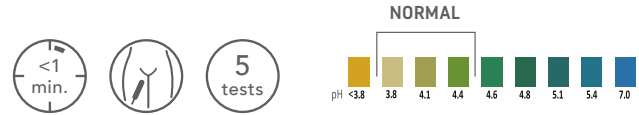


VAGINAL pH TEST

Rapid self-test for the semi-quantitative determination of pH in female vaginal swab specimens



VAGINAL INFECTIONS AND pH

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 system which protects the vagina. This system can effectively avoid colonization by pathogenic germs and the occurrence of vaginal infections.

WHAT IS VAGINAL pH TEST

VAGINAL pH TEST is a rapid dry chemical method for the semiquantitative detection of pH in female vaginal swab specimens to aid in the diagnosis of bacterial vaginosis.

WHO ARE THE INTENDED USERS

Women who feel vaginal discomfort.

WHY - BENEFITS

Vaginitis is a very common feminine disease affecting million of women each year. Vaginitis accounts for over 50% of all gynaecologic office visits. The key to a proper treatment is an early accurate diagnosis to prevent Bacterial Vaginosis complications.

TEST 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.

TECH SPECS

RANGE OF MEASUREMENT	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
3,80 - 7,00	95,00%	99,00%	98,60%

Performance data obtained by clinical study with 220 participants enrolled. PH Vaginal Rapid Test (pH) has been utilized as reference method.

CLINICAL EVIDENCES

1. Pavletic, A. J., Hawes, S. E., Geske, J. A., Bringe, K., & Polack, S. H. (2004). Experience with routine vaginal pH testing in a family practice setting. *Infectious Diseases in Obstetrics and Gynecology*, 12(2), 63–68.
2. Huppert, J. S., Hesse, E. A., Bernard, M. C., Bates, J. R., Gaydos, C. A., & Kahn, J. A. (2012). Accuracy and Trust of Self-Testing for Bacterial Vaginosis. *The Journal of Adolescent Health : Official Publication of the Society for Adolescent Medicine*, 51(4), 400–405.

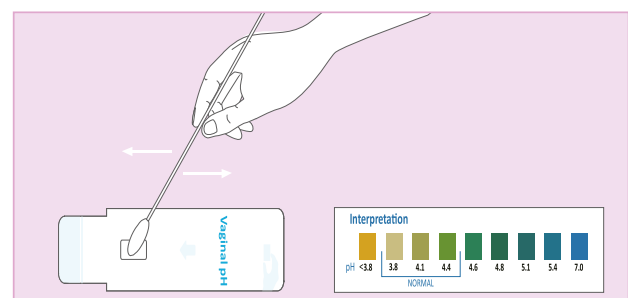
HOW TO USE IT

Insert the head of swab into the vagina and gently press the swab to a point for approximately 10 seconds.

Withdraw the swab from the vagina for testing.

Apply the head of the swab onto the pH area of the Test panel, for at least 5 times.

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.



CONTENT: 5 sealed aluminum pouches with printed colour scale each containing 1 test device; 5 sterile vaginal swabs; 1 Instructions for use leaflet.



VIDEO
TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100013-5	VAGINAL pH TEST	5 TESTS	24 MONTHS