

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

A. 510(k) Number: K081824

B. Purpose for Submission: To add the option for automated extraction of DNA from clinical specimens using the software accessory “BD ProbeTecTM *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay” to direct the BD ViperTM System.

C. Measurand: *Chlamydia trachomatis* DNA

D. Type of Test: Strand displacement nucleic acid amplification assay

E. Applicant: BD Diagnostic System

F. Proprietary and Established Names: BD ProbeTecTM *Chlamydia trachomatis* (CT) Q^x Amplified DNA Assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
MKZ	Class I	21CFR 866.3120 Chlamydia serological reagents	Microbiology (83)

H. Intended Use:

1.) Intended use: The BD ProbeTecCT Q^x Amplified DNA Assay, when tested with the BD ViperTM System in Extracted Mode, 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. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.

2.) Indications for use: Same as intended use

3.) Special conditions for use statement(s): NA

4.) Special instrument requirements: BD ViperTM System

I. Device Description: The BD ProbeTecCT 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 (8, 9). 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 *C. trachomatis* 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 *C. trachomatis* 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 *C. trachomatis*-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 *C. trachomatis*-specific signals to report specimen results as positive, negative, or EC failure.

J. Substantial Equivalence Information:

a) Predicate device name (s):

BD ProbeTecET CT/GC Amplified DNA Assay
 APTIMA Combo 2 Assay

b) Predicate Numbers (s): K984631, K003395

Comparison with predicate:

Comparison of Operating and Technological Characteristics: Assay

BD ProbeTecCTQ Assay	BD ProbeTecCTQ Assay	BD ProbeTecET CT/GC Assay (K984361)
Amplification Technology	Same as BD ProbeTecET CT/GC (K984631)	Strand Displacement Amplification
Priming Microwell		
• Primers	Alternate region of cryptic CT plasmid	Region of cryptic CT plasmid
• Detector	Linear Detector • Flourescein (fluorophore) • Dabcyl (quencher)	Hairpin Detector • Flourescein (fluorophore) • Rhodamine (quencher)

• Nucleotides	4 of 4 nucleotides required for SDA	1 of 4 nucleotides required for SDA
• Non-specific reagents and cofactors	Same as BD ProbeTecET CT/GC (K984631)	Buffering components, magnesium ions, salt and stabilizing reagents
Amplification Microwell		
• Restriction Enzyme	Same as BD ProbeTecET CT/GC (K984631)	<i>Bso</i> BI restriction enzyme
• Polymerase	Same as BD ProbeTecET CT/GC (K984631)	<i>Bst</i> DNA polymerase
• Nucleotides	0 of 4 nucleotides required for SDA	3 of 4 nucleotides required for SDA
• Non-specific reagents and cofactors	Same as BD ProbeTecET CT/GC (K984631)	Buffering components, magnesium ions, salt and stabilizing reagents
Assay Buffer	Bicine-potassium hydroxide-based	Potassium phosphate-based

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:

See Device Description

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

Reproducibility of the BD Viper System using the BD ProbeTecCT 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 ProbeTecCT Q^x Assay. Simulated endocervical and urethral specimens contained a clean endocervical swab whereas the simulated urine and vaginal swab specimens did not. Un-inoculated swab diluent for the BD ProbeTecCT Q^x Assay was used for the CT 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 following table.

Summary of Reproducibility Data on the BD Viper System for the CT Q^x Assay.

Specimen Type	CT EB's/ mL	GC Cells /mL	% Correct	95% CI	MaxRF UMean	Within Run		Between Runs Within Site		Between Site	
						SD	%CV	SD	%C V	SD	%CV
Endocervical / Urethral	0	0	98.5% (133/135)	(94.8- 99.8%)	29.9	233.0	778.5	0.0	0.0	33.9	113.4
	30	0	100.0% (135/135)	(97.3- 100.0%)	2011.2	114.1	5.7	0.0	0.0	14.8	0.7
	0	100	100.0% (135/135)	(97.3- 100.0%)	1.4	6.0	442.7	1.0	76.9	0.0	0.0
	30	250	100.0% (135/135)	(97.3- 100.0%)	1991.9	118.0	5.9	17.6	0.9	10.4	0.5
	75	100	100.0% (135/135)	(97.3- 100.0%)	1954.8	169.4	8.7	0.0	0.0	0.0	0.0
Urine/ Vaginal	0	0	100.0% (135/135)	(97.3- 100.0%)	0.9	5.0	542.4	0.0	0.0	0.0	0.0
	30	0	100.0% (135/135)	(97.3- 100.0%)	1999.8	131.8	6.6	34.2	1.7	0.0	0.0
	0	100	100.0% (135/135)	(97.3- 100.0%)	0.8	3.4	442.4	0.0	0.0	0.0	0.0
	30	250	100.0% (135/135)	(97.3- 100.0%)	1995.2	125.8	6.3	33.1	1.7	52.9	2.7
	75	100	100.0% (135/135)	(97.3- 100.0%)	2014.4	109.5	5.4	0.0	0.0	0.0	0.0

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 ProbeTecCT Q^x Assay. A panel of simulated specimens was tested that comprised CT and GC 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 the following table.

