of Tennessee

Policy

Reimbursement Policy

Diagnosis of Vaginitis

I. Policy Description

Vaginitis is defined as inflammation of the vagina with symptoms of discharge, itching, and discomfort often due to a disruption of the vaginal microflora. The most common infections are bacterial vaginosis, *Candida* vulvovaginitis, and trichomoniasis.[1] Other causes include vaginal atrophy in postmenopausal women, cervicitis, foreign body, irritants, and allergens.[2]

Bacterial vaginosis (BV) is characterized by a shift in microbial species from the normally dominant hydrogen-peroxide producing *Lactobacillus* species to *Gardnerella vaginalis* and anaerobic commensals.[3-7]

Vulvovaginal candidiasis (VVC) is usually caused by *Candida albicans* but can occasionally be caused by other *Candida* species.[8] It is the second most common cause of vaginitis symptoms (after BV) and accounts for approximately one-third of vaginitis cases.[9,10]

Trichomoniasis is caused by the flagellated protozoan *Trichomonas vaginalis*, which principally infects the squamous epithelium in the urogenital tract: vagina, urethra, and paraurethral glands.[11,12]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For individuals with signs and symptoms of vaginitis, testing of pH, testing for the presence of amines, measurement of sialidase activity, saline wet mount, potassium hydroxide (KOH) wet mount, and microscopic examination of vaginal fluids **MEETS COVERAGE CRITERIA**.

2) For individuals with signs and symptoms of vaginitis, direct probe DNA-based identification of *Gardnerella*, *Trichomonas*, and *Candida* (e.g., BD Affirm™ VPIII) **MEETS COVERAGE CRITERIA**.

Reimbursement Policy

3) For individuals with signs and symptoms of vaginitis but with negative findings on wet-mount preparations and a normal pH test, vaginal cultures for *Candida* species for the diagnosis of vulvovaginal candidiasis **MEET COVERAGE CRITERIA**.

For individuals with signs and symptoms of vaginitis, nucleic acid amplification testing (NAAT) or polymerase chain reaction (PCR)-based identification of *Trichomonas vaginalis* **MEETS COVERAGE CRITERIA**.

4) For individuals with risk factors for trichomoniasis (new or multiple partners; history of sexually transmitted infections (STIs), especially HIV; exchange of sex for payment; incarceration; injection drug use), screening for *Trichomonas* **MEETS COVERAGE CRITERIA**.

5) For individuals with complicated vulvovaginal candidiasis (VVC), polymerase chain reaction (PCR) based identification of *Candida* to confirm clinical diagnosis and identify non-albicans *Candida* **MEETS COVERAGE CRITERIA**.

6) For individuals with signs and symptoms of bacterial vaginosis (BV), NAAT specific to the diagnosis of BV (e.g., Aptima® BV; OneSwab® BV Panel PCR with Lactobacillus Profiling by qPCR; SureSwab® Advanced BV, TMA) and single or multitarget PCR testing for the diagnosis of BV **MEETS COVERAGE CRITERIA**.

7) For individuals with signs and symptoms of vaginitis, NAAT panel testing designed to detect more than one type of vaginitis (VVC, BV, and/or trichomoniasis; e.g., BD MAX™ Vaginal Panel, NuSwab® VG, Xpert® Xpress MVP) **MEETS COVERAGE CRITERIA**.

8) For asymptomatic individuals, including asymptomatic pregnant individuals at an average or high risk for premature labor, screening for trichomoniasis and bacterial vaginosis **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

9) For individuals with symptoms of vaginitis, rapid identification of *Trichomonas* by enzyme immunoassay **DOES NOT MEET COVERAGE CRITERIA**.

10) Testing for microorganisms involved in vaginal flora imbalance and/or infertility using molecular-based panel testing **DOES NOT MEET COVERAGE CRITERIA**.

