

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

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

K080739

**B. Purpose for Submission:**

New device

**C. Analyte:**

*Chlamydia trachomatis*

*Neisseria gonorrhoeae*

Type of Test:

Nucleic Acid Amplification

Applicant:

Abbott Molecular Inc.

Proprietary and Established Names:

Abbott RealTime CT/NG

**D. Regulatory Information:**

1. Regulation section:

866.3120

866.3390

2. Classification:

I, II

3. Product Code:

MKZ, LSL

4. Panel:

Microbiology 083

Intended Use:

5. Intended use(s):

The Abbott RealTime CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. The assay may be used to test the following specimens from symptomatic individuals: clinician-collected vaginal swab and male urethral swab specimens; patient-collected vaginal swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: male and female urine.

6. Indication(s) for use:

Same as intended use

7. Special condition for use statement(s):

NA

8. Special instrument Requirements:  
Abbott *m2000* System

Device Description:

Abbott RealTime CT/NG consists of two reagent kits:

- Abbott RealTime CT/NG Amplification Reagent Kit (List No. 8L07-90)
- Abbott RealTime CT/NG Control Kit (List No. 8L07-80)

The Abbott RealTime CT/NG assay uses PCR technology with homogenous real-time fluorescence detection on the *m2000* System. The Abbott *m2000* System consists of the Abbott *m2000sp* and Abbott *m2000rt* instruments. The Abbott *m2000* System integrates sample preparation with nucleic acid amplification and detection to generate assay results. The Abbott *m2000sp* is used for processing samples and the Abbott *m2000rt* is used for amplification and detection.

The Abbott *multi-Collect Specimen Collection Kit* can be used to collect either a swab or a urine specimen. Each Abbott *multi-Collect Specimen Collection Kit* (List No. 9K12) contains:

- One Transport Tube containing 1.2 mL Specimen Transport Buffer
- One Individually Packaged Sterile Specimen Collection Swab (Part No. CD650)
- One disposable transfer pipette.

The Specimen Transport Buffer consists of guanidine thiocyanate, a chaotropic salt, in Tris buffer and is used to stabilize DNA until sample preparation. The individually packaged sterile Specimen Collection Swab is used for swab sample collection and placed directly into the Transport Tube. The transfer pipette is used to add approximately 3 mL of urine to the Transport Tube. The Abbott *multi-Collect Specimen Collection Kit* is for single use only.

**E. Substantial Equivalence Information:**

1. Predicate device name(s):

GEN-PROBE® APTIMA® Combo 2 Assay (Assigned 510(k) No. K043224);  
Becton Dickinson ProbeTec™ ET *Chlamydia trachomatis* /*Neisseria gonorrhoeae*  
Amplified DNA Assay (Assigned 510(k) No. K012351);  
Gen-Probe® APTIMA™ Unisex Swab Specimen Collection Kit for Endocervical and  
Urethral Swab Specimens (K043224);  
Gen-Probe APTIMA Urine Specimen Collection Kit for Male and Female Urine  
(Assigned 510(k) No. K043144);  
Gen-Probe APTIMA Vaginal Swab Specimen Collection Kit  
(Assigned 510(k) No. K032554);  
BD ProbeTec ET Urine Processing Kit Assigned 510(k) No. (K052224).

2. Predicate K number(s):

K043224, K012351, K043224, K043144, K032554, K052224

3. Comparison with predicate:

Feature	Current Application	Amplified Nucleic Acid Predicate Devices	
	Abbott RealTime CT/NG	Gen-Probe Aptima Combo 2	Becton Dickinson ProbeTec ET
Assay Type	<ul style="list-style-type: none"> <li>Qualitative</li> </ul>	<ul style="list-style-type: none"> <li>Qualitative</li> </ul>	<ul style="list-style-type: none"> <li>Qualitative</li> </ul>
CT Analyte Targets	<ul style="list-style-type: none"> <li>CT cryptic plasmid DNA</li> </ul>	<ul style="list-style-type: none"> <li>CT ribosomal RNA</li> </ul>	<ul style="list-style-type: none"> <li>CT cryptic plasmid DNA</li> </ul>
NG Analyte Targets	<ul style="list-style-type: none"> <li>NG genomic DNA</li> </ul>	<ul style="list-style-type: none"> <li>NG ribosomal RNA</li> </ul>	<ul style="list-style-type: none"> <li>NG genomic DNA</li> </ul>
Input Sample Types	<ul style="list-style-type: none"> <li>Self-collected vaginal swab specimens</li> <li>Clinician-collected vaginal swab specimens</li> <li>Male urethral swab specimens</li> <li>Male and female urine specimens</li> </ul>	<ul style="list-style-type: none"> <li>Endocervical swab specimens</li> <li>Self-collected vaginal swab specimens</li> <li>Clinician-collected vaginal swab specimens</li> <li>Male urethral swab specimens</li> <li>Male and female urine specimens.</li> <li>PreservCyt liquid Pap specimens</li> </ul>	<ul style="list-style-type: none"> <li>Endocervical swab specimens</li> <li>Male urethral swab specimens</li> <li>Male and female urine specimens</li> </ul>
Sample Preparation Procedure	<ul style="list-style-type: none"> <li>Automated</li> </ul>	<ul style="list-style-type: none"> <li>Semi-automated/automated</li> </ul>	<ul style="list-style-type: none"> <li>Manual/ semi-automated</li> </ul>
Amplification Technology	<ul style="list-style-type: none"> <li>Real-time PCR</li> </ul>	<ul style="list-style-type: none"> <li>TMA</li> </ul>	<ul style="list-style-type: none"> <li>SDA</li> </ul>
Assay Controls	<ul style="list-style-type: none"> <li>Negative Control</li> <li>Cutoff Control</li> <li>Internal Control</li> </ul>	<ul style="list-style-type: none"> <li>Negative Control</li> <li>Positive Control</li> </ul>	<ul style="list-style-type: none"> <li>Negative Control</li> <li>Positive Control</li> <li>Optional Amplification Control</li> </ul>

Feature	Current Application	Predicate Devices for Urine Specimens	
	Abbott multi-Collect Specimen Collection Kit	Gen-Probe Aptima Urine Specimen Collection Kit	BDProbeTec Urine Processing Kit
Device Description	Contains a transfer pipette for adding approximately 3.0 mL of urine to the Transport Tube. The Transport Tube contains 1.2 mL of Specimen Transport Buffer and is used to stabilize DNA until sample preparation.	Contains a disposable transfer pipette for adding approximately 2 mL of urine to a Specimen Transport Tube containing 2.0 mL of Transport Buffer.	Contains a disposable transfer pipette for adding approximately 2.5 to 3.5 mL of urine to one Urine Preservative Transport or Urine Processing Pouch.

