

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

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

K092704

**B. Purpose for Submission:**

New Device

**C. Measurand:**

*Chlamydia trachomatis*

*Neisseria gonorrhoea*

**D. Type of Test:**

Nucleic Acid Amplification

**E. Applicant:**

Abbott Molecular Inc.

**F. Proprietary and Established Names:**

Abbott RealTime CT/NG

**G. Regulatory Information:**

1. Regulation section:

866.3120

866.3390

2. Classification:

I, II

3. Product code:

MKZ, LSL

4. Panel:

Microbiology 083

**H. Intended Use:**

1. 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: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab

and patient-collected vaginal swab specimens; female and male urine specimens.

2. Indication(s) for use:  
Same as Intended Use
3. Special conditions for use statement(s):  
NA
4. Special instrument requirements:  
Abbott *m2000* System

**I. Device Description:**

Abbott RealTime CT/NG consists of two reagent kits:

- Abbott RealTime CT/NG Amplification Reagent Kit
- Abbott RealTime CT/NG Control Kit

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* 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.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
GEN-PROBE APTIMA Combo 2 Assay (Assigned 510(k) No. K043224);  
Becton Dickenson 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 510(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 Dickenson 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 <i>multi-Collect</i> 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  Abbott <i>multi-Collect</i> Specimen Collection Kit	Predicate Device for Male Urethral Swab Specimens  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.

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

NA

**L. Test Principle:**

See device description

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

1. Analytical performance:

**Analytical Sensitivity**

The Limit of Detection (LOD) claim for the RealTime CT/NG assay is 320 copies of *Chlamydia trachomatis* (CT) target DNA and 320 copies of *Neisseria gonorrhoeae* (NG) target DNA per assay. The assay targets the *Chlamydia trachomatis* 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 is equivalent to approximately 30 to 40 organisms per assay. The LOD of the Abbott RealTime CT/NG assay is defined as CT and NG target DNA concentration detected with a probability of 95% or greater. The CT and NG DNA concentrations detected with 95% probability were determined by testing dilutions of CT and NG target DNA. Probit analysis of the data determined that the concentration of CT DNA detected with 95% probability was 21 copies/assay (95% CI 18 - 28), the concentration of nvCT DNA detected with 95% probability was 29 copies/assay (95% CI 24 - 41), and the concentration of NG DNA detected with 95% probability was 149 copies/assay (95% CI 130 - 176). The claimed assay LOD was confirmed by testing samples that contained 320 copies of CT, nvCT and NG target DNA per assay. The detection rate was 100% (405/405) for CT, 100% (403/403) for nvCT, and 99.5% (403/405) for NG in the assay. An additional study was conducted to challenge the performance of the Abbott RealTime CT/NG assay in samples containing high target numbers of CT, nvCT, or NG in the presence of low target numbers of the opposite analyte. Samples were prepared to contain 320 CT or nvCT target DNA copies and 1 x 10<sup>7</sup> NG target DNA copies per assay, or 1 x 10<sup>7</sup> CT or nvCT target DNA copies and 320 NG target DNA copies per assay. The detection rate of 320 copies of CT or nvCT DNA in the presence of high NG target was 100% (405/405). The

detection rate of 320 copies of NG DNA in the presence of high CT or nvCT target was 100% (405/405). 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 and L1 through L3 were detected at less than 1 Inclusion Forming Units (IFU) per assay. Additionally, nvCT was diluted and was also detected at less than 1 IFU per 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 hwoffii</i>	<i>Helicobacter pylori</i>	<i>Pseudomonas aeruginosa</i> *
<i>Actinomyces israelii</i>	<i>Hepatitis B virus (HBV)</i>	<i>Pseudomonas putida</i>
<i>Aerococcus viridans</i>	<i>Hepatitis C virus (HCV)</i>	<i>Rahnella aquatilis</i>
<i>Aeromonas hydrophila</i>	<i>Herpes Simplex Virus, type I</i> *	<i>Rhizobium radiobacter</i>
<i>Alcaligenes faecalis</i>	<i>Herpes Simplex Virus, type II</i> *	<i>Rhodospirillum rubrum</i>
<i>Arcanobacterium pyogenes</i>	<i>Human immunodeficiency virus (HIV-1)</i>	<i>Ruminococcus productus</i>
<i>Bacillus subtilis</i>	<i>Human Papilloma Virus 16</i>	<i>Salmonella choleraesuis</i>
<i>Bacteroides fragilis</i>	<i>Human Papilloma Virus 18</i>	<i>Salmonella typhimurium</i>
<i>Bacteroides ureolyticus</i>	<i>Kingella denificans</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 gordonae</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**

A precision study was performed at three sites, two external and one internal. Each site was provided a fifteen-member panel. Nine panel members targeted different combinations of CT and NG concentrations and six panel members targeted different combinations of nvCT and NG concentrations. The source material for CT was Vero/LGV-II, strain 434. The source material for nvCT was

strain 68226. The source material for NG was ATCC isolate 27628 and 31426. 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 3 and 4.

