K080739

2.0 510(k) Summary

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Abbott® RealTi*me* CT/NG assay and an ancillary kit called the Abbott® *m*ulti-Collect™ Specimen Collection Kit

Submitted By:	Company Contact:
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Trade Name: Abbott® RealTi*me* CT/NG (List No. 8L07) and Abbott® *m*ulti-Collect™ Specimen Collection Kit (List No. 9K12)

Common Name: In vitro polymerase chain reaction (PCR) assay for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* and

Microbiological Specimen Collection and Transport Device

Classification Name: Nucleic acid test (NAT)

Classification Code: Product Code: LSL, MKZ
Registration Number: 866.3390 (Neisseria), 866.3120 (Chlamydia)
Device Class: 2 (Neisseria), 1 (Chlamydia

Substantially Equivalent Devices:

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. 043144);

Gen-Probe APTIMA Vaginal Swab Specimen Collection Kit (Assigned 510(k) No. K032554);

BD ProbeTec ET Urine Processing Kit Assigned 510(k) No. (K052224).

2.1 Purpose of the Submission

The purpose of this 510(k) is to gain clearance to market the Abbott RealTi*me* CT/NG (List No. 8L07) assay and the Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12).

2.2 Date of Preparation

March 11, 2008.

2.3 Manufacturer:

Abbott Molecular Inc. is the legal manufacturer of the Abbott RealTi*me* CT/NG (List No. 8L07) assay and the Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12).

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The Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12) is manufactured and assembled at the MML Diagnostic Packaging, Inc. facility indicated below:

Name:	Lynn Creitz
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MML Diagnostic Packaging, Inc.
1625 NW Sundial Road
PO Box 458
Troutdale, OR 97060

Establishment Registration No.: 3018348

2.4 Intended Use

The proposed intended use for the Abbott RealTi*me* CT/NG assay is:

The Abbott RealTi*me* 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.

The proposed intended use for the Abbott *m*ulti-Collect Specimen Collection Kit is:

The Abbott *m*ulti-Collect Specimen Collection Kit is intended for the collection and transportation of male and female swab and urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhea*e per instructions provided.

Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Abbott *m*ulti-Collect Specimen Collection Kit is not intended for home use.

2.5 Device Description

Abbott RealTi*me* CT/NG consists of two reagent kits:

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

The Abbott RealTi*me* CT/NG assay uses PCR technology with homogenous real-time fluorescence detection on the *m*2000 System. The Abbott *m*2000 System consists of the Abbott *m*2000*sp* and Abbott *m*2000*rt* instruments. The Abbott *m*2000 System integrates sample preparation with nucleic acid amplification and detection to generate assay results. The Abbott *m*2000*sp* is used for processing samples and the Abbott *m*2000*rt* is used for amplification and detection.

The Abbott *m*ulti-Collect Specimen Collection Kit can be used to collect either a swab or a urine specimen. Each Abbott *m*ulti -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 *m*ulti -Collect Specimen Collection Kit is for single use only.

2.6 Background on Chlamydial and Gonorrheal Disease

Chlamydia are non-motile, Gram-negative, obligate intracellular parasites of eukaryotic cells. They form inclusions in the cytoplasm of the host cell. *Chlamydia trachomatis*, one of three chlamydial species, is the causative agent of the sexually transmitted disease (STD) chlamydia. Chlamydial infections of the urogenital tract are associated with salpingitis, ectopic pregnancies and tubal factor infertility in women as well as nongonococcal urethritis and epididymitis in men.[1-3] The genital site most commonly affected in women is the cervix, but the infection can be asymptomatic and, if untreated, is likely to ascend to the uterus, fallopian tubes and ovaries causing pelvic inflammatory disease (PID).[4] Neonates born of infected mothers can contract inclusion conjunctivitis, nasopharyngeal infections, and pneumonia due to *Chlamydia trachomatis*.[5] Infection by *Chlamydia trachomatis* in men is also often asymptomatic and, if untreated, may lead to epididymitis, a major complication.[3] Patients infected with *Chlamydia trachomatis* may be co-infected with *Neisseria gonorrhoeae*, the causative agent of gonorrhea. Further, patients with treatment indications for gonorrhea but not chlamydia often harbor *Chlamydia trachomatis*.[6] Chlamydia infections may not respond well to recommended regimens for treating *Neisseria gonorrhoeae*. Therefore, unless chlamydial infection has

been ruled out in patients treated for gonorrhea, dual therapy for gonococcal and chlamydial infections is recommended.[7]

