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

March 6, 2023

Re: K223653
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: December 5, 2022
Received: December 6, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
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)*
K223653

Device Name
BD 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 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)
  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

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.

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.

510(k) Summary

BD Vaginal Panel

Summary Preparation Date:

12/5/2022

Submitted by:

BD Integrated 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™ PX/MX System

For the assay: BD 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 MAX Vaginal Panel (DEN160001, K191957, K201017)

Device Establishment

Registration Number: 1119779

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)
  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*

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.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: BD COR™ PX/MX System

Device Description
As with the existing BD Vaginal Panel for use with the BD MAX™ System (K201017), the BD COR™ PX/MX (BD COR) high throughput system conducts sample extraction steps to isolate and concentrate DNA which is then amplified to detect specific sequences for diagnostic purposes.

The BD COR™ System is designed to allow the user to place clinical specimens directly into designated transport racks to be loaded into the System. Once the specimens are loaded, the System will perform the necessary pre-analytical steps such as vortexing, aliquoting into a molecular tube with the

correct diluent, sorting/grouping of the secondary samples for testing by assay, pre-warming and cooling of the sample (where required), and transport of the sample into a molecular analyzer, where extraction, amplification and detection will take place.

Additionally, the steps of ordering tests on the instrument for specific samples will be managed directly by the user interaction with the Laboratory Information System (LIS), which communicates directly with the instrument.

Once the clinical specimens are received in the laboratory and loaded into the transport racks, the user will not be required to directly handle the specimen again prior to result reporting and removal from the system.

Test Principle

The BD Vaginal Panel when performed on the BD COR™ System is designed for use with the BD Molecular Swab Collection kit. Samples are transported to the testing laboratory in BD Molecular Swab Sample Buffer Tubes. The BD COR™ MX Instrument, when combined with the BD COR™ PX Instrument, is to be used for automated sample preparation, extraction and purification of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based real-time PCR.

The BD Vaginal Panel extraction reagents are dried in 96-well microtiter plates that contain binding magnetic affinity beads and Sample Processing Control (SPC). Each well is capable of binding and eluting sample nucleic acids. The SPC monitors the integrity of the reagents and the process steps involved in DNA extraction, amplification and detection, as well as for the presence of potential assay inhibitors.

The BD Vaginal Panel liquid reagent plate includes Wash, Elution and Neutralization buffers. The beads (described above), together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH. Eluted DNA is neutralized and transferred to the Amplification reagent (described below) to rehydrate the PCR reagents. After reconstitution, the BD COR™ PX/MX System dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the BD PCR Cartridge.

Microvalves in the BD PCR Cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture and thus prevent evaporation and contamination. 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 BD COR™ PX/MX System. 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 BD COR™ PX/MX System 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 vaginitis analyte as well as qualitative results for bacterial vaginosis based on detection and quantitation of targeted bacterial vaginosis markers.

Substantial Equivalence[1]

[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 3 provides the similarities and differences between the submitted device and the legally marketed predicate device.

Table 1: Comparison to Predicate Device

Items	BD Vaginal Panel	Predicate - BD MAX™ Vaginal Panel, BD MAX™ System (K201017)
Regulation	Same	866.3975
Product Code	Same	PQA, OUY, OOI, NSU
Device Class	Same	II
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) *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* The BD Vaginal Panel is intended to aid in the diagnosis of vaginal infections in	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 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) *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*

Items	BD Vaginal Panel	Predicate - BD MAX™ Vaginal Panel, BD MAX™ System (K201017)
	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 is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.
Indications for Use	Same	Symptomatic patients
Specimen Type	Same	Clinician and patient-collected female vaginal swab
Collection/ Transport Device	BD Molecular Swab Collection Kit	BD MAX UVE Specimen Collection Kit BD Molecular Swab Collection Kit
Technology	Same	PCR
Organisms Detected	Same	• *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*
Sample Prep/Results	Automated by BD COR™ System	Partially Automated by BD MAX™ System
Assay Controls	Same	Sample Processing Control

Analytical Performance

Analytical performance of the BD Vaginal Panel was evaluated on the BD MAX™ System and the results may be found under DEN160001 with updates described in subsequent submissions K191957 and K201017. As the formulation of the BD Vaginal Panel reagents for use on the BD COR™ System has not changed from those used with the BD MAX™ System, certain analytical studies performed and documented in the package insert on BD MAX™ are equally applicable to the BD COR™ System (specimen stability, analytical sensitivity, inclusivity, cross-reactivity, and interfering substances). The following sections describe the analytical studies that were performed to demonstrate that the assay performance, when used on

the BD COR™ System, is unchanged from the performance demonstrated on the BD MAX™ System. The new analytical studies included: within-laboratory precision and multi-site reproducibility, confirmation of the analytical sensitivity and a cross-contamination study, all performed on the BD COR™ System.

Precision for BD COR™ System

The precision of the BD Vaginal Panel on the BD COR™ System was confirmed to be equivalent to that of the BD MAX™ System. Within-laboratory precision was evaluated for the BD Vaginal Panel on both the BD MAX™ System and the BD COR™ System at one site with one reagent lot. Testing was performed over twelve (12) days, two (2) runs per day, two (2) replicates per panel, for a total of 48 runs. Panel members were made of target organisms (or plasmid DNA for *Megasphaera-1* and BVAB-2) spiked in simulated vaginal matrix. Bacterial vaginosis panel members were prepared at varying concentrations of multiple targeted species with sample compositions designed to generate low positive, moderate positive, high negative, or negative results for bacterial vaginosis. For *Candida* and *Trichomonas vaginalis* panel members, the target organisms were spiked at concentrations based on the assay LoD. Table 4 describes the panel members evaluated.

The qualitative and quantitative precision results for BD COR™ System are presented in Table 5. Second Derivative Peak Abscissa (SDPA), an internal criterion used to determine a final assay result, was selected as a means of assessing quantitative assay reproducibility. Mean SDPA values with variance components (SD and % CV) are shown in Table 6 and Table 7.

