



NEW

CPT 83986

VS-SENSE™ Test

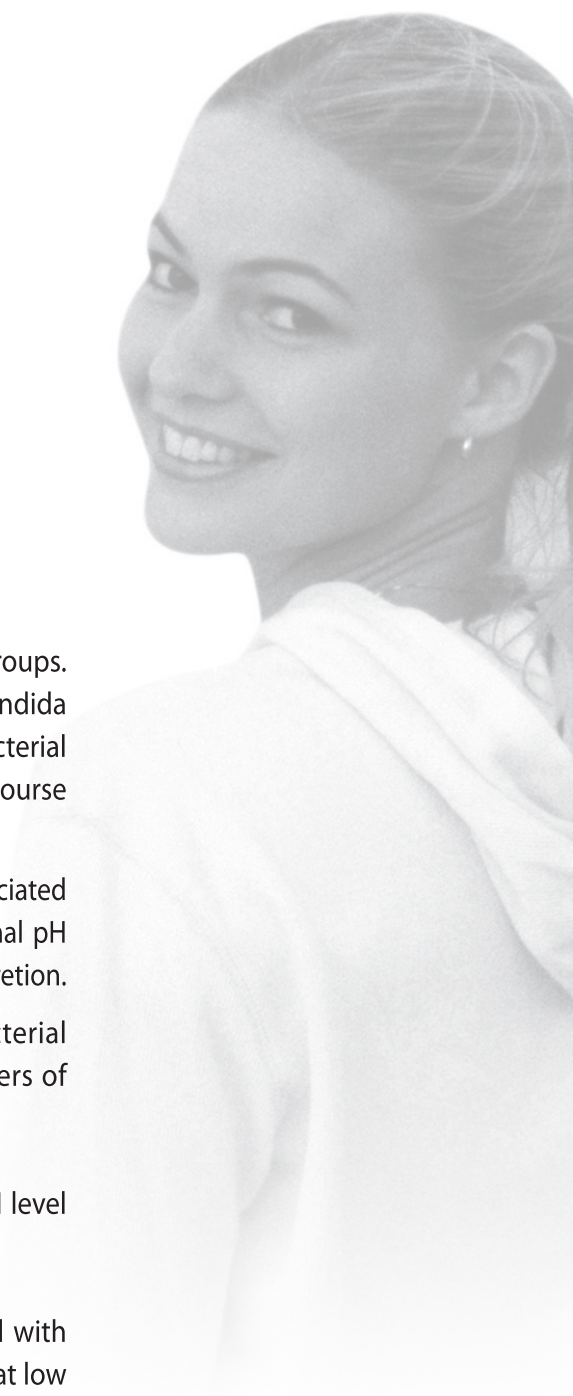
Rapid Acidity Test for Evaluation of Vaginitis

Vaginal infections are a widespread problem among women of all age groups. The three most common vaginal infections are bacterial vaginosis (BV), candida vaginitis (yeast infection) and trichomonas vaginitis. Some infection such as bacterial vaginosis and parasitic infections may cause complications, especially in the course of pregnancy (1, 2, 3).

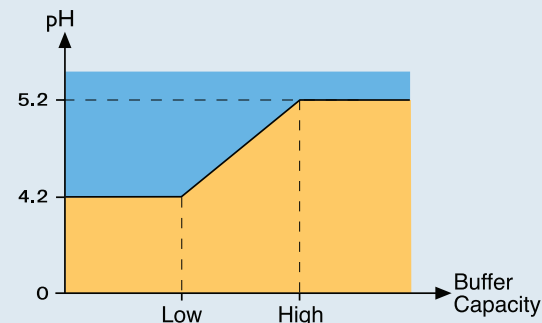
A vaginal infection originating from **Bacterial Vaginosis or Trichomonas** is associated with an elevation of the pH level of the vaginal discharge (exceeding the normal pH level ranged from 3.8 to 4.7) as well as a watery, thin, and homogeneous secretion.

The innovative **VS-SENSE™** diagnostic swab facilitates diagnosis of Bacterial Vaginosis and Trichomonas by identifying changes in the acidity parameters of vaginal secretion:

- **pH Detection:** A positive **VS-SENSE™** test indicates an elevated vaginal pH level ($>4.7+0.3/-0.2$), known to accompany Bacterial Vaginosis and Trichomonas.
- **Buffer Capacity:** The lower buffer capacity (a watery secretion) associated with Bacterial Vaginosis induces color changes of the **VS-SENSE™** polymer, even at low pH values.



Threshold Graph



Clinical study results

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

		Clinical Diagnosis: BV /Trichomonas /other identified pathological situations, capable of elevating pH		
VS-SENSE™		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%].

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, contacts fluids with the combination of pH level, and buffer capacity, which cross a specific threshold, the user observes a blue or green stain on the yellow background.

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 (Bacterial Vaginosis and Trichomonas) are quite probable.

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 vaginal pH level is unlikely.

The VS-SENSE offers immediate results without the need to:

- Use a color scale
- Send a sample to a lab
- Operate time consuming pH paper strips
- Operate time consuming testing devices



REFERENCES:

- 1) Brown D Jr. Clinical variability of bacterial vaginosis and trichomoniasis. J Reprod Med. 2004 Oct;49(10):781-6.
- 2) Leitich H, Bodner-Adler B, Brunbauer M, Kaider A, Egarter C, Husslein P. Bacterial vaginosis as a risk factor for preterm delivery: a meta-analysis. Am J Obstet Gynecol. 2003 Jul;189(1):139-47.
- 3) Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Bacterial vaginosis in sexually experienced and non-sexually experienced young women entering the military. Obstet Gynecol. 2003 Nov;102 (5 Pt 1): 927-33.