

pHizatest® for Vaginal pH Testing (pH range 4.5-7.5)

PURPOSE

Determination of vaginal pH as an aid in

- 1) detection of ruptured amniotic membranes in pregnant women
- 2) detection of bacterial vaginosis and trichomonas infection

PRINCIPLE

The pH of the upper vagina is normally acidic (pH 3.8-4.5). Leakage of amniotic fluid (normal pH 7.0-7.5) raises the pH in vaginal fluid to >4.5. Similarly, bacterial overgrowth, as occurs in bacterial vaginosis and trichomonas, may increase vaginal pH to >4.5. Vaginal yeast infections do not change the pH of the vagina.

The pHizatest® is impregnated with the indicator dye nitrazine (phenaphthazine). The color of the paper changes from bright yellow at pH 4.5 and lower to dark blue at pH 7.0 and higher. Changes in color shades occur with pH increments of 0.5 from pH 4.5 to 7.5. The pH of vaginal fluid is determined by comparing the color of pH paper that has come in contact with a fluid sample to a standard color chart provided with each roll of pH paper.

TESTING PERSONNEL

- Qualified Physicians
- Qualified Nurse Practitioners, Physician Assistants, Midwives
- Qualified Registered Nurses

REAGENTS, EQUIPMENT AND MATERIALS

- pHizatest® by Micro Essential Laboratory (Cat # 0934 or equivalent)
- pH Color Card included with the paper dispenser
- Sterile Gloves

REAGENT STORAGE AND STABILITY

- pHizatest® must be stored in its container at room temperature, out of direct sunlight
- Avoid exposure to excessive direct sun light and to acid or alkaline fumes.
- Once opened, the shelf life is 6 months or the manufacturer's expiration, whichever occurs first. NOTE: POCT Services may assign an expiration date of 6 months from the time of issuance or the manufacturer's expiration, whichever occurs first.

QUALITY CONTROL

ZSFG POCT Services will perform quality control testing of pHizatest®. Performance of new batches (shipments and new lots) will be verified against certified buffers prior to release to POCT sites. Verified papers will be labeled with a sticker on the dispenser.

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SPECIMEN

pHizatest® may be applied directly to pooled vaginal fluid or to a vaginal fluid sample on a cotton swab. Specimen labeling is not required when testing is performed in the presence of the patient and only the sample from one patient is tested at a time.

PROCEDURE

1. Using two patient identifiers (e.g., name and date of birth or medical record number), verify patient identification, and explain procedure to the patient and/or family.
2. Observe universal precautions, wear gloves and other personal protective equipment as appropriate.
3. Remove one to two inches of pH paper from the dispenser for each test. DO NOT allow it to come into contact with any liquid or other substance, which might affect pH.
4. Insert a vaginal speculum and obtain a sample of vaginal discharge or fluid from the back of the vagina using a cotton tipped swab.
5. Smear the fluid from the swab on the pH paper.
6. Observe for immediate color change by comparing to the color chart on the dispenser.
7. Record the pH value, corresponding to the color change, in the patient’s chart. NOTE: A pH >4.5 may indicate ruptured amniotic membranes, bacterial vaginosis, or trichomonas. Semen and urine may also raise the pH to above 4.5.

PROCEDURE NOTES:

- Only use pHizatest® from a dispenser labeled “Exp. Date MM/DD/YY”
- Do not use pHizatest® past the expiration date on the dispenser label
- Do not use pH paper that is color blue BEFORE coming into contact with vaginal fluid
- Following contact with the vaginal fluid, pH paper should be considered potentially infectious and discarded observing standard precautions for microbiological hazards.
- Do not reuse pHizatest®
- For greatest accuracy, color comparisons should be conducted in a combination of fluorescent light and daylight.

Note: Each lot of pHizatest® has been verified for accuracy using NIST traceable standards. Color comparison recommended under a combination of fluorescent light and daylight. The color of the base stock may vary from lot to lot. This will not affect the accuracy of results.

LIMITATIONS

- pH paper, used for semi-quantitative measurement of vaginal pH is intended for use by qualified medical and nursing staff only as an aid to professional diagnosis and treatment
- Antibiotic therapy or infections of the vagina can lead to elevated vaginal pH, which could be interpreted falsely as the presence of amniotic fluid. Where doubt exists, standard microbiological testing should be employed to exclude infection.

- pH testing cannot distinguish amniotic fluid from urine. In instances where there is the possibility of urine contamination and/or where the patient has received antibiotic therapy, “fern” testing may be of value to verify the presence of amniotic fluid.
- False-positive reactions (elevated vaginal pH) may also occur due to alkalinization of the vagina by blood, semen, soap and antiseptic solutions.
- False-negative reactions in the detection of premature rupture of membranes may occur due to decreased efflux of amniotic fluid as the time between membrane rupture and testing increases.

RESULT REPORTING

- Record the numeric pH value in the electronic medical record (EMR) or result sheet.
- Reference Range: ≤ 4.5

CONFIRMATORY TESTING

- pH testing of vaginal fluid is not intended as a stand-alone test for the conditions listed. At the discretion of the provider, per departmental policies or standardized procedures, additional tests or procedures should be performed routinely or when pH testing yields unexpected or discrepant results.

REFERENCES

1. pHizatest® package insert, MicroEssential Laboratory, #93408.
2. Simoes JA, Discacciati MG, Brolazo EM, Portugal PM, Dini DV, Dantas MCM. Clinical diagnosis of bacterial vaginosis. Intl J Gynecol Obstet 2006; 94:28-32.
3. Davidson, KM. Detection of premature rupture of the membranes. Clin Obstet Gynecol 1991;34(4):715-722.

DISTRIBUTION

1. Point of Care Testing Services Master Manual
2. ZSFG Point of Care website: www.sfgh-poct.org

APPENDIX

A. Color Chart



Normal vaginal pH: 3.8-4.5
 Amniotic Fluid pH: 7.0-7.5

Ruptured Amniotic Membranes: pH > 4.5
 Bacterial Vaginosis: pH >4.5