



Chuangxingwell



Vaginitis Combo Rapid Test Kit

Package Insert

For professional in vitro diagnostic use only.



• INTENDED USE

This kit is designed for qualitative detection of hydrogen peroxide (H₂O₂), leukocyte esterase (LE), sialidase catalytic activity (SNa), and pH levels (pH) in female vaginal secretions. Normal levels of these factors are altered during bacterial infection with common vaginosis strains (*Gardnerella vaginalis*, *Peptostreptococcus spp.*, *Prevotella spp.*, *Bacteroides spp.*, and others).

• SUMMARY

Bacterial vaginosis (BV), also known as non-specific vaginitis, is a common infectious disease in women of childbearing age. The disease has a high infection rate, common occurrence of reinfection, and is easily transmitted (both sexually, and non-sexually). BV also predisposes women to an increase risk of premature delivery, endometriosis, pelvic inflammatory disease, vaginal cellulitis, and other reproductive tract infections. Failure to promptly identify and treat the disease can lead to further complications.

Bacterial infections in the vaginal tract are controlled via an acidic environment (~pH 4.0). When an infection occurs, pH levels can rise into a more basic environment. Bacterial pathogens in BV can also express an enzyme SNa, and can induce an inflammatory response where leukocyte infiltration elevates the levels of LE. Finally, as a bacterial infection develops, the loss of H₂O₂ producing *Lactobacilli spp.* can occur in the vaginal tract.

This comprehensive bacterial vaginosis test kit can test vaginal swabs for all of these factors simultaneously. The levels of H₂O₂, LE, SNa, and the pH of the vaginal samples can be immediately measured. Together this kit uses a combinatorial method to test for BV in patients.

• PRINCIPLE

Hydrogen Peroxide Concentration:

Levels of H₂O₂ in the vaginal secretions is determined by the reaction of H₂O₂ with the chemical 4-aminoantipyrine coated onto the sample pad. Catalytic activity from swab H₂O₂ develops color on the pad. When the H₂O₂ concentration

of a sample > 4 μmol / L, the reaction produces a red to purple color. The color depth is proportional to the H₂O₂ concentration. When the sample concentration of H₂O₂ < 4 μmol / L, the reaction pad produces no color to a yellow color.

Leukocyte Esterase Activity:

Levels of LE is measured by reaction of the LE with the chemical 5-Bromo-4-chloro-3-indolyl acetate coated onto the sample pad. A hydrolysis reaction occurs when LE is present at ≥0.2U/mL, a blue to green color develops. The color depth is proportional to LE activity. When the sample concentration contains <0.2U/mL LE, the reaction pad produces no color to a yellow color.

Sialidase Enzyme Activity Detection:

Levels of SNa are measured by a reaction with 5-bromo-4-chloro-3-indolyl-α-DN-acetylneuraminic acid. When SNa is present at ≥0.01U/mL, a catalytic hydrolysis reaction occurs. This reaction product causes a red to purple color to develop when a coloring solution is added. The depth of the color is proportional to the level of SNa activity. When the sample concentration contains <0.01U/mL SNa, the reaction pad produces no color to a yellow color.

pH Value Determination:

pH in the sample is measured by a simple color change in bromocresol green coated onto the reaction pad change. The pH of the sample changes the pad color from yellow to yellow/green, to blue at a pH value above 4.5.

• KIT COMPONENTS

The kit contains the following components. The entire kit can be used for 20 Comprehensive BV Tests.

Components	SIZE
	20 samples/ box
BV Detection Cassette	20 individual cassettes
Sample Diluent	1 bottle, 20mL *
Coloring Reagent	1 bottle, 3mL **
Instruction Manual	1
Color Card	1

- **Special Note:** The components of different lot numbers are not interchangeable

The sample diluent and coloring solution require the addition of distilled or deionized water prior to use.

- * Add 20mL of water to the Sample Diluent bottle
- ** Add 3mL of water to the Coloring Solution bottle

Additional Materials Required:

- Precision pipettes
- Cotton swabs for vaginal sample isolation
- Distilled or deionized water
- 1.5mL or larger volume test tube
- 37°C incubator

• STORAGE AND STABILITY

Store kit and individual package at 2 – 8°C centigrade, away from moisture, and away from light. Avoid freezing. Overall kit and individual cassettes are good for 12 months.

The Sample Diluent is good for 10 days once reconstituted. The individual cassette package should only be opened when detection begins, and the cassette is only good for 4 hours after being opened.

• SAMPLE COLLECTION AND STORAGE

Sample Requirements:

The kit is designed for use with swabs taken from the vaginal cavity. As such, the following should be avoided 24 hours prior to the test.

- Sexual intercourse
- Bathing
- Vaginal lavage
- Douching
- Prescription medication (if possible)

Samples that are not compatible with the test kit:

- Samples during a menstrual period
- Purulent samples
- Bloody samples

Sample Isolation:

The kit is designed to test vaginal swabs for pH, H₂O₂, LE, and SNa levels. Samples swabs should be taken from the lower third of the vaginal wall. Swabs should be rotated for 10-20 seconds in the vaginal vault, with visual confirmation of the presence of vaginal secretions upon isolation.

