

Usage instructions – please read carefully.

## PACKAGE CONTENTS

One package contains hygienically packaged test applicators for the measurement of vaginal pH (see information on the size of the package on the box), a set of usage instructions and a pH color scale on the foil bag.

## FOR YOUR INFORMATION

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 pathogens and the occurrence of vaginal infections. The most important and most natural protection against vaginal problems is therefore a healthy vaginal flora. There are many factors that regulate the composition and dynamics of the vaginal microbial ecosystem and that maintain the natural protective functions of the vagina. One important factor is lacto bacteria, see diagram 1

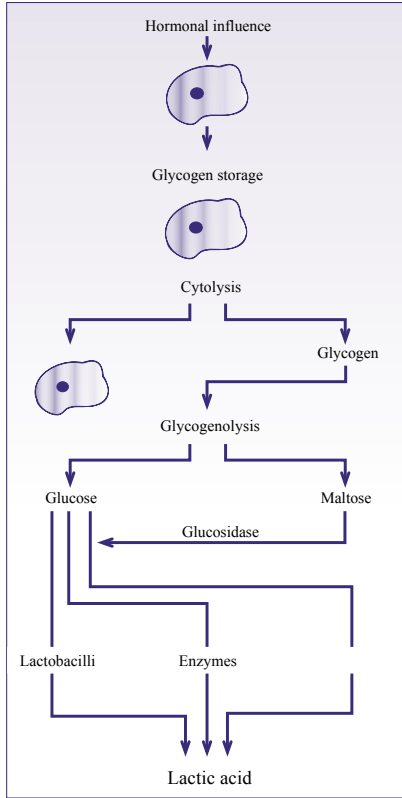


Diagram 1. Diagram showing the degradation of glycogen into lactic acid

Under the influence of lacto bacteria, the glycogen released from the upper vaginal wall 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. The physiological vaginal pH level is therefore dependent on the quantitative presence of the lactic acid.

The pH level in vagina is subject to fluctuations.

Possible causes of an alteration in the vaginal pH level are:

- Bacterial vaginosis (abnormal bacterial colonization of the vagina)
- Bacterial mixed infections
- Sexually transmitted diseases
- Premature rupture of fetal membranes · Estrogen deficiency
- Postoperative infected wounds
- Excessive intimate care
- Treatment with antibiotics

Everyone knows that vinegar and lemon juice are acid and that soap suds are alkaline. The level of "acid" or "alkali" is measured by determining the pH level (pH 1 through 14). Pure water has a pH level of 7.0 and is therefore neutral (neither acid nor alkaline).

A physiological and therefore normal vaginal pH level (pH 3.8 to 4.5) is important for the body's own system of protecting the vagina and the maintenance of a healthy vaginal flora. An increase in the vaginal pH level to values of over 4.5 decreases the quality of life of women who are affected by this

- constitutes a significant risk to health
- increases the risk of premature delivery

## PH-BALANCE® IS THE MODERN CONCEPT OF PROTECTION FOR WOMEN

A disturbance in the micro ecological balance in the vagina (e.g. dysbiosis) is often connected with an increase in the pH level. Vaginal pH levels that are higher than 4.5 can lead to many gynecological complaints and complications.

## Stay healthy through pregnancy with PH - Balance®

Bacterial vaginosis (BV) is diagnosed in approx. 15-20% of all pregnant women.

This increases the risk of

- Premature birth
- Chorioamnionitis (amnionitis)
- A premature rupturing of the fetal membrane
- Fever when giving birth
- Post partum endometritis (an infection of the mucus membrane in the uterus after giving birth)
- A bacterial infection of the fetus

With the help of regular self-testing of the vaginal pH level, pregnant women can decrease the risk of infection.

The measurement of the vaginal pH level is a fixed component of the program for avoiding premature birth according to Prof. E. Saling.

## Intimate care with PH - Balance®

20-30% of all women attending gynecological consultations suffer from vaginal infections with various complaints:

- Itching
- Burning
- Dryness
- Increased discharge
- Fishy odor
- Dysbiosis of the vaginal milieu

A possible cause of complaints of this kind is excessive or incorrect intimate hygiene (douching the vagina too often or using the wrong cleaning products)

With pH - Balance® intimate health problems can be recognized early.

## WHEN IS A GOOD TIME TO USE PH - BALANCE®?

- In cases of bacterial vaginosis (abnormal bacterial colonization of the vagina)
- Suspected dysbiosis
- After treatment against infection (i.e. treatment with antibiotics)
- As part of preventative medical check ups
- During pregnancy
- In the case of a known tendency to give birth prematurely
- After sexual contact with a new partner
- When symptoms appear in the vaginal area (burning, itching, fishy odor, discharge)
- Before and after surgical interventions on the vagina

## LESS EFFORT – GREATER EFFICIENCY

The regular use of pH - Balance® allows determination of the vaginal micro ecological balance or of any disturbance in this balance (e.g. dysbiosis).

We recommend that you perform the measurement twice per week. This will enable you to check whether the pH level of your vagina is acceptable between visits to your gynecologist. There is also no reason why you should not perform the measurement more often. This is particularly recommended if you have already suffered from infections of the vagina during pregnancy or if you have even had a premature birth. Also, if you often suffer from intimate problems, such as itching, burning, fishy odor, or increased discharge.

## TEST PRINCIPLE

pH - Balance® is a reliable, hygienic, pain-free method of determining the vaginal pH level.