Table 2: Precision Study Spiking Concentrations

Concentration Designation	Bacterial Vaginosis (% of positive results expected based on the organism composition)	*Candida and Trichomonas vaginalis* (x LoD)
Moderate Positive	~100	≥2 to ≤5
Low Positive	~95	<2
High BV Negative	~20–80	
BV Negative	~5	
True Negative	0 (No Target)	No Target

Table 3: Qualitative Precision Study Results Summary for Vaginosis and Vaginitis Targets for BD COR™ and BD MAX™ Systems

Target	Level	BD COR™					BD MAX™				
		N Total	N Correct	% Correct	95% CI		N Total	N Correct	%Correct	95% CI	
					LCL	UCL				LCL	UCL
Bacterial Vaginosis	True Negative[a]	288	288	100	98.7	100	288	288	100	98.7	100
	BV Negative[a]	48	48	100	92.6	100	48	48	100	92.6	100
	BV High Negative[b,d]	192	153	79.7	73.4	84.8	192	168	87.5	82.1	91.5
	Low Positive[c]	288	285	99.0	97.0	99.6	288	288	100	98.7	100
	Moderate Positive[d]	192	191	99.5	97.1	99.9	192	192	100	98.0	100
Candida glabrata	True Negative[a]	720	720	100	99.5	100	720	719	99.9	99.2	100
	Low Positive	48	48	100	92.6	100	48	48	100	92.6	100
Candida krusei	True Negative[a]	720	720	100	99.5	100	720	720	100	99.5	100
	Low Positive	48	48	100	92.6	100	48	48	100	92.6	100
Candida albicans	True Negative[a]	720	720	100	99.5	100	720	718	99.7	99.0	99
	Low Positive	48	48	100	92.6	100	48	48	100	92.6	100
	Moderate Positive	48	48	100	92.6	100	48	48	100	92.6	100
Trichomonas vaginalis	True Negative[a]	720	720	100	99.5	100	720	719	99.9	99.2	100
	Low Positive	48	48	100	92.6	100	48	48	100	92.6	100
	Moderate Positive	48	48	100	92.6	100	48	48	100	92.6	100

[a] For the True Negative and BV Negative levels, the reported agreement indicates the percent of negative results.

[b] For the High Negative category, the reported agreement indicates the percent of positive results.

[c] Performance includes combined results from replicates of six panel members containing different organism compositions.

[d] Performance includes combined results from replicates of four panel members containing different organism compositions.

Table 4: Quantitative Precision Summary of Variance Components by Vaginitis Target for BD COR™ System

				Within Run (Residual)		Run		Day		Total	
Target	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Candida glabrata	Low Positive	48	30.88	0.83	2.68	1.00	3.23	0	0	1.30	4.20
Candida krusei	Low Positive	48	28.87	0.23	0.79	0.13	0.45	0	0	0.26	0.91
Candida albicans	Low Positive	48	27.84	0.26	0.94	0	0	0.10	0.35	0.28	1.00
	Moderate Positive	48	27.12	0.20	0.75	0.09	0.32	0	0	0.22	0.82
Trichomonas vaginalis	Low Positive	48	32.70	0.34	1.04	0.20	0.60	0	0	0.39	1.20
	Moderate Positive	48	31.63	0.30	0.96	0.05	0.15	0	0	0.31	0.98

Table 5: Quantitative Precision Summary of Variance Components by Vaginitis Target for BD MAX™ System

				Within Run (Residual)		Run		Day		Total	
Target	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Candida glabrata	Low Positive	48	31.33	0.88	2.81	0.73	2.34	0.36	1.15	1.20	3.83
Candida krusei	Low Positive	48	28.87	0.32	1.11	0.16	0.56	0.17	0.58	0.40	1.37
Candida albicans	Low Positive	48	28.24	0.25	0.90	0.09	0.33	0	0	0.27	0.96
	Moderate Positive	48	27.26	0.26	0.95	0	0	0.17	0.62	0.31	1.14
Trichomonas vaginalis	Low Positive	48	32.64	0.46	1.42	0	0	0	0	0.46	1.42
	Moderate Positive	48	31.63	0.24	0.76	0	0	0	0	0.24	0.76

Reproducibility for BD COR™ System

The reproducibility of the BD Vaginal Panel on the BD COR™ System was confirmed to be equivalent to that of the BD MAX™ System using the same sample categories as defined above for the precision study (Table 4). To evaluate the site-to-site reproducibility, testing was performed at 3 sites (2 external and 1 internal) over 8 days. At each site, 2 operators performed 2 runs on alternate days, for a total of 48 runs. Reproducibility results are summarized in Table 8.

The qualitative and quantitative reproducibility results across sites and by target are presented in Table 9. Second Derivative Peak Abscissa (SDPA), an internal criterion used to determine a final assay result, was selected as a means of assessing quantitative assay reproducibility. Mean SDPA values with variance components (SD and % CV) for BD COR™ System are shown in Table 10 and Table 11.

Table 6: Qualitative Reproducibility by Target and Site for BD COR™ System and BD MAX™ System

				BD COR™				BD MAX™			
Target	Level	Test Site	N Total	N Correct	%Correct	95% CI		N Correct	% Correct	95% CI	
						LCL	UCL			LCL	UCL
Bacterial Vaginosis	True Negative[a]	1	192	192	100	98.0	100	192	100	98.0	100
		2	192	192	100	98.0	100	192	100	98.0	100
		3	192	192	100	98.0	100	192	100	98.0	100
		Overall	576	576	100	99.3	100	576	100	99.3	100
	BV Negative[a]	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
	BV High Negative[b,c]	1	32	25	78.1	61.2	89.0	13	40.6	25.5	57.7
		2	32	17	53.1	36.4	69.1	29	90.6	75.8	96.8
		3	32	28	87.5	71.9	95.0	30	93.8	79.9	98.3
		Overall	96	70	72.9	63.3	80.8	72	75.0	65.5	82.6
	Low Positive[d]	1	64	64	100	94.3	100	63	98.4	91.7	99.7
		2	64	64	100	94.3	100	62	96.9	89.3	99.1
		3	63	63	100	94.3	100	63	100	94.3	100
		Overall	191	191	100	98.0	100	188	98.4	95.5	99.5
	Moderate Positive[d]	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
Candida glabrata	True Negative[a]	1	160	160	100	97.7	100	160	100	97.7	100
		2	160	160	100	97.7	100	160	100	97.7	100
		3	159	159	100	97.6	100	155	97.5	93.7	99.0
		Overall	479	479	100	99.2	100	475	99.2	97.9	99.7
	Low Positive	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
Candida krusei	True Negative[a]	1	160	160	100	97.7	100	160	100	97.7	100
		2	160	160	100	97.7	100	160	100	97.7	100
		3	159	159	100	97.6	100	159	100	97.6	100
		Overall	479	479	100	99.2	100	479	100	99.2	100
	Low Positive	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
Candida albicans	True Negative[a]	1	160	160	100	97.7	100	160	100	97.7	100
		2	160	159	99.4	96.5	99.9	160	100	97.7	100
		3	159	158	99.4	96.5	99.9	156	98.1	94.6	99.4
		Overall	479	477	99.6	98.5	99.9	476	99.4	98.2	99.8
	Low Positive	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
		1	32	32	100	89.3	100	32	100	89.3	100

				BD COR™				BD MAX™			
Target	Level	Test Site	N Total	N Correct	%Correct	95% CI		N Correct	% Correct	95% CI	
						LCL	UCL			LCL	UCL
	Moderate Positive	2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
Trichomonas vaginalis	True Negative[a]	1	160	160	100	97.7	100	160	100	97.7	100
		2	160	160	100	97.7	100	160	100	97.7	100
		3	159	159	100	97.6	100	159	100	97.6	100
		Overall	479	479	100	99.2	100	479	100	99.2	100
	Low Positive	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100
	Moderate Positive	1	32	32	100	89.3	100	32	100	89.3	100
		2	32	32	100	89.3	100	32	100	89.3	100
		3	32	32	100	89.3	100	32	100	89.3	100
		Overall	96	96	100	96.2	100	96	100	96.2	100

[a] For the True Negative and BV Negative levels, the reported agreement indicates the percent of negative results.

