

VAGINAL PH TEST PROFESSIONAL USE

User manual

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

The Vaginal pH test kit is a screening device for use in the detection of the major form of vaginitis in vaginal fluid specimens from women concerned about their vaginal health.

Summary and Explanation of the Test Kit

Vaginitis is defined as irritation of the vagina, a troublesome condition that affects millions of women of all ages in all parts of the world. The most common types of vaginitis are Bacterial vaginitis, etc. It can usually be treated effectively with prescription or over-the-counter medication if correctly diagnosed. However, if left untreated, misdiagnosed or incorrectly treated, vaginitis can produce serious consequences such as sterility or miscarriage, and it can be a precursor to cancer.

The test kit is intended to be used by or under the direction of a trained medical professional. The test kit is very easy to use and only minimal training is necessary for staff level technicians to become proficient in the accurate diagnosis of vaginitis in any particular case. Such trained professionals can also easily instruct or assist patients with the use of the kit on their own. Treatment or recommended treatment regimens require the consultation of a medical professional. Vaginal pH test is not to be used for selfdiagnosis and self-treatment.

Intended use

The Vaginal pH test kit will be used only on site in physician's offices, clinics, and hospital or professional laboratories – point of care sites - where women will visit in person to have the test performed. The test kit procedures may be performed only by trained medical professionals who have carefully read, and understand, the Instructions for Use. Samples must be tested on site, and may not be transported for testing in remote locations.

Principles of the Test

There is a link between vaginal health and pH. Fluctuations in vaginal pH are often normal occurrences resulting from variations during the menstrual cycle, a decrease in pH during pregnancy, or the presence of seminal fluid, blood, amniotic fluid, or cervical mucus. However, an abnormal pH level may also indicate the presence of a vaginal infection, such as BV.

In a healthy vagina, lactobacilli—the main determinant of pH—are instrumental in maintaining vaginal acidity (normal pH is 3.8 to 4.2), and preventing the overgrowth of other aerobic and anaerobic bacteria. In BV, the pH is elevated in association with an increase in microorganisms that impair the growth of lactobacilli. Because of the critical role pH plays in suppressing the growth of BV-associated bacteria, an increased vaginal pH is an important indicator in diagnosing BV.

Most physicians accept the criteria of pH > 4.5 or ≥ 4.7 as one indicator of BV. Regardless of the level used, if a higher than normal vaginal pH is detected, other diagnostic tests should be performed to investigate the presence of BV or other infections.

In order to ensure the accuracy of the pH test, obtaining a reliable vaginal fluid sample is essential. A specimen, should be collected from the anterior or fornix or lateral vaginal wall. It is important that contact with the cervix is avoided because cervical pH is higher than vaginal pH.

pH Zone Color

The normal pH of vaginal fluid is in the range 3.8 – 4.2. After application of the test fluid sample, if the pH test zone turns from pink to grayish purple or blue-green 1 minute, the pH is above 4.7, which indicates a positive result. If the vaginal fluid is below pH 4.7, the color remains pink, indicating normal vaginal pH. The pH zone change to grayish purple or bluish green – an abnormally high pH - is a positive finding, consistent with bacterial vaginitis and/or trichomoniasis, microorganisms that impair the growth of the normal vaginal lactobacilli, which keep pH low.

Warnings and Precautions

- Check the expiration date printed on foil pouch and carton box. Do not use the test kit after the expiration date.
- Do not use the test kit if the foil pouch is not sealed, or if the pouch is broken.
- Do not remove the test from foil pouch until ready to use. Once the foil pouch has been opened, the test strip must be used within 10 minutes.
- To obtain accurate results, the Package Insert Instructions for Use must be read before using the test kit, and followed closely.
- This product is intended only for vaginal fluid use. Do not touch or collect vaginal fluid near the cervix. Do not use vaginal fluid specimens that contain blood.
- Do not use sterile swabs if the package is not sealed or if the seal has been broken.
- Patient vaginal swabs are not appropriate for any other purpose, including bacterial culture, after performing the test.
- Dispose of patient samples in biological sample disposal containers.

Instructions for Use

This test kit is intended for use by a trained medical technician, nurse, nurse practitioner, physician's assistant, or physician, or by a patient under the guidance of one of these trained medical practitioners. The instructions for use shown below should be studied carefully and followed exactly to ensure accurate sample collection and application, and therefore reliable and accurate results.

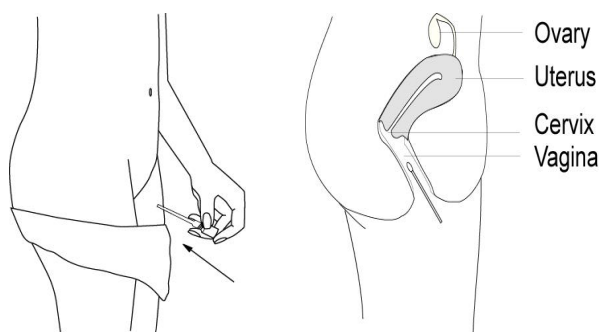
Collection of Vaginal Fluid Sample

Wash hands thoroughly, and observe sterile technique while taking and testing vaginal fluid samples.

