Test Definition: BVRNA

Bacterial Vaginosis, Nucleic Acid Amplification, Vaginal

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.**
2. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
3. Place swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
4. Cap tube securely, and label tube with patient's entire name and collection date and time.
5. 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 Transport tube containing more than one	Reject

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(4) 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