Cell culture, commonly used to detect *Chlamydia trachomatis*, has been replaced by more sensitive nucleic acid tests.[8] Since a specific diagnosis of chlamydia may improve treatment compliance and enhance partner notification, the use of these highly sensitive and specific tests is strongly recommended.[7]

Gonorrhea is one of the most common sexually transmitted diseases in the United States. Over 700,000 new infections of *Neisseria gonorrhoeae* are estimated to occur each year.[9] In men, gonorrhea infection usually results in acute anterior urethritis accompanied by a purulent exudate.[10,11] In women, the infection is most often found in the cervix, but the vagina and uterus also may be infected. Frequently the infection is asymptomatic, especially in women. Without treatment, local complications of gonococcal infection can occur including pelvic inflammatory disease (PID) or acute salpingitis for women and epididymitis for men.[10,11] Rarely, disseminated gonococcal infection, DGI, may occur in untreated patients.[13]

Neisseria gonorrhoeae is a Gram-negative, oxidase-positive diplococcus without flagellae.[12] Culture is commonly used for the detection of *Neisseria gonorrhoeae*. Presumptive diagnosis of gonorrhea is based on the morphological examination, Gram stain, and oxidase measurement of the culture isolate. Confirmation procedures have been used for definitive identification of *Neisseria gonorrhoeae* including sugar fermentation, fluorescent antibody staining, nucleic acid hybridization, and agglutination.[14,15] Nucleic acid tests are widely available for the sensitive detection of *Neisseria gonorrhoeae*.[8]

2.7 Technological Characteristics of the Device as Compared to the Predicate

The primary functional components of the Abbott RealTi*me* CT/NG assay are substantially equivalent to other legally marketed nucleic acid amplification tests (NAAT) intended for the qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG).

The Abbott RealTi*me* CT/NG assay has the same general intended uses as the predicate devices. Although there are some technological differences between the Abbott RealTi*me* CT/NG and the predicate devices, these differences do not raise new types of safety or effectiveness questions.

These devices are similar in that they are designed to prepare nucleic acids for amplification, amplify specific *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) sequences, detect the amplified products, and report qualitative results.

The primary similarities and differences between the Abbott RealTi*me* CT/NG assay and the NAAT predicate devices are shown in Table 2.1.

The primary functional components of the Abbott *m*ulti-CollectSpecimen Collection Kit are substantially equivalent to other legally marketed devices intended for the collection and transportation of clinical specimens for the direct, qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG).

The Abbott *m*ulti-Collect Specimen Collection Kit has the same general intended use as the predicate devices. Although there are some technological differences between the Abbott *m*ulti-Collect Specimen Collection Kit and the predicate devices, these differences do not raise new types of safety or effectiveness questions.

These devices are similar in that they are designed to collect urogenital specimens and to stabilize the nucleic acid of the specimen during transport and storage prior to nucleic acid testing.

The primary similarities and differences between the Abbott *m*ulti-Collect Specimen Collection Kit and the predicate devices are shown in Tables 2.2 through 2.4.

Table 2.1

Similarities and Differences Between Abbott RealTi*me* CT/NG and Nucleic Acid Amplification Predicate Devices

