NUVETEST™

Rapid Acidity Test for Evaluation of Vaginitis

INTENDED USE:
The NUVETEST™ 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 NUVETEST™ 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 NUVETEST™ 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 NUVETEST™ 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 NUVETEST™ and pH tests was estimated and a 95% confidence interval for the differences was calculated.

NUVETEST™ Vs. Clinical Diagnosis n=254

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

NUVETEST™ sensitivity is 86.32% with a 95% exact its binomial CI:[78.74%,91.98%] and the specificty is 93.43% with its respective 95% exact binomial CI:[87.90%, 96.95%].

Nitrazine pH Paper Vs. Clinical Diagnosis n=252

	Clinical Diagnosis: BV /Trichomonas /other identified pathological situations, capable of elevating pH			
		Positive	Negative	Total
Nitrazine pH paper	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%].

REPRODUCIBLITY:
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.

How NUVETEST™ Supplied:
- 25 individually foil-wrapped NUVETEST™ units. item # 23710-008-25 and 2 individualy foil-wrapped units, item # 23710-008-02 (physician sample)
- 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 NUVETEST™ 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 use NUVETEST™ 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 second bullet point.
- **If the patient is pregnant, the stain may indicate an amniotic fluid leakage.**

How Should I store?
Store in a dry place and at room temperature. Please note the expiration date on the individual test package.

Keep NUVETEST™ and all medicines out of reach of children.

INSTRUCTIONS FOR USE/TEST PROCEDURE:
1. Take one NUVETEST™ 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 NUVETEST™ swab approximately 5cm (2") into the mid vagina and rotate the swab several times to contact the vaginal walls.
5. Withdraw the NUVETEST™ 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 NUVETEST™ swab for color changes from yellow to blue or green .
7. Dispose the NUVETEST™ swab after usage as you would any other vaginal swab.

INTERPRETATION OF RESULTS:

Positive NUVETEST™ 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 NUVETEST™ 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 NUVETEST™ unit, check visually that there are no blue or green stains on the yellow tip.
2) If you have used a NUVETEST™ 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 NUVETEST™ results may also be caused by other less common infections or by transient causes of elevated pH levels, such as post semen ejaculation.

To report Suspected Adverse Reactions or side effect, contact Exeltis USA Dermatology, LLC at 1-877-324-9349 (option 2) or FDA at 1-800-FDA-1088 or www.fda.gov/madwatch.

Made in Israel

Distributed by:
Exeltis USA Dermatology, LLC
180 Park Avenue
Florham Park, NJ 07932
1-877-324-9349

www.exeltisUSA.com

Questions?
Call Exeltis USA Dermatology, LLC at 1-877-324-9349.

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