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	15.29	0.265	0.204	0.110	0.135	0.377
2	150	150	15.67	0.411	0.245	0.000	0.179	0.511
3	150	150	3.75	0.466	0.234	0.255	0.000	0.581
4	150	150	9.45	0.503	0.103	0.022	0.000	0.514
5	150	0	...	...	...	...	...	...
6	149	149	17.35	0.229	0.193	0.153	0.159	0.371
7	150	0	...	...	...	...	...	...
8	147	0	...	...	...	...	...	...
9	150	125	1.59	0.674	0.248	0.312	0.000	0.783
10	149	149	15.69	0.334	0.250	0.205	0.286	0.545
11	150	150	15.59	0.428	0.180	0.216	0.289	0.588
12	150	140	3.79	0.461	0.458	0.329	0.000	0.728
13	150	150	9.02	0.269	0.274	0.165	0.261	0.493
14	150	150	15.63	0.284	0.265	0.109	0.413	0.578
15	147	50	1.81	0.575	0.376	0.518	0.000	0.860

<sup>a</sup> *Chlamydia trachomatis* (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. New variant strain (nvCT) concentrations were targeted approximately to 50 IFU/assay in members 10, 11, and 14 and 1 IFU/assay in member 13. Members 12 and 15 were targeted to less than 0.1 IFU/assay, below the claimed assay LOD. Members 5, 7, and 8 did not contain any CT or nvCT organisms.

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

<sup>c</sup> 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 0.960. For member 15, analysis of all replicates with a cycle number (n=52), including those beyond the assay cutoff, resulted in a total SD of 1.037.

<sup>d</sup> The total variability contains within-run, between-run, between-lot, and between-site variability.

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	13.32	0.295	0.157	0.048	0.000	0.337
2	150	150	7.64	0.419	0.182	0.000	0.123	0.473
3	150	150	8.03	0.288	0.146	0.000	0.000	0.323
4	149	0	...	...	...	...	...	...
5	150	150	7.59	0.245	0.184	0.028	0.000	0.308
6	149	0	...	...	...	...	...	...
7	150	150	13.45	0.512	0.105	0.133	0.000	0.539
8	147	0	...	...	...	...	...	...
9	150	69	0.51	0.326	0.000	0.000	0.029	0.327
10	149	149	13.29	0.207	0.147	0.051	0.213	0.335
11	150	150	7.27	0.271	0.159	0.046	0.110	0.336
12	150	150	7.24	0.220	0.180	0.000	0.088	0.297
13	150	0	...	...	...	...	...	...
14	150	0	...	...	...	...	...	...
15	147	47	0.50	0.348	0.102	0.000	0.103	0.377

<sup>a</sup> *Neisseria gonorrhoeae* (NG) concentrations were targeted approximately to 2000 CFU/assay in members 1, 7, and 10; to 20 to 50 CFU/assay in members 2, 3, 5, 11, and 12. Members 9 and 15 were targeted to 0.1 CFU/assay, below the claimed assay LOD. Members 4, 6, 8, 13, and 14 did not contain any NG organisms.

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

<sup>c</sup> The SD is based on positive replicates only. For member 9, analysis of all replicates with a cycle number (n=147), including those beyond the assay cutoff, resulted in a total SD of 1.156. For member 15, analysis of all replicates with a cycle number (n=138), including those beyond the assay cutoff, resulted in a total SD of 1.201.

<sup>d</sup> The total variability contains within-run, between-run, between-lot, and between-site variability.

## Clinical Study Results

Performance characteristics of the Abbott RealTime CT/NG assay were established in a multi-center clinical study conducted in the United States. Specimens were 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) was reported. For CT, female subjects with positive results on both reference urine specimens and negative results on all three reference swab specimens (clinician-collected vaginal swab from NAAT 1 and endocervical swab specimens from both reference assays) were categorized as infected for urine and not infected for swab specimens. A male subject was categorized as infected for CT or NG if a minimum of two positive results was 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 reference NAATs reported negative results for all sample types and if the NG culture assay result was negative. A male subject was categorized as not infected with CT or NG if a total of at least two negative results were reported by the reference NAATs and if the NG culture assay result was negative.

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 4 subjects for CT and 7 subjects for NG.

Abbott RealTime CT/NG test results were compared to the patient infected status for calculation of assay sensitivity and specificity. A total of 6,555 CT and 6,569 NG results were used in the analysis. The results were analyzed by gender, sample type, and the presence of symptoms. The overall sensitivity and specificity for CT was 95.2% and 99.3%, respectively. The overall sensitivity and

specificity for NG was 97.5% and 99.7%, respectively. Sensitivity and specificity for CT for female subjects and male subjects are presented in Tables 5 and 6, respectively. Sensitivity and specificity for NG for female subjects and male subjects are presented in Tables 7 and 8, respectively.

A comparison of patient infected status, individual test results from the reference assays and Abbott RealTime CT/NG assay was performed. CT results for infected and non-infected female subjects are presented in Tables 9 and 10, and for infected and non-infected male subjects in Tables 11 and 12. NG results for infected and non-infected female subjects are presented in Tables 13 and 14, and for infected and non-infected male subjects in Tables 15 and 16.