11) All other tests for vaginitis not addressed above **DO NOT MEET COVERAGE CRITERIA**.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website https://www.cms.gov/medicare-coverage-database/search.aspx . For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

Food and Drug Administration

On October 28, 2016, the FDA approved an automatic class III designation for the BD MAX™ Vaginal Panel.[38] Following the initial approval, an additional 510(k) Substantial Equivalence Determination Decision Summary was released on October 21, 2019, with the following note: "Routine post market surveillance activities informed BD of an unanticipated high rate of nonreportable result rate for the BD MAX Vaginal Panel. Through investigations, BD identified four design modifications intended to improve the tolerance of the BD MAX Vaginal Panel without significantly impacting the validated clinical and analytical performance. . . One of the four design modifications was determined to be significant with the potential to affect the safety or effectiveness of the device and is the focus of this submission. The cumulative changes require minor modifications to the labeling."[82]

On May 23, 2019, the FDA approved the use of the Aptima® BV Assay for the detection and identification of bacterial vaginosis. According to the FDA, "the Aptima BV assay is an in vitro nucleic acid amplification test that utilizes real time transcription-mediated amplification[28] for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including Lactobacillus (*L. gasseri, L. crispatus*, and L. *jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*. The assay reports a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther system using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis."[31]

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

Reimbursement Policy

CPT	Code Description
81515	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, Megasphaera type 1, and Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm reported as positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported
82120	Amines, vaginal fluid, qualitative
83986	pH; body fluid, not otherwise specified
87070	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed
87210	Smear, primary source with interpretation; wet mount for infectious agents (eg, saline, India ink, KOH preps)
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification
87510	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique
87511	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique

Reimbursement Policy

CPT	Code Description
87512	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, quantification
87660	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, direct probe technique
87661	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique
87797	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
87808	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Trichomonas vaginalis
87905	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)
0505U	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism Proprietary test: Vaginal Infection Testing Lab/Manufacturer: NxGen MDx LLC
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens

Reimbursement Policy

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

1. Sobel JD. Vulvovaginitis in healthy women. *Comprehensive therapy*. Jun-Jul 1999;25(6-7):335-46.

2. Sobel JD. Vaginitis in adults: Initial evaluation. Updated November 6, 2023. https://www.uptodate.com/contents/vaginitis-in-adults-initial-evaluation

3. Lamont RF, Sobel JD, Akins RA, et al. The vaginal microbiome: new information about genital tract flora using molecular based techniques. *BJOG : an international journal of obstetrics and gynaecology*. Apr 2011;118(5):533-49. doi:10.1111/j.1471-0528.2010.02840.x

4. Eschenbach DA, Davick PR, Williams BL, et al. Prevalence of hydrogen peroxide-producing Lactobacillus species in normal women and women with bacterial vaginosis. *Journal of clinical microbiology*. Feb 1989;27(2):251-6.

5. Ling Z, Kong J, Liu F, et al. Molecular analysis of the diversity of vaginal microbiota associated with bacterial vaginosis. *BMC genomics*. Sep 07 2010;11:488. doi:10.1186/1471-2164-11-488

6. Hill GB. The microbiology of bacterial vaginosis. *American journal of obstetrics and gynecology*. Aug 1993;169(2 Pt 2):450-4.

7. Sobel JD. Bacterial vaginosis: Clinical manifestations and diagnoses. Updated February 26, 2025. https://www.uptodate.com/contents/bacterial-vaginosis-clinical-manifestations-and-diagnosis

8. CDC. Vulvovaginal Candidiasis (VVC). Updated July 22, 2021. https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm

9. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recommendations and reports : Morbidity and mortality weekly report Recommendations and reports*. Jun 05 2015;64(Rr-03):1-137.

10. Sobel JD, Mitchell C. Candida vulvovaginitis: Clinical manifestations and diagnosis. Updated April 10, 2024. https://www.uptodate.com/contents/candida-vulvovaginitis-clinical-manifestations-and-diagnosis

11. Sobel JD, Mitchell C. Trichomoniasis: Clinical manifestations and diagnosis. Updated July 17, 2023. https://www.uptodate.com/contents/trichomoniasis-clinical-manifestations-and-diagnosis

12. Kissinger P. Epidemiology and treatment of trichomoniasis. *Current infectious disease reports*. Jun 2015;17(6):484. doi:10.1007/s11908-015-0484-7

