

ANA-CHEK® VAGINAL pH TEST

METHOD – VISUAL CHECK SELF-TEST

PRODUCT CODE – RC06



INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of vaginal pH (vaginal acidity) by observing colour change visually.

SUMMARY AND EXPLANATION OF TEST

The pH of normal human vagina is acidic and is usually maintained at <4.5 (normal range 3.9 - 4.5). This is due to predominance of vaginal flora with lactobacilli spp. which produces lactic acid and reduces the pH substantially. In addition to this, vaginal epithelial cells also help in reduction of vaginal pH by net active proton secretion into its immediate environment. Both of these actions occur in response to serum oestrogen levels. Reduction and maintenance of acidic pH is body's natural defence mechanism to fight against infections and STIs. In presence of any kind of STIs or vaginal infection, the vaginal pH is increased or alkalinized mainly by disturbances in lactobacilli population and this forms the basis of testing vaginal pH.

PRINCIPLE OF TEST

Whenever the vaginal secretion or discharge having elevated pH comes in contact with the Ana-Chek® vaginal pH test pad which is already impregnated with indicator dye, the colour of the test pad changes. The normal colour of the test pad is yellow. An elevated pH changes the colour of the test pad from yellow to green or blue depending upon the severity of infection and alkalinity of pH.

CLINICAL SIGNIFICANCE OF TESTING VAGINAL pH

Measuring vaginal pH as a screening test has several clinical significances:

1. Vaginal pH ≥ 5.0 is positively linked to detection of HPV infection. Persistent HPV infection is known to develop in Cervical Cancer. Nearly 99% of cervical cancer is caused due to acquisition and persistence of HPV infection. Hence, measuring vaginal pH can be used as a screening test for cervical cancer.
2. Vaginal pH ≥ 5.0 is positively linked to detection of multiple types of HPV infection. Elevated vaginal pH is associated with 30% greater risk of infection with multiple HPV types.
3. Vaginal pH ≥ 5.0 is positively linked to LSIL (Low-grade Squamous Intraepithelial Lesions) – the cytological marker for cervical cancer.
4. Vaginal pH > 5.0 is positively linked to other STIs such as presence of *C. trachomatis*.
5. Vaginal pH ≥ 5.0 can be a suitable alternative to serum FSH as an initial screening test for perimenopause.

Overall, vaginal pH estimation is useful for screening of HPV infection, cervical cancer, bacterial vaginosis, vaginitis, trichomoniasis, perimenopausal status, leakage of amniotic fluid, etc.

PRECAUTIONS

1. Do not use the test after the expiry date.
2. Discard the test if the pouch containing test is unsealed or colour of the test pad has been changed from yellow to any other colour.
3. Do not touch the test pad or cotton swab tip with bare hands or any other substance.
4. Use each test strip only once. Do not repeat the test using the same test strip previously used before.
5. Adverse humidity and temperature can greatly affect the results. Hence, make sure to use the test immediately once the strip is removed from the pouch.
6. Do not use the test within 72 hours of application of vaginal preparations such as contraceptive creams or antifungal agents.

7. Do not use the test within 5 days after the last day of menstrual periods.
8. Do not use the test within 48 hours of sexual intercourse or vaginal douching.
9. Care should be taken so as not to take urine, blood or semen sample instead of vaginal discharge as they are known to alter pH.
10. In case of suspicion, repeat the test if necessary.

