AmniSure® ROM (Rupture of Membranes) Test
INTENDED USE

• The AmniSure ROM (Rupture Of Membranes) Test is a rapid, qualitative test for the detection of amniotic fluid in vaginal discharge of pregnant women.

• The AmniSure ROM Test detects PAMG-1 protein marker of the amniotic fluid in vaginal discharge.

• The test is indicated for women reporting signs, symptoms, or complaints suggestive of ROM.

• The test will be performed by laboratory staff.
OVERVIEW

• The AmniSure ROM Test kit is a self-contained test system providing qualitative results that are both accurate and do not require collection methods such as speculum examination.

• A sample of amniotic fluid (taken by vaginal swab) is placed into a vial with a solvent. The solvent extracts the sample from the swab for one minute, after which the swab is disposed.
PRINCIPLE

• The AmniSure ROM Test uses the principles of immunochromatography to detect human PAMG-1 (placental alpha microglobulin-1) protein present in amniotic fluid of pregnant women.

• Placental Microglobulin was selected as a marker of fetal membranes rupture due to its unique characteristics, i.e. its high level in amniotic fluid, low level in blood and extremely low background level (50-220 picogram/ml) in cervico-vaginal discharge when the fetal membranes are intact.
Specimen Collection Supplies

- Amnisure kits will be stored in the laboratory.

- When a test is ordered, call the laboratory and request a collection vial.

- Provide patient name and CSN.

- A solvent vial and sterile polyester swab will be sent by the laboratory to the nursing unit.
SPECIMEN COLLECTION

• Take the solvent vial by its cap and shake to ensure all liquid in the vial has dropped on the bottom.
• Open the solvent vial and put it in a vertical position.
• Use the sterile polyester swab provided by the lab.
• Remove the sterile swab from its package.
  
  Note: The polyester tip should not touch anything prior to insertion into vagina.
• Hold the swab in the middle of the stick and while a patient is lying flat on her back, carefully insert the polyester tip of the swab into the vagina until the fingers contact the skin, no more than 2-3 inches (5-7 cm) deep.
Specimen Collection

• Withdraw the swab from the vagina after 1 minute.

• Place the polyester tip of the swab into the vial and rinse in the solvent by rotating for 1 minute.

• Remove and dispose of the swab.

• Place an EPIC label on the vial and write the date and time of collection, and collector ID on the label.

• Send labeled vial to lab immediately.
INTERFERING SUBSTANCES

• When there is a significant presence of blood on the swab, the test can malfunction and is not recommended.

• Vaginal infections or urine do NOT interfere with the results of the AmniSure ROM Test.
LIMITATIONS

• Until the diagnosis of membrane rupture is excluded, avoid digital cervical exam to prevent infection and shorten the latency period. (Exclusion criteria include active vaginal bleeding from any source and placenta previa.)

• Interrupted leakage with minimal residual fluid can lead to false negative result.

• In very rare cases when a sample is taken 12 hours or later after a rupture, a false negative result may occur due to obstruction of the rupture by fetus or resealing of the amniotic sac.

• The test should not be used earlier than 6 hours after the removal of any disinfectant solutions or medicines from the vagina.

• Placenta previa and performing digital exams prior to sample collection can lead to inaccurate test results.

• Test performance in patients without signs or symptoms of ROM is unknown.
LIMITATIONS

• Results should be used in conjunction with other clinical information.

• Failure to detect membrane rupture does not assure the absence of membrane rupture.

• Women may labor spontaneously despite a negative test result.

• The performance of the AmniSure ROM Test has not been established in the presence of the following contaminants: anti-fungal creams or suppositories, K-Y Jelly, Monistat, Baby Powder (Starch and Talc), Replens, or Baby Oil.

• The performance of the AmniSure ROM Test has not been established in the presence of meconium in the amniotic fluid.