



The normal vaginal flora offers a natural protection against infection. A variety of the genus Lactobacillus supports the vaginal flora by keeping the vaginal pH value within a slightly acid range between 3.8 an 4.5 which provides an effective protection against pathogenic bacteria and fungi.

Disruption of the natural balance of bacteria inside the vagina may lead to infection which could pose a threat to your health or to your pregnancy. Vaginal microbial imbalances usually cause an increase in pH value to higher than 4.5 which can not only affect quality of life but also pose a serious risk to your health and increase the risk of premature birth.

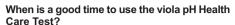
#### Did you know...

...that 20 - 30 % of all patients in a gynaecological department suffer from vaginal infections? They complain about increased discharge, fishy odour as well as itching, burning and vaginal dryness.

...that 15 - 20 % of all women are diagnosed with bacterial vaginosis during pregnancy which constitutes an increased risk of premature birth and premature rupture of fetal membranes?

The viola pH Health Care Test allows the determination of vaginal microbial imbalances at an early stage. It can be used to quickly identify an increase in vaginal pH and prevent vaginal microbial imbalances by periodic self measurement.

Always consult your doctor before making any important medical decision.



We recommend using the viola pH Health Care Test twice a week during pregnancy to make sure the vaginal pH is within the normal range and also between antenatal examinations. However, you may perform measurements more often. This is particularly recommended if you have suffered from vaginal infections during previous pregnancies or if you have already had experience with premature birth.

For women who are not pregnant it is most effective to perform measurements in case there is suspicion of bacterial vaginosis, fungus infections (dysbiosis), if there are symptoms of burning, itching, fishy odour or discharge, after sexual contact with a new partner and after therapies of vaginal infections as well as after surgical interventions on the vagina.

### Before performing the test

Please note that your test result may not be reliable if measurements are performed within 12 hours after sexual intercourse or within 12 hours after having used vaginal medical products (vaginal suppositories, creams, etc.) and within 3 to 4 days after the end of menstrual bleedings. Do not wash or shower the area shortly before taking the measurement and consider that urine may falsify the result. In case the applicator is not used properly the hymen of women who are not yet sexually active may tear.

Determining your vaginal pH level is simple, hygienic and completely painless. Relax and follow accurately the steps on the next page.



# **Performing the Test**

- 1. Wash your hands. Then open the foil and take out the applicator.
- 2. Hold the applicator, using only the round handle area, between your thumb and index finger. Your thumb should always be kept on the reverse side

of the vaginal applicator where there is no pH measurement zone. Avoid the pH measurement zone coming into contact with other liquids.



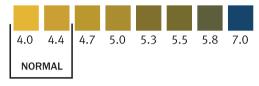
- 3. Sit with your knees spread or with one foot on the toilet seat or another firm surface.
- 4. Now use your free hand to gently spread the vaginal opening, carefully separating the outer labia.
- 5. Insert the vaginal applicator gently into the vagina, in the same way you would use a tampon (approximately 1 3 cm into the vagina but not further than to the round handle area)



- 6. Now press the inserted vaginal applicator against the back wall of the vagina with light pressure for approximately 10 seconds (pushing back towards the rectum), so that the pH measurement zone is well moistened. Sufficient moisture is very important for the test evaluation.
- 7. Now carefully remove the applicator from the vagina and read the result immediately, as long as the measurement zone is wet.

# **Evaluation**

Compare the colour of the pH measurement zone to the colour scale below and note the value of the colour field that is most similar to your measurement. Note that only the scale displayed below must be used for evaluation:



Your vaginal pH value is within the normal range if the colour of the measurement zone is comparable with the colour fields labelled 4.0 and 4.4 on the pH scale.

The colour of the indicator turns brown-green-blue if values above 4.4 are measured. Vaginal pH levels above 4.4 are outside the normal/healthy range.

Test results displaying a measurement zone not uniform in colour signify that the test has probably not been performed properly or the pH measurement zone was not sufficiently moistened with vaginal secretion. If this is the case, you can repeat the measurement with the same vaginal applicator. Discard the applicator (and the packaging material) with your normal household waste after your test result has been evaluated.

If your pH level is not within the normal range on one occasion there is no need for concern. You should repeat the measurement a few hours later or on the next day. If your pH level is still outside the normal range you should discuss the test result with your doctor in order to clarify the cause.

# Notes

The following factors may lead to increased vaginal pH levels:

- Bacterial vaginosis or bacterial mixed infections (possibly through sexually transmitted diseases)
- Premature rupture of the amniotic sac
- False and/or excessive intimate hygiene (frequent vaginal douching, inappropriate hygiene products)
- Estrogen deficiency (estrogen supports the glycogen breakdown to lactic acid)
- Postoperative infected wounds

Consider that numerous factors may temporarily alter the vaginal pH without a disease being present!

You should always consult a doctor in case you experience any of the following symptoms: Bleeding (including spotting), itching or burning in the vagina, fishy or unpleasant odour, burning during urination, symptoms similar to menstruation or suspected release of amniotic fluid.

#### Contents:

2, 3, 5 or 10 foil pouches with 1 applicator and 1 desiccant each, instructions for use



Read instructions carefully before use.
Keep out of reach of children.
Do not use the test after the expiration date.
Store at 4-30 °C (39-86 °F).
Use each applicator only once.
For external use only.
Do not dismantle test applicator.
In-vitro-diagnostic device for self-testing.

