Letter of Medical Necessity for the BD MAX™ Vaginal Panel

[Current Date]

[Medical Director]

[Insurance Name]

[Insurance Address]

[Insurance City, State, Zip Code]

Patient: [Patient Name]

Date of Birth: [Patient Date of Birth]

ID Number: [XXXXX]

Date of Service: [XXXXXX]

Provider: [Laboratory Director Name]

Claim Number: [XXXXX]

Dear [Medical Director]:

I am writing on behalf of my patient, [Patient Name], to request coverage for testing performed to diagnose the cause(s) of her vaginitis symptoms and determine the presence or absence of DNA from organisms associated with bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) and *Trichomonas vaginalis* (TV). The test was performed at [Practice/Laboratory] [Practice/Laboratory Name] in [City, State]. This letter documents the medical necessity for BV, VVC and TV testing by molecular methods and provides information about the patient’s medical history. Results from this test were used to guide appropriate medical care for the patient.

**Patient’s History and Symptoms:**

[Patient Name] is a [Age in Years] year old female who had a suspected diagnosis of vaginitis at the time of her visit with her physician as described by the following ICD-10 codes:

*[Direction: Use ICD-10 Codes listed on lab claim form]*

1.*[Symptom #1 with ICD-10 code]*

2.*[Symptom #2 with ICD-10 code]*

3.*[Symptom #3 with ICD-10 code]*

4.*[Symptom #4 with ICD-10 code]*

*[Direction: If possible, add any additional details, such as if the patient had previously had any other testing that was inconclusive or if it is a recurrent condition.]*

**Rationale for Testing:**

We are committed to using diagnostic test methodologies that provide the most accurate information to guide appropriate clinical decision-making.

Pervasive inaccurate and inconsistent diagnosis of vaginitis due in part to variations in clinical practice, leaves 40% of the women seeking treatment undiagnosed at the initial visit.1 This can lead to continued symptoms, repeat visits, inappropriate treatment, poor antimicrobial stewardship, and unnecessary associated healthcare system costs.1,2 In addition to severely irritating symptoms that disrupt quality of life3, these infections have serious risks, including pre-term birth2,4 or low birth-weight babies4, late term miscarriage2, increased risk of STI transmission or acquisition such as HIV,2,4,5,6 and Pelvic Inflammatory Disease (PID)2, as well as increased risks associated with outpatient procedures and inpatient surgeries.2,4

Peer-reviewed published data concludes misdiagnosis of vaginal complaints when relying on clinical diagnosis based on traditional non-molecular diagnostic techniques is rather high with misjudgment of VVC and BV exceeding 60%.7 Although the Amsel criteria for BV and microscopy for VVC are traditional non-molecular methods, these methods did not enhance the diagnostic correctness of clinical diagnosis.3 Although the Nugent Score is another non-molecular method considered for use as a diagnostic tool, this method is limited by its complexity, subjectivity and availability, and does not permit the identification of several bacterial morphotypes associated with BV.4,9 In addition, the Nugent Score is not standardized

and does not permit the identification of several species, leading to misidentification.10 Overall, traditional non-molecular methods tend to be subjective and lacking in sensitivity and specificity.3,11 [These] methods often are highly manual and require a special skillset and volume-related experience not available to all clinicians, resulting in incorrect diagnosis and poor subsequent treatment.3

Evidence exists in support of improved diagnosis through molecular amplified diagnostic testing for VVC and BV.

For VVC detection, studies show that multiplex polymerase chain reaction (PCR) tests provide a rapid, simple, and reliable alternative to conventional methods to identify common clinical fungal isolates.12 For BV detection, published data concludes that “quantitative determination of the presence of *G. vaginalis, A. vaginae, Eggerthella, Prevotella,* BVAB2 and *Megasphaera* type-1 as well as the depletion of *Lactobacillus* [is] highly accurate for BV diagnosis. Measurements of abundance of normal and BV microbiota relative to total bacteria in vaginal fluid may provide more accurate BV diagnosis, and be used for test of cure, rather than qualitative detection or absolute counts of BV related microorganisms.”4 This conclusion supports the use of nucleic acid amplification test (NAAT) technology for detection of BV, and points to the additional need for consideration of the ratio of normal (*Lactobacilli*) flora.

