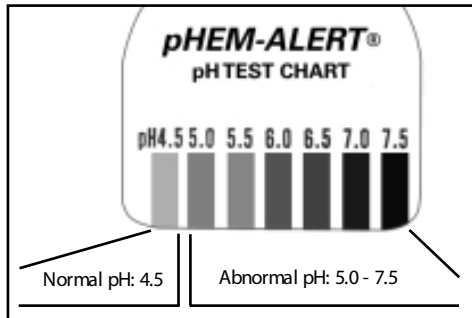


Under a bright light bulb or daylight, look at (compare) the color of the paper on the device and the colors on the color chart. Slide the device back and forth until you find the color on the color chart that looks the same as the color on the device. Write

down the number of the color that best matches the color on the device. This is your vaginal pH number.

RESULT AND WHAT TO DO WITH IT

Look for your vaginal pH number and color in the figure below. Your color and number can tell whether your vaginal pH is normal or abnormal.



If your pH is 5.0 or greater, call your healthcare provider to discuss your symptoms and the result of this test before treating yourself. There are no over the counter medications available for treatment of a high vaginal pH.

If you are pregnant, always discuss your symptoms and the result of this test with your health care provider and NEVER treat yourself.

If you have any questions about this product, call our toll-free customer service line at (425) 882-1179. Always consult your healthcare provider with any questions of a medical nature.

LIMITATIONS:

Each of the following can increase vaginal pH levels if present in the vagina when you test for pH.

cervical mucus - blood - semen - bacteria/Trichomonas perimenopause (low estrogen) - menopause (lower estrogen)

QUESTIONS & ANSWERS

Q. What is vaginal pH?

A. Vaginal pH indicates the acidity of the vagina. Normal is 4.5, abnormal is 5.0-7.5.

Q. Does vaginal itching, burning and discharge always mean a yeast (fungal) infection?

A. No! Less than 30% of vaginal itching, burning and discharge is due to yeast (fungal) infection.

Q. If I have vaginal itching, vaginal discharge and a vaginal pH of 4.5 could I try an antiyeast medication?

A. Yes, If you are not pregnant! But seek medical attention if symptoms do not go away. If you are pregnant NEVER treat yourself.

Q. If I have vaginal itching, vaginal discharge and burning, and my vaginal pH is 5.0 - 7.5, what should I do?

A. Contact your healthcare provider for advice as soon as possible.

Understanding Vaginal pH

The following summary is for those who wish to better understand the body's natural process for producing vaginal acidity.

A normal estrogen level produces normal vaginal cells that contain glycogen (sugar). A normal bacteria common to the vagina is Lactobacillus acidophilus. The Lactobacillus digests the vaginal cell sugar and produces hydrogen peroxide and lactic acid, keeping normal vaginal pH at 4.0 to 4.5. This helps to suppress abnormal bacteria but does not suppress yeast. When abnormal bacteria or Trichomonas suppress Lactobacillus, the lactic acid level drops causing the vaginal pH to rise to an abnormal level of 5.0 - 7.5.

Performance Information:

A study of 96 premenopausal women with symptoms of vaginal infection was conducted. Of the 88 women with complete information, twenty of twenty-one women (95%) with a physician's diagnosis of bacterial or trichomonas infection had a pH > 4.5 while fifty of sixty-seven women (75%) with yeast or normal findings had a pH of ≤ 4.5. Overall, therefore, 70 of 88 women (80%) had their results confirmed by a physician.

References

- [1] Sexually Transmitted Diseases Treatment Guidelines 2002 CDC, MMWR, May 10, 2002/Vol. 51/No.RR-6.
- [2] Caillouette J.C. et al.; Vaginal pH as a marker for bacterial pathogens and menopausal status: Am J Obstet Gynecol; 6/97: Vol. 176, No. 6
- [3] Diagnosis of Vaginitis; APGO Educational Series in Women Health Issue; 1996
- [4] Vaginitis; ACOG Technical Bulletin Number 226; 7/96

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pHEM-ALERT™

For Women with Vaginal Symptoms:

Itching
Burning
Unpleasant Odor
Unusual Discharge

This is NOT a test for diseases such as HIV, chlamydia, herpes, gonorrhea or syphilis.

CAUTION:

DO NOT use this test during your menstrual period or during the five days immediately following it.

Use each test one time only.

Incorrect test results can be caused by contact with blood, semen or certain vaginal products. See Limitations, Warnings and Precautions inside for when not to use this test.

Please read instructions carefully before use! If you have any questions, call your healthcare provider or Gynex Customer Service at 425-882-1179.

STORAGE:

Store pHEM-ALERT™ in a dry place at room temperatures that do not exceed 86° F, or fall below 59° F.

DO NOT USE THIS PRODUCT AFTER THE EXPIRATION DATE PRINTED ON THE PACKAGE. DO NOT USE THIS PRODUCT IF THE PACKAGE IS DAMAGED.