Characterization of System Reproducibility at Target Levels below the Analytical Limit of Detection for the CT Q^x Assay.

Specimen Type	Dilution of Analytical LOD	% Positive	95% CI (Positive)	Max RFU Mean (Positive)	% Negative	95% CI (Negative)	Max RFU Mean (Negative)
Endocervical/ Urethral	1:10	70.2 (158/225)	(63.8, 76.1)	1794.2	29.8 (67/225)	(23.9, 36.2)	2.6
Endocervical/ Urethral	1:100	10.2 (23/225)	(6.6, 14.9)	1643.8	89.8 (202/225)	(85.1, 93.4)	1.6
Urine/Vaginal	1:10	64.4 (145/225)	(57.8, 70.7)	1733.9	35.6 (80/225)	(29.3, 42.2)	4.6
Urine/Vaginal	1:100	10.7 (24/225)	(7.0, 15.5)	1666.6	89.3 (201/225)	(84.5, 93.0)	2.4

b. *Linearity/assay reportable range:* NA

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* The recommended Positive, Negative and Internal Control material were tested a sufficient number of times with acceptable results on all testing days.

d. *Detection limit:* The Limits of Detection (LODs) for the CT Q^x Assay with *C. trachomatis* serovar H in urine and swab specimens when extracted on the BD Viper System were determined to be < 15 CT elementary bodies (EB) per mL for neat and Q^x UPT urine and < 30 CT EB per mL for expressed vaginal and endocervical swab specimens. A correlation of EB to Inclusion-forming units (IFU) suggests that the CT Q^x assay LODs with serovar H in urine and swab specimens correspond to < 1 IFU per mL (15). The CT Q^x Assay on the BD Viper System in extracted mode was able to detect 16 isolates representing 15 CT serovars (A, B, Ba, C, D, E (2)*, F, G, H, I, J, K, LGV1, LGV2, and LGV3) with ≥ 95% proportion positive at a concentration of 15 EB per mL in CT/GC Q^x Swab Diluent.

* Testing with CT serovar E included the nvCT strain, a new variant with a deletion in the cryptic plasmid. (21)

e. *Analytical specificity:*

1. Cross Reactivity: DNA from 141 organisms listed in the following table was extracted on the BD Viper System and tested with the BD ProbeTec CT Q^x Amplified DNA Assay. All potential cross-reactive species were tested at > 1x10⁸ cells/mL except where noted. The CT Q^x Assay did not cross-react with any of the organisms tested.

Potential Cross-reacting Microorganisms

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

		<i>parahaemolyticus</i>	
<i>Edwardsiella tarda</i>	<i>Mycobacterium gordonae</i>	<i>Yersinia enterocolitica</i>	
<i>Enterobacter cloacae</i>	<i>Mycobacterium smegmatis</i>	<i>Branhamella catarrhalis</i> (5)	
<i>Enterococcus faecalis</i>	<i>Peptostreptococcus anaerobius</i>	<i>Neisseria cinerea</i> (2)	
<i>Enterococcus faecium</i>	<i>Peptostreptococcus asaccharolyticus</i>	<i>Neisseria elongata</i> subsp. <i>glycolytica</i>	

(n) number of strains tested in the BD ProbeTecCT Q^x Assay

* Tested at > 1x10⁷ cells or EB per mL; **Tested at > 1x10⁶ cells or viral particles per mL; ***Tested at ≥ 1x10⁶ genomic equivalents per mL;**** tested at ≥ 1x10⁵ TCID₅₀/mL

2. Interference: The performance of the BD ProbeTecCT 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 and/or urine specimens. Potential interfering substances were spiked into Q^x UPT urine and vaginal swab specimen matrices in both the presence and the absence of CT elementary bodies (30 CT EB/mL in urine matrix and 90 CT EB/mL in swab matrix). Results are summarized in the following table.

GC Q^x Interfering Substances

Interpretation	Swab	Urine
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 <i>C. trachomatis</i>	Blood (≤1%) Seminal fluid Mucus Antibiotics Analgesics 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 <i>C. trachomatis</i> Organisms associated with Urinary Tract Infections
May cause extraction control (EC) failures	Blood (> 60%)	Not applicable

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^x Swab Diluent. Positive samples consisted of a representative analyte (at 10⁵ CT EB/mL) spiked into CT/GC Q^x Swab Diluent. 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). 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). Cross-contamination and carryover rates across the three BD Viper Systems are summarized in table.

Cross Contamination and Carryover Contamination

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

2. Comparison studies:

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

3. Clinical studies:

- a. *Clinical Sensitivity:* NA
- b. *Clinical specificity:* NA

Performance Characteristics

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 female subjects and 479 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 7 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 472 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 472 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 CT 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/AC assay and another commercially available NAAT (Nucleic Acid Amplification Test). Specimen testing was conducted either at the site of specimen collection or at a designated BD Viper testing site.

