

AmniSure® ROM (Rupture of Membranes) Test

Anna Vischio, M.D., MPH, PGY IV, Department of Pathology and Laboratory Medicine

The Danbury Hospital Department of Pathology and Laboratory Medicine is pleased to announce the availability of the AmniSure® ROM test for the detection of amniotic fluid in vaginal secretions of pregnant women. AmniSure® is a rapid, immunochromographic test for PAMG-1 (placental alpha microglobulin-1), a protein present in amniotic fluid. AmniSure® is intended to aid in the detection of rupture of fetal membranes in pregnant women who report signs, symptoms or complaints suggestive of ROM.

The timely and accurate diagnosis of ROM is crucial because it may be associated with serious neonatal and maternal consequences. Failure to identify patients with ROM, premature rupture of membranes (PROM) or preterm premature rupture of membranes (PPROM) may lead to infection, oligohydramnios, preterm delivery, fetal distress, prolapsed cord and abruptio placenta.

A study was performed at Danbury Hospital comparing the AmniSure® test to the current diagnostic methods for ROM including the nitrazine pH test, microscopic fern test and visual assessment of amniotic fluid pooling. Vaginal secretion specimens from 25 pregnant women triaged at Danbury Hospital’s Labor and Delivery Unit were collected from October 6, 2010 to January 26, 2011. The nitrazine pH and fern tests and visual assessment of vaginal amniotic fluid pooling were performed by OB/GYN physicians as per normal procedures. In addition, a vaginal swab sample was collected for the AmniSure® test, which was performed by the laboratory. Physicians were blinded to the results of the AmniSure® test. Sensitivity, specificity, positive and negative predictive value and overall test accuracy were calculated vs. the final determination of ROM following clinical record (chart) review. The results follow:

Performance Metrics (%)

	AmniSure Test	Fern Test	Nitrazine Test
Sensitivity	93.3	73.3	86.7
Specificity	100	100	70.0
PPV	100	100	81.3
NPV	90.9	71.4	77.8
Accuracy	96.0	84.0	80.0

SPECIMEN REQUIREMENTS:

A vaginal swab must be collected using the sterile polyester swab provided in the AmniSure® ROM test kit.

Vaginal Sample Collection: With the patient in position for a pelvic exam, insert the tip of the sterile polyester swab provided into the vagina until the fingers contact the skin no more than 2-3 inches deep. Withdraw the swab from the vagina **after one minute**. Place the polyester tip into the plastic vial and rinse the swab in the solvent by rotating for **one minute**. The vial must be securely capped. Remove and dispose of the swab. Label the plastic vial provided with the patient identification information, including patient name **and** medical record number. Write the time of collection on the label. Place the specimen into a biohazard bag and seal it. The sample **must be delivered directly to the Microbiology Lab within 15 minutes of collection**.

TESTS REQUESTS:

Requests for the test will be performed on pregnant women who report signs, symptoms or complaints suggestive of ROM. Requests can be placed in CPOE/Soarian as AmniSure.

EXPECTED RESULTS:

The AmniSure® ROM test is expected to be positive in women with rupture of fetal membranes and indicates that PAMG-1 (placental alpha microglobulin-1) protein is present in vaginal secretions. A negative test result is expected if ROM has not occurred. Questions regarding this test may be directed to the Microbiology section of the laboratory at 203-739-7685.

References:

1. Cousins LM et al., "AmniSure® Placental alpha Microglobulin-1 Rapid Immunoassay versus Standard Diagnostic Methods for Detection of Rupture of Membranes", *Am J Perinatol* 2005; 22:317-320.
2. Lockwood C.J. et al., *Am. J. Obstet. Gynecol.* 1994, 171, No 1, pp. 146-150.
3. Caughey AB, Robinson JN, and Norwitz, ER. *Contemporary Diagnosis and Management of Preterm Premature Rupture of Membranes. Rev Obstet Gynecol.* 2008; 1 (1):11-22D.
4. Petrunin, "Immunochemical identification of organ specific human placental alpha-globulin and its concentration in amniotic fluid", *Akush Ginekol (Mosk)* 1977 Jan (1):64-5.
5. Y. Takarinov, D. Petrunin Et al. 1980; "Two new Human Placenta-Specific α -Globulins: Identification, Purification, Localization, and Clinical Investigation", *The Human Placenta*, Ed by A. Klopper et al., Acad. Press, London-NY, pp. 35-46.
6. 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.
7. Lee, S, Park J "Measurement of Placental Alpha-Microglobulin-1 in Cervicovaginal Discharge to Diagnose Rupture of Membranes", *Obstet Gynecol* 2007; 109: 634-640.
8. Lee SM, Lee J, Seong HS, Lee SE, Park JS, Romero R, Yoon BNH. *The Clinical Significance of a Positive AmniSure Test in Women with Term Labor with Intact Membranes. J Matern Fetal Neonatal Med* 2009; 22(4): 305-310.

REQUISITIONS FOR PATIENT TESTING:

Please remember to include the first and last name of the clinician ordering the test to ensure that reports are forwarded to the correct recipient. The first and last name of the patient is also required on the requisition as well as the medical record number, date of birth and/or social security number.

"Previous issues of Technically Speaking can be accessed at <http://www.danburyhospital.org/About-Us/Publications/Technically-Speaking.aspx>