GARDNERELLA VAGINALIS

For in *Vitro* diagnostic use only

Diagnostic rapid test for the detection of *Gardnerella vaginalis* in urogenital swabs *and urine*

I. INTRODUCTION AND INTENDED USE

Sexually transmitted diseases (STD's) are among the most common causes of illness in the world and have health, social and economic consequences for many countries. Among the different sexually transmitted diseases, bacterial vaginosis, candidiasis and trichomoniasis are responsible for 90% of cases of infectious origin. Bacterial vaginosis (BV) is characterized by the substitution of the vaginal flora, normally dominated by lactobacilli, by a complex and abundant flora of strictly or optionally anaerobic bacteria that are normally found in vagina (*Gardnerella vaginalis, Bacteroides sp, Peptostreptococus, Mobiliuncus sp*). Abundant foul–smelling vaginal secretions are the typical symptom of infection by *Gardnerella vaginalis* (GV).

II. PRINCIPLE OF THE TEST

The test strip in the device includes: 1) a pink-colored conjugate pad containing colloidal gold coupled with *Gardnerella vaginalis* monoclonal antibodies, and 2) a nitrocellulose membrane containing a test line (T-line) and a control line (C-line). The T-line is coated with *Gardnerella vaginalis* antibody, and the C-line is coated with antibodies anti-species. When *Gardnerella vaginalis* antigens are present in the specimen, the T-line will become a pink-colored band. If antigen to *Gardnerella vaginalis* are not present or are present below the detectable level, no T-line will develop. The C-line should always appear as a pink-colored band regardless of the presence of antigen to *Gardnerella vaginalis.* The C-line serves as an internal qualitative control of the test system to indicate that an adequate volume of specimen has been applied and the flow occurred.

III. REAGENTS AND MATERIALS

Each kit contains:

1. **Gardnerella Vaginalis strip (20):** each sealed with a test strip and a dessicant in the pouch
2. **Diluent - Extraction buffer (1 x 20 mL):** dilution buffer, containing NaN_3 (<0,1%), a detergent and proteins.
3. **Positive Control (1 x 0,5 mL):** N.1 vial with dropper containing non-infectious components, sodium azide (NaN_3) as preservative.
   Negative Control: use Diluent- Extraction buffer
4. **Instruction for use (1)**

Required materials (not supplied)

Test tubes 3 or 5 mL - Disposable gloves – Sterile swabs

IV. STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (+2°C - +30ºC). Do not freeze.

V. SPECIAL PRECAUTIONS

1) The kit is for professional use and for in vitro diagnosis only.
2) Do not use after expiration date. Do not use the test if pouch is damaged.
3) Read carefully the Instruction for use before using this kit.
4) The test should remain in the sealed pouch until use.
5) All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
6) All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7) The test should be discarded in a proper biohazard container after testing.
8) The test must be carried out within 2 hours of opening the sealed bag.

VI. SPECIMENS COLLECTION

Urine sample: *collect a urine specimen in a clean glass, plastic or wax coated container. Please do not use preservatives. If the test is not run immediately after sample collection, please take the equal volume of sample buffer of kit into test tube, and mix well with sample. The diluted sample should be stored at 2-8°C, and brought back to room temperature (15-30°C) before testing. If testing is delayed more than 48 hours, the specimen should be frozen at -20°C or lower. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed in room temperature.*

Swab sample: Collect specimen with a sterile swab from vaginal cavity. Process the swab as soon as possible after specimen collection. The test does not require live organisms for processing. If you cannot perform the test immediately, extract the swabs in Sample Buffer as per protocol and store the extracted specimen at 2–8°C for up to 24 hours.

VII. PROCEDURES

Allow the tests, samples and buffers to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pack until ready to perform the assay.

Urine:

1. Dispense 3-4 drops (about 0.8 mL) of Diluent into a test tube.
2. Pipette equal volume 3-4 drops (about 0.8 mL) of urine sample into test tube and mix well in 10 seconds.
3. Remove a Gardnerella V Test Strip from its foil pouch.
4. Holding the strip vertically, place it in the specimen test tube. Do not immerse the strip past the maximum line.
5. The test strip can be left in the tube or removed from the tube when red dye begins to migrate through the test line.
6. Read results at 15 minutes (positive results may be seen earlier)

Swab:

1. Dispense 1.0 mL of Diluent into a test tube.
2. Place the sample swab into the tube. Mix the sample buffer by rotating the swab vigorously in the tube.
3. Allow the swab to soak in sample buffer for 30-60 seconds.
4. Mix again and remove the swab, pressing against the side of the tube to extract as much liquid as possible.
5. Discard the swab.
6. Remove a Gardnerella V Test Strip from its foil pouch.
7. Holding the strip vertically, place it in the specimen test tube. Do not immerse the strip past the maximum line.
8. The test strip can be left in the tube or removed from the tube when red dye begins to migrate through the test line.
9. Read results at 15 minutes (positive results may be seen earlier)

For the Positive and Negative controls add 6 drops to an empty tube and use the same assay procedure (from point 6 on for swab).

VIII. INTERPRETING THE RESULTS

Positive: two red lines (C) and (T) are visible in the control and test areas of the window. The intensity of the band colour in the test region is proportional to the antigen concentration in the sample. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Negative: In the reading window only 1 red band appears in the control region "C". This is the control line assuring the correctness of test performance.

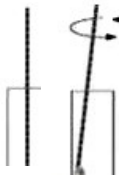
Invalid: No band appears in the control region. A sample should never be identified as positive if you do not see a control line. If the control line is not formed, the test is invalid and must be repeated.

Swab

1. Sample buffer

2. Sample collection

3. Mix for 30-60 seconds



Urine

1. Urine sample

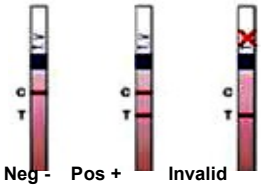
2. Dispense 3-4 drops of sample buffer into test tube

3. Pipette equal volume of urine sample and mix well in 10 seconds

4. Insert the strip

5. Waiting 15 minutes

6. Read the results



Neg - **Pos +** **Invalid**

IX. PERFORMANCE

Correlation, Sensitivity-Specificity: determined on 273 vaginal swabs samples. The gold standard used was a positive Amsel method confirmed by Gardnerella V PCR method.

Method	True Positive	False positive	True Negative	False negative	Specificity %	Sensitivity %
Culture	143	5	121	4	96,62	96,8
Amsel	143	3	138	2	97,94	98,57
Mascia Brunelli GV	143	2	126	2	98,62	98,46
PCR	143	0	130	0	100	100

The Gardnerella Vaginalis (Mascia Brunelli) test has a specificity of **98.6%** and sensitivity **98.5%** vs PCR

X. LIMITS OF THE KIT

The results obtained with this kit must be interpreted together with other clinical information and laboratory findings available to the physician. A positive result does not preclude the possibility of infections by other pathogens.

This test provides a presumptive diagnosis of *Gardnerella V*. infection during the acute phase of infection. Samples collected after acute phases of infection may contain titles of antigens below the threshold of sensitivity of the reagent. If the test result is negative and clinical symptoms persist, additional testing using other diagnostic methods is recommended.

XI. REFERENCES see Italian version

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (20 tests) **REF. VQ81601**

1. Gardnerella Vaginalis strip	20 Strips
2. Extraction Buffer-Diluent	1 x 20 mL
3. Positive Control	1 x 0.5 mL
4. Instruction for use	1 item

EDMA (EDMS) CODE 1490909000 IVD