Feature	Current Application	Predicate Device for Male Urethral Swab Specimens
	Abbott multi-Collect Specimen Collection Kit	Gen-Probe Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens
Device Description	Contains an individually packaged sterile Specimen Collection Swab that is placed into the Transport Tube after swab sampling. The Transport Tube contains 1.2 mL of Specimen Transport Buffer and is used to stabilize DNA until sample preparation.	Contains an individually packaged sterile Endocervical Cleaning Swab and an individually packaged sterile Specimen Collection Swab that is placed into the Transport Tube after swab sampling. The Transport Tube contains 2.9 mL of Specimen Transport Buffer and is used to stabilize DNA until sample preparation. The Gen-Probe Aptima Unisex Swab Specimen Collection Kit can be used to collect either Endocervical or Male Urethral Swab specimens.

Feature	Current Application	Predicate Device for Vaginal Swab Specimens
	Abbott multi-Collect Specimen Collection Kit	Gen-Probe Aptima Vaginal Swab Specimen Collection Kit
Device Description	The Abbott multi-Collect Specimen Collection Kit contains a transfer pipette for adding approximately 3.0 mL of urine to the Transport Tube and an individually packaged sterile Specimen Collection Swab that is placed into the Transport Tube after swab sampling. The Transport Tube contains 1.2 mL of Specimen Transport Buffer and is used to stabilize DNA until sample preparation. The Abbott multi-Collect Specimen Collection Kit can be used to collect either a swab or a urine specimen.	The Gen-Probe Aptima Vaginal Swab Specimen Collection Kit contains an individually packaged sterile Specimen Collection Swab that is placed into the Transport Tube after swab sampling. The Transport Tube contains 2.9 mL of Specimen Transport Buffer and is used to stabilize DNA until sample preparation. The Gen-Probe Aptima Vaginal Swab Specimen Collection Kit is used to collect Vaginal Swab Specimens.

Standard/Guidance Document Referenced (if applicable):  
NA

Test Principle:  
See H. Device Description

## F. Performance Characteristics (if/when applicable):

### 1. Analytical performance:

#### Analytical Sensitivity

The analytical sensitivity of the Abbott RealTime CT/NG assay was determined by testing dilutions of *Chlamydia trachomatis* (CT) target DNA and *Neisseria gonorrhoeae* (NG) target DNA. Testing was performed with three lots of amplification reagents on three *m2000* Systems. Probit analysis of the data determined that the concentration of CT DNA detected with 95% probability was 39 copies/assay (95% CI 33 - 51), and the concentration of NG DNA detected with 95% probability was 192 copies/assay (95% CI 176-220).

The limit of detection (LoD) claim for the RealTime CT/NG assay is 320 copies of CT target DNA and 320 copies of NG target DNA per assay. The limit of detection (LoD) is defined as the CT and NG DNA concentration detected with a probability of 95% or greater.

The CT/NG assay targets the *Chlamydia* cryptic plasmid (present at approximately 7 to 10 copies per *Chlamydia* organism) and the multicopy opacity gene of *Neisseria gonorrhoeae* (repeated up to 11 times per organism). Thus, 320 copies of target DNA translates to approximately 30 to 40 organisms per assay.

The claimed LOD for the Abbott RealTime CT/NG assay was confirmed by testing a sample containing 320 copies of CT target DNA and 320 copies of NG target DNA per assay. The detection rate was 100% (403/403) for both CT and NG in the assay. A study was conducted to challenge the performance of the Abbott RealTime CT/NG assay in samples containing high target numbers of either CT or NG in the presence of low target numbers of the opposite analyte. The detection rate of 320 copies of CT DNA in the presence of high NG target was 100% (400/400). The detection rate of 320 copies of NG DNA in the presence of high CT target was 98.5% (398/404).

The analytical sensitivity of the Abbott RealTime CT/NG assay for detecting *Chlamydia trachomatis* serovars A through L was determined by testing dilutions of each serovar. Serovars A through K, L1, and L2 were detected at less than 1 Inclusion Forming Units (IFU) per assay and serovar L3 was detected at less than 3 IFU/assay.

The analytical sensitivity of the Abbott RealTime CT/NG assay for detecting 28 different isolates of *Neisseria gonorrhoeae* was determined by testing dilutions of each isolate. All isolates were detected at less than 1 Colony Forming Unit (CFU)/assay.

### **Evaluation of Potential Cross-Reactants**

A total of 111 strains of bacteria, viruses, parasites, yeast, and fungi were tested for potential cross reactivity in the Abbott RealTime CT/NG assay (table below). These included organisms that are phylogenetically related to CT and NG, and those that can be found in the urogenital tract. Purified DNA or RNA was diluted to a final concentration of  $1 \times 10^7$  copies/assay. HBV DNA and HCV RNA were added directly into the PCR reaction at approximately  $3 \times 10^5$  and  $9 \times 10^6$  copies per reaction, respectively. All results were negative for both CT and NG.

A total of 32 culture isolates were tested for potential cross reactivity in the Abbott RealTime assay. These included 27 organisms listed in table below, and *Neisseria cinerea*, *Neisseria lactamica*, *Neisseria sicca*, Ca Ski cells containing HPV 16, and Hela cells containing HPV 18. Ca Ski cells containing HPV 16 and Hela cells containing HPV 18 were tested at  $10^5$  cells per assay, *C. pneumoniae* and *C. psittaci* were tested at  $10^6$  EB per assay, HSV-1 and HSV-2 were tested at  $10^6$  genomes per assay, and the rest of the organisms were tested at  $10^6$  Colony Forming Units (CFU) per assay. All results were negative for both CT and NG.

