510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K091730

B. Purpose for Submission:

To obtain a Substantial Equivalence determination for the addition of BD SurePath™ Preservative Fluid for collecting gynecological specimens as an additional sample type to be tested on the BD Viper™ System previously cleared (K081825).

C. Measurand:

Neisseria gonorrhoeae DNA

D. Type of Test:

Qualitative determination of *Neisseria gonorrhoeae* DNA using the Strand Displacement Amplification technology

E. Applicant:

Becton, Dickson, and Company

F. Proprietary and Established Names:

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LSL	Class II	21CFR 866.3390 *Neisseria* spp. direct serological test reagents	Microbiology (83)

H. Intended Use:

The BD ProbeTec™ *Neisseria gonorrhoeae* (GC) 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 *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 using an aliquot that is removed prior to processing for the BD SurePath™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.

3) Special conditions for use statement(s):

For Prescription use only

4) Special instrument requirements:

BD Viper™ System with automated nucleic acid extraction mode

I. Device Description:

The BD ProbeTec GC Q^{x} Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe. The reagents for SDA are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The BD Viper™ System pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Amplification Microwell which is sealed to prevent contamination and then incubated in one of the two thermally-controlled fluorescent readers. The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak fluorescence (Maximum Relative Fluorescent Units (MaxRFU)) over the course of the amplification process and by comparing this measurement to a predetermined threshold value. In addition to the fluorescent probe used to detect amplified *N. gonorrhoeae* target DNA, a second labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the *N. gonorrhoeae* -specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is rehydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the BD Viper System and an automated algorithm is applied to both the EC and *N. gonorrhoeae* -specific signals to report results as positive, negative, or EC failure.

J. Substantial Equivalence Information:

a) Predicate device name (s):

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay
Gen-Probe APTIMA Assay for *Neisseria gonorrhoeae* (AGC)

b) Predicate Numbers:

K081825
K062440

3. Comparison with predicate:

Device Comparison: GCQ Assay Specimen Collection and Processing on the BD Viper System in Extracted Mode

	BD ProbeTec GCQ Assay, PreservCyt Solution Specimens (Device)	**BD ProbeTec GCQ Assay, Swab and Urine Specimens (K081825)**	**Gen-Probe AGC (K062440)**
Specimen Types	• Same as K081825 • Gynecological specimen in SurePath Preservative Fluid	• Endocervical swab (females) • Vaginal self-collected swab (in a clinical setting) (females) • Urethral swab (males) • Neat urine (female and male) • UPT urine (female and male)	• Endocervical swab (females) • Vaginal swab (females) • Urethral swab (males) • Neat urine (female and male) • UTT urine (female and male) • Gynecological specimen in PreservCyt Solution
Specimen Collection and Transport Accessories	• Same as K081825 • Liquid Based Cytology Specimen (LBC) Dilution Tube	• Endocervical kit • Urethral kit • Vaginal kit • UPT • Neat urine (Qx Sample Tube)	• Unisex swab kit • Vaginal swab kit • Urine collection kit • Specimen transfer kit (for gynecological specimen in PreservCyt Solution)

Device Comparison: Specimen Collection

	BD ProbeTec GCQ Assay, SurePath Preservative Fluid (Device)	**Gen-Probe AGC (K062440)**
Specimen Collection	• Gynecological specimen collected and placed in SurePath Preservative Fluid (per TriPath's instruction for use). • Sample for CTQ/GCQ testing is drawn from original cytology specimen vial before the specimen is processed for cytology testing.	• Gynecological specimen collected and placed in SurePath Preservative Fluid (per TriPath's instruction for use). • LBC specimen is first processed for cytology and then an aliquot is drawn from the remaining specimen in the vial for CT/GC testing.

Device Comparison: Specimen Processing

	BD ProbeTec GCQ Assay, SurePath Preservative Fluid (Device)	**BD ProbeTec GCQ Assay, Swab and Urine Specimens (K081825)**
Specimen Processing	• Same as K081825 without the 15 minute pre-warm step for LBC Dilution Tube specimens • Use of LBC Specimen Rack to prevent pre-warming of LBC specimens	Pre-warm specimens (swabs and urines) for 15 minutes before running BD Viper System

K. **Standard/Guidance Document Referenced (if applicable):**

NA

L. Test Principle:

When used with the BD Viper System, the BD ProbeTec GC Q^x Amplified DNA Assay involves automated extraction of DNA from clinical specimens through the chemical lysis of cells, followed by binding of DNA to para-magnetic particles, washing of the bound nucleic acid and elution in an amplification-compatible buffer. When present, *N. gonorrhoeae* DNA is then detected by Strand Displacement Amplification (SDA) of a specific target sequence in the presence of a fluorescently labeled detector probe.

M. Performance Characteristics (if/when applicable):

Clinical Performance Characteristics

Prevalence:

Hypothetical positive and negative predictive values (PPV & NPV) for the GC Q^x Assay from the multi-center clinical trial for swabs and urines are shown in Table 1. Hypothetical positive and negative predictive values (PPV & NPV) for the GC Q^x Assay from the multi-center clinical trial for BD SurePath specimens are shown in Table 2. These calculations are based on hypothetical prevalence and overall sensitivity and specificity (compared to the patient infected status) of 99.3% and 99.3% for swabs and urines, and 100% and 99.9% for BD SurePath specimens. In addition, PPV and NPV based on actual prevalence, sensitivity and specificity are shown in Tables 6A, 6B, 7A, and 7B. PPV was calculated using: (Sensitivity * Prevalence) / (Sensitivity*Prevalence + (1 - Specificity) * (1 - Prevalence)). NPV was calculated using: (Specificity * (1 - Prevalence)/ (1-Sensitivity) * Prevalence + Specificity * (1-Prevalence).

Table 1 .**GC Hypothetical Positive and Negative Predictive Values (Swabs/Urines) Compared to Patient Infected Status**

Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
2	99.3	99.3	74.3	100.0
5	99.3	99.3	88.2	100.0
10	99.3	99.3	94.0	99.9
20	99.3	99.3	97.3	99.8
30	99.3	99.3	98.4	99.7
40	99.3	99.3	99.0	99.5
50	99.3	99.3	99.3	99.3

Table 2. **GC Hypothetical Positive and Negative Predictive Values (BD SurePath) Compared to Patient Infected Status**

Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
2	100.0	99.9	95.3	100.0
5	100.0	99.9	98.1	100.0
10	100.0	99.9	99.1	100.0
20	100.0	99.9	99.6	100.0
30	100.0	99.9	99.8	100.0
40	100.0	99.9	99.9	100.0
50	100.0	99.9	99.9	100.0

MaxRFU Frequency Distribution:

A total of 6284 GC Q^x Assay results from swab and urine specimens were evaluated from seven geographically diverse clinical sites. A frequency distribution of the initial MaxRFU values for the GC Q^x assay is shown in Figure A. The distribution of MaxRFU values from GC Q^x true positive, true negative, false positive and false negative specimens (i.e., from those specimens that yielded results which were discordant with the patient infected status (PIS)) is shown in Table 3A.

A total of 1715 GC Q^x Assay results from **BD SurePath** specimens were evaluated from eleven geographically diverse clinical sites. A frequency distribution of the initial MaxRFU values for the GC Q^x assay is shown in Figure B. The distribution of MaxRFU values from GC Q^x true positive, true negative, false positive and false negative specimens (i.e., from those specimens that yielded results which were discordant with the patient infected status (PIS)) is shown in Table 3B.

