



VS-SENSE™ Rapid Acidity Test for Evaluation of Vaginitis

What is VS-SENSE™?

The VS-SENSE™ is a qualitative, visually-read swab for clinicians who wish to evaluate women with vaginal symptoms. The test indicates by color change whether a vaginal secretion has disordered acidity parameters. Results are based on combined indication of pH level and buffer capacity (watery secretion) which characterizes Bacterial Vaginosis and Trichomoniasis.

Some Facts

- › Vaginitis is a very common disease affecting millions of women each year.
- › Vaginitis accounts for over 50 percent of all gynecologic office visits.
- › The key to proper Vaginitis treatment is accurate diagnosis.
- › There is a need for a tool that enables a clinician to diagnose the causes of the patient's Vaginitis and prescribe the correct treatment.

VS-SENSE™ Key Benefits

- › Assists the gynecologist in diagnosis of BV / TV
- › Helps diagnose combined infections - When BV and/or TV and Candida are mixed
- › Rapid (10 seconds) office test
- › Clear to read and interpret
- › Reduces the need to send a discharge specimen for a lab test
- › Enables appropriate treatment on the patient's first visit

How does VS-SENSE™ work?

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, comes into contact with fluids with an elevated pH level, the user observes a Blue or Green stain on the Yellow indicator.

User Friendly
Cost Saving
Quick Results



Performance

Sensitivity	86.32%
Specificity	93.43%
PPV	91.8%
NPV	88.9%

Unlike other standard commercial pH tests like Nitrazine paper, the VS-SENSE™ indicator combines two Amsel criteria in a dynamic range, high pH levels (abnormal acidity) and watery discharge (low buffer capacity).

The VS-SENSE™ threshold is set as follows:

1. $\text{pH} \leq 4.2$ the swab tip stays Yellow.
2. $\text{pH} \geq 5.2$ the swab tip stains Blue or Green.
3. $5.2 > \text{pH} > 4.2$ the swab tip stains Blue-Green only if the buffer capacity is low.

Combining both characteristics (pH and Buffer Capacity) increases the sensitivity of the test.

Please refer to the in-pack leaflet for full instructions on how to use and interpret results.

The VS-SENSE™ OTC

The VS-SENSE™-OTC is intended for use by women experiencing abnormal vaginal discharge (e.g. excessive, with an unusual color or unpleasant odor), or other symptoms such as itching, irritation or a burning sensation. The use of VS-SENSE™ OTC may help to determine if the symptoms are caused by infection that may require follow-up by healthcare provider.

The VS-SENSE™ OTC is comprised of a vaginal swab with a specific handle for self-testing, coated with an innovative proprietary polymer, the same as in the VS-SENSE™ PRO.



VS-SENSE™ OTC
for self-testing

VS-SENSE™ for
clinician's use

How do women treat abnormal vaginal discharge?

- › Use leftover treatments without proper diagnosis
- › Purchase OTC treatments (where available)
- › Treat themselves incorrectly
- › Perform damaging vaginal douching

Results of incorrect treatments are Prolonged pain and uncomfortable feeling, side effects, unnecessary financial costs, repeat visits to the clinic, elevated vulnerability to STD infections.

Self-diagnosis with VS-SENSE™-OTC can prevent all those!

The availability of over-the-counter (OTC) antifungal medication for immediate treatment, increases the necessity for a device like VS-SENSE™ OTC to help women self-test to exclude infections which may require follow-up by healthcare provider. VS-SENSE™ OTC offers women a chance to be aware of their condition and follow up on the success of their treatment.

F-3-VS1-BR1U Rev.280818