SILEX®

PH-S23H Vaginal pH Test Device

For in vitro diagnostic use byself-testing.

INTENDED USE

Vaginal pH Test Device is a fast pH value test of vaginal fluid specimens. It is not automated and it is semi-quantitative for determination of the vaginal pH range. It is designed for self-testing and in-vitro-diagnostic use to see if the vagina is under normal stage. It is as an aid in the diagnosis of Bacterial vaginosis.

The intended population is women of menstruating age. It is intended for use by women who have any of the following symptoms: vaginal itching, vaginal burning or an abnormal color, odor, or excessive amount of vaginal discharge.

INTRODUCTION

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.

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[1]. 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. 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[2].

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

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 those are higher than 4.5 can lead to many gynecological complaints and compilations.

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 partumendometritis (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.

When is a Good Time to Use pH Test Device?

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 Test Device allows determination of the vaginal micro ecological balance or of any disturbance in this balance (e.g. dysbiosis).

This test is a home use kit. We recommend that you perform the measurement twice per week in your home. 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.

PRINCIPLE

Vaginal pH Test Deviceis 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.

Vaginal pH Test Device is a patent pending medical product.

Vaginal pH Test Devices 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.

MATERIALS

Materials Provided

- Test device
- 1 pH color scale on the foil bag
- 1 Desiccant
- Instruction for Use

Materials Required But Not Provided

- Timer

PRECAUTIONS

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).

Do not perform the test if the foil package is damaged.

Read the instruction for use carefully before performing the test.

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 (vaginalsuppositories, 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 doctor.

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.

After finished the test, discard the test device according to the local regulation.

STORAGE AND STABILITY

The kit should be stored at 2-30°Cuntil the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use and preferably be used within 2 h after first opening of the primary container. Protect the kit from humidity. Care should be taken to protect the components of the kit from contamination. Do not use the test if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

PROCEDURE

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



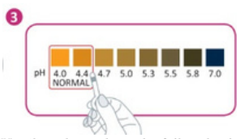
1. Wash your hands before starting the test.
2. Open the package, remove a test and open the foil. Only touch the applicator in the round handle area.
3. Hold the applicator in the handle area between your thumb and index finger, as shown in diagram 1 as below:

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.



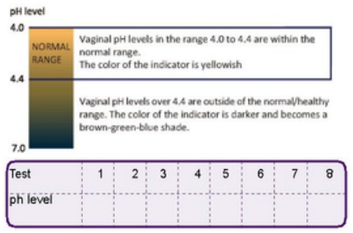
4. Avoid the pH measurement zone coming into contact with other liquids. 5. Sit with your knees spread or with one foot on the toilet seat or other firm surface. 6. Now use your free hand to gently spread the vaginal opening, carefully separating the outer labia.
7. Insert the vaginal applicator gently into the vagina, in the same way that you would use a tampon, see diagram 2as below, (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.

INTERPRETATION OF 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 withthe 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.

Use the color scale on the foil packagingto evaluate the test result.



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.

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

LIMITATIONS OF THE TEST

This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding).

If you are pregnant, consult your healthcare provider before use, as interpreting test results during pregnancy requires professional knowledge.

Do not perform the test if it is less than 1 day before, or 5 days after your period.

Do not perform the test if you have any signs of menstruation or any vaginal bleeding.

Do not perform the test if it is less than 48 hours after sexual intercourse or vaginal douching.

Do not perform the test if you are perimenopausal or menopausal and are not on hormonal therapy.

Other factors may affect vaginal acidity (pH) levels. These include blood, semen, menopause and perimenopause (low estrogen), bacteria and Trichomoniasis.

Do not use test while sweating (e.g. during or immediately after exercise).

Do not use this test until 72 hours after the application of vaginal preparations like contraceptive creams. Antifungal treatments do not interfere with test results.

PERFORMANCE CHARACTERISTICS

Measuring range:

The measuring range of Vaginal pH Test Device includes pH values from 4.0 to 7.0.

Test attributes: sensitivity and specificity

The product VaginalpH Test Device was tested in comparison with a pH meter. The sensitivity was 100% and the specificity 100%.

Fitness for purpose:

A lay study was conducted.Totally, 100 specimens were tested by 100 non-professional individuals to evaluate the performance for ASSURE VaginalpHTest Device. The study was performed on 43 negative specimens (Vaginal pH levels in the range 4.0~4.4) and 57 positive specimens(Vaginal pH levels over 4.5~7.0) have been tested in the assays. Based on the study, the Assure Tech Vaginal pH Test Devicepresented good performance with the overall accuracy of 100%.

Interference Evaluation:

Medicinal products weretested as potential interference factors. None of the products tested at interfered with detectionofpositive or negative control sample:

the concentrations indicated

Substance; Concentration (w/v)				
	K-YJelly, 20%	Replens, 20%	Delfen, 20%	Conceptrol, 20%
	Gyne-Lotrim-3 20%	Vagistat-1,20%	Massengil, 2%	Summer'sEve, 20%
	Vagisil, 20%	Vaginex, 20%	Vagisil Powder, 4%	

LITERATURE REFERENCES

1. Nester EW, Anderson DG, Roberts CE Jr, et al.Microbiology: A Human Perspective. 4th ed. New York, NY: McGraw-Hill; 2004:304-306,639-640.
2. Coyle EA, Prince RA. Urinary tract infections and prostatitis. In: DiPiro JT, Talbert RL, Yee GC, etal.Pharmacotherapy: A Pathophysiologic Approach. 7th ed. New York, NY: McGraw-Hill; 2008:1899-1913.

GLOSSARY OF SYMBOLS

□	Catalog number	□	Temperature limitation
□	Consult instructions for use	□	Batch code
□	In vitro diagnostic medical device	□	Use by
□	Manufacturer	□	Contains sufficient for <n> tests
□	Do not reuse	□	Authorized representative in the European Community
	CE marking according to IVD Medical Device Directive 98/79/EC		

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