Figure A: Frequency Distribution of MaxRFU for the GC Q^x Assay (Swabs/Urines)

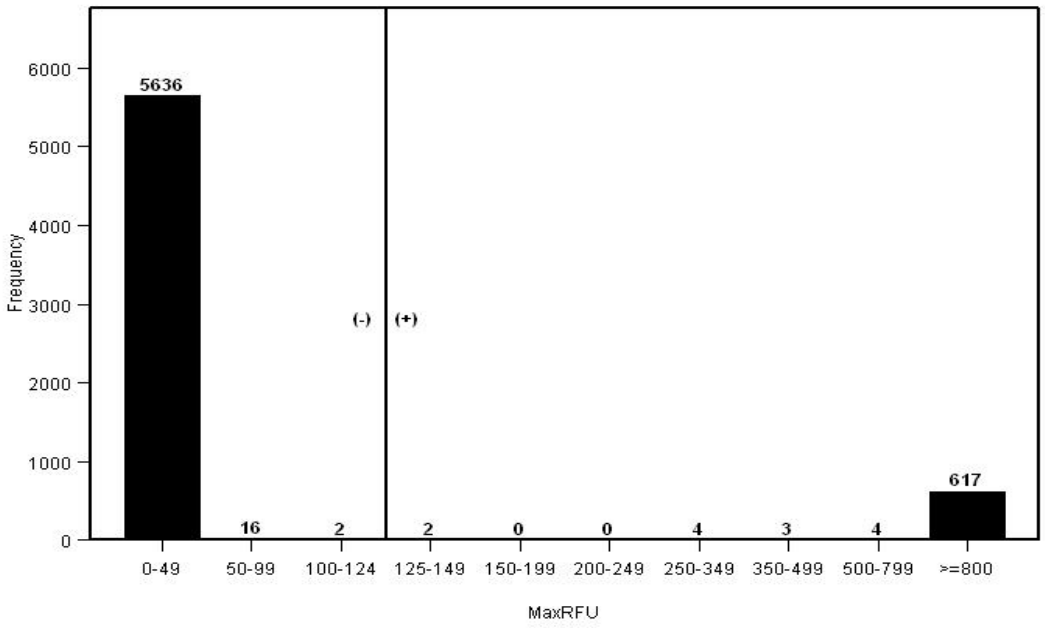

Figure B: Frequency Distribution of MaxRFU for the GC Q^x Assay (BD SurePath Specimens)

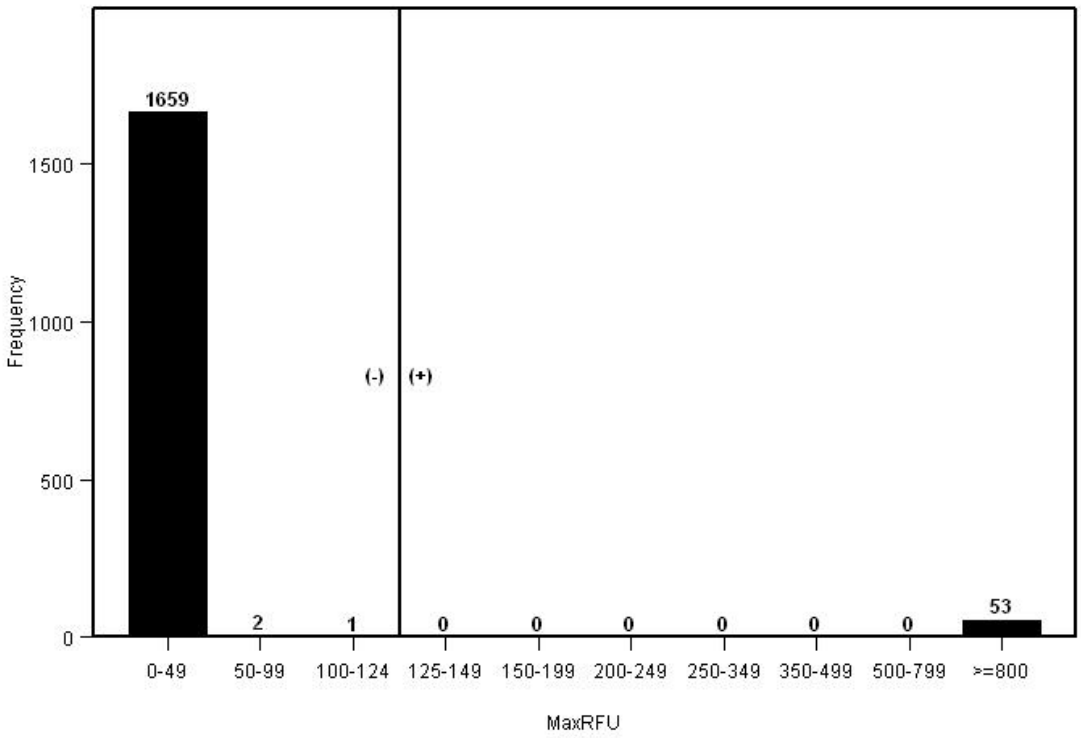

Table 3A: GC Q^x MaxRFU Ranges for False Negative, False Positive, True Negative and True Positive Results (Swabs/Urines)

MaxRFU Ranges		0-49	50-99	100-124	125-149	150-199	200-249	250-349	350-499	500-799	>=800
Total		5636	16	2	2	0	0	4	3	4	617
FN	FNU	2	0	0	0	0	0	0	0	0	0
	FS	1	0	0	0	0	0	0	0	0	0
	FUPT	1	0	0	0	0	0	0	0	0	0
	Total	4	0	0	0	0	0	0	0	0	0
FP	FNU	0	0	0	0	0	0	1	1	0	3
	FS	0	0	0	0	0	0	1	0	0	2
	FUPT	0	0	0	0	0	0	0	1	0	2
	FV	0	0	0	2	0	0	0	0	1	5
	MNU	0	0	0	0	0	0	1	0	1	5
	MS	0	0	0	0	0	0	0	0	0	6
	MUPT	0	0	0	0	0	0	0	1	0	5
	Total	0	0	0	2	0	0	3	3	2	28
TN	FNU	920	3	0	0	0	0	0	0	0	0
	FS	918	5	1	0	0	0	0	0	0	0
	FUPT	925	0	0	0	0	0	0	0	0	0
	FV	913	6	1	0	0	0	0	0	0	0
	MNU	655	0	0	0	0	0	0	0	0	0
	MS	646	1	0	0	0	0	0	0	0	0
	MUPT	655	1	0	0	0	0	0	0	0	0
	Total	5632	16	2	0	0	0	0	0	0	0
TP	FNU	0	0	0	0	0	0	0	0	0	63
	FS	0	0	0	0	0	0	0	0	0	64
	FUPT	0	0	0	0	0	0	0	0	0	64
	FV	0	0	0	0	0	0	1	0	0	64
	MNU	0	0	0	0	0	0	0	0	0	112
	MS	0	0	0	0	0	0	0	0	2	110
	MUPT	0	0	0	0	0	0	0	0	0	112
	Total	0	0	0	0	0	0	1	0	2	589

Table 3B: GC Q^x MaxRFU Ranges for False Negative, False Positive, True Negative and True Positive Results (BD SurePath Specimens)

MaxRFU Range	0-49	50-99	100-124	125-149	150-199	200-249	250-349	350-499	500-799	≥800
FN	0	0	0	0	0	0	0	0	0	0
FP	0	0	0	0	0	0	0	0	0	2
TN	1659	2	1	0	0	0	0	0	0	0
TP	0	0	0	0	0	0	0	0	0	51
Total	1659	2	1	0	0	0	0	0	0	53

Controls:

During the swab/urine clinical evaluation, there were no GC Q^x positive control failures from 253 GC Q^x plate runs. For the GC Q^x negative control, a failure was observed in 1 of 253 GC Q^x plate runs. During the **BD SurePath** specimen clinical evaluation, there was one GC Q^x positive control failure and no GC Q^x negative control failures from 120 GC Q^x plates that were run. The CT/GC Q^x positive and negative control MaxRFU values observed in the clinical trials are shown in Table 4.

Table 4: Distribution of MaxRFU Results for the GC Q^x Assay Negative and Positive Controls

Control	Statistic	Swab and Urine Specimen Clinical Study	BD SurePath Specimen Clinical Study
GC Q^x Negative Control	N	252	120
MaxRFU	Maximum	17	42
	95th Percentile	7	0
	Median	0	0
	Mean	1	0
	5th Percentile	0	0
	Minimum	0	0
GC Q^x Positive Control	N	253	120
MaxRFU	Maximum	2242	2156
	95th Percentile	2083	1982
	Median	1835	1786
	Mean	1814	1777
	5th Percentile	1502	1478
	Minimum	530	1370

Swab and Urine Specimen Clinical Study:

Clinician-collected endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female Q^x UPT and neat urine specimens were collected from 1059 symptomatic and asymptomatic female subjects and 787 symptomatic and asymptomatic male subjects attending OB/GYN, sexually transmitted disease (STD) and family planning clinics at seven geographically diverse clinical sites in North America. Subjects were classified as symptomatic if they reported symptoms such as dysuria, urethral discharge, 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 symptoms. Sixty five female subjects and 13 male subjects were excluded from the data analysis due to age requirement violations, antibiotic treatment in the last 21 days, opting to withdraw from the study after initially consenting, failure to obtain paired swab and urine specimens, urine quantity less than 20 mL, or transport and storage errors related to specimen collection. Therefore, the final data analysis included 994 compliant female subjects and 774 compliant male subjects.