[b] For the BV High Negative category, the reported agreement indicates the percent of positive results.

[c] Performance includes results from replicates of a single panel member.

[d] Performance includes combined results from replicates of two panel members containing different organism compositions.

Table 7: Quantitative Reproducibility Site-to-Site Summary by Vaginitis Target for BD COR™ System

				Within Run (Residual)		Between Run		Between Day		Between Site		Total	
Target	Level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Candida glabrata	Low Positive	96	30.30	0.53	1.76	0	0	0	0	0.26	0.87	0.59	1.96
Candida krusei	Low Positive	96	28.93	0.20	0.71	0.07	0.23	0	0	0	0	0.22	0.74
Candida albicans	Low Positive	96	26.69	0.38	1.44	0	0	0.16	0.59	0.07	0.25	0.42	1.57
	Moderate Positive	96	26.08	0.30	1.14	0.04	0.17	0.06	0.24	0.12	0.48	0.33	1.27
Trichomonas vaginalis	Low Positive	96	32.85	0.38	1.17	0	0	0	0	0.15	0.45	0.41	1.25
	Moderate Positive	96	31.66	0.30	0.93	0	0	0.04	0.13	0	0	0.30	0.94

Table 8: Quantitative Reproducibility Site-to-Site Summary by Vaginitis Target for BD MAX™ System

				Within Run (Residual)		Between Run		Between Day		Between Site		Total	
Target	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Candida glabrata	Low Positive	96	30.95	0.71	2.28	0	0	0.20	0.64	0.51	1.66	0.89	2.89
Candida krusei	Low Positive	96	29.09	0.42	1.44	0.15	0.53	0	0	0	0	0.45	1.54
Candida albicans	Low Positive	96	27.34	0.42	1.55	0.20	0.72	0	0	0	0	0.47	1.71
	Moderate Positive	96	26.49	0.42	1.59	0	0	0.05	0.18	0	0	0.43	1.60
Trichomonas vaginalis	Low Positive	96	32.73	0.46	1.40	0	0	0.21	0.65	0.24	0.73	0.56	1.71
	Moderate Positive	96	31.69	0.42	1.31	0	0	0	0	0.08	0.25	0.42	1.34

Quality Controls

External Control materials are not provided by BD; however, Quality Control procedures are included in the package insert. Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program:

- Commercially available positive control materials
- *Trichomonas vaginalis* (ATCC 30001)
- *Candida albicans* (ATCC 10231)
- *Candida glabrata* (ATCC 2001)
- *Candida krusei* (ATCC 6258)

The assay includes a Specimen Processing Control (SPC) that is present in the Extraction Tube. The SPC monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances.

Analytical Sensitivity Confirmation for BD COR™ System

The analytical sensitivity/Limit of Detection (LoD) of the BD Vaginal Panel on the BD COR™ System was confirmed to be equivalent to that of the BD MAX System with use of the BD Molecular Swab Collection Kit. The study design included using 20 panels of Vaginosis and/or Vaginitis targets at varying concentration levels created using the LoD previously determined on the BD MAX™ System at the target levels identified in Table 11. Samples were prepared by spiking of representative vaginosis target and/or vaginitis target in the presence of simulated vaginal matrix (SVM). Testing was conducted over more than 3 days using qualified BD Vaginal Panel reagents and included two BD COR™ PX/MX Systems and four BD MAX™ Systems.

A Two, One-Sided Test (TOST) of Equivalence was performed for the low positive (1.99x LoD) and moderate positive (5x LoD) target levels for each strain. The 90% confidence intervals for the difference in mean Ct.score between the BD COR™ System and BD MAX™ Systems were determined for each strain at each target level. Equivalence of the two systems is established when it is contained within the equivalence margin of [-6% of the reference mean, +6% of the reference mean]. TOST analysis was not performed on High Negative (C5) *Candida spp*. panel members based on the proportion positivity being less than 95% at C5, a predicate requirement. SDPA and 95% confidence intervals were

generated. Equivalence between the BD COR™ System and BD MAX™ Systems is demonstrated at the High Negative level by overlapping 95% confidence intervals.

Results from the study demonstrate that the analytical sensitivity of the BD Vaginal Panel on BD COR™ is equivalent to the analytical sensitivity (LoD) demonstrated on the BD MAX™ System as shown in Table 12 and Table 13.

Table 9: Analytical Sensitivity Confirmation Panel Members

Low Positive (1.99x C95)			Moderate Positive (5x C95)			High Negative (C5)		
Panel	Target	Concentration	Panel	Target	Concentration	Panel	Target	Concentration
1	Cgla	402 CFU/mL	8	Cgla	1010 CFU/mL	15	Cgla	10 CFU/mL
2	GV	1914 CFU/mL	9	GV	4810 CFU/mL	16	Ckru	6 CFU/mL
	Ckru	2060 CFU/mL		Ckru	5175 CFU/mL			
3	BVAB	923 Copies/mL	10	BVAB	2320 Copies/mL	17	Calb	53 CFU/mL
	Calb	35396 CFU/mL		Calb	88935 CFU/mL			
4	Mega	4507 Copies/mL	11	Mega	11325 Copies/mL	18	Cpara	399 CFU/mL
	Cpara	61013 CFU/mL		Cpara	153300 CFU/mL			
5	Ljens	1015 CFU/mL	12	Ljens	2550 CFU/mL	19	Cdub	52 CFU/mL
	Cdub	7964 CFU/mL		Cdub	20010 CFU/mL			
6	Lcrisp	109 CFU/mL	13	Lcrisp	275 CFU/mL	20	Ctrop	16 CFU/mL
	Ctrop	623 CFU/mL		Ctrop	1565 CFU/mL			
7	Ato	253 CFU/mL	14	Ato	635 CFU/mL			
	TV	44 Cells/mL		TV	110 Cells/mL			

Table 10: Analytical Sensitivity Confirmation in Vaginal Swab for BD COR™ System for the Vaginosis Targets

Target	Target Level	System	N	Proportion Positivity	Mean Ct.Score	Difference in Mean Ct.Score [COR - MAX] and 90% CI	Equivalence Interval	Equivalence Established
Atopobium vaginae	Low Positive	COR	48	100%	26.23	0.21 (0.11, 0.31)	(-1.56, 1.56)	Yes
		MAX	48	100%	26.02			
	Moderate Positive	COR	48	100%	25.02	0.12 (-0.02, 0.26)	(-1.49, 1.49)	Yes
		MAX	48	100%	24.90			
BVAB-2*	Low Positive	COR	48	100%	29.79	0.19 (0.06, 0.33)	(-1.78, 1.78)	Yes
		MAX	48	100%	29.60			
	Moderate Positive	COR	48	100%	28.52	0.21 (0.10, 0.32)	(-1.70, 1.70)	Yes
		MAX	48	100%	28.31			
Megasphaera*	Low Positive	COR	48	98%	30.35	0.34 (0.15, 0.52)	(-1.80, 1.80)	Yes
		MAX	48	100%	30.01			
	Moderate Positive	COR	48	100%	29.18	0.27 (0.13, 0.41)	(-1.73, 1.73)	Yes
		MAX	48	100%	28.91			
Gardnerella vaginallis	Low Positive	COR	48	100%	28.69	0.23 (0.12, 0.34)	(-1.71, 1.71)	Yes
		MAX	48	98%	28.45			
	Moderate	COR	48	100%	27.47	0.20	(-1.64, 1.64)	Yes

