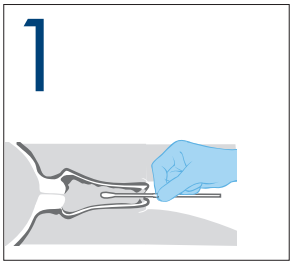
PPV: positive predictive value.

NPV: negative predictive value.

N/A: not available.

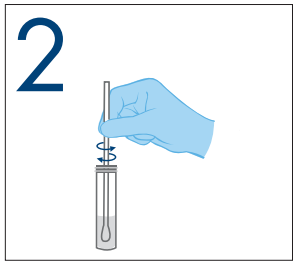
Test procedure*

Collect sample



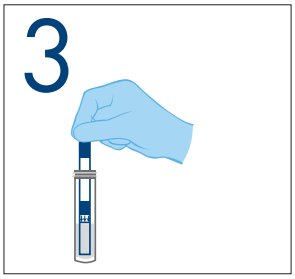
Collect sample of vaginal discharge with sterile collection swab (no speculum required).

Transfer to solvent



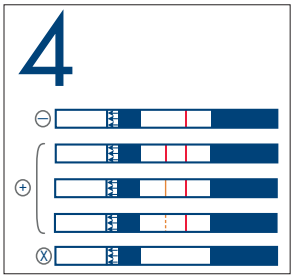
Rinse specimen swab in solvent vial. Discard swab.

Insert test strip



Insert test strip into vial to initiate PAMG-1 detection process.

Read results



Remove test strip from vial, observe and record results.

Reading results

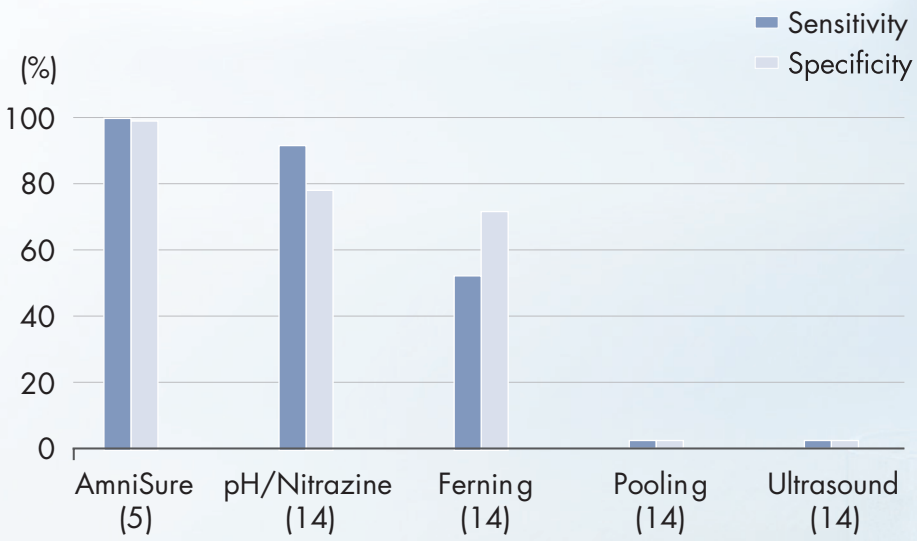
Positive: two red lines	**Negative: one red control line**
PROM may be diagnosed with clinical judgement	PROM may be ruled out with clinical judgement
	Negative result 
Important notice Faint or broken lines should always be read as positive.	Invalid result 

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

How does AmniSure compare to other ROM diagnostics?

Nitrazine, pooling, and ferning used in combination yield a negative predictive value (NPV) of only 54.5% compared to 91.3% for PAMG-1 detection with AmniSure. AmniSure also provides reliable results in the presence of common interfering substances known to interfere with traditional methods (5), including:

- Urine
- Trace blood
- Semen
- Vaginal infections



Superior sensitivity and specificity. 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 ROM 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.

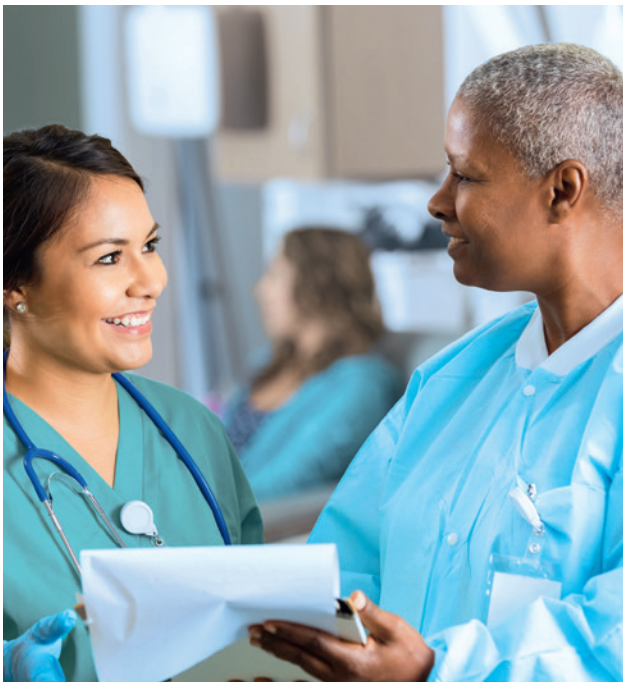
How many cases are you over-treating?

