

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:** K090827

**B. Purpose for Submission:** Addition of the PreservCyt<sup>®</sup> Solution as a new specimen type taken from gynecological swab specimens stored in PreservCyt<sup>®</sup> Solution. The BD ProbeTec<sup>™</sup> *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay” and BD Viper<sup>™</sup> System were 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:** BD Diagnostic System

**F. Proprietary and Established Names:** BD ProbeTec<sup>™</sup> *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay

**G. Regulatory Information:**

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

**H. Intended Use:**

The **BD ProbeTec<sup>™</sup> *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay**, when tested with the **BD Viper<sup>™</sup> 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 PreservCyt<sup>®</sup> Solution using an aliquot that is removed prior to processing for additional gynecological testing. The assay is indicated for use with asymptomatic and symptomatic females and symptomatic males 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<sup>™</sup> System with automated nucleic acid extraction mode

**I. Device Description:** The BD ProbeTec GC Q<sup>x</sup> 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<sup>TM</sup> 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<sup>TM</sup> *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assay Gen-Probe APTIMA Assay for *Neisseria gonorrhoeae* (AGC)

b) Predicate Numbers (s):

K081825

K062440

Comparison with predicate:

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

	<b>BD ProbeTec GCQ Assay, PreservCyt Solution Specimens (Device)</b>	<b>BD ProbeTec GCQ Assay, Swab and Urine Specimens (K081825)</b>	<b>Gen-Probe AGC (K062440)</b>
<b>Specimen Types</b>	<ul style="list-style-type: none"> <li>• Same as K081825</li> <li>• Gynecological specimen in PreservCyt® Solution</li> </ul>	<ul style="list-style-type: none"> <li>• Endocervical swab (females)</li> <li>• Vaginal self-collected swab (in a clinical setting) (females)</li> <li>• Urethral swab (males)</li> <li>• Neat urine (female and male)</li> <li>• UPT urine (female and male)</li> </ul>	<ul style="list-style-type: none"> <li>• Endocervical swab (females)</li> <li>• Vaginal swab (females)</li> <li>• Urethral swab (males)</li> <li>• Neat urine (female and male)</li> <li>• UTT urine (female and male)</li> <li>• Gynecological specimen in PreservCyt® Solution</li> </ul>
<b>Specimen Collection and Transport Accessories</b>	<ul style="list-style-type: none"> <li>• Same as K081825</li> <li>• Liquid Based Cytology Specimen (LBC) Dilution Tube</li> </ul>	<ul style="list-style-type: none"> <li>• Endocervical kit</li> <li>• Urethral kit</li> <li>• Vaginal kit</li> <li>• UPT</li> <li>• Neat urine (Qx Sample Tube)</li> </ul>	<ul style="list-style-type: none"> <li>• Unisex swab kit</li> <li>• Vaginal swab kit</li> <li>• Urine collection kit</li> <li>• Specimen transfer kit (for gynecological specimen in PreservCyt® Solution)</li> </ul>

#### Device Comparison: Specimen Collection

	<b>BD ProbeTec GCQ Assay, PreservCyt Solution Specimens (Device)</b>	<b>Gen-Probe AGC (K062440)</b>
<b>Specimen Collection</b>	<ul style="list-style-type: none"> <li>• Gynecological specimen collected and placed in PreservCyt® Solution (per Cytyc Corporation’s instructions for use).</li> <li>• Sample for CTQ/GCQ testing is drawn from original cytology specimen vial before the specimen is processed for cytology testing.</li> </ul>	<ul style="list-style-type: none"> <li>• Gynecological specimen collected and placed in PreservCyt® Solution (per Cytyc Corporation’s instructions for use).</li> <li>• LBC specimen is first processed for cytology and then an aliquot is drawn from the remaining specimen in the vial for CT/GC testing.</li> </ul>

#### Device Comparison: Specimen Processing

	<b>BD ProbeTec GCQ Assay, PreservCyt Solution Specimens (Device)</b>	<b>BD ProbeTec GCQ Assay, Swab and Urine Specimens (K081825)</b>
<b>Specimen Processing</b>	<ul style="list-style-type: none"> <li>• Same as K081825 without the 15 minute pre-warm step for LBC Dilution Tube specimens</li> <li>• Use of LBC Specimen Rack to prevent prewarming of LBC specimens</li> </ul>	Pre-warm specimens (swabs and urines) for 15 minutes before running BD Viper System

