



LIMING BIO

# Bacterial vaginosis Rapid Test Device

REF	500080	Specimen: Swab
Language: English	Version: 01	
Effective Date: 2009-05		

## INTENDED USE

The StrongStep® Bacterial vaginosis(BV) Rapid Test Device is intend to measure the vaginal pH for aid in the diagnosis of Bacterial vaginosis.

## INTRODUCTION

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.

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

## PRINCIPLE

The StrongStep® BV Rapid Test 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.

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.

## KIT COMPONENTS

- 20 Individually packed test devices
- 1 Instructions for use

## PRECAUTIONS

- Use each test only once
- Use only for intended purpose, not for consumption
- The test 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 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

## STORAGE AND STABILITY

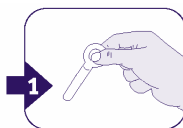
- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.

## TESTING PROCEDURE

1. Wash your hands before starting the test.
2. Open the package, remove a test and open the foil. Only touch the test in the round handle area.
3. Hold the test 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 test opposite to the pH measurement zone. If you use the vaginal test 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 test 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

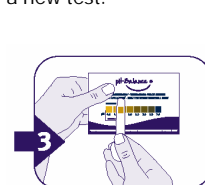
vagina.

## INTERPRETATION OF RESULTS

Read the result immediately after removing the vaginal test, 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 the used test as 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 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.



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	
7.0	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.

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

## GLOSSARY OF SYMBOLS

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



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