Microorganism/Virus		
<i>Achromobacter xerosis</i>	<i>Haemophilus ducreyi</i> *	<i>Proteus vulgaris</i>
<i>Acinetobacter calcoaceticus</i>	<i>Haemophilus influenzae</i>	<i>Providencia stuartii</i>
<i>Acinetobacter lwoffii</i>	<i>Helicobacter pylori</i>	<i>Pseudomonas aeruginosa</i> *
<i>Actinomyces israelii</i>	Hepatitis B virus (HBV)	<i>Pseudomonas putida</i>
<i>Aerococcus viridans</i>	Hepatitis C virus (HCV)	<i>Rahnella aquatilis</i>
<i>Aeromonas hydrophila</i>	Herpes Simplex Virus, type I*	<i>Rhizobium radiobacter</i>
<i>Alcaligenes faecalis</i>	Herpes Simplex Virus, type II*	<i>Rhodospirillum rubrum</i>
<i>Arcanobacterium pyogenes</i>	Human immunodeficiency virus (HIV-1)	<i>Ruminococcus productus</i>
<i>Bacillus subtilis</i>	Human Papilloma Virus 16	<i>Salmonella choleraesuis</i>
<i>Bacteroides fragilis</i>	Human Papilloma Virus 18	<i>Salmonella typhimurium</i>
<i>Bacteroides ureolyticus</i>	<i>Kingella denitrificans</i>	<i>Serratia marcescens</i> *
<i>Bifidobacterium adolescentis</i>	<i>Kingella kingae</i>	<i>Staphylococcus aureus</i> *
<i>Bifidobacterium breve</i>	<i>Klebsiella oxytoca</i>	<i>Staphylococcus epidermidis</i> *
<i>Brevibacterium linens</i>	<i>Klebsiella pneumoniae</i>	<i>Staphylococcus saprophyticus</i> *
<i>Campylobacter jejuni</i>	<i>Lactobacillus acidophilus</i> *	<i>Streptococcus agalactiae</i> *
<i>Candida albicans</i> *	<i>Lactobacillus brevis</i> *	<i>Streptococcus bovis</i>
<i>Candida glabrata</i>	<i>Lactobacillus delbrueckii subsp. lactis</i>	<i>Streptococcus mitis</i>
<i>Candida parapsilosis</i>	<i>Lactobacillus jensenii</i>	<i>Streptococcus mutans</i>
<i>Candida tropicalis</i>	<i>Legionella pneumophila</i>	<i>Streptococcus pneumoniae</i>
<i>Chlamydia pneumoniae</i> *	<i>Listeria monocytogenes</i>	<i>Streptococcus pyogenes</i>
<i>Chlamydia psittaci</i> *	<i>Micrococcus luteus</i> *	<i>Streptococcus salivarius</i>
<i>Chromobacterium violaceum</i>	<i>Mobiluncus mulieris</i>	<i>Streptococcus sanguinis</i>
<i>Chryseobacterium meningosepticum</i>	<i>Moraxella (Branhamella) catarrhalis</i>	<i>Streptomyces griseinus</i>
<i>Citrobacter freundii</i>	<i>Moraxella lacunata</i>	<i>Trichomonas vaginalis</i>
<i>Clostridium sporogenes</i>	<i>Moraxella osloensis</i>	<i>Ureaplasma urealyticum</i>
<i>Corynebacterium genitalium</i> *	<i>Morganella morganii</i>	<i>Veillonella parvula</i>
<i>Corynebacterium xerosis</i>	<i>Mycobacterium goodii</i>	<i>Vibrio parahaemolyticus</i>
<i>Cryptococcus neoformans</i>	<i>Mycobacterium smegmatis</i> *	<i>Weissella paramesenteroides</i>
<i>Cytomegalovirus</i>	<i>Mycoplasma genitalium</i>	<i>Yersinia enterocolitica</i>

\* Tested with purified DNA or RNA and with culture isolates.

## 2. Comparison studies:

### a. Method comparison with predicate device:

NA

### b. Matrix comparison:

NA

## 3. Clinical studies:

### Precision Study

A precision study was performed at three sites, two external and one internal. Each site was provided with a nine-member panel that was prepared targeting different combinations of CT and NG concentrations. The targeted concentration for CT ranged from 0 to 4,500 IFU/assay and for NG from 0 to 2,000 CFU/assay. Five replicates of each panel member were tested in each run. Thirty runs (10 per site) were performed for a total of 150 replicates of each panel member. The study included three amplification reagent lots. Each site tested two amplification reagent lots. A variance components analysis for a

nested model was performed on delta cycle (DC) values, and the results are summarized in tables below.

Panel Member <sup>a</sup>	No. Tested <sup>b</sup>	No. Positive	Mean Delta Cycle	Within-Run Component SD <sup>c</sup>	Between-Run Component SD <sup>c</sup>	Between-Lot Component SD <sup>c</sup>	Between Site Component SD <sup>c</sup>	Total SD <sup>c,d</sup>
1	150	150	14.78	0.300	0.194	0.066	0.137	0.388
2	149	149	15.15	0.385	0.139	0.285	0.000	0.499
3	149	149	3.21	0.591	0.241	0.000	0.047	0.640
4	150	150	8.89	0.385	0.156	0.169	0.162	0.477
5	148	0	...	...	...	...	...	...
6	148	148	16.88	0.167	0.207	0.149	0.215	0.373
7	150	0	...	...	...	...	...	...
8	149	1	0.67	...	...	...	...	...
9	148	103	1.09	0.201	0.000	0.192	0.000	0.665

<sup>a</sup> CT concentrations were targeted approximately to 4500 IFU/assay in members 1, 2, and 6 and to 45 IFU/assay in member 4. Member 3 was targeted approximately to 0.75 IFU/assay and member 9 to 0.2 IFU/assay both below the claimed assay LOD. Members 5, 7, and 8 did not contain any CT organisms.

<sup>b</sup> Invalid replicates were excluded from the analysis.

The SD is based on positive replicates only. For member 9, analysis of all replicates with a cycle number (n=133), including those beyond the assay cutoff, resulted in a total SD of 0.966.

The total variability contains within-run, between-run, between-lot, and between-site variability.

### Precision Study: NG Results

Panel Member <sup>a</sup>	No. Tested <sup>b</sup>	No. Positive	Mean Delta Cycle	Within-Run Component SD <sup>c</sup>	Between-Run Component SD <sup>c</sup>	Between-Lot Component SD <sup>c</sup>	Between Site Component SD <sup>c</sup>	Total SD <sup>c,d</sup>
1	150	150	13.43	0.382	0.172	0.000	0.147	0.444
2	149	149	7.89	0.430	0.064	0.097	0.166	0.475
3	149	149	8.24	0.270	0.149	0.057	0.060	0.319
4	150	0	...	...	...	...	...	...
5	148	148	7.80	0.231	0.198	0.040	0.185	0.358
6	147	0	...	...	...	...	...	...
7	150	150	13.59	0.539	0.191	0.000	0.205	0.608
8	149	0	...	...	...	...	...	...

