

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k091287

B. Purpose for Submission:

New device

C. Measurand:

pH (vaginal)

D. Type of Test:

Qualitative, colorimetric test for acidity read visually.

E. Applicant:

Common Sense Ltd.

F. Proprietary and Established Names:

VS-Sense™

G. Regulatory Information:

1. Regulation section:

21CFR862.1550, Urinary pH (non-quantitative) test system

2. Classification:

Class I, subject to limitation from exemption 862.9(6)

3. Product code:

CEN

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for 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 Nugent Gram stain, to aid in determining conditions characterized by elevated vaginal pH, such as bacterial vaginosis.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

None

I. Device Description:

Vaginal swab containing the colorimetric indicator, nitrazine yellow

J. Substantial Equivalence Information:

1. Predicate device name(s):

Phem Check TM

2. Predicate K number(s):

k960648

3. Comparison with predicate:

Both devices are vaginal pH indicators with similar indications. The VS Sense device shows a blue or green stain on a swab to indicate pH of 4.7 or above. The predicate device uses pH indicator paper mounted on a flat probe.

K. Standard/Guidance Document Referenced (if applicable):

No recognized standards were referenced.

L. Test Principle:

The test includes a colorimetric pH indicator incorporated into a vaginal swab. The swab turns blue or green when the vaginal discharge pH level is ≥ 4.7 .

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The test swabs were tested with samples of 100mM citrate phosphate buffer, pH ranging from 3.0 to 7.0, and the color was recorded. Reproducibility was evaluated for three product lots, by three operators, over two days, using masked samples. The total number of samples tested per pH level was 54. The pH of the samples included 3.0, 4.0, 4.3, 4.5, 4.7, 5.0, 5.2, 5.5, 6.0, and 7.0. All samples at pH of 4.5 and below were negative (yellow); Samples at 4.7 and above were positive (colors ranging from light green near 4.7, to purple near pH=7.0).

Similar cutoff results were obtained when tests were shipped for transport/stability testing.

In addition, as supplemental support for repeatability, ten physicians each collected duplicate patient samples from patients they were examining. The same results were obtained for each repeat measurement.

b. *Linearity/assay reportable range:*

Not applicable. See precision and clinical study section for ranges tested.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The VS-Sense is traceable to standardized buffers by electrometric measurements (ANSI Standard ASTM D 1293-99).

Stability testing supported expiration date.

d. *Detection limit:*

See precision/reproducibility section above.

e. *Analytical specificity:*

Interference was tested using control solutions at pH 4.0, 5.0, and 5.5 (both 20 mM and 100 mM Phosphate-Citrate buffer). A variety of over-the counter

vaginal products were tested, including lubricants, antifungal treatments, antiseptic creams, and spermicides. Two hundred milligrams of each product tested was added to 7 uL of the buffered solutions. The VS Sense was exposed to each mixture and the result was recorded. No interference was observed for GLOVAN, micronazole nitrate, Liquibeads, Vagigard, Vagistat - 1, Monistat or Gyno Pevaryl. All tested products that showed some interference are listed in the package insert.

f. Assay cut-off:

See precision/reproducibility, section above.

2. Comparison studies:

a. Method comparison with predicate device:

See “Clinical Studies” section, below.

b. Matrix comparison:

Not applicable. The test uses only vaginal swabs.

3. Clinical studies:

a. Clinical Sensitivity:

A total of 254 women participated in a study to evaluate performance of the VS Sense. The study was conducted at three US sites. Subjects included were pre-menopausal symptomatic women aged 18 or above, with acute vulvovaginal symptoms, who were willing and able to sign the consent form. Women were excluded from the study if any of the following applied: menopausal, blood in vaginal secretions, had sexual relations or applied vaginal douche within previous 12 hours, applied vaginal medication within the last 3 days, or had symptoms and signs of pelvic inflammatory disease.

At the clinic, a nurse obtained a vaginal secretion specimen with the VS-Sense swab, and results were immediately recorded and were, unavailable to the clinician performing the subsequent exam and diagnosis. Following this, a clinician performed a speculum vaginal exam. Samples were obtained for microscopy, gram stain, and yeast and trichomonas culture (using Diamond’s medium or InPouch TV), KOH whiff (amine) test, and nitrazine paper test. Positive BV was defined by Gram stain Nugent score > 7 and positivity for 3 Amsel criteria. Nurse’s results with the VS-Sense were compared to the physician’s clinical diagnosis. Positive clinical diagnosis was defined as positive in one of the following tests: Trichomonas culture in Diamond’s medium or InPouch TMTV, BV as determined by Gram stain, or BV as

determined by 3 positive Amsel criteria (one of which had to include at least 20% Clue cells). Atrophic vaginitis and desquamative inflammatory vaginitis were diagnosed by standard clinical examination and by microscopic observation, respectively.

Results of this study in terms of VS Sense versus clinical diagnosis are shown in the table below:

VS Sense	Clinical Diagnosis	
	Positive	Negative
Positive	101	9
Negative	16	128

Sensitivity of 86%, with 95% CI: [78%, 91%]

Specificity of 94%, with 95% CI: [88%, 97%]

Overall agreement: 90%

Results in terms of the comparator/Nitrazine paper were also evaluated versus clinical diagnosis. Results are shown in the table below:

Nitrazine paper	Clinical Diagnosis	
	Positive	Negative
Positive	91	24
Negative	9	128

Sensitivity of 91%, with 95% CI: [84%, 96%]

Specificity of 84%, with 95% CI: [77%, 90%]

Overall agreement: 87%

b. *Clinical specificity:*

See clinical sensitivity, above.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

A pH level in the range of 3.8 to 4.2 is considered normal.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.