I am requesting that [Patient Name] be approved for BV, VVC and TV testing using a PCR-based methodology (Test Code XXXX; CPT Code XXXXX) offered by our [Practice/Laboratory] [Practice/Laboratory Name]. This test is performed using the FDA- cleared test for bacterial vaginitis, the BD MAX™ Vaginal Panel. The analytical and clinical data was evaluated by the FDA and the test was cleared in 2016. This test “can accurately diagnose most common bacterial, fungal, and protozoan causes of vaginitis. Women and their clinicians seeking accurate diagnosis and appropriate selection of efficacious treatment for symptoms of vaginitis might benefit from this molecular test.”13 Physicians choose to order this test from our laboratory due to its validated performance and ability to provide them with accurate diagnostic information to guide treatment of their patients.

Testing for BV, VVC and TC using PCR-based technology is medically necessary to obtain an accurate diagnosis for this patient and supports the ordering physician’s ability to make an appropriate treatment decision regarding the use of antifungals and antibiotics for clinical patient management. I hope you will support this letter of medical necessity for [Patient Name]. Please feel free to contact me at [Phone Number] if you have additional questions.

Sincerely,

[Laboratory Director Name], MD

NPI #: [Lab NPI #]

Contact information:

 [Lab Name] [Address]

 [City], [State] [Zip]

Contact Phone No.: [Phone Number]

**1.** Carr P. Cost-Effectiveness of Diagnostic Strategies for Vaginitis. *JGIM*. 2005 Sep;20(9):793-9. **2.** Hainer BL, Gibson MV. Vaginitis: diagnosis and treatment. *A Fam Phys.* 2011;83:807–815. **3.** Powell K. Vaginal thrush: quality of life and treatments. *Br J Nurs* 2010;19:1106–1111. **4.** Sherrard J, Wilson J, Donders G, Mendling W, Jensen JS. 2018 European (IUSTI/WHO) International Union against sexually transmitted infections (IUSTI) World Health Organisation (WHO) guideline on the management of vaginal discharge. *Int J STD AIDS*. 2018 Nov;29(13):1258–1272. doi: 10.1177/0956462418785451. Epub 2018 Jul 27. PMID: 30049258. **5.** Powell AM, Nyirjesy P. Recurrent vulvovaginitis. *Best Pract Res Clin Obstet and Gynaecol* 2014;28:967–976. **6.** Lamont RF, Sobel JD, Akins RA, et al. The vaginal microbiome: New information about genital tract flora using molecular based techniques. *BJOG* 2011;118:533–549. **7.** Schwiertz A, Taras D, Rusch K, et al. Throwing the dice for the diagnosis of vaginal complaints? *Annals of Clinical Microbiology and Antimicrobials*, 2006;5:4. **8.** Shipitsyna E, Roos A, Datcu R, Hallén A, Fredlund H, et al. Composition of the Vaginal Microbiota in Women of Reproductive Age – Sensitive and Specific Molecular Diagnosis of Bacterial Vaginosis Is Possible? *PLoS ONE* 2013;8:4. e60670. doi: 10.1371/journal.pone.0060670 **9.** Modak et al. *J Infect Dev Ctries* 2011;5(5):353–360. **10.** Menard et al. Molecular Quantification of Gardnerella vaginalis and Atopobium vaginae Loads to Predict Bacterial Vaginosis. *Clinical Infectious Disease* 2008;47:33-43. **11.** Chow, L. Vaginitis Diagnosis: An Opportunity to Improve Patient Care, *Dark Daily Report*, 2010. **12.** Luo G, Mitchell TG. Rapid identification of pathogenic fungi directly from cultures by using*icrobiol* 2002;40(8):2860–2865. **13.** Gaydos et al. Clinical Validation of a Test for the Diagnosis of Vaginitis. *Obstet Gynecol.* 2017;130(1):181-189..1097/AOG.0000000000002090.