Five specimens were collected from each of the 994 eligible female subjects. A urine specimen was collected and split into Q^x UPT, neat urine and the two reference urine specimen collection devices followed by a vaginal swab specimen and three randomized endocervical swab specimens. Up to four specimens were collected from each of the 774 eligible male subjects. Up to three randomized urethral swab specimens were collected followed by a urine specimen that was split into Q^x UPT, neat urine and the two reference urine specimen collection devices. BD ProbeTec GC Q^x assay results were generated from the Q^x UPT and neat urine specimens, the vaginal swab specimen, one endocervical swab specimen and one male urethral swab specimen. The remaining two endocervical swab specimens, up to two male urethral swab specimens, and the two reference urine specimens for each male and female subject were tested using two reference methods: the BD ProbeTec ET CT/GC/AC assay and another commercially available NAAT (Nucleic Acid Amplification Test). Specimen testing was conducted either at the site of collection or at a designated BD Viper testing site.

All performance calculations were based on the total number of **BD ProbeTec** GC Q^x assays results for endocervical, vaginal and male urethral swab specimens, and male and female Q^x UPT and neat urine specimens compared to a patient infected status (PIS) algorithm for each gender. In the algorithm, the designation of a subject as being infected with GC or not was based on endocervical swab and urine specimen results from the commercially available **BD ProbeTec** ET CT/GC/AC assay and the other commercially available NAAT. Subjects were considered infected with GC if two of the four endocervical swab and urine specimens (or two of the three or four urethral swab and urine specimens) tested positive in the **BD ProbeTec** ET GC/AC assay and the other reference NAAT (one specimen testing positive in each NAAT). Subjects were considered non-infected if less than two reference NAAT results were positive. A total of 6284 **BD ProbeTec** GC Q^x assay results from symptomatic and asymptomatic female and male subjects was used to calculate sensitivity and specificity. Sensitivity and specificity by specimen type and symptomatic status are presented in Table 6A.

Performance of the assay with endocervical swabs, patient collected vaginal swabs specimens (in a clinical setting), female UPT and neat urine was assessed in the clinical study. Separate performance was calculated for specimens collected from pregnant females. Sensitivity compared to patient infected status for FS, FV, FNU,

and FUPT was 100% (3/3). In each case, specificity was 100% (24/24) for FS, FV, FNU, and FUPT separately.

Table 9A summarizes the number of results from symptomatic and asymptomatic female subjects for swabs and urine specimens designated as infected or non-infected with GC according to the PIS algorithm. Table 9B summarizes the number of results from symptomatic and asymptomatic male subjects for swab and urine specimens designated as infected or non-infected with GC according to the PIS algorithm. Table 9C summarizes the number of results from symptomatic and asymptomatic female subjects for BD SurePath specimens designated as infected or non-infected with GC according to the PIS algorithm.

BD SurePath Specimen Clinical Study:

Endocervical swab specimens and BD SurePath specimens were collected from 1728 compliant female subjects attending family planning, OB/GYN, and sexually transmitted disease clinics at eleven geographically diverse clinical sites in North America. Subjects were classified as symptomatic if they reported symptoms such as dysuria, coital pain/difficulty/bleeding, abnormal vaginal discharge, or pelvic/uterine/adnexal pain. Subjects were classified as asymptomatic if they did not report symptoms.

Three randomized endocervical swab specimens and a BD SurePath specimen were collected from each female subject. The three reference endocervical swabs were tested with the BD ProbeTec ET CT/GC/AC assay, the BD ProbeTec GC Q^x assay, and another commercially available NAAT (Nucleic Acid Amplification Test). Sensitivity and specificity for BD SurePath specimens were calculated by comparing results to a patient infected status (PIS) algorithm. The designation of positive or negative PIS was based on the endocervical swab specimen results from the three reference methods. At least two positive reference results were required to establish a subject as PIS-positive. At least two negative reference results were required to establish a subject as PIS-negative. Sensitivity and specificity by symptomatic status are presented in Table 6B.

The distribution of cervical sampling devices used in the clinical study according to clinical collection site is summarized in Table 5.

Table 8 summarizes the GC Q^x assay performance for BD SurePath specimens compared to PIS by clinic type.

Table 9C summarizes the number of results from symptomatic and asymptomatic subjects designated as infected or non-infected with GC according to the PIS algorithm.

Table 5. Summary of Cervical Sampling Devices Used in the BD SurePath Specimen Clinical Study

Cervical Sampling Device Used	Clinical Collection Site Number											Total
	1	2	3	4	5	6	7	8	9	10	11	
Broom-Type Device	54	50	511	18	374	0	127	0	0	71	0	1205
Spatula/Cytobrush	0	25	0	0	182	112	32	24	103	8	37	523

Table 6A: GC Q^x Assay Performance for Swabs and Urines Compared to Patient Infected Status (by specimen type and symptomatic status)

			Performance Compared to Patient Infected Status						
Specimen Type	**Symptomatic**	**N**	**Sensitivity**	**95% C.I.**	**Specificity**	**95% C.I.**	**PPV**	**NPV**	**Error Initial/Final**
FS	A	450	96.3% (26/27)	(81.0% - 99.9%)	99.5% (421/423)	(98.3% - 99.9%)	92.5%	99.8%	3/0
	S	542	100.0% (38/38)	(90.7% - 100.0%)	99.8% (503/504)	(98.9% - 100.0%)	97.4%	100.0%	2/2
	Total	992	98.5% (64/65)	(91.7% - 100.0%)	99.7% (924/927)	(99.1% - 99.9%)	95.9%	99.9%	5/2
FV	A	449	100.0% (27/27)	(87.2% - 100.0%)	98.6% (416/422)	(96.9% - 99.5%)	82.0%	100.0%	0/0
	S	544	100.0% (38/38)	(90.7% - 100.0%)	99.6% (504/506)	(98.6% - 100.0%)	95.0%	100.0%	0/0
	Total	993	100.0% (65/65)	(94.5% - 100.0%)	99.1% (920/928)	(98.3% - 99.6%)	88.5%	100.0%	0/0
FNU	A	450	96.3% (26/27)	(81.0% - 99.9%)	99.3% (420/423)	(97.9% - 99.9%)	89.8%	99.8%	0/0
	S	543	97.4% (37/38)	(86.2% - 99.9%)	99.6% (503/505)	(98.6% - 100.0%)	94.8%	99.8%	0/0
	Total	993	96.9% (63/65)	(89.3% - 99.6%)	99.5% (923/928)	(98.7% - 99.8%)	93.1%	99.8%	0/0
FUPT	A	450	100.0% (27/27)	(87.2% - 100.0%)	99.5% (421/423)	(98.3% - 99.9%)	92.7%	100.0%	0/0

			Performance Compared to Patient Infected Status						
Specimen Type	**Symptomatic**	**N**	**Sensitivity**	**95% C.I.**	**Specificity**	**95% C.I.**	**PPV**	**NPV**	**Error Initial/Final**
	S	543	97.4% (37/38)	(86.2% - 99.9%)	99.8% (504/505)	(98.9% - 100.0%)	97.3%	99.8%	0/0
	Total	993	98.5% (64/65)	(91.7% - 100.0%)	99.7% (925/928)	(99.1% - 99.9%)	95.8%	99.9%	0/0
MS[1]	A	508	100.0% (12/12)	(73.5% - 100.0%)	99.2% (492/496)	(97.9% - 99.8%)	75.5%	100.0%	0/0
	S	257	100.0% (100/100)	(96.4% - 100.0%)	98.7% (155/157)	(95.5% - 99.8%)	98.0%	100.0%	1/0
	Total	765	100.0% (112/112)	(96.8% - 100.0%)	99.1% (647/653)	(98.0% - 99.7%)	95.0%	100.0%	1/0
MNU[1]	A	517	100.0% (12/12)	(73.5% - 100.0%)	99.2% (501/505)	(98.0% - 99.8%)	74.6%	100.0%	0/0
	S	257	100.0% (100/100)	(96.4% - 100.0%)	98.1% (154/157)	(94.5% - 99.6%)	97.1%	100.0%	0/0
	Total	774	100.0% (112/112)	(96.8% - 100.0%)	98.9% (655/662)	(97.8% - 99.6%)	93.9%	100.0%	0/0
MUPT[1]	A	517	100.0% (12/12)	(73.5% - 100.0%)	99.2% (501/505)	(98.0% - 99.8%)	74.6%	100.0%	1/0
	S	257	100.0% (100/100)	(96.4% - 100.0%)	98.7% (155/157)	(95.5% - 99.8%)	98.0%	100.0%	0/0
	Total	774	100.0% (112/112)	(96.8% - 100.0%)	99.1% (656/662)	(98.0% - 99.7%)	95.0%	100.0%	1/0
Total		6284	99.3% (592/596)	(98.3% - 99.8%)	99.3% (5650/5688)	(99.1% - 99.5%)	93.7%	99.9%	7/2

Table 6B: GC Q^x Assay Performance for BD SurePath Specimens Compared to Patient Infected Status (by symptomatic status)

		Performance Compared to Patient Infected Status						
Symptomatic Status	N	Sensitivity	95% C.I.	Specificity	95% C.I.	PPV	NPV	Error Initial/Final
A	1157	100.0% (32/32)	(89.1% - 100.0%)	99.8% (1123/1125)	(99.4% - 100.0%)	93.5%	100.0%	2/0
S	558	100.0% (19/19)	(82.4% - 100.0%)	100.0% (539/539)	(99.3% - 100.0%)	100.0%	100.0%	0/0
Total	1715[2]	100.0% (51/51)	(93.0% - 100.0%)	99.9% (1662/1664)	(99.6% - 100.0%)	96.90	100.0%	2/0

Table 7A: GC Q^x Assay Performance for Swabs and Urines Compared to Patient Infected Status (by clinical site).