All performance calculations were based on the total number of BD ProbeTec CT 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 CT or not was based on endocervical swab and urine specimen results from the commercially available BD ProbeTec ET CT/AC assay and another commercially available NAAT. Subjects were considered infected with CT 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 CT/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 5388 BD ProbeTec CT Q^x assay results was used to calculate sensitivity and specificity. Sensitivity and specificity by specimen type and symptomatic status are presented in the table below.

Performance of the assay with endocervical swabs, patient collected vaginal swab 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 was 62.5% (5/8): the test and reference NAAT swab specimens were negative; the test and reference NAAT urine

specimens were positive yielding a PIS positive result. FV sensitivity was 75% (6/8): the test and reference NAAT swab specimens were negative; the test and reference NAAT urine specimens were positive yielding a PIS positive result. FNU and FUPT sensitivity were 100% (8/8). Specificity was 94.7% (18/19) for FS, FV, FNU, and FUPT separately.

Tables below summarize the results from symptomatic and asymptomatic subjects designated as infected or non-infected with CT according to the PIS algorithm.

CT Q^x Assay Performance Compared to Patient Infected Status (by specimen type and symptomatic status)

Specimen Type	Symptomatic	N	Sensitivity	95% C.I.	Specificity	95% C.I.	PPV%	NPV%	Error Initial/Final
FS	N	450	93.0% (53/57)	(83.0% - 98.1%)	98.0% (385/393)	(96.0% - 99.1%)	86.9	99.0	2/0
	Y	543	89.7% (52/58)	(78.8% - 96.1%)	98.6% (478/485)	(97.0% - 99.4%)	88.1	98.8	1/1
	Total	993	91.3% (105/115)	(84.6% - 95.8%)	98.3% (863/878)	(97.2% - 99.0%)	87.5	98.9	3/1
FV	N	449	98.2% (56/57)	(90.6% - 100.0%)	99.5% (390/392)	(98.2% - 99.9%)	96.6	99.7	0/0
	Y	544	94.8% (55/58)	(85.6% - 98.9%)	99.0% (481/486)	(97.6% - 99.7%)	91.7	99.4	0/0
	Total	993	96.5% (111/115)	(91.3% - 99.0%)	99.2% (871/878)	(98.4% - 99.7%)	94.1	99.5	0/0
FN	N	450	93.0% (53/57)	(83.0% - 98.1%)	100.0% (393/393)	(99.1% - 100.0%)	100.0	99.0	0/0
	Y	543	93.1% (54/58)	(83.3% - 98.1%)	99.0% (480/485)	(97.6% - 99.7%)	91.5	99.2	0/0
	Total	993	93.0% (107/115)	(86.8% - 96.9%)	99.4% (873/878)	(98.7% - 99.8%)	95.5	99.1	0/0
FUPT	N	450	94.7% (54/57)	(85.4% - 98.9%)	99.5% (391/393)	(98.2% - 99.9%)	96.4	99.2	0/0
	Y	543	91.4% (53/58)	(81.0% - 97.1%)	99.0% (480/485)	(97.6% - 99.7%)	91.4	99.0	0/0

Specimen Type	Symptomatic	N	Sensitivity	95% C.I.	Specificity	95% C.I.	PPV%	NPV%	Error Initial/Final
	Total	993	93.0% (107/115)	(86.8% - 96.9%)	99.2% (871/878)	(98.4% - 99.7%)	93.9	99.1	0/0
MS	N	215	88.6% (31/35)	(73.3% - 96.8%)	98.9% (178/180)	(96.0% - 99.9%)	93.9	97.8	1/0
	Y	257	93.9% (62/66)	(85.2% - 98.3%)	97.9% (187/191)	(94.7% - 99.4%)	93.9	97.9	1/0
	Total	472	92.1% (93/101)	(85.0% - 96.5%)	98.4% (365/371)	(96.5% - 99.4%)	93.9	97.9	2/0
MN	N	215	100.0% (35/35)	(90.0% - 100.0%)	98.9% (178/180)	(96.0% - 99.9%)	94.6	100.0	0/0
	Y	257	97.0% (64/66)	(89.5% - 99.6%)	99.5% (190/191)	(97.1% - 100.0%)	98.5	99.0	0/0
	Total	472	98.0% (99/101)	(93.0% - 99.8%)	99.2% (368/371)	(97.7% - 99.8%)	97.1	99.5	0/0
MUPT	N	215	100.0% (35/35)	(90.0% - 100.0%)	98.9% (178/180)	(96.0% - 99.9%)	94.6	100.0	0/0
	Y	257	97.0% (64/66)	(89.5% - 99.6%)	97.4% (186/191)	(94.0% - 99.1%)	92.8	98.9	0/0
	Total	472	98.0% (99/101)	(93.0% - 99.8%)	98.1% (364/371)	(96.2% - 99.2%)	93.4	99.5	0/0
Total		5388	94.5% (721/763)	(92.6% - 96.0%)	98.9% (4575/4625)	(98.6% - 99.2%)	93.5	99.1	5/1

Note: For female subjects, infections localized to the endocervix or urethra have been reported in the literature (16-20). Analyses were performed on the endocervical swab specimens and female UPT and neat urine specimens to further characterize the ten negative female endocervical swabs (105/115) and the eight negative female UPT and neat urine specimens (107/115).

