

# SAFECARE CE

## BV PH Rapid Test Device

### INTENDED USE

#### PH Rapid Test Device 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 Rapid Test Device

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

It increases the risk of these:

- 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.

### PRINCIPLE

The PH Rapid Test Device is a reliable, hygienic, pain-free method of determining the vaginal pH level. As soon as the pH measurement zone on the device 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.

### WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- Do not touch the reagent areas of the device.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used device should be discarded according to local regulations after testing.

### COMPOSITION

- Individually packed test devices
- Package insert

### STORAGE AND STABILITY

Store as packaged in the pouch either at room temperature or refrigerated (4-30°C). Keep out of direct sunlight. The device is stable through the expiration date printed on the pouch. Do not remove the desiccant. DO NOT FREEZE. Do not use beyond the expiration date.

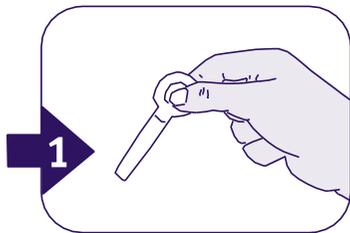
### SPECIMEN

The specimen should be collected by a applicator and tested as soon as possible.

### TEST 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.



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.



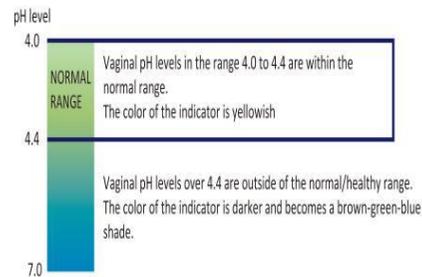
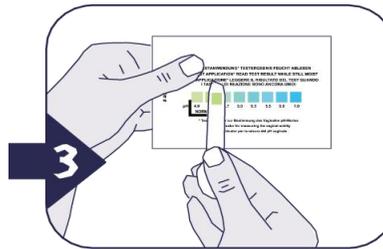
(approx. 1 inch into the vagina – but not further than the round handle area) Inserting the vaginal applicators is completely pain-free.

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.

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 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.

**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.

### INTERPRETATION OF RESULTS



### 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.

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

### PERFORMANCE CHARACTERISTICS

The BV PH Rapid Test Device showed good agreement with a doctor's diagnosis, and the accuracy is over 98%.

### LIMITATIONS OF THE TEST

- Use each applicator only once.
- Use only for intended purpose, not for consumption.
- The swab 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.
- 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
- 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.

### INDEX OF SYMBOLS

	Do not reuse		For in vitro diagnostic use only
	Stored between 4-30°C		Consult instruction for use
	Caution		Lot number
	Use by		Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged
	Authorized Representative in the European Community		

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