First, thoroughly swab the inner and outer labia of the patient with a sterile wipe to reduce the exterior bacterial count from the vaginal opening.

Insert the swabs about two to three inches into the vagina. Do not insert near the cervix, as pH results would be inaccurate.

Drawing 1– Insertion of sterile swab into vagina

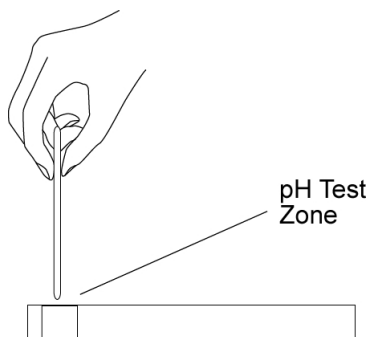


Gently stroke the inner walls of the vagina with the swabs, ensuring that the swabs are all moistened thoroughly. Leave the swabs in the vagina several minutes to ensure they are saturated with vaginal fluid.

Remove the swab from the vagina.

Rub the swab saturated with fluid sample onto the pH zone. Discard the swab in a biological specimen container. Read the pH color after 1 minute, and compare the result with the color chart.

Drawing 2 – Application of swab onto pH Zone.



Quality Control

Each production lot of Vaginal pH test strips is tested rigorously at the factory before packaging and shipping, with both positive and negative control reagents. Positive and negative control reagent kits are available if a clinic or pharmacy wishes to conduct in house control procedures. The positive and negative control reagents are designed to produce the color changes expected for positive or negative results on the Vaginal pH test cassette.

Kit Storage

Store the Vaginal pH test kit at 4-30 degrees C (39 - 86 degrees F), out of direct sunlight.

Interpretation of Results from the Vaginal pH Test Kit

It cannot be emphasized enough that accurate results require that the vaginal fluid sample collection methodology and test application methodology be performed according to the instructions in this document.

Test Zone Color Interpretation

A grayish purple or bluish green color indicates a positive result, a pH above 4.7. This may indicate a bacterial infection. No color change indicates a pH below 4.7, which is normal for the vagina. This indicates the absence or very low level of bacterial infection or Trichomoniasis.

Test Result	Positive Color	Negative Color	Positive Result Interpretation	Negative Result Interpretation
Test Zone				
pH Zone 1	Grayish purple to bluish green	Pink	Bacterial Vaginitis and/or Trichomonas	No or low level bacterial infection. Trichomonas still possible

References

Andersch B, Lindell D, Dahlen I, Brandberg A. Bacterial vaginosis and the effect of intermittent prophylactic treatment with an acid lactate gel. *Gynecol Obstet Invest.* 1990;30:114-119.
 Barrington JW, Linton D, O'Leary A, et al. Anaerobic (bacterial) vaginosis and premalignant disease of the cervix. *J Obstet Gynaecol* 1997;17:383- 385.
 Borchardt KA, Al-Haraci S, Maida N. Prevalence of Trichomonas vaginalis in a male sexually transmitted disease clinic population by interview, wet mount microscopy and the InPouch TV test. *Genitourin Med* 1995;71:405-406.
 Platz-Christensen JJ, Sundstrom E, Larsson P-G. Bacterial vaginosis and cervical intraepithelial neoplasia. *Acta Obstet Gynecol Scand* 1994;73:586- 588.
 Cohen CR, Duerr A, Pruithithada N, Rugpao S, Hillier S, et al. Bacterial vaginosis and HIV seroprevalence among female commercial sex workers in Chiang Mai, Thailand. *AIDS* 1995;9:1093-1097.

Graphical Symbols Used

	Temperature limit
	In vitro diagnostic medical device
	Product code
	Consult instructions for use

	Disposable device, do not re-use
	Authorized representative in the European community
	In vitro diagnostic medical device compliant with Directive 98/79 / EC
	Don't use if package is damaged
	Expiration date
	Lot number
	Contains sufficient for "n" tests
	Manufacturer
	Sterilized using ethylene oxide
	Imported by

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

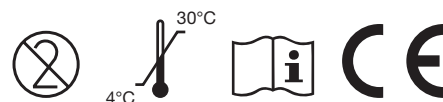
GIMA 29110

Ameritech Diagnostic Reagent (Jiaxing) Co., Ltd
 K4-2 Science Technology Garden,
 Economic Development Zone, 314500 Tongxiang,
 Zhejiang, P.R. China
 Made in China

V03-01

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FOR PROFESSIONAL USE



Swab

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