- Of the 115 female subjects defined as positive by the PIS algorithm, ten had infections localized to the urethra as indicated by the urine reference result (*i.e.*, BD ProbeTec ET CT/AC assay and other NAAT endocervical swab specimens were negative, BD ProbeTec ET CT/AC assay and other NAAT urine specimens were positive). The BD ProbeTec CT Q^x assay was negative for nine of the ten endocervical swab specimens from these subjects.
- Of the 115 female subjects defined as positive by the PIS algorithm, three had infections localized to the endocervix as indicated by the endocervical reference result (*i.e.*, BD ProbeTec ET CT/AC assay and other NAAT urine specimens were negative, BD ProbeTec ET CT/AC assay and other NAAT endocervical swab

specimens were positive.) The BD ProbeTec CT Q^x assay was negative for UPT and neat urine for these three subjects.

CT Q^x Assay Performance Compared to Patient Infected Status (by clinical site).

Specimen Type	Clinical Site	Prevalence	n	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
FS ¹	1	16.1%	15 5	96.0% (24/25)	(79.6% - 99.9%)	96.2% (125/130)	(91.3% - 98.7%)	5	82.8%	99.2%
	2	11.0%	15 5	88.2% (15/17)	(63.6% - 98.5%)	98.6% (136/138)	(94.9% - 99.8%)	6	88.2%	98.6%
	3	12.3%	73	88.9% (8/9)	(51.8% - 99.7%)	100.0% (64/64)	(94.4% - 100.0%)	2	100.0 %	98.5%
	4	18.1%	10 5	89.5% (17/19)	(66.9% - 98.7%)	100.0% (86/86)	(95.8% - 100.0%)	6	100.0 %	97.7%
	5	10.0%	70	100.0% (7/7)	(59.0% - 100.0%)	96.8% (61/63)	(89.0% - 99.6%)	0	77.8%	100.0 %
	6	8.5%	36 5	90.3% (28/31)	(74.2% - 98.0%)	98.5% (329/334)	(96.5% - 99.5%)	3	84.8%	99.1%
	7	10.0%	70	85.7% (6/7)	(42.1% - 99.6%)	98.4% (62/63)	(91.5% - 100.0%)	0	85.7%	98.4%
FV ²	1	16.1%	15 5	100.0% (25/25)	(86.3% - 100.0%)	97.7% (127/130)	(93.4% - 99.5%)	5	89.3%	100.0 %
	2	11.0%	15 5	100.0% (17/17)	(80.5% - 100.0%)	99.3% (137/138)	(96.0% - 100.0%)	6	94.4%	100.0 %
	3	12.3%	73	77.8% (7/9)	(40.0% - 97.2%)	100.0% (64/64)	(94.4% - 100.0%)	2	100.0 %	97.0%
	4	18.1%	10 5	94.7% (18/19)	(74.0% - 99.9%)	100.0% (86/86)	(95.8% - 100.0%)	6	100.0 %	98.9%
	5	10.0%	70	100.0% (7/7)	(59.0% - 100.0%)	96.8% (61/63)	(89.0% - 99.6%)	0	77.8%	100.0 %
	6	8.5%	36 5	96.8% (30/31)	(83.3% - 99.9%)	100.0% (334/334)	(98.9% - 100.0%)	3	100.0 %	99.7%
	7	10.0%	70	100.0% (7/7)	(59.0% - 100.0%)	98.4% (62/63)	(91.5% - 100.0%)	0	87.5%	100.0 %
FNU ³	1	16.1%	15 5	92.0% (23/25)	(74.0% - 99.0%)	97.7% (127/130)	(93.4% - 99.5%)	5	88.5%	98.4%

¹ 22 of the 115 FS PIS positive subjects were co-infected with GC.

² 22 of the 115 FV PIS positive subjects were co-infected with GC.

³ 22 of the 115 FNU positive subjects were co-infected with GC.

