

AmnioTest

Ruptured Membranes Assessment Module

**HAWAI'I
PACIFIC
HEALTH**

**KAPI'OLANI
MEDICAL CENTER**
FOR WOMEN & CHILDREN





AmnioTest™

AmnioTest™ is a qualitative, pH-based, swab screening system intended as an aid in detecting rupture of amniotic membrane in pregnant women.





How AmnioTest™ Works

- Amniotic fluid has a neutral pH while the pH of the upper vagina is normally acidic. Rupture of the amniotic membrane can result in small volumes of amniotic fluid leaking into the upper vagina. The presence of amniotic fluid tends to elevate the pH of the upper vagina. Detection of this pH increase using a pH indicator dye has been shown to assist in determining the presence of amniotic fluid.
- A pH of 6.5 or higher is suggestive of membrane rupture
- Nitrazine swab qualitatively detects pH levels between 5.0-7.5



Quality Control (QC)

- Reagents
 - 2 buffers, ph 5.0 and 7.5
- 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



Precautions

- Storage
 - Reagents and swabs are stored at room temperature (15-30°C)
- Do not use expired swabs
- Do not reuse swabs



PROCEDURE

Step 1 - PEEL

- Remove sterile swab from individual wrapper by peeling open the AmnioTest™ sleeve.
- Note: Do not allow swab tip to come in contact with anything before test is performed.

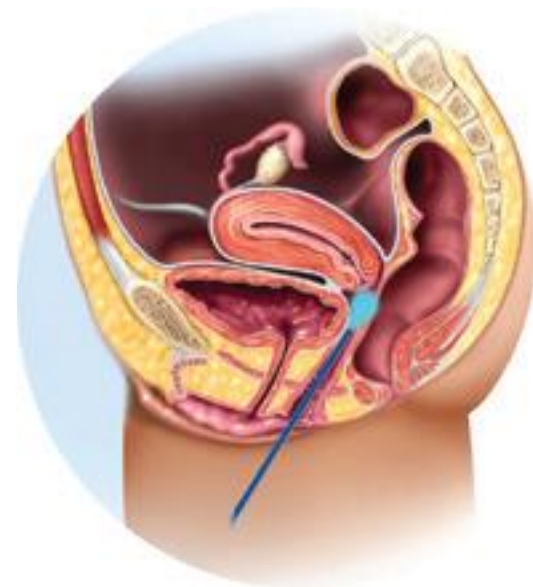




PROCEDURE

Step 2 - SWAB

- Part the labia to expose the cervix. Insert swab so that nitrazine tip gently comes in contact with the upper vaginal tissue for about **15 seconds**.
- A speculum may be used during this phase of the procedure to limit swab exposure to anything that may affect pH (i.e. urine, bacteria).





PROCEDURE

Step 3 - READ

- After carefully removing swab, immediately compare the swab tip color to the interpretation card supplied by Pro-Lab and record the corresponding pH level.
- Discard swab.
- Exposure to light or humidity may affect performance of the product.



****Be sure to review the technical insert provided by Pro-Lab if you are unsure about any step in the procedure, including interpretation of results.**





Test Limitations

- **Causes of False positive:**
 - Antibiotic therapy
 - Infections of the vagina
 - Blood
 - Semen
 - Alkaline urine
 - Other fluids that are alkaline
- **Causes of False negative:**
 - Incorrect specimen collection
 - Very little amniotic fluid leaking
- A negative test result does not preclude the possibility of rupture of the amniotic membrane in pregnant women. Other clinical finds should be considered when interpreting negative results.

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



Congratulations!

You have completed this module. You may proceed to the Post Exam.