The prevalence of CT and NG in this study was dependent on several factors including age, gender, clinic type, presence of symptoms, and the method of testing. The prevalence per collection site determined by the Abbott RealTime CT/NG assay for endocervical swab specimens is presented in Table 17, for clinician-collected and self-collected vaginal swab specimens is presented in Table 18; for female urine specimens in Table 19; and for male urethral swab and male urine specimens in Tables 20 and 21, respectively.

The Positive and Negative Predictive Values (PPV and NPV) were calculated using hypothetical prevalence rates and the Abbott RealTime CT/NG assay sensitivity and specificity determined from the clinical study. The overall sensitivity and specificity for CT was 95.2% and 99.3%, respectively. The overall sensitivity and specificity for NG was 97.5% and 99.7%, respectively. Estimates of the PPV and NPV for the Abbott RealTime CT/NG assay are presented in Table 22 for CT and Table 23 for NG.

Specimen	Symptoms	n	True	False	True	False	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
			Positive	Positive	Negative	Negative		
Endocervical	Symptomatic	616	60	1	551	4	93.8 (84.8, 98.3)	99.8 (99.0, 100.0)
Clinician- Collected Vaginal Swab	Symptomatic	615	63	0	551	1	98.4 (91.6, 100.0)	100.0 (99.3, 100.0)
	Asymptomatic	594	35	4	554	1	97.2 (85.5, 99.9)	99.3 (98.2, 99.8)
Self- Collected Vaginal Swab	Symptomatic	587	62	6	518	1	98.4 (91.5, 100.0)	98.9 (97.5, 99.6)
	Asymptomatic	586	36	5	544	1	97.3 (85.8, 99.9)	99.1 (97.9, 99.7)
Urine	Symptomatic	737	73	2	655	7	91.3 (82.8, 96.4)	99.7 (98.9, 100.0)
	Asymptomatic	686	43	2	638	3	93.5 (82.1, 98.6)	99.7 (98.9, 100.0)

Specimen	Symptoms	n	True	False	True	False	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
			Positive	Positive	Negative	Negative		
Urethral Swab	Symptomatic	669	128	9	523	9	93.4 (87.9, 97.0)	98.3 (96.8, 99.2)
Urine	Symptomatic	822	171	6	637	8	95.5 (91.4, 98.1)	99.1 (98.0, 99.7)
	Asymptomatic	643	84	4	552	3	96.6 (90.3, 99.3)	99.3 (98.2, 99.8)

Specimen	Symptoms	n	True	False	True	False	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
			Positive	Positive	Negative	Negative		
Endocervical	Symptomatic	619	22	1	593	3	98.0 (68.8, 97.5)	99.8 (99.1, 100.0)
Clinician- Collected Vaginal Swab	Symptomatic	616	26	0	589	1	96.3 (81.0, 99.9)	100.0 (99.4, 100.0)
	Asymptomatic	593	17	0	576	0	100.0 (80.5, 100.0)	100.0 (99.4, 100.0)
Self- Collected Vaginal Swab	Symptomatic	589	25	2	561	1	96.2 (80.4, 99.9)	99.6 (98.7, 100.0)
	Asymptomatic	587	17	0	570	0	100.0 (80.5, 100.0)	100.0 (99.4, 100.0)
Urine	Symptomatic	736	30	3	701	2	93.8 (79.2, 99.2)	99.6 (98.8, 99.9)
	Asymptomatic	687	19	3	661	4	82.6 (61.2, 95.0)	99.5 (98.7, 99.9)

Specimen	Symptoms	n	True	False	True	False	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
			Positive	Positive	Negative	Negative		
Urethral Swab	Symptomatic	676	188	5	482	1	99.5 (97.1, 100.0)	99.0 (97.6, 99.7)
Urine	Symptomatic	823	228	5	587	3	98.7 (96.3, 99.7)	99.2 (98.0, 99.7)
	Asymptomatic	643	11	0	632	0	100.0 (71.5, 100.0)	100.0 (99.4, 100.0)

NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
+	+	+	+	+	+	+	+	+	38	24	62
+	+	+	+	NA	+	+	+	+	1	0	1
+	+	+	+	NA	+	+	NA	+	1	0	1
+	+	+	+	NA	+	NA	NA	+	1	0	1
+	+	NA	+	NA	+	+	+	NA	0	1	1
+	+	+	+	+	+	+	NA	+	4	2	6
+	+	+	+	+	+	NA	+	+	2	1	3
+	+	+	+	+	NA	+	+	+	4	2	6
+	+	+	+	+	+	NA	NA	+	1	0	1
+	+	+	+	+	NA	+	NA	+	1	0	1
+	+	+	+	+	NA	NA	+	+	1	0	1
+	+	+	+	+	NA	NA	NA	+	3	1	4
+	+	+	+	-	+	+	+	+	1	2	3
+	+	+	-	+	NA	NA	NA	+	1	0	1
+	-	+	+	+	+	+	+	+	2	0	2
+	+	-	+	-	+	+	+	+	1	0	1
-	+	+	-	+	NA	+	+	+	0	1	1
-	+	-	+	+	+	+	+	+	1	0	1
-	+	-	+	+	NA	+	+	+	1	0	1
-	-	+	-	+	NA	NA	NA	+	0	1	1
+	+	+	NA	+	+	+	NA	-	1	0	1
+	+	+	+	-	NA	NA	+	-	1	0	1
+	+	+	+	-	+	+	+	-	3	0	3
+	+	-	+	NA	+	+	+	-	1	0	1
+	+	-	+	-	+	+	+	-	1	0	1
+	+	-	+	-	NA	NA	NA	-	0	1	1
-	+	-	+	-	NA	NA	+	-	0	1	1
+	+	+	+	+	-	+	+	+	1	1	2
+	+	+	-	+	-	NA	NA	+	1	0	1
-	+	+	-	+	-	NA	+	+	2	0	2
-	-	+	-	+	-	NA	+	+	1	1	2
-	+	-	-	+	-	NA	+	-	0	1	1
+	-	+	-	+	NA	-	-	+	1	0	1
-	-	+	NA	+	-	-	-	+	0	1	1
-	-	+	-	+	-	-	-	+	2	4	6

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

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

\* Subjects with positive results on both reference urine specimens and negative results on all three reference swab specimens (clinician-collected vaginal swab from NAAT 1 and endocervical swab specimens from both reference assays) were categorized as infected for urine and not infected for swab specimens.

NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
-	-	-	-	-	-	-	-	-	392	414	806
-	-	-	-	NA	-	-	-	-	43	24	67
-	-	-	-	NA	-	-	-	NA	1	0	1
-	-	-	-	NA	-	-	NA	-	2	3	5
-	-	-	-	NA	-	NA	-	-	3	3	6
-	-	-	-	NA	NA	-	-	-	4	1	5
-	-	-	-	NA	NA	-	-	NA	1	1	2
-	-	-	-	NA	-	NA	NA	-	1	1	2
-	-	-	-	NA	NA	NA	NA	-	7	2	9
-	-	-	NA	-	-	-	-	-	9	24	33
-	-	-	NA	-	-	-	NA	-	0	1	1
-	-	-	NA	-	-	NA	-	-	0	1	1
-	-	-	NA	-	NA	-	-	-	0	1	1
-	-	-	NA	-	NA	NA	NA	-	0	2	2
-	-	NA	-	-	-	-	-	-	0	1	1
-	NA	-	-	-	-	-	-	-	0	1	1
-	NA	-	-	-	NA	-	NA	-	0	1	1
NA	-	-	-	-	-	NA	-	-	0	1	1
-	-	-	-	-	-	-	-	NA	2	7	9
-	-	-	-	-	-	-	NA	-	49	32	81
-	-	-	-	-	-	NA	-	-	20	25	45
-	-	-	-	-	NA	-	-	-	22	19	41
-	-	-	-	-	-	-	NA	NA	1	2	3
-	-	-	-	-	NA	-	-	NA	2	1	3
-	-	-	-	-	-	NA	NA	-	6	3	9
-	-	-	-	-	NA	-	NA	-	7	5	12
-	-	-	-	-	NA	NA	-	-	6	3	9
-	-	-	-	-	NA	NA	NA	-	64	50	114
-	-	-	-	+	-	-	-	-	1	1	2
-	-	-	-	+	-	NA	-	-	0	1	1
-	-	-	NA	+	-	-	-	-	1	0	1
-	-	-	+	-	-	-	-	-	3	0	3
-	-	-	+	NA	-	-	-	-	0	1	1
-	-	-	+	-	-	NA	-	-	2	0	2
-	-	-	+	-	NA	NA	NA	-	1	0	1
-	-	+	-	-	-	-	-	-	0	2	2
-	-	+	-	-	-	-	-	NA	0	1	1
-	-	+	-	-	NA	NA	NA	-	1	0	1
-	+	-	-	-	-	-	-	-	2	2	4
-	+	-	-	-	-	-	NA	-	1	0	1
-	+	-	-	-	-	NA	NA	-	1	1	2
-	+	-	-	-	-	NA	NA	NA	0	1	1
+	-	-	-	-	-	-	-	-	2	2	4
+	+	-	-	-	-	NA	NA	-	1	0	1
+	+	-	-	-	NA	NA	NA	-	0	2	2
-	-	-	-	NA	-	-	-	+	0	1	1
-	-	-	-	-	-	-	+	-	2	1	3
-	-	-	-	NA	-	-	+	-	1	0	1
-	-	-	-	-	-	+	NA	-	0	1	1
-	-	+	-	-	-	-	-	+	0	1	1
-	+	-	-	-	-	NA	+	-	1	0	1
-	+	-	-	-	+	NA	NA	-	0	1	1
-	+	+	-	-	-	-	NA	+	1	0	1
-	+	+	-	-	NA	NA	NA	+	1	0	1
+	+	-	-	-	-	+	+	-	0	1	1
+	+	-	-	-	+	NA	NA	-	0	1	1
+	+	-	-	-	+	+	+	-	0	2	2
+	+	+	-	-	+	NA	+	-	0	1	1
+	+	+	-	-	+	NA	+	NA	1	0	1

