



# KAISER PERMANENTE®

<b>DOCUMENT NUMBER:</b>
<b>DOCUMENT TITLE:</b>
<b>DOCUMENT NOTES:</b>

<b>LOCATION:</b>	<b>VERSION:</b>
<b>DOC TYPE:</b>	<b>STATUS:</b>

<b>EFFECTIVE DATE:</b>	<b>NEXT REVIEW DATE:</b>
<b>RELEASE DATE:</b>	<b>EXPIRATION DATE:</b>

<b>AUTHOR:</b>	<b>PREVIOUS NUMBER:</b>
<b>OWNER:</b>	<b>CHANGE NUMBER:</b>

## Amniotic Fluid pH Using Phenaphthazine Paper

---

<b>Purpose</b>	This procedure provides instruction for determining the pH of the vaginal secretion specimen and whether or not the amniotic fluid is present. Presence of amniotic fluid is an indication that rupture of amniotic sac/membranes may have occurred. This is a qualitative test granted waived status under CLIA.
<b>Scope</b>	This procedure may be performed by trained personnel approved to perform clinical laboratory tests as defined in Section 1206 of the California Business and Professional Code (Cal Bus & Prof Code) or per departmental policy (e.g., Registered Nurse - RN, Licensed Vocational Nurse - LVN, Medical Assistant - MA, Certified Registered Nurse Anesthetist - CRNA, Certified Nurse Midwife - CNM, Nurse Practitioner - NP, Medical Doctor - MD, Doctor of Osteopathy - DO, Physician Assistant - PA, Respiratory Care Practitioner - RCP, Perfusionist), whichever is more restrictive.
<b>Policy</b>	<ul style="list-style-type: none"><li>• This qualitative screening test is intended to be performed by the appropriate POCT personnel as an aid in detecting rupture of the amniotic membrane of pregnant women/expectant mothers.</li><li>• Based on the pH test result of the vaginal fluid specimen, the ordering provider will determine the appropriate and required follow up testing, as necessary, i.e., Fern Testing.</li><li>• POCT personnel must be tested and evaluated for visual color discrimination and should only perform the test if the employee is able to discriminate colors produced by this test.</li></ul>
<b>Specimen Source</b>	Vaginal secretions/fluids <ul style="list-style-type: none"><li>• Use sterile cotton-tip applicator (cotton swab) to collect the required sample.</li><li>• Once sample is collected, it is stable at room temperature for 2 to 5 minutes. Testing must be performed immediately after</li></ul>
<b>Specimen Rejection</b>	Do not perform test if sample is visibly contaminated with blood.
<b>Safety Precautions</b>	<ul style="list-style-type: none"><li>• Observe standard precautions when collecting blood. Follow blood collection protocols and procedures. Wear personal protective equipment (PPE), as required. Handle all specimens as if they contain infectious agents.</li><li>• Refer to the safety manual for additional information. Discard of used test reagent and materials in the biohazardous waste.</li></ul>

*Continued on next page*

## Amniotic Fluid pH Using Phenolphthazine Paper, Continued

---

### Reagents and Materials

- Phenolphthazine (pH) paper (pH 4.5-7.5)
    - NitraTest paper or Phenazine Paper
  - Control Solutions/Buffer Solutions from Fisher Scientific:
    - Buffer Solution (pH 4.0): OneLink #10308440
    - Buffer Solution (pH 7.0): OneLink #10229740
  - Sterile Cotton-tipped applicator/Cotton Swab
  - Personal Protective Equipment (i.e., Gloves, etc.)
- 

### Storage or Reagents & Materials

- Phenolphthazine (pH) paper (pH 4.5-7.5):
- Store at room temperature (15°–30° C Avoid exposure to acid or alkaline fumes and excessive heat.
  - Avoid Excessive heat. Exposure to light or humidity may affect performance of product.
  - Protect against exposure to acid and alkaline fumes before use.
  - The pH paper is stable through the expiration date printed on the original container/box.
  - Store the pH paper roll dispenser in its original box when not in use.
- Control Solutions/Buffer Solutions (pH 4.0 and 7.0) – Fisher Scientific
- Store at room temperature 15°–30° C.
  - Stable until the manufacturer's expiration dates printed on bottles.
- Sterile Cotton-tipped applicator
- Store at room temperature 15°–30° C.
- 

### Quality Control

- Each Control Solution/Buffer Solution, pH 4.0 and pH 7.0, should be tested as follows:
- With each new operator (e.g., during initial training)
  - With each day of use and when a new roll of Nitrazine (pH) paper is opened
  - With each a new shipment and/or lot number of Phenolphthazine (pH) paper and Buffer Solutions
  - Or as otherwise required by the local laboratory's internal procedure (e.g., each box)
  - Record the control results in the QC log, including the lot number and expiration dates of the pH paper and Buffer Solutions, date and initials.

