



Vaginal pH Rapid Test (Vaginal Swab)	
Instructions For Use	English
REF IVPH-504H	For Self-testing use

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 (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 (BV), Thrush and Trichomoniasis in conjunction with other symptoms.

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 foetus, thus symptoms and results should always be discussed with a healthcare professional.

PRINCIPLE

A pH indicator 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 closest match in colour between the test panel and colour scale and corresponding pH value is considered the approximate pH value of the applied vaginal specimen.

PRECAUTIONS

- | | |
|--|--|
| <ol style="list-style-type: none"> Keep out of the reach of children. This device is for self-testing. For <i>in vitro</i> diagnostic use only DO NOT use after the expiration date printed on the foil pouch. DO NOT eat, drink, or smoke in the area where the specimens and kits are handled. The used test should be discarded hygienically according to local regulations. Humidity and temperature can adversely affect results. DO NOT use the test if the foil pouch is damaged. Use each test only once, discard after use. Only use the swab provided in the kit. DO NOT open the test foil pouch until you are ready to start the test. | <ol style="list-style-type: none"> Only open the swab package 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.³ DO NOT use this test until five days after your period is over. Do not eat the desiccant in the package. |
|--|--|

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.

MATERIAL PROVIDED

- 1 or more Vaginal pH tests
- 1 or more Sterile Swabs
- Instructions For Use

MATERIAL REQUIRED BUT NOT PROVIDED

- Tissue or Toilet paper.

PREPARATION and SPECIMEN COLLECTION

The Vaginal pH Rapid Test (Vaginal Swab) is performed using a female vaginal swab specimen.

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

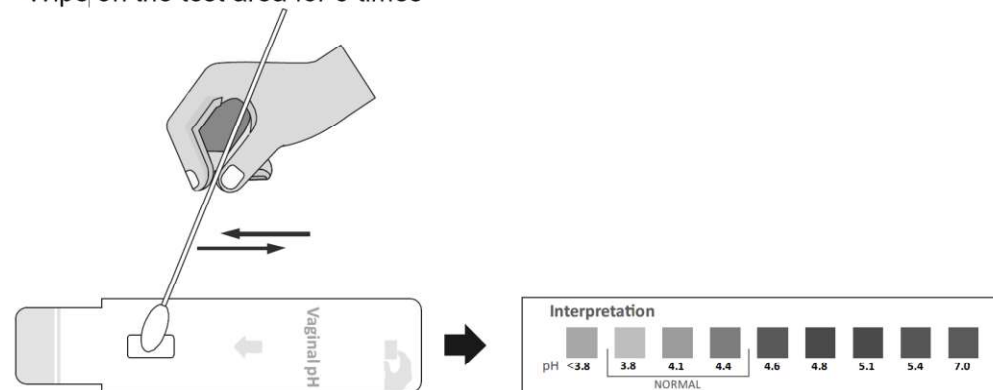
Remove the test panel from the sealed pouch and use within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

- Wash hands thoroughly before commencing.
 - Open the test foil pouch and place the test panel on a clean and level surface.
 - Open the swab package, remove the swab from pouch, do not touch the head of the swab (polyester head) to any external surface or with your fingers.
 - Separate the labia so the vagina is exposed.
 - Insert the head of swab gently into the vagina for approximately 5 cm (2 inches), i.e. approximately the length of an AA size battery, and gently press the swab to a point, then hold for approximately 10 seconds.
- IMPORTANT NOTE:** 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.

DIRECTIONS FOR USE

- Apply the head of the swab onto the pH indicator zone of the test panel, as shown below, and wipe backwards and forwards at least 5 times, to ensure complete transfer of secretion on the pH indicator zone of the test panel.
- Read the result immediately while the indicator zone is still wet. Compare the colour in the pH indicator 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 pH indicator zone. After evaluation, dispose of the used panel and swab.

Wipe on the test area for 5 times



READING THE RESULTS

Results are obtained by visually comparing the pH indicator 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 Orange-Yellow.

