

"Become actively involved in your care. This means learning all you can about your own high-risk condition...ask questions and if you don't understand the answers, keep asking...find out what options are available and what the consequences are of each one...participate in decisions being made about your care."

<http://www.sidelines.org/what-is-sidelines/>

Sidelines is a 501(c)(3) non-profit organization providing international support for women and their families experiencing complicated pregnancies and premature births.

To contact Sidelines,  
call (888) 447-4754  
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# ✓ AmniSURE®

AmniSure® is a safe, reliable, rapid, non-invasive test for rupture of fetal membranes that does not require a speculum examination.

Ask your medical caregiver if he or she is aware of the new AmniSure® technology.

For more information visit  
[www.amnisure.com](http://www.amnisure.com)



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## “Did my water break?”

Rupture of fetal membranes can occur at any point in pregnancy. The earlier it occurs, the greater the potential for complications.

# AmniSURE®

A next-generation, rapid,  
non-invasive test for  
Rupture of Fetal Membranes

## Water breaking or premature rupture?

It's a familiar scene: all of a sudden you notice a gushing of liquid and a puddle at your feet, and you know – it's time. You know that at the right moment, the amniotic sac that has been protecting your baby through nine months of pregnancy will rupture and the accompanying gushing out of "water" will signal that labor is about to begin.

Fetal membranes and amniotic fluid create a protective environment that is crucial for fetus development. Normally, these membranes rupture just at the right time before the onset of active labor. Sometimes, however, membranes may rupture prematurely, and rather than a gushing of liquid, the leakage can be barely detectable or mistaken for another fluid. The earlier in pregnancy that the premature rupture occurs, the greater the potential for complications.

## Why worry?

Here are some important facts about Rupture Of (fetal) Membranes (ROM) that reflect the importance of diagnosing this symptom in a timely and reliable manner:

- ✓ Approximately one out of every ten women have their water break prematurely.
- ✓ Premature ROM is associated with 30-40% of preterm deliveries.
- ✓ Prematurity, in turn, causes 85% of neonatal morbidity and mortality.
- ✓ Maternal infection rates can be as high as 60%.
- ✓ In cases of very early premature rupture, maternal death rates are 1-2 cases per 1000.
- ✓ Additional complications can arise involving the umbilical cord and the placenta.

## What if ROM is suspected?

Failing to detect ROM quickly and correctly can result in delayed treatment and serious complications. On the other hand, diagnosing a rupture where none exists can lead to unnecessary and potentially harmful intervention. This is why having the right diagnostic tool is so critical.

Here is a typical scenario if ROM is suspected. First, a doctor or nurse would speak to you about your symptoms; then he or she would perform one or more tests, usually involving a speculum exam or deep specimen collection. The health practitioner would visually inspect for the presence of fluid, analyze a specimen, and possibly perform an ultrasound evaluation.

If the diagnosis was negative for rupture, you might be sent home. If the diagnosis was positive or inconclusive, you would be kept for observation. If ROM was suspected and you were at term, labor might be induced. If ROM was suspected and you were at an early gestation stage, you might be given tocolytics to delay labor, corticosteroids to speed up or boost the baby's development and strength, and/or antibiotics to fight potential infection.

Any of these treatments (or lack of treatment) could be unnecessary, inappropriate or harmful depending on whether or not the correct diagnosis has been made.

So much hinges, therefore, on the reliability of the diagnostic tools that are available to the medical community for the diagnosis of ROM. Unfortunately, until now, these tools have had serious limitations; they were developed using older medical and scientific technologies, and they were either invasive or inaccurate, or both.

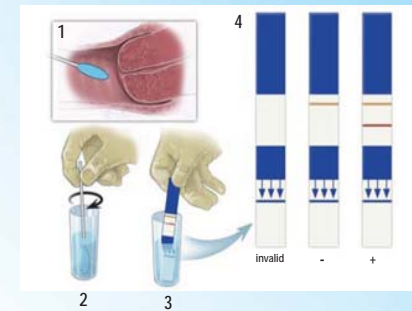
## How can I be SURE?

AmniSure® is a next-generation diagnostic test that helps detect fetal membranes rupture. It is the first FDA-approved rapid strip test for ROM that is both reliable and non-invasive.

## How does AmniSure® work?

AmniSure® detects the presence of amniotic fluid. While it is currently available for use by medical professionals only and you can't yet buy AmniSure® at a drug store, it is as simple to use as the kind of pregnancy test that is sold for home use.

Data describes AmniSure as being ~ 99% accurate.\* The test involves collecting a sample with a swab that is inserted vaginally for one minute. The swab is washed in a supplied vial with a solvent for one minute and disposed of. Then the AmniSure® test strip is dipped into the vial. The test result is indicated visually over the next few minutes by the presence of one or two lines on the test strip. Depending on what shows up on the test strip, either there is NO membrane rupture, or there IS a rupture; or the result is unclear and the test needs to be taken again.



1. Sample of vaginal secretion is taken by sterile swab
2. Swab is rinsed in a vial with solvent and then discarded
3. Test strip is dipped in the vial for ~ 5 minutes
4. Test strip is removed from the vial and results are read:

- ✓ One line: there is NO membrane rupture
- ✓ Two lines: there IS a rupture
- ✓ No lines: the test is INVALID and should be repeated

\* References:

Larry M. Cousins, M.D. et al. "AmniSure® Placental Alpha Microglobulin-1: Rapid Immunoassay versus Standard Diagnostic Methods for Detection of Rupture of Membrane." American Journal of Perinatology, June 2005.

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