Target	Target Level	System	N	Proportion Positivity	Mean Ct.Score	Difference in Mean Ct.Score [COR - MAX] and 90% CI	Equivalence Interval	Equivalence Established
	Positive	MAX	48	100%	27.27	(0.10, 0.30)		
Lactobacillus jensenii	Low Positive	COR	48	100%	24.65	0.50 (0.39, 0.61)	(-1.45, 1.45)	Yes
		MAX	48	100%	24.15			
	Moderate Positive	COR	48	100%	23.41	0.48 (0.39, 0.57)	(-1.38, 1.38)	Yes
		MAX	48	100%	22.93			
Lactobacillus crispatus	Low Positive	COR	48	100%	26.52	0.40 (0.24, 0.56)	(-1.57, 1.57)	Yes
		MAX	48	100%	26.12			
	Moderate Positive	COR	48	100%	25.18	0.27 (0.15, 0.39)	(-1.49, 1.49)	Yes
		MAX	48	100%	24.91			

**BVAB and Megasheara on non-cultivatable organisms. Plasmids were used for the LoD confirmation study.*

Table 11: Analytical Sensitivity Confirmation in Vaginal Swab for BD COR™ System for the Vaginitis Targets

Target	Target Level	System	N	Proportion Positivity (95% CI for High Negatives)	Mean SDPA	Difference in Mean SDPA [COR - MAX] with 90% CI	Equivalence Interval	Equivalence Established
Trichomonas vaginalis	Low Positive	COR	48	100%	32.31	0.17 (0.06, 0.28)	(-1.93, 1.93)	Yes
		MAX	48	100%	32.14			
	Moderate Positive	COR	48	100%	31.34	-0.10 (-0.21, 0.01)	(-1.89, 1.89)	Yes
		MAX	48	100%	31.44			
Candida albicans	*High Negative	COR	48	90% (78%, 95%)	34.33			
		MAX	48	90% (78%, 95%)	34.30			
	Low Positive	COR	48	100%	27.75	0.15 (0.00, 0.29)	(-1.66, 1.66)	Yes
		MAX	48	100%	27.61			
	Moderate Positive	COR	48	100%	26.89	0.07 (-0.12, 0.26)	(-1.61, 1.61)	Yes
		MAX	48	100%	26.82			
Candida parapsilosis	*High Negative	COR	48	71% (57%, 82%)	35.39			
		MAX	48	67% (53%, 78%)	35.17			
	Low Positive	COR	48	100%	29.39	0.43 (0.21, 0.65)	(-1.74, 1.74)	Yes
		MAX	48	100%	28.96			
	Moderate Positive	COR	48	100%	28.15	0.31 (0.08, 0.53)	(-1.67, 1.67)	Yes
		MAX	48	100%	27.85			
Candida tropicalis	*High Negative	COR	48	85% (73%, 93%)	34.69			
		MAX	48	85% (73%, 93%)	34.45			
	Low Positive	COR	48	100%	30.83	0.28 (0.12, 0.44)	(-1.83, 1.83)	Yes
		MAX	48	100%	30.55			
	Moderate Positive	COR	48	100%	29.92	0.22	(-1.78, 1.78)	

Target	Target Level	System	N	Proportion Positivity (95% CI for High Negatives)	Mean SDPA	Difference in Mean SDPA [COR - MAX] with 90% CI	Equivalence Interval	Equivalence Established
		MAX	48	100%	29.70	(0.06, 0.37)		
Candida dubliniensis	*High Negative	COR	48	58% (44%, 71%)	34.20			
		MAX	48	65% (50%, 77%)	34.54			
	Low Positive	COR	48	100%	28.92	0.39	(-1.71, 1.71)	Yes
		MAX	48	100%	28.53	(0.19, 0.59)		
	Moderate Positive	COR	48	100%	27.66	0.22	(-1.65, 1.65)	Yes
		MAX	48	100%	27.43	(0.02, 0.43)		
Candida glabrata	*High Negative	COR	48	73% (59%, 83%)	36.04			
		MAX	48	69% (55%, 80%)	37.83			
	Low Positive	COR	48	100%	29.64	0.05	(-1.78, 1.78)	Yes
		MAX	48	100%	29.59	(-0.12, 0.22)		
	Moderate Positive	COR	48	100%	28.59	0.26	(-1.70, 1.70)	Yes
		MAX	48	100%	28.33	(0.12, 0.40)		
Candida krusei	*High Negative	COR	48	44% (31%, 58%)	36.48			
		MAX	48	54% (40%, 67%)	36.55			
	Low Positive	COR	48	100%	29.35	0.32	(-1.74, 1.74)	Yes
		MAX	48	100%	29.04	(0.14, 0.50)		
	Moderate Positive	COR	48	100%	28.17	0.28	(-1.67, 1.67)	Yes
		MAX	48	100%	27.89	(0.16, 0.40)		

*TOST analysis was not performed on High Negative Candida spp. (C5) panel members based on the proportion positivity being less than 95% at C5, a predicate requirement. Overlapping 95% confidence intervals between the both the BD MAX and COR platforms indicates equivalency at the High Negative level.

Cross-Contamination for BD COR™ System

A study was conducted to investigate cross-contamination while processing samples with high bacterial loads of BD Vaginal Panel targets. A panel made of alternating high positive and negative members was used at a prevalence of 50% high positive samples to simulate the most sensitive case for cross-contamination. In the high positive panel member, vaginosis markers were represented by a combination of *L. jensenii* (5.57E+07 CFU/mL), *G. vaginalis* (4.29E+07 CFU/mL), *A. vaginae* (1.65E+08 CFU/mL), and BVAB-2 (1.00E+09 copies/mL) while vaginitis targets were represented by *T. vaginalis* (8.0E+03 cells/mL). The negative member did not contain any target analytes. Of the 543 negative samples tested, 1 false positive result was observed, demonstrating a contamination rate of 0.18% (95% CI: 0.03- 1.04%), which met the predefined study acceptance criteria.

Clinical Agreement Study between BD MAX™ and BD COR™ Systems

The performance of the BD Vaginal Panel on the BD COR™ System was evaluated in a clinical agreement study by comparing the assay results obtained on the BD COR™ System to the results obtained on the BD MAX™ System. BD MAX™ results served as the reference in the clinical agreement study.

