

VS-SENSE™ Test

Rapid Acidity Test for Evaluation of Vaginitis

INTENDED USE:

The VS-SENSE™ TEST is a qualitative, visually-read swab for clinicians who wish to evaluate women with vaginal symptoms. The device is a vaginal pH indicator swab intended to be used in conjunction with other clinical examinations, such as the Amsel criteria or the Nugent Gram stain, to aid in determining conditions characterized by elevated vaginal pH, such as bacterial vaginosis.

SUMMARY AND EXPLANATION OF THE TEST:

Vaginal infections are a widespread problem among women of all age groups. The common causes of vaginitis are: bacteria, fungus, and parasites. Some infection such as bacterial and parasitic infections may cause complications (1, 2, 3), especially in the course of pregnancy.

The clinical evaluation of a vaginal discharge for bacterial vaginosis should include the examination of four Amsel criteria: thin homogeneous discharge (watery discharge); elevated pH; amine test (the whiff test); and the presence of clue cells under a microscope.

Normal vaginal pH may range from 3.8 to 4.5. A vaginal infection originating from a bacterial source is associated with an elevation of the pH level of the vaginal discharge and a watery, thin, and homogeneous secretion. Seventy to eighty percent of patients suffering from bacterial vaginosis and 90% of patients suffering from parasitic infection have an elevated vaginal pH. (See references 2, 4, 5, 6, 7 and 8).

The VS-SENSE™ TEST indicates abnormal vaginal discharge acidity by identifying changes in the pH level. The test cutoff is set at pH 4.7 (+0.3/-0.2 pH units); there may be variations due to sensitivity to buffer capacity). When the vaginal secretion has a pH above this cutoff, the test tip will be stained (or partially stained) green or blue. The test, when combined with clinical examination, assists the physician in diagnosing conditions which are associated with elevated pH levels.

PRINCIPLES OF THE TEST:

The VS-SENSE™ TEST is comprised of a vaginal swab, coated with an innovative proprietary polymer, which contains the colorimetric pH indicator, Nitrazine Yellow. When the polymer, which is yellow before use, come into contact with fluids with elevated pH level, the user observes a blue or green stain on the yellow background.

Clinical study design and results:

The performance of the VS-SENSE™ TEST has been clinically tested to serve as a substitute to traditional pH paper testing. In our clinical study a total of 254 women were enrolled and completed the study.

The inclusion (selection) criteria were (1) Symptomatic women, ages 18 and above who are still having regular menstruation. (2) Subjects willing and able to sign the informed consent form. (3) Subjects with acute vulvovaginal symptoms.

The exclusion criteria were (1) Subjects are unable or unwilling

to cooperate with study procedures. (2) Subjects are currently participating in another clinical study that may directly or indirectly affect the results of this study. (3) Menopausal women. (4) Women with blood present in their vaginal secretion. (5) Subjects that have had sexual relations or applied vaginal douche within the previous 12 hours. (6) Subjects that applied vaginal medications within the last 3 days. (7) Subjects with symptoms and signs of pelvic inflammatory disease.

The difference between the sensitivities and specificities of VS-SENSE™ TEST and pH tests was estimated and a 95% confidence interval for the differences was calculated.

VS- SENSE™ TEST Vs. Clinical Diagnosis n=254

VS-SENSE	Clinical Diagnosis: BV / Trichomonas /other identified pathological situations, capable of elevating pH			Total
	Positive	Negative	Total	
Positive	101	9	110	
Negative	16	128	144	
Total	117	137	254	

VS-SENSE™ TEST sensitivity is 86.32% with a 95% exact binomial CI:[78.74%,91.98%] and the specificity is 93.43% with its respective 95% exact binomial CI:[87.90%, 96.95%].

Nitrazine pH Paper Vs. Clinical Diagnosis n=252

Nitrazine pH paper	Clinical Diagnosis: BV /Trichomonas /other identified pathological situations, capable of elevating pH			Total
	Positive	Negative	Total	
Positive	91	24	115	
Negative	9	128	137	
Total	100	152	252	

According to the results presented in the table above, it can be seen that the pH test sensitivity is 91.0% with a 95% exact binomial CI: [83.60%, 95.80%] and its specificity is 84.2% with its respective 95% exact binomial CI:[77.42%, 89.61%].

