



# VagiSense®

## VAGINAL INFECTION SCREENING TEST

Carefully read the entire insert before using this product.

**VagiSense®** is an easy-to-use screening test for women, who sense their vaginal discharge is abnormal, to obtain an initial indication regarding the potential causes of their abnormal vaginal discharge.

A vaginal discharge is **abnormal** if it is **excessive**, has an **unusual colour**, or has an **abnormal odour**, compared to usual discharge. The test can be performed also in cases of **itching** or **burning** with a normal discharge.

### Summary and Explanation of the Test

Vaginal infections are quite common and often a recurring problem among women of all age groups.

An indication of abnormal acidity of the vaginal discharge can help evaluate whether your vaginal symptoms are likely caused by an infection that may require follow-up with your healthcare professional.

Some vaginal infections known to be associated with abnormal vaginal acidity have no non-prescription treatments, and must be treated by a healthcare professional. Some cases of abnormal discharge with abnormal acidity may be caused by a combination of infections.

**VagiSense®** tests your vaginal discharge and indicates whether your vaginal acidity is normal or abnormal. If your test results are positive (abnormal vaginal acidity), discuss your symptoms and results with your healthcare professional and **do not treat yourself**. For accurate infection diagnosis, your healthcare professional may use various assessment methods to determine your specific condition.

Some menopausal women may have an elevated vaginal pH, and therefore may receive a positive result with **VagiSense®** even though they are not suffering from a bacterial or parasitic infection.

Vaginal infections may be very risky for pregnant women and dangerous for the mother and her fetus, thus symptoms and results should always be discussed with your healthcare professional.

### Principle of Operation

**VagiSense®** changes colour when the acidity of the vaginal discharge is abnormal (pH level is elevated or the discharge is "watery"). "Watery" discharge and elevated vaginal pH levels are known to accompany bacterial and parasitic infections.

When the **VagiSense®** yellow tip comes in contact with vaginal discharge with abnormal acidity, it changes colour to blue or green. The colour change creates a stain which is darker and easily observed over the yellow background.

### Indications for Use

**VagiSense®** is a non-prescription home screening test, to be used by women of menstruating age, to test vaginal pH (acidity). It is intended to be used by women who have any of the following symptoms: vaginal itching or burning, abnormal vaginal discharge colour or odour, or excessive discharge.

**VagiSense®** determines whether your symptoms are more likely caused by a bacterial or parasitic infection that may require follow-up with your healthcare professional. Results are observed through a blue or green stain on the yellow tip. **If you are pregnant**, consult your healthcare professional before using **VagiSense®** and never try to treat yourself before discussing your symptoms and the results of this test with your healthcare professional.

### Package Contents

2 individually foil-wrapped **VagiSense®** tests and 1 package insert. **Keep the 2 individually foil-wrapped VagiSense® tests sealed and use immediately after opening.**

### Conditions & Limitations for Use

- 1) To ensure valid results, do not use **VagiSense®** in any of the following conditions: (a) It is less than one day before or the day after your period; (b) There are signs of menstruation or any vaginal bleeding; (c) It is less than 12 hours after sexual intercourse or vaginal douching.
- 2) Do not insert the swab deeper than the handling point.
- 3) Do not use **VagiSense®** to test for sexually transmitted diseases such as HIV, chlamydia, herpes, gonorrhea or syphilis.
- 4) Do not use **VagiSense®** until 72 hours after the application of vaginal preparations like contraceptive creams or lubricants.

### Directions for Use

- 1 Wash and dry your hands.
- 2 Unwrap the individual **VagiSense®** test (swab). If the swab is damaged or the swab tip is stained, dispose of the test and use a new one.
- 3 Make sure that the swab tip does not come into contact with anything before insertion into the vaginal entrance.



- 4 Hold the **VagiSense®** test with your fingers on the handle of the swab.



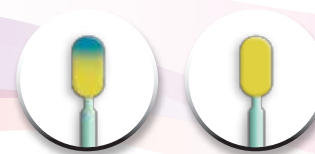
- 5 Separate the vaginal outer layer skin so the vagina is exposed.



- 6 Insert the yellow tip of the **VagiSense®** test until your fingers reach the outer skin of the vagina (approximately 5 cm into the mid vagina) and rotate the swab several times. Do not touch the vaginal entrance.

- 7 Withdraw the **VagiSense®** test from your vagina. Carefully avoid the tip coming into contact with anything, and check that it has collected a visible amount of secretion.
- 8 Wait 10 seconds. Check the tip of the **VagiSense®** test for colour changes from yellow to blue or green. Note: if any blood stain appears on the **VagiSense®** test, disregard the results.
- 9 Dispose the **VagiSense®** test after usage as you would with any other feminine hygiene product.

### Interpretation of Results



#### Positive Result:

After 10 seconds, if any part of the **VagiSense®** tip is stained blue or green, your vaginal acidity is abnormal, and the risk of having a bacterial or parasitic infection is high; you should consult your healthcare professional.

#### Negative Result:

If the **VagiSense®** tip is not stained after 10 seconds, the risk of having a bacterial or parasitic infection is low; you may have a yeast infection and you may consider using non-prescription treatments.

### Repeating the Test

If you are not certain that the **VagiSense®** yellow tip came into contact with vaginal discharge, perform a second test immediately after the first, using a new **VagiSense®** test. If the **VagiSense®** yellow tip is stained blue or green on either test, your vaginal acidity is abnormal, and the risk of having a bacterial or parasitic infection is high; you should consult your healthcare professional.

### Reporting Results to Your Healthcare Professional

Positive results should be reported to your healthcare professional as soon as possible.

### Storage and Stability

Store in a dry place at room temperature. Keep the **VagiSense®** test sealed until use to avoid contamination. Check the expiration date on the individual test package before using this product. Keep out of reach of children.

Manufactured by:  
Common Sense Ltd.  
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Distributed by:  
Paladin Labs Inc.  
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[www.vagisense.ca](http://www.vagisense.ca)

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