Specimen Type	Collect Site	Prevalence	N	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
FS[3]	1	8.4%	155	100.0% (13/13)	(75.3% - 100.0%)	99.3% (141/142)	(96.1% - 100.0%)	5	92.9	100.0
	2	10.4%	154	93.8% (15/16)	(69.8% - 99.8%)	99.3% (137/138)	(96.0% - 100.0%)	6	93.7	99.3
	3	6.8%	73	100.0% (5/5)	(47.8% - 100.0%)	98.5% (67/68)	(92.1% - 100.0%)	2	83.3	100.0
	4	19.0%	105	100.0% (20/20)	(83.2% - 100.0%)	100.0% (85/85)	(95.8% - 100.0%)	6	100.0	100.0
	5	1.4%	70	100.0% (1/1)	(2.5% - 100.0%)	100.0% (69/69)	(94.8% - 100.0%)	0	100.0	100.0
	6	2.2%	365	100.0% (8/8)	(63.1% - 100.0%)	100.0% (357/357)	(99.0% - 100.0%)	3	100.0	100.0

[3] Of the 1728 compliant female subjects, 13 subjects did not have a GC Q^x assay result for the BD SurePath specimen, therefore the final data analysis included 1715 compliant female subjects.
[3] 22 of the 65 FS PIS positive subjects were co-infected with CT

Specimen Type	Collect Site	Prevalence	N	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
	7	2.9%	70	100.0% (2/2)	(15.8% - 100.0%)	100.0% (68/68)	(94.7% - 100.0%)	0	100.0	100.0
FV[4]	1	8.4%	155	100.0% (13/13)	(75.3% - 100.0%)	99.3% (141/142)	(96.1% - 100.0%)	5	92.9	100.0
	2	10.3%	155	100.0% (16/16)	(79.4% - 100.0%)	97.1% (135/139)	(92.8% - 99.2%)	6	80.0	100.0
	3	6.8%	73	100.0% (5/5)	(47.8% - 100.0%)	100.0% (68/68)	(94.7% - 100.0%)	2	100.0	100.0
	4	19.0%	105	100.0% (20/20)	(83.2% - 100.0%)	97.6% (83/85)	(91.8% - 99.7%)	6	90.9	100.0
	5	1.4%	70	100.0% (1/1)	(2.5% - 100.0%)	100.0% (69/69)	(94.8% - 100.0%)	0	100.0	100.0
	6	2.2%	365	100.0% (8/8)	(63.1% - 100.0%)	99.7% (356/357)	(98.4% - 100.0%)	3	88.9	100.0
	7	2.9%	70	100.0% (2/2)	(15.8% - 100.0%)	100.0% (68/68)	(94.7% - 100.0%)	0	100.0	100.0
FNU[5]	1	8.4%	155	100.0% (13/13)	(75.3% - 100.0%)	98.6% (140/142)	(95.0% - 99.8%)	5	86.7	100.0
	2	10.3%	155	93.8% (15/16)	(69.8% - 99.8%)	97.8% (136/139)	(93.8% - 99.6%)	6	83.3	99.3
	3	6.8%	73	100.0% (5/5)	(47.8% - 100.0%)	100.0% (68/68)	(94.7% - 100.0%)	2	100.0	100.0
	4	19.2%	104	100.0% (20/20)	(83.2% - 100.0%)	100.0% (84/84)	(95.7% - 100.0%)	6	100.0	100.0
	5	1.4%	70	100.0% (1/1)	(2.5% - 100.0%)	100.0% (69/69)	(94.8% - 100.0%)	0	100.0	100.0
	6	2.2%	366	100.0% (8/8)	(63.1% - 100.0%)	100.0% (358/358)	(99.0% - 100.0%)	3	100.0	100.0
	7	2.9%	70	50.0% (1/2)	(1.3% - 98.7%)	100.0% (68/68)	(94.7% - 100.0%)	0	100.0	98.6
FUPT[6]	1	8.4%	155	100.0% (13/13)	(75.3% - 100.0%)	99.3% (141/142)	(96.1% - 100.0%)	5	92.9	100.0
	2	10.3%	155	93.8% (15/16)	(69.8% - 99.8%)	99.3% (138/139)	(96.1% - 100.0%)	6	93.8	99.3
	3	6.8%	73	100.0% (5/5)	(47.8% - 100.0%)	100.0% (68/68)	(94.7% - 100.0%)	2	100.0	100.0
	4	19.2%	104	100.0% (20/20)	(83.2% - 100.0%)	98.8% (83/84)	(93.5% - 100.0%)	6	95.2	100.0

[4] 22 of the 65 FV PIS positive subjects were co-infected with CT.
[5] 22 of the 65 FNU PIS positive subjects were co-infected with CT.
[6] 22 of the 65 FUPT PIS positive subjects were co-infected with CT.

Specimen Type	Collect Site	Prevalence	N	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
	5	1.4%	70	100.0% (1/1)	(2.5% - 100.0%)	100.0% (69/69)	(94.8% - 100.0%)	0	100.0	100.0
	6	2.2%	366	100.0% (8/8)	(63.1% - 100.0%)	100.0% (358/358)	(99.0% - 100.0%)	3	100.0	100.0
	7	2.9%	70	100.0% (2/2)	(15.8% - 100.0%)	100.0% (68/68)	(94.7% - 100.0%)	0	100.0	100.0
MS[7]	1	10.5 %	313	100.0% (33/33)	(89.4% - 100.0%)	99.6% (279/280)	(98.0% - 100.0%)	11	96.7%	100.0%
	2	40.5 %	79	100.0% (32/32)	(89.1% - 100.0%)	95.7% (45/47)	(85.5% - 99.5%)	10	94.1%	100.0%
	4	20.6 %	170	100.0% (35/35)	(90.0% - 100.0%)	98.5% (133/135)	(94.8% - 99.8%)	11	94.5%	100.0%
	5	6.0 %	182	100.0% (11/11)	(71.5% - 100.0%)	99.4% (170/171)	(96.8% - 100.0%)	5	91.4%	100.0%
	7	4.8 %	21	100.0% (1/1)	(2.5% - 100.0%)	100.0% (20/20)	(83.2% - 100.0%)	0	100.0%	100.0%
MNU[8]	1	10.5 %	313	100.0% (33/33)	(89.4% - 100.0%)	99.3% (278/280)	(97.4% - 99.9%)	11	94.4%	100.0%
	2	40.5 %	79	100.0% (32/32)	(89.1% - 100.0%)	95.7% (45/47)	(85.5% - 99.5%)	10	94.1%	100.0%
	4	20.6 %	170	100.0% (35/35)	(90.0% - 100.0%)	97.8% (132/135)	(93.6% - 99.5%)	11	92.2%	100.0%
	5	5.8 %	191	100.0% (11/11)	(71.5% - 100.0%)	100.0% (180/180)	(98.0% - 100.0%)	5	100.0%	100.0%
	7	4.8 %	21	100.0% (1/1)	(2.5% - 100.0%)	100.0% (20/20)	(83.2% - 100.0%)	0	100.0%	100.0%
MUPT[9]	1	10.5 %	313	100.0% (33/33)	(89.4% - 100.0%)	98.9% (277/280)	(96.9% - 99.8%)	11	91.4%	100.0%
	2	40.5 %	79	100.0% (32/32)	(89.1% - 100.0%)	97.9% (46/47)	(88.7% - 99.9%)	10	97.0%	100.0%
	4	20.6 %	170	100.0% (35/35)	(90.0% - 100.0%)	99.3% (134/135)	(95.9% - 100.0%)	11	97.4%	100.0%

[7] 37 of the 112 MS PIS positive subjects were co-infected with CT.
[8] 37 of the 112 MNU PIS positive subjects were co-infected with CT.

