Frequently Asked Questions

What is AmniSure® and how can it help?

AmniSure® is a rapid test that aids in detecting Rupture Of [fetal] Membranes (ROM) in women with signs and symptoms suggestive of ROM. ROM presents the risks of infection, fetal distress, prolapse of the umbilical cord, postnatal endometritis and abruptio placenta.[1,3] Premature ROM could also lead to premature delivery. All these consequences increase the likelihood of fetal and maternal morbidity and mortality. AmniSure® can help diagnose ROM in a timely and accurate manner, so that appropriate and opportune measures can be taken.

Under what conditions and when is the use of AmniSure® recommended?

The test is for use by healthcare professionals to aid in the detection of fetal membranes rupture in pregnant women when they report signs, symptoms, or complaints suggestive of such a rupture. AmniSure® should be used in sites or by qualified personnel (physicians, certified nurse-midwives, or labor and delivery nurses certified to evaluate ROM) similar to those of clinical trials that were performed on the product. AmniSure® can therefore be used in a variety of settings, from OB/GYN clinics and doctors' offices to outpatient clinics and labor admitting rooms.

How does the test work?

AmniSure® is a one-step immunochromatographic device. The test is based on the use of several, specifically selected, monoclonal antibodies that detect trace amounts of the amniotic fluid protein PAMG-1, which is present in cervico-vaginal discharge after the rupture of the fetal membranes. During the test procedure, PAMG-1 from the sample sequentially binds to a monoclonal antibody conjugated with the label particles, and then to antibodies immobilized on an insoluble carrier.

What is PAMG-1?

Placental alpha microglobulin-1 is a protein expressed by the cells of the decidual part of the placenta. During pregnancy, PAMG-1 is secreted into the amniotic fluid.

What is the benefit of PAMG-1 over other antigens?

PAMG-1 was selected as a marker of fetal membranes rupture due to its extremely low background level in the presence of intact fetal membranes, when measured in cervico-vaginal discharge.

Based on published data, the AmniSure® test is ~99% accurate.[1-5] In clinical trials, an AmniSure® test correlated with the clinical diagnosis obtained through the *combined* usage of three routinely used tests—nitrazine, ferning, and pooling. The simplicity of the test provides for equally accurate results when the test is conducted in OB/GYN clinics and exam rooms. The diagnostic accuracy of the AmniSure® test relies on its sensitivity threshold, which is set at the low level of 5 ng/ml (while the background cervico-vaginal concentration of PAMG-1 is only 0.05-0.22 ng/ml).

Can samples be stored for subsequent testing?

Whenever possible, the AmniSure® test should be performed immediately after sample collection. If necessary, however, samples can be stored in a refrigerator (at +4°C) for six hours.

Is a false result possible?

In cases where trace amounts of blood are present on the swab, the test functions properly. When there is a significant presence of blood on the swab, the test can malfunction and its use is not recommended. In such cases, a separate sample without considerable amounts of blood should be taken and tested. The test result may be negative when the sample is taken 12 or more hours after a presumed fetal membrane rupture has occurred (i.e. due to a possible "resealed" rupture or the temporary obstruction of leakage).

Will medical procedures affect the results of the test?

Yes. AmniSure® should not be used within 6 hours after the removal of any disinfectant solutions or medications from the vagina.

How should the AmniSure® test kit be stored?

A sealed AmniSure® test must be stored in a dry place, at +4°C to +24°C. The test should not be frozen or used beyond the expiration date stamped on the product. AmniSure® must be used within 6 hours after opening and the test kit components should not be reused.

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AmniSure®

Rapid, Reliable, Non-Invasive Test for ROM

(Rupture Of [fetal] Membranes)

ACCURATE
~99% accurate according to published data[1-6]

SENSITIVE
Detects miniscule amounts of amniotic fluid in vaginal discharge

NO SPECULUM
No need for speculum exam, additional reagents, or other equipment

FDA CLEARED, CE MARKED
The first FDA-cleared ROM immunoassay

RAPID
The result can be evaluated visually in minutes

ONE DEVICE
Covering the entire diagnostic spectrum – from the most difficult cases (micro-ruptures) to confirmatory diagnosis[1]

NEW TECHNOLOGY
Monoclonal antibodies – new generation device employing immunochromatographic method

WIDE USER BASE
An aid to physicians, the test can also be performed by nurses and nurse-midwives