Note: The pHEM-ALERT™ test device is CLIA waived

Distributed by:
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Tel: 425-882-1179, Fax: 425-895-0115
e-mail: service@Gynex.com

pHEM-ALERT™

DEVICE DESCRIPTION

pHEM-ALERT™ is an easy, convenient, single-use device for vaginal pH testing. This test may help you decide if your vaginal symptoms are likely caused by an infection.

pHEM-ALERT™ is comprised of a 2-inch device. A piece of pH paper is attached to one side near the tip of the device while the other end is a textured handle. The device is inserted into the vagina and touched to the vaginal wall to moisten the pH paper. The device is then withdrawn and a number is determined by comparing the color of the pH paper to the color chart.

A normal vaginal pH number of 4.5 is important to your health.

Vaginal infections can be due to a variety of causes. The pHEM-ALERT™ does not identify specific causes of vaginal infection. However, in general, a yeast infection does not raise the normal vaginal pH value of 4.5. Other types of infections can cause the pH to increase to 5.0 or greater. Therefore, by measuring your vaginal pH, this test may help you decide if your symptoms are more likely caused by yeast, Trichomonas or a bacterial infection.

A pH higher than normal or 5.0-7.5, usually indicates a need for further tests to be performed by your healthcare provider. Do not self treat with over-the-counter antifungal creams. Call your healthcare provider first to discuss your symptoms and the result of this test.

Vaginal infections in pregnancy can be very dangerous to the unborn child [1]. If you are pregnant, always discuss your symptoms and the result of this test with your healthcare provider and NEVER treat yourself.

INDICATIONS FOR USE:

The pHEM-ALERT™ test measures vaginal pH, and is intended for use by women who have any of the following vaginal symptoms:

itching - burning - unpleasant odor - unusual discharge

This test may help decide if these symptoms are caused by an infection that may require follow-up by your healthcare provider. This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding) or who may currently be pregnant. Pregnant women may use this test, but should always discuss the results with their healthcare provider.

Note: The pHEM-ALERT™ test device is CLIA waived

WARNINGS AND PRECAUTIONS:

Pregnant women who have vaginal symptoms should NEVER treat themselves before talking to their healthcare provider.

This is NOT a test for sexually transmitted diseases, such as HIV, chlamydia, herpes, gonorrhea or syphilis.

DO NOT use this test until 72 hours after the application of vaginal preparations like contraceptive creams and antifungal agents.

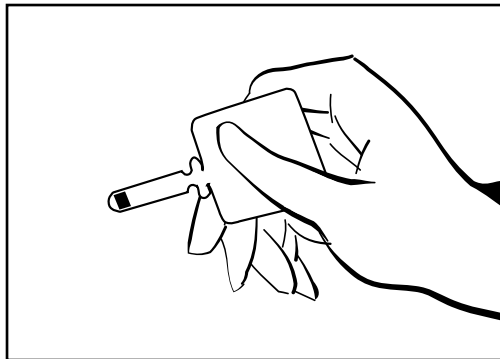
DO NOT use this test until 48 hours after sexual intercourse or douching.

DO NOT use this test until 5 days after your period is over.

INSTRUCTIONS FOR USE:

Testing your vaginal pH is quick, easy and painless. Relax and take your time. Follow these step-by-step instructions. Wash your hands before using this test. Then follow the simple steps below.

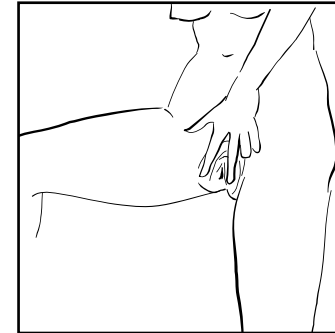
Remove the pHEM-ALERT™ test device and color chart from the package. The test device has test paper on one end and a handle on the other end.



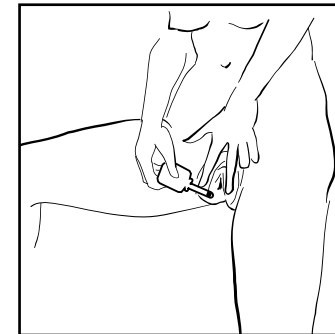
Hold the handle of the test device between your thumb and forefinger. Your thumb must lay on the flat part of the handle on the test paper side.

KEEP HOLDING THE TEST DEVICE AND DO NOT LET THE END WITH THE TEST PAPER TOUCH ANYTHING.

The colors on the color chart change from bright yellow (4.5) to a dark blue (7.5)



Sit with your knees spread apart, or stand with one foot on the toilet seat or other firm surface. Using your free hand, gently spread apart the folds of skin that cover the vaginal opening.



Insert only the slim end of the device gently into your vagina, as you would a tampon. Make sure that you know which side of the test device has the paper on it as you insert it.



Insert the thin end of the device until the handle rests against the outside skin of the vagina.

Gently tilt the device so that the thumb side with the pH paper on it gently touches the inside wall of the vagina. Press the paper against the vaginal wall for 5 seconds.

Remove the device from your vagina, being careful not to touch the paper to anything.