### Summary of Clinical Studies

Performance characteristics of the Abbott RealTime CT/NG assay were established in a multi-center clinical study conducted in the United States. Specimens were prospectively collected from subjects at 16 geographically diverse sites that included physician private practices, public and private STD clinics, and a hospital emergency room. A total of 3,832 male and female, asymptomatic and symptomatic subjects were enrolled. Study subjects were classified as symptomatic if the subject reported STD-related symptoms.

Specimens collected from each female subject included urine, endocervical swabs, self-collected vaginal swab, and clinician-collected vaginal swabs. Specimens collected from each male subject included urine and urethral swabs. Specimen testing methods included the Abbott RealTime CT/NG assay, two commercially available nucleic acid amplification tests (NAAT) for CT and NG, and culture for NG. The NAATs and the NG culture were used as reference assays in the clinical study.

For females, self-collected vaginal swab and urine specimens were collected first, followed by endocervical swab for culture. Remaining swab specimen collection was randomized to minimize bias. For males, urethral swab for culture was collected first. Remaining swab specimen collection was randomized to minimize bias. Urine specimen was collected after the swab specimens.

For each subject, a patient infected status was determined based on the combined results from the reference assays. A female subject was categorized as infected for CT or NG if a minimum of two positive results (at least one from each reference NAAT) were reported. A male subject was categorized as infected for CT or NG if a minimum of two positive results were reported. If the reference NG culture assay result was positive, the subject was categorized as infected regardless of NAAT results.

A female subject was categorized as not infected with CT or NG if at least one of the If patient infected status could not be determined due to missing and/or indeterminate results from the reference assays, the subject was excluded from the analysis. Patient infected status could not be determined for 33 subjects for CT and 35 subjects for NG.

The tables below summarize the clinical trial data.

*Chlamydia trachomatis* Clinical Sensitivity and Specificity  
Female Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Clinician-Collected Vaginal Swab	Symptomatic	732	74	8	644	6	92.5	(84.4, 97.2)	99.8	(97.6, 99.5)
Self-Collected Vaginal Swab	Symptomatic	699	71	6	618	4	94.7	(86.9, 98.5)	99.0	(97.9, 99.6)
Urine	Symptomatic	746	75	3	662	6	92.6	(84.6, 97.2)	99.5	(98.7, 99.9)
	Asymptomatic	692	44	5	641	2	95.7	(85.2, 99.5)	99.2	(98.2, 99.7)

*Chlamydia trachomatis* Clinical Sensitivity and Specificity  
Male Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Urethral Swab	Symptomatic	825	167	11	635	12	93.3	(88.6, 96.5)	98.3	(97.0, 99.1)
Urine	Symptomatic	839	178	2	654	5	97.3	(93.7, 99.1)	99.7	(98.9, 100.0)
	Asymptomatic	659	89	2	566	2	97.8	(92.3, 99.7)	99.6	(98.7, 100.0)



*Neisseria gonorrhoeae* Clinical Sensitivity and Specificity  
Female Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Clinician-Collected Vaginal Swab	Symptomatic	733	30	1	701	1	96.8	(83.3, 99.9)	99.9	(99.2, 100.0)
Self-Collected Vaginal Swab	Symptomatic	700	29	2	688	1	96.7	(82.8, 99.9)	99.7	(98.9, 100.0)
Urine	Symptomatic	746	30	2	712	2	93.8	(79.2, 99.2)	99.7	(99.0, 100.0)
	Asymptomatic	693	20	3	667	3	87.0	(66.4, 97.2)	99.6	(98.7, 99.9)

*Neisseria gonorrhoeae* Clinical Sensitivity and Specificity  
Male Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Urethral Swab	Symptomatic	829	234	4	589	2	99.2	(97.0, 99.9)	99.3	(98.3, 99.8)
Urine	Symptomatic	840	237	3	597	3	98.8	(96.4, 99.7)	99.5	(98.5, 99.9)
	Asymptomatic	658	11	0	647	0	100.0	(71.5, 100.0)	100.0	(99.4, 100.0)

CT Clinical Sensitivity and Specificity by Clinical Testing Site

Specimen	Testing Site	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Clinician-Collected Vaginal Swab	1	391	41	4	342	4	91.1	(78.8 – 97.5)	98.8	(97.1 – 99.7)
	2	229	22	2	203	2	91.7	(73.0 – 99.0)	99.0	(96.5 – 99.9)
	3	112	11	2	99	0	100.0	(71.5 – 100.0)	98.0	(93.0 – 99.8)
	All	732	74	8	644	6	92.5	(84.4 – 97.2)	98.8	(97.6 – 99.5)
Self-Collected Vaginal Swab	1	373	38	4	329	2	95.0	(83.1 – 99.4)	98.8	(97.0 – 99.7)
	2	220	22	1	195	2	91.7	(73.0 – 99.0)	99.5	(97.2 – 100.0)
	3	106	11	1	94	0	100.0	(71.5 – 100.0)	98.9	(94.3 – 100.0)
	All	699	71	6	618	4	94.7	(86.9 – 98.5)	99.0	(97.9 – 99.6)
Female Urine	1	751	74	4	669	4	94.9	(87.4 – 98.6)	99.4	(98.5 – 99.8)
	2	388	28	1	357	2	93.3	(77.9 – 99.2)	99.7	(98.5 – 100.0)
	3	299	17	3	277	2	89.5	(66.9 – 98.7)	98.9	(96.9 – 99.8)
	All	1438	119	8	1303	8	93.7	(88.0 – 97.2)	99.4	(98.8 – 99.7)

CT Clinical Sensitivity and Specificity by Clinical Testing Site

Specimen	Testing Site	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Male Urethral Swab	1	574	124	6	440	4	96.9	(92.2 – 99.1)	98.7	(97.1 – 99.5)
	2	115	23	2	82	8	74.2	(55.4 – 88.1)	97.6	(91.7 – 99.7)
	3	136	20	3	113	0	100.0	(83.2 – 100.0)	97.4	(92.6 – 99.5)
	All	825	167	11	635	12	93.3	(88.6 – 96.5)	98.3	(97.0 – 99.1)
Male Urine	1	936	184	1	746	5	97.4	(93.9 – 99.1)	99.9	(99.3 – 100.0)
	2	221	40	3	177	1	97.6	(87.1 – 99.9)	98.3	(95.2 – 99.7)
	3	341	43	0	297	1	97.7	(88.0 – 99.9)	100.0	(98.8 – 100.0)
	All	1498	267	4	1220	7	97.4	(94.8 – 99.0)	99.7	(99.2 – 99.9)

