IVD

BACTERIAL VAGINOSIS (BV) ASSAY

Catalog No. M0206

20 tests

INTENDED USE

Autobio BV assay is a rapid test which is used in the obstetrics and gynecology divisions in a health care institution, or used prior to a surgery, for the detection of bacterial vaginosis and the monitoring of therapies.

INTRODUCTION

BV is a synergistic polymicrobial syndrome characterized by a depletion of normal flora in the vagina such as *Lactobacillus* species and an increase in the quantities of vaginal anaerobic bacteria such as *Gardnerella vaginalis, Bacteroides, Mobiluncus*, etc. BV is one of the most common gynecopathies and relapses easily. 50 percent BV patients are easy to give premature birth or deliver low-birth weight infants. Their babies may possibly suffer from all kinds of sequelae. BV is a risky factor leading to chorioamnionitis, amniotic fluid infection, endometritis infected following caesarean birth, bad pregnancy and some pregnancy-related complications. Besides, BV is mainly related to salpingitis, pelvic inflammatory disease, entopic pregnancy, infertility, urinary tract infection, surgical infection and female tumor. Due to these harms to women and pregnancy, it is of great clinical significance to test BV in obstetrics, gynecology and prior to surgical abortion. However, as BV is not a single germ infection but a polymicrobial infection, the clinical diagnosis is due to this made difficult.

This assay is rapid, does not require special instrument, is highly sensitive, easy to operate and accurate. The results are easy to be distinguished and the cost is low. The clinical evaluation showed the agreement with Amsel method (Gold standard) is above 90%. It has valuable clinical utility, suitable for hospitals and clinics of all levels and all types.

BIOLOGICAL PRINCIPLE OF THE PROCEDURE

This assay is based on an enhanced BV specific amine experiment which employs scientific amplification. By utilizing the latest technology, the drawbacks of conventional amine experiment were eliminated.

MATERIALS PROVIDED

1. Test Card: (20 cards)
2. Extract Solution: (1 bottle)
3. Sample Diluent: (1 bottle)
4. Negative Control: (1 bottle)
5. Positive Control: (1 bottle)
6. Sample Tube: (20 tubes)

STORAGE OF TEST KIT AND INSTRUMENTATION

Unopened kits should be stored at 2℃ – 8℃ upon receipt. The test kit could be used throughout the expiration date of the kit (1 year from the date of manufacture). Refer to the package label for the expiration date.

SPECIMEN COLLECTION, PREPARATION, TRANSPORT AND STORAGE

1. Vaginal secretions may be used as specimens.
2. Collect specimens from the secretions of vaginal fornix with a sterile swab. Specimens must be assayed on the same day of collection.

PRECAUTIONS AND WARNINGS

1. for *in vitro* diagnostic use only, for professional use only
2. This package insert must be fully understood prior to operation. The operation must be stringently in accordance with the instruction for use.

3. This product has been granted a state utility new type patent in P.R. China, patent No ZL01252019.5.
4. The assay should be operated at room temperature (15 – 30℃) with a relative humidity of 45% – 85%. After each assay, the rest of the reagents should be stored at 2 – 8℃.
5. Do not collect specimens after sexual intercourse or during the menstruation period. Specimens must be fresh.
6. This assay adopts a new technology. The entry of the specimen could not be observed visually.
7. If the test window is wet, the result is invalid. Specimens should be assayed on another Test Card.
8. Wear disposable gloves when dealing with specimens and reagents. Wash hands after operations. All specimens must be regarded as potentially infectious materials. Waster material must be disposed of safely according to relevant local and national requirements.
9. Components with different lot numbers are allowed to be exchanged.

ASSAY PROCEDURE

1. Collect vaginal secretions with a sterile swab, then place the swab in a Sample Tube, add 6~8 drops of Sample Diluents into Sample Tube. Wash thoroughly, then gently press the wall of the tube, refluxing the solution adsorbed in the swab back into the Tube, then damp the swab.
2. Take out a Test Card, press the Sample Tube, add the whole content of the processed specimen into the test window. When the specimen is fully absorbed, add 4 drops of Extract Solution. Read the result within 5 minutes.
3. As for Negative Control and Positive Control, add 4 drops of Negative Control or Positive Control into the test window. After the control is fully absorbed, add 4 drops of Extract Solution, read results within 5 minutes.

INTERPRETATION OF RESULTS

1. If the test line in the test window turns to red，a positive result could be reported.
2. If the test line has no obvious change in color or is still yellow, a negative result could be reported.

LIMITATIONS

BV assay tests specific metabolites from anaerobic flora. *Trichomonas vaginalis* might lead to a false positive result. In addition, sexual intercourse and menstruation may interfere with assay results, hence these types of specimens are not allowed to be assayed.

REFERENCES

1. Briselden A. M., Moncla B. J., Stevens C. E., Hillier S. L. *J. Clin. Microbiol.* **1992,** 30, 663.
2. Ma Y. *Chinese J. Lab. Med.* **2000,** 23, 303.

SYMBOLS

LOT	**BATCH CODE**
	USE BY
	MANUFACTURER
Σ	**CONTAINS SUFFICIENT FOR <n> TESTS**
IVD	**IN VITRO DIAGNOSTIC MEDICAL DEVICE**
8 °C 2 °C	**TEMPERATURE LIMITATION**

IVD

REF	**CATALOGUE NUMBER**
	CONSULT INSTRUCTIONS FOR USE

for order and inquiries, please contact

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