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

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

NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MU	MU	MUS	MU	Symptomatic (MUS/MU)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	114	56	170
+	+	+	+	NA	1	0	1
+	+	+	NA	+	30	12	42
+	+	NA	+	+	5	1	6
+	+	NA	NA	+	2	1	3
+	+	-	+	+	5	3	8
+	+	-	NA	+	5	0	5
+	-	+	+	+	1	0	1
-	+	+	+	+	0	1	1
NA	+	+	NA	+	1	0	1
-	+	+	NA	+	0	2	2
+	+	+	-	+	5	3	8
-	+	+	-	+	3	5	8
+	+	+	+	-	1	1	2
+	+	+	NA	-	3	0	3
+	+	-	+	-	1	0	1
+	+	-	NA	-	2	0	2
+	-	+	NA	-	0	1	1
+	+	-	-	-	1	1	2

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

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

NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MU	MU	MUS	MU	Symptomatic (MUS/MU)	Asymptomatic (Urine Only)	Total
-	-	-	-	-	479	421	900
-	-	-	-	NA	6	2	8
-	-	-	NA	-	100	83	183
-	-	NA	-	-	25	36	61
-	-	NA	NA	-	8	4	12
-	NA	-	-	-	1	0	1
NA	-	-	NA	-	1	0	1
-	-	+	-	-	3	0	3
-	+	-	-	-	3	2	5
+	-	-	-	-	4	0	4
-	-	+	NA	-	1	2	3
-	+	-	NA	-	1	0	1
+	-	-	NA	-	3	4	7
-	-	-	+	-	5	0	5
-	-	+	+	-	1	0	1
+	-	-	+	-	2	0	2
-	-	-	-	+	2	0	2
-	-	-	NA	+	2	1	3
-	-	+	NA	+	0	1	1
-	+	-	-	+	0	1	1
+	-	-	NA	+	1	1	2
-	-	+	+	+	1	0	1

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

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

Culture E	NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
	E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
+	+	+	+	+	+	+	+	+	+	9	6	15
+	+	+	+	+	NA	+	+	NA	+	1	0	1
+	+	+	+	+	+	+	+	NA	+	1	1	2
+	+	+	+	+	+	+	NA	+	+	0	1	1
+	+	+	+	+	+	NA	NA	NA	+	1	0	1
+	+	+	+	+	+	NA	NA	NA	+	2	0	2
-	+	+	+	+	+	+	+	+	+	4	5	9
-	+	+	+	+	+	+	NA	+	+	0	1	1
-	+	+	+	+	+	NA	+	+	+	0	1	1
-	+	+	+	+	+	+	NA	NA	+	0	1	1
-	+	+	+	+	-	+	+	+	+	3	0	3
-	+	+	+	+	-	NA	NA	NA	+	1	0	1
-	+	+	+	-	+	NA	+	+	+	1	0	1
+	-	+	-	+	+	+	+	+	+	1	0	1
-	+	+	-	+	NA	NA	NA	NA	+	1	0	1
-	+	+	-	-	+	NA	+	+	+	1	0	1
-	+	-	+	-	+	+	NA	+	+	1	0	1
-	-	+	-	+	NA	NA	+	+	+	0	1	1
-	-	-	+	-	+	NA	NA	NA	+	0	1	1
+	+	+	+	+	-	NA	NA	NA	-	0	1	1
+	+	+	-	+	NA	+	NA	NA	-	0	1	1
+	+	+	-	+	-	+	+	NA	-	0	1	1
-	+	+	+	+	-	+	+	+	-	1	0	1
-	+	+	-	+	-	+	+	+	-	1	1	2
-	+	+	+	+	+	-	+	+	+	1	0	1
-	NA	+	+	-	+	-	+	+	+	0	1	1
-	-	+	-	+	-	-	+	+	+	1	0	1
-	-	-	+	-	+	-	-	-	+	1	0	1

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

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

**Table 14: NG Analysis Per Patient Infected Status - NON-INFECTED FEMALE Subjects**

Culture	NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
	E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
-	-	-	-	-	-	-	-	-	-	409	423	832
-	-	-	-	-	NA	-	-	-	-	52	27	79
-	-	-	-	-	NA	-	-	NA	-	2	3	5
-	-	-	-	-	NA	-	NA	-	-	4	3	7
-	-	-	-	-	NA	NA	-	-	-	4	0	4
-	-	-	-	-	NA	NA	-	-	NA	1	0	1
-	-	-	-	-	NA	-	NA	NA	-	1	1	2
-	-	-	-	-	NA	NA	NA	NA	-	6	2	8
-	-	-	-	NA	-	-	-	-	-	7	24	31
-	-	-	-	NA	-	-	-	NA	-	1	1	2
-	-	-	-	NA	-	NA	NA	NA	-	0	2	2
NA	-	-	-	NA	-	-	-	-	-	0	2	2
NA	-	-	-	NA	-	-	NA	-	-	0	1	1
NA	-	-	-	NA	-	NA	-	-	-	0	1	1
-	-	NA	-	-	-	-	-	-	-	0	1	1
-	-	NA	-	-	-	NA	-	NA	-	0	1	1
NA	-	NA	-	-	-	-	-	-	-	0	1	1
-	NA	-	-	-	-	-	NA	-	-	0	1	1
NA	-	-	-	-	-	-	-	-	-	1	0	1
NA	-	-	-	-	-	-	-	NA	-	0	1	1
-	-	-	-	-	-	-	-	-	NA	4	9	13
-	-	-	-	-	-	-	-	NA	-	50	28	78
-	-	-	-	-	-	-	-	NA	-	22	26	48
-	-	-	-	-	-	-	NA	-	-	21	19	40
-	-	-	-	-	-	-	-	NA	NA	1	3	4
-	-	-	-	-	-	-	NA	-	NA	1	0	1
-	-	-	-	-	-	NA	-	-	NA	1	1	2
-	-	-	-	-	-	-	NA	NA	-	9	4	13
-	-	-	-	-	-	-	NA	-	NA	6	4	10
-	-	-	-	-	-	NA	NA	-	-	7	4	11
-	-	-	-	-	-	NA	NA	NA	-	59	50	109
-	-	-	-	-	+	-	-	-	-	17	13	30
-	-	-	-	-	+	-	-	NA	-	2	1	3
-	-	-	-	-	+	-	NA	-	-	2	1	3
-	-	-	-	-	+	NA	-	-	-	1	0	1
-	-	-	-	-	+	NA	-	NA	-	1	0	1
-	-	-	-	-	+	NA	NA	NA	-	6	4	10
-	-	-	-	+	-	-	-	-	-	1	6	7
-	-	-	-	+	-	NA	NA	-	-	1	0	1
-	-	-	-	+	NA	-	-	-	NA	1	0	1
-	-	-	+	-	-	-	-	-	-	1	0	1
-	-	-	+	-	-	-	-	NA	-	0	1	1
-	-	+	-	-	-	-	-	-	-	1	1	2
-	-	+	-	-	-	NA	NA	NA	-	1	0	1
-	+	-	-	-	-	-	-	NA	-	1	0	1
-	+	-	-	-	-	NA	-	NA	-	0	1	1
-	+	-	-	-	-	NA	NA	NA	-	2	0	2
-	-	-	-	+	+	-	-	-	-	0	1	1
-	+	+	-	-	-	-	NA	-	-	0	1	1
-	-	-	-	-	-	-	-	-	+	1	0	1
-	-	-	-	-	-	NA	NA	NA	+	1	0	1
-	-	-	+	-	-	-	-	-	+	0	3	3
-	+	+	+	-	-	NA	NA	NA	+	1	0	1
-	-	+	-	-	-	-	-	+	-	1	0	1
-	-	+	+	-	-	-	NA	+	-	1	0	1
-	-	-	-	-	-	+	-	-	-	1	0	1
-	-	-	-	-	-	+	NA	-	-	0	1	1

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

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		Total
	MUS	MU	MU	MUS	MU	Symptomatic (MUS/MU)	Asymptomatic (Urine Only)	
+	+	+	+	+	+	140	1	141
+	+	+	+	NA	+	32	1	33
+	+	+	NA	+	+	2	1	3
+	+	NA	+	+	+	1	0	1
+	+	NA	NA	+	NA	1	0	1
NA	+	+	+	+	+	2	0	2
NA	+	+	+	NA	+	4	0	4
+	+	+	-	+	+	8	0	8
+	+	-	+	+	+	2	0	2
-	+	+	+	+	+	27	4	31
-	+	+	+	NA	+	5	2	7
-	+	+	NA	+	+	1	0	1
-	NA	+	+	NA	+	1	0	1
-	+	+	NA	NA	+	1	0	1
-	+	+	-	+	+	1	0	1
+	-	-	+	+	+	1	0	1
-	-	+	+	+	+	0	1	1
+	+	-	-	+	-	1	0	1
-	+	+	+	+	-	1	0	1
-	-	+	+	-	+	0	1	1
+	-	-	-	-	-	1	0	1
-	-	-	-	-	-	1	0	1
+	-	-	-	-	-	1	0	1

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

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

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		Total
	MUS	MU	MU	MUS	MU	Symptomatic (MUS/MU)	Asymptomatic (Urine Only)	
-	-	-	-	-	-	418	456	874
-	-	-	NA	-	-	32	36	68
-	-	-	NA	NA	-	9	6	15
-	NA	-	-	-	-	1	1	2
-	NA	-	-	NA	-	1	0	1
NA	-	-	-	-	-	7	6	13
-	-	-	-	-	NA	7	2	9
-	-	-	-	NA	-	96	96	192
-	-	-	+	-	-	13	21	34
NA	-	-	+	-	-	0	1	1
-	-	-	+	NA	-	3	4	7
-	-	+	-	-	-	2	2	4
-	-	+	-	NA	-	0	1	1
-	+	-	-	-	-	2	2	4
-	-	-	-	+	-	1	0	1
-	+	-	-	+	-	2	0	2
-	-	-	-	NA	+	3	0	3
-	-	-	+	+	+	1	0	1
-	+	-	-	+	+	1	0	1

