

newfoundland

# Vaginal Infection Test



Watch the instruction video



REF 180013-1

## What is the Newfoundland Vaginal Infection Test?

A self-test to determine the pH of vaginal swab specimens to aid in the diagnosis of common vaginal infections including bacterial vaginosis. For more information, please visit our website <https://www.newfoundland.io/tests/vaginal-infection>

## What are vaginal infections?

A healthy vagina has a slightly acidic pH level (between 3.8 to 4.5), which maintains a balance between the good and bad bacteria present in the vagina. If there is a change in this pH it can be an indication that you may be suffering from bacterial vaginosis (BV). Alternatively, symptoms such as vaginal itching/burning or a thick, white discharge could be a sign of a thrush infection.

You can reduce your chances of vaginal infections and alleviate the symptoms by doing the following:

- Use only water and plain soap to wash your genital area
- Wear loose, cotton underwear
- Avoid vaginal deodorants, washes or douches
- Have showers instead of baths

## Who is the Newfoundland Vaginal Infection Test for?

The Newfoundland Vaginal Infection Test should be used to diagnose vaginal infections and help select the right treatment plan. Symptoms include soreness, itching and changes in vaginal discharge.

Risk of vaginal infection can be increased if you are sexually active, use vaginal hygiene products, are taking antibiotics or have a health condition that affects your immune system. Vaginal infections can be very risky for pregnant women and present a danger to both mother and foetus. Test results should therefore be discussed with your GP.

## Precautions

1. Read the instructions carefully before use. Incorrect operation can cause unreliable results.
2. For self-testing *in-vitro* diagnostic use only. Each test is for single use only.
3. Do not use after the expiry date or if the pouch has been damaged. The test should remain in the sealed pouch until use.
4. Store the test kit between 2°C and 30°C. Do not freeze. Humidity and temperature can adversely affect results.
5. Do not eat, drink or smoke in the area where the specimens or kits are handled.
6. Keep out of the reach of children.
7. The test is for external use only. Do not swallow.
8. Handle with care. To dispose of the test kit, the test and box contents should be placed safely in a bin and thrown away with your household waste.
9. Only remove the swab from packaging immediately before use. Use only the swab provided.

## Limitations

1. Do not use this test for 72 hours after the application of contraceptive creams and vaginal medical products.
2. Do not use this test within 48 hours of sexual intercourse.
3. Do not use this test while on your period. Wait 5 days until after your period has finished before performing the test to avoid unreliable results.
4. Some menopausal women may have an elevated vaginal pH, and therefore may produce an abnormal result even if they do not have a vaginal infection.
5. Do not shower or wash the genital area immediately before taking the test.
6. Please be aware that contamination from urine may cause unreliable results.
7. This test is not suitable for children under the age of 16.
8. Please take caution not to insert the swab beyond the recommended 2 inches as this may risk rupturing the hymen.
9. This is not a test for sexually transmitted diseases, such as HIV, chlamydia, herpes, gonorrhoea or syphilis.

## Contents



Test and colour scale



Vaginal swab

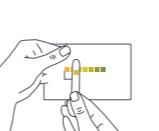


Instructions for use

## Instructions

To watch the instructions in video format, please scan the above QR code or follow <https://www.newfoundland.io/tests/vaginal-infection> to how-to video.

1. Wash your hands with warm water and soap, carefully drying your hands afterwards.
2. Open the package and remove the swab from the pouch. Do not touch the head of the swab.
3. Separate the labia so the vagina is exposed. Gently insert the head of the swab about 2 inches into the vagina and rotate for approximately 10 seconds. This is important to ensure that the head of the swab absorbs sufficient vaginal secretions.
4. Withdraw the swab from the vagina and press the head of the swab onto the pH area of the test panel at least 5 times, making sure sufficient sample is applied.
5. Read the result immediately while the pH area is still wet by comparing the colour in the pH test panel against the colour scale on the foil pouch to find the closest colour match. After reading the result, dispose of the used panel and swab.



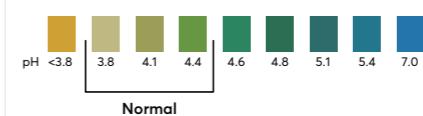
## Results

### Normal range

Vaginal pH levels in the range of 3.8-4.4 are within the normal range. The colour of the indicator is yellow-green.

### Abnormal range:

When the pH level is over 4.4, the colour of the indicator is green-blue, suggesting bacterial vaginosis or trichomoniasis vaginalis.



## FAQs

### How does the test work?

The Newfoundland Vaginal Infection Test is a rapid dry chemical method for the semiquantitative detection of pH in female vaginal swab specimens. A pH paper is used to determine pH levels in vaginal secretion. As soon as the swab containing the specimen comes in contact with the pH paper, a colour change occurs. The result is considered to be equivalent to the numerical value of the colour on the colour scale closest in appearance to the colour obtained with the test.

### How accurate is the test?

The Newfoundland Vaginal Infection Test is 98.6% accurate. Although this test is reliable, it is still possible false positive and false negative results may be produced.

### Can I take the test at any time?

No, there are some restrictions on when to use this test. Please refer to the Limitations section for more information.

### What should I do if the result is abnormal?

An abnormal vaginal pH does not necessarily mean that you have a vaginal infection (see Limitations for further details). However, if you return a result with a vaginal pH in the abnormal range, you should contact your GP to discuss further.

### What should I do if the result is normal?

If your vaginal pH is in the normal range, this indicates that you do not have a bacterial vaginal infection. If symptoms persist, please contact your GP.

### What are the common symptoms of vaginal infections?

Some vaginal infections often have no symptoms. However, any of the following could indicate a vaginal infection:

- A change to the colour, odour or consistency of your vaginal discharge
- Soreness or a dry, itchy vagina
- Pain during urination and/or sex

### What is the difference between thrush and bacterial vaginosis?

Thrush is a fungal infection caused by an overgrowth of yeast which often leads to symptoms such as vaginal itching, soreness or a cottage cheese-like white vaginal discharge.

Bacterial vaginosis is caused by an overgrowth of bacteria naturally found in your vagina. Symptoms usually include a fishy odour and a greyish-white, watery discharge.

## Medical devices inside the kit

STERILE R

Swab

CE See the label of the swab included in the kit

 Sufficient for <n> test

 Temperature Limit

 Do not reuse

 For in vitro diagnostic use

 Lot Number

 Do not use if package is damaged

 Use by

 Catalogue number

 Sterilised using irradiation

 Authorised Representative in the European Community

 CE Marking

 Read the instructions before use

 Legal manufacturer

 PRIMA Lab SA  
Via Antonio Monti 7  
CH-6828 Balerna, Switzerland

 Qarad EC-REP BV  
Pas 257, 2440 Geel, Belgium

CE 0483

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