Clinical vaginal specimens obtained from both internal and external collections were used for this comparison study. Clinical panels were created by pooling the previously collected clinical specimens and, where necessary, spiking in a high positive clinical specimen or pooling positive specimens at specific Secondary Derivative Peak Abscissa (SDPAs) to reach the necessary analyte

level(s) for Cgroup and TV. In addition, contrived samples were created by spiking organisms into simulated matrix. For *C. glabrata* and *C. krusei*, contrived samples were created by spiking organisms into negative vaginal matrix or in simulated vaginal matrix because of their very low prevalence. For BV, contrived panel members with different BV marker combinations were prepared using simulated vaginal matrix. These samples are denoted as BV Contrived. Additionally, the Cgroup, TV, and negative vaginitis panel members in natural vaginal matrix were analyzed for BV targets. These samples are denoted as BV Natural.

The clinical agreement study included 700 panel members. The panel members were prepared so the majority of positive specimens for each analyte were at the low positive and moderate positive level. Three aliquots were prepared for each panel member. Each aliquot was tested on the BD COR™ System and BD MAX ™ System with the order of system testing randomized. Testing occurred at two external sites and one internal site.

To demonstrate that the performance of the BD Vaginal Panel on the BD COR™ System is equivalent to the performance on BD MAX™, both positive/negative percent agreement analysis and Deming regression analysis of the Ct.Score or SDPA values were performed. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) between the BD MAX™ and the BD COR™ Systems were calculated separately for each target. For each target, the PPA and NPA were calculated for each of the three sites where BD COR™ testing occurred, against composite comparator results where the positive or negative status of a panel member is defined by ≥2 out of 3 evaluable results obtained on the BD MAX™. PPA and NPA estimates were also averaged across the three BD COR™ testing sites. The PPA and NPA results as well as the corresponding 95% confidence interval at each BD COR™ testing site and the average across all three BD COR™ testing sites are summarized in Tables 14–19 for each target. The denominator for PPA and NPA calculations includes panel members with equivocal comparator results from BD MAX™, as indicated at the bottom of the tables. Equivocal BD MAX™ comparator result is defined as one positive, one negative, and one non-evaluable result from the BD MAX™.

The systematic differences in numeric value between Ct.Score or SDPA results from BD COR™ and BD MAX™ were evaluated by the Weighted Deming regression analysis based on the average Ct.Score or SDPA of BD COR™ results and the average Ct.Score or SDPA of BD MAX™ results of a given panel member across all corresponding testing sites. The results from the Deming regression analysis are provided in Figure 1 - Figure 4–4 for *C. albicans*, *C. glabrata*, *C. krusei*, and TV. Due to the aggregate BV result reporting, the Deming results are not provided for the Vaginosis targets (*Atopobium vaginae, Gardnerella vaginalis, Lactobacillus* spp., BVAB-2 and *Megasphera-1)*. The point estimate of intercept and slope as well as the corresponding 95% Confidence Interval of each Deming regression line are provided in Table 20. Additionally, the Weighted Deming regression bias estimate along with 95% confidence interval at different analyte levels are presented in Table 21.

Table 12: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for BV Contrived Specimens

Targeted Organism: BV Contrived		BD MAX™ Result	
BD COR™ Test Site	**BD COR™ Result**	**Positive**	**Negative**
1	Positive	72	0
	Negative	0	100
	Total	72	100
PPA: 100% (72/72); 95% CI: (94.9, 100) NPA: 100% (100/100); 95% CI: (96.3, 100) OPA: 100% (172/172); 95% CI: (97.8, 100) Number of non-evaluable samples: 0			
2	Positive	71	0
	Negative	1	100
	Total	72	100
PPA: 98.6% (71/72); 95% CI: (92.5, 99.8) NPA: 100% (100/100); 95% CI: (96.3, 100) OPA: 99.4% (171/172); 95% CI: (96.8, 99.9) Number of non-evaluable samples: 0			
3	Positive	72	0
	Negative	0	100
	Total	72	100
PPA: 100% (72/72); 95% CI: (94.9, 100) NPA: 100% (100/100); 95% CI: (96.3 100) OPA: 100% (172/172); 95% CI: (97.8, 100) Number of non-evaluable samples: 0			
Overall: Average PPA: 99.5%; Bootstrap 95% CI: (98.4, 100) Average NPA: 100%; Bootstrap 95% CI: N/A Average OPA: 99.8%; Bootstrap 95% CI: (99.3, 100) Average number of BD MAX™ equivocal results: 0 Note 1: Confidence intervals for point estimates at each site are calculated by a score method. Note 2: Confidence intervals for point estimates averaged over 3 sites are calculated by a bootstrap method.			

Table 13: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for BV Natural Specimens

Targeted Organism: BV Natural		BD MAX™ Result	
BD COR™ Test Site	**BD COR™ Result**	**Positive**	**Negative**
1	Positive	226	6
	Negative	6	114
	Total	232	120
PPA: 97.4% (226/232); 95% CI: (94.5, 98.8) NPA: 95.0% (114/120); 95% CI: (89.5, 97.7) OPA: 96.6% (340/352); 95% CI: (94.1, 98.0) Number of non-evaluable samples: 2			
2	Positive	228	4
	Negative	5	116
	Total	233	120
PPA: 97.9% (228/233); 95% CI: (95.1, 99.1) NPA: 96.7% (116/120); 95% CI: (91.7, 98.7) OPA: 97.5% (344/353); 95% CI: (95.2, 98.7) Number of non-evaluable samples: 1			
3	Positive	228	5
	Negative	4	113
	Total	232	118
PPA: 98.3% (228/232); 95% CI: (95.7, 99.3) NPA: 95.8% (113/118); 95% CI: (90.5, 98.2) OPA: 97.4% (341/350); 95% CI: (95.2, 98.6) Number of non-evaluable samples: 4			
Overall: Average PPA: 97.8%; Bootstrap 95% CI: (96.3, 99.1) Average NPA: 95.8%; Bootstrap 95% CI: (93.1, 98.2) Average OPA: 97.2%; Bootstrap 95% CI: (95.8, 98.4) Average number of BD MAX™ equivocal results: 0 Note 1: Confidence intervals for point estimates at each site are calculated by a score method. Note 2: Confidence intervals for point estimates averaged over 3 sites are calculated by a bootstrap method.			

Table 14: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for *C. glabrata*

Targeted Organism: C. glabrata		BD MAX™ Result	
BD COR™ Test Site	**BD COR™ Result**	**Positive**	**Negative**
1	Positive	58	0
	Negative	0	125
	Total	58	125
PPA: 100% (58/58); 95% CI: (93.8, 100) NPA: 100% (125/125); 95% CI: (97.0, 100) OPA: 100% (183/183); 95% CI: (97.9, 100) Number of non-evaluable samples: 1			
2	Positive	57	0
	Negative	0	125
	Total	57	125
PPA: 100% (57/57); 95% CI: (93.7, 100) NPA: 100% (125/125); 95% CI: (97.0, 100) OPA: 100% (182/182); 95% CI: (97.9, 100) Number of non-evaluable samples: 2			
3	Positive	57	0
	Negative	0	122
	Total	57	122
PPA: 100% (57/57); 95% CI: (93.7, 100) NPA: 100% (122/122); 95% CI: (96.9, 100) OPA: 100% (179/179); 95% CI: (97.9, 100) Number of non-evaluable samples: 5			
Overall: Average PPA: 100%; Bootstrap 95% CI: N/A Average NPA: 100%; Bootstrap 95% CI: N/A Average OPA: 100%; Bootstrap 95% CI: N/A Average number of BD MAX™ equivocal results: 0 Note 1: Confidence intervals for point estimates at each site are calculated by a score method. Note 2: Confidence intervals for point estimates averaged over 3 sites are calculated by a bootstrap method.			