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

1. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. <http://www.fda.gov/cdrh/ode/guidance/337.pdf>
2. CLSI EP5-A2 “Evaluation of Precision Performance of Quantitative Measurement Methods”,

### 3. CLSI EP12-A “User Protocol for Evaluation of Qualitative Test Performance”.

#### **L. Test Principle:**

The BD ProbeTec GC Q<sup>x</sup> Amplified DNA Assay is designed for use with the BD ProbeTec *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/GC) Q<sup>x</sup> specimen collection and transport devices, applicable reagents, the BD Viper System and BD Fox Extraction. Specimens are collected and transported in their respective transport devices which preserve the integrity of the *N. gonorrhoeae* DNA over the specified ranges of temperature and time.

Urine and swab specimens undergo a pre-warm step in the BD Viper Lysing Heater to dissolve mucus and homogenize the specimen. After cooling, the specimens are loaded onto the BD Viper System which then performs all the steps involved in extraction and amplification of target DNA, without further user intervention. The specimen is transferred to an Extraction Tube that contains ferric oxide particles in a dissolvable film and dried Extraction Control. A high pH is used to lyse the bacterial cells and liberate their DNA into solution. Acid is then added to lower the pH and induce a positive charge on the ferric oxide, which in turn binds the negatively charged DNA. The particles and bound DNA are then pulled to the sides of the Extraction Tube by magnets and the treated specimen is aspirated to waste. The particles are washed and a high pH Elution Buffer is added to recover the purified DNA. Finally, a Neutralization Buffer is used to bring the pH of the extracted solution to the optimum for amplification of the target.

The BD ProbeTec GC Q<sup>x</sup> 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 fluorescently-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 re-hydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the BD Viper instrument and an automated

algorithm is applied to both the EC and *N. gonorrhoeae*-specific signals to report specimen results as positive, negative, or EC failure.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

A reproducibility study of the BD Viper System using the BD ProbeTec GC Q<sup>x</sup> Assay was 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 PreservCyt Solution was tested with the BD ProbeTec GC Q<sup>x</sup> Assay. Uninoculated LBC Specimen Dilution Tubes containing PreservCyt Solution 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 the table below.

**Summary of Reproducibility Data for LBC Specimens on the BD Viper System for the GC Q<sup>x</sup> 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	24.8	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

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<sup>x</sup> Assay. These additional specimens comprised CT and GC organisms seeded into LBC Specimen Dilution Tubes containing PreservCyt Solution 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<sup>x</sup> and GC Q<sup>x</sup> 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 the table below.

**Characterization of System Reproducibility at Target Levels below the Analytical Limit of Detection for the GC Q<sup>x</sup> 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

b. *Linearity/assay reportable range:* NA

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* A total of 142 positive and 142 negative assay controls were tested a sufficient number of times with acceptable results on all testing days at all testing sites. Additionally, a total of 71 processing controls were tested a sufficient number of times with acceptable results on all testing days at all testing sites.

d. *Detection limit:* The Limits of Detection (LODs) for the GC Q<sup>x</sup> Assay with *Neisseria gonorrhoeae* strain ATCC 19424 in PreservCyt specimens when extracted on the BD Viper System were determined to be ≤ 100 GC cells per mL. The GC Q<sup>x</sup> Assay on the BD Viper System in extracted mode was able to detect 17 GC strains with ≥ 95% proportion positive at a concentration of 50 cells per mL in clean diluted PreservCyt Solution.

e. *Analytical specificity:*

1. Cross Reactivity: Same as described in K081825 submission. Cross reactivity studies were not repeated for this submission.

2. Interference: The performance of the BD ProbeTec GC Q<sup>x</sup> 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 PreservCyt specimens. Potential interfering substances were spiked into UPT urine and vaginal swab specimen matrices as well as PreservCyt 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 the following table.