NG Clinical Sensitivity and Specificity by Clinical Testing Site

Specimen	Testing Site	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Clinician-Collected Vaginal Swab	1	391	13	0	378	0	100.0	(75.3 – 100.0)	100.0	(99.0 – 100.0)
	2	230	13	1	215	1	92.9	(66.1 – 99.8)	99.5	(97.4 – 100.0)
	3	112	4	0	108	0	100.0	(39.8 – 100.0)	100.0	(96.6 – 100.0)
	All	733	30	1	701	1	96.8	(83.3 – 99.9)	99.9	(99.2 – 100.0)
Self-Collected Vaginal Swab	1	376	12	0	364	0	100.0	(73.5 – 100.0)	100.0	(99.0 – 100.0)
	2	219	13	2	203	1	92.9	(66.1 – 99.8)	99.0	(96.5 – 99.9)
	3	105	4	0	101	0	100.0	(39.8 – 100.0)	100.0	(96.4 – 100.0)
	All	700	29	2	668	1	96.7	(82.8 – 99.9)	99.7	(98.9 – 100.0)
Female Urine	1	754	26	4	720	4	86.7	(69.3 – 96.2)	99.4	(98.6 – 99.8)
	2	388	18	1	368	1	94.7	(74.0 – 99.9)	99.7	(98.5 – 100.0)
	3	297	6	0	291	0	100.0	(54.1 – 100.0)	100.0	(98.7 – 100.0)
	All	1439	50	5	1379	5	90.9	(80.0 – 97.0)	99.6	(99.2 – 99.9)

NG Clinical Sensitivity and Specificity by Clinical Testing Site

Specimen	Testing Site	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Male Urethral Swab	1	574	164	3	406	1	99.4	(96.7 – 100.0)	99.3	(97.9 – 99.8)
	2	116	33	1	81	1	97.1	(84.7 – 99.9)	98.8	(93.4 – 100.0)
	3	139	37	0	102	0	100.0	(90.5 – 100.0)	100.0	(96.4 – 100.0)
	All	829	234	4	589	2	99.2	(97.0 – 99.9)	99.3	(98.3 – 99.8)
Male Urine	1	936	173	3	758	2	98.9	(95.9 – 99.9)	99.6	(98.9 – 99.9)
	2	222	39	0	183	0	100.0	(91.0 – 100.0)	100.0	(98.0 – 100.0)
	3	340	36	0	303	1	97.3	(85.8 – 99.9)	100.0	(98.8 – 100.0)
	All	1498	248	3	1244	3	98.8	(96.5 – 99.8)	99.8	(99.3 – 100.0)

**CT Analysis According to Patient Infected Status**  
**INFECTED FEMALE Subjects**

NAAT 1			NAAT 2		RealTime CT/NG			No. of Subjects		
E	CCV	FU	E	FU	CCV	SCV	FU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	+	+	+	53	30	83
+	+	+	+	NA	+	+	+	1	0	1
+	+	+	+	NA	+	NA	+	2	0	2
+	+	NA	+	NA	+	+	NA	0	1	1
+	+	+	NA	+	+	+	+	1	0	1
+	+	+	+	+	+	NA	+	2	1	3
+	+	+	+	+	NA	NA	+	1	0	1
+	+	+	+	-	+	+	+	2	2	4
+	+	+	-	+	+	+	+	2	2	4
+	-	+	+	+	+	+	+	2	0	2
+	+	-	+	-	+	+	+	1	0	1
-	+	+	-	+	+	+	+	1	1	2
-	+	-	+	+	+	+	+	1	0	1
-	+	-	+	-	+	+	+	0	1	1
-	-	+	-	+	+	+	+	0	1	1
+	+	+	+	-	+	+	-	3	0	3
+	+	-	+	NA	+	+	-	1	0	1
+	+	-	+	-	+	+	-	1	1	2
-	+	-	+	+	+	+	-	1	0	1
+	+	+	-	+	-	NA	+	1	0	1
-	+	+	-	+	-	+	+	1	0	1
+	-	+	-	+	-	-	+	1	0	1
-	-	+	NA	+	-	-	+	0	1	1
-	-	+	-	+	-	-	+	3	5	8
-	+	-	-	+	+	-	-	0	1	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen; FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen; U = Urine.

NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**CT Analysis According to Patient Infected Status**  
**NON-INFECTED FEMALE Subjects**

NAAT 1			NAAT 2		RealTime CT/NG			No. of Subjects		
E	CCV	FU	E	FU	CCV	SCV	FU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
-	-	-	-	-	-	-	-	524	528	1052
-	-	-	-	NA	-	-	-	55	33	88
-	-	-	-	NA	-	-	NA	2	1	3
-	-	-	-	NA	-	NA	-	2	1	3
-	-	-	-	NA	NA	-	-	2	1	3
-	-	-	-	NA	NA	-	NA	1	0	1
-	-	-	NA	-	-	-	-	9	28	37
-	-	-	NA	-	NA	-	-	0	1	1
-	-	-	NA	-	NA	-	NA	0	1	1
-	-	NA	-	-	-	-	-	0	1	1
-	NA	-	-	-	-	-	-	0	2	2
NA	-	-	-	-	NA	-	-	0	1	1
-	-	-	-	-	-	-	NA	2	7	9
-	-	-	-	-	-	NA	-	30	17	47
-	-	-	-	-	NA	-	-	6	7	13
-	-	-	-	-	-	NA	NA	3	2	5
-	-	-	-	-	NA	-	NA	1	2	3
-	-	-	-	-	NA	NA	-	11	2	13
-	-	-	-	+	-	-	-	1	2	3
-	-	-	NA	+	-	-	-	1	0	1
-	-	-	+	-	-	-	-	5	0	5
-	-	-	+	NA	-	-	-	0	1	1
-	-	-	+	-	NA	-	-	1	0	1
-	-	+	-	-	-	-	-	0	2	2
-	-	+	-	-	NA	NA	-	1	0	1
-	+	-	-	-	-	-	-	3	2	5
-	+	-	-	-	-	NA	-	0	1	1
+	-	-	-	-	-	-	-	2	2	4
+	+	-	-	-	-	-	-	0	2	2

