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 inclusion (selection) criteria were (1) Symptomatic women, (2) Susceptible to the vaginal discharge of vaginal infections from parasitic infection have an elevated vaginal pH. (See Clinical Diagnosis). (3) Postmenopausal women. (4) Women with abnormal vaginal discharge originating from a bacterial source. (5) Subjects with symptoms of vaginal discharge and a watery, thin, and transparent vaginal acidity by identifying changes in the pH level. The test cutoff is 4.7.

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 transparent vaginal acidity. 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 elevated pH level. The user observes a blue or green stain on the vaginal wall of the mid vagina. Do not insert 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 douche solutions or medications which alter vaginal acidity (such as Misipril, Miconezole Nitrate cream, Agisten-V, Septalon, Miconezole 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 packaging. Do not use lubricants which alter vaginal acidity (such as MipHil, Miconazole Nitrate cream, Agisten-V, Septalon, Miconezole Nitrate vaginal cream, Vagigard, Monistat), or any other vaginal swab.

2. Keep the individual test package sealed until use.

3. If you are not using a speculum, separate the labios so the vagina is exposed.

4. Insert the yellow tip of the VS-SENSE™ TEST swab approximately 3cm (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 discharge.

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 leakage.

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 tap water, and observe the color change to blue or green. In addition users should follow their laboratory guidelines for quality control.