13. Paladine HL, Desai UA. Vaginitis: Diagnosis and Treatment. *Am Fam Physician*. Mar 1 2018;97(5):321-329.

14. Jones A. Bacterial Vaginosis: A Review of Treatment, Recurrence, and Disparities. *The Journal for Nurse Practitioners*. 2019/06/01/ 2019;15(6):420-423. doi:10.1016/j.nurpra.2019.03.010

15. Kairys N, Garg M. *Bacterial Vaginosis*. StatPearls [Internet]; 2024. https://www.ncbi.nlm.nih.gov/books/NBK459216/

16. Landers DV, Wiesenfeld HC, Heine RP, Krohn MA, Hillier SL. Predictive value of the clinical diagnosis of lower genital tract infection in women. *American journal of obstetrics and gynecology*. Apr 2004;190(4):1004-10. doi:10.1016/j.ajog.2004.02.015

17. Anderson MR, Klink K, Cohrssen A. Evaluation of vaginal complaints. *Jama*. Mar 17 2004;291(11):1368-79. doi:10.1001/jama.291.11.1368

18. Ellis I, Lerch MM, Whitcomb DC. Genetic testing for hereditary pancreatitis: guidelines for indications, counselling, consent and privacy issues. *Pancreatology : official journal of the International Association of Pancreatology (IAP) [et al]*. 2001;1(5):405-15.

19. Brown H, Drexler M. Improving the Diagnosis of Vulvovaginitis: Perspectives to Align Practice, Guidelines, and Awareness. *Popul Health Manag*. Oct 2020;23(S1):S3-s12. doi:10.1089/pop.2020.0265

20. Diba K, Namaki A, Ayatolahi H, Hanifian H. Rapid identification of drug resistant Candida species causing recurrent vulvovaginal candidiasis. *Medical mycology journal*. 2012;53(3):193-8.

21. Mahmoudi Rad M, Zafarghandi A, Amel Zabihi M, Tavallaee M, Mirdamadi Y. Identification of Candida species associated with vulvovaginal candidiasis by multiplex PCR. *Infectious diseases in obstetrics and gynecology*. 2012;2012:872169. doi:10.1155/2012/872169

22. Tabrizi SN, Pirotta MV, Rudland E, Garland SM. Detection of Candida species by PCR in self-collected vaginal swabs of women after taking antibiotics. *Mycoses*. 2006:523-4. vol. 6.

23. Weissenbacher T, Witkin SS, Ledger WJ, et al. Relationship between clinical diagnosis of recurrent vulvovaginal candidiasis and detection of Candida species by culture and polymerase chain reaction. *Archives of gynecology and obstetrics*. Feb 2009;279(2):125-9. doi:10.1007/s00404-008-0681-9

24. Giraldo P, von Nowaskonski A, Gomes FA, Linhares I, Neves NA, Witkin SS. Vaginal colonization by Candida in asymptomatic women with and without a history of recurrent vulvovaginal candidiasis. *Obstetrics and gynecology*. Mar 2000;95(3):413-6.

25. Briselden AM, Hillier SL. Evaluation of affirm VP Microbial Identification Test for Gardnerella vaginalis and Trichomonas vaginalis. *Journal of clinical microbiology*. Jan 1994;32(1):148-52.

26. CDC. Trichomoniasis. Updated September 21, 2022. https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm

27. Garrett N, Mitchev N, Osman F, et al. Diagnostic accuracy of the Xpert CT/NG and OSOM Trichomonas Rapid assays for point-of-care STI testing among young women in South Africa: a cross-sectional study. *BMJ Open*. Feb 19 2019;9(2):e026888. doi:10.1136/bmjopen-2018-026888

28. Schwebke JR, Taylor SN, Ackerman R, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. *Journal of clinical microbiology*. Jan 28 2020;58(2)doi:10.1128/jcm.01643-19

29. Page S. Bacterial Vaginosis and Symptomatic Vaginitis Test. https://www.ruclear.co.uk/testing/bacterial-vaginosis/

30. Hologic. Accurate Testing for Vaginitis. 2023. https://hologicwomenshealth.com/vaginitis/

31. FDA. 510(k) Substantial Equivalence Determination Decision Memorandum: Aptima BV Assay. https://www.accessdata.fda.gov/cdrh_docs/reviews/K190452.pdf