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

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

<b>Table 17: Prevalence of CT and/or NG By Collection Site: Symptomatic Female Endocervical Specimens</b>						
<b>Site<sup>a</sup></b>	<b>Female Endocervical</b>					
	<b>% Prevalence (# Positive / # Tested)</b>					
	<b>CT+/NG+</b>		<b>CT+/NG-<sup>b</sup></b>		<b>CT-/NG+<sup>b</sup></b>	
1	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)
3	3.2	(2/63)	6.3	(4/63)	1.6	(1/63)
4	0.0	(0/26)	11.5	(3/26)	0.0	(0/26)
5	0.0	(0/12)	0.0	(0/12)	0.0	(0/12)
6	0.0	(0/8)	12.5	(1/8)	0.0	(0/8)
7	2.3	(4/172)	9.3	(16/172)	2.3	(4/172)
8	0.0	(0/38)	7.9	(3/38)	2.6	(1/38)
9	7.7	(3/39)	15.4	(6/39)	0.0	(0/39)
10	2.6	(3/116)	6.9	(8/116)	2.6	(3/116)
11	3.4	(1/29)	17.2	(5/29)	3.4	(1/29)
12	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)
13	0.0	(0/16)	0.0	(0/16)	0.0	(0/16)
14	0.0	(0/34)	2.9	(1/34)	0.0	(0/34)
15	3.8	(1/26)	0.0	(0/26)	0.0	(0/26)
16	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)
<b>ALL</b>	<b>2.3</b>	<b>(14/616)</b>	<b>7.6</b>	<b>(47/616)</b>	<b>1.6</b>	<b>(10/616)</b>

<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.

**Table 18: Prevalence of CT and/or NG By Collection Site:  
Symptomatic and Asymptomatic Clinician-Collected and Self-Collected Vaginal Swab Specimens**

Site <sup>a</sup>	Clinician-Collected Vaginal Swab % Prevalence (# Positive / # Tested)			Self-Collected Vaginal Swab % Prevalence (# Positive / # 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 (0/40)	0.0 (0/40)	0.0 (0/40)	0.0 (0/41)	0.0 (0/41)
3	1.5 (2/134)	4.5 (6/134)	0.7 (1/134)	2.3 (3/130)	3.8 (5/130)	0.8 (1/130)
4	0.0 (0/26)	7.7 (2/26)	0.0 (0/26)	0.0 (0/26)	15.4 (4/26)	0.0 (0/26)
5	0.0 (0/16)	0.0 (0/16)	0.0 (0/16)	0.0 (0/17)	0.0 (0/17)	0.0 (0/17)
6	0.0 (0/9)	11.1 (1/9)	0.0 (0/9)	0.0 (0/8)	12.5 (1/8)	0.0 (0/8)
7	3.8 (9/238)	9.2 (22/238)	3.8 (9/238)	3.9 (9/230)	10.0 (23/230)	3.9 (9/230)
8	0.0 (0/46)	8.7 (4/46)	4.3 (2/46)	0.0 (0/47)	10.6 (5/47)	4.3 (2/47)
9	5.6 (3/54)	14.8 (8/54)	3.7 (2/54)	4.3 (2/47)	12.8 (6/47)	6.4 (3/47)
10	1.9 (3/162)	11.1 (18/162)	1.9 (3/162)	2.6 (4/152)	13.8 (21/152)	2.0 (3/152)
11	1.1 (3/261)	7.3 (19/261)	1.5 (4/261)	1.2 (3/258)	7.4 (19/258)	1.6 (4/258)
12	0.0 (0/11)	0.0 (0/11)	0.0 (0/11)	0.0 (0/11)	0.0 (0/11)	0.0 (0/11)
13	0.0 (0/61)	0.0 (0/61)	0.0 (0/61)	0.0 (0/59)	0.0 (0/59)	0.0 (0/59)
14	0.0 (0/75)	1.3 (1/75)	1.3 (1/75)	0.0 (0/72)	2.8 (2/72)	0.0 (0/72)
15	1.9 (1/53)	0.0 (0/53)	0.0 (0/53)	1.9 (1/52)	0.0 (0/52)	0.0 (0/52)
16	0.0 (0/22)	0.0 (0/22)	4.5 (1/22)	0.0 (0/23)	4.3 (1/23)	4.3 (1/23)
ALL	1.7 (21/1208)	6.7 (81/1208)	1.9 (23/1208)	1.9 (22/1173)	7.4 (87/1173)	2.0 (23/1173)

<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.