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen; FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen; U = Urine.  
 NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**CT Analysis According to Patient Infected Status**  
**NON-INFECTED FEMALE Subjects**

NAAT 1			NAAT 2		RealTime CT/NG			No. of Subjects		
E	CCV	FU	E	FU	CCV	SCV	FU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
-	-	-	-	-	-	-	+	1	1	2
-	-	+	-	-	-	-	+	0	2	2
-	+	+	-	-	-	NA	+	1	0	1
-	-	-	-	NA	-	+	-	1	0	1
-	-	-	-	-	-	+	-	2	1	3
-	+	-	-	-	-	+	-	0	1	1
-	+	-	-	-	NA	+	-	0	1	1
-	-	-	-	NA	+	-	-	1	0	1
-	-	-	-	-	+	-	-	1	1	2
-	-	-	-	-	+	NA	-	1	0	1
-	+	-	-	-	+	NA	-	1	0	1
+	+	-	-	-	+	-	+	0	1	1
-	+	+	-	-	+	NA	+	1	0	1
-	+	-	-	-	+	+	-	1	0	1
+	+	-	-	-	+	+	-	1	3	4
+	+	+	-	-	+	+	NA	1	0	1
+	+	+	-	-	+	+	+	0	1	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen; FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen; U = Urine.  
 NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**CT Analysis According to Patient Infected Status**  
**INFECTED MALE Subjects**

NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MU	MU	MUS	MU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	144	70	214
+	+	NA	+	+	7	2	9
NA	+	+	+	+	1	0	1
+	+	+	NA	+	3	3	6
+	+	-	+	+	9	3	12
+	+	-	+	NA	1	0	1
+	+	-	NA	+	2	0	2
+	-	+	+	+	1	0	1
-	+	+	+	+	0	2	2
+	+	+	+	-	1	0	1
+	+	-	+	-	3	0	3
+	-	+	+	-	0	1	1
+	+	+	-	+	8	3	11
-	+	+	-	+	3	6	9
+	+	-	-	-	1	1	2

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen; U = Urine.  
 NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**CT Analysis According to Patient Infected Status**  
**NON-INFECTED MALE Subjects**

NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MU	MU	MUS	MU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
-	-	-	-	-	582	510	1092
-	-	NA	-	-	33	39	72
-	-	NA	NA	-	1	1	2
-	NA	-	-	-	2	0	2
NA	-	-	NA	-	1	0	1
-	-	-	-	NA	3	2	5
-	-	-	NA	-	11	4	15
-	-	+	-	-	3	2	5
-	+	-	-	-	4	2	6
+	-	-	-	-	7	2	9
+	-	-	NA	-	0	1	1
-	-	-	-	+	1	0	1
-	-	+	-	+	0	1	1
-	+	-	-	+	0	1	1
-	-	-	+	-	5	2	7
-	-	NA	+	-	0	1	1
-	-	+	+	-	2	0	2
+	-	-	+	-	3	2	5
-	-	+	+	+	1	0	1

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen; U = Urine.

NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**NG Analysis According to Patient Infected Status**  
**INFECTED FEMALE Subjects**

Culture	NAAT 1			NAAT 2		RealTime CT/NG			No. of Subjects		
E	E	CCV	FU	E	FU	CCV	SCV	FU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	+	+	+	+	12	8	20
+	+	+	+	+	NA	+	NA	+	1	0	1
+	+	+	+	+	+	NA	NA	+	1	0	1
+	+	+	+	+	-	+	+	+	0	1	1
-	+	+	+	+	+	+	+	+	5	8	13
-	+	+	+	+	-	+	+	+	4	0	4
-	+	+	+	-	+	+	+	+	1	0	1
-	NA	+	+	-	+	+	+	+	0	1	1
+	-	+	-	+	+	+	+	+	1	0	1
-	+	+	-	+	NA	+	+	+	1	0	1
-	+	+	-	-	+	+	+	+	1	0	1
-	+	-	+	-	+	+	+	+	1	0	1
-	-	+	-	+	NA	+	+	+	0	1	1
-	-	+	-	+	-	+	+	+	1	0	1
+	+	+	-	+	NA	+	+	-	0	1	1
+	+	+	-	+	-	+	+	-	0	1	1
-	+	+	+	+	-	+	+	-	1	0	1
-	+	+	-	+	-	+	+	-	1	1	2
-	-	-	+	-	+	-	-	+	1	1	2

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen; FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen; U = Urine.

NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**NG Analysis According to Patient Infected Status**  
**NON-INFECTED FEMALE Subjects**

Culture	NAAT 1			NAAT 2		RealTime CT/NG			No. of Subjects		
E	E	CCV	FU	E	FU	CCV	SCV	FU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
-	-	-	-	-	-	-	-	-	546	538	1084
-	-	-	-	-	NA	-	-	-	65	34	99
-	-	-	-	-	NA	NA	-	-	2	1	3
-	-	-	-	-	NA	-	NA	-	3	0	3
-	-	-	-	-	NA	-	-	NA	1	0	1
-	-	-	-	NA	-	-	-	-	8	27	35
-	-	-	-	NA	-	NA	-	NA	0	1	1
NA	-	-	-	NA	-	-	-	-	0	3	3
NA	-	-	-	NA	-	NA	-	-	0	1	1
-	-	NA	-	-	-	-	-	-	0	2	2
NA	-	NA	-	-	-	-	-	-	0	1	1
-	NA	-	-	-	-	NA	-	-	0	1	1
NA	-	-	-	-	-	-	-	-	1	1	2
-	-	-	-	-	-	-	-	NA	4	8	12
-	-	-	-	-	-	-	NA	-	31	16	47
-	-	-	-	-	-	NA	-	-	5	7	12
-	-	-	-	-	-	-	NA	NA	3	3	6
-	-	-	-	-	-	NA	-	NA	1	4	5
-	-	-	-	-	-	NA	NA	-	13	3	16
-	-	-	-	-	+	-	-	-	26	18	44
-	-	-	-	-	+	-	NA	-	3	1	4

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen; FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen; U = Urine.  
 NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**NG Analysis According to Patient Infected Status**  
**NON-INFECTED FEMALE Subjects**

