

Vaginal pH Rapid Test Panel (Vaginal Swab)

REF AUVP2AT

English

Package Insert - For Self-testing

A rapid test for the semi-quantitative determination of pH in female vaginal swab specimens. For self-test *in vitro* diagnostic use only.

INTENDED USE

The Vaginal pH Rapid Test Panel (Vaginal Swab) is a rapid dry chemical method for the semi-quantitative detection of pH in female vaginal swab specimens to aid in the diagnosis of bacterial vaginosis.

SUMMARY

Vaginal infections are quite common and often a recurring problem among women of all age groups. An indication of abnormal acidity of the vaginal discharge can help evaluate whether the vaginal symptoms are likely caused by an infection that may require follow-up with a healthcare professional.¹ An acidic vaginal pH value of 3.8 to 4.5 is a basic requirement for the optimal functioning of the body's own system of protecting the vagina. This system can effectively avoid colonization by pathogenic germs and the occurrence of vaginal infections.² Under the influence of lacto bacteria, the glycogen released from the upper vaginal epithelium degrades to form the sugar glucose and then lactic acid. This results in an acid environment forming in the vagina, with a pH value that is usually 3.8 to 4.5. This acidic vaginal environment forms effective protection against infections, because the vast majority of bacteria that cause disease cannot thrive under such conditions.³ Some vaginal infections known to be associated with abnormal vaginal acidity have no non-prescription treatments, and must be treated by a healthcare professional.⁴ Some cases of abnormal discharge with abnormal acidity may be caused by a combination of infections.⁵ Vaginal infections may be very risky for pregnant women and dangerous for the mother and her fetus, thus symptoms and results should always be discussed with a healthcare professional.

PRINCIPLE

A pH paper is used to determine pH levels in specimen obtained through a vaginal swab. As soon as the swab containing the specimen from vagina comes in contact with the pH paper encased in the test panel, a colour change occurs. Different pH levels can result in different grades and shades of colour with each colour grade/shade specifying a particular pH level on the colour scale. The colour obtained on the pH paper after application of the vaginal swab is then compared with the colour scale provided with the test unit. The result is considered to be approximately equivalent to the numerical value of the colour on the colour scale closest in appearance to the colour obtained on pH paper.

REAGENT

The test contains bromocresol green coated on the colour pad.

PRECAUTIONS

- For self-test *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not use test if pouch is damaged.
- Use each test panel only once.
- Only use the swab provided in the kit.
- Only open the package of swab before specimen collection.
- DO NOT use this test until 72 hours after the application of vaginal preparations like contraceptive creams and vaginal medical products (antifungal agents, vaginal suppositories, creams, gels, douching etc.).
- DO NOT use this test until 48 hours after sexual intercourse or douching.
- DO NOT use this test until 5 days after the period is over.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The Vaginal pH Rapid Test Panel (Vaginal Swab) can be performed using female vaginal swab specimen.

- Wash hands before starting the test.
- Open the package, remove the swab from pouch, and do not touch the head of the swab (polyester head).
- Separate the labia so the vagina is exposed.
- Insert the head of swab gently into the vagina and gently press the swab to a point, when approximately 2 inches of swab (approximately length of an AA size battery) is into the vagina for approx. 10 seconds). A time of approximately 10 seconds is important to ensure that the head of swab becomes well moistened with vaginal secretions. Sufficient moisture is very important for the test evaluation.
- Withdraw the swab from the vagina for testing.

MATERIALS PROVIDED

- Test Panel
- Package insert
- Sterile Swab

MATERIALS REQUIRED BUT NOT PROVIDED

- Toilet Paper

DIRECTIONS FOR USE

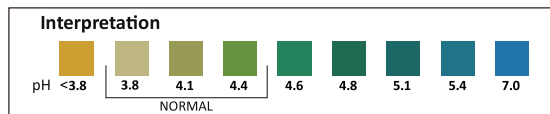
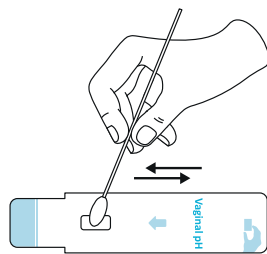
Allow the test and swab specimen to reach room temperature (15-30°C) prior to testing.

- Remove the test panel from the seal pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the test panel on a clean and balance desk or take it by your free hand.
- Apply the head of swab onto pH area of the test panel **at least 5 times**, making sure enough secretion is applied on the pH area of the test panel.
- Read the result immediately while the measurement zone is still wet. Compare the colour in the pH measurement zone with the colour scale on the foil pouch and note the value on the colour scale that is closest to the colour on the test unit. After evaluation, dispose of the used panel and swab.