Specimen Type	Collect Site	Prevalence	N	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
	5	5.8 %	191	100.0% (11/11)	(71.5% - 100.0%)	99.4% (179/180)	(96.9% - 100.0%)	5	91.1%	100.0%
	7	4.8 %	21	100.0% (1/1)	(2.5% - 100.0%)	100.0% (20/20)	(83.2% - 100.0%)	0	100.0%	100.0%

[1] 22 of the 65 FV PIS positive subjects were co-infected with CT.
[1] 22 of the 65 FNU PIS positive subjects were co-infected with CT.
[1] 22 of the 65 FUPT PIS positive subjects were co-infected with CT.
[1] 37 of the 112 MS PIS positive subjects were co-infected with CT.
[1] 37 of the 112 MNU PIS positive subjects were co-infected with CT.
[1] 37 of the 112 MUPT PIS positive subjects were co-infected with CT.

Table 7B: GC Q^x Assay Performance for BD SurePath Specimens Compared to Patient Infected Status (by clinical site)

			Performance Compared to Patient Infected Status						
Collect Site	Prevalence	N	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV	NPV
1	10.8%	74	100.0% (8/8)	(63.1% - 100.0%)	100.0% (66/66)	(94.6% - 100.0%)	7	100.0%	100.0%
2	3.9%	103	100.0% (4/4)	(39.8% - 100.0%)	100.0% (99/99)	(96.3% - 100.0%)	1	100.0%	100.0%
3	0.0%	37	NA		100.0% (37/37)	(90.5% - 100.0%)	0	NA	NA
4	25.9%	54	100.0% (14/14)	(76.8% - 100.0%)	97.5% (39/40)	(86.8% - 99.9%)	4	93.3%	100.0%
5	4.3%	69	100.0% (3/3)	(29.2% - 100.0%)	100.0% (66/66)	(94.6% - 100.0%)	1	100.0%	100.0%
6	1.6%	555	100.0% (9/9)	(66.4% - 100.0%)	99.8% (545/546)	(99.0% - 100.0%)	2	89.0%	100.0%
7	2.0%	511	100.0% (10/10)	(69.2% - 100.0%)	100.0% (501/501)	(99.3% - 100.0%)	5	100.0%	100.0%
8	1.3%	159	100.0% (2/2)	(15.8% - 100.0%)	100.0% (157/157)	(97.7% - 100.0%)	2	100.0%	100.0%
9	0.0%	112	NA		100.0% (112/112)	(96.8% - 100.0%)	0	NA	NA
10	5.6%	18	100.0% (1/1)	(2.5% - 100.0%)	100.0% (17/17)	(80.5% - 100.0%)	0	100.0%	100.0%
11	0.0%	23	NA		100.0% (23/23)	(85.2% - 100.0%)	0	NA	NA

Table 8: GC Q^x Assay Performance for BD SurePath Specimens Compared to Patient Infected Status (by clinic type)

			Performance Compared to Patient Infected Status					
Clinic Type	**Prevalence**	**N**	**Sensitivity**	**95% C.I.**	**Specificity**	**95% C.I.**	**PPV%**	**NPV%**
Family Planning	1.4%	844	100.0% (12/12)	(73.5% - 100.0%)	99.9% (831/832)	(99.3% - 100.0%)	93.4%	100.0%
OB/GYN	1.8%	548	100.0% (10/10)	(69.2% - 100.0%)	100.0% (538/538)	(99.3% - 100.0%)	100.0%	100.0%
STD	9.0%	323	100.0% (29/29)	(88.1% - 100.0%)	99.7% (293/294)	(98.1% - 100.0%)	97.1%	100.0%

Table 9A: Analysis of GC Positive/Negative Swab and Urine Specimens from Female Subjects Based on Patient Infected Status

	NAAT 1		NAAT 2		BD ProbeTec GC Q^x Amplified DNA Assay						
PIS GC	Endocervical Swab	Urine	Endocervical Swab	Urine	Q^x Endocervical Swab	Q^x Vaginal Swab	Neat Urine	Q^x UPT Urine	Symptomatic Status A	S	Total
+	-	+	+	+	-	+	+	+	1	0	1
	+	-	+	-	+	+	-	-	0	1	1
	+	-	+	-	+	+	+	+	3	0	3
	+	-	+	+	+	+	+	+	1	1	2
	+	+	+	-	+	+	+	+	2	1	3
	+	+	+	+	+	+	-	+	1	0	1
	+	+	+	+	+	+	+	+	19	35	54
Total PIS Positive									27	38	65
-	NA	-	-	-	-	-	-	-	12	2	14
	-	NA	E	-	-	-	NA	NA	0	1	1
	-	NA	-	-	-	-	-	-	1	1	2
	-	I	-	-	-	-	-	-	5	1	6
	-	-	NA	-	-	-	-	-	1	2	3
	-	-	E	-	-	-	-	-	1	0	1
	-	-	-	-	ET	-	-	-	0	1	1
	-	-	-	-	LE	-	-	-	0	1	1
	-	-	-	-	-	NA	-	-	1	0	1
	-	-	-	-	-	-	-	-	390	484	874
	-	-	-	-	-	-	-	+	0	1	1
	-	-	-	-	-	-	+	-	1	1	2
	-	-	-	-	-	+	-	-	4	1	5
	-	-	-	-	-	+	+	-	0	1	1
	-	-	-	-	-	+	+	+	1	0	1
	-	-	-	-	+	-	-	-	0	1	1
	-	-	+	-	-	-	-	-	1	3	4
	-	-	+	-	+	-	-	-	1	0	1
	-	+	-	-	-	-	-	-	1	2	3
	+	-	-	-	-	-	-	-	2	3	5

	+	+	-	-	+	+	+	+	1	0	1
Total PIS Negative									423	506	929

I Indeterminate

LE Liquid Level Error

Table 9B: Analysis of GC Positive/Negative Swab and Urine Specimens from Male Subjects Based on Patient Infected Status

	NAAT 1		**NAAT 2**		**BD ProbeTec** GC Q^x Amplified DNA Assay			**Symptomatic Status**		
PIS GC	**Urethral Swab**	**Urine**	**Urethral Swab**	**Urine**	**Q^x Urethral Swab**	**Neat Urine**	**Q^x UPT Urine**	A	S	Total
+	+	+	+	+	+	+	+	11	81	92
	+	+	NA	+	+	+	+	1	13	14
	NA	+	+	+	+	+	+	0	6	6
Total PIS Positive								**12**	**100**	**112**
-	-	I	-	-	-	-	-	4	1	5
	-	I	NA	-	-	-	-	1	0	1
	-	-	E	-	-	-	-	2	0	2
	-	-	-	E	-	-	-	0	1	1
	-	-	-	-	NA	-	-	9	0	9
	-	-	-	-	-	-	-	422	124	546
	-	-	-	-	-	-	+	2	1	3
	-	-	-	-	-	+	-	1	1	2
	-	-	-	-	-	+	+	1	0	1
	-	-	-	-	+	-	-	3	0	3
	-	-	-	+	-	-	-	2	1	3
	-	-	+	-	-	-	-	2	1	3
	-	-	+	+	+	+	-	0	1	1
	-	-	NA	-	-	-	-	29	11	40
	-	+	-	-	-	-	-	1	0	1
	-	NA	-	-	-	-	-	1	0	1
	+	-	-	-	-	-	-	0	1	1
	+	+	NA	-	-	-	-	0	1	1
	NA	-	-	-	-	-	-	22	11	33
	NA	-	-	-	-	+	-	1	0	1
	NA	-	+	-	-	-	-	1	0	1
	NA	-	+	+	+	+	+	1	1	2
	NA	+	-	-	-	-	-	0	1	1
Total PIS Negative								**505**	**157**	**662**

Table 9C: Analysis of GC Positive/Negative BD SurePath Specimens Based on Patient Infected Status

					Symptomatic Status		
PIS GC	**AC2 Swab**	**ProbeTec Swab**	**Qx Swab**	**SurePath**	**A**	**S**	**Total**
+	-	+	+	+	0	1	1
	+	-	+	+	1	1	2
	+	+	+	+	31	17	48
Total PIS Positive					**32**	**19**	**51**
-	-	-	+	+	1	0	1
	-	+	-	+	1	0	1
	-	I	-	-	2	2	4
	-	-	NA	-	6	1	7
	-	-	-	-	1103	531	1634
	-	-	+	-	6	1	7
	-	+	-	-	5	3	8
	+	-	-	-	1	1	2
Total PIS Negative					**1125**	**539**	**1664**

GC Q^X Assay Analytical Sensitivity:

The Limits of Detection (LODs) for the GC Q^x Assay with *Neisseria gonorrhoeae* strain ATCC 19424 in urine and swab specimens when extracted on the BD Viper System were determined to be < 50 cells per mL for neat and Q^x UPT urine and < 100 GC cells per mL for expressed vaginal, endocervical swab, and BD SurePath specimens.

