

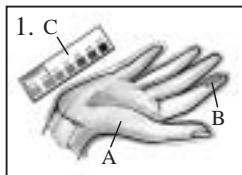
CAREPLAN[®] VpH

Test glove for measuring the vaginal pH, as developed by Prof. Saling and Dr. Heimann.

Please read the entire instruction leaflet carefully.

PACK CONTENTS

This pack contains 20 hygienically packed test gloves coated with a pH indicator, a instruction leaflet and a pH colour scale.



A. Glove

B. pH indicator area on the index finger

C. Colour scale (on the back of the pack)

INDICATIONS

The CarePlan[®] VpH test is designed for measuring the acidity of the vaginal environment (vaginal pH). In most cases, the vaginal pH provides an early indication of any abnormality in the vaginal environment. These abnormalities often encourage the development of infections. Infections of this kind are a frequent cause of premature births (= birth before the week 37 of pregnancy), low-birth-weight babies, and reduced fertility.¹⁻⁹

The micro-organisms in the vagina usually keep each other in balance; Lactobacilli predominate and are responsible for the acidic pH (the normal pH is between 4.0 and 4.4). This natural protection ensures that disease-causing micro-organisms are not so easily able to spread, to ascend into the womb and to trigger labour pain there or to cause premature bursting of the waters and therefore premature birth. The increasing colonisation of the vagina by infectious bacteria often goes unnoticed by the mother-to-be. If an infection of this kind is detected early, prompt medical treatment can be given and the risk of premature birth reduced. This is why it is so important to start measuring the pH of the vagina regularly from as early as possible in the pregnancy.

Please note: Self-examination for pregnant women is a procedure *additional* to the regular prenatal care examination by the physician.

MEASURING THE pH OF THE VAGINA

The CarePlan® VpH test glove is an easy, risk-free, painless way to measure the pH. The glove is hygienically packed and intended for single use. We recommend that the measurement is performed twice a week. This allows you to ascertain for yourself whether the acidity of your vagina is normal in between check-ups with your doctor. There is no reason why you cannot do the test more frequently. This is particularly advisable if you have experienced vaginal infections before, during this or a previous pregnancy.

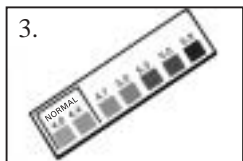
PERFORMING THE TEST



1. Open the pack just before you perform the test and remove a test glove. Put the test glove on your right hand, even if you are left-handed. Avoid touching the test strip. (See figure 1.)

2. In the same way as when you insert a tampon, place your index finger about 2 – 3 cm inside your vagina, turning your finger slightly as you do so. This is most easily done by placing your foot on a bed or chair, for example, and using your other hand to spread apart the lips of your vagina. (Figure 2). Do not insert your index finger by more than 3 cm.
3. Now withdraw your index finger and compare the colour that the test strip has turned with the colour scale and read the result immediately, while the test paper is still moist.
4. Throw the used glove away.

READING AND INTERPRETING THE TEST RESULT



- Read your result immediately after you remove your finger, while the test paper is still moist.
- Compare the colour that the indicator has turned with the colour scale. Make a note of which colour shade most closely matches your own measurement (Fig. 3).

1. If the colour of the test strip is yellowish, the pH is within the normal range (between 4.0 and 4.4).
2. A pH of over 4.4 is outside the normal range. In this case, the colour of the indicator is darker, brown to green, and the vaginal environment is not acidic enough.

Do not be concerned if your pH is not within the normal pH range on one occasion. Just make sure that you perform a second test a few hours later or the next morning. If the pH is still not within the normal range, you should consult your doctor as soon as possible so that the reason for this shift in pH can be investigated. Please keep in mind that stress and certain foods can temporarily change the pH.

You should consult your doctor as soon as possible not only if your pH continues to be outside the normal range but also if you experience any of the following warning signs:

- a foul-smelling or greatly increased discharge (a slight increase is normal during pregnancy);
- Intimate burning or itching;
- Increased urge to urinate (although here, too, some increase is normal during pregnancy) or burning when urinating;
- Bleeding or spotting;
- Fever;
- Persistent diarrhoea;
- Period-like pains (spreading into the groin or back, frequent hardening of the abdominal wall)
- Suspected leakage of amniotic fluid;

IMPORTANT NOTES

- Each glove is for single use only.
- Do not use after the expiry date (see pack).
- You should not perform the test within 12 hours of having sexual intercourse, or after putting any substance into your vagina (such as a spray, cream, gel etc.), before you use this test, and to wait until 3-4 days after your period has ended (if you are not using this test during pregnancy). All these factors may temporarily change the acidity of the vagina and give invalid results. Please note that the use of antibiotics can also influence the vaginal pH. But you are still recommended to continue the measurements.
- Do not wash or shower your private parts immediately before the test.

- After passing urine, make sure that none is left around the entrance to the vagina (wipe thoroughly). Urine can distort the pH.
- Do not douche. This would change the pH. However, douching is not recommended in any case because it has a negative influence on the vaginal environment.
- Please note: With the test gloves, you will only be measuring the pH. This measurement will not tell you whether or not you have an infection. Unfortunately, some micro-organisms, especially fungi, can multiply even in an acidic environment (but fungal infections alone do not usually cause premature births). So, although an acidic vaginal environment (normal pH) does not mean absolutely certain protection, it does provide very good protection from most of the micro-organisms that can induce premature birth.

STORAGE

- Store the hygienically packed test gloves in the closed original box.
- Store in a dry place at temperatures between 2 °C and 30 °C. Do not freeze.
- Keep out of reach of children.

RELIABILITY OF THE TEST

The reliability of the CarePlan® VpH tests has been compared with an Ag/AgCl reference electrode. The results show a very good correlation.

Linear y (electrode) = 0.944 x + 0.036;

correlation coefficient: r = 0.9633

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