Table 15: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for *C. krusei*

Targeted Organism: C. krusei		BD MAX™ Result	
BD COR™ Test Site	**BD COR™ Result**	**Positive**	**Negative**
1	Positive	50	0
	Negative	0	125
	Total	50	125
PPA: 100% (50/50); 95% CI: (92.9, 100) NPA: 100% (125/125); 95% CI: (97.0, 100) OPA: 100% (175/175); 95% CI: (97.9, 100) Number of non-evaluable samples: 2			
2	Positive	49	0
	Negative	0	125
	Total	49	125
PPA: 100% (49/49); 95% CI: (92.7, 100) NPA: 100% (125/125); 95% CI: (97.0, 100) OPA: 100% (174/174); 95% CI: (97.8, 100) Number of non-evaluable samples: 3			
3	Positive	51	0
	Negative	0	122
	Total	51	122
PPA: 100% (51/51); 95% CI: (93.0, 100) NPA: 100% (122/122); 95% CI: (96.9, 100) OPA: 100% (173/173); 95% CI: (97.8, 100) Number of non-evaluable samples: 4			
Overall: Average PPA: 100%; Bootstrap 95% CI: N/A Average NPA: 100%; Bootstrap 95% CI: N/A Average OPA: 100%; Bootstrap 95% CI: N/A Average number of BD MAX™ equivocal results: 0 Note 1: Confidence intervals for point estimates at each site are calculated by a score method. Note 2: Confidence intervals for point estimates averaged over 3 sites are calculated by a bootstrap method.			

Table 16: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for Cgroup

Targeted Organism: Candida Group		BD MAX™ Result	
BD COR™ Test Site	**BD COR™ Result**	**Positive**	**Negative**
1	Positive	115	1
	Negative	2	124
	Total	117	125
PPA: 98.3% (115/117); 95% CI: (94.0, 99.5) NPA: 99.2% (124/125); 95% CI: (95.6, 99.9) OPA: 98.8% (239/242); 95% CI: (96.4, 99.6) Number of non-evaluable samples: 2			
2	Positive	117	2
	Negative	0	123
	Total	117	125
PPA: 100% (117/117); 95% CI: (96.8, 100) NPA: 98.4% (123/125); 95% CI: (94.4, 99.6) OPA: 99.2% (240/242); 95% CI: (97.0, 99.8) Number of non-evaluable samples: 2			
3	Positive	118	1
	Negative	0	121
	Total	118	122
PPA: 100% (118/118); 95% CI: (96.8, 100) NPA: 99.2% (121/122); 95% CI: (95.5, 99.9) OPA: 99.6% (239/240); 95% CI: (97.7, 99.9) Number of non-evaluable samples: 4			
Overall: Average PPA: 99.4%; Bootstrap 95% CI: (98.5, 100) Average NPA: 98.9%; Bootstrap 95% CI: (97.4, 100) Average OPA: 99.2%; Bootstrap 95% CI: (98.3, 99.9) Average number of BD MAX™ equivocal results: 0 Note 1: Confidence intervals for point estimates at each site are calculated by a score method. Note 2: Confidence intervals for point estimates averaged over 3 sites are calculated by a bootstrap method.			

Table 17: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for TV

Targeted Organism: TV		BD MAX Result	
BD COR Test Site	**BD COR Result**	**Positive**	**Negative**
1	Positive	110	0
	Negative	0	125
	Total	110	125
PPA: 100% (110/110); 95% CI: (96.6, 100) NPA: 100% (125/125); 95% CI: (97.0, 100) OPA: 100% (235/235); 95% CI: (98.4, 100) Number of non-evaluable samples: 1			
2	Positive	109	0
	Negative	1	125
	Total	110	125
PPA: 99.1% (109/110); 95% CI: (95.0, 99.8) NPA: 100% (125/125); 95% CI: (97.0, 100) OPA: 99.6% (234/235); 95% CI: (97.6, 99.9) Number of non-evaluable samples: 1			
3	Positive	110	0
	Negative	0	122
	Total	110	122
PPA: 100% (110/110); 95% CI: (96.6, 100) NPA: 100% (122/122); 95% CI: (96.9, 100) OPA: 100% (232/232); 95% CI: (98.4, 100) Number of non-evaluable samples: 4			
Overall: Average PPA: 99.7%; Bootstrap 95% CI: (99.0, 100) Average NPA: 100%; Bootstrap 95% CI: N/A Average OPA: 99.9%; Bootstrap 95% CI: (99.5, 100) Average number of BD MAX™ equivocal results: 0 Note 1: Confidence intervals for point estimates at each site are calculated by a score method. Note 2: Confidence intervals for point estimates averaged over 3 sites are calculated by a bootstrap method.			

Table 18: Weighted Deming Regression Coefficients for Ct.Score for BD COR™ vs. BD MAX™

Master Mix	Target	Site	Intercept (95%CI)	Slope (95%CI)
MM2 (SDPA)	*C. glabrata*	Overall	1.00 (-4.13, 6.12)	0.98 (0.80, 1.16)
	Cgroup		-5.44 (-8.29, -2.59)	1.19 (1.09, 1.30)
	C. krusei		3.08 (-1.53, 7.68)	0.90 (0.73, 1.06)
	TV		-2.77 (-4.63, -0.91)	1.09 (1.02, 1.15)

Table 19: Weighted Deming Regression Bias Estimate for BD COR™ vs. BD MAX™

Master Mix	Target	Actual Level	Ct.score/SDPA of BD MAX™	Bias Estimate	95% CI
MM2 (SDPA)	*C. glabrata*	High Positive	27.68	0.38	(0.15, 0.62)
		Moderate Positive	28.96	0.36	(0.19, 0.53)
		Low Positive	29.87	0.34	(0.06, 0.61)
		Negative	40.00	0.11	(-1.92, 2.15)
	Cgroup	High Positive	24.05	-0.83	(-1.21, -0.45)
		Moderate Positive	27.16	-0.23	(-0.42, -0.04)
		Low Positive	30.12	0.34	(-0.03, 0.70)
		Negative	40.00	2.23	(0.87, 3.59)
	C. krusei	High Positive	27.00	0.32	(0.09, 0.55)
		Moderate Positive	28.33	0.19	(0.06, 0.31)
		Low Positive	29.59	0.06	(-0.20, 0.32)
		Negative	40.00	-1.00	(-2.93, 0.93)
	TV	High Positive	26.36	-0.48	(-0.76, -0.21)
		Moderate Positive	30.24	-0.14	(-0.31, 0.03)
		Low Positive	32.83	0.08	(-0.17, 0.33)
		Negative	40.00	0.70	(0.05, 1.35)