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AmniSure®

Rapid, Reliable, Non-Invasive Test for ROM

The Diagnosis of Premature Rupture of Membranes (ROM)

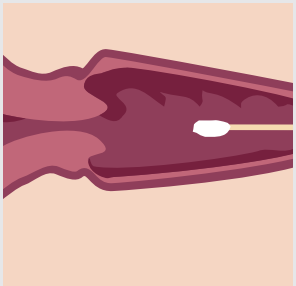
Diagnosing Rupture Of fetal Membranes (ROM) is of critical importance for the clinician.[1-3] An accurate diagnosis of ROM at any term during pregnancy is crucial to timely and proper treatment and to determine the need for prompt hospitalization.[3] The failure to identify patients with ROM can result in a delay or inability to implement salutary obstetric measures. Conversely, the false positive diagnosis of ROM can lead to inappropriate or untimely interventions such as hospitalization or induction of labor.

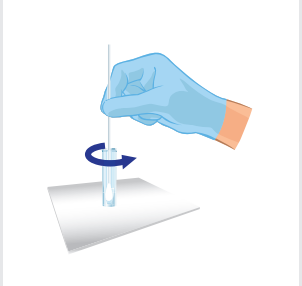
The accurate diagnosis of ROM, however, remains a frequent clinical problem in obstetrics.[3-4] Many currently-used tests have significant limitations and are to some degree invasive, requiring sample collection using speculum examination.[1]

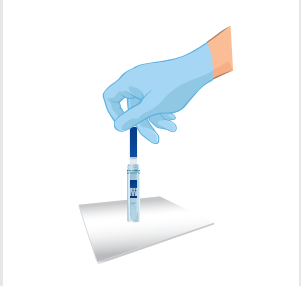
AmniSure® is a rapid, non-invasive test that aids in the detection of ROM in pregnant women with signs and symptoms suggestive of the condition. It provides an easy-to-interpret, accurate, and timely diagnosis that enables clinicians to take opportune measures to prevent complications.

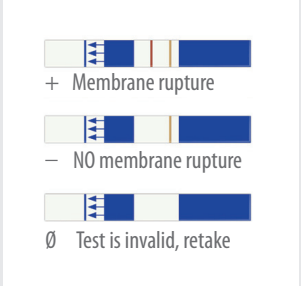
The AmniSure® test does not require a speculum examination. The sample is taken by sterile swab, which is inserted only 5-7 cm deep into the vagina. A clear "Yes/No" result can be read in minutes (Figure 1).

Figure 1 / Abbreviated Test Procedure

1. 
Sample of vaginal discharge is taken by sterile vaginal swab (no speculum required)

2. 
Swab is rinsed in vial with solvent and then disposed of

3. 
Test strip is inserted into vial and removed when two lines are visible, or at 10 minutes

4. 

Test strip is extracted from the vial and results are observed

How it Works

AmniSure® is a one-step immunochromatographic assay. It detects trace amounts of PAMG-1, a protein found in amniotic fluid that appears in vaginal discharge after fetal membranes rupture. Monoclonal antibodies are used to detect the protein.