The GC Q^x Assay on the BD Viper System in extracted mode was able to detect 17 GC strains (ATCC 19424, 27628, 27629, 27630, 27632, 27633, 27631, 21823, 51803, 23051, 31407, 31953, 35201, 31397, 31151, 43785, 51804) with ≥ 95% proportion positive at a concentration of 50 cells per mL in CT/GC Q^x Swab Diluent.

GC Q^X Assay Analytical Specificity:

DNA from 141 organisms listed in Table 10 was extracted on the BD Viper System and tested with the BD ProbeTec GC Q^x Amplified DNA Assay. All potential cross-reactive species were tested at $\geq 1x10^8$ cells/mL except where noted. Two *N. cinerea* and two *N. lactamica* strains were shown to cross-react in the GC Q^x assay.

Table 10: Potential Cross-reacting Microorganisms

Acinetobacter calcoaceticus	*Enterococcus faecium*	*Peptostreptococcus asaccharolyticus*	*Neisseria elongata* subsp. *glycolytica*
Acinetobacter lwoffi	Epstein Barr Virus***	*Peptostreptococcus productus*	*Neisseria elongata* subsp. *nitroreduscens* (2)
Actinomyces israelii	*Escherichia coli*	*Plesiomonas shigelloides*	*Neisseria elongata*
Adenovirus***	*Flavobacterium meningosepticum*	*Propionibacterium acnes*	*Neisseria flava* (4)
Aeromonas hydrophilia	*Gardnerella vaginalis*	*Providencia stuartii*	*Neisseria flavescens* (4)
*Alcaligenes faecalis**	*Gemella haemolysans*	*Pseudomonas aeruginosa*	*Neisseria lactamica* (7)
*Bacillus subtilis**	*Haemophilus influenzae*	*Salmonella minnesota*	*Neisseria meningitidis* (12)
Bacteroides fragilis	Herpes Simplex Virus **	*Salmonella typhimurium*	*Neisseria mucosa* (5)
*Candida albicans**	Human papillomavirus (16 and 18)***	*Staphylococcus aureus*	*Neisseria perflava (8)*
*Candida glabrata**	*Kingella kingae*	*Staphylococcus epidermidis*	*Neisseria polysaccharea* (2)
*Candida tropicalis**	*Klebsiella pneumoniae*	*Streptococcus agalactiae*	*Neisseria sicca* (5)
Chlamydia trachomatis	*Lactobacillus acidophilus**	*Streptococcus mitis*	*Neisseria subflava* (15)
*Chlamydia pneumoniae****	*Lactobacillus brevis*	*Streptococcus mutans*	*Neisseria weaverii* (3)
*Chlamydia psittaci**	*Lactobacillus jensenii**	*Streptococcus pneumoniae**	
Citrobacter freundii	*Listeria monocytogenes*	*Streptococcus pyogenes*	
Clostridium perfringens	*Mobiluncus mulieris*	*Streptomyces griseus***	
Corynebacterium renale	*Moraxella lacunata**	*Trichomonas vaginalis***	
*Cryptococcus neoformans**	*Moraxella osloensis*	*Veillonella parvula*	
Cytomegalovirus**	*Morganella morganii*	*Vibrio parahaemolyticus*	
Edwardsiella tarda	*Mycobacterium gordonae*	*Yersinia enterocolitica*	
Enterobacter cloacae	*Mycobacterium smegmatis*	*Branhamella catarrhalis* (5)	
Enterococcus faecalis	*Peptostreptococcus anaerobius*	*Neisseria cinerea* (2)	

(n) number of strains tested in the BD ProbeTec GC Q^x Assay
* Tested at > $1x10^7$ cells or EB/mL; **Tested at > $1x10^6$ cells or viral particles per mL; ***Tested at $\geq$ $1x10^6$ genomic equivalents per mL;**** tested at $\geq$ $1x10^5$ $TCID_{50}$/mL

GC Q^x Interfering Substances:

The performance of the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode was evaluated in the presence of potential interfering substances which may be encountered in swab, urine, and/or BD SurePath specimens. Potential interfering substances were spiked into UPT urine and vaginal swab specimen matrices as well as BD SurePath specimens in LBC Specimen Dilution Tubes, in both the presence and the absence of GC organisms (150 GC cells/mL in urine matrix and 300 GC cells/mL in swab/LBC Specimen Dilution Tube matrix). Results are summarized in Table 11.

Table 11: GC Q^x Interfering Substances

Interpretation	Swab	Urine	SurePath
No Interference Observed	Blood (≤ 60%) Seminal Fluid Mucus Over The Counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ($1x10^6$ cells/mL) $1x10^6$ EB/mL *Chlamydia trachomatis*	Blood (≤1%) Seminal fluid Mucus Antibiotics Analgesics Phenazopyridine Over The Counter deodorant sprays and powders Hormones Leukocytes Albumin <1 mg/mL Glucose Acidic urine (pH 4.0) Alkaline urine (pH 9.0) Bilirubin $1x10^6$ EB/mL *Chlamydia trachomatis* Organisms associated with Urinary Tract Infections	Blood (≤ 1%) Seminal Fluid Mucus Over The Counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ($1x10^6$ cells/mL) $1x10^6$ EB/mL *Chlamydia trachomatis*
May cause extraction control (EC) failures	Blood (> 60%)	Not applicable	Not applicable
May cause False Negative results	Not applicable	Not applicable	Not applicable

Neat and Q^x UPT Urine Stability:

Pools of GC negative male and female urine specimens were used in analytical experiments to support the urine storage and transport stability claims. For neat urine, pools were co-spiked with CT serovar H and GC strain ATCC 19424 at 45 EB per mL and 150 cells per mL, respectively. Neat urine specimens were stored at either 2-8°C for 1, 3 or 7 days; or at 30°C for 8, 24 or 30 h; or at -20°C for 180 days. At each time point, samples were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

For Q^x UPT urine, pooled specimens were co-spiked with CT serovar H and GC strain ATCC 19424 at 45 EB per mL and 150 cells per mL, respectively. The spiked urine specimen pools were then stored at either 2-8°C for 24 h or 30°C for 8 h prior to transfer into Q^x UPT tubes. The Q^x UPT specimens were then stored either at 2-8°C for 14, 21 or 30 days; or at 30°C for 14, 21 or 30 days; or at -20°C for 180 days. At each time point Q^x UPT specimens were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/duration). The expected results

were obtained with the GC Q^x assay under all conditions tested.

Vaginal Dry and Expressed Swab Stability:

Pools of GC negative vaginal swab matrix were used in analytical experiments to support the storage and transport stability claims for dry vaginal swab specimens. Pools were co-spiked with CT serovar H and GC strain ATCC 19424 to achieve 90 EB per mL and 300 cells per mL, respectively, when seeded onto swabs and expressed in CT/GC Q^x Swab Diluent. Seeded dry swabs were stored at 2-8^{o}C for 3, 7, or 14 days; or at 30^{o}C for 3, 7 or 14 days; or at -20^{o}C for 30, 60, or 180 days. At each time point, dry swabs were removed from storage and expressed into 2 mL of CT/GC Q^x Swab Diluent and evaluated with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

Pools of GC negative vaginal swab matrix were used in analytical experiments to support the storage and transport stability claims for expressed vaginal swab specimens. Pools were spiked with CT serovar H and GC strain ATCC 19424 to achieve 90 EB per mL and 300 cells per mL, respectively. The spiked swab matrix was stored at 2-8^{o}C for 7, 14 or 30 days; or at 30^{o}C for 7, 14 or 30 days; or at -20^{o}C for 30, 60, or 180 days. At each time point, samples were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

Endocervical and Urethral Swab Specimen Stability:

Pools of GC negative endocervical swab matrix were used in analytical experiments to support the storage and transport stability claims for endocervical and urethral swab specimens. Pools of swab matrix were spiked with CT serovar H and GC strain ATCC 19424 at 90 EB per mL and 300 cells per mL, respectively. The pools were dispensed in 2 mL volumes into BD sample tubes to simulate "wet" endocervical specimens and stored at either 2-8^{o}C for 7, 14 or 30 days; or at 30^{o}C for 7, 14 or 30 days; or at -20^{o}C for 30, 60, or 180 days. At each time point, samples were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/ duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

Post Pre-warm Specimen Stability:

Pools of male and female GC negative neat urine specimens were used in analytical experiments to support the storage stability claims for pre-warmed neat and Q^x UPT urine specimens. Pooled specimens were spiked with CT serovar H and GC strain ATCC 19424 at 45 EB per mL and 150 cells per mL, respectively and either added to Q^x UPT

tubes or left untreated as neat urine. Both specimen types were pre-warmed at 114°C for 15 min, and cooled for 15 min. After the pre-warm process, specimen tubes were stored at either 2-8°C for 1, 3 or 7 days; or at 30°C for 1, 3 or 7 days; or at -20°C for 30 or 180 days. At each time point samples were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