Culture	NAAT 1			NAAT 2		RealTime CT/NG			No. of Subjects		
E	E	CCV	FU	E	FU	CCV	SCV	FU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
-	-	-	-	+	-	-	-	-	2	6	8
-	-	-	-	+	NA	-	-	NA	1	0	1
-	-	-	+	-	-	-	-	-	1	1	2
-	-	+	-	-	-	-	-	-	2	0	2
-	+	-	-	-	-	-	-	-	2	1	3
-	+	-	-	-	-	NA	-	-	1	0	1
-	-	-	-	+	+	-	-	-	0	1	1
-	-	-	+	-	-	-	-	+	0	3	3
-	+	+	+	-	-	-	NA	+	1	0	1
-	-	+	-	-	-	-	+	-	1	0	1
-	-	-	-	-	-	+	-	-	0	1	1
-	-	-	-	-	NA	+	-	-	0	1	1
-	-	+	-	-	-	+	-	-	0	1	1
-	+	+	-	-	-	+	-	-	0	1	1
-	-	+	+	-	-	+	+	+	1	0	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen; FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen; U = Urine.  
 NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**NG Analysis According to Patient Infected Status**  
**INFECTED MALE Subjects**

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MUS	MU	MU	MUS	MU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	+	169	2	171
+	+	+	NA	+	+	3	1	4
+	+	NA	NA	+	NA	1	0	1
+	+	NA	+	+	+	1	0	1
NA	+	+	+	+	+	6	0	6
+	+	+	+	NA	+	6	0	6
+	+	+	-	+	+	9	0	9
+	+	-	+	+	+	2	0	2
-	+	+	+	+	+	35	6	41
-	+	+	+	+	NA	1	0	1
-	+	+	NA	+	+	2	0	2
-	NA	+	+	+	+	1	0	1
-	+	+	-	+	+	1	0	1
+	-	-	+	+	+	1	0	1
-	+	+	+	+	-	1	0	1
+	+	-	-	+	-	1	0	1
+	+	+	+	-	+	1	0	1
-	-	+	+	-	+	0	2	2
+	-	-	-	-	-	1	0	1

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen; U = Urine.

NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

**NG Analysis According to Patient Infected Status**  
**NON-INFECTED MALE Subjects**

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MUS	MU	MU	MUS	MU	Symptomatic (SCV/CCV/U)	Asymptomatic (Urine Only)	Total
-	-	-	-	-	-	516	559	1075
-	-	-	NA	-	-	40	42	82
-	-	-	NA	NA	-	1	1	2
-	-	NA	-	-	-	1	0	1
-	NA	-	-	-	-	1	1	2
-	NA	-	-	NA	-	1	0	1
NA	-	-	-	-	-	7	6	13
-	-	-	-	-	NA	3	4	7
-	-	-	-	NA	-	8	6	14
-	-	-	+	-	-	16	25	41
NA	-	-	+	-	-	0	1	1
-	-	+	-	-	-	2	3	5
-	+	-	-	-	-	2	2	4
-	-	-	-	-	+	1	0	1
-	-	-	-	+	-	0	1	1
-	+	-	-	+	-	2	0	2
-	-	-	+	+	+	1	0	1
-	+	-	-	+	+	1	0	1

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen; U = Urine.

NA includes "indeterminate" results from reference assays, specimens not available, or missing results.



**Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site  
Symptomatic and Asymptomatic Female Urine Specimens**

Site <sup>a</sup>	Female Urine					
	% Prevalence (Number Positive/Number Tested)					
	CT+/ NG+		CT+/ NG – <sup>b</sup>		CT –/ NG+ <sup>b</sup>	
1	0.0	(0/61)	0.0	(0/61)	0.0	(0/61)
3	1.6	(3/183)	4.4	(8/183)	1.1	(2/183)
4	0.0	(0/50)	8.0	(4/50)	2.0	(1/50)
5	0.0	(0/21)	0.0	(0/21)	0.0	(0/21)
6	0.0	(0/16)	6.3	(1/16)	6.3	(1/16)
7	3.1	(9/295)	8.5	(25/295)	3.7	(11/295)
8	0.0	(0/56)	7.1	(4/56)	3.6	(2/56)
9	4.6	(3/65)	16.9	(11/65)	6.2	(4/65)
10	2.4	(4/168)	10.7	(18/168)	1.8	(3/168)
11	2.1	(6/289)	9.3	(27/289)	1.4	(4/289)
12	0.0	(0/11)	0.0	(0/11)	0.0	(0/11)
13	0.0	(0/71)	0.0	(0/71)	0.0	(0/71)
14	0.0	(0/80)	3.8	(3/80)	0.0	(0/80)
15	1.7	(1/60)	0.0	(0/60)	0.0	(0/60)
16	0.0	(0/25)	0.0	(0/25)	4.0	(1/25)
All	1.8	(26/1451)	7.0	(101/1451)	2.0	(29/1451)

<sup>a</sup>No evaluable results were available from Site 2.

<sup>b</sup>Does not include specimens that were positive for both CT and NG.

**Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site:  
Symptomatic Clinician-Collected and Symptomatic Self-Collected Vaginal Swab Specimens**

Site <sup>a</sup>	Clinician-Collected Vaginal Swab						Self-Collected Vaginal Swab					
	% Prevalence (Number Positive/Number Tested)						% Prevalence (Number Positive/Number Tested)					
	CT+/ NG+		CT+/ NG – <sup>b</sup>		CT –/ NG+ <sup>b</sup>		CT+/ NG+		CT+/ NG – <sup>b</sup>		CT –/ NG+ <sup>b</sup>	
1	0.0	(0/23)	0.0	(0/23)	0.0	(0/23)	0.0	(0/24)	0.0	(0/24)	0.0	(0/24)
3	2.3	(2/88)	4.5	(4/88)	2.3	(2/88)	2.4	(2/84)	4.8	(4/84)	2.4	(2/84)
4	0.0	(0/42)	9.5	(4/42)	2.4	(1/42)	0.0	(0/37)	10.8	(4/37)	2.7	(1/37)
5	0.0	(0/15)	0.0	(0/15)	0.0	(0/15)	0.0	(0/15)	0.0	(0/15)	0.0	(0/15)
6	0.0	(0/16)	12.5	(2/16)	6.3	(1/16)	0.0	(0/14)	7.1	(1/14)	7.1	(1/14)
7	3.4	(7/207)	10.6	(22/207)	3.4	(7/207)	3.6	(7/196)	10.2	(20/196)	4.1	(8/196)
8	0.0	(0/47)	6.4	(3/47)	2.1	(1/47)	0.0	(0/49)	8.2	(4/49)	2.0	(1/49)
9	7.0	(3/43)	14.0	(6/43)	0.0	(0/43)	5.6	(2/36)	11.1	(4/36)	0.0	(0/36)
10	2.4	(3/125)	11.2	(14/125)	1.6	(2/125)	2.5	(3/120)	12.5	(15/120)	1.7	(2/120)
11	2.9	(1/34)	23.5	(8/34)	2.9	(1/34)	2.9	(1/34)	23.5	(8/34)	2.9	(1/34)
12	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)
13	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)
14	0.0	(0/38)	5.3	(2/38)	0.0	(0/38)	0.0	(0/36)	2.8	(1/36)	0.0	(0/36)
15	3.7	(1/27)	0.0	(0/27)	0.0	(0/27)	3.6	(1/28)	0.0	(0/28)	0.0	(0/28)
16	0.0	(0/12)	0.0	(0/12)	0.0	(0/12)	0.0	(0/12)	0.0	(0/12)	0.0	(0/12)
All	2.3	(17/744)	8.7	(65/744)	2.0	(15/744)	2.2	(16/712)	8.6	(61/712)	2.2	(16/712)