Sample Preservation:

Samples should be run immediately if possible. If not possible, store the collected swab in a collection pouch at 2-8°C. Detection should be completed within 12 hours of collection.

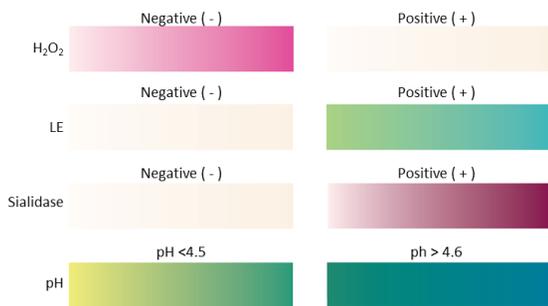
TESTING METHODS

1. Before testing, read the manual completely.
2. Ensure kit and sample have been stored as stated in the manual.
3. Take out enough individual foil bags as needed for the samples on hand.
4. Bring each individual the BV Detection Cassette foil bag to room temperature.
5. Open the foil bags and take out the cassette.
6. Place the vaginal swab directly onto the pH reaction hole, and record the resulting color
7. Using a 1.5mL or larger test tube, add 0.5mL–1.0mL of Sample Diluent.
8. Place the sample swab in the test tube.
9. Gently press the swab repeatedly against the side of the test tube wall to extract the secretions from the sample.
10. Add 1 drop (40uL) of the sample material to the H₂O₂, LE, and SNa reaction wells in the BV test cassette.
11. Next, add 1 drop (40uL) of the color reagent to the SNa reaction well only.
12. Place the cassette in a 37°C incubator for 15 minutes to develop the color.
13. Evaluate the results.

EVALUATION OF TEST RESULTS

Color Interpretation:

The testing cassette should be read immediately following the 15-minute incubation at 37°C.



Results are determined as follows:

Positive:

- H₂O₂: Reaction color red-purple; < 4µmol/L
- LE: Reactions shows no coloration; ≥ 0.2U/mL
- SNa: Reaction is red- purple; ≥ 0.01U/mL
- pH: Reaction is Yellow to green; ≤ 4.5

Negative:

- H₂O₂: Reaction is colorless-yellow; ≥ 4µmol/L
- LE: Reactions shows green-blue color; < 0.2U/mL
- SNa: Reaction is colorless-yellow; < 0.01U/mL
- pH: Reaction is green-blue; > 4.5

Limitations of the Assay:

- This kit is only used to assist in the diagnosis of bacterial vaginosis, and is a qualitative assay.
- The qualitative results of this kit are interpreted by the naked eye, and are subjective in nature.
- The results should be combined with clinical microscopic examination to confirm the results.

Performance characteristics:

- Minimum detection limit: H₂O₂ 4µmol/L, LE 0.2U/mL, SNa 0.01 U / mL, and pH 3.6.
- Positive reference rate: The positive rate of the positive reference was ≥ 95%.
- Negative reference rate: The negative rate of the negative reference was ≥ 95%.
- Repeatability: 10 test cards were evaluated simultaneously. A positive reference sample was tested on these cards, and all cards showed a positive coloring result for all 4 tests.
- Inter-assay Precision: Three different lots of kits were used to test a positive reference material simultaneously. All cards from all batches were shown to have a positive coloring result for all 4 tests.

SAFETY MEASURES

Warning statements:

- This kit is an in vitro diagnostic test kit.
- Please read this manual carefully before use to ensure you are familiar with the procedure.
- The kit can be manually operated, and the results can be measured accurately by the naked eye
- This kit can be used in conjunction with a vaginal bacterial detector.
- Clearly label the identity of the test card once it is opened for both the assay, and the patient ID.
- The coloring reagent is for use only after the sample has been added to the sample pad.
- In the patient file, please note the patients name, ID number, and the test results.
- In the patient file, also note the lot number, and expiration date of the BV test kit for future records.
- Purulent samples, bloody samples, and viscous samples may result in a brown color reaction. This coloring change is non-specific and is not a valid result for the assay. Please do not use these sample types.
- The test cassette must be used within 4 hours after opening the foil bag.
- The sample must be read within 12 hours of sample collection.
- Swabs that cannot be read immediately must be stored at 2 – 8°C following collection.

Waste treatment:

- This reagent is a disposable product. Please dispose of the used product according to your Medical Waste Management Regulations.
- Dispose of medical waste after using of this product in accordance with local regulations.
- Following use, this product contains human-derived substances that may be contaminated. There are no known methods to fully ensure the presence of non-infectious substances. All completed cassettes should be treated as infectious agents.

REFERENCES

1. Yunan et al.: Chinese J of Medical Inspection 2000, 23:303-304.
2. Advances in diagnosis and treatment of bacterial vaginosis[J]. Chinese Journal of Gynecology and Obstetrics, 2005,21(3):131-133.

SYMBOLS

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
	Batch Code		Do Not Use if Package is Damaged
	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Authorized representative in the European Community		



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