

pHEM-ALERT® FOR TESTING VAGINAL pH LEVEL

CPT Code: 83986
Medicare Code: 83986QW

The pHEM-ALERT® probe is a very convenient and easy to use device that provides a method for a physician to quickly check the pH level of a patient's vagina. The pH level of the vaginal wall can be helpful in determining various vaginal conditions (Normal pH is 4.0-4.5). For example, the vaginal pH of greater than 4.5, in conjunction with additional tests and procedures, may indicate ruptured membranes⁽¹⁾(pH 7.0-7.5), vaginosis^(2,3) (pH 5.0-6.5) or an estrogen imbalance⁽⁴⁾. The procedure only takes a few minutes including set-up and preparation.

The pHEM-ALERT® features a small strip of phenolphthalein (Nitrazine®) pH paper at the tip. As is well documented, pH paper changes color upon moisture contact to indicate pH levels.

Storage

Store dry at a room temperature between 15°-30°C (59°-86°F). Do not use product after expiration date. Avoid excessive heat.

Limits of Procedure

The pHEM-ALERT® probe is meant to assist in a vaginal evaluation but should not be the sole basis of a therapeutic decision. Vaginal pH is one part of a complete examination and may indicate the need for additional tests and procedures.

Warnings and Precautions

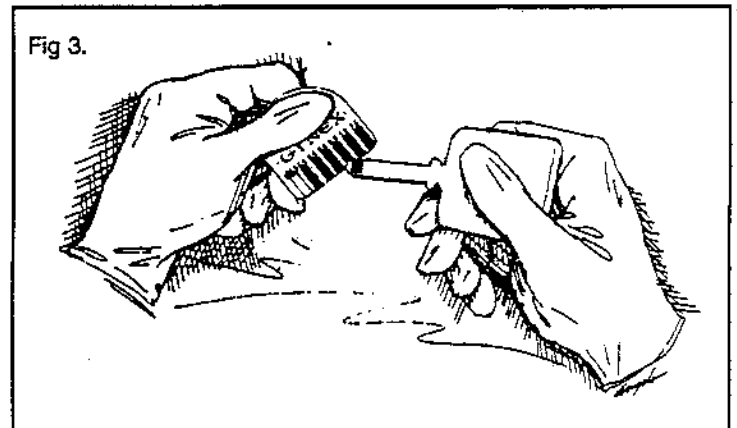
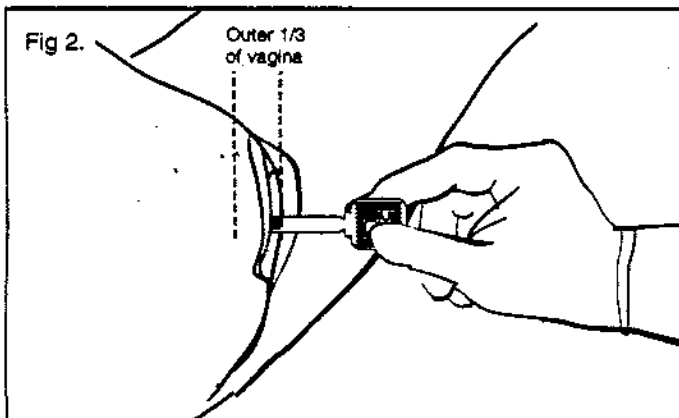
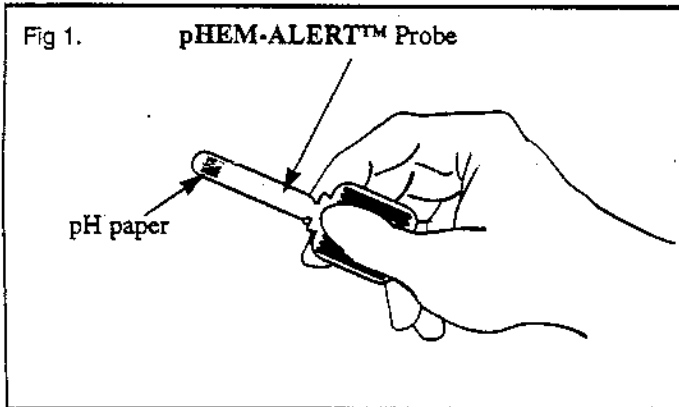
The pHEM-ALERT® is for *in vitro* diagnostic use only. Do not use it if the seal on the package is broken. Do not insert the pHEM-ALERT® tip farther than the outer third of the vagina. Do not perform this test on a patient that is bleeding or has had recent intercourse. View the results under incandescent light only, not under fluorescent lights.

Trademark Notice

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INSTRUCTIONS FOR USE

1. With the patient in a typical examination position, examine the vagina for blood or cervical mucus. Make sure the patient has not had recent intercourse or douching.
2. Carefully remove a pHEM-ALERT® probe from the pouch taking care not to touch the pH paper at the tip. Hold the probe by the handle for the proper insertion. (Fig 1.)
3. Insert the pHEM-ALERT® probe to the outer 1/3 of the vagina (Fig 2.). Avoid contact with blood (pH 7.4) or cervical mucus (pH 7.0).
4. Press the pH paper strip against the side wall of the vagina for 2 seconds or long enough to moisten the paper.
5. Remove the pHEM-ALERT® probe and immediately compare the color of the paper at the tip to the pH Color Chart provided (Fig 3). View the results under incandescent light only, not under fluorescent lights.
6. Record the pH number. Normal vaginal wall pH is 4.0-4.5. If the reading is high, such as 5.0-7.5, repeat the test to confirm the reading and record the results. High readings can result due to the presence of blood, cervical mucus, amniotic fluid, semen or vaginal medications (example: contraceptive gels, douches, etc.).



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Bibliography: pHEM-ALERT® REFERENCES

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4. Willson JR. The aging woman. Sciarra JJ, Gynecol. Obstet. 1987; 92: 1-12