<sup>a</sup>No evaluable results were available from Site 2.

<sup>b</sup>Does not include specimens that were positive for both CT and NG.

**Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site:  
Symptomatic Male Urethral Swab**

Site <sup>a,b</sup>	Urethral Swab					
	% Prevalence (Number Positive/Number Tested)					
	CT+/ NG+		CT+/ NG <sup>-c</sup>		CT -/ NG+ <sup>c</sup>	
3	14.2	(17/120)	13.3	(16/120)	19.2	(23/120)
4	9.0	(6/67)	6.0	(4/67)	9.0	(6/67)
5	0.0	(0/23)	8.7	(2/23)	4.3	(1/23)
6	0.0	(0/11)	18.2	(2/11)	9.1	(1/11)
7	9.5	(9/95)	17.9	(17/95)	20.0	(19/95)
8	7.3	(13/178)	16.3	(29/178)	20.2	(36/178)
9	12.0	(20/167)	13.8	(23/167)	37.1	(62/167)
10	4.9	(4/81)	18.5	(15/81)	12.3	(10/81)
12	0.0	(0/3)	0.0	(0/3)	0.0	(0/3)
13	0.0	(0/26)	3.8	(1/26)	0.0	(0/26)
14	0.0	(0/15)	0.0	(0/15)	13.3	(2/15)
15	0.0	(0/7)	0.0	(0/7)	0.0	(0/7)
16	3.0	(1/33)	0.0	(0/33)	18.2	(6/33)
All	8.5	(70/826)	13.2	(109/826)	20.1	(166/826)

<sup>a</sup> Male specimens were not collected from Site 1.

<sup>b</sup> No symptomatic Male Urethral Swab specimens were available from site 2 and 11.

<sup>c</sup> Does not include specimens that were positive for both CT and NG.

**Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site:  
Symptomatic and Asymptomatic Male Urine Specimens**

Site <sup>a</sup>	Urine					
	% Prevalence (Number Positive/Number Tested)					
	CT+/ NG+		CT+/ NG <sup>-b</sup>		CT -/ NG+ <sup>b</sup>	
2	0.0	(0/6)	0.0	(0/6)	0.0	(0/6)
3	13.7	(25/183)	9.8	(18/183)	12.6	(23/183)
4	4.0	(4/101)	5.9	(6/101)	6.9	(7/101)
5	0.0	(0/34)	5.9	(2/34)	2.9	(1/34)
6	0.0	(0/53)	18.9	(10/53)	1.9	(1/53)
7	6.7	(12/179)	16.8	(30/179)	10.1	(18/179)
8	4.8	(14/291)	14.8	(43/291)	12.7	(37/291)
9	10.1	(21/208)	20.2	(42/208)	31.3	(65/208)
10	2.8	(4/145)	21.4	(31/145)	6.9	(10/145)
11	0.0	(0/2)	100.0	(2/2)	0.0	(0/2)
12	0.0	(0/3)	0.0	(0/3)	0.0	(0/3)
13	0.0	(0/60)	1.7	(1/60)	0.0	(0/60)
14	0.0	(0/75)	1.3	(1/75)	2.7	(2/75)
15	0.0	(0/55)	3.6	(2/55)	0.0	(0/55)
16	0.0	(0/101)	2.0	(2/101)	5.9	(6/101)
All	5.3	(80/1496)	12.7	(190/1496)	11.4	(170/1496)

<sup>a</sup> Male specimens were not collected from Site 1.

<sup>b</sup> Does not include specimens that were positive for both CT and NG.

**Positive and Negative Predictive Values for Hypothetical Prevalence Rates  
for *Chlamydia trachomatis***

<b>Prevalence Rate (%)</b>	<b>Sensitivity (%)</b>	<b>Specificity (%)</b>	<b>Positive Predictive Value (%)</b>	<b>Negative Predictive Value (%)</b>
0.5	95.0	99.2	37.4	100.0
1.0	95.0	99.2	54.5	99.9
2.0	95.0	99.2	70.8	99.9
5.0	95.0	99.2	86.2	99.7
10.0	95.0	99.2	93.0	99.4
15.0	95.0	99.2	95.4	99.1
20.0	95.0	99.2	96.7	98.8
25.0	95.0	99.2	97.5	98.3
30.0	95.0	99.2	98.1	97.9

**Positive and Negative Predictive Values for Hypothetical Prevalence Rates  
for *Neisseria gonorrhoeae***

<b>Prevalence Rate (%)</b>	<b>Sensitivity (%)</b>	<b>Specificity (%)</b>	<b>Positive Predictive Value (%)</b>	<b>Negative Predictive Value (%)</b>
0.5	98.0	99.7	62.1	100.0
1.0	98.0	99.7	76.7	100.0
2.0	98.0	99.7	87.0	100.0
5.0	98.0	99.7	94.5	99.9
10.0	98.0	99.7	97.3	99.8
15.0	98.0	99.7	98.3	99.6
20.0	98.0	99.7	98.8	99.5
25.0	98.0	99.7	99.1	99.3
30.0	98.0	99.7	99.3	99.1

**N. Proposed Labeling:**

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

**O. Conclusion:**

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