As soon as the convex pH measurement zone on the applicator comes into contact with vaginal secretion, a color change occurs that can be assigned to a value on the color scale. This value is the test result.

pH - Balance® is a patent pending medical product. pH-Balance® is a vaginal applicator of approx. 3 inch in length with a pH measurement stripe integrated into it (MERCK pH indicator rods, pH 4.0 - 7.0, non-blood, 1.09542.0001). The vaginal applicator consists of a round handle area and an insertion tube of approx. 2 inch in length. On one side at the tip of the insertion tube is a window, where the indicator area of the pH strip is located (pH measurement zone).

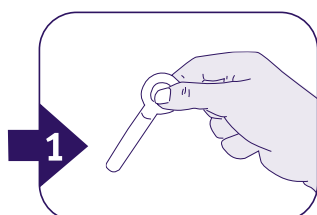
The round handle makes it safe to touch the vaginal applicators. The vaginal applicator is inserted approx. one inch into the vagina and the pH measurement zone is pressed gently against the back wall of the vagina. This moistens the pH measurement zone with vaginal secretion. The vaginal applicator is then removed from the vagina and the pH level is read.

Usage instructions – please read carefully.

## PERFORMING THE TEST

Determining the vaginal pH level is simple and completely pain-free. Relax and follow the steps below exactly.

1. Wash your hands before starting the test.
2. Open the package, remove a test and open the foil. Only touch the applicator in the round handle area.



3. Hold the applicator in the handle area between your thumb and index finger, as shown in diagram 1.

The thumb should always be kept on the side of the vaginal applicators opposite to the pH measurement zone. If you use the vaginal applicator in this way, each test will be performed correctly.

4. Avoid the pH measurement zone coming into contact with other liquids.
5. Sit with your knees spread or with one foot on the toilet seat or other firm surface.
6. Now use your free hand to gently spread the vaginal opening, carefully separating the outer labia.



7. Insert the vaginal applicator gently into the vagina, in the same way that you would use a tampon, see diagram 2.

(approx. 1 inch into the vagina – but not further than the round handle area)  
Inserting the vaginal applicators is **completely pain-free**.

8. Now press the inserted tube against the back wall of the vagina with light pressure for approx. 10 seconds (pushing back towards the rectum), so that the pH measurement zone becomes well moistened. Sufficient moisture is very important for the test evaluation.
9. Now carefully remove the vaginal applicator from the vagina.

## READING AND EVALUATING THE TEST RESULTS

Read the result immediately after removing the vaginal applicators, while the measurement zone is still damp. Compare the color in the pH measurement zone with the color scale on the foil packaging and note the value on the color scale that is most similar to the pH level you have measured. After evaluation, you may dispose of the used applicator with the regular household waste.

| Test     | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|----------|---|---|---|---|---|---|---|---|
| pH level |   |   |   |   |   |   |   |   |

**IMPORTANT:** If the pH measurement does not display a uniform color after the test has been performed, this is a warning that the test has not been performed properly. A possible cause is that the pH measurement zone was not sufficiently moistened with vaginal secretion. If this is the case, you can perform the measurement again with the same vaginal applicator. However, you can also use a new test.



Use the color scale on the foil packaging to evaluate the test result

pH level

4.0

**NORMAL RANGE**

Vaginal pH levels in the range 4.0 to 4.4 are within the normal range.  
The color of the indicator is yellowish

4.4

Vaginal pH levels over 4.4 are outside of the normal/healthy range. The color of the indicator is darker and becomes a brown-green-blue shade.

7.0

## WHAT TO DO, IF THE PH LEVEL IS NOT IN THE NORMAL RANGE

If the pH level is not in the normal range on one occasion, there is no need to worry. If this happens, repeat the measurement a few hours later or on the next day. If the pH level is still not in the normal range at that point, you should discuss the test result with your doctor, so that the cause of the increased pH value can be clarified. Please remember that many factors can temporarily alter the vaginal pH level, without a disease being present (see also “Important notes”)

If the following symptoms arise and the vaginal pH level is repeatedly high, you should always consult your doctor:

- Bleeding, including spotting
- Suspected release of amniotic fluid · Symptoms similar to menstruation · Fever
- Burning during urination
- Itching or burning in the vagina · Increased discharge
- Fishy, unpleasant odor

## IMPORTANT NOTES

- Use each applicator only once
- Use only for intended purpose, not for consumption
- The applicator determines only the pH value and not the presence of any infection.
- An acidic pH value is not 100% protection against infections. If you notice symptoms despite a normal pH value, contact your doctor.
- Do not perform the test after the expiration date (see date on packaging)
- Certain occurrences may alter the vaginal pH value temporarily and lead to false results. You should therefore take into account the following time limits before performing the test / taking a measurement:
  - Measure at least 12 hours after sexual activity
  - Measure at least 12 hours after the use of vaginal medical products (vaginal suppositories, creams, gels, etc.)
  - Measure only 3-4 days after the end of a period if you are using the test when not pregnant
  - measure at least 15 minutes after urination because remaining urine can lead to false test results
- 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 do
- If the test applicator is not used properly, this may lead to a tearing of the hymen in women who are not yet sexually active. This is similar to the use of a tampon

## STORAGE

Store the test in the sealed packaging and keep out of reach of children.

If you have questions about this product, please call customer service in your country. Our employees will be available to assist you.

Find out about locations close to you where you can obtain pH - Balance® at: