December 19, 2024

Becton, Dickinson and Company
Joseph Basore
Staff Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K243725
Trade/Device Name: BD Vaginal Panel
Regulation Number: 21 CFR 866.3975
Regulation Name: Device That Detects Nucleic Acid Sequences From Microorganisms Associated With Vaginitis And Bacterial Vaginosis
Regulatory Class: Class II
Product Code: PQA, OUY, OOI, NSU
Dated: November 22, 2024
Received: December 3, 2024

Dear Joseph Basore:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S
Digitally signed by Bryan M. Grabias -S
Date: 2024.12.19 12:29:18 -05'00'

Bryan Grabias, Ph. D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243725

Device Name
BD Vaginal Panel; BD MAX™ Vaginal Panel

Indications for Use *(Describe)*
The BD Vaginal Panel is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), Candida species associated with vulvovaginal candidiasis, and/or Trichomonas vaginalis. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- Bacterial vaginosis (BV) markers (Individual markers are not reported)
  - o Lactobacillus spp. (L. crispatus and L. jensenii)
  - o Gardnerella vaginalis
  - o Atopobium vaginae
  - o Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
  - o Megasphaera-1
- Vulvovaginal candidiasis (VVC) markers (Markers are reported in the following groups)
  - o Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis)
  - o Candida glabrata
  - o Candida krusei
- Trichomonas vaginalis (TV)

The assay may be used to detect DNA associated with BV, VVC, and TV, or a subset of these conditions per clinician order, in vaginal swab specimens collected from patients who are symptomatic for vaginitis/vaginosis. The BD Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.

The BD Vaginal Panel is available for use with the BD MAX™ System or the BD COR™ System.

The BD MAX™ Vaginal Panel performed on the BD MAX™ System is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and of targeted organism markers), Candida species associated with vulvovaginal candidiasis, and/or Trichomonas vaginalis. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- Bacterial vaginosis markers (Individual markers not reported)
  - o Lactobacillus spp. (L. crispatus and L. jensenii)
  - o Gardnerella vaginalis
  - o Atopobium vaginae
  - o Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
  - o Megasphaera-1
- Vulvovaginal candidiasis (VVC) markers (markers are reported in the following groups)
  - o Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C.dubliniensis)
  - o Candida glabrata
  - o Candida krusei

• Trichomonas vaginalis (TV)

The assay may be used to detect BV, VVC, and/or TV, or a subset of these conditions per clinician order, in vaginal swab specimens collected from patients who are symptomatic for vaginitis/vaginosis. The BD MAX™ Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

BD Vaginal Panel

Summary Preparation Date:

11/22/2024

Submitted by:

BD Diagnostic Solutions
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Joseph Basore, Ph.D., RAC
Staff Regulatory Affairs Specialist
Tel: 616-301-4068
Email: Joseph.Basore@bd.com

Proprietary Names:

For the instrument: BD COR™ System, BD MAX™ System

For the assay: BD Vaginal Panel, BD MAX™ Vaginal Panel

Common Names:

For the instrument: High-throughput molecular system

For the assay: Bacterial Vaginosis Assay
Vaginitis Assay
TV Assay
Candida Assay

Regulatory Information

Regulation section: 21 CFR 866.3975 – Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis

Classification: Class II (Special Controls)

Panel: Microbiology (83)

Product Code(s):

PQA Vaginitis and Bacterial Vaginosis Nucleic Acid Detection System
OUY *Trichomonas vaginalis* Nucleic Acid Amplification Test System
OOI Real Time Nucleic Acid Amplification System
NSU Instrumentation for Clinical Multiplex Test Systems

Predicate Device

BD Vaginal Panel (DEN160001, K191957, K201017, K223653)

Device Establishment

Registration Number: 1119779

Intended Use

BD Vaginal Panel (For use with BD COR™ System)

The BD Vaginal Panel is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), *Candida* species associated with vulvovaginal candidiasis, and/or *Trichomonas vaginalis*. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- Bacterial vaginosis (BV) markers (Individual markers are not reported)
  - *Lactobacillus spp. (L. crispatus and L. jensenii)*
  - *Gardnerella vaginalis*
  - *Atopobium vaginae*
  - *Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)*
  - *Megasphaera-1*
- Vulvovaginal candidiasis (VVC) markers (Markers are reported in the following groups)
  - *Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis)*
  - *Candida glabrata*
  - *Candida krusei*
- *Trichomonas vaginalis* (TV)

The assay may be used to detect DNA associated with BV, VVC, and TV, or a subset of these conditions per clinician order, in vaginal swab specimens collected from patients who are symptomatic for vaginitis/vaginosis. The BD Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.

The BD Vaginal Panel is available for use with the BD MAX™ System or the BD COR™ System.

BD MAX™ Vaginal Panel

The BD MAX™ Vaginal Panel performed on the BD MAX™ System is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and of targeted organism markers), *Candida* species associated with vulvovaginal candidiasis, and/or *Trichomonas vaginalis*. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- Bacterial vaginosis (BV) markers (Individual markers are not reported)
    - *Lactobacillus* spp. (*L. crispatus* and *L. jensenii*)
    - *Gardnerella vaginalis*
    - *Atopobium vaginae*
    - Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
    - *Megasphaera-1*
- Vulvovaginal candidiasis (VVC) markers (Markers are reported in the following groups)
    - *Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C.dubliniensis)*
    - *Candida glabrata*
    - *Candida krusei*
- *Trichomonas vaginalis*

The assay may be used to detect DNA associated with BV, VVC, and TV, or a subset of these conditions per clinician order, in vaginal swab specimens collected from patients who are symptomatic for vaginitis/vaginosis. The BD MAX™ Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: BD COR™ System, BD MAX™ System

Device Description

The BD Vaginal Panel is an automated, qualitative *in vitro* diagnostic test for bacterial vaginosis markers, *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis*. From a single specimen, a vaginal swab collected from a patient who is symptomatic for vaginitis or vaginosis, the test provides qualitative (positive/negative) results for the presence of the following conditions and/or organisms:

- Bacterial vaginosis (based on detection of *Lactobacillus* spp. (*L. crispatus* and *L. jensenii*), *Gardnerella vaginalis, Atopobium vaginae*, Bacterial Vaginosis Associated Bacteria-2, and *Megasphaera*-1)
- *Candida* spp. (*C. albicans, c. tropicalis, C. parapsilosis,* and *C. dubliniensis*)
- *Candida glabrata*
- *Candida krusei*
- *Trichomonas vaginalis*

The BD Vaginal Panel is available for use with the BD MAX™ System or the BD COR™ System under the trade names BD MAX™ Vaginal Panel and BD Vaginal Panel, respectively. The assay previously provided results for all five targets for every specimen run, regardless of whether the ordering clinician desires evaluation of all reported conditions. After clearance of this 510(k) submission, BD will release updates to the BD MAX™ and BD COR ™ software to allow users the versatility to mask results, per specimen, based on the order received from the clinician. This change allows a laboratory to use the BD Vaginal Panel to test a specimen for an individual target group (BV, VVC, or TV) or any two of the three targeted conditions, in addition to the current configuration that reports all three conditions simultaneously.

Test Principle

The BD Vaginal Panel is designed for use with the BD Molecular Swab Collection Kit. Samples are transported to the testing laboratory in Sample Buffer Tubes. The Sample Buffer Tubes are vortexed to release cells from the swab into the buffer, after which they are loaded on the BD MAX™ System or the BD COR™ System, along with instrument-specific consumables. No further operator intervention is necessary, and the following automated procedures occur. The bacterial cells are lysed, and DNA is extracted, captured, and concentrated on magnetic beads. After an elution step, the DNA solution is added to reagents containing specific primers and probes used to amplify and detect the genetic targets if present. After reconstitution, the instrument dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the PCR Cartridge. Microvalves in the cartridge are sealed by the system prior to initiating PCR to contain the amplification mixture and thus prevent evaporation and contamination. Upon amplification, signal detection and interpretation are performed automatically by the instrument using real time PCR. The Extraction reagent includes a Sample Processing Control, which monitors the integrity of the reagents as well as the process steps involved in DNA extraction, amplification, and detection, and checks for the presence of potential assay inhibitors.

The amplified DNA targets are detected using hydrolysis (TaqMan®) probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end, with a quencher moiety.

Probes labeled with different fluorophores are used to detect the target analytes in different optical channels of the instrument. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'-3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The amount of fluorescence detected in the optical channels used for the BD Vaginal Panel is directly proportional to the quantity of the corresponding probe that is hydrolyzed. The instrument monitors these signals at each cycle of the PCR and interprets the data at the end of the reaction to provide qualitative test results for each analyte (i.e., positive or negative).

The BD Vaginal Panel is divided into two Master Mixes, as described below.

- The **Vaginitis** Master Mix contains reagents for detection of the following targets:
  - *Candida* spp (*C. albicans, C. tropicalis, C. parapsilosis* and *C. dubliniensis*)
  - *Candida glabrata*
  - *Candida krusei*
  - *Trichomonas vaginalis*
- The **Vaginosis** Master Mix contains reagents for detection of the following bacterial vaginosis markers:
  - *Gardnerella vaginalis*
  - *Lactobacillus* crispatus and *Lactobacillus jensenii*
  - *Atopobium vaginae*
  - Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
  - *Megasphaera*-1

Substantial Equivalence[1]

Table 1 provides the similarities and differences between the submitted device and the legally marketed predicate device.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1: Comparison to Predicate Device

Items	Predicate - BD Vaginal Panel (K223653)	Subject -BD MAX Vaginal Panel	Subject – BD Vaginal Panel (For use with BD COR™ System)
Regulation	866.3975	Same	Same
Product Code	PQA, OUY, OOI, NSU	Same	Same
Device Class	II	Same	Same
Intended Use	The BD Vaginal Panel is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis* from vaginal swabs in patients who are symptomatic for vaginitis/vaginosis. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from: • Bacterial vaginosis markers (Individual markers not reported) o *Lactobacillus* spp. (*L. crispatus* and *L. jensenii*) o *Gardnerella vaginalis* o *Atopobium vaginae* o Bacterial Vaginosis Associated Bacteria-2 (BVAB-2) o *Megasphaera-1*	The BD MAX™ Vaginal Panel performed on the BD MAX™ System is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and of targeted organism markers), *Candida* species associated with vulvovaginal candidiasis, and/or *Trichomonas vaginalis*. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from: • Bacterial vaginosis (BV) markers (Individual markers are not reported) o *Lactobacillus* spp. (*L. crispatus* and *L. jensenii*) o *Gardnerella vaginalis* o *Atopobium vaginae* o Bacterial Vaginosis Associated Bacteria-2 (BVAB-2) o *Megasphaera-1*	The BD Vaginal Panel is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), *Candida* species associated with vulvovaginal candidiasis, and/or *Trichomonas vaginalis*. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from: • Bacterial vaginosis (BV) markers (Individual markers are not reported) o *Lactobacillus* spp. (*L. crispatus* and *L. jensenii*) o *Gardnerella vaginalis* o *Atopobium vaginae* o Bacterial Vaginosis Associated Bacteria-2 (BVAB-2) o *Megasphaera-1*

Items	Predicate - BD Vaginal Panel (K223653)	Subject -BD MAX Vaginal Panel	Subject – BD Vaginal Panel (For use with BD COR™ System)

	• *Candida* spp. (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*)
	• *Candida glabrata*
	• *Candida krusei*
	• *Trichomonas vaginalis*
	
	The BD Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.
	
	The BD Vaginal Panel is available for use with the BD MAX™ System or the BD COR™ System.
		• Vulvovaginal candidiasis (VVC) markers (markers are reported in the following groups)
		  ○ *Candida* spp. (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C.dubliniensis*)
		  ○ *Candida glabrata*
		  ○ *Candida krusei*
		• *Trichomonas vaginalis* (TV)
		
		The assay may be used to detect BV, VVC, and/or TV, or a subset of these conditions per clinician order, in vaginal swab specimens collected from patients who are symptomatic for vaginitis/vaginosis. The BD MAX™ Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.
			• Vulvovaginal candidiasis (VVC) markers (Markers are reported in the following groups)
			  ○ *Candida* spp. (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*)
			  ○ *Candida glabrata*
			  ○ *Candida krusei*
			• *Trichomonas vaginalis* (TV)
			
			The assay may be used to detect DNA associated with BV, VVC, and TV, or a subset of these conditions per clinician order, in vaginal swab specimens collected from patients who are symptomatic for vaginitis/vaginosis. The BD Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.
			
			The BD Vaginal Panel is available for use with the BD MAX™ System or the BD COR™ System.

Indications for Use	Symptomatic patients	Same	Same
Specimen Type	Clinician and patient-collected female vaginal swab	Same	Same
Collection/ Transport Device	BD Molecular Swab Collection Kit	Same	Same
Technology	PCR	Same	Same

<table>
<tr><th>Items</th><th>Predicate - BD Vaginal Panel (K223653)</th><th>Subject -BD MAX Vaginal Panel</th><th>Subject – BD Vaginal Panel (For use with BD COR™ System)</th></tr>
<tr><td>Organisms Detected</td><td>Lactobacillus spp. (L. crispatus and L.jensenii)
Gardnerella vaginalis
Atopobium vaginae
Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
Megasphaera-1
Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis)
Candida glabrata
Candida krusei
Trichomonas vaginalis</td><td>Same</td><td>Same</td></tr>
<tr><td>Sample Prep/ Results</td><td>BD MAX™ System or BD COR™ System</td><td>BD MAX™ System</td><td>BD COR™ System</td></tr>
<tr><td>Assay Controls</td><td>Sample Processing Control</td><td>Same</td><td>Same</td></tr>
<tr><td>Target Detection</td><td><table><tr><td rowspan="2">Channels – Dyes</td><td colspan="2">Targets</td></tr><tr><td>Vaginitis MM</td><td>Vaginosis MM</td></tr><tr><td>ROX</td><td>Candida group[1]</td><td>Lactobacillus crispatus/ jensenii</td></tr><tr><td>FAM</td><td>Trichomonas vaginalis</td><td>Atopobium vaginae</td></tr><tr><td>VIC – Cal Fluor Orange 560</td><td>Candida glabrata</td><td>Megasphaera-1/ BVAB-2</td></tr></table></td><td>Same</td><td>Same</td></tr>
</table>

<table>
<tr><th>Items</th><th>Predicate - BD Vaginal Panel (K223653)</th><th>Subject -BD MAX Vaginal Panel</th><th>Subject – BD Vaginal Panel (For use with BD COR™ System)</th></tr>
<tr><td></td><td><table><tr><td>Cy5 – Quasar 670</td><td>Candida krusei</td><td>Gardnerella vaginalis</td></tr><tr><td>Cy5.5 – Quasar 705</td><td>SPC</td><td>SPC</td></tr></table>
[1]Candida group includes: C. albicans, C. parapsilosis, C. tropicalis, and C. dubliniensis</td><td></td><td></td></tr>
<tr><td>Extraction</td><td>Magnetic affinity beads with lyticase</td><td>Same</td><td>Same</td></tr>
<tr><td>On-board lysis</td><td>On-board lysis of all specimens</td><td>Same</td><td>Same</td></tr>
<tr><td>Results Metric</td><td>Ct score, SDPA, cycEP</td><td>Same</td><td>Same</td></tr>
<tr><td>Results on BD COR™ or BD MAX™ System</td><td><table><tr><th>Assay Result Reported</th><th>Result</th></tr><tr><td>TV POS</td><td>Trichomonas vaginalis DNA Detected</td></tr><tr><td>TV NEG</td><td>No Trichomonas vaginalis DNA Detected</td></tr><tr><td>TV UNR</td><td>Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification</td></tr></table></td><td>Same</td><td>Same</td></tr>
</table>

Items	Predicate - BD Vaginal Panel (K223653)		Subject -BD MAX Vaginal Panel	Subject – BD Vaginal Panel (For use with BD COR™ System)
	Cgroup POS	*Candida* group DNA Detected (*C. albicans* and/or *C. tropicalis* and/or *C. parapsilosis* and/or *C. dubliniensis*)		
	Cgroup NEG	No *Candida* group DNA Detected (No *C. albicans, C. tropicalis, C. parapsilosis,* or *C. dubliniensis*)		
	Cgroup UNR	Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification		
	Cgla POS	*Candida glabrata* DNA Detected		
	Cgla NEG	No *Candida glabrata* DNA Detected		
	Cgla UNR	Unresolved – inhibitory sample or reagent failure; no target or		

Items	Predicate - BD Vaginal Panel (K223653)		Subject -BD MAX Vaginal Panel	Subject – BD Vaginal Panel (For use with BD COR™ System)
		Sample Processing Control amplification		
	Ckru POS	*Candida krusei* DNA Detected		
	Ckru NEG	No *Candida krusei* DNA Detected		
	Ckru UNR	Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification		
	BV POS	Vaginosis Panel DNA detected. (Detection of marker combinations related to bacterial vaginosis: *Gardnerella vaginalis,* and/or *L. crispatus,* and/or *L. jensenii,* and/or *Atopobium vaginae,* and/or BVAB-2, and/or *Megasphaera-1)*		
	BV NEG	Detection of marker combinations related to normal vaginal flora		

Items	Predicate - BD Vaginal Panel (K223653)		Subject -BD MAX Vaginal Panel	Subject – BD Vaginal Panel (For use with BD COR™ System)
	BV UNR	Unresolved – inhibitory sample or reagent failure; no target or Sample Processing Control amplification		
	IND	Indeterminate result due to BD MAX™ System failure (with error or alert messages)		
	INC	Incomplete Run (with error or alert messages)		
Results Reported	For all specimens: 1. BV + TV + VVC		One of the following, based on clinician order: 1. BV + TV + VVC 2. BV + TV 3. BV + VVC 4. TV + VVC 5. BV 6. TV 7. VVC	One of the following, based on clinician order: 1. BV + TV + VVC 2. BV + TV 3. BV + VVC 4. TV + VVC 5. BV 6. TV 7. VVC

Analytical and Clinical Performance

The clinical utility of the Vaginal Panel is unchanged from the clinical utility described in DEN160001. BD has determined that introducing the capability to order a subset of the conditions evaluated by the Vaginal Panel while masking the results for those conditions that are not ordered has no clinical impact. Currently, the BD Vaginal Panel tests for all three common causes of vaginitis / vaginosis (BV, VVC, and TV). Enabling the assay to report results for only a subset of the conditions does not change the specimen type, the test conditions, or the logic that is used to determine whether a specimen is positive or negative for the associated condition; conditions that are *not* ordered are simply not reported to the user. The three conditions are biologically distinct – bacterial infection, fungal infection, and a protozoan parasite; each condition has no bearing on the other, despite resulting in very similar symptoms. Therefore, analytical and clinical performance of the assays is not impacted.