Figure 1: Deming Regression for the BD Vaginal Panel on the BD COR™ System versus the BD MAX™ System – *C. glabrata*

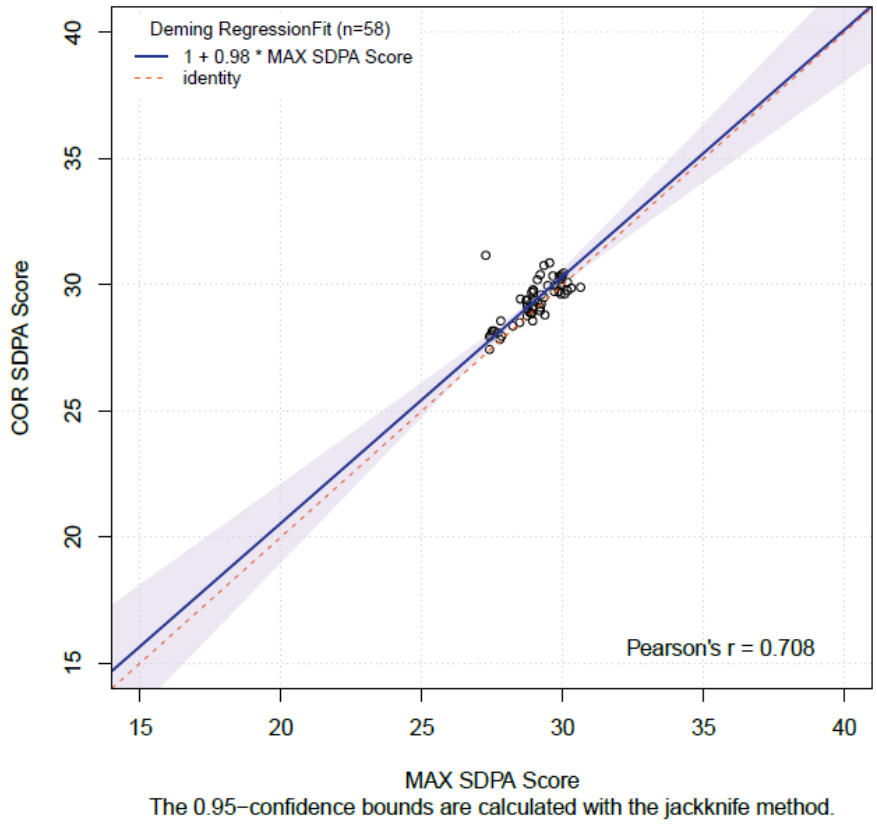


Figure 2: Deming Regression for the BD Vaginal Panel on the BD COR™ System versus the BD MAX™ System - Cgroup

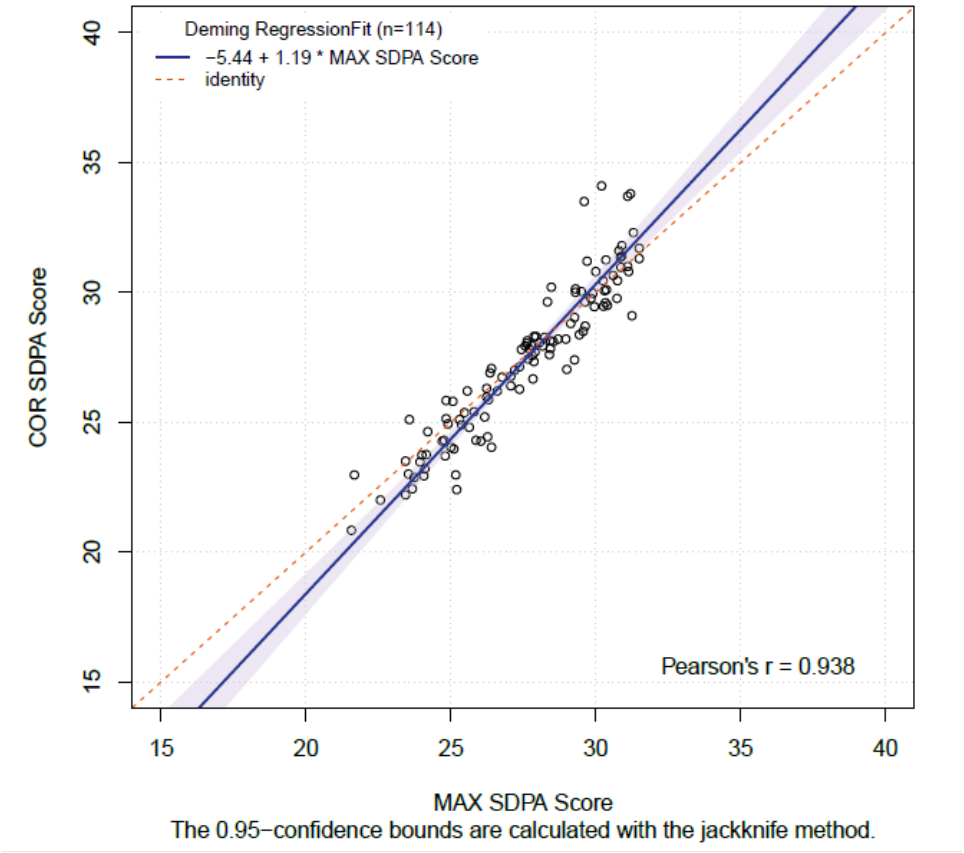


Figure 3: Deming Regression for the BD Vaginal Panel on the BD COR™ System versus the BD MAX™ System – *C. krusei*