For more information contact 2San

2San Pty Ltd, E: helpdesk@2san.com
Level 35, Tower One, W: www.2san.com
100 Barangaroo Avenue,
Sydney, NSW 2000

Wipe swab on the test area at least 5 times



INTERPRETATION OF RESULTS

Results are obtained by visually comparing the PH measurement zone with the colour scale on the foil pouch.

NORMAL RANGE:

Vaginal pH levels in the range 3.8-4.4 are within the normal range.

The colour of indicator is Yellow-Green.

ABNORMAL RANGE:

Vaginal pH levels over 4.4 or under 3.8 are outside of the normal/healthy range. When pH level is over 4.4, colour of the indicator is Green-Blue, when pH levels is under 3.8, it is bright Yellow.

WARNINGS & LIMITATIONS

- Some menopausal women may have an elevated vaginal pH, and therefore may receive an abnormal result with vaginal pH Rapid Test Panel even though they are not suffering from a bacterial or parasitic infection.
- Certain circumstances (menstrual period, sex intercourse, use of vaginal medical products) can temporarily alter the pH level of vagina and may lead to false results. Therefore, please note the precautions when performing the test:
- Do not wash or shower the area immediately before taking the measurement.
- Be aware that urine may cause a false test result.
- Never begin any treatment before you have discussed the result of the test with a doctor.
- In cases of improper use, rupture of hymen may occur as it occurs when using tampons.
- This is NOT a test for sexually transmitted diseases, such as HIV, chlamydia, herpes, gonorrhoea or syphilis.

PERFORMANCE CHARACTERISTICS

A clinical evaluation was conducted comparing the results obtained using the Vaginal pH rapid test to Culture method. The clinical trial included 110 vaginal swab specimens. The results demonstrated 94.4% specificity and 98.9% sensitivity with an overall accuracy of 98.1%.

EXTRA INFORMATIONS

1. Question: Could I use the test at anytime?

Answer: No. There are some restrictions on when to use this test because to certain circumstances can temporarily alter the pH level of the vagina and may lead to false results. Therefore, please find the precautions in this package insert and use the test.

2. Question: Can the positive results show that the subject has bacterial vaginosis?

Answer: Not necessarily. Some menopausal women may have an elevated vaginal pH, hence may receive a positive result even without suffering from bacterial or parasitic infection. Initiate any treatment, only after consultation with doctor.

3. Question: What is the reason that may result in wrong test results?

Answer: A wide range of factors can affect the test results, including inaccurate specimen collection, insufficient moistening of the swab, insufficient application of specimen on the test area.

4. Question: How do I know the test is valid?

Answer: You can contact local dealers to purchase the control of this test.

BIBLIOGRAPHY












- Panda Subrat, Das Ananya, Singh Ahanthem Santa, Pala Star. Vaginal pH: A marker for menopause. Journal of mid-life health, 2014, Vol.5 (1), pp.34-7.
- Roy Subir, Cailhouette James C, Faden Joel S, Roy Tapon, Ramos Diana E. Improving appropriate use of antifungal medications: the role of an over-the-counter vaginal pH self-test device. Infectious Diseases in Obstetrics and Gynecology, 2004, Vol.11 (4), pp.209-16.
- Maloney C, Oliver M L. Effect of local conjugated estrogens on vaginal pH in elderly women. American Medical Directors Association. Journal, 2003, Vol.2 (2), pp.51-5.
- Hanna N F, Taylor-Robinson D, Kalodiki-Karamanolis M, Harris J R, McFadyen I R. The relation between vaginal pH and the microbiological status in vaginitis. British Journal of Obstetrics and Gynaecology, 1985, Vol.92 (12), pp.1267-71.
- Nakra Natasha A, Madan Pellett, Buckley Niall et. Loss of Innate Host Defense Following Unprotected Vaginal Sex. The Journal of infectious diseases, 2016, Vol.213 (5), pp.840-7.

APPLICABLE PRODUCTS

This package insert applies to the following products:

PRODUCT NAME	TESTS PER KIT	REF
Vaginal pH Rapid Test Panel (Bacterial Vaginosis)	1 test kit	AUVP2AT
Vaginal pH Rapid Test Panel (Bacterial Vaginosis)	2 test kit	

INDEX OF SYMBOLS

	Consult Instructions For Use
	For <i>in vitro</i> diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged
	Tests per kit
	Use by
	Lot Number
	Manufacturer
	Catalog #
	Do not reuse
	Authorised representative in EU



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Hangzhou, 310018 P.R. China
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Email: info@alltests.com.cn



EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
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Sterile swabs:



COPAN ITALIA Spa

Via F. Perotti 10,
25125 Brescia, Italy
www.copangroup.com



Or



Jiangsu Changfeng Medical Industry Co., Ltd.

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