#### *Note:*

- *The Phenolphthazine (pH) paper measures pH values generally to within 1 pH unit in the range of 4.5-7.5 visually.*
  - *NitraTest paper or Phenazine Paper is used to differentiate between the acidic pH of normal vaginal fluid/secretion and the basic pH of amniotic fluid.*
-

## Amniotic Fluid pH Using Phenolphthazine Paper, Continued

### Quality Control Procedure

Follow the steps below for perform Quality Control testing.

Step	Action						
1	Tear off two pieces/strips of pH paper from the Nitrazine pH paper dispenser, approximately 2 to 3 inches in length.						
2	Testing of pH paper using Buffer Solution pH 4.0: <ul style="list-style-type: none"> <li>Apply a drop of Buffer Solution pH 4.0 to one strip of pH paper</li> <li>Shake off any excess solution gently.</li> <li>Immediately match/compare the color developed on the strip pH paper being tested with the closest color indicated on the pH paper dispenser.</li> <li>Record the pH result on the Quality Control log</li> </ul>						
3	Repeat step 2 to perform Quality Control testing on Buffer Solution pH 7.0						
4	Evaluate and interpret the QC results as follows: <table border="1" style="margin-left: 40px;"> <thead> <tr> <th>If the pH result is...</th> <th>Then the QC result is ...</th> </tr> </thead> <tbody> <tr> <td>4.0 to 4.5</td> <td>Acceptable QC result</td> </tr> <tr> <td>7.0 to 7.5</td> <td>Acceptable QC result</td> </tr> </tbody> </table>	If the pH result is...	Then the QC result is ...	4.0 to 4.5	Acceptable QC result	7.0 to 7.5	Acceptable QC result
If the pH result is...	Then the QC result is ...						
4.0 to 4.5	Acceptable QC result						
7.0 to 7.5	Acceptable QC result						
5	If both results are within the expected pH results/values, proceed with testing patient's vaginal secretion sample (collected using the sterile cotton swab). <b>Note:</b> <i>If any of the QC results is not acceptable, follow instructions for Troubleshooting Failed QC.</i>						

### Troubleshooting Failed QC

Follow the corrective action steps **in the order listed below**.

Step	Action
1	Repeat the test using another strip/piece of pH Paper from the same opened pH paper dispenser and same (opened) and appropriate Buffer Solution.
2	If color and the pH result still does not match, then repeat the QC testing using a brand new bottle of Buffer Solution(s) and a new roll/dispenser of pH paper.
3	If either or both QC results is still out of range, contact the local Point of Care Coordinator. <b>Do NOT perform patient testing</b> until the problem is resolved.
4	Record all corrective actions/steps taken and its outcome on the QC log.

