**BD MAX Vaginal Panel Procedure**

1. **PRINCIPLE**
	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 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.
	2. 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:
		1. Bacterial vaginosis markers (Individual markers not reported)
			1. Lactobacillus spp. (L. crispatus and L. jensenii)
			2. Gardnerella vaginalis
			3. Atopobium vaginae
			4. Bacterial Vaginosis Associated Bacteria-2 (BVAB-2) Megasphaera-1
		2. Candida spp. (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis)
		3. Candida glabrata
		4. Candida krusei
		5. Trichomonas vaginalis
	3. 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.
	4. Physicians traditionally diagnose vaginitis using the combination of symptoms, physical examination, pH of vaginal fluid, microscopy, and the whiff test. When combined, these tests display a sensitivity and specificity of 81 and 70% respectively for bacterial vaginosis; 84 and 85% for vulvovaginal candidiasis; and 85 and 100% for trichomoniasis when compared with a molecular assay.
	5. The BD MAX Vaginal Panel is designed for use with the BD MAX UVE Specimen Collection kit. Samples are transported to the testing laboratory in BD MAX UVE Sample Buffer Tubes. The Sample Buffer Tubes are vortexed to release cells from the swab into the buffer. The Sample Buffer Tubes, Unitized Reagent Strips and PCR Cartridges are loaded on the BD MAX System. No further operator intervention is necessary, and the following automated procedures occur.
	6. The cells are lysed, and DNA is extracted, captured, and concentrated on magnetic beads. After an elution step, DNA is added to reagents containing specific primers and probes used to amplify and detect the genetic targets, if present.
	7. Upon amplification, signal detection and interpretation are performed automatically by the BD MAX System using real-time PCR. Each Extraction Tube 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.
	8. A combination of lytic and extraction reagents is used to perform cell lysis and DNA extraction. Nucleic acids released from the target organisms are captured on magnetic affinity beads. The beads, together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH variation.
	9. Eluted DNA is neutralized and transferred to the Master Mix Tubes to rehydrate the PCR reagents. After reconstitution, the BD MAX System 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 in order to contain the amplification mixture and thus prevent evaporation and contamination.
	10. 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 MAX System.
	11. 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.
	12. 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 MAX Vaginal Panel is directly proportional to the quantity of the corresponding probe that is hydrolyzed.
	13. The BD MAX 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 analyte of the vaginitis targets (i.e., positive, or negative) and positive or negative BV results are obtained from the combination of bacterial vaginosis marker signals.
2. **AVAILABLILITY**
	1. Test will be run once per day, Monday-Friday.
3. **SPECIMEN COLLECTION**
	1. Specimens should be collected using the BD Molecular Swab Collection kit instructions.
4. **MATERIALS AND EQUIPMENT**
	1. Materials
		1. BD MAX™ Molecular Swab Collection Kit (BD, Cat. No. 443925
		2. BD MAX™ PCR Cartridges (BD Cat. No. 437519)
		3. BD MAX™ Vaginal Panel Kit (BD Cat. No. 443712)
	2. Equipment
		1. BD MAX™ Instrument
		2. VWR multi-tube vortexer (VWR Cat No. 58816-115)
		3. Vortex Genie
		4. NALGENE™ Cryogenic Vial Holder (VWR, Cat. No. 66008-783)
5. **STORAGE AND HANDLING**
	1. Specimen
		1. Collected specimens should be transported between 2-30°C.
		2. Keep collection kits from freezing or extreme heat.
		3. Once in the lab, the specimen can be stored between 2-30°C for a maximum of 8 days or refrigerated (2-8°C) for a maximum of 14 days.
	2. Vaginal Panel Test Kit
		1. BD MAX ™ Vaginal Panel test kits can be stored at 2-25°C through stated expiration date.
		2. Do not use the kit if the label that seals the outer box is broken on arrival.
		3. BD MAX™ Vaginal Panel Master Mixes and Extraction Tubes should be kept in their foil pouches until they are used.
		4. Once opened, the tubes must be used within 14 days. Always write a 2 week out-date on the foil pouch when opened for the first time.