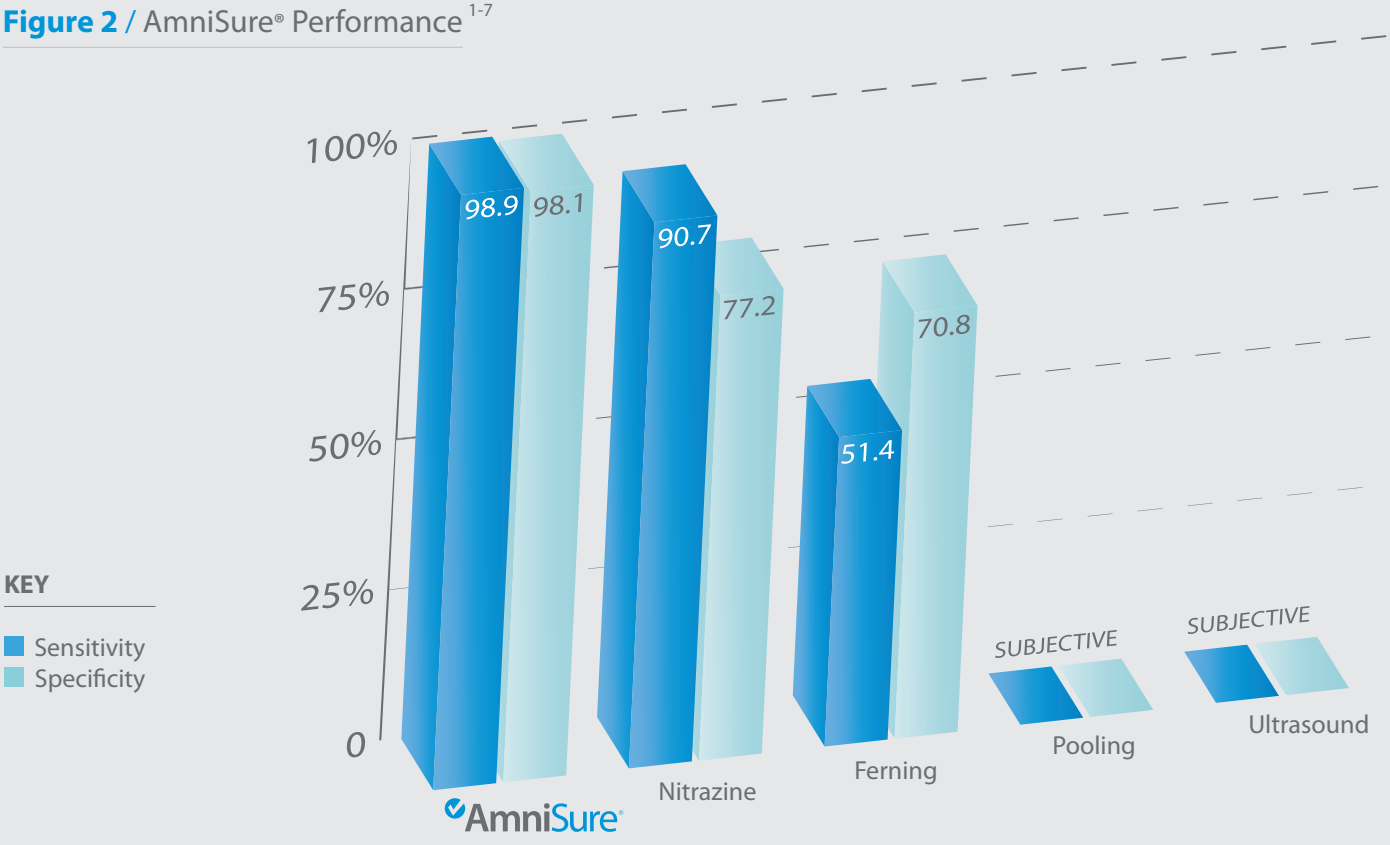
AmniSure® works within a wide range of PAMG-1 concentrations potentially found in vaginal discharge (from 5 ng/ml to 100 µg/ml). The diagnostic accuracy of the test allows it to detect even a minuscule amount of released amniotic fluid. With intact fetal membranes, the test does not normally detect PAMG-1 due to its low background concentration.

Performance Metrics

The clinical performance of the AmniSure® test was determined by three studies, where it was compared to a control consisting of a clinical diagnosis provided by a *combination* of the routinely used nitrazine, ferning, and pooling tests.[1-3] A control diagnosis was established when two out of three control tests gave identical results. In these studies, a total of 432 patients with gestational ages ranging from 11 to 41 weeks were evaluated at multiple sites.

Relative to the control diagnosis determined by the routine clinical tests, AmniSure®'s sensitivity and specificity were estimated at 98.9% and 98.1%, respectively.[1-3] Accuracy: ~ 99%.[1-7]

Figure 2 / AmniSure® Performance [1-7]



References

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3. Caughey AB, Robinson JN, and Norwitz, ER. Contemporary Diagnosis and Management of Preterm Premature Rupture of Membranes. Rev Obstet Gynecol. 2008; 1 (1):11-22.
4. Chen FC, Dudenhausen JW. Comparison of Two Rapid Strip Tests Based on IGFBP-1 and PAMG-1 for the Detection of Amniotic Fluid. Am J Perinatol. 2008; 25 (4):243-6.
5. Lee SE, Park JS. Measurement of Placental Alpha- Microglobulin-1 in Cervicovaginal Discharge to Diagnose Rupture of Membranes. Obstet Gynecol. 2007; 109:634-640.
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7. El-Messidi A, Cameron A., Diagnosis of premature rupture of membranes: inspiration from the past and insights for the future. J Obstet Gynaecol Can. 2010 Jun;32(6):561-9.