32. MDLabs. 166 Bacterial Vaginosis Panel by Real-Time PCR (with Lactobacillus Profiling by qPCR). https://www.mdlab.com/resources/testing-menu/?code=166

33. Fredricks DN, Fiedler TL, Thomas KK, Oakley BB, Marrazzo JM. Targeted PCR for detection of vaginal bacteria associated with bacterial vaginosis. *Journal of clinical microbiology*. Oct 2007;45(10):3270-6. doi:10.1128/JCM.01272-07

34. Quest. SureSwab® Advanced Bacterial Vaginosis (BV), TMA. Quest Diagnostics, Inc. https://testdirectory.questdiagnostics.com/test/test-detail/10016/sureswab-advanced-bacterial-vaginosis-bv-tma?q=sureswab&cc=MASTER

35. Sekisui Diagnostics. OSOM® BVBLUE® Test. https://sekisuidiagnostics.com/products-all/osom-bvblue-test/

36. Quest. SureSwab® Advanced Vaginitis, TMA. Quest Diagnostics, Inc. https://testdirectory.questdiagnostics.com/test/test-detail/10119/sureswab-advanced-vaginitis-tma?p=r&q=sureswab&cc=MASTER

37. Quest. SureSwab® Advanced Vaginitis Plus, TMA. Quest Diagnostics, Inc. https://testdirectory.questdiagnostics.com/test/test-detail/10120/sureswab-advanced-vaginitis-plus-tma?q=sureswab&cc=MASTER

38. FDA. EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR BD MAX Vaginal Panel. U.S. Food and Drug Administration. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160001.pdf

39. Amsel R, Totten PA, Spiegel CA, Chen KC, Eschenbach D, Holmes KK. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. *The American journal of medicine*. Jan 1983;74(1):14-22.

40. Spiegel CA. Bacterial vaginosis. *Clinical microbiology reviews*. Oct 1991;4(4):485-502.

41. Amegashie CP, Gilbert NM, Peipert JF, Allsworth JE, Lewis WG, Lewis AL. Relationship between nugent score and vaginal epithelial exfoliation. *PLoS One*. 2017;12(5):e0177797. doi:10.1371/journal.pone.0177797

42. Menard JP, Fenollar F, Henry M, Bretelle F, Raoult D. Molecular quantification of Gardnerella vaginalis and Atopobium vaginae loads to predict bacterial vaginosis. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Jul 01 2008;47(1):33-43. doi:10.1086/588661

43. Cartwright CP, Lembke BD, Ramachandran K, et al. Development and validation of a semiquantitative, multitarget PCR assay for diagnosis of bacterial vaginosis. *Journal of clinical microbiology*. Jul 2012;50(7):2321-9. doi:10.1128/jcm.00506-12

44. Menard JP, Mazouni C, Fenollar F, Raoult D, Boubli L, Bretelle F. Diagnostic accuracy of quantitative real-time PCR assay versus clinical and Gram stain identification of bacterial vaginosis. *European journal of clinical microbiology & infectious diseases : official publication of the European Society of Clinical Microbiology*. Dec 2010;29(12):1547-52. doi:10.1007/s10096-010-1039-3

45. Dumonceaux TJ, Schellenberg J, Goleski V, et al. Multiplex detection of bacteria associated with normal microbiota and with bacterial vaginosis in vaginal swabs by use of oligonucleotide-coupled fluorescent microspheres. *Journal of clinical microbiology*. Dec 2009;47(12):4067-77. doi:10.1128/jcm.00112-09

46. Baron EJ, Miller JM, Weinstein MP, et al. A guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2013 recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)(a). *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Aug 2013;57(4):e22-e121. doi:10.1093/cid/cit278

47. Huppert JS, Mortensen JE, Reed JL, et al. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of Trichomonas vaginalis in young women. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Jul 15 2007;45(2):194-8. doi:10.1086/518851

48. Sobel JD, Subramanian C, Foxman B, Fairfax M, Gygax SE. Mixed vaginitis-more than coinfection and with therapeutic implications. *Current infectious disease reports*. Apr 2013;15(2):104-8. doi:10.1007/s11908-013-0325-5

49. Sobel JD. Epidemiology and pathogenesis of recurrent vulvovaginal candidiasis. *American journal of obstetrics and gynecology*. Aug 01 1985;152(7 Pt 2):924-35.