**GC Q<sup>x</sup> Interfering Substances.**

<b>Interpretation</b>	<b>Swab</b>	<b>Urine</b>	<b>PreservCyt</b>
No Interference Observed	Blood ( $\leq 60\%$ ) Seminal Fluid Mucus Over The Counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ( $1 \times 10^6$ cells/mL) $1 \times 10^6$ cells/mL <i>Neisseria gonorrhoeae</i>	Blood ( $\leq 1\%$ ) 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 $1 \times 10^6$ cells/mL <i>Neisseria gonorrhoeae</i> Organisms associated with Urinary Tract Infections	Blood ( $\leq 1\%$ ) Seminal Fluid Mucus Over The Counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ( $1 \times 10^6$ cells/mL) $1 \times 10^6$ cells/mL <i>Neisseria gonorrhoeae</i>
May cause extraction control (EC) failures	Blood ( $> 60\%$ )	Not applicable	Glacial Acetic Acid + Blood ( $\leq 5\%/1\%$ V/V)
May cause False Negative results	Not applicable	Not applicable	Glacial Acetic Acid + Blood ( $\leq 5\%/1\%$ V/V)

f. Assay cut-off: NA

**g. 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<sup>x</sup> 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<sup>x</sup> 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<sup>x</sup> 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<sup>x</sup> Swab Diluent and 0.54% (6/1104) for the LBC Specimen Dilution Tube with PreservCyt Solution. Cross-contamination and carryover contamination across the three BD Viper Systems are summarized in the following table.

### Cross Contamination and Carryover Contamination (PreservCyt)

Media Type	BD Viper System	Cross-Contamination			Carryover Contamination		
		n	Positive Results	Percent Positive	n	Positive Results	Percent Positive
PreservCyt Solution	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

#### 2. Comparison studies:

- a. *Method comparison with predicate method:* See below under Performance Characteristics
- b. *Matrix comparison:* NA

#### 3. Clinical studies:

- a. *Clinical Sensitivity:* See under performance characteristics
- b. *Clinical specificity:* See under performance characteristics

### Performance Characteristics

#### PreservCyt Specimen Clinical Study

Endocervical swab specimens and PreservCyt specimens were collected from 2079 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. Two subjects were excluded due to an undetermined patient infected status. Three subjects did not have a PreservCyt specimen result. Therefore there were 2074 subjects evaluated.

Three randomized endocervical swab specimens and a PreservCyt 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<sup>x</sup> assay, and another commercially available NAAT (Nucleic Acid Amplification Test). Sensitivity and specificity for PreservCyt 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. Data are presented in the following tables.

**Summary of Cervical Sampling Devices Used in the PreservCyt Specimen Clinical Study**

Cervical Sampling Device Used	Clinical Collection Site Number											Total
	2	3	4	5	6	7	8	9	10	11	12	
Broom-Type Device	89	0	0	45	16	464	272	83	0	99	0	1068
Spatula/Cytobrush	74	154	95	0	0	52	0	209	282	0	145	1011

**GC Q<sup>x</sup> Assay Performance for PreservCyt Specimens Compared to Patient Infected Status (by symptomatic status)**

Symptomatic Status	n	Performance Compared to Patient Infected Status				PPV%	NPV %	Error Initial/Final
		Sensitivity	95% C.I.	Specificity	95% C.I.			
A	1349	92.3% (24/26)	(74.9% - 99.1%)	100.0% (1323/1323)	(99.7% - 100.0%)	100%	99.9%	1/0
S	725	100.0% (17/17)	(80.5% - 100.0%)	99.9% (707/708)	(99.2% - 100.0%)	95.9%	100%	0/0
Total	2074	95.3% (41/43)	(84.2% - 99.4%)	99.95% (2030/2031)	(99.7% - 100.0%)	100%	99.9%	1/0

**GC Q<sup>x</sup> Assay Performance for PreservCyt Specimens Compared to Patient Infected Status (by clinical site)**

Collection Site	Prevalence	n	Performance Compared to Patient Infected Status						
			Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV %	NPV %
1	5.5%	163	88.9% (8/9)	(51.8% - 99.7%)	100.0% (154/154)	(97.6% - 100.0%)	5	100.0 %	99.4%
2	5.2%	154	100.0% (8/8)	(63.1% - 100.0%)	99.3% (145/146)	(96.2% - 100.0%)	1	88.7%	100.0 %
3	3.2%	95	100.0% (3/3)	(29.2% - 100.0%)	100.0% (92/92)	(96.1% - 100.0%)	2	100.0 %	100.0 %
4	13.3%	45	100.0% (6/6)	(54.1% - 100.0%)	100.0% (39/39)	(91.0% - 100.0%)	2	100.0 %	100.0 %
5	0.0%	16	NA	NA	100.0% (16/16)	(79.4% - 100.0%)	0	NA	NA
6	1.6%	516	100.0% (8/8)	(63.1% - 100.0%)	100.0% (508/508)	(99.3% - 100.0%)	2	100.0 %	100.0 %
7	2.9%	272	87.5% (7/8)	(47.3% - 99.7%)	100.0% (264/264)	(98.6% - 100.0%)	3	100.0 %	99.6%
8	0.0%	292	NA	NA	100.0% (292/292)	(98.7% - 100.0%)	0	NA	NA