Specimen Type	Clinical Site	Prevalence	n	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
	2	11.0%	155	82.4% (14/17)	(56.6% - 96.2%)	100.0% (138/138)	(97.4% - 100.0%)	6	100.0%	97.9%
	3	12.3%	73	88.9% (8/9)	(51.8% - 99.7%)	100.0% (64/64)	(94.4% - 100.0%)	2	100.0%	98.5%
	4	18.3%	104	100.0% (19/19)	(82.4% - 100.0%)	97.6% (83/85)	(91.8% - 99.7%)	6	90.5%	100.0%
	5	10.0%	70	100.0% (7/7)	(59.0% - 100.0%)	100.0% (63/63)	(94.3% - 100.0%)	0	100.0%	100.0%
	6	8.5%	366	93.5% (29/31)	(78.6% - 99.2%)	100.0% (335/335)	(98.9% - 100.0%)	3	100.0%	99.4%
	7	10.0%	70	100.0% (7/7)	(59.0% - 100.0%)	100.0% (63/63)	(94.3% - 100.0%)	0	100.0%	100.0%
	FUPT ⁴	1	16.1%	155	96.0% (24/25)	(79.6% - 99.9%)	97.7% (127/130)	(93.4% - 99.5%)	5	88.9%
2		11.0%	155	82.4% (14/17)	(56.6% - 96.2%)	99.3% (137/138)	(96.0% - 100.0%)	6	93.3%	97.9%
3		12.3%	73	88.9% (8/9)	(51.8% - 99.7%)	100.0% (64/64)	(94.4% - 100.0%)	2	100.0%	98.5%
4		18.3%	104	100.0% (19/19)	(82.4% - 100.0%)	100.0% (85/85)	(95.8% - 100.0%)	6	100.0%	100.0%
5		10.0%	70	100.0% (7/7)	(59.0% - 100.0%)	100.0% (63/63)	(94.3% - 100.0%)	0	100.0%	100.0%
6		8.5%	366	93.5% (29/31)	(78.6% - 99.2%)	99.4% (333/335)	(97.9% - 99.9%)	3	93.5%	99.4%
7		10.0%	70	85.7% (6/7)	(42.1% - 99.6%)	98.4% (62/63)	(91.5% - 100.0%)	0	85.7%	98.4%
MS ⁵	1	24.1%	203	87.8% (43/49)	(75.2% - 95.4%)	98.1% (151/154)	(94.4% - 99.6%)	9	93.5%	96.2%
	2	22.4%	76	100.0% (17/17)	(80.5% - 100.0%)	98.3% (58/59)	(90.9% - 100.0%)	10	94.4%	100.0%
	4	23.8%	101	95.8% (23/24)	(78.9% - 99.9%)	100.0% (77/77)	(95.3% - 100.0%)	11	100.0%	98.7%
	5	15.5%	71	90.9% (10/11)	(58.7% - 99.8%)	96.7% (58/60)	(88.5% - 99.6%)	3	83.3%	98.3%

⁴ 22 of the 115 FUPT positive subjects were co-infected with GC.

⁵ 33 of the 101 MS positive subjects were co-infected with GC.

Specimen Type	Clinical Site	Prevalence	n	Sensitivity	95% C.I.	Specificity	95% C.I.	# CT (+) and GC (+)	PPV%	NPV%
	7	0.0%	21	NA	NA	100.0% (21/21)	(83.9% - 100.0%)	0	NA	NA
MNU ⁶	1	24.1%	20	98.0% (48/49)	(89.1% - 99.9%)	99.4% (153/154)	(96.4% - 100.0%)	9	98.0%	99.4%
	2	22.4%	76	100.0% (17/17)	(80.5% - 100.0%)	100.0% (59/59)	(93.9% - 100.0%)	10	100.0%	100.0%

Analysis of CT Positive/Negative Specimens from Female Subjects Based on Patient Infected Status

PIS CT	NAAT 1		NAAT 2		BD ProbeTec CT Q ^x Amplified DNA Assay				Symptomatic Status		
	Endocervical Swab	Urine	Endocervical Swab	Urine	Q ^x Endocervical Swab	Q ^x Vaginal Swab	Neat Urine	Q ^x UPT Urine	A	S	Total
+	-	+	-	+	-	-	+	+	0	2	2
	-	+	-	+	-	+	-	-	1	0	1
	-	+	-	+	-	+	+	+	2	4	6
	-	+	-	+	+	-	+	+	1	0	1
	-	+	+	+	-	+	+	+	1	0	1
	-	+	+	+	+	+	+	+	1	3	4
	+	NA	+	+	+	+	+	+	0	1	1
	+	-	+	-	+	+	-	-	1	2	3
	+	-	+	+	+	-	-	-	0	1	1
	+	-	+	+	+	+	-	-	0	1	1
	+	-	+	+	+	+	-	+	1	0	1
	+	-	+	+	+	+	+	-	1	0	1
	+	-	+	+	+	+	+	+	0	2	2
	+	+	-	+	+	+	+	+	1	0	1
+	+	+	+	+	+	-	+	1	0	1	
+	+	+	+	+	+	+	-	0	1	1	
Total PIS Positive									57	58	115
-	NA	-	-	-	-	-	-	-	11	2	13
	NA	-	-	+	-	-	-	-	1	0	1
	-	NA	-	-	-	-	NA	NA	0	1	1
	-	NA	-	-	-	-	-	-	1	0	1

⁶ 33 of the 101 MNU positive subjects were co-infected with GC.