Continued on next page

## Amniotic Fluid pH Using Phenaphthazine Paper, Continued

Testing Patient  
 Sample

Step	Action														
1	<p>Tear off one piece/strip of pH paper from the Nitrazine pH paper dispenser, approximately 2 to 3 inches in length. Set it aside.</p> <p><i>Note:</i>  <b>The pH paper should not have contact with the patient at any time.</b></p>														
2	<p>Collect the vaginal secretion/fluid sample to be tested from the patient:</p> <ul style="list-style-type: none"> <li>• Use two identifiers to verify that the sample is being collected from the correct patient.</li> <li>• Use gloves and sterile cotton swab to carefully collect the vaginal secretion/fluid sample. <b>Avoid touching the mucus plug in the cervix.</b></li> <li>• Make sure that the sample is tested immediately, within two to five minutes after collection.</li> </ul>														
3	<p>Touch the tip of the cotton swab with patient’s vaginal secretion/fluid sample unto the strip of Nitrazine pH paper.</p> <ul style="list-style-type: none"> <li>• Shake off any excess solution gently, as necessary.</li> </ul>														
4	<p>Immediately examine the pH results and compare the color that has developed on the moistened pH paper with the color chart indicated on the pH dispenser/container.</p> <p><i>Note:</i>  <b>The color on the pH paper being tested will fade after several minutes.</b></p> <p><b>Interpret the pH results as indicated in the table below:</b></p> <table border="1" data-bbox="592 1276 1412 1556"> <thead> <tr> <th>If the color is...</th> <th>The pH result is...</th> </tr> </thead> <tbody> <tr> <td>Yellow</td> <td>5.0</td> </tr> <tr> <td>Olive Yellow</td> <td>5.5</td> </tr> <tr> <td>Olive Green</td> <td>6.0</td> </tr> <tr> <td>Blue Green</td> <td>6.5</td> </tr> <tr> <td>Blue Gray</td> <td>7.0</td> </tr> <tr> <td>Deep Blue</td> <td>7.5</td> </tr> </tbody> </table> <p>The amniotic fluid is generally 7 to 7.5, whereas vaginal secretions are in the range of 4.5 to 5.5. If the pH result is between 5.0 – 6.0, the membranes are probably intact. If the pH result is between 6.5 – 7.5, the membranes are probably ruptured.</p>	If the color is...	The pH result is...	Yellow	5.0	Olive Yellow	5.5	Olive Green	6.0	Blue Green	6.5	Blue Gray	7.0	Deep Blue	7.5
If the color is...	The pH result is...														
Yellow	5.0														
Olive Yellow	5.5														
Olive Green	6.0														
Blue Green	6.5														
Blue Gray	7.0														
Deep Blue	7.5														
5	<p>Record the patient’s pH result directly in KP HealthConnect, or use Manual Patient Log/Form.</p>														

Continued on next page

## Amniotic Fluid pH Using Phenaphthazine Paper, Continued

---

**Expected Results**

The pH paper remains yellow, olive-yellow, or olive-green in color (pH 4.0-6.0).

---

**Procedural Notes**

- The pH of the vaginal secretion specimen is determined by comparing the color of the tested pH paper with the corresponding color on the chart indicated on the pH paper dispenser.
  - False positive reactions may result from:
    - Vaginal infections, i.e., *Trichomonas vaginalis*, which may affect and raise the vaginal pH
    - Presence of blood or cervical mucus.
  - False negative reaction may occur (more frequently), whenever there's a scant/inadequate amount of fluid present.
- 

**Non-Controlled Documents**

The following non-controlled documents support this procedure.

- The Joint Commission, CAMH, Waived Testing, 2014
  - College of American Pathologists, Point-of-Care Testing Checklist
  - COLA Accreditation Manual
  - Bristol-Myers Squibb Company, Princeton, NJ, NitraTest Paper Product Instructions, 2015.
  - Decon Laboratories, Inc., Phenazine Paper Product Instructions, 2015.
  - Analysis of pH with Nitrazine (Phenaphthazine) Paper by Bristol-Myers Squibb, Carolinas HealthCare System
  - Nitrazine Testing Policy, Kaiser Permanente Redwood City Medical Center, 2012.
  - Nitrazine (pH) Testing, Kaiser Permanente Northern California Region, 2012
  - Phenazine pH Procedure, Massachusetts General Hospital, 2011
  - Tests Granted Waived Status Under CLIA
- 

**Controlled Documents**

The following controlled document supports this procedure.

Regional Parent Document Reference Number: SCPMG-PPP-0177 Rev. 01

Reference
Regional Point-of-Care Quality Assurance Program

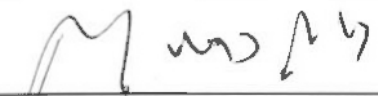
---

*Continued on next page*

## Amniotic Fluid pH Using Phenaphthazine Paper, Continued

---

Reviewed and approved by:

Signature	Date
	1/18/16
Darryl Erik Palmer-Toy, MD, PhD SCPMG Laboratory Systems Director	

---

Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name: _____ Operations Director, Area Laboratory	
Name: _____ CLIA Laboratory Director	

---

*Continued on next page*

## Amniotic Fluid pH Using Phenaphthazine Paper, Continued

---

### HISTORY PAGE

---

Type of Change: New, Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
New					

---