50. Dan M, Leshem Y, Yeshaya A. Performance of a rapid yeast test in detecting Candida spp. in the vagina. *Diagnostic microbiology and infectious disease*. May 2010;67(1):52-5. doi:10.1016/j.diagmicrobio.2009.12.010

51. Chatwani AJ, Mehta R, Hassan S, Rahimi S, Jeronis S, Dandolu V. Rapid testing for vaginal yeast detection: a prospective study. *American journal of obstetrics and gynecology*. Apr 2007;196(4):309.e1-4. doi:10.1016/j.ajog.2006.11.025

52. Marot-Leblond A, Nail-Billaud S, Pilon F, Beucher B, Poulain D, Robert R. Efficient diagnosis of vulvovaginal candidiasis by use of a new rapid immunochromatography test. *Journal of clinical microbiology*. Dec 2009;47(12):3821-5. doi:10.1128/jcm.01168-09

53. Hopwood V, Evans EG, Carney JA. Rapid diagnosis of vaginal candidosis by latex particle agglutination. *Journal of clinical pathology*. Apr 1985;38(4):455-8.

54. Matsui H, Hanaki H, Takahashi K, et al. Rapid detection of vaginal Candida species by newly developed immunochromatography. *Clinical and vaccine immunology : CVI*. Sep 2009;16(9):1366-8. doi:10.1128/cvi.00204-09

55. Abbott J. Clinical and microscopic diagnosis of vaginal yeast infection: a prospective analysis. *Annals of emergency medicine*. May 1995;25(5):587-91.

56. Lynch T, Peirano G, Lloyd T, et al. Molecular Diagnosis of Vaginitis: Comparing Quantitative PCR and Microbiome Profiling Approaches to Current Microscopy Scoring. *Journal of clinical microbiology*. Sep 2019;57(9)doi:10.1128/jcm.00300-19

57. Cartwright CP, Pherson AJ, Harris AB, Clancey MS, Nye MB. Multicenter study establishing the clinical validity of a nucleic-acid amplification-based assay for the diagnosis of bacterial vaginosis. *Diagnostic microbiology and infectious disease*. Nov 2018;92(3):173-178. doi:10.1016/j.diagmicrobio.2018.05.022

58. Gaydos CA, Beqaj S, Schwebke JR, et al. Clinical Validation of a Test for the Diagnosis of Vaginitis. *Obstetrics and gynecology*. Jul 2017;130(1):181-189. doi:10.1097/aog.0000000000002090

59. Schwebke JR, Gaydos CA, Nyirjesy P, Paradis S, Kodsi S, Cooper CK. Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. *Journal of clinical microbiology*. Jun 2018;56(6)doi:10.1128/jcm.00252-18

60. Sherrard J. Evaluation of the BD MAX Vaginal Panel for the detection of vaginal infections in a sexual health service in the UK. *Int J STD AIDS*. Mar 2019;30(4):411-414. doi:10.1177/0956462418815284

61. Sumeksri P, Koprasert C, Panichkul S. BVBLUE test for diagnosis of bacterial vaginosis in pregnant women attending antenatal care at Phramongkutklao Hospital. *J Med Assoc Thai*. Nov 2005;88 Suppl 3:S7-13.

62. Myziuk L, Romanowski B, Johnson SC. BVBlue test for diagnosis of bacterial vaginosis. *Journal of clinical microbiology*. May 2003;41(5):1925-8.

