Becton, Dickinson and Company
Katie Edwards
Regulatory Affairs Project Manager
7 Loveton Circle
Sparks, Maryland 21152

January 8, 2019

Re: K182692
Trade/Device Name: BD MAX CTGCTV2, BD MAX System
Regulation Number: 21 CFR 866.3860
Regulation Name: Trichomonas vaginalis nucleic acid assay
Regulatory Class: Class II
Product Code: OUY, MKZ, LSL
Dated: January 4, 2019
Received: January 7, 2019

Dear Katie Edwards:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182692

Device Name
BD MAX™ CTGCTV2

Indications for Use *(Describe)*

The BD MAX™ CTGCTV2 assay, performed on the BD MAX™ System, incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)
- *Trichomonas vaginalis* (TV)

The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep™ Pap test.

The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis.

Ancillary Collection kits:

The BD MAX 3-in-1 Swab Collection Kit is intended to be used in clinical settings according to the instructions provided for collection and transport of vaginal and endocervical swab specimens. This transport system is for use for testing with BD MAX products.

The BD MAX Urine Transport Kit is intended to be used in clinical settings according to the instructions provided for collection, preservation and transport of urine specimens. This transport system is for use for testing with the BD MAX products.

The BD MAX LBC Sample Buffer Tubes are intended to be used in clinical settings according to the instructions provided for the preservation and transport of Liquid-Based Cytology (LBC) specimens. This transport system is for use for testing with the BD MAX products.

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 MAX™ CTGCTV2

Summary Preparation Date:

12/28/2018

Submitted by:

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

Contact:

Katie Edwards
Regulatory Affairs Project Manager
Tel: 410-316-4975
Email: Katie_Edwards@bd.com

Proprietary Names:

For the instrument:

BD MAX™ System

For the assay:

BD MAX CTGCTV2

Common Names:

For the instrument:

Bench-top molecular diagnostics workstation

For the assay:
CT assay
GC assay
TV assay

Regulatory Information

Regulation section:

866.3860 – *Trichomonas vaginalis* Nucleic Acid Amplification Test System

Classification:
Class II

Panel:
Microbiology (83)

Product Code(s):

MKZ *Chlamydia trachomatis*

LSL *Neisseria gonorrhoeae*

OUY *Trichomonas vaginalis*

Predicate Device:

BD MAX™ CT/GC/TV [510(k) K151589]

Performance Standards:

Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*, August 4, 2015.

Intended Use:

The BD MAX™ CTGCTV2 assay, performed on the BD MAX™ System, incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)
- *Trichomonas vaginalis* (TV)

The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep™ Pap test.

The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis.

Special Conditions for Use Statement: For prescription use

Special Instrument Requirements: BD MAX System

Device Description:

The BD MAX System and the BD MAX CTGCTV2 are comprised of an instrument with associated hardware and accessories, disposable microfluidic cartridges, master mixes, unitized reagent strips, and extraction reagents. The instrument automates sample preparation including target lysis, DNA extraction and concentration, reagent rehydration, and target nucleic acid amplification and detection using real-time PCR. The assay includes a Sample 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. The BD MAX System software automatically interprets test results. A test result may be called

as POS, NEG, UNR, IND or INC for each of the assay's targets, based on the amplification status of the target and of the Sample Processing Control. IND (Indeterminate) or INC (Incomplete) results are due to BD MAX System level failure.

Test Principle:

The BD MAX CTGCTV2 assay is designed for use with the applicable BD MAX specimen collection and transport devices, including the BD MAX™ Urine Transport Kit, the BD MAX™ LBC Sample Buffer Tubes or the BD MAX™ 3-in-1 Swab Collection Kit. The specimen is collected from the patient and transported to the testing laboratory using the appropriate transport device under conditions of time and temperature that have been determined to maintain the integrity of the target nucleic acids.

LBC samples are pre-warmed on the BD Pre-warm Heater before testing on the BD MAX System. None of the other specimen types undergo a pre-warm step. The Sample Buffer Tubes are recapped with a septum cap prior to processing on the BD MAX System. A worklist is created and the Sample Buffer Tube, the BD MAX CTGCTV2 Unitized Reagent Strip and the BD MAX PCR Cartridge are loaded onto the BD MAX System. The BD MAX System automates sample preparation, including target organism lysis, DNA extraction and concentration, reagent rehydration, and target nucleic acid amplification and detection using real-time PCR. The BD MAX System performs results interpretation automatically. The assay also includes a Sample Processing Control (SPC) that is present in the Extraction Tube. The Sample Processing Control monitors DNA extraction steps, thermal cycling steps, reagent integrity and presence of inhibitory substances.

Nucleic acids that are released from the target organisms as a result of cell lysis during the extraction process are captured on magnetic affinity beads. The beads, together with the bound nucleic acids, are washed using Wash Buffer and the nucleic acids are eluted by a combination of heat and pH. Eluted DNA is neutralized using Neutralization Buffer and transferred to the Master Mix 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 BD MAX PCR Cartridge. Microvalves in the BD MAX PCR Cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture, thus preventing evaporation and contamination.

The BD MAX CTGCTV2 assay is comprised of two targets for *Chlamydia trachomatis* (detected on the same optical channel), two targets for *Neisseria gonorrhoeae* (detected on two different optical channels) and one target for *Trichomonas vaginalis* (detected on one optical channel). Only one *Chlamydia trachomatis* target is required to be positive in order to report a positive result. Both *Neisseria gonorrhoeae* targets are required to be positive in order to report a positive result. 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 amplicons for target analytes and the Sample Processing Control in five different optical channels of the BD MAX 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 MAX System monitors these signals at the end of each cycle and interprets the data at the end of the reaction to provide qualitative test results for each analyte (i.e., positive or negative).

Substantial Equivalence:

Table 1 provides the similarities and differences between the BD MAX CTGCTV2 and the predicate device.

Table 1: Comparison to Predicate Device

Items	***BD MAX CTGCTV2***			***BD MAX CT/GC/TV***		
510(k)#	K182692			K151589		
Regulation	866.3860			866.3860		
Product Code	MKZ, LSL, OUY			MKZ, LSL, OUY		
Device Class	II			II		
Intended Use	The BD MAX CTGCTV2 assay, performed on the BD MAX System, incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from: *Chlamydia trachomatis* (CT) *Neisseria gonorrhoeae* (GC) *Trichomonas vaginalis* (TV) The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis.			The BD MAX CT/GC/TV assay, as performed using the BD MAX System incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC) and/or *Trichomonas vaginalis* (TV). The assay may be used for detection of CT and/or GC DNA in male urine specimens, and the detection of CT, GC and/or TV DNA in female urine specimens, clinician-collected female endocervical swab specimens and patient-collected vaginal swab specimens (in a clinical setting). The assay is indicated for use to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis in asymptomatic and symptomatic individuals.		
Indications for Use	Asymptomatic and Symptomatic Patients			Asymptomatic and Symptomatic Patients		
Specimen Type	Clinician-collected vaginal swab, patient-collected vaginal swab, endocervical swab, PreservCyt LBC, female and male urine			Endocervical swab, patient-collected vaginal swab, female and male urine		
Technology	PCR			PCR		
Organisms Detected	CT, GC and TV			CT, GC and TV		
Sample Prep / Interpretation of Results	Automated by BD MAX System			Automated by BD MAX System		
Assay Controls	Sample Processing Control			Sample Processing Control		
Target Detection	**Target**	**Dye**	**Channel**	**Target**	**Dye**	**Channel**
	CT	FAM	FAM	CT	FAM	FAM
	CT	FAM	FAM	CT	FAM	FAM
	GC (GC1)	CFO	VIC	GC (GC1)	CFO	VIC
	GC (GC2)	Q705	CY5.5	NA	NA	NA
	TV	Q670	CY5	TV	Q670	CY5
Collection/ Transport Device	Swab Sample Buffer Tube (2.0 mL) Urine Sample Buffer Tube (0.5 mL) LBC Sample Buffer Tube (1.5 mL)			UVE Sample Buffer Tube (1.5 mL)		
Sample Prep	1 swab added to Swab Sample Buffer Tube 2.0 mL urine added to Urine Sample Buffer Tube			1 swab or 1.0 mL urine added to UVE Sample Buffer Tube		

	0.5 mL LBC added to LBC Sample Buffer Tube			
Prewarm	Pre-warm only LBC samples prior to extraction		Pre-warm all UVE samples prior to extraction	
Extraction	Same		Magnetic affinity beads with protease	
On-board lysis	On-board lysis of all specimens		No on-board lysis	
Results Metric	Ct score		SDPA with minimum endpoint threshold	
Results Interpretation	**Assay Result Reported**	**Interpretation of Result**	**Assay Result Reported**	**Interpretation of Result**
	CT POS	*Chlamydia trachomatis* DNA Detected	CT POS	*Chlamydia trachomatis* DNA Detected
	CT NEG	No *Chlamydia trachomatis* DNA Detected	CT NEG	No *Chlamydia trachomatis* DNA Detected
	CT UNR	Unresolved – Inhibitory sample or reagent failure; no target or Sample Processing Control amplification	CT UNR	Unresolved – Inhibitory sample or reagent failure; no target or Sample Processing Control amplification
	GC POS[a]	*Neisseria gonorrhoeae* DNA Detected	GC POS	*Neisseria gonorrhoeae* DNA Detected
	GC NEG	No *Neisseria gonorrhoeae* DNA Detected	GC NEG	No *Neisseria gonorrhoeae* DNA Detected
	GC UNR	Unresolved – Inhibitory sample or reagent failure; no target or Sample Processing Control amplification	GC UNR	Unresolved – Inhibitory sample or reagent failure; no target or Sample Processing Control amplification
	TV POS	*Trichomonas vaginalis* DNA Detected	TV POS	*Trichomonas vaginalis* DNA Detected
	TV NEG	No *Trichomonas vaginalis* DNA Detected	TV NEG	No *Trichomonas vaginalis* DNA Detected
	TV UNR	Unresolved – Inhibitory sample or reagent failure; no target or Sample Processing Control amplification	TV UNR	Unresolved – Inhibitory sample or reagent failure; no target or Sample Processing Control amplification
	IND	Indeterminate result due to BD MAX System failure (with Warning or Error Codes)	IND	Indeterminate result due to BD MAX System failure (with Warning or Error Codes)
	INC	Incomplete Run (with Warning or Error Codes)	INC	Incomplete Run (with Warning or Error Codes)

[a] Detection of both GC1 and GC2 gene targets required to report a positive result.

Analytical Performance

Precision

Within-laboratory precision was evaluated for the BD MAX CTGCTV2 assay at one site with one reagent lot. Testing was performed over 12 days, with 2 runs per day (2 technologists, alternating operators each day), for a total of 24 runs. Test samples were contrived in female urine, in vaginal swab clinical matrix and in PreservCyt LBC specimen matrix and included *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* panel members. Each panel member was tested in two replicates.

The following target concentrations were used for spiking levels of the target organisms contained in each panel member:

- Moderate Positive (MP): 3X LoD
- Low Positive (LP): 1.5X LoD
- High Negative (HN): <1X LoD
- True negative (TN): no target

Precision study results for the BD MAX CTGCTV2 are described in **Table 2**.

Table 2: Overall Precision Study Results (Percent Agreement with Expected Results)

Category	***Chlamydia trachomatis* (n), 95% CI**			***Neisseria gonorrhoeae* (n), 95% CI**			***Trichomonas vaginalis* (n), 95% CI**	
	Swab	***Urine***	***LBC*[c]**	***Swab***	***Urine***	***LBC*[c]**	***Swab***	***Urine***
TN[a]	100% (336/336) 98.9-100	100% (336/336) 98.9-100	99.4% (334/336) 97.9-99.8	100% (336/336) 98.9-100	100% (336/336) 98.9-100	100% (336/336) 98.9-100	100% (336/336) 98.9-100	100% (336/336) 98.9-100
HN[b]	31.3% (15/48) 19.9-45.3	31.3% (15/48) 19.9-45.3	18.8% (9/48) 10.2-31.9	27.1% (13/48) 16.6-41.0	29.2% (14/48) 18.2-43.2	16.7% (8/48) 8.7-29.6	37.5% (18/48) 25.2-51.6	68.8% (33/48) 54.7-80.1
LP	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100	97.9% (47/48) 89.1-99.6	100% (48/48) 92.6-100	100% (48/48) 92.6-100	97.9% (47/48) 89.1-99.6	100% (48/48) 92.6-100
MP	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100	100% (48/48) 92.6-100

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.
[c] PreservCyt LBC

Reproducibility

For the Site-to-Site reproducibility study, three sites (2 external and one internal) were provided the same panels as described for the Precision study, above. Each site performed testing on eight distinct days (consecutive or not), wherein each day, two panels were tested by two technologists (alternating operators each day).

All targets ranged from 99.6% to 100% for TN, 11.5% to 78.1% for HN, 97.9% to 100% for LP and 97.9% to 100% for MP categories (**Table 3**). Ct score, internal criterion used to determine a final assay result, was selected as an additional means of assessing assay reproducibility. Overall mean Ct score values with variance components (SD and %CV) are shown in Tables **Table 4** through **Table 6**.

Table 3: MAX CTGCTV2 Site-to-Site Reproducibility Study Results (Percent Agreement with Expected Results)

Category	*Chlamydia trachomatis (n), 95% CI*			*Neisseria gonorrhoeae (n), 95% CI*			*Trichomonas vaginalis (n), 95% CI*	
	Swab	***Urine***	***LBC[c]***	***Swab***	***Urine***	***LBC[c]***	***Swab***	***Urine***
TN[a]	99.6% (669/672) 98.7-99.8	100% (672/672) 99.4-100	100% (672/672) 99.4-100	100% (672/672) 99.4-100	100% (672/672) 99.4-100	99.9% (671/672) 99.2-100	99.9% (671/672) 99.2-100	100% (672/672) 99.4-100
HN[b]	20.8% (20/96) 13.9-30.0	35.4% (34/96) 26.6-45.4	21.9% (21/96) 14.8-31.1	34.4% (33/96) 25.6-44.3	28.1% (27/96) 20.1-37.8	11.5% (11/96) 6.5-19.4	37.5% (36/96) 28.5-47.5	78.1% (75/96) 68.9-85.2
LP	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	99.0% (95/96) 94.3-99.8	99.0% (95/96) 94.3-99.8	97.9% (94/96) 92.7-99.4	99.0% (95/96) 94.3-99.8	99.0% (95/96) 94.3-99.8
MP	100% (96/96) 96.2-100	99.0% (95/96) 94.3-99.8	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	97.9% (94/96) 92.7-99.4

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.
[c] PreservCyt LBC

Table 4: *C. trachomatis* Site-to-Site Quantitative Reproducibility Across Sites with Pooled Days, Runs and Replicates

Matrix Type	***Cat***	***Agree /N***	***Mean***	***Within Run***		***Between Run***		***Between Day***		***Between Operator***		***Between Site***		***Total***	
				SD	***%CV***	***SD***	***%CV***	***SD***	***%CV***	***SD***	***%CV***	***SD***	***%CV***	***SD***	***%CV***
Swab	HN	20/96	36.6	1.1	3.1	1.8	4.9	0.1	0.4	0.0	0.0	0.0	0.0	2.1	5.8
	LP	96/96	33.2	0.7	2.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.7	2.1
	MP	96/96	32.1	0.6	2.0	0.0	0.0	0.2	0.5	0.0	0.0	0.1	0.4	0.7	2.1
Urine	HN	34/96	36.8	1.6	4.3	0.0	0.0	0.8	2.1	0.0	0.0	0.4	1.0	1.8	4.9
	LP	96/96	32.9	0.7	2.3	0.0	0.0	0.7	2.0	0.3	0.9	0.0	0.0	1.1	3.2
	MP	95/96	33.9	1.1	3.1	0.1	0.4	0.2	0.4	0.0	0.0	0.0	0.0	1.1	3.2
LBC[a]	HN	21/96	38.1	0.7	1.9	2.0	5.1	0.0	0.0	1.4	3.8	0.0	0.0	2.5	6.6
	LP	96/96	34.6	1.1	3.2	0.4	1.2	0.3	0.9	0.0	0.0	0.7	2.0	1.4	4.0
	MP	96/96	33.1	0.6	1.8	0.0	0.0	0.2	0.7	0.0	0.0	0.2	0.7	0.7	2.1

[a] PreservCyt LBC

Table 5: *N. gonorrhoeae* Site-to-Site Quantitative Reproducibility Across Sites with Pooled Days, Runs and Replicates

Target	*Matrix Type*	*Cat*	*Agree /N*	*Mean*	*Within Run*		*Between Run*		*Between Day*		*Between Operator*		*Between Site*		*Total*	
					SD	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*
GC1	Swab	HN	33/96	36.3	2.1	5.7	0.9	2.5	0.0	0.0	0.0	0.0	0.6	1.7	2.3	6.4
		LP	95/96	32.5	0.9	2.8	0.0	0.0	0.3	0.9	0.0	0.0	0.1	0.3	1.0	2.9
		MP	96/96	31.4	0.5	1.5	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.2	0.5	1.5
	Urine	HN	27/96	36.5	2.1	5.8	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.0	2.2	6.1
		LP	95/96	32.5	1.1	3.4	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	1.1	3.5
		MP	96/96	32.8	0.9	2.6	0.4	1.3	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.9
	LBC[a]	HN	11/96	35.5	1.4	3.9	0.0	0.0	0.9	2.7	0.0	0.0	0.0	0.0	1.7	4.7
		LP	94/96	32.1	0.5	1.6	0.4	1.2	0.3	1.0	0.1	0.4	0.1	0.4	0.7	2.3
		MP	96/96	30.7	0.5	1.5	0.5	1.5	0.0	0.0	0.0	0.0	0.4	1.2	0.7	2.4
GC2	Swab	HN	33/96	34.2	1.1	3.2	0.1	0.4	0.0	0.0	0.0	0.0	0.0	0.0	1.1	3.2
		LP	95/96	30.9	0.7	2.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.2
		MP	96/96	29.8	0.4	1.3	0.0	0.0	0.0	0.0	0.1	0.4	0.2	0.7	0.4	1.5
	Urine	HN	27/96	34.8	1.4	4.0	0.9	2.5	0.0	0.0	0.4	1.1	0.5	1.5	1.8	5.1
		LP	95/96	31.0	0.7	2.4	0.0	0.0	0.0	0.0	0.1	0.2	0.0	0.0	0.7	2.4
		MP	96/96	31.2	0.6	1.9	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.8	0.6	2.1
	LBC[a]	HN	11/96	35.3	0.8	2.2	1.1	3.1	0.0	0.0	0.0	0.0	0.8	2.3	1.6	4.5
		LP	94/96	30.5	0.4	1.2	0.4	1.3	0.3	1.1	0.0	0.0	0.2	0.8	0.7	2.2
		MP	96/96	29.2	0.3	1.1	0.4	1.3	0.2	0.7	0.1	0.5	0.3	1.0	0.6	2.2

[a] PreservCyt LBC

Table 6: *T. vaginalis* Site-to-Site Quantitative Reproducibility Across Sites with Pooled Days, Runs and Replicates

Matrix Type	*Cat*	*Agree /N*	*Mean*	*Within Run*		*Between Run*		*Between Day*		*Between Operator*		*Between Site*		*Total*	
				SD	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*
Swab	HN	36/96	36.9	1.8	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.8	5.0
	LP	95/96	33.2	0.7	2.2	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.7	0.8	2.3
	MP	96/96	32.3	0.5	1.6	0.0	0.0	0.0	0.0	0.1	0.3	0.0	0.0	0.5	1.6
Urine	HN	75/96	37.2	2.4	6.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.4	6.6
	LP	95/96	32.5	0.7	2.2	0.0	0.0	0.3	0.9	0.2	0.6	0.2	0.5	0.8	2.5
	MP	94/96	33.7	0.8	2.4	0.3	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.9	2.6

For the Lot-to-Lot reproducibility study, two operators each completed a single run of each panel member on two instruments for each of three lots of reagents over an 8-day period, at one testing site. The panels used were the same as described under the Precision heading, above. Results from one reagent lot of the site to site reproducibility study were used to comprise data for one lot of reagents for the Lot-to-Lot study.

The overall Lot-to-Lot reproducibility percent agreement across all targets ranged from 99.4% to 100% for TN, 10.4% to 75.0% for HN, 95.8% to 100% for LP and 95.8% to 100% for MP categories (**Table 7**). The Lot-to-Lot quantitative reproducibility according to Ct score is also shown in **Table 8** to **Table 10**.

Table 7: Lot-to-Lot Reproducibility (Percent Agreement with Expected Results)

Category	*Chlamydia trachomatis* (n), 95% CI			*Neisseria gonorrhoeae* (n), 95% CI			*Trichomonas vaginalis* (n), 95% CI	
	Swab	***Urine***	***LBC[c]***	***Swab***	***Urine***	***LBC[c]***	***Swab***	***Urine***
TN[a]	99.4% (668/672) 98.5-99.8	100% (672/672) 99.4-100	99.6% (669/672) 98.7-99.8	99.9% (671/672) 99.2-100	100% (672/672) 99.4-100	100% (672/672) 99.4-100	100% (672/672) 99.4-100	100% (672/672) 99.4-100
HN[b]	22.9% (22/96) 15.6-32.3	37.5% (36/96) 28.5-47.5	15.6% (15/96) 9.7-24.2	24.0% (23/96) 16.5-33.4	24.0% (23/96) 16.5-33.4	10.4% (10/96) 5.8-18.1	40.6% (39/96) 31.3-50.6	63.5% (61/96) 53.6-72.5
LP	100% (96/96) 96.2-100	100% (96/96) 96.2-100	99.0% (95/96) 94.3-99.8	99.0% (95/96) 94.3-99.8	95.8% (92/96) 89.8-98.4	100% (96/96) 96.2-100	99.0% (95/96) 94.3-99.8	99.0% (95/96) 94.3-99.8
MP	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	95.8% (92/96) 89.8-98.4	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.
[c] PreservCyt LBC

Table 8: *Chlamydia trachomatis* Lot-to-Lot Quantitative Reproducibility Study Results

Matrix Type	***Cat***	***Agree /N***	***Mean***	***Within Run***		***Between Run***		***Between Day***		***Between Operator***		***Between Lot***		***Total***	
				SD	***%CV***	***SD***	***%CV***	***SD***	***%CV***	***SD***	***%CV***	***SD***	***%CV***	***SD***	***%CV***
Swab	HN	22/96	37.3	1.1	2.9	2.2	5.9	1.2	3.1	0.0	0.0	0.0	0.0	2.7	7.3
	LP	96/96	33.6	1.0	2.9	0.4	1.2	0.0	0.0	0.2	0.6	0.3	0.7	1.1	3.3
	MP	96/96	32.6	0.8	2.3	0.0	0.0	0.3	1.0	0.1	0.4	0.1	0.3	0.8	2.6
Urine	HN	36/96	38.0	2.9	7.8	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.8	3.0	7.8
	LP	96/96	32.9	0.6	1.8	0.5	1.6	0.0	0.0	0.2	0.5	0.0	0.0	0.8	2.4
	MP	96/96	34.0	1.0	3.0	0.1	0.4	0.0	0.0	0.3	0.8	0.2	0.6	1.1	3.2
LBC[a]	HN	15/96	38.8	1.8	4.7	1.4	3.6	0.0	0.0	1.2	3.0	0.0	0.0	2.6	6.7
	LP	95/96	34.8	1.1	3.0	0.4	1.0	0.0	0.0	0.3	0.9	0.0	0.0	1.2	3.3
	MP	96/96	33.4	0.7	2.0	0.3	1.0	0.4	1.3	0.2	0.7	0.0	0.0	0.9	2.7

[a] PreservCyt LBC

Table 9: *Neisseria gonorrhoeae* Lot-to-Lot Quantitative Reproducibility Study Results

Target	*Matrix Type*	*Cat*	*Agree /N*	*Mean*	*Within Run*		*Between Run*		*Between Day*		*Between Operator*		*Between Lot*		*Total*	
					SD	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*
GC1	Swab	HN	23/96	36.4	1.5	4.1	0.0	0.0	1.3	3.6	1.0	2.9	1.1	2.9	2.5	6.8
		LP	95/96	32.7	1.5	4.4	0.6	1.7	0.0	0.0	0.0	0.0	0.0	0.0	1.6	4.7
		MP	96/96	31.6	0.7	2.2	0.1	0.4	0.0	0.0	0.0	0.0	0.2	0.7	0.8	2.4
	Urine	HN	23/96	36.8	2.5	6.8	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.0	2.6	7.1
		LP	92/96	32.6	1.3	4.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	1.3	4.0
		MP	92/96	32.8	0.9	2.8	0.2	0.8	0.0	0.0	0.0	0.0	0.1	0.2	1.0	2.9
	LBC [a]	HN	10/96	37.8	2.9	7.6	0.0	0.0	0.0	0.0	0.0	0.0	3.5	9.4	4.6	12.1
		LP	96/96	32.1	0.6	1.8	0.0	0.1	0.1	0.5	0.2	0.7	0.0	0.0	0.6	2.0
		MP	96/96	30.7	0.5	1.7	0.3	0.9	0.4	1.4	0.3	1.0	0.0	0.0	0.8	2.6
GC2	Swab	HN	23/96	35.4	1.1	3.2	1.1	3.0	1.7	4.8	0.0	0.0	1.0	2.8	2.5	7.1
		LP	95/96	31.1	0.7	2.2	0.3	0.8	0.0	0.0	0.0	0.0	0.2	0.6	0.8	2.4
		MP	96/96	30.2	0.6	2.1	0.2	0.5	0.0	0.0	0.0	0.0	0.2	0.8	0.7	2.3
	Urine	HN	23/96	35.1	1.8	5.2	1.3	3.7	1.0	2.9	0.0	0.0	0.0	0.0	2.5	7.0
		LP	92/96	31.1	0.8	2.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	2.7
		MP	92/96	31.6	0.7	2.4	0.0	0.0	0.0	0.0	0.2	0.6	0.0	0.0	0.8	2.4
	LBC [a]	HN	10/96	36.0	1.1	3.0	0.0	0.0	1.2	3.3	0.0	0.0	1.1	3.0	1.9	5.3
		LP	96/96	30.6	0.4	1.2	0.5	1.5	0.1	0.3	0.2	0.8	0.0	0.0	0.7	2.1
		MP	96/96	29.4	0.4	1.5	0.3	1.1	0.3	1.2	0.3	1.0	0.0	0.0	0.7	2.4

[a] PreservCyt LBC

Table 10: *Trichomonas vaginalis* Lot-to-Lot Quantitative Reproducibility Study Results

Matrix Type	*Cat*	*Agree /N*	*Mean*	*Within Run*		*Between Run*		*Between Day*		*Between Operator*		*Between Lot*		*Total*	
				SD	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*	*SD*	*%CV*
Swab	HN	39/96	36.8	2.1	5.8	0.0	0.0	0.0	0.0	0.3	0.7	0.0	0.0	2.1	5.8
	LP	95/96	33.4	1.2	3.7	0.0	0.0	0.3	0.9	0.0	0.0	0.3	1.0	1.3	4.0
	MP	96/96	32.4	0.7	2.3	0.1	0.4	0.1	0.3	0.1	0.2	0.0	0.0	0.8	2.4
Urine	HN	61/96	37.0	1.9	5.2	0.0	0.0	0.5	1.2	0.0	0.0	0.0	0.0	2.0	5.4
	LP	95/96	32.5	0.7	2.1	0.1	0.3	0.0	0.0	0.0	0.0	0.1	0.4	0.7	2.1
	MP	96/96	33.8	1.0	3.1	0.0	0.0	0.0	0.0	0.2	0.5	0.0	0.0	1.1	3.1

Sample Storage

Swab specimens must be transferred to a BD MAX Swab Sample Buffer Tube immediately after collection. First void urine specimens must be transferred from the collection cup to the BD MAX Urine Sample Buffer Tube immediately after collection. Once in the BD MAX Sample Buffer Tube, swab and urine specimens can be stored for up to 21 days at 2-30 °C and then up to an additional 30 days at -20 °C (**Table 11**).

Table 4: Swab and Urine Specimen Storage and Transport

Specimen Stability	Transport and/or Storage Time/Temperature
In BD MAX Swab or Urine Sample Buffer Tube	Up to 21 days at 2-30 °C and then up to an additional 30 days at -20 °C

LBC specimens in the vial prior to transfer to the BD MAX LBC Sample Buffer Tube can be stored up to 14 days at 2–30 °C. Once in the BD MAX LBC Sample Buffer Tube, samples can be stored for up to 21 days at 2–30 °C and then up to an additional 30 days at -20 °C, prior to or after pre-warm (**Table 12**).

Table 5: LBC Specimen Storage and Transport

Specimen Stability	Transport and/or Storage Time/Temperature
Prior to transfer to BD MAX LBC Sample Buffer Tube	Up to 14 days at 2-30 °C
In BD MAX LBC Sample Buffer Tube (prior to or after pre-warm)	Up to 21 days at 2-30 °C
In BD MAX LBC Sample Buffer Tube (after pre-warm)	and then up to an additional 30 days at -20 °C

Controls

External Control materials are not provided by BD; however, Quality Control strains and 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:

Chlamydia trachomatis serovar H (ATCC VR-879)

Neisseria gonorrhoeae (ATCC 19424)

Trichomonas vaginalis (ATCC 30001)

External negative control

Use a non-inoculated BD MAX Swab Sample Buffer Tube

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

The analytical sensitivity/Limit of Detection (LoD) in urine, vaginal swab and PreservCyt LBC specimen matrix was determined by preparing microbial suspensions from each of two (2) representative strains of the target organisms inoculated into pooled female urine, pooled vaginal swab and pooled PreservCyt LBC matrix in sample buffer with multiple concentrations of each representative strain. Each matrix suspension was tested with at least 20 replicates per LoD concentration across 3 different reagent lots. Analytical sensitivity (LoD), defined as the lowest concentration at which at least 95% of all replicates tested positive, is represented in **Table 13**.

Table 6: BD MAX CTGCTV2 Limits of Detection

Organism	***Strain***	***Specimen***	***LoD Concentration (units/mL)[a]***
Chlamydia trachomatis	Serovar H	Urine	2.5
		Swab	2.5
		PreservCyt	5
	Serovar D	Urine	1.25
		Swab	5
		PreservCyt	5
Neisseria gonorrhoeae	ATCC 19424	Urine	30
		Swab	15
		PreservCyt	30
	ATCC 49226	Urine	15
		Swab	30
		PreservCyt	60
Trichomonas vaginalis	ATCC 30001	Urine	5
		Swab	7.5
	ATCC 50143	Urine	2.5
		Swab	1.88

[a] Units/mL LoD concentration represented in Elementary Bodies (EB)/mL for *Chlamydia trachomatis*, cells/mL for *Neisseria gonorrhoeae* and TV/mL for *Trichomonas vaginalis*.

Analytical Inclusivity

Inclusivity testing was performed for 13 additional *Chlamydia trachomatis* serovars, 30 additional *Neisseria gonorrhoeae* strains and 8 additional *Trichomonas vaginalis* strains by spiking into female urine, vaginal swab and PreservCyt LBC pools prepared in sample buffer at concentrations targeting the predetermined LoD for each organism. Each serovar/strain was tested in 20 replicates with at least three different reagent lots. The results for *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* are presented in **Table 14** through **Table 16** and show the concentrations which were detected in at least 19/20 replicates (≥95%).

Table 7: Inclusivity Results – *Chlamydia trachomatis*

Organism	***Serovar***	***Swab***		***Urine***		***PreservCyt***	
		EBs/mL	***% POS***	***EBs/mL***	***% POS***	***EBs/mL***	***% POS***
Chalmydia trachomatis	A	5	100	2.5	100	5	100
	B	5	100	2.5	100	5	100
	C	5	≥ 95	2.5	100	5	100
	E	5	100	2.5	100	5	100
	F	5	100	2.5	100	5	100
	G	5	100	2.5	100	5	100
	I	5	100	2.5	100	5	100
	J	5	100	2.5	100	5	100
	K	5	100	2.5	100	5	100
	LGV1	5	100	2.5	100	5	100
	LGV2	5	100	2.5	100	5	100
	LGV3	5	100	2.5	100	5	100
	vE	5	100	2.5	100	5	100

Table 8: Inclusivity Results – *Neisseria gonorrhoeae*

Organism	***Number Strains***	***Swab***		***Urine***		***PreservCyt***	
		Cells/mL	***% POS***	***Cells/mL***	***% POS***	***Cells/mL***	***% POS***
Neisseria gonorrhoeae	30	NA	NA	NA	NA	60	≥95
	27	30	≥95	NA	NA	NA	NA
	3	45	≥95	NA	NA	NA	NA
	29	NA	NA	30	≥95	NA	NA
	1	NA	NA	45	100	NA	NA

Table 9: Inclusivity Results - *Trichomonas vaginalis*

Organism	***ATCC Strain***	***Swab***		***Urine***	
		TV/mL	***% POS***	***TV/mL***	***% POS***
Trichomonas vaginalis	30092	7.5	100	5	100
	30184	7.5	≥ 95	5	100
	30185	7.5	100	5	100
	30186	7.5	≥ 95	5	100
	30235	7.5	100	5	100
	30236	7.5	100	5	100
	30238	7.5	≥ 95	5	100
	30240	7.5	100	5	100

Analytical Specificity

The BD MAX CTGCTV2 assay was performed on samples containing phylogenetically related microorganisms likely to be found in urogenital specimens (**Table 17**). The bacterial cells, yeasts, viruses and parasites were tested in the Sample Buffer Tube at $2x10^6$ cells/mL, genomic DNA cp/mL, or EB/mL, and viruses were tested at $1x10^5$ viral particles or genomic equivalents/mL.

98% of bacterial strains, yeasts, parasites and viruses tested produced negative results with the BD MAX CTGCTV2. *Pentatrichomonas hominis* (commensal of the large intestine) produced positive results at a concentration ≥ 1.00 x 10^5 TV/mL for *Trichomonas vaginalis* and negative results for all other targets with the BD MAX CTGCTV2 assay. *Trichomonas tenax* (commensal of the oral cavity) produced positive results at a concentration ≥ 1.88 TV/mL for *Trichomonas vaginalis* and negative results for all other targets with the BD MAX CTGCTV2 assay.

Table 17: Specificity Organisms (Bacteria, Yeasts, Parasites and Viruses)

Organism	Organism	Organism
Achromobacter xerosis	*Escherichia coli*	*Neisseria mucosa* (3) [a]
Acinetobacter calcoaceticus	*Escherichia vulneris*	*Neisseria perflava*
Acinetobacter lwoffi	*Fuseobacterium nucleatum*	*Neisseria polysaccharea*
Actinomyces israelii	*Gardnerella vaginalis*	*Neisseria sicca* (3)
Actinomyces pyogenes	*Gemella haemolysans*	*Neisseria subflava* (14) [a]
Aerococcus viridans	*Haemophilus ducreyi*	*Paracoccus denitrificans*
Aeromonas hydrophilia	*Haemophilus influenzae*	*Pentatrichomonas hominis*
Agrobacterium radiobacter	Herpes Simplex Virus I	*Peptostreptococcus anaerobius*
Alcaligenes faecalis	Herpes Simplex Virus II	*Peptostreptococcus productus*
Atopobium vaginae	HIV 1	*Plesiomonas shigelloides*
Bacillus subtilis	HPV 16	*Prevotella bivia*
Bacteroides fragilis	*Kingella dentrificans*	*Propionibacterium acnes*
Bacteroides ureoeolyticus	*Kingella kingae*	*Proteus mirabilis*
Bifidobacterium adolescentis	*Klebsiella oxytoca*	*Proteus vulgaris*
Bifidobacterium brevi	*Klebsiella pneumoniae*	*Providencia stuartii*
Blastocystis hominis	*Lactobacillus acidophilus*	*Pseudomonas aeruginosa*
Branhamella catarrhalis	*Lactobacillus brevis*	*Pseudomonas fluorescens*
Brevibacterium linens	*Lactobacillus jensenii*	*Pseudomonas putida*
Campylobacter jejuni	*Lactobacillus lactis*	*Rahnella aquatilis*
Candida albicans	*Lactobacillus vaginalis*	*Rhodospirilium rubrum*
Candida gabralta	*Legionella pneumophilia* (2) [a]	*Saccharomyces cerevisiae*
Candida parapsilosis	*Leuconostoc paramensenteroides*	*Salmonella minnesota*
Candida tropicalis	*Listeria monocytogenes*	*Salmonella typhimurium*
Chlamydiophila pneumoniae	*Micrococcus leutus*	*Serratia marcescens*
Chlamydiophila psittaci (2) [a]	*Mobiluncus curtisii*	*Staphylococcus aureus,*non-protein
Chromobacterium violaceum	*Moraxella lacunata*	*Staphylococcus aureus*, protein-A
Citrobacter freundii	*Moraxella osloensis*	*Staphylococcus epidermidis*
Clostridium difficile	*Morganella morganii*	*Staphylococcus saprophyticus*
Clostridium perfringens	*Mycobacterium smegmatis*	*Streptcoccus bovis*
Corynebacterium genitalium biovar1	*Mycoplasma genitalium*	*Streptococcus agalactiae* (Group B)
Corynebacterium xerosis	*Mycoplasma hominis*	*Streptococcus mitis*
Cryptococcus neoformans	*Neisseria cinerea* (4)[a]	*Streptococcus mutans*
Cytomegalovirus	*Neisseria denitrificans*	*Streptococcus pneumoniae*
Deinococcus radiodurans	*Neisseria elongate* (3) [a]	*Streptococcus pyogenes* (Group A)
Derxia gummosa	*Neisseria flava*	*Streptococcus salivarius*
Eikenella corrodens	*Neisseria flavescens* (2) [a]	*Streptococcus sanguis*
Elizabethkingia meningosepticum	*Neisseria lactamica* (9) [a]	*Streptomyces griseinus*
Enterobacter aerogenes	*Neisseria meningitidis* A	*Trichomonas tenax*
Enterobacter cloacae	*Neisseria meningitidis* B	*Ureaplasma urealyticum*
Enterococcus avium	*Neisseria meningitidis* C (4) [a]	*Vibrio parahaemolyticus*
Enterococcus faecalis	*Neisseria meningitidis* D	*Yersinia enterocolitica*
Enterococcus faecium	*Neisseria meningitidis* W135	
Erysipelothrix rhusiopathiae	*Neisseria meningitidis* Y	

[a] The number in parenthesis indicates the number of strains tested.

Interfering Substances

Forty-four (44) biological and chemical substances that may be present in urogenital specimens were evaluated for potential interference at concentrations that may be found in urogenital specimens.

Negative urine, vaginal swab and PreservCyt LBC pooled specimens and a target mix of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* positive at 3X LoD were tested with each substance. Potentially interfering substances in urine specimens include whole blood. Potentially interfering substances in vaginal swab specimens include VCF Contraceptive Foam and Film, Conceptrol Contraceptive Gel, Monistat 3 cream, Vaginal Anti-Itch Cream, McKesson Lubricating Jelly, Surgilube, Aquagel, Acyclovir, Metronidazole, Replens, mucous and whole blood. Potentially interfering substances in PreservCyt LBC specimens include Vaginal Anti-Itch Cream, Metronidazole Gel, Replens, mucous, whole blood, McKesson Lubricating Jelly, Surgilube and Aquagel. The following substances shown in **Table 18** through **Table 20** did not cause interference with the BD MAX CTGCTV2 assays at the concentrations shown below.

Table 108: Endogenous and Exogenous Substances Tested for Interference in Urine

Substance	***Concentration***
Norethindrone	16 ng/mL
17-α-Ethinylestradiol	0.96 ng/mL
4-Acetamidophenol	160 µg/mL
Acetylsalicylic Acid	521.6 µg/mL
Naproxen	400 µg/mL
Ibuprofen	400 µg/mL
Human Serum Albumin	0.8 mg/mL
Glucose	0.96 mg/mL
Amoxicillin Trihydrate	60.16 µg/mL
Metronidazole	96 µg/mL
Tetracycline Hydrochloride	12 µg/mL
Azithromycin	9.6 µg/mL
Ceftriaxone	648.8 µg/mL
Sulfamethoxazole	320 µg/mL
Trimethoprim	32 µg/mL
Erythromycin	48 µg/mL
Mucous (Bovine Cervical)	4% v/v
Whole Blood	0.6% v/v [a]
Semen	4% v/v
Leukocytes	$2x10^6$ cells/mL
Phenazopyridine Hydrochloride	160 µg/mL
High pH (NaOH)	pH 9
Low pH (HCl)	pH 4
Bilirubin	0.16 mg/mL
Feminine Deodorant Spray	0.68% v/v
Talcum Powder	2.64% v/v

[a] May interfere with the BD MAX CTGCTV2 assay when at concentrations higher than shown.

Table 19: Endogenous and Exogenous Substances Tested for Interference in Swab Specimens

Substance	***Concentration***
VCF Contraceptive Foam	15 µL/mL[a]
VCF Contraceptive Film	0.5 µL/mL[a]
Conceptrol Contraceptive Gel	3 µL/mL[a]
Gyne-Lotrimin 3	50 µL/mL
Monistat 3 Cream	0.1 µL/mL[a]
Tioconazole 1	50 µL/mL
Vaginal Anti-Itch Cream	0.1 µL/mL[a]
Vaginal Lubricant Liquid - water based	50 µL/mL
Preparation H Hemorrhoid Gel	50 µL/mL
Antiviral (Zovirax – Acyclovir)	0.01 µL/mL[a]
Metronidazole Gel (AntiProtozoal)	1.25 µL/mL[a]
Replens (Vaginal Moisturizer)	0.1 µL/mL[a]
Douche	50 µL/mL
Feminine Deodorant Spray	50 µL/mL
Progesterone	20 ng/mL
Estradiol	1.2 ng/mL
Mucous (Bovine Cervical)	4.5% v/v[a]
Semen	5% v/v
Whole Blood	8 µL/mL[a]
Leukocytes	$1x10^6$ cells/mL
Aquagel	0.0345 mg/mL[a]
McKesson Lubricating Jelly	0.445 mg/mL[a]
Surgilube	0.41 mg/mL[a]
KY Lubricating Jelly	137.5 mg/mL

[a] May interfere with the BD MAX CTGCTV2 assay when at concentrations higher than shown.

Table 20: Endogenous and Exogenous Substances Tested for Interference in PreservCyt LBC Specimens

Substance	***Concentration***
Vaginal Lubricant	2% v/v
Douche	2% v/v
Vaginal Deodorant Spray	2% v/v
Progesterone	20 ng/mL
Estradiol	1.2 ng/mL
Leukocytes	1 x 10^6 cells/mL
Semen	2% v/v
Monistat 3	2% v/v
Clotrimazole 7	2% v/v
Tioconazole 1	2% v/v
Vaginal contraceptive film	2% v/v
Vaginal contraceptive foam	2% v/v
Contraceptive gel	2% v/v
Vaginal anti-itch Cream	1% v/v[a]
Zovirax (Acyclovir) Cream	2% v/v
Metronidazole Gel 0.75%	0.01% v/v[a]
Replens (Vaginal Moisturizer)	0.1% v/v[a]
Mucous (Bovine Cervical)	1.9% v/v[a]
Whole Blood	0.5% v/v[a]
Aquagel	0.276 mg/mL[a]
McKesson Lubricating Jelly	3.56 mg/mL[a]
Surgilube	328 mg/mL[a]
KY Lubricating Jelly	1,100 mg/mL

[a] May interfere with the BD MAX CTGCTV2 assay when at concentrations higher than shown.

Carryover/Cross-Contamination

High positive samples containing *Chlamydia trachomatis* (VR-879, Serovar H) spiked into pooled PreservCyt LBC matrix at a concentration of ≥1 x 10^6 EB/mL were processed with negative samples consisting of LBC Sample Buffer Tubes without any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were tested in 18 runs by alternating negative and positive samples, using three BD MAX instruments for a total of 216 positive and 216 negative samples tested. Of the 216 negative samples tested, two false positive results were obtained (0.93%, 95% CI: 0.25% - 3.31%).

Mixed Infection/Competitive Interference

Three test samples prepared in pooled clinical matrix (swab, urine and PreservCyt LBC) each containing one of the target organisms (*Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis*) at 1.5X their respective LoD, were tested with a high target mix comprised of the other two BD MAX CTGCTV2 analytes at a concentration ≥ 1x10^6 EB, cells or TV/mL to simulate mixed infections. The samples were tested in 20 replicates. All three low target organisms were successfully detected at ≥95% by the BD MAX CTGCTV2 assay in the presence of the other two organisms at high concentrations in urine, vaginal swab and PreservCyt LBC specimens. When assessed across all organisms and sample types, the observed Ct score shift ranged from -0.1 to 4.5 for *Chlamydia*

trachomatis, from -1.8 to 5.8 for *Neisseria gonorrhoeae*, and from 1.0 to 4.8 for *Trichomonas vaginalis*.

Clinical Performance Studies

Twelve geographically diverse clinical sites in North America participated in the clinical trial to evaluate the BD MAX CTGCTV2 assay. Two thousand five hundred and forty-seven (2,547) female subjects and 1,159 male subjects representing ages 18 and over were enrolled from sexually transmitted disease (STD), OB/GYN, and family planning clinics. Subjects were classified as symptomatic if they reported symptoms such as dysuria, urethral discharge, itching, odor, coital pain/difficulty/bleeding, testicular or scrotum pain/swelling, abnormal vaginal discharge, or pelvic/ uterine/adnexal pain. Subjects were classified as asymptomatic if they did not report these symptoms.

Eight specimens were collected from each eligible female subject: one first-catch urine, two randomized patient-collected vaginal swab specimens, two randomized clinician-collected vaginal swab specimens, two randomized endocervical swab specimens and one PreservCyt LBC specimen (collected using either the cervical broom or brush/spatula). One urine specimen was collected from each of the eligible male subjects. Samples were prepared for BD MAX CTGCTV2 and reference testing in accordance with the appropriate specimen collection kit package insert instructions.

All specimens from enrolled subjects were tested across five clinical trial testing sites. Samples with initial non-reportable (Unresolved, Indeterminate or Incomplete) results were repeated from the BD MAX Sample Buffer Tube. Following a valid repeat test, 0.3% (38/13,649) specimens remained non-reportable and were excluded from the sensitivity and specificity statistical analysis. The final data analysis included 2,536 evaluable female subjects and 1,149 evaluable male subjects. The estimates of performance of the BD MAX CTGCTV2 assay for *Chlamydia trachomatis* included: 2,508 patient-collected vaginal swabs, 2,502 clinician-collected vaginal swabs, 2,512 endocervical swabs, 2,469 PreservCyt LBC, 2,416 female urine and 1,140 male urine specimens. The estimates of performance of the BD MAX CTGCTV2 assay for *Neisseria gonorrhoeae* included: 2,506 patient-collected vaginal swabs, 2,503 clinician-collected vaginal swabs, 2,511 endocervical swabs, 2,470 PreservCyt LBC, 2,419 female urine and 1,142 male urine specimens. The estimates of performance of the BD MAX CTGCTV2 assay for *Trichomonas vaginalis* included: 1,742 patient-collected vaginal swabs, 1,732 clinician-collected vaginal swabs, 1,646 female urine and 1,141 male urine specimens. Exclusions included but were not limited to: missing specimens and/or reference test results, transport, collection, shipping, and/or processing errors.

Clinical Performance of Chlamydia trachomatis and Neisseria gonorrhoeae

The clinical performance of the BD MAX CTGCTV2 for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in females and males was calculated compared to a Patient Infected Status (PIS). The female PIS was established by testing urine and cervical specimens with two different FDA cleared NAATs (Nucleic Acid Amplification Test) where female subjects were designated as infected if at least two different reference NAATs were positive for urine and cervical specimens. For the purpose of data analysis, females who tested positive with the two comparator NAATs in urine only (negative in swabs with both NAATs), were considered non-infected when calculating the performance of the assay for swab specimens. The male PIS was established by testing urine specimens using up to three different FDA cleared NAATs where male subjects were designated as infected if 2 out of 3 reference NAAT results were positive. Subjects were categorized as non-infected if 2 out of 3 reference NAAT results were negative. The resulting performance is shown in **Table 21**.

Table 21: *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Performance Compared to PIS

Gender	Specimen Type	Symptom status	*Chlamydia trachomatis*		*Neisseria gonorrhoeae*	
			% Sens	% Spec	% Sens	% Spec
Female	Vaginal Clinician	A	98.2 55/56 90.6-99.7	98.8 1,076/1,089 98-99.3	100 15/15 79.6-100	99.8 1,129/1,131 99.4-100
		S	98.6 71/72 92.5-99.8	99.0 1,272/1,285 98.3-99.4	96.4 27/28 82.3-99.4	99.9 1,328/1,329 99.6-100
		All	98.4 126/128 94.5-99.6	98.9 2,348/2,374 98.4-99.3	97.7 42/43 87.9-99.6	99.9 2,457/2,460 99.6-100
	Vaginal Self	A	98.2 55/56 90.6-99.7	98.9 1,077/1,089 98.1-99.4	100 15/15 79.6-100	99.6 1,126/1,130 99.1-99.9
		S	98.6 71/72 92.5-99.8	98.5 1,271/1,291 97.6-99	100 28/28 87.9-100	100 1,333/1,333 99.7-100
		All	98.4 126/128 94.5-99.6	98.7 2,348/2,380 98.1-99	100 43/43 91.8-100	99.8 2,459/2,463 99.6-99.9
	Endo-cervical	A	96.4 54/56 87.9-99	99.4 1,084/1,090 98.8-99.7	100 15/15 79.6-100	99.9 1,131/1,132 99.5-100
		S	93.1 67/72 84.8-97	99.1 1,282/1,294 98.4-99.5	92.9 26/28 77.4-98	100 1,336/1,336 99.7-100
		All	94.5 121/128 89.1-97.3	99.2 2,366/2,384 98.8-99.5	95.3 41/43 84.5-98.7	100 2,467/2,468 99.8-100
	LBC Preserv-Cyt	A	92.6 50/54 82.4-97.1	99.7 1,076/1,079 99.2-99.9	100 15/15 79.6-100	99.9 1,118/1,119 99.5-100
		S	92.9 65/70 84.3-96.9	99.8 1,264/1,266 99.4-100	88.9 24/27 71.9-96.1	100 1,309/1,309 99.7-100
		All	92.7 115/124 86.8-96.1	99.8 2,340/2,345 99.5-99.9	92.9 39/42 81-97.5	100 2,427/2,428 99.8-100
Male	Urine	A	97.3 71/73 90.5-99.2	99.6 667/670 98.7-99.8	100 12/12 75.8-100	100 732/732 99.5-100
		S	96.3 77/80 89.5-98.7	99.1 314/317 97.3-99.7	99.1 110/111 95.1-99.8	99.7 286/287 98.1-99.9
		All	96.7 148/153 92.6-98.6	99.4 981/987 98.7-99.7	99.2 122/123 95.5-99.9	99.9 1,018/1,019 99.4-100

Clinical Performance of Trichomonas vaginalis

The clinical performance of the BD MAX CTGCTV2 for the detection of *Trichomonas vaginalis* infection in females and males was calculated compared to a PIS. The female PIS was established by testing vaginal specimens with two different FDA cleared molecular tests, across three different instrument platforms, where female subjects were designated as infected if 2 out of 3 reference test results were positive. Subjects were categorized as non-infected if 2 out of 3 reference test results were negative. The male PIS was established by testing urine specimens using up to three different FDA cleared NAATs where male subjects were designated as infected if 2 out of 3 reference test results were positive. Subjects were categorized as non-infected if 2 out of 3 reference test results were negative. The resulting performance is shown in **Table 22**.

Table 22: *Trichomonas vaginalis* Performance Compared to the PIS

Gender	***Specimen Type***	***Symptom status***	***Trichomonas vaginalis***	
			% Sens	***% Spec***
Female	Vaginal Clinician	A	98.5 66/67 92.0-99.7	99.6 687/690 98.7-99.9
		S	97.5 116/119 92.8-99.1	99.6 853/856 99.0-99.9
		All	97.8 182/186 94.6-99.2	99.6 1540/1546 99.2-99.8
	Vaginal Self	A	97.0 65/67 89.8-99.2	99.1 685/691 98.1-99.6
		S	98.4 120/122 94.2-99.5	99.2 855/862 98.3-99.6
		All	97.9 185/189 94.7-99.2	99.2 1540/1553 98.6-99.5
Male	Urine	A	96.2 25/26 81.1-99.3	99.6 678/681 98.7-99.9
		S	100 22/22 85.1-100	100 412/412 99.1-100
		All	97.9 47/48 89.1-99.6	99.7 1,090/1,093 99.2-99.9

Clinical Performance of Female Urine

The clinical performance of the BD MAX CTGCTV2 for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* infection in female urine was calculated compared to a Composite Comparator Algorithm (CCA) utilizing urine samples from up to three reference NAATs to generate reference results for each analyte. Female subjects were designated as positive if 2 out of 3 reference NAAT results were positive. Subjects were categorized as negative if 2 out

of 3 reference NAAT results were negative. The resulting performance expressed as positive percent agreement (PPA) and negative percent agreement (NPA) is shown in **Table 23**.

Additionally, the results obtained when using urine specimens in females were evaluated against the PIS based on cervical and urine algorithm. In the clinical study conducted for the BD MAX CTGCTV2 assay, female urine detected 5.8% fewer *Chlamydia trachomatis* infections than clinician and self-collected vaginal swabs and 1.9% fewer *Chlamydia trachomatis* infections than endocervical swabs. Female urine detected 2.4% fewer *Neisseria gonorrhoeae* infections than clinician-collected vaginal swabs and 4.7% fewer *Neisseria gonorrhoeae* infections than patient-collected vaginal swabs. There was no difference in the detection of *Neisseria gonorrhoeae* infections when comparing female urine and endocervical swabs.

Table 23: Clinical Performance of BD MAX CTGCTV2 in Female Urine, Compared to the CCA

Specimen Type	***Symp. Status***	***Chlamydia trachomatis***		***Neisseria gonorrhoeae***		***Trichomonas vaginalis***	
		PPA	***NPA***	***PPA***	***NPA***	***PPA***	***NPA***
Female Urine	A	98.1 51/52 89.9-99.7	99.2 1,037/1,045 98.5-99.6	100 14/14 78.5-100	99.9 1,085/1,086 99.5-100	100 58/58 93.8-100	99.8 646/647 99.1-100
	S	98.6 70/71 92.4-99.8	99.4 1,241/1,248 98.8-99.7	100 25/25 86.7-100	100 1,294/1,294 99.7-100	100 115/115 96.8-100	99.4 821/826 98.6-99.7
	All	98.4 121/123 94.3-99.6	99.3 2,278/2,293 98.9-99.6	100 39/39 91.0-100	100 2,379/2,380 99.8-100	100 173/173 97.8-100	99.6 1,467/1,473 99.1-99.8

Of all the specimens initially evaluated with the BD MAX CTGCTV2 assay, 1.1% of vaginal clinician-collected, 1.3% of patient-collected vaginal swab, 0.9% of endocervical swab, 0.2% of PreservCyt LBC and 0.9% of urine specimens initially reported as Unresolved. Following a valid repeat test, 0.3% of clinician-collected vaginal swab, 0.4% of patient-collected vaginal swab, 0.1% of endocervical swab, 0.0% of PreservCyt LBC and 0.1% of urine specimens remained Unresolved. The total numbers in **Table 24** are based on compliant specimens and BD MAX CTGCTV2 results.

Table 24: Unresolved Rates

Specimen Type	***Initial Unresolved Rate***		***Final Unresolved Rate with Valid Repeat***	
	Percent	***95% CI***	***Percent***	***95% CI***
Vaginal Clinician-Collected	1.1% (28/2,517)	(0.8%, 1.6%)	0.3% (7/2,517)	(0.1%, 0.6%)
Vaginal Patient-Collected	1.3% (34/2,525)	(1.0%, 1.9%)	0.4% (10/2,525)	(0.2%, 0.7%)
Endocervical	0.9% (22/2,519)	(0.6%, 1.3%)	0.1% (3/2,516)	(0.0%, 0.3%)
LBC PreservCyt	0.2% (6/2,473)	(0.1%, 0.5%)	0.0% (0/2,471)	(0.0%, 0.2%)
Urine	0.9% (34/3,621)	(0.7%, 1.3%)	0.1% (3/3,620)	(0.0%, 0.2%)

Of all the specimens initially evaluated with the BD MAX CTGCTV2 assay, 0.7% of clinician-collected vaginal swab, 0.6% of patient-collected vaginal swab, 0.6% of endocervical swab, 1.2% of PreservCyt LBC and 1.2% of urine specimens initially reported as Incomplete. Following a valid repeat test, 0.0% of all specimen types remained Incomplete. The total numbers in **Table 25** are based on compliant specimens and BD MAX CTGCTV2 results.

Table 25: Indeterminate Rates

Specimen Type	*Initial Indeterminate Rate*		*Final Indeterminate Rate with Valid Repeat*	
	Percent	*95% CI*	*Percent*	*95% CI*
Vaginal Clinician-Collected	0.8% (20/2,517)	(0.5%, 1.2%)	0.2% (6/2,517)	(0.1%, 0.5%)
Vaginal Patient-Collected	0.9% (23/2,525)	(0.6%, 1.4%)	0.1% (3/2,525)	(0.0%, 0.3%)
Endocervical	0.8% (19/2,519)	(0.5%, 1.2%)	0.1% (2/2,516)	(0.0%, 0.3%)
LBC PreservCyt	0.2% (6/2,473)	(0.1%, 0.5%)	0.0% (0/2,471)	(0.0%, 0.2%)
Urine	0.2% (9/3,621)	(0.1%, 0.5%)	0.1% (3/3,620)	(0.0%, 0.2%)

Of all the specimens initially evaluated with the BD MAX CTGCTV2 assay, 0.7% of clinician-collected vaginal swab, 0.6% of patient-collected vaginal swab, 0.6% of endocervical swab, 1.2% of PreservCyt LBC and 1.2% of urine specimens initially reported as Incomplete. Following a valid repeat test, 0.0% of all specimen types remained Incomplete. The total numbers in **Table 26** are based on compliant specimens and BD MAX CTGCTV2 results.

Table 26: Incomplete Rates

Specimen Type	*Initial Incomplete Rate*		*Final Incomplete Rate with Valid Repeat*	
	Percent	*95% CI*	*Percent*	*95% CI*
Vaginal Clinician-Collected	0.7% (17/2,517)	(0.4%, 1.1%)	0.0% (0/2,517)	(0.0%, 0.2%)
Vaginal Patient-Collected	0.6% (14/2,525)	(0.3%, 0.9%)	0.0% (1/2,525)	(0.0%, 0.2%)
Endocervical	0.6% (14/2,519)	(0.3%, 0.9%)	0.0% (0/2,516)	(0.0%, 0.2%)
LBC PreservCyt	1.2% (30/2,473)	(0.9%, 1.7%)	0.0% (0/2,471)	(0.0%, 0.2%)
Urine	1.2% (45/3,621)	(0.9%, 1.7%)	0.0% (0/3,620)	(0.0%, 0.1%)

Expected Values

The positivity rate of the MAX CTGCTV2, as observed during the multi-center clinical study, is shown by specimen type in **Table 27** and **Table 28**.

Table 117: BD MAX CTGCTV2 Clinical Study Female Positivity

% Positive (No. positive/No. of valid results)													
Site	*Chlamydia trachomatis*					*Neisseria gonorrhoeae*					*Trichomonas vaginalis*		
	CCVS[a]	SCVS[b]	Endo	LBC[c]	Urine	CCVS[a]	SCVS[b]	Endo	LBC[c]	Urine	CCVS[a]	SCVS[b]	Urine
1	3.4% 10/294	3.4% 10/297	3.3% 10/299	2.7% 8/298	3.1% 9/295	0.3% 1/294	0.7% 2/297	0.3% 1/299	0.3% 1/298	0.3% 1/295	23.1% 68/295	23.7% 71/299	23.4% 69/295
2	3.7% 18/486	5.1% 25/490	4.7% 23/489	3.8% 18/471	4.7% 23/489	1.0% 5/486	0.8% 4/489	0.6% 3/489	0.4% 2/471	0.8% 4/489	10.7% 52/486	12.0% 59/490	11.6% 57/491
3	5.3% 7/132	6.0% 8/133	4.5% 6/132	3.8% 5/133	4.5% 6/134	2.3% 3/132	2.3% 3/133	2.3% 3/132	2.3% 3/133	2.2% 3/134	6.8% 9/132	7.5% 10/133	7.5% 10/134
4	17.2% 5/29	17.2% 5/29	17.2% 5/29	13.8% 4/29	10.3% 3/29	3.4% 1/29	3.4% 1/29	3.4% 1/29	3.4% 1/29	3.4% 1/29	20.7% 6/29	20.7% 6/29	20.7% 6/29
5	7.1% 13/182	7.1% 13/182	5.5% 10/182	6.0% 11/182	7.7% 14/182	3.3% 6/182	3.3% 6/182	2.7% 5/182	2.7% 5/182	2.7% 5/182	14.8% 27/182	14.3% 26/182	14.3% 26/182
6	7.3% 35/482	7.0% 34/483	5.4% 26/481	5.2% 25/484	6.2% 28/453	1.5% 7/482	1.7% 8/482	1.5% 7/481	1.2% 6/484	1.5% 7/453	6.6% 32/482	7.9% 38/482	6.6% 30/453
7	6.7% 5/75	6.7% 5/75	7.9% 6/76	6.4% 5/78	7.9% 6/76	0.0% 0/75	0.0% 0/75	0.0% 0/76	0.0% 0/78	0.0% 0/76	10.7% 8/75	12.0% 9/75	11.8% 9/76
8	3.9% 11/283	4.6% 13/283	3.9% 11/282	3.6% 10/276	3.7% 10/272	0.0% 0/283	0.0% 0/282	0.0% 0/282	0.0% 0/276	0.0% 0/272	1.4% 4/283	1.1% 3/282	1.1% 3/272
9	12.8% 33/257	11.6% 30/259	11.2% 29/259	10.6% 25/235	10.9% 28/256	6.2% 16/257	6.6% 17/259	6.2% 16/257	6.8% 16/235	5.5% 14/256	18.7% 48/257	18.1% 47/259	16.8% 43/256
10	9.4% 12/127	11.0% 14/127	10.2% 13/127	7.9% 10/127	7.9% 10/127	4.7% 6/127	4.7% 6/127	4.7% 6/127	4.7% 6/127	4.7% 6/127	7.9% 10/127	7.9% 10/127	7.9% 10/127
11	2.5% 4/157	1.9% 3/156	0.6% 1/157	0.0% 0/157	1.9% 3/157	0.0% 0/157	0.0% 0/156	0.0% 0/157	0.0% 0/157	0.0% 0/157	1.3% 2/157	1.3% 2/156	1.3% 2/157
Total	6.1% 153/2504	6.4% 160/2514	5.6% 140/2513	4.9% 121/2470	5.7% 140/2470	1.8% 45/2504	1.9% 47/2511	1.7% 42/2511	1.6% 40/2470	1.7% 41/2470	10.6% 266/2505	11.2% 281/2514	10.7% 265/2472

[a] Clinician-collected vaginal swab

[b] Self-collected vaginal swab

[c] PreservCyt LBC

Table 128: BD MAX CTGCTV2 Clinical Study Male Positivity

% Positive (No. positive/No. of valid results)			
Site	***Chlamydia trachomatis***	***Neisseria gonorrhoeae***	***Trichomonas vaginalis***
1	17.0% 8/47	2.1% 1/47	0.0% 0/47
2	18.9% 28/148	23.6% 35/148	2.0% 3/148
3	12.0% 35/291	9.6% 28/291	5.2% 15/291
4	10.0% 36/359	7.2% 26/359	3.3% 12/359
5	13.3% 13/98	4.1% 4/98	5.1% 5/98
6	17.6% 35/199	14.6% 29/199	7.5% 15/199
Total	13.6% 155/1,142	10.8% 123/1,142	4.4% 50/1,142

Positive and Negative Predictive Value

Hypothetical Positive Predictive Value (PPV) and Negative Predictive Value (NPV) based on observed sensitivity and specificity as compared to the Patient Infected Status are shown in **Table 29**.

Table 13: Hypothetical PPV and NPV for BD MAX CTGCTV2

Specimen Type	Hypothetical Prevalence	*Chlamydia trachomatis*		*Neisseria gonorrhoeae*		*Trichomonas vaginalis*	
		% PPV 95% CI	% NPV 95% CI	% PPV 95% CI	% NPV 95% CI	% PPV 95% CI	% NPV 95% CI
Vaginal[a]	1%	44.9% (36.3%, 53.9%)	100% (99.9%, 100%)	87.5% (73.8%, 96.1%)	100% (99.9%, 100%)	61.7% (47.3%, 76.4%)	100% (99.9%, 100%)
	2%	62.2% (53.5%, 70.3%)	100% (99.9%, 100%)	93.4% (85.1%, 98.0%)	100% (99.8%, 100%)	76.5% (64.5%, 86.7%)	100% (99.9%, 100%)
	5%	80.9% (74.8%, 85.9%)	99.9% (99.7%, 100%)	97.3% (93.6%, 99.2%)	99.9% (99.6%, 100%)	89.4% (82.4%, 94.4%)	99.9% (99.7%, 100%)
	10%	90.0% (86.2%, 92.8%)	99.8% (99.4%, 100%)	98.7% (96.9%, 99.6%)	99.9% (99.1%, 100%)	94.7% (90.8%, 97.3%)	99.8% (99.4%, 99.9%)
	15%	93.4% (90.9%, 95.3%)	99.7% (99.0%, 99.9%)	99.2% (98.0%, 99.8%)	99.8% (98.5%, 100%)	96.6% (94.0%, 98.3%)	99.6% (99.1%, 99.9%)
	20%	95.3% (93.4%, 96.7%)	99.6% (98.6%, 99.9%)	99.4% (98.6%, 99.8%)	99.7% (97.9%, 100%)	97.6% (95.7%, 98.8%)	99.5% (98.7%, 99.8%)
	25%	96.4% (94.9%, 97.5%)	99.5% (98.2%, 99.9%)	99.6% (98.9%, 99.9%)	99.6% (97.3%, 100%)	98.2% (96.7%, 99.1%)	99.3% (98.2%, 99.7%)
Endocervical	1%	55.8% (44.5%, 66.7%)	99.9% (99.9%, 100%)	96.0% (80.8%, 99.3%)	100% (99.8%, 100%)	-	-
	2%	71.9% (61.8%, 80.2%)	99.9% (99.8%, 99.9%)	98.0% (89.5%, 99.6%)	99.9% (99.7%, 100%)	-	-
	5%	86.8% (80.7%, 91.2%)	99.7% (99.4%, 99.9%)	99.2% (95.6%, 99.9%)	99.8% (99.2%, 99.9%)	-	-
	10%	93.3% (89.8%, 95.7%)	99.4% (98.8%, 99.7%)	99.6% (97.9%, 99.9%)	99.5% (98.3%, 99.9%)	-	-
	15%	95.7% (93.3%, 97.2%)	99.0% (98.1%, 99.5%)	99.8% (98.7%, 100%)	99.2% (97.3%, 99.8%)	-	-
	20%	96.9% (95.2%, 98.0%)	98.6% (97.3%, 99.3%)	99.8% (99.0%, 100%)	98.9% (96.3%, 99.7%)	-	-
	25%	97.7% (96.4%, 98.5%)	98.2% (96.5%, 99.1%)	99.9% (99.3%, 100%)	98.5% (95.1%, 99.6%)	-	-
LBC PreservCyt	1%	81.5% (65.2%, 91.1%)	99.9% (99.9%, 100%)	95.8% (80.1%, 99.2%)	99.9% (99.8%, 100%)	-	-
	2%	89.9% (79.1%, 95.4%)	99.9% (99.7%, 99.9%)	97.9% (89.0%, 99.6%)	99.9% (99.6%, 99.9%)	-	-
	5%	95.8% (90.7%, 98.2%)	99.6% (99.3%, 99.8%)	99.2% (95.4%, 99.9%)	99.6% (99.0%, 99.9%)	-	-
	10%	98.0% (95.4%, 99.1%)	99.2% (98.5%, 99.6%)	99.6% (97.8%, 99.9%)	99.2% (97.9%, 99.7%)	-	-
	15%	98.7% (97.0%, 99.4%)	98.7% (97.7%, 99.3%)	99.7% (98.6%, 100%)	98.8% (96.8%, 99.6%)	-	-
	20%	99.1% (97.9%, 99.6%)	98.2% (96.8%, 99.0%)	99.8% (99.0%, 100%)	98.2% (95.5%, 99.4%)	-	-
	25%	99.3% (98.4%, 99.7%)	97.6% (95.8%, 98.7%)	99.9% (99.3%, 100%)	97.7% (94.0%, 99.2%)	-	-
Urine	1%	61.6% (42.5%, 77.8%)	100% (99.9%, 100%)	91.1% (64.4%, 98.3%)	100% (100%, 100%)	78.3% (55.1%, 91.4%)	100% (99.9%, 100%)
	2%	76.5% (59.9%, 87.6%)	99.9% (99.8%, 100%)	95.4% (78.5%, 99.2%)	100.0% (99.9%, 100%)	87.9% (71.3%, 95.5%)	100% (99.8%, 100%)
	5%	89.3% (79.4%, 94.8%)	99.8% (99.6%, 99.9%)	98.2% (90.4%, 99.7%)	100% (99.8%, 100%)	94.9% (86.5%, 98.2%)	99.9% (99.4%, 100%)
	10%	94.6% (89.1%, 97.5%)	99.6% (99.2%, 99.8%)	99.1% (95.2%, 99.8%)	99.9% (99.5%, 100%)	97.5% (93.1%, 99.1%)	99.8% (98.8%, 100%)
	15%	96.6% (92.8%, 98.4%)	99.4% (98.7%, 99.8%)	99.4% (96.9%, 99.9%)	99.9% (99.2%, 100%)	98.4% (95.5%, 99.5%)	99.6% (98.1%, 99.9%)
	20%	97.5% (94.8%, 98.9%)	99.2% (98.2%, 99.6%)	99.6% (97.8%, 99.9%)	99.8% (98.9%, 100%)	98.9% (96.8%, 99.6%)	99.5% (97.3%, 99.9%)
	25%	98.1% (96.1%, 99.1%)	98.9% (97.6%, 99.5%)	99.7% (98.4%, 99.9%)	99.7% (98.5%, 100%)	99.2% (97.6%, 99.7%)	99.3% (96.5%, 99.9%)

[a] *The sensitivity and specificity estimates for the patient- and clinician-collected vaginal swabs are similar; the PPV and NPV for vaginal swabs was calculated based on the averages of those estimates.*