Department: **Perinatal**	Original #: New	DMS #: **PN 7032**
Section: **Clinical Operations**	Effective Date:	Page: Page **1** of **5**
Title: **Rapid Amniotic Fluid Swab Test**	Review/Revision Date:	
Accountable Dept./Committee: Approved by: MEC		

WORK PLACE SAFETY:

1. Always use Standard Precautions including Personal Protective Equipment (PPE) when handling any blood/body fluid.
2. Hand washing is the single most effective means of controlling the spread of infection; remember to always **WASH YOUR HANDS.**

REFERENCES:

Point-of-Care Testing Quality Assurance Program, MCW 2653.00.
Pro-Lab Package Insert, Revised 03/12.
College of American Pathologists Point-of-Care Checklist, January 4, 2012.
The Joint Commission, Waived Testing, 2012.

PURPOSE:

To aid in detecting rupture of amniotic membrane in pregnant women at the point of service.

POLICY:

1. Rapid Amniotic Fluid Swab Test is a qualitative, pH based, swab screening system intended as an aid in detecting rupture of amniotic membrane in pregnant women.
2. The Rapid Amniotic Fluid Swab Test is tested only as a waived test. The main laboratory will not perform any patient testing.
3. Nursing testing areas are responsible to submit each new lot number or new shipment of lot number to the Laboratory for validation.
4. The Laboratory is responsible to perform External Quality Control on each new lot number or shipment.
5. Staff must be tested and evaluated for visual color discrimination and may not perform the test if the employee is unable to discriminate colors produced by this test.

PRINCIPLE:

A swab impregnated with nitrazine yellow dye is brought into contact with the upper vagina. The swab absorbs fluid associated with the tissue and the dye develops a color which correlates with the pH of the absorbed fluid over the range pH 5.5 to pH 7.5.

Amniotic fluid has a neutral pH while the pH of the upper vagina is normally acidic. A pH of 6.5 or higher in the upper vagina is consistent with leakage of amniotic fluid. Rupture of the amniotic fluid can result in small volumes of amniotic fluid leakage 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.

SPECIMEN COLLECTION AND PREPARATION:

1. Remove a swab from its protective sleeve. DO NOT touch the tip of the swab or allow it to come in contact with any liquid or any substance which might affect pH.

2. Part of the labia exposing the cervix and carefully insert the swab into the vagina. Do not allow the swab to come into contact with vaginal tissue during entry.

3. Allow first and only contact of the AmnioTest swab tip to occur with upper vaginal tissue (posterior vaginal fornix and external cervical os)

4. Allow the tip to remain in contact with upper vaginal tissue for about 15 seconds.

5. Carefully remove the swab and immediately examine the color of the tip.

REAGENT AND STORAGE:

1. Store disposable swabs impregnated with nitrazine yellow dye at room temperature at 15º – 30º C (59º– 86º F).
2. Product stored under these conditions will be stable until the expiry date shown on the label.
3. Exposure to light or humidity may affect performance of product.

MATERIALS NEEDED:

A timer or watch

PROCEDURE:

A. QUALITY CONTROL

1. External Quality Control Testing (Performed by Laboratory)

   a. The Laboratory will perform external quality controls utilizing buffer solutions corresponding to the pH values listed on the AmnioTest Color Card.

1) Remove one AmnioTest swab from its sleeve.

2) Wet the swab's tip with 3 – 4 drops of buffer solution.

3) Immediately compare the color developed on the swab tip to the closest matching color on the AmnioTest Color Card.

4) If the pH value written next to the color selected on the card corresponds to the pH value of the buffer solution then the swab is performing as expected. If the pH indicated on the Color Card fails to match the pH of the buffer used, repeat the test with a fresh swab. If the pH still does not match, the swab is not performing as expected and the remaining kit should not be used to test clinical specimens.

5) Individual swabs tested in this manner should be discarded and must not be used for testing clinical samples.