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 neonate (14).

- Using various combinations of traditional methodologies, 2–22% of cases can be falsely diagnosed (15).
- Current ROM 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 pPROM still accounts for 25–30% of premature births (19).

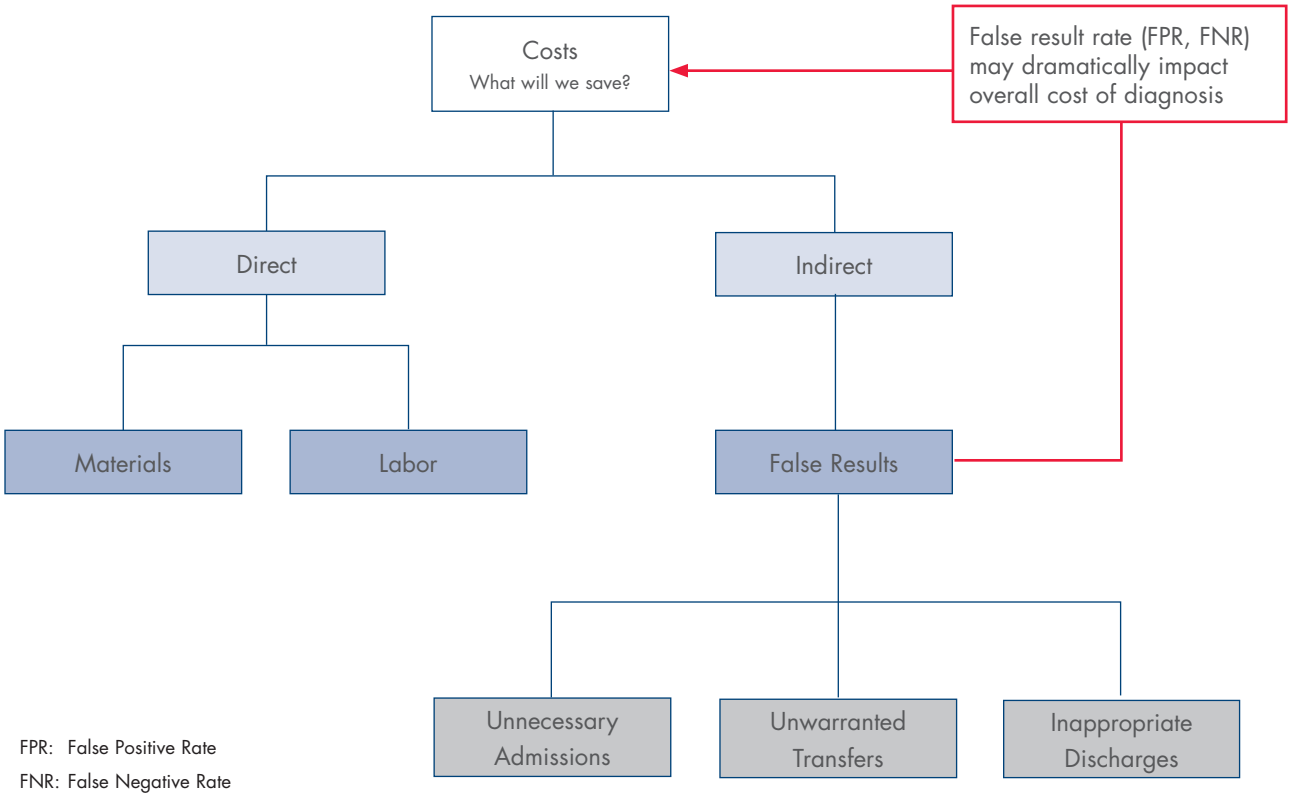


A **false positive** can result in unnecessary medications, transfers, hospital admission, and induction (10, 20–23).

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 when using the PAMG-1 test (15), primarily due to reductions in:

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



FPR: False Positive Rate
FNR: False Negative Rate

Clinical evidence supports diagnostic accuracy.*

Start with AmniSure.

Use AmniSure as an aid in ROM diagnosis 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 ROM diagnostic found to correlate 99% with indigo carmine intra-amniotic injection, recognized by ACOG as the ROM testing gold standard (7)
- Demonstrated by multiple studies to be a more accurate aid in detecting PROM than other ROM tests, including IGFBP-1 (8, 9, 23, 26)

* Results should be used alongside appropriate clinical judgement.

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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