AmniSure
Ruptured Membranes Assessment Module

HAWAIʻI PACIFIC HEALTH | KAPIʻOLANI MEDICAL CENTER FOR WOMEN & CHILDREN

AmniSure

- AmniSure ROM is a point of care test that can aid in the detection of ROM in pregnant women reporting signs, symptoms, or complaints suggestive of ROM.

Patient Criteria for AmniSure Testing

- <37weeks 0 days gestation, not in active labor with possible ruptured membranes
- ≥37 weeks 0 days gestation, not in active labor with equivocal testing (negative pooling, negative amniostat, negative ferning)
- The AmniSure may be used on additional patients at the discretion of the attending or resident

How AmniSure Works

- Uses the principles of immunochromatograpahy to detect human PAMG-1 (placental α1-microglobulin) protein present in amniotic fluid of pregnant women
- High levels of PAMG1 are found in amniotic fluid, conversely, extremely low levels are found in blood and cervicovaginal discharge when the fetal membranes are intact

Precautions

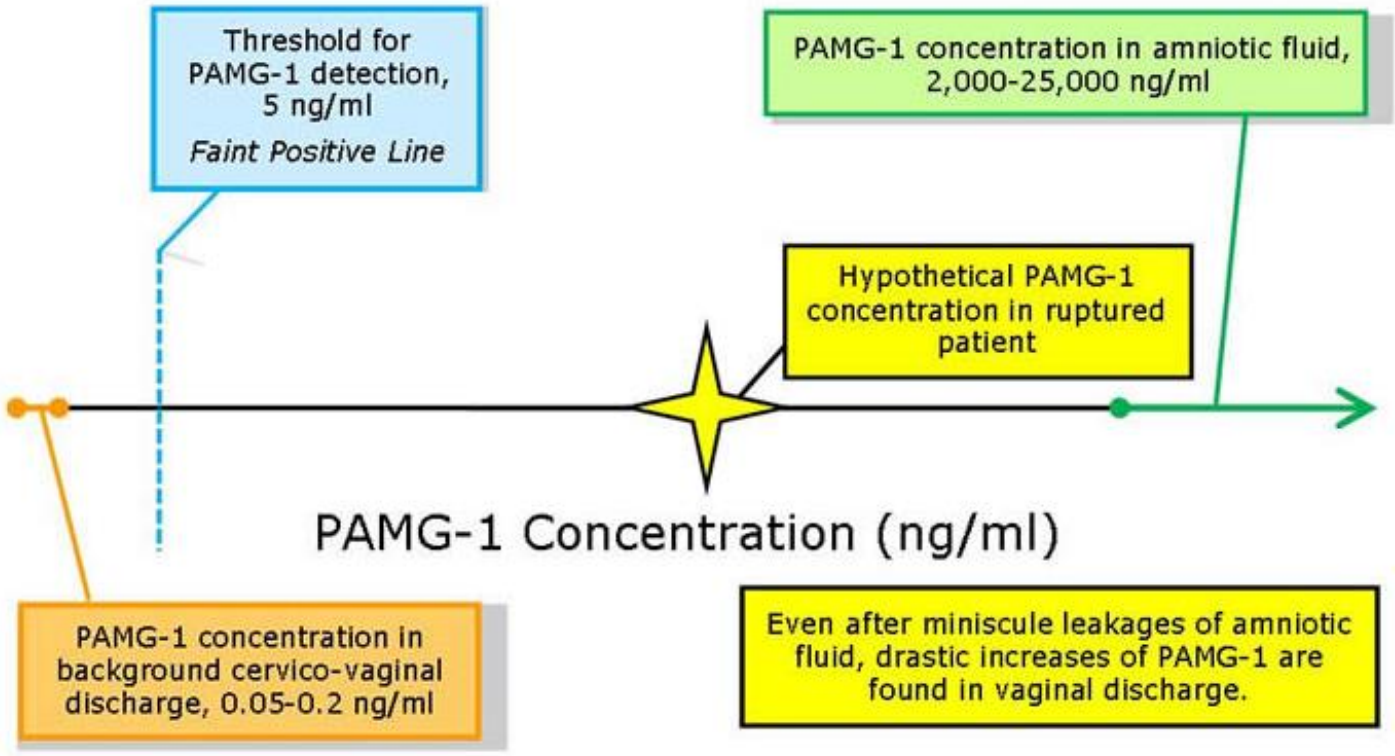
- Storage
  - Kits are stored in a dry place at (4-24ºC)
- Do not use expired kits
- Do not reuse swabs
- Do not bend or fold the test strip or the aluminum foil pouch

Quality Control (QC)

- Reagents
  - Negative-Saline
  - Positive-reconstituted freeze dried PAMG-1 protein