**Table 19: Prevalence of CT and/or NG By Collection Site:  
Symptomatic and Asymptomatic Female Urine Specimen**

Site <sup>a</sup>	Female Urine % Prevalence (# Positive / # Tested)		
	CT+/NG+	CT+/NG <sup>-b</sup>	CT-/NG+ <sup>b</sup>
1	0.0 (0/60)	0.0 (0/60)	0.0 (0/60)
3	1.8 (3/165)	3.6 (6/165)	1.8 (3/165)
4	0.0 (0/49)	8.2 (4/49)	2.0 (1/49)
5	0.0 (0/21)	0.0 (0/21)	0.0 (0/21)
6	0.0 (0/15)	6.7 (1/15)	6.7 (1/15)
7	3.1 (9/293)	8.5 (25/293)	3.8 (11/293)
8	0.0 (0/57)	7.0 (4/57)	3.5 (2/57)
9	4.6 (3/65)	15.4 (10/65)	4.6 (3/65)
10	2.4 (4/168)	11.3 (19/168)	1.8 (3/168)
11	1.4 (4/284)	8.8 (25/284)	2.1 (6/284)
12	0.0 (0/11)	0.0 (0/11)	0.0 (0/11)
13	0.0 (0/70)	0.0 (0/70)	0.0 (0/70)
14	0.0 (0/79)	2.5 (2/79)	0.0 (0/79)
15	1.7 (1/59)	0.0 (0/59)	0.0 (0/59)
16	0.0 (0/26)	0.0 (0/26)	3.8 (1/26)
ALL	1.7 (24/1422)	6.8 (96/1422)	2.2 (31/1422)

<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.

**Table 20: Prevalence of CT and/or NG By Collection Site: Symtomatic Male Urethral Swab**

Site <sup>a,b</sup>	Urethral Swab					
	% Prevalence (# Positive / # Tested)					
	CT+/NG+		CT+/NG <sup>-c</sup>		CT-/NG <sup>+c</sup>	
3	12.0	(10/83)	12.0	(10/83)	16.9	(14/83)
4	5.6	(2/36)	2.8	(1/36)	8.3	(3/36)
5	0.0	(0/22)	9.1	(2/22)	4.5	(1/22)
6	0.0	(0/6)	16.7	(1/6)	16.7	(1/6)
7	11.1	(9/81)	17.3	(14/81)	17.3	(14/81)
8	7.5	(11/147)	15.6	(23/147)	21.1	(31/147)
9	11.4	(17/149)	13.4	(20/149)	38.3	(57/149)
10	5.5	(4/73)	17.8	(13/73)	13.7	(10/73)
12	0.0	(0/3)	0.0	(0/3)	0.0	(0/3)
13	0.0	(0/24)	0.0	(0/24)	0.0	(0/24)
14	0.0	(0/14)	0.0	(0/14)	14.3	(2/14)
15	0.0	(0/6)	0.0	(0/6)	0.0	(0/6)
16	3.7	(1/27)	0.0	(0/27)	14.8	(4/27)
ALL	8.0	(54/671)	12.5	(84/671)	20.4	(137/671)

<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 or 11.

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

**Table 21: Prevalence of CT and/or NG By Collection Site: Symtomatic and Asymptomatic Male Urine Specimens**

Site <sup>a</sup>	Urine					
	% Prevalence (# Positive / # 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	15.1	(26/172)	8.7	(15/172)	9.9	(17/172)
4	4.2	(4/96)	6.3	(6/96)	7.3	(7/96)
5	0.0	(0/35)	5.7	(2/35)	2.9	(1/35)
6	0.0	(0/41)	22.0	(9/41)	2.4	(1/41)
7	6.7	(12/179)	16.8	(30/179)	10.1	(18/179)
8	5.2	(15/290)	15.2	(44/290)	12.4	(36/290)
9	10.1	(21/208)	20.7	(43/208)	30.8	(64/208)
10	1.4	(2/145)	20.7	(30/145)	8.3	(12/145)
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	(0/76)	1.3	(1/76)	2.6	(2/76)
15	0.0	(0/53)	3.8	(2/53)	0.0	(0/53)
16	0.0	(0/101)	1.0	(1/101)	5.9	(6/101)
ALL	5.5	(80/1467)	12.7	(186/1467)	11.2	(164/1467)

<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.

**Table 22: Positive and Negative Predictive Values for Hypothetical Prevalence Rates for CT**

% Prevalence Rate	% Sensitivity	% Specificity	% Positive Predictive Value	% Negative Predictive Value
0.5	95.2	99.3	40.6	100.0
1.0	95.2	99.3	57.9	100.0
2.0	95.2	99.3	73.5	99.9
5.0	95.2	99.3	87.7	99.7
10.0	95.2	99.3	93.8	99.5
15.0	95.2	99.3	96.0	99.2
20.0	95.2	99.3	97.1	98.8
25.0	95.2	99.3	97.8	98.4
30.0	95.2	99.3	98.3	98.0

**Table 23: Positive and Negative Predictive Values for Hypothetical Prevalence Rates for NG**

% Prevalence Rate	% Sensitivity	% Specificity	% Positive Predictive Value	% Negative Predictive Value
0.5	97.5	99.7	62.0	100.0
1.0	97.5	99.7	76.7	100.0
2.0	97.5	99.7	86.9	99.9
5.0	97.5	99.7	94.5	99.9
10.0	97.5	99.7	97.3	99.7
15.0	97.5	99.7	98.3	99.6
20.0	97.5	99.7	98.8	99.4
25.0	97.5	99.7	99.1	99.2
30.0	97.5	99.7	99.3	98.9

**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.