


pH Nitrazine Paper Screening Test	SRF-WI.0670	Page 1 of 5
 KAISER PERMANENTE KFH San Rafael Clinical Laboratory	Point of Care 99 Montecillo Rd San Rafael, CA 94903	

1. PURPOSE

The Nitrazine (Phenaphthazine) paper test is used to measure vaginal pH. The Nitrazine paper test is a point of care test used to assess leakage of amniotic fluid due to premature rupture of the membranes or to aid in the diagnosis of bacterial vaginosis.

In this case Nitrazine paper is used to screen for the possible presence or leakage of amniotic fluid in the birth canal. If the Nitrazine test is positive, the provider follows up with a Fern Test, which is a Provider Performed Microscopy test.

pHizatest paper is a nitrazine indicator paper intended for in-vitro quantitative determination of pH in the 4.5 – 7.5 range.

2. POLICY

Standard Precautions must be used throughout the procedure.

Quality Control (QC) is run once a week that nitrazine test is performed. The QC results are recorded on the QC / Patient test Log.

Only credentialed staff or trained staff with a current competency assessment may perform patient testing.

Patient results are logged and recorded on the QC/Patient test Log and then into the patient's chart.

3. PRINCIPLE


Nitrazine paper is impregnated with an indicator dye, Phenaphthazine. The color changes as pH changes, giving a range of colors from yellow through blue.

The Nitrazine pH test is a screen for presence of amniotic fluid.

- Negative test: paper remains yellow to olive green in color (pH 4.5 – 6.0)
- Positive test: paper turns blue green to deep blue in color (pH 6.5 – 7.5), suggesting the presence of amniotic fluid.

4. SCOPE

MDs, NPs, and RNs may perform this test after appropriate training and competencies and after demonstrating that the colors utilized in the test can be discerned.

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5. SPECIMEN REQUIREMENTS

Fresh vaginal pool specimen.


Specimen collection and labelling requirement: 2 unique patient identifiers

6. MATERIALS

Follow standard precautions and dispose all waste appropriately.

- pH Indicator paper and pH paper container.
 - pH paper should be stored at room temperature, out of direct sunlight.
 - Unopened pHizatest should be used by the printed expiration date.
 - Once opened, shelf life is 6 months.
- Disposable pipettes/tubes
- pH Nitrazine QC/Patient test Log sheet
- Sterile swab
- Gloves
- Fresh vaginal pool specimen collected according to clinical protocols.
 - The specimen is estimated to be stable for 2-5 minutes at room temperature.
- pH control, NIST certified buffer solution, 2 levels between 5.0 and 8.0.
 - Store buffers at room temperature.
 - Buffers are stable until the expiration date printed on the bottles.

Item	Manufacturer	Vendor	How Packaged	One link number
Buffer Solution, pH 5.00 (Certified)	Fisher Chemical SB102-1	Fisher Scientific	bottle	10353676
Buffer Solution, pH 7.00 (Certified)	Fisher Chemical SB107-500	Fisher Scientific	bottle	10229740
pHizatest Nitrazine Paper	Micro Essential Lab Cat# 934	Fisher Scientific	Case of 10 paper rolls	10352249

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7. QUALITY CONTROL

Each lot of pHizatest has been verified for accuracy using NIST traceable standards. Expired rolls should be disposed of.

- Once every week, test, and record two pH control solutions and record results in pH QC log sheet.
- Must be performed each week of patient testing.
- Locate pH controls in small plastic bottles at room temperature.
- Apply 1 drop of each level to nitrazine pH strip or paper (over sink or gauze pad observing standard precautions).
- Record pH reading on Nitrazine Testing QC Log sheet. The pH must be within 0.5 of the designated pH to be acceptable.
- Repeat steps with the pH 7.0 buffer solution.
- Report results outside range to charge nurse/manager and record in Out of Limits Log.
- If controls are out of range, do not report any patient results until corrective action has been taken.


8. TROUBLESHOOTING

If QC testing is outside of the expected ranges use the following as a guideline to troubleshoot:

1. Repeat the procedure.
2. Check the buffer solution to make sure that it is not expired and repeat using a new aliquot of pH buffer
3. Repeat using a different Nitrazine test roll.
4. If controls are still out of range, or for any testing issue, call the Laboratory Point of Care Coordinator for assistance.

9. PROCEDURE

- Verify patient's identity using two unique identifiers (name and MRN#).
- Collect a fresh sample of vaginal pool fluid in a clean receptacle.
 - The specimen is estimated to be stable for 2-5 minutes at room temperature.
- Apply aliquot of fluid to nitrazine pH strip or paper.

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- Examine the nitrazine paper as soon as possible after touching specimen to it as the color will fade after several minutes.
- Record results on the Patient Log and in the Patient's Medical Record.
 - Negative test: paper remains yellow to olive green in color (pH 4.5 – 6.0)
 - Positive test: paper turns blue green to deep blue in color (pH 6.5 suggesting the presence of amniotic fluid).

Note: Only a provider with current competency certification performs Fern Testing if the Nitrazine screen is positive.

10. RESULTS

Any resultant pH reading should be considered along with other laboratory and clinical findings to derive a final diagnosis.


If the nitrazine test is negative but the ferning is positive, there is probably a rupture of membranes.

If nitrazine test is positive and the ferning test is negative, a second specimen should be obtained.

- Record results on the Patient Log and Patient's Medical Record.
- Report results for Nitrazine test for vaginal pH as numeric value.
- Report results for Nitrazine test for detection of amniotic fluid as:
 - pH 6.5 – 7.5 = positive
 - pH 6.0 and below = negative

11. LIMITATIONS

- Nitrazine screening test is highly sensitive but not very specific.
- Protect pH strips against exposure to acid or alkaline fumes.
- Color comparison recommended under a combination of fluorescent light and daylight. Base stock color of paper may vary from lot to lot, this will not affect the accuracy of the pH reading.
- The specimen is estimated to be stable for 2-5 minutes at room temperature after collection.

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- Contamination with blood will interfere with reading. Bloody specimen should be read with caution, as it is difficult to interpret the color reaction.
- The Nitrazine paper measures pH generally within 1 pH unit between the range of 4.5 to 7.5 visually.
- False positive results may occur from specimen contamination due to heavy vaginal discharge, blood, cervical mucus, semen, alkaline urine, and soap. Note that cervical mucus, blood, urine, and glove powder have an alkaline ph.
- False negative results can result from prolonged rupture of membranes (longer than 24 hours) or when only a small quantity has leaked.
- Ferning test is less sensitive but more specific than the nitrazine test.

12. REFERENCES

1. Helper, Opal. 1966. *Manual of Clinical Laboratory Methods*, 4th Edition; Charles Thomas, Springfield, Illinois; pg 5.
2. Fisher Health Care 2002-2003. Fisher Scientific Company Santa Clara, CA; pg 780-781
3. Addison, Lois Anne. Obstetrical Ferning Test. *Laboratory Medicine*, July 1999, Volume 30, Number 7, p451.
4. Peter P. Toth, MD, PhD and A. Jothivijayarani, MD. Obstetrics: Premature Rupture of Membranes (PROM) *University of Iowa Family Practice Handbook*, 3rd Edition, Chapter 8
5. pHizatest Nitrazine paper product insert
6. McPherson & Pincus: Henry's Clinical Diagnosis and Management by Laboratory Methods, 23rd ed.
7. Policy adapted from Kaiser Permanente Medical Center, Oakland: Nitrazine Test, (E. Terry)
8. Policy adapted from Kaiser Permanente Medical Center, San Francisco: Nitrazine Screening Test. (A. Peretti) 5/2005.