- Frequency
  - New shipment/lot, monthly thereafter
  - Clinical symptoms do not match results
  - Suspicion that product performance is compromised or when kits have not been stored according to manufacturer instructions

AmniSure: Procedure Detection of PAMG-1



AmniSure: Procedure
Step 1 – Specimen Collection

- Insert 2-3 inches deep (no speculum needed)
- Hold in place for 1 minute to ensure saturation
- Ensure that provided sterile swab touches nothing prior to insertion

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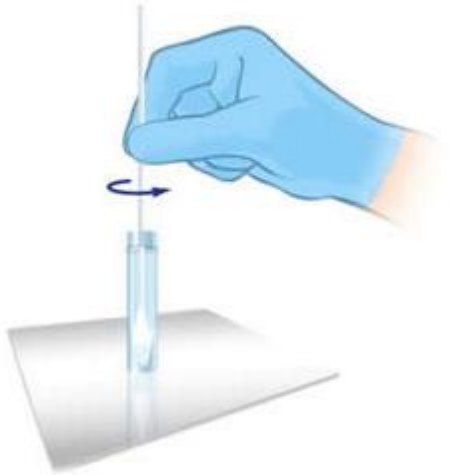
AmniSure: Procedure
Step 2 - Extraction

- Shake solvent vial to ensure all liquid in the vial has dropped on the bottom
- Insert swab into vial
- Rotate specimen in vial for 1 minute
- Dispose of swab. DO NOT break off swab and leave in vial



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AmniSure: Procedure
Step 3 – Testing Sample

- Insert test strip with arrows facing down into vial within 30 minutes of sample collection
- Remove test strip from the vial if two lines are visible or after 10 minutes sharp
- Place on dry, flat surface to read. DO NOT read after 15 minutes

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AmniSure: Procedure Timing

- Collecting sample – 1 minute for saturation of swab
- Diluting sample – 1 minute rotation in vial
- Testing sample – within 30 minutes of dilution
- Running test – remove test strip from vial if 2 lines are visible or after 10 minutes sharp
- Reading test – DO NOT read after 15 minutes

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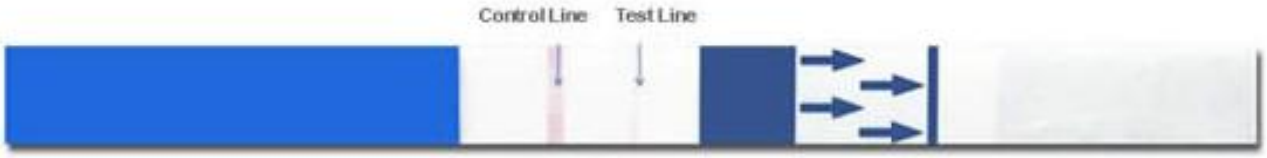

Faint or broken lines should always be interpreted as a **positive** result.

If both the **control line and test line** are visible, the test result is **positive**.

If only the one **control line** is visible on the test strip, the test result is **negative**.

If **no lines** are visible, the test result is **invalid**.

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Test Limitations

- Significant presence of blood
- Rupture occurred more than 12 hours (false negative)
- Earlier than 6 hours after removal of any disinfectant solutions or medicines from the vagina
- If any of the following contaminants are found: meconium, anti-fungal creams/suppositories, KY jelly, Monistat, baby powder, Replens, baby oil
- Results should be used in conjunction with other clinical information

Any patient result that is inconsistent with patient's clinical condition should be repeated.

Remember to Check the Following:

- There are no cleansing agents or medicines applied that could destroy the sample
- Procedural timing was strictly followed
- The provided sterile swab touched nothing prior to insertion
- The test strip was not bent or damaged
- There are no significant blood admixture
- The test kit was stored according to manufacturer instructions between 4-24ºC or 40-75ºF

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Frequently Asked Questions:

- Is a faint line a positive result?

  Yes, even faint and broken lines are a positive result.

- What is the maximum time between the sample collection and insertion of the strip into the vial?

  Up to 30 minutes. If the sample is not run within 30 minutes, refrigerate up to 6 hours.

- What is the maximum time between opening the test strip and using it?

  You can leave a test strip open for up to 6 hours.

- What do I do if liquid doesn't flow up the strip?

  Flick the vial lightly with your finger and/or shake the vial a little bit to help the lateral flow.

REMINDER: Patient Criteria for Routine AmniSure Testing

- <37weeks 0 days gestation, not in active labor with possible ruptured membranes
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- The AmniSure may be used on additional patients at the discretion of the attending or resident

Please watch the AmniSure Training Video. To view the video, copy and paste the following website to another browser.

https://www.qiagen.com/us/resources/e-learning/videos/amnisure-training/

After viewing the video, you may proceed to the Post Exam.