REPRODUCIBILITY:

The pH cutoff and reproducibility of the test was evaluated by multiple operators at multiple sites for three product lots. A total of 150 samples were tested at pH levels ranging from 3.5 to 5.0 Samples at pH 4.7 or greater (in 100 mM phosphate citrate buffer) were always read as positive. In the same buffer, samples 4.5 and below were always read as negative. A variation of +0.3/-0.2 was observed depending on buffer capacity.

REAGENTS AND MATERIALS SUPPLIED:

- 2/25 individually foil-wrapped VS-SENSE™ TEST units.
- 1 package insert.

WARNINGS AND PRECAUTIONS:

- Collect vaginal discharge from the anterior fornix or lateral vaginal wall of the mid vagina. Do not insert the VS-SENSE™ TEST further than 5 cm (2") in the vagina, to avoid contact with the cervix mucus, where pH levels are known to be higher than normal vaginal pH.

- Do not use lubricants which alter vaginal acidity (such as Astroglide, Ultragel, Durex play feel, LOVE GEL, K-Y Jelly).
- To ensure valid results, do not perform the VS-SENSE™ TEST in any of the following conditions: (a) less than one day before or the day after the patient's menstrual period; (b) there are signs of menstruation or any vaginal bleeding; (c) less than 12 hours after sexual intercourse or use of vaginal products such as douching solutions or medications which alter vaginal acidity (such as MipHil, Miconazole Nitrate cream, Agisten-V, Septalon, Miconazole Nitrate vaginal cream, Vagigard, Monistat), or products listed above in number 2.
- If the patient is pregnant, the stain may indicate an amniotic fluid leakage.

STORAGE AND STABILITY:

Store in a dry place and at room temperature. Please note the expiration date on the individual test package.

INSTRUCTIONS FOR USE/TEST PROCEDURE:

1. Take one VS-SENSE™ TEST swab unit out of the bulk package.
2. Keep the individual test package sealed until use.
3. If you are not using a speculum, separate the labia so the vagina is exposed.
4. Insert the yellow tip of the VS-SENSE™ TEST swab approximately 5cm (2") into the mid vagina and rotate the swab several times to contact the vaginal walls.
5. Withdraw the VS-SENSE™ TEST swab without touching the vulva surface and check that it has collected a visible amount of discharged secretion.
6. Wait 10 seconds and check the tip of the VS-SENSE™ TEST swab for color changes from yellow to blue or green .
7. Dispose the VS-SENSE™ TEST swab after usage as you would any other vaginal swab.

INTERPRETATION OF RESULTS:

Positive VS-SENSE™ TEST Result:



If the tip is stained or partially stained blue or green, vaginal acidity is disordered and diseases associated with high pH are quite probable. Additional testing for Bacterial Vaginosis and Trichomoniasis should be considered.

Important: If the patient is pregnant and the tip is stained blue or green, the color may indicate an amniotic fluid leak.

Negative VS-SENSE™ TEST Result:



If after 10 seconds the tip is not stained, i.e. completely yellow, the vaginal acidity is normal and the risk of having a disease associated with elevated pH level is unlikely.

QUALITY CONTROL:

- 1) Before using a VS-SENSE™ TEST unit, check visually that there are no blue or green stains on the yellow tip.
- 2) If you have used a VS-SENSE™ TEST unit, and obtained negative results which you want to confirm, wet the tip of the swab with plain tap water, and observe the color change to blue or green. In addition users should follow their laboratory guidelines for quality control.

LIMITATIONS OF THE PROCEDURE:

- 1) Test results may be affected by improper handling: contact with cervical mucus, no secretion collected, and contact with water.
- 2) Positive VS-SENSE™ TEST results may also be caused by other less common infections or by transient causes of elevated pH levels, such as post semen ejaculation.

Manufacturer:

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Questions?

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