STORAGE AND STABILITY

Store as packed in sealed pouch at Room Temperature (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 OR SAMPLE COLLECTION PROCEDURE

The Ana-Chek® vaginal pH test can be performed using female vaginal secretion as specimen. To collect the vaginal secretion, follow the steps as explained below:

1. Wear hand gloves, if available, before taking the sample.
2. Open the package and remove the cotton swab. Do not touch the cotton tip of the swab. Make sure that the swab tip does not come in contact with anything else before inserting in vaginal canal that can alter the pH.
3. Separate the labia of vagina with the other hand so the vaginal inner wall is exposed.
4. Carefully insert the cotton swab tip into the vagina and gently push the swab to a point when approximately 2 inches of the swab is into the vagina so that it reaches the cervix area and rotate the swab for 10 seconds. A time of 10 seconds is important to ensure that the head of the swab becomes well moistened with vaginal secretions. Sufficient moisture is very important for the test evaluation.
5. Withdraw the swab from the vagina for the testing. Make sure that the swab does not collect any blood or urine sample as this may cause erroneous results. If the swab is wet because of blood or urine, discard the swab and use a fresh swab.

DIRECTIONS FOR USE

1. Observe universal precautions such as usage of gloves and any other precautionary equipment.
2. Unwrap the pouch and remove the test pad and place it on a clean and dry table.
3. Collect the sample of vaginal secretion as explained earlier in specimen collection procedure.
4. Place the cotton swab tip on the test pad and gently rotate the tip on the test pad. Make sure not to vigorously rub the test pad by scratching it with swab tip.
5. Observe for change in colour on the test pad after 60 seconds and record the observation.
6. Compare the colour of the test pad with the standard colour chart provided with the kit to determine the vaginal pH.

INTERPRETATION OF RESULT

After placing the cotton swab tip on the test pad, observe for colour change in the test pad region. The test kit is designed to measure vaginal pH ranging from 4.0 to 7.0 with an incremental change of 0.5 units. Compare the colour of test pad with the colour on standard colour chart to know the numerical value of the pH corresponding to the colour on test pad.

Normal Result: The vaginal pH levels in the range of 4.0 – 5.0 (4.0, 4.5 and 5.0) is normal. The colour of the test pad is yellow.

Abnormal Result: The vaginal pH levels of 5.5 and above is abnormal. The colour of the test pad is green to blue depending on the severity of alkalization of the vaginal pH. pH of 5.5 is considered as indicator of mild infection and more than 6.0 is considered as indicator of severe infection.

Note: It is possible that the colour on test pad does not match exactly with the colour given on the colour chart. In such cases, take the value of pH corresponding to the colour from colour chart that is closest to the colour on test pad.

LIMITATIONS OF TEST

1. Vaginal pH may be elevated in conditions other than STIs such as:
 - 1.1. Pregnant women.
 - 1.2. Sampling done on any days other than 7-12 days of menstruation cycle.
 - 1.3. Women who had sexual intercourse within last 3 days.
 - 1.4. Women undergoing vaginal medications.
 - 1.5. Women undergoing vaginal douches.
 - 1.6. Women undergoing hormone replacement therapy.
 - 1.7. Women having vaginitis (based on previous history, vaginal examination and culture in suspected cases) for perimenopausal status.
 - 1.8. Women nearing menopausal age.
 - 1.9. Women having or nearing menstrual periods.
2. In case of improper use, rupture of hymen may occur as it occurs when using tampons.
3. This is NOT a test for sexually transmitted infections such as HIV, Chlamydia, Herpes, Gonorrhoea, Syphilis, etc.

NEXT STEP AFTER POSITIVE RESULT

This test is a screening test only. Any medical decision should be warranted with further investigations of cytological, culture or molecular tests to arrive to any conclusion. Visit your gynaecologist or family physician immediately if the vaginal pH is abnormal or elevated.

BIBLIOGRAPHY

1. Megan AC, Ana CR, Julia CG, Rolando H, Allan H, Sholom W, Robert B, Mark S. A large population-based study of age-related associations between vaginal pH and human papillomavirus infection. BMC Infec Dis 2012; 12:33.
2. Amal ZA, Wafaa MA, Tarek AK. Vaginal pH as a marker for the perimenopause: A comparison with FSH. JMIR 2005; 26-3:273-278.
3. James CC, Charles FS, Grenith JZ. Vaginal pH as a marker for bacterial pathogens and menopausal status. Am J Obs Gyn 1997; 176:1270-1277.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry