DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 6, 2016

BD Diagnostic Systems
Becton, Dickinson, and Company
Katie Edwards, Regulatory Affairs Project Manager
7 Loveton Circle
Sparks, MD 21152

Re: K151589
Trade/Device Name: BD MAX™ CT/GC/TV
Regulation Number: 21 CFR 866.3860
Regulation Name: *Trichomonas vaginalis* nucleic acid assay
Regulatory Class: II
Product Code: OUY, MKZ, LSL
Dated: August 19, 2016
Received: August 22, 2016

Dear Ms. 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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Steven R. Gitterman -S

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151589

Device Name
BD MAX™ CT/GC/TV

Indications for Use *(Describe)*
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.

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 CT/GC/TV

Summary Preparation Date:

September 1, 2016

Submitted by:

BD Life Sciences
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152

Contact:
Katie Edwards
Regulatory Affairs Project Manager

Tel: 410-316-4975
Fax: 410-316-4188
Email: Katie_Edwards@bd.com

Proprietary Names:

For the instrument:

BD MAX™

For the assay:

BD MAX CT/GC/TV

Common Names:

For the instrument:

Bench-top molecular diagnostics workstation

For the assay:

CT Assay
GC Assay
TV Assay

Regulatory Information

Regulation section:

866.3120 – *Chlamydia* serological reagents
866.3390 – *Neisseria* spp. direct serological test reagents
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

Becton Dickinson ProbeTec™ ET *Chlamydia trachomatis* (CT) Q^X Amplified DNA Assay [510(k) K081824]

Becton Dickinson ProbeTec™ ET *Neisseria gonorrhoeae* (GC) Q^X Amplified DNA Assay [510(k) K081825]

Becton Dickinson ProbeTec™ *Trichomonas Vaginalis* (TV) Q^X Amplified DNA Assay [510(k) K130268]

Device Establishment

GeneOhm Sciences Canada, Inc. (BD Diagnostics)
2555 Boul. du Parc-Technologique
Quebec, QC G1P 4S5
Canada

Registration Number: 3007420875

Performance Standards

No performance standards have been developed under Section 514 of the Food, Drug and Cosmetic Act.

Intended Use

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.

Special Conditions for Use Statement: For prescription use

Special Instrument Requirements: BD MAX System

Device Description

The BD MAX System and the BD MAX CT/GC/TV 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 or UNR 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 failure.

Test Principle

The specimen is collected from the patient using the BD MAX UVE Specimen Collection Kit and transported to the laboratory under conditions of time and temperature that have been determined to maintain the integrity of the target nucleic acids. The sample is vortexed briefly and then heated on the BD Pre-warm Heater to dissolve mucous, homogenize the specimen matrix and lyse the target organisms. After cooling automatically, the BD MAX UVE Sample Buffer Tubes are recapped with a septum cap. A worklist is created and the BD MAX UVE Sample Buffer Tube, the BD MAX CT/GC/TV Unitized Reagent Strip and the BD MAX PCR Cartridge are loaded on 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 that is present in the Extraction Tube. The Sample Processing Control monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances.

Following cell lysis, the released nucleic acids are captured on magnetic affinity beads. The beads, with the bound nucleic acids, are washed using Wash Buffer and the nucleic acids are eluted by heat in Elution Buffer. 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 to contain the amplification mixture, thus preventing evaporation and contamination. The amplified DNA targets are detected using hydrolysis

(TaqMan®) probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end, with a quencher moiety. Probes labeled with different fluorophores are used to detect amplicons for target analytes and the Sample Processing Control in four 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 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[1]

Table 1 shows the similarities and differences between the BD MAX CT/GC/TV and the predicate device.

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

Table 1: Comparison to Predicate Device

Items	*BD MAX CT/GC/TV*	*BD ProbeTec™ ET CT Q^x Amplified DNA Assay*	*BD ProbeTec™ ET GC Q^x Amplified DNA Assay*	*BD ProbeTec™ TV Q^x Amplified DNA Assay*
510(k)#	K151589	K081824	K081825	K130268
Regulation	866.3120, 866.3390, 866.3680	866.3120	866.3390	866.3860
Product Code	MKZ, LSL, OUY	MKZ	LSL	OUY
Device Class	II	I	Same	Same
Intended Use	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.	The BD ProbeTec *Chlamydia trachomatis* Q*x* Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Chlamydia trachomatis* DNA in clinician collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.	The BD ProbeTec™ *Neisseria gonorrhoeae* Q*x* Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper LT™ System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.	The BD ProbeTec™ *Trichomonas vaginalis* (TV) Q*x* Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Trichomonas vaginalis* DNA in clinician-collected female endocervical swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and female urine specimens. The assay is indicated for use with asymptomatic and symptomatic females to aid in the diagnosis of trichomoniasis.
Indications for Use	Asymptomatic and Symptomatic Patients	Same	Same	Same
Specimen Type	Endocervical swab, patient-collected vaginal swab, female and male urine	Endocervical swab, patient-collected vaginal swab, male urethral swab, male and female urine (UPT and neat)	Endocervical swab, patient-collected vaginal swab, male urethral swab, male and female urine (UPT and neat)	Endocervical swab, patient-collected vaginal swab, female urine
Technology	PCR	SDA	SDA	SDA
Organisms Detected	CT, GC and TV	CT	GC	TV
Sample Prep /Interpretation of Results	Automated by BD MAX System	Automated by BD Viper System	Automated by BD Viper System	Automated by BD Viper System
Assay Controls	Sample Processing Control	Extraction Control	Extraction Control	Extraction Control

Analytical Performance

Precision

Within-laboratory precision was evaluated for the BD MAXCT/GC/TV at one (1) internal site. The Precision Study panel members were divided into four (4) categories, based upon organism concentration relative to the LoDs established for each of the three (3) assay targets and expected correct percent positive/negative, as follows:

- True negative (TN – Negative Clinical Matrix): negative 100% of the time
- Moderate positive (MP): Above the assay LoD ("C100", ~2–3x LoD); positive 100% of the time
- Low positive (LP): At assay LoD ("C95", ~1–1.5x LoD); positive approximately 95% of the time
- High negative (HN): Below assay LoD (~0.25–0.5x LoD); negative between 5 and 85% of the time

Each panel member was prepared in a matrix of either pooled negative vaginal clinical swab specimen or female urine. Testing was performed in duplicate, over 12 days, with 2 runs per day, by 2 different technologists. The Precision Study results are summarized in **Table 2**, stated as percent observed versus expected.

Table 2: Within-laboratory Precision Testing Results

Panel Member Level	***Percent (%) Observed versus Expected***					
	C. trachomatis		***N. gonorrhoeae***		***T. vaginalis***	
	Swab	*Urine*	*Swab*	*Urine*	*Swab*	*Urine*
True Negative	100% (336/336) 98.9-100	100% (336/336) 98.9-100	100% (48/48) 92.6-100	100% (336/336) 98.9-100	100% (336/336) 98.9-100	100% (48/48) 92.6-100
High Negative	79.2% (38/48) 65.7-88.3	79.2% (38/48) 65.7-88.3	54.2% (26/48) 40.3-67.4	10.4% (5/48) 4.5-22.2	56.3% (27/48) 42.3-69.3	14.6% (7/48) 7.2-27.2
Low Positive	100% (48/48) 92.6-100	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
Moderate Positive	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.

Reproducibility

For the Site-to-Site reproducibility study, three (3) sites (two external and one internal) were provided with a total of sixteen (16) panels per site, each consisting of 10 tubes. The panels used were the same as described above for the Precision Study. Each site performed the study on eight (8) non-consecutive days, wherein each day, two (2) panels were tested, each by one (1) of two (2) technologists.

The overall Site-to-Site Reproducibility percent agreement ranged from 99.9 to 100.0%, 15.6% to 78.1%, 96.9% to 100% and 100% for the TN, HN, LP and MP categories, respectively (see **Table 3**). The qualitative and quantitative reproducibility across sites and by target is presented in **Tables 4** through **9**. End Point fluorescence (EP) and Second Derivative Peak Abscissa (SDPA), internal criterion used to

determine final assay results, was selected as an additional means of assessing assay reproducibility. Overall mean EP and SDPA values with variance components (SD and %CV) are shown in **Tables 5**, **7** and **9**.

Table 3: MAX CT/GC/TV Site-to-Site Reproducibility Study Results

Category	***Percent Observed versus Expected***					
	***C. trachomatis* (n), 95% CI**		***N. gonorrhoeae* (n), 95% CI**		***T. vaginalis* (n), 95% CI**	
	Swab	*Urine*	*Swab*	*Urine*	*Swab*	*Urine*
TN	100% (672/672) 99.4-100	99.9% (671/672) 99.2-100	100% (96/96) 96.2-100	100% (672/672) 99.4-100	100% (672/672) 99.4-100	100% (96/96) 96.2-100
HN	78.1% (75/96) 68.9-85.2	75.0% (72/96) 65.5-82.6	55.2% (53/96) 45.3-64.8	15.6% (15/96) 9.7-24.2	52.1% (50/96) 42.2-61.8	35.4% (34/96) 26.6-45.4
LP	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	100% (96/96) 96.2-100	96.9% (93/96) 91.2-98.9	100% (96/96) 96.2-100
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	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.

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

Category	***Type***	***x LoD***	***Site***						***Total***	
			1		*2*		*3*			
			Agree/N	*%*	*Agree/N*	*%*	*Agree/N*	*%*	*Agree/N*	*%*
TN	Swab	0	224/224	100	224/224	100	224/224	100	672/672	100
	Urine		223/224	99.6	224/224	100	224/224	100	671/672	99.9
HN	Swab	0.2	29/32	90.6	21/32	65.6	25/32	78.1	75/96	78.1
	Urine		28/32	87.5	20/32	62.5	24/32	75.0	72/96	75.0
LP	Swab	1.5	32/32	100	32/32	100	32/32	100	96/96	100
	Urine		32/32	100	32/32	100	32/32	100	96/96	100
MP	Swab	3	32/32	100	32/32	100	32/32	100	96/96	100
	Urine		32/32	100	32/32	100	32/32	100	96/96	100

Table 5: *C. trachomatis* Site-to-Site Quantitative Reproducibility Across Sites, Days, Runs and Within Run

Variable	*Type*	*Cat.*	*Agreed/ 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*
EP	Swab	HN	75/96	1563.3	556.6	35.6	285.2	18.2	0.0	0.0	0.0	0.0	337.2	21.6	710.6	45.5
		LP	96/96	2170.9	417.7	19.2	268.7	12.4	0.0	0.0	0.0	0.0	345.6	15.9	605.1	27.9
		MP	96/96	2264.4	297.6	13.1	215.9	9.5	0.0	0.0	0.0	0.0	232.0	10.2	434.8	19.2
	Urine	HN	72/96	1488.8	601.0	40.4	340.6	22.9	0.0	0.0	142.0	9.5	0.0	0.0	705.2	47.4
		LP	96/96	2221.5	380.7	17.1	201.4	9.1	96.5	4.3	224.8	10.1	279.6	12.6	568.7	25.6
		MP	96/96	2219.0	308.9	13.9	207.6	9.4	0.0	0.0	36.7	1.7	213.9	9.6	430.8	19.4
SDPA	Swab	HN	75/96	37.3	1.4	3.9	0.1	0.3	0.4	1.0	0.0	0.0	0.4	0.9	1.5	4.1
		LP	96/96	34.8	0.8	2.4	0.0	0.0	0.0	0.0	0.1	0.2	0.3	1.0	0.9	2.6
		MP	96/96	34.4	0.6	1.8	0.3	0.8	0.0	0.0	0.1	0.2	0.6	1.6	0.9	2.6
	Urine	HN	72/96	37.8	1.6	4.3	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.2	1.7	4.5
		LP	96/96	33.6	0.7	2.0	0.3	1.0	0.3	0.8	0.1	0.3	0.6	1.8	1.0	2.9
		MP	96/96	32.9	0.6	1.8	0.1	0.3	0.1	0.4	0.1	0.2	0.6	1.8	0.8	2.6

Table 6: *N. gonorrhoeae* Site-to-Site Qualitative Reproducibility Across Sites with Pooled Days, Runs and Replicates

Category	*Type*	*x LoD*	*Site*						*Total*	
			1		*2*		*3*			
			Agree/N	*%*	*Agree/N*	*%*	*Agree/N*	*%*	*Agree/N*	*%*
TN	Swab	0	32/32	100	32/32	100	32/32	100	96/96	100
	Urine		224/224	100	224/224	100	224/224	100	672/672	100
HN	Swab	0.15	16/32	50.0	15/32	46.9	22/32	68.8	53/96	55.2
	Urine	0.25	8/32	25.0	3/32	9.4	4/32	12.5	15/96	15.6
LP	Swab	1.5	32/32	100	32/32	100	32/32	100	96/96	100
	Urine		32/32	100	32/32	100	32/32	100	96/96	100
MP	Swab	3	32/32	100	32/32	100	32/32	100	96/96	100
	Urine		32/32	100	32/32	100	32/32	100	96/96	100

Table 7: *N. gonorrhoeae* Site-to-Site Quantitative Reproducibility Across Sites, Days, Runs and Within Run

Variable	*Type*	*Cat*	*Agreed/ 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*
EP	Swab	HN	53/96	974.2	369.2	37.9	0.0	0.0	0.0	0.0	55.9	5.7	119.8	12.3	392.1	40.3
		LP	96/96	1518.0	199.1	13.1	227.5	15.0	0.0	0.0	75.8	5.0	260.2	17.1	406.0	26.7
		MP	96/96	1715.0	265.8	15.5	186.6	10.9	84.0	4.9	0.0	0.0	299.7	17.5	449.8	26.2
	Urine	HN	15/96	1615.2	0.9	0.1	600.8	37.2	0.0	0.0	0.0	0.0	68.3	4.2	604.6	37.4
		LP	96/96	2260.4	364.6	16.1	225.1	10.0	0.0	0.0	107.1	4.7	437.8	19.4	621.9	27.5
		MP	96/96	2420.7	737.0	30.4	0.0	0.0	0.0	0.0	0.0	0.0	162.8	6.7	754.8	31.2
SDPA	Swab	HN	53/96	35.6	1.1	3.2	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	1.1	3.2
		LP	96/96	33.6	0.7	2.0	0.3	0.9	0.0	0.0	0.1	0.2	0.1	0.4	0.7	2.2
		MP	96/96	32.6	0.6	1.7	0.2	0.8	0.0	0.0	0.2	0.6	0.3	1.0	0.7	2.2
	Urine	HN	15/96	37.8	0.7	1.9	2.2	5.8	0.0	0.0	0.0	0.0	1.1	3.0	2.6	6.7
		LP	96/96	33.8	0.8	2.3	0.2	0.5	0.0	0.0	0.3	0.8	0.0	0.0	0.8	2.5
		MP	96/96	32.8	0.6	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.6	0.7	2.0

Table 8: *T. vaginalis* Site-to-Site Qualitative Reproducibility Across Sites with Pooled Days, Runs and Replicates

Category	***Type***	***x LoD***	***Site***						***Total***	
			1		*2*		*3*			
			Agree/N	*%*	*Agree/N*	*%*	*Agree/N*	*%*	*Agree/N*	*%*
TN	Swab	0	224/224	100	224/224	100	224/224	100	672/672	100
	Urine		32/32	100	32/32	100	32/32	100	96/96	100
HN	Swab	0.25	15/32	46.9	15/32	46.9	20/32	62.5	50/96	52.1
	Urine	0.05	4/32	12.5	19/32	59.4	11/32	34.4	34/96	35.4
LP	Swab	1.5	30/32	93.8	31/32	96.9	32/32	100	93/96	96.9
	Urine		32/32	100	32/32	100	32/32	100	96/96	100
MP	Swab	3	32/32	100	32/32	100	32/32	100	96/96	100
	Urine		32/32	100	32/32	100	32/32	100	96/96	100

Table 9: *T. vaginalis* Site-to-Site Quantitative Reproducibility Across Sites, Days, Runs and Within Run

Variable	*Type*	*Cat.*	*Agreed/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*
EP	Swab	HN	50/96	2172.0	946.7	43.6	0.0	0.0	414.0	19.1	0.0	0.0	450.2	20.7	1127.1	51.9
		LP	93/96	3068.7	1063.7	34.7	0.0	0.0	0.0	0.0	0.0	0.0	779.8	25.4	1318.9	43.0
		MP	96/96	3519.5	875.1	24.9	0.0	0.0	0.0	0.0	23.4	0.7	809.1	23.0	1192.1	33.9
	Urine	HN	34/96	1887.5	747.1	39.6	200.7	10.6	0.0	0.0	0.0	0.0	0.0	0.0	773.6	41.0
		LP	96/96	3076.8	289.8	9.4	76.5	2.5	0.0	0.0	78.9	2.6	115.4	3.8	330.7	10.7
		MP	96/96	3092.0	199.4	6.4	184.0	5.9	0.0	0.0	0.0	0.0	206.0	6.7	340.6	11.0
SDPA	Swab	HN	50/96	37.6	1.9	5.1	0.0	0.0	0.0	0.0	0.2	0.6	0.0	0.0	1.9	5.1
		LP	93/96	35.3	1.2	3.3	0.5	1.5	0.0	0.0	0.0	0.0	0.0	0.0	1.3	3.6
		MP	96/96	35.0	1.0	2.8	0.0	0.0	0.3	1.0	0.3	0.8	0.0	0.0	1.1	3.1
	Urine	HN	34/96	38.3	1.6	4.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.6	4.1
		LP	96/96	34.6	0.5	1.6	0.2	0.6	0.1	0.2	0.2	0.5	0.1	0.2	0.6	1.8
		MP	96/96	33.5	0.3	1.0	0.2	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.3

For the Lot-to-Lot reproducibility study, two operators each completed a single run of 10 panel members on a single instrument for each of three lots of reagents over an 8-day period. 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 99.9% to 100%, 29.2% to 72.9%, and 100% for the TN, HN, LP and MP categories, respectively (**Table 10**).

Table 10: Lot-to-Lot Reproducibility

Target	*Type*	*Level*	*Correct*	*Total*	*% Correct*	*95% CI*
Chlamydia trachomatis	Swab	TN**	672	672	100	(99.4-100)
		HN*	70	96	72.9	(63.3-80.8)
		LP	96	96	100	(96.2-100)
		MP	96	96	100	(96.2-100)
	Urine	TN	672	672	100	(99.4-100)
		HN	70	96	72.9	(63.3-80.8)
		LP	96	96	100	(96.2-100)
		MP	96	96	100	(96.2-100)
Neisseria gonorrhoeae	Swab	TN	96	96	100	(96.2-100)
		HN	40	96	41.7	(32.3-51.7)
		LP	96	96	100	(96.2-100)
		MP	96	96	100	(96.2-100)
	Urine	TN	672	672	100	(99.4-100)
		HN	44	96	45.8	(36.2-55.8)
		LP	96	96	100	(96.2-100)
		MP	96	96	100	(96.2-100)
Trichomonas vaginalis	Swab	TN	671	672	99.9	(99.2-100)
		HN	56	96	58.3	(48.3-67.7)
		LP	96	96	100	(96.2-100)
		MP	96	96	100	(96.2-100)
	Urine	TN	96	96	100	(96.2-100)
		HN	28	96	29.2	(21.0-38.9)
		LP	96	96	100	(96.2-100)
		MP	96	96	100	(96.2-100)

* HNs are dilutions of the LoD designed to produce results that are negative for 5% to 85% of replicates. As such, "% Correct" correlates to the percent of negative results.
** TNs were blanks, therefore, "% Correct" correlates to the percent of negative results.

Sample Storage

First void urine specimens must be transferred from the collection cup to the BD MAX UVE Sample Buffer Tube within 4 hours of collection when kept at 2-30 °C or within 24 hours of collection when stored at

2-8 °C. Clinician-collected endocervical swab and patient-collected vaginal swab specimens must be transferred immediately or within two hours after collection to the BD MAX UVE Sample Buffer Tube when kept at 2-30 °C. Protect against exposure to excessive heat.

Table 11: Specimen Stability Prior to Transfer into the BD MAX UVE Sample Buffer Tube

Specimen Stability	**Specimen Type**	**Transport and/or Storage Temperature**	
		2-30°C	**2-8°C**
Prior to Transfer into BD MAX UVE Sample Buffer Tube	Urine	4 hours	24 hours
	Vaginal/Endocervical Swab	2 hours	2 hours

Urine or swab sample in BD MAX UVE Sample Buffer Tubes can be transported and stored for up to 5 days at 2-30 °C or up to 30 days at -20 °C prior to pre-warm.

Table 12: Sample Stability in BD MAX UVE Sample Buffer Tube Prior to Pre-Warm

Sample Stability	**Specimen Type**	**Transport and/or Storage Temperature**	
		2-30°C	**-20°C**
In BD MAX UVE Sample Buffer Tube	Urine, Vaginal/Endocervical Swab	5 days	30 days

Once pre-warmed, samples previously stored at the 2-30 °C condition (Table 12) can be stored for an additional 5 days at 2-30 °C or an additional 30 days at -20 °C (Table 13) before testing on the BD MAX System. Once pre-warmed, samples previously stored at the -20 °C condition (Table 12) can be stored for an additional 5 days at -20 or 2-30 °C (Table 13) before testing on the BD MAX System.

NOTE: Combined sample stability [prior to pre-warm (Table 12) and post pre-warm (Table 13)] can not exceed a total of 35 days.

Table 13: Sample Stability in BD MAX UVE Sample Buffer Tube Post Pre-Warm

Sample Stability	**Specimen Type**	**Storage Temperature**	
		2-30°C	**-20°C**
Post Pre-warm *(previously stored* 2-30 *°C)*	Urine, Vaginal/Endocervical Swab	5 days	30 days
Post Pre-warm *(previously stored* -20 *°C)*	Urine, Vaginal/Endocervical Swab	5 days	5 days

Controls

External Control materials are not provided by BD; however, suggestions of appropriate 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™ UVE 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 or LoD) for the BD MAX CT/GC/TV was determined for each assay target individually. Two (2) representative bacterial suspensions were prepared for each of the target organisms and were inoculated into the UVE Sample Buffer Tube along with pooled negative matrix (both vaginal swab and female urine were evaluated, separately). The pooled negative matrix was created from specimens obtained from patients that were characterized by the BD MAX CT/GC/TV. The organism concentrations were used to simulate positive samples with a wide range of organism loads. The LoD was determined for each organism tested with both vaginal swab and female urine target-negative matrix. The results from the LoD study can be found in **Table 14**.

Table 14: BD MAX CT/GC/TV Target Limits of Detection

Organism	***Strain***	***Specimen***	***LoD Concentration (units/mL)[a]***
Chlamydia trachomatis	Serovar H	Urine	11
		Vaginal Swab	9
	Serovar D	Urine	5
		Vaginal Swab	13
Neisseria gonorrhoeae	ATCC 19424	Urine	60
		Vaginal Swab	60
	ATCC 49226	Urine	181
		Vaginal Swab	117
Trichomonas vaginalis	ATCC 30001	Urine	10
		Vaginal Swab	5
	ATCC 50143	Urine	34
		Vaginal Swab	10

[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.*

The BD MAX CT/GC/TV assay could detect ≥95% proportion positive results with fifteen (15) additional *Chlamydia trachomatis* serovars (A, B, Ba, C, E, vE, F, G, I, J, K, L1, L2, L2a and L3), thirty (30) *Neisseria gonorrhoeae* strains and eight (8) *Trichomonas vaginalis* strains (ATCC 30092, 30184, 30185, 30187, 30236, 30237, 30235 and 30186). These 53 serovars/strains represented public collections and well-characterized clinical isolates and were inoculated at 1X LoD in BD MAX UVE Sample Buffer and tested with both pooled female urine and pooled vaginal swab specimens. The BD MAX CT/GC/TV assay correctly identified 51 of the serovars/strains tested for urine specimens and 49 of the serovars/strains tested for vaginal swab specimens upon initial testing. Three (3) strains of *Trichomonas vaginalis* and one (1) serovar of *Chlamydia trachomatis* in vaginal swab specimen, in addition to two (2) strains of *Neisseria gonorrhoeae* in urine, did not meet acceptance criteria and were further evaluated. Of the six (6) strains further evaluated, one (1) was detected at 2X LoD and five (5) were detected at 1X LoD.

Analytical Specificity

The BD MAX CT/GC/TV assay was performed on samples containing phylogenetically related species and other organisms (bacteria, viruses) likely to be found in urogenital specimens. The bacterial cells, yeasts and parasites were tested in the BD MAX UVE Sample Buffer Tube at $1x10^6$ cells/mL, genomic DNA cp/mL, or elementary bodies/mL, and viruses were tested at $1x10^5$ viral particles or genomic equivalents/mL.

- 98% (168/170) of bacterial strains, yeast, parasites and viruses tested produced negative results with the BD MAX CT/GC/TV assay. No cross-reaction was observed for *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.
- *Pentatrichomonas hominis* (commensal of the large intestine) produced positive results at a concentration ≥ 3.39×10^5 TV/mL for *Trichomonas vaginalis* and negative results for all other targets with the BD MAX CT/GC/TV assay.
- *Trichomonas tenax* (commensal of the oral cavity) produced positive results at a concentration ≥ 10 TV/mL for *Trichomonas vaginalis* and negative results for all other targets with the BD MAX CT/GC/TV assay.

Interfering Substances

Fourty-four (44) biological and chemical substances occasionally used or found in urogenital specimens were evaluated for potential interference with the BD MAX CT/GC/TV assay near the LoD for each particular target. Three (3) organisms (*Eschericia coli*, *Gardnerella vaginalis* and *Candida albicans,*) were also tested at a high concentration in order to assess bacterial interference. Included in this study were antibiotic, analgesic, antifungal, hormonal, and contraceptive pools which contained combinations of the various chemicals or biological organisms that were tested at a concentration that may be found in urogenital specimens. Potentially interfering substances in urine specimens included whole blood (**Table 16**). Potentially interfering substances in vaginal swab specimens include VCF® Contraceptive Foam, Conceptrol® Contraceptive Gel, Vaginal Anti-Itch Cream, Acyclovir, Metronidazole and whole blood (**Table 17**). VCF Contraceptive Foam, Conceptrol® Contraceptive Gel and Acyclovir demonstrated potential interference at concentrations greater than 25µL/mL in vaginal swab specimens. Vaginal Anti-Itch Cream and Metronidazole demonstrated potential interference at concentrations greater than 2.5µL/mL in vaginal swab specimens. Whole blood demonstrated potential interference at concentrations greater than 0.04% v/v in urine and 0.66µL/mL in vaginal swab specimens.

Table 16: Endogenous and Exogenous Interfering Substances Tested in Urine

Brand Name or Description	Result	Brand Name or Description	Result
Norethindrone	NI	*Escherichia coli*	NI
17-α-Ethinylestradiol	NI	*Gardneralla vaginalis*	NI
4-Acetamidophenol	NI	*Candida albicans*	NI
Acetylsalicylic Acid	NI	Mucous (Bovine Cervical)	NI
Naproxen	NI	Whole Blood	I[a]
Ibuprofen	NI	Semen	NI
Human Serum Albumin	NI	Leukocytes	NI
Glucose	NI	Phenazopyridine Hydrochloride	NI
Amoxicillin Trihydrate	NI	High pH	NI
Metronidazole	NI	Low pH	NI
Tetracycline Hydrochloride	NI	Bilirubin	NI
Azithromycin	NI	Feminine Deodorant Spray	NI
Ceftriaxone	NI	Talcum Powder	NI
Sulfamethoxazole	NI		
Trimethoprim	NI		
Erythromycin	NI		

NI: No reportable interference with the BD MAX CT/GC/TV
[a] 0.04% v/v maximum concentration where interference was not observed

Table 17: Endogenous and Exogenous Interfering Substances Tested in Vaginal Swab Matrix

Brand Name or Description	Result	Brand Name or Description	Result
VCF Contraceptive Foam	I[a]	Douche	NI
VCF Contraceptive Film	NI	Feminine Deodorant Spray	NI
Conceptrol Contraceptive Gel	I[a]	Progesterone	NI
Gyne-Lotrimin 3	NI	Estradiol	NI
Monistat 3	NI	Mucous (Bovine Cervical)	NI
Tioconazole 1	NI	Semen	NI
Vaginal Anti-Itch Cream	I[b]	Whole Blood	I[c]
Vaginal Lubricant Liquid - water based	NI	Leukocytes	NI
Preparation H Hemorrhoid Gel	NI		
Antiviral (Zovirax – Acyclovir)	I[a]		
AntiProtozoal (Metronidazole)	I[b]		

NI: No reportable interference with the BD MAX CT/GC/TV
I: Interference with the BD MAX CT/GC/TV
[a] 25 µL/mL maximum concentration where interference was not observed
[b] 2.5 µL/mL maximum concentration where interference was not observed
[c] 0.66 µL/mL maximum concentration where interference was not observed

Carryover/Cross-Contamination

A study was conducted to investigate within-run carryover and between-run carryover while processing specimens with a high load of *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* in the BD MAX CT/GC/TV. A panel made of one high positive member containing the three target organisms and one negative member was used to prepare numerous samples. Strains of *Chlamydia trachomatis* (VR-879, Serovar H), *Neisseria gonorrhoeae* (ATCC 19424) and *Trichomonas vaginalis* (ATCC 30001) were used for the high positive panel member (1×10^6 CFU per mL). The negative member did not contain any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were tested in each run by alternating negative and positive samples. Two (2) operators performed a total of 6 consecutive runs across 3 BD MAX instruments for a total of 18 runs containing 24 samples. Of the 432 readings across all targets, no false positive results were obtained.

Mixed Infection/Competitive Interference

The mixed infection/competitive interference study was designed to evaluate the ability of the BD MAX CT/GC/TV assay to detect low positive results in the presence of other targets at high concentrations. Three (3) organisms (*Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis*) were individually prepared at 1.5x their respective LOD to serve as a low target in the BD MAX UVE Sample Buffer Tube. A high target mix comprised of the organisms representative of the other two BD MAX CT/GC/TV analytes at a concentration of $\geq 1x10^6$ EB, cells or TV/mL into the BD MAX UVE Sample Buffer Tube along with pooled urine or vaginal swab specimens and tested to simulate mixed infections. All three low target organisms were successfully detected by the BD MAX CT/GC/TV when combined with their respective simulated high target concentration mixed infection preparations in vaginal swab specimens. *Chlamydia trachomatis* and *Trichomonas vaginalis* low target organisms were successfully detected by the BD MAX CT/GC/TV assay when combined with their respectived simulated high target concentration mixed infection preparations in urine specimens. The *Neisseria gonorrhoeae* low target in urine specimen required further evaluation and was successfully detected (95.31% (61/64)) when combined with the high target mixed infection preparations at a concentration of 1×10^6 EB and TV/mL.

Clinical Performance Studies

The Clinical Accuracy study was designed to assess the performance of the BD MAX CT/GC/TV assay for the identification of *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis*, from urine specimens, clinician-collected endocervical swab specimens and patient-collected vaginal swab specimens (in a clinical setting) from symptomatic or asymptomatic subjects. This multicenter study evaluated results obtained with the BD MAX CT/GC/TV compared to reference methods defining the Patient Infected Status (PIS).

Nine (9) geographically diverse clinical sites in North America participated in the clinical study to evaluate the BD MAX CT/GC/TV assay, eight (8) of which were collection sites that also performed testing and one (1) clinical reference lab that only performed reference testing. Two thousand one hundred and sixty-six (2166) female subjects and 908 male subjects from OB/GYN, sexually transmitted disease (STD) and family planning clinics were enrolled in the *Chlamydia trachomatis* and *Neisseria gonorrhoeae* assay portion of the study. Of these, one thousand three hundred and twenty-seven (1327) female subjects were enrolled in the *Trichomonas vaginalis* assay portion of the study. 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.

The final data analysis included 2114 evaluable female subjects for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, with 1291 of these female subjects evaluable for *Trichomonas vaginalis*. For males, 892 were evaluable subjects for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* analyses. From these compliant subjects, *Chlamydia trachomatis* performance was calculated from 1836 patient-collected vaginal swab, 1831 endocervical swab, 1849 female urine and 830 male urine specimens. *Neisseria gonorrhoeae* evaluable specimens included 1836 patient-collected vaginal swab, 1824 endocervical swab, 1849 female urine and 840 male urine specimens. *Trichomonas vaginalis* compliant specimens consisted of 1048 patient-collected vaginal swab, 1039 endocervical swab, and 1047 female urine specimens. Assay performance compared to PIS is reported in **Table 18**.

Table 18: Assay Performance Compared to PIS Composite Reference Method Algorithm

Gender	Spec	Symp	CT		GC		TV	
			%Sens	%Spec	%Sens	%Spec	%Sens	%Spec
Female	Vag Swab	A	100 (51/51) 93.0-100	98.7 (734/744) 97.5-99.3	94.1 (16/17) 73.0-99.0	99.9 (777/778) 99.3-100	93.1 (27/29) 78.0-98.1	97.5 (270/277) 94.9-98.8
		S	98.9 (89/90) 94.0-99.8	98.6 (938/951) 97.7-99.2	96.3 (26/27) 81.7-99.3	99.8 (1012/1014) 99.3-99.9	96.7 (119/123) 91.9-98.7	99.5 (616/619) 98.6-99.8
		ALL	99.3 (140/141) 96.1-99.9	98.6 (1672/1695) 98.0-99.1	95.5 (42/44) 84.9-98.7	99.8 (1789/1792) 99.5-99.9	96.1 (146/152) 91.7-98.2	98.9 (886/896) 98.0-99.4
	Endo Swab	A	94.1 (48/51) 84.1-98.0	99.1 (737/744) 98.1-99.5	94.1 (16/17) 73.0-99.0	100 (777/777) 99.5-100	96.6 (28/29) 82.8-99.4	98.2 (270/275) 95.8-99.2
		S	96.6 (84/87) 90.3-98.8	99.4 (943/949) 98.6-99.7	96.3 (26/27) 81.7-99.3	99.9 (1002/1003) 99.4-100	92.7 (114/123) 86.7-96.1	99.8 (611/612) 99.1-100
		ALL	95.7 (132/138) 90.8-98.0	99.2 (1680/1693) 98.7-99.6	95.5 (42/44) 84.9-98.7	99.9 (1779/1780) 99.7-100	93.4 (142/152) 88.3-96.4	99.3 (881/887) 98.5-99.7
	Urine	A	92.3 (48/52) 81.8-97.0	99.7 (747/749) 99.0-99.9	88.9 (16/18) 67.2-96.9	99.5 (779/783) 98.7-99.8	93.1 (27/29) 78.0-98.1	98.2 (272/277) 95.8-99.2
		S	91.1 (82/90) 83.4-95.4	99.4 (952/958) 98.6-99.7	100 (28/28) 87.9-100	99.9 (1019/1020) 99.4-100	92.8 (116/125) 86.9-96.2	99.8 (615/616) 99.1-100
		ALL	91.5 (130/142) 85.8-95.1	99.5 (1699/1707) 99.1-99.8	95.7 (44/46) 85.5-98.8	99.7 (1798/1803) 99.4-99.9	92.9 (143/154) 87.7-96.0	99.3 (887/893) 98.5-99.7
Male	Urine	A	98.6 (69/70) 92.3-99.7	99.5 (378/380) 98.1-99.9	80.0 (4/5) 37.6-96.4	100 (447/447) 99.1-100	-	-
		S	94.6 (105/111) 88.7-97.5	99.3 (267/269) 97.3-99.8	100 (103/103) 96.4-100	100 (285/285) 98.7-100	-	-
		ALL	96.1 (174/181) 92.2-98.1	99.4 (645/649) 98.4-99.8	99.1 (107/108) 94.9-99.8	100 (732/732) 99.5-100	-	-

Of the 6573 specimens initially evaluated with the BD MAX CT/GC/TV assay, 1.6% of patient-collected vaginal swab, 1.8% of endocervical swab and 1.5% of urine specimens initially reported as Unresolved. Following a valid repeat test, 0.5% of patient-collected vaginal swab, 0.8% of endocervical swab and 0.4% of urine specimens remained Unresolved. The total numbers in **Table 19** are based on compliant specimens and BD MAX CT/GC/TV results.

Table 19: Unresolved Rates

	Initial Unresolved Rate		**Final Unresolved Rate with Valid Repeat**	
Specimen Type	**Estimate**	**95% CI**	**Estimate**	**95% CI**
Vaginal Swab	1.6% (31/1910)	(1.1%, 2.3%)	0.5% (9/1908)	(0.2%, 0.9%)
Endocervical	1.8% (34/1907)	(1.3%, 2.5%)	0.8% (16/1902)	(0.5%, 1.4%)
Urine	1.5% (41/2756)	(1.1%, 2.0%)	0.4% (11/2752)	(0.2%, 0.7%)

Of the 6573 specimens initially evaluated with the BD MAX CT/GC/TV assay, 0.9% of patient-collected vaginal swab, 0.4% of endocervical swab and 0.9% of urine specimens initially reported as Indeterminate. Following a valid repeat test, 0.3% of patient-collected vaginal swab, 0.1% of endocervical swab and 0.2% of urine specimens remained Indeterminant. The total numbers in **Table 20** are based on compliant specimens and BD MAX CT/GC/TV results.

Table 20: Indeterminate Rates

	Initial Indeterminate Rate		**Final Indeterminate Rate with Valid Repeat**	
Specimen Type	**Percent**	**95% CI**	**Percent**	**95% CI**
Vaginal Swab	0.9% (17/1910)	(0.6%, 1.4%)	0.3% (5/1908)	(0.1%, 0.6%)
Endocervical	0.4% (8/1907)	(0.2%, 0.8%)	0.1% (2/1902)	(0.0%, 0.4%)
Urine	0.9% (25/2756)	(0.6%, 1.3%)	0.2% (5/2752)	(0.1%, 0.4%)

Of the 6573 specimens initially evaluated with the BD MAX CT/GC/TV assay, 1.7% of patient-collected vaginal swab, 1.7% of endocervical swab and 1.9% of urine specimens initially reported as Incomplete. Following a valid repeat test, 0.1% of patient-collected vaginal swab, 0.1% of endocervical swab and 0.1% of urine specimens remained Incomplete. The total numbers in **Table 21** are based on compliant specimens and BD MAX CT/GC/TV results.

Table 21: Incomplete Rates

	Initial Incomplete Rate		Final Incomplete Rate with Valid Repeat	
Specimen Type	**Estimate**	**95% CI**	**Estimate**	**95% CI**
Vaginal Swab	1.7% (33/1910)	(1.2%, 2.4%)	0.1% (1/1908)	(0.0%, 0.3%)
Endocervical	1.7% (32/1907)	(1.2%, 2.4%)	0.1% (1/1902)	(0.0%, 0.3%)
Urine	1.9% (52/2756)	(1.4%, 2.5%)	0.1% (2/2752)	(0.0%, 0.3%)

Expected Values

The prevalence of specimens that are positive for *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis* depends upon the patient population. Factors include the type of clinic, patient age, risk factors, gender, and test method. In the BD MAX CT/GC/TV clinical study, a total of 1990 female subjects for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, and 1085 female subjects for *Trichomonas vaginalis* were compliant at the subject and composite reference method algorithm level. For male subjects, a total of 873 for *Chlamydia trachomatis* and 876 for *Neisseria gonorrhoeae* were compliant at the subject and composite reference method algorithm level.

Table 22: BD MAX CT/GC/TV Clinical Study Prevalence

Gender	Symptom Status	Site	*Chlamydia trachomatis*	*Neisseria gonorrhoeae*	*Trichomonas vaginalis*
Female	A	1	18.5% (5/27)	7.4% (2/27)	15.4% (2/13)
		2	8.5% (5/59)	0.0% (0/59)	24.1% (7/29)
		3	6.0% (13/216)	0.9% (2/216)	8.8% (3/34)
		4	1.8% (2/113)	1.8% (2/113)	2.2% (1/45)
		5	1.2% (1/81)	0.0% (0/81)	10.9% (5/46)
		6	6.5% (2/31)	0.0% (0/31)	0.0% (0/10)
		7	9.1% (23/254)	5.1% (13/254)	9.8% (13/133)
		8	3.7% (3/82)	3.7% (3/82)	0.0% (0/9)
		All	6.3% (54/863)	2.5% (22/863)	9.7% (31/319)
	S	1	13.1% (8/61)	3.3% (2/61)	21.0% (13/62)
		2	9.4% (10/106)	2.8% (3/106)	17.2% (15/87)
		3	7.0% (14/199)	1.0% (2/199)	22.5% (9/40)
		4	4.3% (2/47)	0.0% (0/47)	8.7% (2/23)
		5	5.4% (11/202)	1.0% (2/202)	10.3% (20/194)
		6	2.9% (2/70)	1.4% (1/70)	24.1% (14/58)
		7	11.9% (42/352)	5.7% (20/352)	15.2% (41/269)
		8	10.0% (9/90)	0.0% (0/90)	39.4% (13/33)
		All	8.7% (98/1127)	2.7% (30/1127)	16.6% (127/766)
	Total		7.6% (152/1990)	2.6% (52/1990)	14.6% (158/1085)
Male	A	1	11.1% (2/18)	0.0% (0/18)	N/A
		2	14.6% (19/130)	0.8% (1/132)	
		4	8.8% (3/34)	0.0% (0/34)	
		6	9.4% (6/64)	1.6% (1/64)	
		7	18.2% (42/231)	1.3% (3/231)	
		All	15.1% (72/477)	1.0% (5/479)	
	S	1	37.4% (34/91)	35.2% (32/91)	
		2	24.2% (37/153)	22.1% (34/154)	
		4	50.0% (4/8)	25.0% (2/8)	
		6	22.9% (8/35)	14.3% (5/35)	
		7	27.5% (30/109)	29.4% (32/109)	
		All	28.5% (113/396)	26.4% (105/397)	
	Total		21.2% (185/873)	12.6% (110/876)	

Positive and Negative Predictive Value

Hypothetical Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated and are represented in **Tables 23-25** for *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis*, respectively. These calculations are based on the hypothetical prevalence and overall sensitivity and specificity compared to the Patient Infected Status.

Table 23: Hypothetical PPV and NPV for *Chlamydia trachomatis* Compared to PIS

Prevalence	Sensitivity	Specificity	PPV	NPV
1%	95.7% (576/602)	99.2% (5696/5744)	53.6%	100%
2%			70.0%	99.9%
5%			85.8%	99.8%
10%			92.7%	99.5%
20%			96.6%	98.9%
30%			98.0%	98.2%
40%			98.7%	97.2%
50%			99.1%	95.8%

Table 24: Hypothetical PPV and NPV for *Neisseria gonorrhoeae* Compared to PIS

Prevalence	Sensitivity	Specificity	PPV	NPV
1%	97.1% (235/242)	99.9% (6098/6107)	86.9%	100.0%
2%			93.1%	99.9%
5%			97.2%	99.8%
10%			98.7%	99.7%
20%			99.4%	99.3%
30%			99.6%	98.8%
40%			99.8%	98.1%
50%			99.8%	97.2%

Table 25: Hypothetical PPV and NPV for *Trichomonas vaginalis* Compared to PIS

Prevalence	Sensitivity	Specificity	PPV	NPV
1%	94.1% (431/458)	99.2% (2654/2676)	53.6%	99.9%
2%			70.0%	99.9%
5%			85.8%	99.7%
10%			92.7%	99.3%
20%			96.6%	98.5%
30%			98.0%	97.5%
40%			98.7%	96.2%
50%			99.1%	94.4%