Collection Site	Prevalence	n	Performance Compared to Patient Infected Status						
			Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV %	NPV %
9	0.0%	282	NA	NA	100.0% (282/282)	(98.7% - 100.0%)	0	NA	NA
10	0.0%	97	NA	NA	100.0% (97/97)	(96.3% - 100.0%)	0	NA	NA
11	0.7%	142	100.0% (1/1)	(2.5% - 100.0%)	100.0% (141/141)	(97.4% - 100.0%)	0	100.0 %	100.0 %

**GC Q<sup>x</sup> Assay Performance for PreservCyt Specimens Compared to Patient Infected Status (by clinic type)**

Clinic Type	Prevalence	n	Performance Compared to Patient Infected Status						
			Sensitivity	95% C.I.	Specificity	95% C.I.	PPV %	NPV %	
Family Planning	0.7%	118	100.0% (8/8)	(63.1% - 100.0%)	100.0% (1179/1179)	(99.7% - 100.0%)	100.0 %	100.0 %	
OB/GYN	3.0%	367	90.9% (10/11)	(58.7% - 99.8%)	100.0% (356/356)	(99.0% - 100.0%)	100.0 %	99.7%	
STD	4.6%	520	95.8% (23/24)	(78.9% - 99.9%)	99.8% (495/496)	(98.9% - 100.0%)	95.9%	99.8%	

**Analysis of GC Positive/Negative PreservCyt Specimens Based on Patient Infected Status**

PIS GC	AC2 Swab	ProbeTec Swab	Viper Swab	PreservCyt	Symptomatic Status		Table 13C: Total
					A	S	
+	NA	+	+	+	1	3	4
	+	-	+	-	1	0	1
	+	-	+	+	1	0	1
	+	+	NA	+	1	0	1
	+	+	+	+	1	0	1
	+	+	+	+	+	21	14
<b>Total PIS Positive</b>					<b>26</b>	<b>17</b>	<b>43</b>
-	NA	-	-	-	181	79	260
	-	I	-	-	1	0	1
	-	-	NA	-	3	0	3
	-	-	LE	-	2	0	2
	-	-	-	-	1129	624	1753
	-	-	-	+	0	1	1
	-	-	+	-	2	0	2
	-	+	-	-	4	3	7
+	-	-	-	-	1	1	2
<b>Total PIS Negative</b>					<b>1323</b>	<b>708</b>	<b>2031</b>

**4. Clinical cut-off:** Clinical cut-off was validated during the swab and urine clinical trial (K081825). The cutoff was 125 MaxRFU (> 125 MaxRFU = positive; < 125 MaxRFU = negative). The same cutoff was utilized for the clinical trial to validate the performance of the PreservCyt Solution specimens when tested with the GCQ assay on the BD Viper System in extracted mode.

**5. Expected values/Reference range:**

**A. Prevalence:** The prevalence of positive *N. gonorrhoeae* specimens in patient populations depends upon: clinic type, age, risk factors, gender, and test method. The prevalence observed with the GC Q<sup>x</sup> Assay during a multi-center clinical trial for PreservCyt specimens ranged from 0.0% to 13.3% based on the data presented in the table “GC Q<sup>x</sup> Assay Performance for PreservCyt Specimens Compared to Patient Infected Status (by clinical site)” under performance.

**B. Positive and Negative Predictive Value:** Hypothetical positive and negative predictive values (PPV & NPV) for the GC Q<sup>x</sup> Assay from the multi-center clinical trial for PreservCyt specimens are shown in the following table. These calculations are based on hypothetical prevalence and overall sensitivity and specificity (compared to the patient infected status) of 95.3% and 99.95% for PreservCyt specimens.

**GC Hypothetical Positive and Negative Predictive Values (PreservCyt) Compared to Patient Infected Status**

Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
2	95.3	99.95	97.5	99.9
5	95.3	99.95	99.0	99.8
10	95.3	99.95	99.5	99.5
20	95.3	99.95	99.8	98.8
30	95.3	99.95	99.9	98.0
40	95.3	99.95	99.9	97.0
50	95.3	99.95	99.9	95.5

**N. Instrument:** Same as described in K081825.

**O. System Descriptions:** Same as described in K081825

**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.