Pools of GC negative vaginal and endocervical swab specimen matrices in CT/GC Q^x Swab Diluent were used in analytical experiments to support the storage stability claims for pre-warmed expressed vaginal, endocervical, and male urethral swab specimens. For both types of matrix, pooled specimens were spiked with CT serovar H and GC strain ATCC 19424 at 90 EB per mL and 300 cells per mL, respectively and aliquotted into 2 mL volumes in BD specimen tubes. The tubes were pre-warmed at 114°C for 15 min and cooled for 15 min. After the pre-warm process, the specimen tubes were stored either at 2-8°C for 3 or 7 days; or at 30°C for 3 or 7 days; or at -20°C for 30 or 180 days. At each time point, samples were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Thirty-two assay replicates were generated for each condition (sample type/temperature/duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

BD SurePath Specimen Stability:

Pools of CT and GC negative BD SurePath clinical specimens were used in analytical experiments to support the storage and stability claims. Pools were co-spiked with CT serovar H and GC strain ATCC 19424 to achieve 90 EB per mL and 300 cells per mL, respectively. The pools were dispensed in 10 mL volumes in BD SurePath vials and stored at either 2-8°C or 30°C. After 30 days, 0.5 mL from each vial was removed and added to an LBC Specimen Dilution Tube The specimens in the LBC Dilution Tube were then stored at 2-8°C for 30 or 90 days; or at 30°C for 30 or 90 days; or at -20°C for 90 days. At each time point, samples were removed from storage and tested with the BD ProbeTec GC Q^x Assay on the BD Viper System in extracted mode. Twenty-four assay replicates were generated for each condition (temperature/duration). The expected results were obtained with the GC Q^x assay under all conditions tested.

Reproducibility:

Reproducibility of the BD Viper System using the BD ProbeTec GC Q^x Assay was evaluated at three clinical sites on one BD Viper System per site. A panel of simulated specimens was tested that comprised CT and GC organisms seeded into swab diluent for the BD ProbeTec GC Q^x Assay. Simulated endocervical and urethral specimens contained a clean endocervical swab whereas the simulated urine and vaginal swab specimens did not. Uninoculated swab diluent for the BD ProbeTec GC Q^x Assay was used for the GC negative samples. Nine replicates of each panel member were tested every day for five days on each BD Viper System. The data are summarized in Table 12A.

Table 12A: Summary of Reproducibility Data for Swabs and Urines on the BD Viper System for the GC Q^x Assay

						Within Run		Between Runs Within Site		Between Site	
Specimen Type	CT EB's/mL	GC Cells/mL	% Correct	95% CI	MaxRFU Mean	SD	%CV	SD	%CV	SD	%CV
Endocervical / Urethral	0	0	99.3% (134/135)	(95.9%, 100.0%)	13.8	151.3	1096.3	0.0	0.0	0.6	4.3
	30	0	98.5% (133/135)	(94.8%, 99.8%)	28.1	220.7	785.3	0.0	0.0	33.8	120.3
	0	100	100.0% (135/135)	(97.3%, 100.0%)	1859.5	94.1	5.1	0.0	0.0	19.2	1.0
	30	250	100.0% (135/135)	(97.3%, 100.0%)	1847.3	117.6	6.4	0.0	0.0	25.9	1.4
	75	100	100.0% (135/135)	(97.3%, 100.0%)	1855.9	119.4	6.4	0.0	0.0	42.2	2.3
Urine / Vaginal	0	0	99.3% (134/135)	(95.9%, 100.0%)	15.7	162.3	1031.1	0.0	0.0	0.0	0.0
	30	0	100.0% (135/135)	(97.3%, 100.0%)	1.1	3.1	295.8	0.7	69.7	0.5	48.3
	0	100	100.0% (135/135)	(97.3%, 100.0%)	1899.0	86.1	4.5	22.8	1.2	0.0	0.0
	30	250	100.0% (135/135)	(97.3%, 100.0%)	1884.2	94.0	5.0	13.8	0.7	0.0	0.0
	75	100	100.0% (135/135)	(97.3%, 100.0%)	1867.2	87.7	4.7	0.0	0.0	19.2	1.0

A second study was conducted internally to characterize the reproducibility of test results (i.e., proportion positive or negative) at target levels below the analytical Limit of Detection (LOD) of the **BD ProbeTec** GC Q^x Assay. A panel of simulated specimens was tested that comprised GC and CT organisms seeded into Q^x swab diluent at two different levels each of which was below the respective analytical LOD for the organisms (1:10, 1:100). These levels were selected to fall within the dynamic range of the analytical LOD curve of the assay. Fifteen replicates of each panel member were tested every day for five days across three **BD Viper** Systems. The data are summarized in Table 12B.

Table 12B: Characterization of System Reproducibility at Target Levels below the Analytical Limit of Detection for the GC Q^x Assay for Swabs and Urines.

Specimen	Dilution of Analytical LOD	% Positive	95% CI (Positive)	Max RFU Mean (Positive)	% Negative	95% CI (Negative)	Max RFU Mean (Negative)
Endocervical/Urethral	1:10	92.9 (209/225)	(88.7, 95.9)	1324.6	7.1 (16/225)	(4.1, 11.3)	41.4
Endocervical/Urethral	1:100	30.7 (69/225)	(24.7, 37.1)	835.9	69.3 (156/225)	(62.9, 75.3)	7.2
Urine/Vaginal	1:10	90.7 (204/225)	(86.1, 94.1)	1165.9	9.3 (21/225)	(5.9, 13.9)	34.2
Urine/Vaginal	1:100	22.7 (51/225)	(17.4, 28.7)	872.7	77.3 (174/225)	(71.3, 82.6)	7.8

A reproducibility study of the **BD Viper** System using the **BD ProbeTec** GC Q^x Assay was also evaluated for Liquid Based Cytology (LBC) specimens at three clinical sites on one **BD Viper** System per site. A panel of simulated specimens comprising CT and GC organisms seeded into LBC Specimen Dilution Tubes containing LBC medium was tested with the **BD ProbeTec** GC Q^x Assay. Uninoculated LBC Specimen Dilution Tubes containing LBC medium were used for the GC negative samples. Nine replicates of each panel member were tested every day for five days on each **BD Viper** System. The data are summarized in Table 16C. Two additional levels were included in the panels to characterize the reproducibility of test results (i.e., proportion positive or negative) at target levels below the analytical Limit of Detection (LOD) of the **BD ProbeTec** GC Q^x Assay. These additional specimens comprised CT and GC organisms seeded into LBC Specimen Dilution Tubes containing LBC medium at dilutions of 1:10 and 1:100 of the respective analytical LODs of each analyte. These levels were selected to fall within the dynamic range of the analytical LOD curves for the **BD ProbeTec** CT Q^x and GC Q^x assays. Nine replicates of each panel member were tested every day for five days across the three **BD Viper** Systems. The data are summarized in Table 12D.

Table 12C: Summary of Reproducibility Data for LBC Specimens on the BD Viper System for the GC Q^x Assay

					Within Run		Between Runs Within Site		Between Site	
CT EB's/mL	GC Cells/mL	% Correct	95% CI	Mean MaxRFU	SD	%CV	SD	%CV	SD	%CV
0	0	100.0% (135/135)	(97.3% - 100.0%)	1.21	4.00	330.38	0.00	0.00	0.00	0.00
30	0	100.0% (135/135)	(97.3% - 100.0%)	0.98	7.47	761.30	0.00	0.00	0.17	17.04
0	100	100.0% (135/135)	(97.3% - 100.0%)	1982.77	83.92	4.23	0.00	0.00	0.00	0.00
30	250	100.0% (135/135)	(97.3% - 100.0%)	1983.66	87.76	4.42	0.00	0.00	24.80	1.25
75	100	100.0% (135/135)	(97.3% - 100.0%)	1920.14	81.94	4.27	59.45	3.10	0.00	0.00

Table 12D: Characterization of System Reproducibility at Target Levels below the Analytical Limit of Detection for the GC Q^x Assay for LBC Specimens

Dilution of Analytical LOD	% Positive	95% CI (Positive)	MaxRFU Mean (Positive)	% Negative	95% CI (Negative)	MaxRFU Mean (Negative)
1:10	74.1 (100/135)	(65.8 - 81.2)	1159.2	25.9 (35/135)	(18.8 - 34.2)	21.2
1:100	8.9 (12/135)	(4.7 - 15.0)	1136.5	91.1 (123/135)	(85.0 - 95.3)	6.6

System Cross Contamination and Carryover:

An internal study was conducted to evaluate the risk of producing a false positive result in either the same run on the BD Viper System in extracted mode (within run cross-contamination) or in a subsequent run (between run carryover). Testing was conducted using negative and positive samples on three BD Viper Systems. Negative samples consisted of CT/GC Q^x Swab Diluent/LBC Specimen Dilution Tube with PreservCyt Solution. Positive samples consisted of a representative analyte (10^5 CT EB/mL) spiked into CT/GC Q^x Swab Diluent/LBC Specimen Dilution Tube with PreservCyt Solution. The overall rate of cross-contamination (i.e., with alternating columns of positive and negative samples and a prevalence of 50%) was 0.41% (9/2208) for the CT/GC Q^x Swab Diluent and 0.45% (5/1104) for the LBC Specimen Dilution Tube with PreservCyt Solution. The overall rate of carryover contamination (i.e., carryover between successive runs when the prevalence was 50% in the previous run) was 0.36% (8/2208) for the CT/GC Q^x Swab diluent and 0.54% (6/1104) for the LBC Specimen Dilution Tube with PreservCyt Solution. Cross-contamination and carryover rates across the three BD Viper Systems are summarized in Tables 13 and 14.