PIS CT	NAAT 1		NAAT 2		BD ProbeTec CT Q ^x Amplified DNA Assay				Symptomatic Status		
	Endocervical Swab	Urine	Endocervical Swab	Urine	Q ^x Endocervical Swab	Q ^x Vaginal Swab	Neat Urine	Q ^x UPT Urine	A	S	Total
-	I	-	-	-	-	-	-	5	1	6	
-	-	NA	-	-	-	-	-	1	2	3	
-	-	-	-	LE	-	-	-	0	1	1	
-	-	-	-	-	-	NA	-	1	0	1	
-	-	-	-	-	-	-	-	362	456	818	
-	-	-	-	-	-	-	+	1	2	3	
-	-	-	-	-	-	+	-	0	2	2	
-	-	-	-	-	-	+	-	0	1	1	
-	-	-	-	+	+	-	-	6	2	8	
-	-	-	+	-	-	-	-	0	4	4	
-	-	-	+	-	+	+	-	0	1	1	
-	-	+	-	-	-	-	-	1	3	4	
-	-	+	-	-	-	+	-	1	0	1	
-	-	+	-	+	+	-	-	1	1	2	
-	-	+	-	+	+	+	-	1	0	1	
-	-	+	+	-	-	+	-	0	1	1	
-	-	+	+	+	+	+	-	0	1	1	
-	-	+	+	+	+	+	+	0	1	1	
-	+	-	-	-	-	-	-	0	1	1	
+	-	-	-	-	-	-	-	0	2	2	
+	+	-	-	-	+	+	+	0	1	1	
Total PIS Negative								393	486	879	

I Indeterminate

LE Liquid Level Error

Analysis of CT Positive/Negative Specimens from Male Subjects Based on Patient Infected Status

PIS CT	NAAT 1		NAAT 2		BD ProbeTec CT Q ^x Amplified DNA Assay			Symptomatic Status		
	Urethral Swab	Urine	Urethral Swab	Urine	Q ^x Urethral Swab	Neat Urine	Q ^x UPT Urine	A	S	Total
+	NA	+	+	+	+	+	+	0	6	6
	-	+	-	+	-	+	+	3	2	5
	-	+	+	-	-	-	-	0	1	1
	-	+	+	+	+	+	+	1	4	5
	+	-	+	+	-	+	+	0	1	1
	+	-	+	+	+	-	-	0	1	1
	+	+	NA	+	+	+	+	2	5	7
	+	+	-	+	+	+	+	0	1	1
	+	+	+	-	+	+	+	0	1	1
	+	+	+	+	-	+	+	1	0	1

	+	+	+	+	+	+	+	28	44	72
Total PIS Positive								35	66	101
-	NA	-	-	-	-	-	-	4	12	16
	NA	-	-	-	-	-	+	0	1	1
	-	I	NA	-	-	-	-	1	0	1
	-	I	-	-	-	-	-	4	1	5
	-	-	NA	-	-	-	-	10	20	30
	-	-	-	-	-	-	-	157	146	303
	-	-	-	-	-	-	+	0	2	2
	-	-	-	-	+	-	-	0	2	2
	-	-	-	-	+	-	+	0	1	1
	-	-	-	+	-	-	-	0	3	3
	-	-	+	-	-	-	-	1	1	2
	-	-	+	-	+	-	-	0	1	1
	-	-	+	-	+	+	+	1	0	1
	-	-	+	+	-	+	+	0	1	1
	+	-	-	-	-	-	-	1	0	1
+	+	NA	-	+	+	+	1	0	1	
Total PIS Negative								180	191	371

Neat and Q^x UPT Urine Stability

Pools of CT 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 60 days. At each time point, samples were removed from storage and tested with the BD ProbeTecCT 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 CT 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 specimen pools 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 60 days. At each time point Q^x UPT specimens were removed from storage and tested with the BD ProbeTecCT 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 CT Q^x assay under all conditions tested.

Vaginal Dry and Expressed Swab Stability

Pools of CT 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°C for 3, 7, or 14 days; or at 30°C for 3, 7 or 14 days; or at -20°C for 30 or 60 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 CT 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 CT Q^x assay under all conditions tested.

Pools of CT 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°C for 7, 14 or 30 days; or at 30°C for 7, 14 or 30 days; or at -20°C for 30 or 60 days. At each time point, samples were removed from storage and tested with the BD ProbeTec CT 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 CT Q^x assay under all conditions tested.

Endocervical and Urethral Swab Specimen Stability

Pools of CT 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°C for 7, 14 or 30 days; or at 30°C for 7, 14 or 30 days; or at -20°C for 30 or 60 days. At each time point, samples were removed from storage and tested with the BD ProbeTec CT 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 CT Q^x assay under all conditions tested.