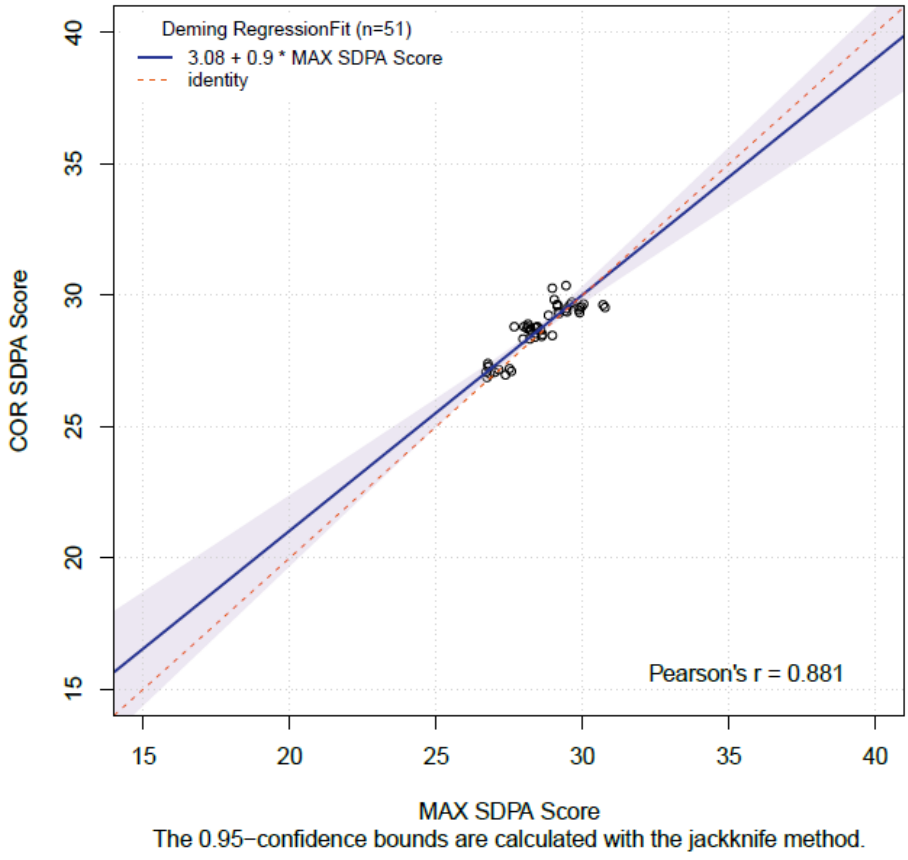
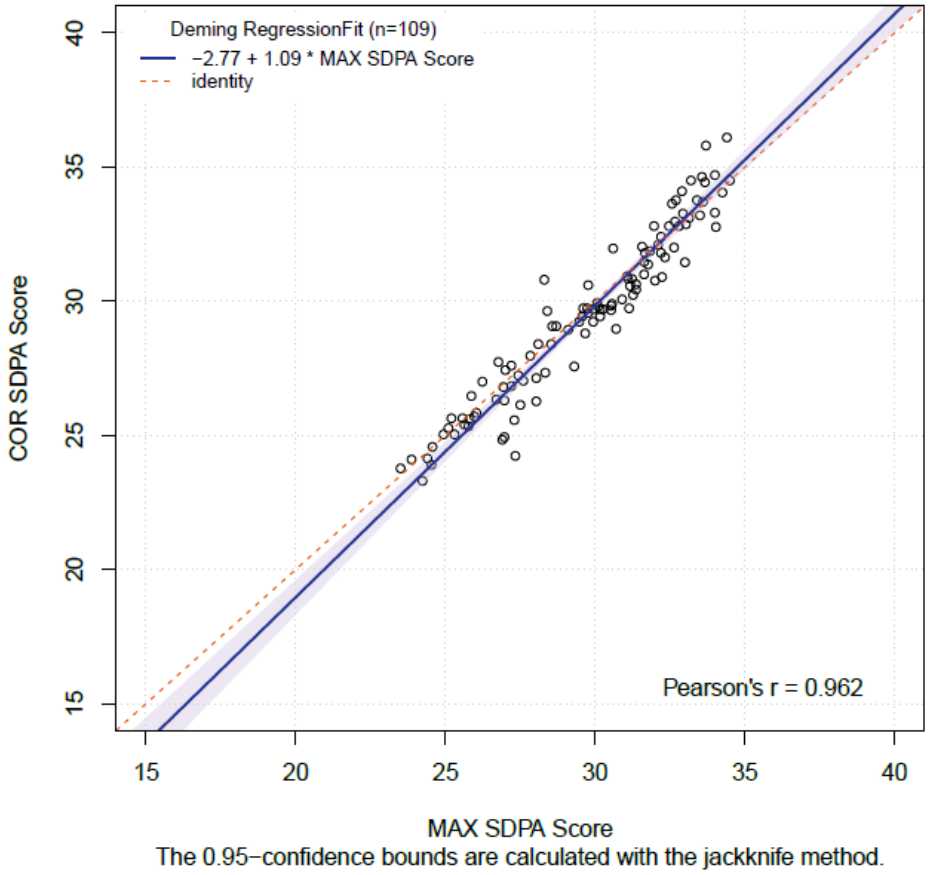


Figure 4: Deming Regression for the BD Vaginal Panel on the BD COR™ System versus the BD MAX™ System – TV



BD Vaginal Panel Non-Reportable Results for BD COR™ System

As with BD MAX™, BD COR™ System results that were due to an internal control failure, extraction transfer failure, or liquid level failure are considered non-reportable. Additionally, on BD COR™ System, incomplete (INC) results may occur on the MX instrument after the specimen has been aspirated for extraction (i.e., aborted runs due to Inventory Robot (IR) error). INC results that occur on MX were also included in the BD COR™ System non-reportable rate calculation. Error results on BD COR™ System were marked noncompliant if they were due to an operator error and were not included in the Non-reportable rate calculation. Non-reportable rates on BD COR™ System are shown in Table 22.

Table 20: Summary of BD COR™ Total Non-Reportable Rate for Combined Target by BD COR™ Test Site

Combined Target	Unresolved[b] Rate		Indeterminate[c] Rate		Incomplete[d] Rate		Total UNR+IND+INC Rate	
BD COR™ Test Site	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)
1	0.6% (4/681) (0.2, 1.5)	0.0% (0/681) (0.0, 0.6)	0.0% (0/681) (0.0, 0.6)	0.0% (0/681) (0.0, 0.6)	0.0% (0/681) (0.0, 0.6)	0.0% (0/681) (0.0, 0.6)	0.6% (4/681) (0.2, 1.5)	0.0% (0/681) (0.0, 0.6)
2	0.6% (4/685) (0.2, 1.5)	0.0% (0/683) (0.0, 0.6)	0.4% (3/685) (0.1, 1.3)	0.0% (0/683) (0.0, 0.6)	0.0% (0/685) (0.0, 0.6)	0.0% (0/683) (0.0, 0.6)	1.0% (7/685) (0.5, 2.1)	0.0% (0/683) (0.0, 0.6)
3	0.3% (2/681) (0.1, 1.1)	0.0% (0/680) (0.0, 0.6)	0.0% (0/681) (0.0, 0.6)	0.0% (0/680) (0.0, 0.6)	0.0% (0/681) (0.0, 0.6)	0.0% (0/680) (0.0, 0.6)	0.3% (2/681) (0.1, 1.1)	0.0% (0/680) (0.0, 0.6)
Overall	0.5% (10/2047) (0.3, 0.9)	0.0% (0/2044) (0.0, 0.2)	0.1% (3/2047) (0.0, 0.4)	0.0% (0/2044) (0.0, 0.2)	0.0% (0/2047) (0.0, 0.2)	0.0% (0/2044) (0.0, 0.2)	0.6% (13/2047) (0.4, 1.1)	0.0% (0/2044) (0.0, 0.2)

[a] The final rate is calculated with the number of remaining non-reportable events after repeat testing.
b Unresolved, invalid SPC due to presence of inhibitory substances or reagent failure.
c Indeterminate, BD COR™ System failure (with Warning or Error Codes).
d Incomplete Run, aborted run or BD COR™ System failure that halts robot operations (with Warning or Error Codes).