Table 13: Cross Contamination and Carryover Contamination (Swab/Urine).

Assay Dispense Mode Selected	BD Viper System	Cross-Contamination			Carryover Contamination		
		n	Positive Results	Percent Positive	n	Positive Results	Percent Positive

Dual Assay	**1**	**736**	**5**	**0.68**	**736**	**1**	**0.14**
	2	**736**	**0**	**0.00**	**736**	**3**	**0.41**
	3	**736**	**4**	**0.54**	**736**	**4**	**0.54**
	Overall	**2208**	**9**	**0.41**	**2208**	**8**	**0.36**
Single Assay	**1**	**190**	**0**	**0.00**	**186**	**0**	**0.00**
	2	**188**	**1**	**0.53**	**186**	**1**	**0.54**
	3	**188**	**0**	**0.00**	**186**	**0**	**0.00**
	Overall	**566**	**1**	**0.18**	**568**	**1**	**0.18**

Table 14: Cross Contamination and Carryover Contamination (LBC Medium)

Medium Type	BD Viper System	Cross-Contamination			Carryover Contamination		
		n	Positive Results	Percent Positive	n	Positive Results	Percent Positive
PreservCyt	1	368	1	0.27	368	1	0.27
	2	368	3	0.82	368	0	0.00
	3	368	1	0.27	368	5	0.45
	Overall	1104	5	0.45	1104	6	0.54

Table 15: Analysis of GC Positive/Negative Swab and Urine Specimens from Female Subjects Based on Patient Infected Status

	NAAT 1		NAAT 2		BD ProbeTec GC Q^x Amplified DNA Assay						
PIS GC	Endocervical Swab	Urine	Endocervical Swab	Urine	Q^x Endocervical Swab	Q^x Vaginal Swab	Neat Urine	Q^x UPT Urine	Symptomatic Status		
									A	S	Total
+	-	+	+	+	-	+	+	+	1	0	1
	+	-	+	-	+	+	-	-	0	1	1
	+	-	+	-	+	+	+	+	3	0	3
	+	-	+	+	+	+	+	+	1	1	2
	+	+	+	-	+	+	+	+	2	1	3
	+	+	+	+	+	+	-	+	1	0	1
	+	+	+	+	+	+	+	+	19	35	54
Total PIS Positive									27	38	65
-	NA	-	-	-	-	-	-	-	12	2	14
	-	NA	E	-	-	-	NA	NA	0	1	1
	-	NA	-	-	-	-	-	-	1	1	2
	-	I	-	-	-	-	-	-	5	1	6
	-	-	NA	-	-	-	-	-	1	2	3
	-	-	E	-	-	-	-	-	1	0	1
	-	-	-	-	ET	-	-	-	0	1	1
	-	-	-	-	LE	-	-	-	0	1	1
	-	-	-	-	-	NA	-	-	1	0	1
	-	-	-	-	-	-	-	-	390	484	874
	-	-	-	-	-	-	-	+	0	1	1
	-	-	-	-	-	-	+	-	1	1	2
	-	-	-	-	-	+	-	-	4	1	5
	-	-	-	-	-	+	+	-	0	1	1

	-	-	-	-	-	+	+	+	1	0	1
	-	-	-	-	+	-	-	-	0	1	1
	-	-	+	-	-	-	-	-	1	3	4
	-	-	+	-	+	-	-	-	1	0	1
	-	+	-	-	-	-	-	-	1	2	3
	+	-	-	-	-	-	-	-	2	3	5
	+	+	-	-	+	+	+	+	1	0	1
Total PIS Negative									423	506	929

I Indeterminate

LE Liquid Level Error

Table 16: Analysis of GC Positive/Negative Swab and Urine Specimens from Male Subjects Based on Patient Infected Status

	NAAT 1		**NAAT 2**		**BD ProbeTec GC Q^x Amplified DNA Assay**			**Symptomatic Status**		
PIS GC	**Urethral Swab**	**Urine**	**Urethral Swab**	**Urine**	**Q^x Urethral Swab**	**Neat Urine**	**Q^x UPT Urine**	A	S	Total
+	+	+	+	+	+	+	+	11	81	92
	+	+	NA	+	+	+	+	1	13	14
	NA	+	+	+	+	+	+	0	6	6
Total PIS Positive								**12**	**100**	**112**
-	-	I	-	-	-	-	-	4	1	5
	-	I	NA	-	-	-	-	1	0	1
	-	-	E	-	-	-	-	2	0	2
	-	-	-	E	-	-	-	0	1	1
	-	-	-	-	NA	-	-	9	0	9
	-	-	-	-	-	-	-	422	124	546
	-	-	-	-	-	-	+	2	1	3
	-	-	-	-	-	+	-	1	1	2
	-	-	-	-	-	+	+	1	0	1
	-	-	-	-	+	-	-	3	0	3
	-	-	-	+	-	-	-	2	1	3
	-	-	+	-	-	-	-	2	1	3
	-	-	+	+	+	+	-	0	1	1
	-	-	NA	-	-	-	-	29	11	40
	-	+	-	-	-	-	-	1	0	1
	-	NA	-	-	-	-	-	1	0	1
	+	-	-	-	-	-	-	0	1	1
	+	+	NA	-	-	-	-	0	1	1
	NA	-	-	-	-	-	-	22	11	33
	NA	-	-	-	-	+	-	1	0	1
	NA	-	+	-	-	-	-	1	0	1
	NA	-	+	+	+	+	+	1	1	2
	NA	+	-	-	-	-	-	0	1	1
Total PIS Negative								**505**	**157**	**662**

Table 17: Analysis of GC Positive/Negative BD SurePath Specimens Based on Patient Infected Status.

					Symptomatic Status		
PIS GC	**AC2 Swab**	**ProbeTec Swab**	**Qx Swab**	**SurePath**	**A**	**S**	**Total**
+	-	+	+	+	0	1	1
	+	-	+	+	1	1	2
	+	+	+	+	31	17	48
Total PIS Positive					*32*	*19*	*51*
-	-	-	+	+	1	0	1
	-	+	-	+	1	0	1
	-	I	-	-	2	2	4
	-	-	NA	-	6	1	7
	-	-	-	-	1103	531	1634
	-	-	+	-	6	1	7
	-	+	-	-	5	3	8
	+	-	-	-	1	1	2
Total PIS Negative					*1125*	*539*	*1664*

N. Instrument:

BD Viper™ System in extracted mode with the addition of the CTQ and GCQ Assays: The BD Viper System with the capability of automated nucleic acid extraction is the third generation of the BD Viper robotic platform for amplified DNA analysis. The system builds upon its predecessors, the BD Viper Instrument (K023955) and the BD Viper System (K052481).

O. System Descriptions:

Viewing the BD Viper System from the perspective of assay workflow, the level of automation added to enable automated nucleic acid extraction on the existing BD Viper System includes the following:

(1) Chemical lysis of organisms in clinical specimens,
(2) Chemical extraction and purification of DNA using paramagnetic particles facilitated by employment of an extractor block containing a movable magnet assembly;
(3) Elution of extracted DNA into SDA-compatible buffer; and
(4) Transfer of the eluate from the extraction tube to the assay priming microwells.

Beyond these additions to the existing BD Viper System's workflow, the following processing functions are common to both systems (extracted and non-extracted):

(5) Priming microwell heat spike;
(6) Transfer of sample from priming microwells to prewarmed amplification microwells located directly on the reader stage/heater;
(7) Amplification microwell plate sealing and movement of the sealed amplification microwells into the fluorescent reader;
(8) Amplification temperature control and fluorescent photodetection; and
(9) Calculation and result interpretation.

P. Other Supportive Device and Instrument Information:

NA

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.