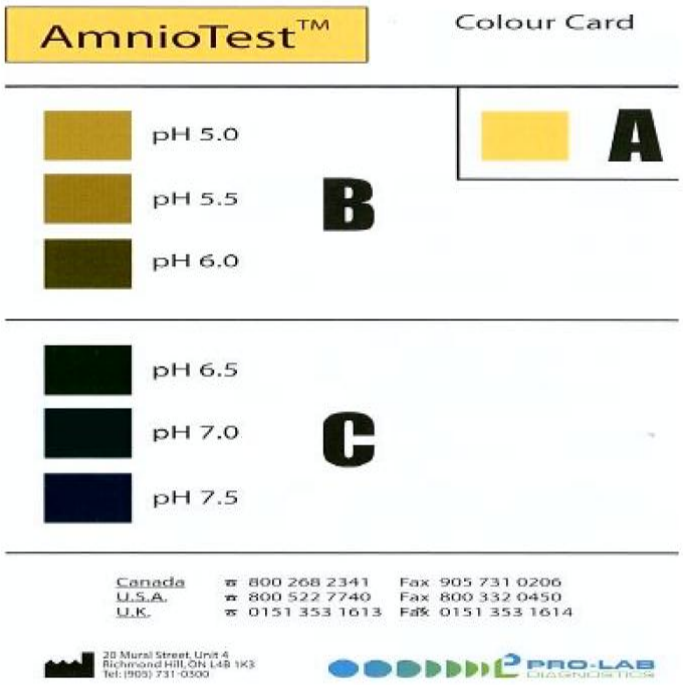
B. PATIENT TESTING

TESTING PROCEDURE:

Step	Action
1.	**"Peel".** Remove the 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.
2.	**"Swab".** Insert swab so that nitrazine tip gently comes in contact with the upper cervical area for 10-15 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).
3.	**"Read".** After carefully removing swab, simply compare the swab tip color to the interpretation card supplied by Pro-Lab and record the corresponding pH level.
4.	**Interpretation:** The color of the tip of the AmnioTest swab after use should be compared to the sample colors of the enclosed AmnioTest Color Card.

Group	Color	Approximate pH Value	Indication Consistent with:
A	Yellow	Not applicable	Fresh swabs
B	Yellow/Gold	5.0	Intact Amniotic Membrane
	Yellow/Olive	5.5	
	Olive	6.0	
C	Dark Green	6.5	Possible Ruptured Membrane
	Dark Blue/Green	7.0	
	Navy Blue	7.5 or higher	

Result Interpretation



6.	**Documentation of Results**
	In KP Health Connect: • Test is ordered by MD, RN, or LVN. • Document on Adult/Child POCT Doc Flow Sheet for in patient areas. • Enter patient result on “Vaginal pH”

LIMITATIONS:

1) Pro-Lab AmnioTest is designed to be used by qualified medical professional s and is intended as an aid to professional diagnosis.
2) AmnioTest can only indicate a change in pH value and should be used only as indicated in the Test Procedure described above.
3) Antibiotic therapy or infections of the vagina can lead to elevated vaginal pH resulting in a false interpretation of determining the presence of amniotic fluid. Where doubt exists, standard microbiological testing should be employed to exclude infection.
4) False negative results may occur with tests of this nature. A negative test result does not preclude the possibility of rupture of the amniotic membrane in pregnant women. Other clinical findings should be considered when interpreting negative test results.
5) Sample colors on the Color Card are examples and should not be interpreted as an absolute match for actual test results.

PRO-LAB DIAGNOSTICS

AmnioTest™ Rapid Amniotic Fluid Swab Test

AmnioTest™ is designed to assist in the detection of rupture of the fetal membrane. It offers the most efficient, cost effective, reliable, and simple to use point-of-care screen test to aid in the detection of amniotic fluid in near-term patients. Along with a simple quality control regimen, AmnioTest™ is an invaluable tool for OB-GYN and L+D clinics.

Simple Test Procedure

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.

2. "Swab"
Insert swab so that nitrazine tip gently comes in contact with the upper cervical area for 10-15 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).

3. "Read"
After carefully removing swab, simply compare the swab tip colour to the interpretation card supplied by Pro-Lab and record the corresponding pH level. Discard swab and return box to storage area being sure to close lid properly. Exposure to light or humidty may affect performance of the proudct.

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.

www.pro-lab.com