

## Overview

### Useful For

Aid for diagnosis of bacterial vaginosis

This test is **not intended for use** in medico-legal applications.

### Method Name

Transcription Mediated Amplification

### NY State Available

Yes

## Specimen

### Specimen Type

Vaginal

### Specimen Required

**Specimen Type:** Vaginal

**Supplies:** Aptima Multitest Swab Collection Kit (T584)

**Container/Tube:** Aptima Multitest Swab

**Specimen Volume:** Swab

#### Collection Instructions:

- 1. Specimen must be collected using the Aptima Multitest Swab Collection Kit.**
- Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
- Place swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
- Cap tube securely, and label tube with patient's entire name and collection date and time.
- Maintain swab container between 2 and 30 degrees C (refrigerate temperature is preferred) and transport within 30 days of collection. If longer storage is needed, store frozen between -20 and -70 degrees C for up to 60 days.

### Specimen Minimum Volume

See Specimen Required

### Reject Due To

|   |        |
|---|--------|
| Incorrect swab                          | Reject |
| Transport tube containing more than one |        |

|      |  |
|------|--|
| swab |  |
|------|--|

**Specimen Stability Information**

| Specimen Type | Temperature              | Time    | Special Container |
|---------------|--------------------------|---------|-------------------|
| Vaginal       | Refrigerated (preferred) | 30 days | APTIMA VIAL       |
|               | Ambient                  | 30 days | APTIMA VIAL       |
|               | Frozen                   | 60 days | APTIMA VIAL       |

**Clinical & Interpretive****Clinical Information**

The Aptima BV (bacterial vaginosis) assay is intended to aid in the diagnosis of BV in individuals with clinical presentation consistent with vaginitis and/or vaginosis. Vaginitis is characterized by a spectrum of signs and symptoms, including vaginal/vulvar irritation, odor, discharge, and pruritus. Vaginitis may develop as a result of mechanical or chemical irritants (eg, feminine hygiene products, contraceptive materials) or due to a dysbiosis of the microbiota in the vaginal tract. Up to 90% of vaginitis cases are infectious, due to BV, vulvovaginal candidiasis (*Candida* vaginitis: CV) and/or trichomoniasis (*Trichomonas vaginalis*: TV). BV, CV, and TV individually account for 22% to 50%, 17% to 39%, and 4% to 35% of vaginitis cases, respectively. BV has been associated with pelvic inflammatory disease, cervicitis, elevated risk of acquisition of sexually transmitted infections (such as chlamydia, gonorrhea, herpes simplex virus, and HIV), spontaneous abortion, and preterm birth.

Bacterial vaginosis is characterized by a change in the vaginal microbiota dominated by *Lactobacillus* species to a polymicrobial anaerobe-dominated microbiota that includes *Gardnerella vaginalis*, *Atopobium vaginae*, *Prevotella*, *Bacteroides*, *Peptostreptococcus*, *Mobiluncus*, *Sneathia* (*Leptotrichia*), *Mycoplasma*, and BV-associated bacteria. A change in the normal vaginal microbiota is associated with the development of multiple signs and symptoms (eg, discharge, vaginal discomfort, and discharge). Diagnosis of BV can alternatively be established based on clinical criteria alone, referred to as Amsel's criteria, which include measuring vaginal pH, assessment for the presence of clue cells (eg, epithelial cells layered with bacterial cells), discharge, and malodor.

**Reference Values**

Negative

**Interpretation**

**Positive:** Results should be interpreted alongside clinical presentation. Up to 40% of asymptomatic patients may test positive by this assay. Assay result is based on relative amounts of *Lactobacillus* (*Lactobacillus gasseri*, *Lactobacillus crispatus*, *Lactobacillus jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*. Individual organisms are not reported.

**Negative:** A negative result does not exclude infection. Assay result is based on relative amounts of *Lactobacillus* (*L. gasseri*, *L. crispatus*, *L. jensenii*), *G. vaginalis*, and *A. vaginae*.

**Inconclusive:** Repeat testing on a new sample is recommended if clinically indicated.

**Cautions**

Therapeutic failure or success cannot be determined with the Aptima bacterial vaginosis (BV) assay since nucleic acid may persist following appropriate antimicrobial therapy.

Bacterial species targeted by the Aptima BV assay may comprise part of the normal microbiome for a significant number of women; a BV positive result should be interpreted in conjunction with other clinical data available to the clinician.

A negative result does not preclude a possible infection. Reliable results are dependent on adequate specimen collection, transport, storage, and processing.

Performance of the assay has not been evaluated in individuals younger than 14 years.

Additional microorganisms not detected by the Aptima BV assay such as *Prevotella* species, *Mobiluncus* species, *Ureaplasma*, *Mycoplasma*, and numerous fastidious or uncultivated anaerobes have also been found in women with BV but are less associated with BV due to their relatively low prevalence, sensitivity, and/or specificity.

Interference with the Aptima BV assay was observed in the presence of the following substances: mucus (1.5% V/V), vaginal moisturizing gel (0.5% W/V) and tioconazole (5% W/V).

Cross-reactivity was observed with the Aptima BV assay in the presence of *Lactobacillus acidophilus* (1x10<sup>4</sup> CFU/mL).

**Clinical Reference**

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187
2. Muzny CA, Cerca N, Elnaggar JH, Taylor CM, Sobel JD, Van Der Pol B. State of the art for diagnosis of bacterial vaginosis. J Clin Microbiol. 2023;61(8):e0083722. doi:10.1128/jcm.00837-22

**Performance****Method Description**

The Aptima BV (bacterial vaginosis) assay is an *in vitro* nucleic acid amplification test that utilizes real time transcription-mediated amplification for detection and quantitation of ribosomal RNA from bacteria associated with BV, including *Lactobacillus* (*Lactobacillus gasseri*, *Lactobacillus crispatus*, *Lactobacillus jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*. The Panther system detects and discriminates between four fluorescent signals corresponding to *Lactobacillus* group, *Atopobium vaginae*, *Gardnerella vaginalis*, and IC amplification products. Signal emergence times for each target organism are compared to calibration information to determine the BV Positive or Negative status of each sample. (Package Insert: Aptima BV Assay. Hologic, Inc; 9/2020)

**PDF Report**

No

**Day(s) Performed**

Monday through Sunday

**Report Available**

1 to 4 days

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Mayo Clinic Laboratories - Rochester Superior Drive

**Fees & Codes****Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

81513

**LOINC® Information**

| Test ID | Test Order Name                    | Order LOINC® Value |
|---------|------------------------------------|--------------------|
| BVRNA   | Bacterial Vaginosis, Amplified RNA | 103590-6           |

| Result ID | Test Result Name                   | Result LOINC® Value |
|-----------|------------------------------------|---------------------|
| 620738    | Bacterial Vaginosis, Amplified RNA | 103590-6            |