Post Pre-warm Specimen Stability

Pools of male and female CT negative neat urine 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 days. At each time point samples were removed from storage and tested with the BD ProbeTec CT 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 CT Q^x assay under all conditions tested.

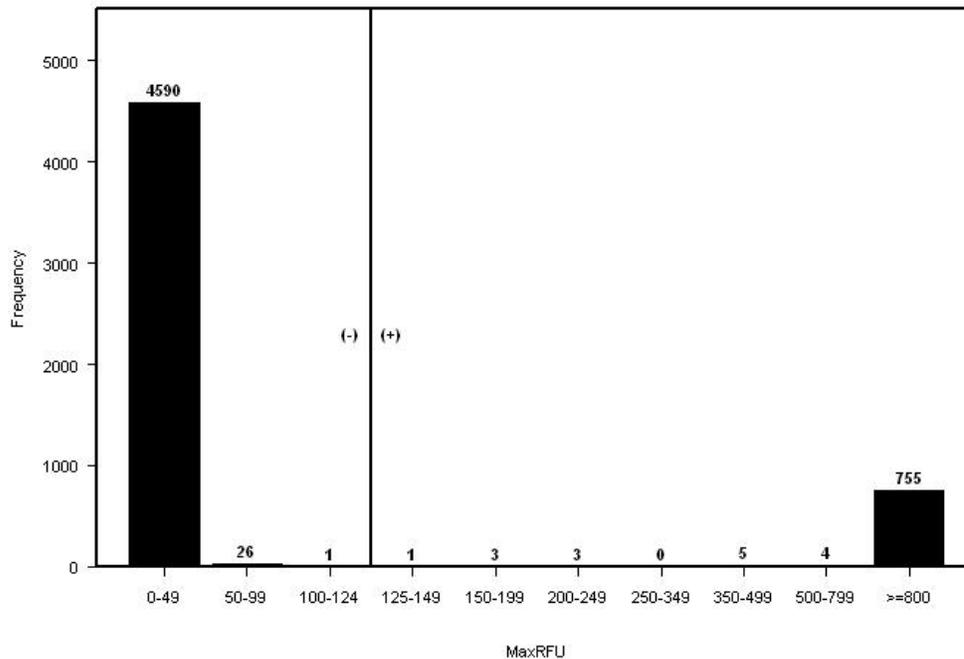
Pools of CT negative vaginal and endocervical swab specimen matrices in CT/GC Q^x Swab Diluent were used in analytical experiments to support the storage stability claims for pre-warmed expressed vaginal, endocervical, and male urethral swab specimens. For both types of matrix, pooled specimens were 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 days. At each time point, samples were removed from storage and tested with the BD ProbeTecCT 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 CT Q^x assay under all conditions tested.

4. MaxRFU Frequency Distribution:

A total of 5388 CT Q^x Assay results was evaluated at seven geographically diverse clinical sites. A frequency distribution of the initial MaxRFU values for the CT Q^x assay is shown in Figure A. The distribution of MaxRFU values from CT 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 the table below.

Figure A: Frequency Distribution of MaxRFU for the CT Q^x Assay.



CT Q^x MaxRFU Ranges for False Negative, False Positive, True Negative and True Positive Results

	MaxRFU range	0-49	50-99	100-124	125-149	150-199	200-249	250-349	350-499	500-799	≥ 800
n		4590	26	1	1	3	3	0	5	4	755
FN	FNU	8	0	0							
	FS	10	0	0							
	FUPT	8	0	0							
	FV	4	0	0							
	MNU	2	0	0							

	MaxRFU range	0-49	50-99	100-124	125-149	150-199	200-249	250-349	350-499	500-799	≥ 800
n		4590	26	1	1	3	3	0	5	4	755
	MS	8	0	0							
	MUPT	2	0	0							
	Total	42	0	0							
FP	FNU				0	1	0	0	0	0	4
	FS				0	0	0	0	2	2	11
	FUPT				0	0	2	0	0	0	5
	FV				0	1	0	0	0	0	6
	MNU				0	0	0	0	0	1	2
	MS				0	1	0	0	0	0	5
	MUPT				1	0	1	0	0	0	5
	Total				1	3	3	0	2	3	38
TN	FNU	868	5	0							
	FS	857	6	0							
	FUPT	866	5	0							
	FV	866	4	1							
	MNU	368	0	0							
	MS	364	1	0							
	MUPT	359	5	0							
	Total	4548	26	1							
TP	FNU				0	0	0	0	2	1	104
	FS				0	0	0	0	1	0	104
	FUPT				0	0	0	0	0	0	107
	FV				0	0	0	0	0	0	111
	MNU				0	0	0	0	0	0	99
	MS				0	0	0	0	0	0	93
	MUPT				0	0	0	0	0	0	99
	Total				0	0	0	0	3	1	717

Controls: During the clinical evaluation, there were no CT Q^x positive control failures from 253 CT Q^x plate runs. For the CT Q^x negative control, a failure was observed in 1 of 253 CT Q^x plate runs. The CT/GC Q^x positive and negative control MaxRFU values observed in the clinical trials are shown in the table below.

