HACKETTSTOWN REGIONAL MEDICAL CENTER
Department Policy Manual – Labor and Delivery

Amnisure for Ruptured (fetal) Membrane

Effective Date:	January 19, 2009	**Policy No:**	POC OB 0001-1
Cross Referenced:	July 19, 2010	**Origin:**	Point of Care Tests
Reviewed Date:	7/10;11/11;6/12	**Authority:**	Cristina Hom, MLS (ASCP), POC Coordinator
Revised Date:	September 5, 2012	**Page:**	1 of 3

SCOPE:
Labor and Delivery nurses and Licensed Individual Practitioner.

PURPOSE:
To aid in the diagnosis of premature rupture of fetal membrane (PROM) in pregnant women with signs, symptoms and complaints that are suggestive of PROM.

DEFINITION:
PROM – Premature Rupture of Membrane
QC – Quality Control
PAMG 1 – Placental Alpha 1 Microglobulin
LIP – Licensed Independent Practitioner

POLICY:
1. This test must be ordered by the Physicians and/or LIP (Licensed Independent Practitioner) when the PROM (Premature Rupture of {fetal} Membrane) is suspected.
2. Quality controls will be done in the laboratory by the POC coordinator for every new lot of test kits. Results will be entered in the QC log sheet.
3. Only authorized clinicians may perform the Amnisure testing. Authorized clinicians are those individuals who have attended a training session and successfully passed the quiz.
4. Patient results will be entered in nurse's progress notes.
5. Test must be performed immediately after sample collection. If necessary, samples can be stored in a monitored refrigerator (2 - 4°C) for up to six hours.
6. Test is **not recommended** when there is a heavy discharge of blood. It causes a false positive result.
7. Use only a **Polyester** swab; Do Not use cotton, Dacron or rayon swab.
8. Repeat test that is invalid.
9. New employees must be screened for color blindness in Employee Health and complete a competency.
10. All employees will be recertified through an annual competency.

NOTE: Amnisure should not be used within 6 hours after the removal of any disinfectant solutions or medicines from the vagina.

PRINCIPLE:
Amnisure is a one-step immunochromatographic assay. Three monoclonal antibodies are used in the test to detect PAMG-1, one of the amniotic fluid proteins that appear in the vaginal secretion after the membranes rupture. With intact fetal membranes, the test does not normally detect PAMG-1 due to its low background concentration. Amnisure works within a wide range of PAMG-1 concentrations in vaginal secretion from 5ng/ml to 100mcg/ml. Diagnostic accuracy of the test relies on only miniscule amount of released amniotic fluid. Amnisure assay also does not require speculum examination.

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STORAGE: Store the kit in a dry place at 4 to 20°C. **DO NOT FREEZE**. Test kit is stable until expiration date on the foil pouch but once opened the test strip should be used within 6 hrs. Fresh human amniotic fluid (use for QC) can be stored under refrigeration at 4 – 8 C for up to 24 hours. It is preferable to run the QC immediately after preparing the sample with saline solution.

MATERIALS:

- Amnisure test kit in foil pouch
- Sterile Polyester swab (supplied in kit)
- Plastic vial with solvent (supplied in kit; contains 0.9% sodium chloride, 0.01% triton x 100, 0.01 NaN3)
- Timer.

PATIENT PROCEDURE:

1. Take the solvent vial by its cap and shake well to make sure all liquid in the vial has dropped on the bottom. Open the solvent vial and put it in a vertical position.
2. To collect a sample from the surface of the vagina use the sterile Polyester swab provided. Remove the sterile swab from its package following instructions on the package. The Polyester tip should not touch anything, prior to its 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 deep. **Withdraw the swab from the vagina after 1 minute**.
3. Place the Polyester tip into the vial and rinse the swab in the solvent by rotating for one minute.
4. Remove and dispose of the swab.
5. Tear open the foil pouch at the tear notches and remove the AmniSure test strip.
6. Dip the white end of the test strip (marked with arrows) into the vial with solvent **for no less than 5 minutes and no longer than 10 minutes**. Strong leakage of amniotic fluid will make the results visible early (after 5 minutes) while a very small leak will take the full 10 minutes.
7. Remove the test strip if two stripes are clearly visible in the vial (no earlier than 5 minutes) after 10 minutes sharp. Read the results by placing the test on a clean, dry, flat surface. **Do not read or interpret the results after 15 minutes have passed since dipping the test strip into the vial.**
8. **Make sure the top line is read first (this is the built in control). If line is present, control is Pass. If not present, control is Fail and test is considered invalid. Repeat the test.**
9. Fill in the patient log sheet.
10. Enter result in Cerner by following the steps below:
    A) Go to **Adhoc form.**
    B) Choose **Women's Services.**
    C) Choose **POC Testing OB HRMC (please note that other POC results can also be entered here).**
    D) Click **chart**.

E) The top left will be for **Amnisure**; enter your build-in control result in the **Amnisure QC** area by choosing either **PASS or FAIL before entering patient's result**. Documentation is not complete until this is entered.
F) For patient's result, choose either **Positive or Negative**.
G) Hit verify when all entries are completed.

INTERPRETATION OF RESULTS:

One Line = NO MEMBRANE RUPTURE = **NEGATIVE**
Two Lines = THERE IS A RUPTURE = **POSITIVE**
No line = TEST IS INVALID = **take another test**

NOTE: The darkness of stripes may vary. The test is valid even if the color of stripes is faint or uneven. Do not try to interpret the test result based on the darkness of the stripes

QUALITY CONTROL PROCEDURES:

1. Take the vial containing 10ng of freeze-dried Human PAMG-1 protein and add 1 ml of saline solution to it. Shake the resulting solution for few seconds.
2. Use the solution from step #1 for positive quality control of the Amnisure test.
3. Dip the white end of the test strip (marked with arrows) into the positive control solution for 10 minutes sharp.
4. Remove the test strip after 10 minutes sharp. Read the results by placing the test on a clean, dry, flat surface. Do not read or interpret the results after 15 minutes have passed since dipping the test strip into the vial.
5. Use a saline solution for negative control and follow step # 3 and 4.
6. Follow the interpretation of results and enter results in QC log sheet.

NOTE: Quality Control procedure will be done by the POC Coordinator of the Laboratory for each new lot of test kits and/or every 30 days whichever comes first. New test kits will be brought to the OB/L&D unit when both levels of QC have passed.

LIMITATIONS:

1. The AmniSure test is for the in vitro detection of human amniotic fluid PAMG-1 protein in vaginal secretion of pregnant women. The test should be used to evaluate patients with clinical signs/symptoms suggestive of fetal membranes rupture.
2. No quantitative interpretation should be made based on the test results.
3. Amnisure should not be used earlier than 6 hours after the removal of any disinfectant solutions or medicines from the vagina.
4. Presence of blood, collected with the swab, can lead to **false positive** result.

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5. When 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.
6. Women may labor spontaneously despite a negative test result.
7. The performance of the Amnisure test has not been established in the presence of the following contaminants: meconium, anti-fungal creams or suppositories, K-Y Jelly, Monistat, baby powder (starch and talc) Replens and baby oil.

REFERENCES:

1. Amnisure International LLC ROM Test Overview.
2. Amnisure Test kit package insert.
3. Amnisure freeze dried PAMG-1 protein package insert