		5. Always keep the pouches closed with air removed and desiccant present when not in use.
		6. Do not use reagents if protective pouch is broken/open on arrival or if there is no desiccant present.
		7. ZeptoMetrix controls for BD MAX Vaginal Panel should be stored at 2-8°C and are stable until the expiration date.
6. **QUALITY CONTROL**
	1. External Controls
		1. Positive and negative external processing controls are to be run monthly to monitor sample preparation and to QC new lots/shipments of kits and after system maintenance such as PMs and software upgrades to monitor sample preparation.
		2. Positive external controls, purchased from Microbiologics, are intended to monitor for substantial reagent failure.
		3. Negative external control is intended to detect reagent or environmental contamination by target nucleic acids.
			1. For New Lot/New Shipment and monthly QC, both analytes must be run along with a negative control. Perform by adding a positive pooled pellet containing each analyte into a buffer tube. Also, place a negative pellet into a separate buffer tube.
			2. DO NOT OPEN FOIL POUCH UNTIL IT IS NECESSARY
		4. No patient results will be reported unless all control results are as expected.
		5. Bring any unexpected control results to the attention of the Senior or Lead Medical Technologist, Director, Assistant Director, or Manager.
		6. If a repeat of an External Control is warranted, a new buffer tube must be inoculated.
	2. Internal Control
		1. Each Extraction tube contains a Sample Processing Control (IC) which is a plasmid containing a synthetic target DNA sequence. The Sample Processing Control (IC) is extracted, eluted, and amplified along with any DNA present in the processed specimen, ensuring the predictivity of the assay.
		2. The Sample Processing Control (IC) monitors the efficiency of DNA capture, washing and elution during the sample processing step, as well as the efficiency of DNA amplification and detection during PCR analysis.
			1. If the Sample Processing Control (IC) fails to meet the acceptance criteria, the result of the specimen will be reported as UNR and should be rerun from the buffer tube.
	3. Environmental wipe testing is performed monthly. All test areas are swabbed and run as test patients. Refer to Monthly BD MAX™ Environmental Testing sheet for directions.
	4. Positivity Rate is monitored monthly.
	5. Refer to the laboratory’s Individualized Quality Control Plan (IQCP) for BD Max Vaginal Panel for complete details of the QC data and QA plan approved by the Director.
7. **TEST PROCEDURE**
	1. Use 3% Hydrogen Peroxide to clean the BD MAX™, racks, hood, and surrounding bench area.
		1. DO NOT clean the mirror within the BD MAX™. Lightly dust with clean gauze only if needed.
	2. Run a pending report using test code VPPCR, dating back at least 1 week. Account for all pending specimens
	3. BD MAX™ operation:
		1. Put on clean gloves then log into BD MAX™ using your personal “username” and “password”.
		2. Place one sample buffer tube for each specimen to be run into a NALGENE™ Cryogenic Vial Holder.
		3. Click the RUN tab at the bottom of the screen and fill in the appropriate fields.
		4. Test: choose BD MAX™ Vaginal Panel from the dropdown list.
		5. Lot number: use the dropdown list and choose the lot number from the in use Vaginal Panel kit.
		6. External Control: this should be left blank while entering patient specimen information.
		7. With the curser in the Sample Tube window, scan the 2-D barcode on the side of the tube.
		8. The curser will automatically move to the Accession window. Scan the accession number from the patient sample. Continue in this manner until all specimens are logged into BD MAX™.
	4. Specimen preparation:
		1. Place all specimens in NALGENE™ Cryogenic Vial Holder.
		2. Vortex specimen for 1 minute using pre-set timer on the multi-tube vortexer.
		3. Following the recommendation from the company, specimens should sit for 90 mins before running and should be revortexed after 4 hours.
		4. Remove NALGENE™ Cryogenic Vial Holder from vortexer.
		5. Remove and discard the clear cap (with swab attached) from the corresponding sample buffer tube. If swab is not attached, the swab can remain in the sample buffer tube.
		6. Place a blue septum cap on the sample buffer tube without touching the top area to avoid carry-over contamination. This specimen collection method will be discontinued. However, they can still be run as long as the expiration date is valid. These specimen buffer tubes that require a cap change are the BD UVE collection kits (Ref 443376)
		7. Specimens received in the BD Molecular Swab Collection Kit have a foil top. The cap can remain on the specimen.
		8. Continue in this manner until all Sample Buffer Tubes caps are replaced with the septum cap.
		9. CHANGE GLOVES BEFORE MOVING TO NEXT SPEICMEN ANYTIME THEY BECOME CONTAMINATED WITH SPECIMEN
		10. Leave specimens to sit for 90 minutes after vortexing before starting the run.
	5. Utilizing the Run Wizard to assist in loading the BD MAX System Racks
		1. The run wizard has the ability to assist in proper placement of the Reagent Strips for maximum usage and minimal waste of the PCR card.
		2. Select the Run Wizard box to the left of the worklist screen.
		3. Choose the Scan Cartridge tab to the right of the window.
		4. Scan the barcode from the front of the cartridge. The spaces crossed out on the graphic indicate a used spot. If five spots are used, you can begin setting up reagent strips in the sixth position, etc.
	6. Setting up the Vaginal Panel Reagent Strips:
		1. Remove the required number of BD MAX™ Vaginal Panel Reagent Strips from the BD MAX™ Vaginal Panel kit. Gently tap each strip onto a hard surface to ensure that all the liquids are at the bottom of the tubes and place in the metal BD MAX™ system rack. Push strip in and down to lock into place.
		2. Remove the required number of Vaginal Panel Extraction Tube(s) and Vaginal Panel Master Mix tube(s) from their protective pouches. Remove excess air, and close pouches with the zip seal with desiccant remaining inside. Once opened, the bags expire after 14 days. Write an out-date of 14 days on the bag to ensure integrity of tubes.
		3. Place one (1) BD MAX™ Vaginal Panel Extraction Tube (white foil seal) into Position 1 of each of the BD MAX™ Vaginal Panel Strips as shown in Figure 1 below.
		4. Place one (1) BD MAX™ Vaginal Panel Vaginosis Master Mix Tube (green foil seal) into Position 2 of each of the BD MAX™ Vaginal Panel Strips as shown in Figure 1 below.
		5. Place one (1) BD MAX™ Vaginal Panel Vaginitis Master Mix Tube (blue foil seal) into Position 4 of each of the BD MAX™ Vaginal Panel Strips as shown in Figure 1 below.
		6. Snap all the tubes into the strips until they are secure.

Figure 1: Snap BD MAX Vaginal Extraction Tubes and Master Mix Tubes into Reagent Strips.



* + 1. Place each tube in the BD MAX™ System Rack.
		2. Place System Rack(s) into BD MAX™, ensuring proper placement in the instrument.
		3. Close the lid of the BD MAX™.
		4. At the BD MAX™ computer, select Start icon at the bottom of the screen. Enter the run name. Cataloging will begin.
1. **POST ANALYSIS**
	1. IMMEDIATELY REVIEW ALL RESULTS
	2. Any UNR, INC or IND results must be repeated using the sample buffer tube. See Interpretation section below for more detailed information.
	3. If a septum cap was damaged during the run, replace it with a new one before rerunning or storing the sample.
	4. Any patient specimen that still has not yielded a result after the second attempt will be reported as Invalid for some or all non-resulted analytes.
	5. Specimens must be re-tested within 5 hours of the end of the run if stored at 2-30°C or within 5 days if refrigerated (2-8°C).
	6. If repeated results do not match, always report the positive result.
	7. Setting up repeat buffer tubes on the BD MAX computer
		1. Under the RUN tab, scan the sample buffer tube to be repeated.
		2. Select OK in the popup window.
		3. Highlight the specimen from the list.
		4. Add an “R” to the end of the accession number, select ENTER.
		5. Select SAVE.
	8. Setting up new reagent strips
		1. Set up a new reagent strips using new Extraction and Master Mix Tubes for each sample to be repeated.
		2. Vortex the buffer tubes for 1 full minute (if it has been >4 hours since previously vortexed) and place in the System Rack.
		3. Load System rack and start.
2. **INTERPRETATION**
	1. Results are available on the Results tab in the Results window on the BD MAX™ System monitor. The BD MAX™ System software automatically interprets test results.