SEE REVERSE SIDE FOR MORE INFORMATION.

Test Result	pH < 3.8		pH >= 3.8 & pH < 4.4		pH > 4.4	
	Abnormal pH Range		Normal pH range		Abnormal pH range	
Symptoms	With and without any symptoms	White vaginal discharge (often like cottage cheese), which does not usually smell. ⁶ Itching and irritation around the vulva and vagina. ⁶ Soreness and stinging during sex or when you pee. ⁶	No Symptoms	An unusual vaginal discharge that has a strong fishy smell, particularly after sex. ⁷ A change to the colour and consistency of your discharge, such as becoming greyish-white and thin and watery. ⁷ Usually, no soreness or itching. ⁷	Abnormal vaginal discharge, it may be thick, thin, or frothy and yellow green in colour. ⁸ Producing more discharge than normal, which may also have an unpleasant fishy smell. ⁸ Soreness, swelling and itching around the vagina, sometimes the inner thighs also become itchy. ⁸ Pain or discomfort when passing urine or during sex. ⁸	
Possible Diagnosis	Abnormal	Possible Thrush	Possibility Normal	Possible Bacterial Vaginosis (BV)	Possible Trichomoniasis	
In the case of possible infection what to do next	Repeat test a few hours later or next day. Consult your doctor or health care professional for advice and treatment options.		Repeat test on a regular interval or if you develop any new symptoms.	Repeat test a few hours later or next day. Consult your doctor or health care professional for advice and treatment options.		
If you are concerned about the test result or your symptoms consult your doctor or healthcare professional before taking any medical decisions or initiating any treatment.						

PERFORMANCE CHARACTERISTICS

A clinical performance study was carried out on the Vaginal pH Rapid Test Panel (Vaginal Swab) test on 220 specimens (200 normal and 20 abnormal confirmed by comparison with the StrongStep® Bacterial vaginosis (BV) Rapid Test) the test had an overall accuracy of 98.6%.

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.^{4,5}
- In up to 50% of women both Bacterial Vaginosis and Trichomoniasis can be present with no noticeable symptoms.^{7,8}
- Thrush can present with no symptoms.⁶
- Certain circumstances (menstrual period, sexual 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.

QUESTIONS AND ANSWERS

- Question:** Can I use the test at any time?
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, please read the precautions section and take these into account before using the test.
- Question:** Can an abnormal result determine 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. Do **NOT** initiate any treatment or make any medical decisions based on the results of this test without consulting your doctor or healthcare professional.

- Question:** What factors can affect the test resulting in an incorrect normal or abnormal result?
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. Please read the preparation, specimen collection and directions for use sections and carefully follow the instructions.
- Question:** How do I know the test is valid?
Answer: Repeat the test a few hours later or next day. If you have concerns on the result of the test, then consult your doctor or health care professional for advice and treatment options.



If you have questions about the instructions or your results, please contact our Customer Care Helpline UK 0800 0430318 or R.O.I 0818 333 181

BIBLIOGRAPHY

- 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 etc. Loss of Innate Host Defense Following Unprotected Vaginal Sex. The Journal of infectious diseases, 2016, Vol.213 (5), pp.840-7.
- 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.
- 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.
- 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.
- NHS web site for Thrush: <https://www.nhs.uk/conditions/thrush-in-men-and-women/>
- NHS web site for Bacterial Vaginosis (BV): <https://www.nhs.uk/conditions/bacterial-vaginosis/>
- NHS Web site for Trichomoniasis: <https://www.nhs.uk/conditions/trichomoniasis/>

INDEX OF SYMBOLS

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

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China

0123

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

Sterile Swabs

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

0197

IVPH-504H
PN: 01290A (SC-564A)
REV: 06/24



Imported by and Manufactured For:
CIGA Healthcare Ltd, Kilcran House, Kildowney
Road, Ballymena, BT44 9EY, Northern Ireland.
info@suresign.com
www.suresign.com

Number: 14602411100
Revision date: 2024-06-26