Distribution of MaxRFU Results for the CT Q^x Assay Positive and Negative Controls

Control	Max RFU					
	n	Range	5th Percentile	Mean	Median	95th Percentile
CT Q ^x Negative Control	252	0 - 41	0.0	0.7	0.0	4.3
CT Q ^x Positive Control	253	629 - 2378	1597.7	1939.4	1968.8	2184.0

5. Expected values/Reference range:

A. Prevalence: The prevalence of positive *C. trachomatis* specimens in patient populations depends upon: clinic type, age, risk factors, gender, and test method. The prevalence observed with the CT Q^x Assay during a multi-center clinical trial ranged from 8.5% to 18.3% for female specimens and 0% to 24.1% for male specimens.

B. Positive and Negative Predictive Value: Hypothetical positive and negative predictive values (PPV & NPV) for the CT Q^x Assay are shown in Table 5. These calculations are based on hypothetical prevalence and overall sensitivity and specificity (compared to the patient infected status) of 94.5% and 98.9%, respectively. In addition, PPV and NPV based on actual prevalence, sensitivity and specificity are shown in Tables 8 and 9. PPV was calculated using: $(\text{Sensitivity} * \text{Prevalence}) / (\text{Sensitivity} * \text{Prevalence} + (1 - \text{Specificity}) * (1 - \text{Prevalence}))$. NPV was calculated using: $(\text{Specificity} * (1 - \text{Prevalence}) / (1 - \text{Sensitivity}) * \text{Prevalence} + \text{Specificity} * (1 - \text{Prevalence}))$.

CT Hypothetical Positive and Negative Predictive Values Compared to Patient Infected Status.

Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
2	94.5	98.9	64.1	99.9
5	94.5	98.9	82.1	99.7
10	94.5	98.9	90.7	99.4
20	94.5	98.9	95.6	98.6
30	94.5	98.9	97.4	97.7
40	94.5	98.9	98.3	96.4
50	94.5	98.9	98.9	94.7

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).

Comparison of Operating and Technological Characteristics

	BD Viper System: Extracted mode of operation	BD Viper System Non- extracted mode of operation (K052481)
Thermal Module: • Priming Temperature • Priming to Amplification Transfer Temperature • Amplification	<ul style="list-style-type: none"> • Same as BD Viper System K052481 • 70°C • Same as BD Viper System K052481 	<ul style="list-style-type: none"> • 70°C • 70°C to 52.5°C • 52.5°C

Temperature		
Amplification Plate Sealing	<ul style="list-style-type: none"> • Same as BD Viper System K052481 	<ul style="list-style-type: none"> • Automated sealing of amplification plate
Optical Module: Fluorescent readers	<ul style="list-style-type: none"> • Same as BD Viper System K052481 • Same as BD Viper System K052481 • Extraction control read on ROX 	<ul style="list-style-type: none"> • Automatic amplification plate transfer into resident readers (2 readers) • Target read on FAM channel • ROX channel not used
Software Module		
Sample log-in	<ul style="list-style-type: none"> • Same as BD Viper System K052481 • Patient Sample Location Identification (optional) 	<ul style="list-style-type: none"> • Bar-code or key entered accession numbers
Algorithm	<ul style="list-style-type: none"> • MaxRFU – Maximum (normalized) Relative Fluorescence Units 	<ul style="list-style-type: none"> • MOTA – Method Other Than Acceleration (area under the curve)
Menu	<ul style="list-style-type: none"> • Same as BD Viper System K052481 • Added: CTQ, GCQ and CTQ/GCQ 	<ul style="list-style-type: none"> • CT or CT/GC
Controls and System Checks		
Assay Controls	<ul style="list-style-type: none"> • Positive and negative run controls • Automated control rehydration • Extraction control • Specimen processing control procedure 	<ul style="list-style-type: none"> • Positive and negative run controls • Manual control rehydration • Specimen processing control procedure
System Checks	<ul style="list-style-type: none"> • Same as BD Viper System K052481 • Extraction reagent checks • Liquid Waste reservoir check 	<ul style="list-style-type: none"> • Consumables, Pipettor, Thermal, Optical, Fluid Volumes
Waste and Waste Disposal		
<ul style="list-style-type: none"> • Waste Composition • Liquid Waste Disposal Container • Liquid Waste Neutralizer 	<ul style="list-style-type: none"> • Same as BD Viper System K052481 and liquid waste (extraction reagents) • Modified waste disposal bottle • Neutralization pouch for liquid waste 	<ul style="list-style-type: none"> • Solid waste (pipette tips) • Waste disposal bottle resident, not used except in aborted run condition • NA

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.

Software: The FDA has reviewed applicant's Hazard Analysis and Software development processes for the device

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.