	2. Unresolved (UNR) results may be obtained in the event that specimen-associated inhibition or reagent failure prevents proper target or IC amplification. If the IC does not amplify, the sample will be reported as UNR; however, any positive (POS) assay results will be reported, and no targets will be called NEG. Refer to post-analysis section above for repeat test procedure. Alternatively, the sample can be set up again.
	3. Indeterminate (IND) results may be obtained in the event that a system failure occurs. Refer to post-analysis section above for repeat test procedure. Alternatively, the sample can be set up again.
	4. Incomplete (INC) results may be obtained in the event that the Specimen Preparation or the PCR failed to complete. Refer to post-analysis section above for repeat test procedure. Alternatively, the sample can be set up again.
	5. A complete copy of the report from the BD MAX™ will be printed for every run.
		1. To print a report from the BD MAX™, go to results tab in the results window on the BD MAX™ monitor. Select the run from the list. View run, uncheck “Plots” and print.
	6. Results are based on the following algorithm:

|  |  |
| --- | --- |
| Assay Result Reported | Interpretation of Result |
| 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 |
| BV UNR | Unresolved- inhibitory sample or reagent failure; no target detected and no amplification of Sample Processing Control (IC) |
| Cgroup POS | *Candida* groupDNA Detected (*Candida albicans* and/or *Candida tropicalis* and/or *Candida parapsilosis* and/or *Candida dubliniensis*) |
| Cgroup NEG | No *Candida* group detected (*Candida albicans* and/or *Candida tropicalis* and/or *Candida parapsilosis* and/or *Candida dubliniensis*) |
| Cgroup UNR | Unresolved- inhibitory sample or reagent failure; no target detected and no amplification of Sample Processing Control (IC) |
| Ckru POS | *Candida krusei* DNA Detected |
| Ckru NEG | No *Candida krusei*detected |
| Ckru UNR | Unresolved- inhibitory sample or reagent failure; no target detected and no amplification of Sample Processing Control (IC) |
| Cgla POS | *Candida glabrata*DNA detected |
| Cgla NEG | No *Candida glabrata*detected |
| Cgla UNR | Unresolved- inhibitory sample or reagent failure; no target detected and no amplification of Sample Processing Control (IC) |
| TV POS | *Trichomonas vaginalis* DNA Detected |
| TV NEG | No *Trichomonas vaginalis* DNA detected |
| TV UNR | Unresolved- inhibitory sample or reagent failure; no target detected and no amplification of Sample Processing Control (IC) |
| IND | Indeterminate result due to BD MAX™ System failure (with Warning or Error Codes) |
| INC | Incomplete run (with Warning or Error Codes) |

1. **RESULTLING IN SOFT**
	1. Resulting Negative and Positive targets:
		1. From SoftLab, go to “Interfaces”, and “Instrument Menu”.
		2. Select “RBDMX1, RBDMX2, and RBMX3” “BD MAX™”
		3. Select “Loadlist and todays results”, “Not Posted”, “By Sequence”.
		4. Each order will be highlighted individually. Verify the result against the instrument printout.
		5. To add result comments, i.e., Invalid reports:
			1. Highlight the order number on left of screen.
			2. At bottom of screen click on Lab Results.
			3. Open “Comment” box and add comment/phone report using @CALM.
			4. Click back to Instrument tab and save when asked.
			5. Click Post All to verify the report.
			6. Order number should disappear from list on left.
	2. Resulting Invalids
		1. Invalid specimens must be manually resulted in result entry.
			1. Go to result entry.
			2. In the Order: box, enter the Order number, select Next.
			3. Select “Invalid” from the GPP window for the invalid targets.
			4. Select Verify All
2. **LIMITATIONS**
	1. The BD MAX Vaginal Panel is intended for use only with the BD MAX UVE Specimen Collection kit or BD Molecular Swab Collection Kit.
	2. The BD MAX Vaginal Panel should only be used with the BD MAX System by trained personnel.
	3. The BD MAX Vaginal Panel has not been validated for vaginal swab specimens collected by patients at home.
	4. Collection and testing of patient-collected vaginal swab specimens with the BD MAX Vaginal Panel is not intended to replace exam by a clinician. Vaginal infections may result from other causes or concurrent infections may occur.
	5. Public health recommendations should be consulted regarding testing for additional sexually transmitted diseases for patients with a positive result for Bacterial Vaginosis or T. vaginalis with the BD MAX™ Vaginal Panel.
	6. Additional microorganisms not detected by the BD MAX Vaginal Panel such as Prevotella, Lachnospira, Sneathia, Mobiluncus, Mycoplasma hominis, and Ureaplasma spp. have also been found in women with bacterial vaginosis but are less associated with BV due to their relatively low prevalence, sensitivity and/or specificity.
	7. Patients under 18 years old were not evaluated.
	8. A Cgroup positive result can be due to one or multiple Candida species.
	9. Lubricants or other products containing substances such as carbomers, can increase the non-reportable rate obtained with BD MAX Vaginal Panel.
	10. Reliable assay results are dependent on adequate specimen collection. Follow the procedures in this package insert and the BD MAX™ UVE Specimen Collection Kit or BD Molecular Swab Collection Kit. Failure to follow specimen collection instructions may cause an increase in non-reportable results.
	11. Interference with the BD MAX™ Vaginal Panel was observed in the presence of the following substances: Conceptrol Vaginal Contraceptive Gel, Clotrimazole Vaginal Cream, Monistat 3 Cream, Vagisil Cream, Replens Vaginal Moisturizing Gel, Surgilube, McKesson Lubricating Jelly, Aquasonic Clear, Metronidazole, Leukocytes. The following substances were observed to interfere at levels above the stated concentrations: Preparation H Hemorrhoidal Cream (>0.8 µL/mL), Zovirax Acyclovir 5% Cream (>3.1 µL/mL), VCF Contraceptive Foam (>3.1 µL/mL), KY Jelly Personal Lubricant (>12.5 µL/mL), MUKO Lubricating Jelly (>3.3 µL/mL), Whole Blood (>12.5 µL/mL or >1.25% v/v).
	12. Interference with the BD MAX Vaginal Panel was observed in the presence of the following microorganisms: Lactobacillus amylovorus, Lactobacillus delbrueckii subsp. bulgaricus, Lactobacillus kefirgranum and Lactobacillus helveticus, that may all be used in probiotics. Interference with Lactobacillus kefiranofaciens has not been determined.
	13. Cross-reactivity with the BD MAX Vaginal Panel may be observed with the following organisms: Lactobacillus acidophilus, detected in human stool; Trichomonas tenax, a commensal of the oral cavity.
	14. The following organisms were observed to cross-react above the stated concentrations: Olsenella uli (> 6.6 x 10⁴ CFU/mL) and Atopobium rimae (> 4.4 x 10⁴ CFU/mL), both isolated from oral cavity; Lactobacillus delbrueckii subsp. lactis (> 3.9 x 10³ CFU/mL), detected in human stool; Pichia fermentans (> 6.0 x 10³ CFU/mL), from coffee beans and fruit.
	15. All strains tested in the Inclusivity study were detected. However, three (3) out of 10 tested Gardnerella vaginalis strains and 1 out of 5 Lactobacillus crispatus strains were detected only at high concentrations (9 X LoD and 5 X LoD respectively).
	16. The effects of other potential variables such as vaginal discharge, use of tampons and specimen collection variables have not been determined.
	17. As with many diagnostic tests, results from the BD MAX Vaginal Panel should be interpreted in conjunction with other laboratory and clinical data available to the physician.
	18. Candida species can be present as commensal organisms in a significant percentage of women and BD MAX Vaginal Panel results should be considered in conjunction with other clinical and patient information to determine the disease status.
	19. If the BD MAX™ Vaginal Panel result is IND, INC, or UNR (for one or more targets) then the test should be repeated.
	20. Good laboratory technique is essential for the proper performance of this assay. Due to the high analytical sensitivity of this test, extreme care should be taken to preserve the purity of all materials and reagents.
	21. Bacterial vaginosis marker combinations that generate positive results for bacterial vaginosis can be commensal in a significant percentage of women and therefore positive results for bacterial vaginosis should be considered in conjunction with other clinical and patient information to determine the disease status.
	22. Erroneous test results may occur from improper specimen collection, handling or storage, technical error, sample mix-up or because the number of organisms in the sample is below the analytical sensitivity of the test.
	23. A positive test result does not necessarily indicate the presence of viable organisms. A positive result is indicative of the presence of target DNA.
	24. The BD MAX Vaginal Panel cannot be used to assess therapeutic success or failure since target nucleic acids may persist following antimicrobial therapy.
	25. As with all PCR-based tests, extremely low levels of target below the LoD of the assay may be detected, but results may not be reproducible.
	26. False negative results may occur due to loss of nucleic acid from inadequate collection, transport or storage of specimens, or due to inadequate cell lysis. The Sample Processing Control has been added to the test to aid in the identification of specimens that contain inhibitors to PCR amplification. The Sample Processing Control does not indicate if nucleic acid has been lost due to inadequate collection, transport or storage of specimens, or if cells have been adequately lysed.
	27. At very low load, false negative Candida glabrata results may occur for specimens containing more than one analyte.
	28. At very low load, false negative Candida spp. results may occur for specimens containing more than one BV analyte at high loads.
	29. At very low load, false negative Candida spp., C. krusei or C. glabrata results may occur for specimens containing high load of T. vaginalis.
	30. Mutations or polymorphisms in primer- or probe-binding regions may affect detection resulting in a false negative result with the BD MAX™ Vaginal Panel.
	31. This test is a qualitative test and does not provide quantitative values nor indicate the quantity of organisms present.
3. **NOTES**
	1. Unitized Reagent Strips must be checked for proper liquid fills and to ensure all pipette tips are present.
	2. Always check that there are sufficient tests remaining on the PCR cards before starting the run. If the BD MAX™ is unable to start the PCR step, an internal clock will begin, and the run will abort if the issue is not resolved in time.
	3. Caution should be used during cleaning with chemicals. Splashing onto barcodes of kit components will render them unreadable.
	4. The following conditions may cause erroneous results. **Do Not:**
		1. Use any part of the BD MAX™ Vaginal Panel kit after the stated expiration date.
		2. Use a kit where the outer seal has been broken at time of delivery.
		3. Use reagents if the protective pouched are opened or broken upon arrival.
		4. Use reagents if desiccant is not present or is broken in pouch.
		5. Remove desiccant from pouch.
		6. Use reagents if the protective foil cover on the tube is broken or damaged.
		7. Mix reagents across different lots or mix them between different pouches.
	5. Kits should be kept free from excessive heat and humidity. Prolonged exposure to increased humidity may affect product performance.
	6. Do not interchange or reuse buffer tube clear caps or septum caps to avoid contamination.
	7. Performing the BD MAX™ Vaginal Panel outside the recommended time or temperature ranges for specimen transport and storage may produce invalid results. Assays not performed within specific time frames should be repeated.
	8. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
	9. Positive results do not rule out co-infection with other organisms not detected by this test and may not be the sole or definitive cause of patient illness.
	10. Clean gloves should be worn whenever handling kit components to avoid contamination from handling specimens. Gloves should be changed as soon as they become visibly contaminated.
	11. In cases where other PCR tests are conducted in the same area, care must be taken to ensure the assay and its reagents are not contaminated by microbial DNA or DNase. Gloves must ALWAYS be changed before handling reagents and cartridges.
4. **TECHNICAL SUPPORT**
	1. Technical Support- 800-638-8663
	2. technical\_services@bd.com
5. **REFERENCES**
	1. BD MAX™ Vaginal Panel PI ver. P0258(03) 2022 11
	2. BD MAX™ Vaginal Panel Validation Report
	3. BD MAX™ Molecular Swab Collection kit package insert.
6. **REVISIONS**
	1. 6/7/2019 - Added 90-minute rest period after vortexing specimens and updated limitations according to new package insert.
	2. 6/29/2021 – Testing removed from Miriam Hospital and implemented at Rhode Island Hospital
	3. 10/18/2023: Updated after moving to Coro.