Vaginal pH Rapid Test Panel (Vaginal Swab) Package Insert

For Self-testing

REF IVPH-504H	English

A rapid test for the semi-quantitative determination of pH in female vaginal swab specimens.

For self-testing 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.

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.

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.[1]

Some vaginal infections known to be associated with abnormal vaginal acidity have no non-prescription treatments, and must be treated by a healthcare professional.[2]

Some cases of abnormal discharge with abnormal acidity may be caused by a combination of infections.

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 color change occurs. Different pH levels can result in different grades and shades of color with each color grade/shade specifying a particular pH level on the color scale. The color obtained on the pH paper after application of the vaginal swab is then compared with the color scale provided with the test unit. The result is considered to be approximately equivalent to the numerical value of the color on the color scale closest in appearance to the color obtained on pH paper.

【PRECAUTIONS】

1. For self-testing *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. The used test should be discarded according to local regulations.
4. Humidity and temperature can adversely affect results.
5. Do not use test if pouch is damaged.
6. Use each test panel only once.
7. Only use the swab provided in the kit.
8. Only open the package of swab before specimen collection.
9. **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.).
10. **DO NOT** use this test until 48 hours after sexual intercourse.[3]
11. **DO NOT** use this test until 5 days after the period is over.
12. The product testing area displays green at the initial phase.

【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.

1. Wash hands before starting the test.
2. Open the package, remove the swab from pouch, do not touch the head of the swab (polyester head).
3. Separate the labia so the vagina is exposed.
4. 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.
5. Withdraw the swab from the vagina for testing.

【MATERIALS】

Materials Provided

• Test Panel • Sterile Swab • Package Insert

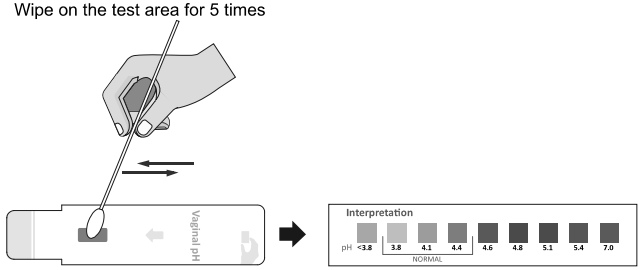
Materials Required But Not Provided

• Toilet Paper

【DIRECTIONS FOR USE】

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

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



【INTERPRETATION OF RESULTS】

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

NORMAL RANGE: Vaginal pH levels in the range 3.8-4.4 are within the normal range. The color 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, color of the indicator is Green-Blue, when pH levels is under 3.8, it is bright Yellow.

【LIMITATIONS】

1. 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.[4,5]
2. 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.
3. Do not wash or shower the area immediately before taking the measurement.
4. Be aware that urine may cause a false test result.
5. Never begin any treatment before you have discussed the result of the test with a doctor.
6. In cases of improper use, rupture of hymen may occur as it occurs when using tampons.
7. This is NOT a test for sexually transmitted diseases, such as HIV, chlamydia, herpes, gonorrhea or syphilis.

【EXTRA INFORMATIONS】

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

Answer: No. There are some restrictions on when to use this test because 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 abnormal results show that the subject has bacterial vaginosis?

Answer: Not necessarily. Some menopausal women may have an elevated vaginal pH, hence may receive an abnormal 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】

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3. Roy Subir, Caillouette 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.
4. 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.
5. 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.

Index of symbols

⚠	Caution	Σ	Tests per kit	EC REP	Authorized representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot number	REF	Catalog #
	Do not use if package is damaged		Consult instructions for use		Manufacturer

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 0123

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Global Network Oy
Kalsiittikuja 6
20250 Turku, Finland

Sterile swabs:

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District,
Yangzhou, 225109 Jiangsu,
P.R. China

CE 0197

Or

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

CE 0123

Number:14604132800
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