63. Bradshaw CS, Morton AN, Garland SM, Horvath LB, Kuzevska I, Fairley CK. Evaluation of a point-of-care test, BVBlue, and clinical and laboratory criteria for diagnosis of bacterial vaginosis. *Journal of clinical microbiology*. Mar 2005;43(3):1304-8. doi:10.1128/jcm.43.3.1304-1308.2005

64. Anand KV, Pimple SA, Mishra GA, et al. Reliability of conventional Papanicolaou smear in diagnosing bacterial vaginosis among women with clinical genital infection. *South Asian J Cancer*. Jan-Mar 2020;9(1):13-16. doi:10.4103/sajc.sajc_421_18

65. Hilbert DW, Smith WL, Chadwick SG, et al. Development and Validation of a Highly Accurate Quantitative Real-Time PCR Assay for Diagnosis of Bacterial Vaginosis. *Journal of clinical microbiology*. Apr 2016;54(4):1017-24. doi:10.1128/jcm.03104-15

66. Hologic. Aptima® BV and CV/TV Assay. Hologic, Inc. https://hologicwomenshealth.com/products/aptimabvandcvtvassay/

67. FDA Clearance of Aptima BV and Aptima CV/TV Molecular Assays Ushers in New Era of Comprehensive and Objective Diagnostic Testing for Vaginitis. 2019. https://investors.hologic.com/press-releases/press-release-details/2019/FDA-Clearance-of-Aptima-BV-and-Aptima-CVTV-Molecular-Assays-Ushers-in-New-Era-of-Comprehensive-and-Objective-Diagnostic-Testing-for-Vaginitis/default.aspx

68. Richter SS, Otiso J, Goje OJ, et al. Prospective Evaluation of Molecular Assays for Diagnosis of Vaginitis. *Journal of clinical microbiology*. Dec 23 2019;58(1)doi:10.1128/jcm.01264-19

69. Kong AM, Jenkins D, Troeger KA, Kim G, London RS. Diagnostic Testing of Vaginitis: Improving the Value of Care. *Population Health Management*. 2021/08/01 2021;24(4):515-524. doi:10.1089/pop.2021.0143

70. Evans A, Fragala MS, Upadhyay P, French A, Goldberg SE, Reddy J. Utilization of Syndromic Vaginitis Diagnostic Testing Reduces 6-Month Follow-Up Outpatient Service Healthcare Costs-A Real-World Data Analysis. *Healthcare (Basel)*. Nov 5 2024;12(22)doi:10.3390/healthcare12222204

71. CDC. Diseases Characterized by Vulvovaginal Itching, Burning, Irritation, Odor or Discharge. Updated July 22, 2021. https://www.cdc.gov/std/treatment-guidelines/vaginal-discharge.htm

72. CDC. Bacterial Vaginosis. Updated July 22, 2021. https://www.cdc.gov/std/treatment-guidelines/bv.htm

73. USPSTF. Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: Screening. 2020;

74. Hainer BL, Gibson MV. Vaginitis: Diagnosis and Treatment. *American Family Physician*. 2011;83(7):807-815.

75. Owens DK, Davidson KW, Krist AH, et al. Screening for Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: US Preventive Services Task Force Recommendation Statement. *Jama*. Apr 7 2020;323(13):1286-1292. doi:10.1001/jama.2020.2684

76. ACOG. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstetrics and gynecology*. Jan 2020;135(1):e1-e17. doi:10.1097/AOG.0000000000003604

77. Pappas PG, Kauffman CA, Andes DR, et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Feb 15 2016;62(4):e1-50. doi:10.1093/cid/civ933

78. Miller JM, Binnicker MJ, Campbell S, et al. Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM) ∗. *Clinical Infectious Diseases*. 2024;doi:10.1093/cid/ciae104

79. Yudin MH, Money DM. No. 211-Screening and Management of Bacterial Vaginosis in Pregnancy. *J Obstet Gynaecol Can*. Aug 2017;39(8):e184-e191. doi:10.1016/j.jogc.2017.04.018

80. van Schalkwyk J, Yudin MH. Vulvovaginitis: screening for and management of trichomoniasis, vulvovaginal candidiasis, and bacterial vaginosis. *J Obstet Gynaecol Can*. Mar 2015;37(3):266-274. doi:10.1016/s1701-2163(15)30316-9

81. Australian STI Management Guidelines for Use in Primary Care. Bacterial vaginosis. 2024;

82. FDA. 510(k) Substantial Equivalence Determination Decision Summary: BD MAX Vaginal Panel, BD MAX System. https://www.accessdata.fda.gov/cdrh_docs/reviews/K191957.pdf