	Current Application	Amplified Nucleic Acid Predicate Devices	
Feature	**Abbott RealTi*me* CT/NG**	**Gen-Probe Aptima Combo 2**	**Becton Dickenson ProbeTec ET**
Assay Type	• Qualitative	• Qualitative	• Qualitative
CT Analyte Targets	• CT cryptic plasmid DNA	• CT ribosomal RNA	• CT cryptic plasmid DNA
NG Analyte Targets	• NG genomic DNA	• NG ribosomal RNA	• NG genomic DNA
Input Sample Types	• Self-collected vaginal swab specimens • Clinician-collected vaginal swab specimens • Male urethral swab specimens • Male and female urine specimens	• Endocervical swab specimens • Self-collected vaginal swab specimens • Clinician-collected vaginal swab specimens • Male urethral swab specimens • Male and female urine specimens. • PreservCyt liquid Pap specimens	• Endocervical swab specimens • Male urethral swab specimens • Male and female urine specimens
Sample Preparation Procedure	• Automated	• Semi-automated/automated	• Manual/ semi-automated
Amplification Technology	• Real-time PCR	• TMA	• SDA
Assay Controls	• Negative Control • Cutoff Control • Internal Control	• Negative Control • Positive Control	• Negative Control • Positive Control • Optional Amplification Control

Table 2.2

Similarities and Differences between Abbott *m*ulti-Collect Specimen Collection Kit and the Predicate Devices (Urine Specimen Collection)

Feature	Current Application Abbott *m*ulti-Collect Specimen Collection Kit	Predicate Devices for Urine Specimens 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.

Table 2.3
Similarities and Differences between Abbott *m*ulti-Collect Specimen Collection Kit and the Predicate Devices (Urethral Swab Specimen Collection)

Feature	Current Application Abbott *m*ulti-Collect 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.

Table 2.4
Similarities and Differences between Abbott *m*ulti-Collect Specimen Collection Kit and the Predicate Devices (Vaginal Swab Specimen Collection)

Feature	Current Application Abbott *m*ulti-Collect Specimen Collection Kit	Predicate Device for Vaginal Swab Specimens 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.

2.8 Summary of Nonclinical Studies

Analytical Sensitivity

The analytical sensitivity of the Abbott RealTi*me* 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 *m*2000 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 RealTi*me* 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 RealTi*me* 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 RealTi*me* 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 RealTi*me* 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 RealTi*me* 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 RealTi*me* CT/NG assay (Table 2.5). 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 1×10^7 copies/assay. HBV DNA and HCV RNA were added directly into the PCR reaction at approximately 3×10^5 and 9×10^6 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 7.5, 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.

Table 2.5

Potentially Cross-Reactive Microorganisms/Viruses

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

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

Table 2.5 (Continued)

Potentially Cross-Reactive Microorganisms/Viruses

Microorganism/Virus	
Deinococcus radiodurans	*Mycoplasma hominis*
Derxia gummosa	*Neisseria flava**
Eikenella corrodens	*Neisseria meningitidis-A**
*Enterobacter cloacae**	*Neisseria meningitidis-B**
Enterobacter aerogenes	*Neisseria meningitidis-C**
Enterococcus avium	*Neisseria meningitidis-D**
*Enterococcus faecalis**	*Neisseria perflava**
Enterococcus faecium	*Pantoea agglomerans*
*Escherichia coli**	*Peptostreptococcus anaerobius*
Fusobacterium nucleatum	*Plesiomonas shigelloides*
Gardnerella vaginalis	*Propionibacterium acnes*
Gemella haemolysans	*Proteus mirabilis**

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

Evaluation of Potentially Interfering Substances

The potential for interference in the Abbott RealTi*me* CT/NG assay was assessed with substances that may be found in swab and/or urine specimens. Substances were spiked into a swab and/or urine matrix containing 320 copies of CT and NG target DNA per assay, and into a swab and/or urine matrix without CT or NG DNA.

No interference in the performance of the Abbott RealTi*me* CT/NG assay was observed in the presence of the substances listed in Table 2.6.

Table 2.6

Substances That Do Not Interfere with the Abbott RealTime CT/NG Assay

Substance	Matrix	Highest Concentration Tested
Zovirax® Cream 5%	Swab	0.25
CLOTRIMAZOLE Vaginal Cream (2%)	Swab	0.25%
Delfen®	Swab	0.25%
KY® Jelly	Swab	0.25%
Lubrin®	Swab	0.25%
Metrogel-Vaginal®	Swab	0.25%
Miconazole® 3 Suppository	Swab	0.25%
Monostat-1™ Dose Treatment (tioconazole ointment)	Swab	0.25%
Norforms® Deodorant Suppositories	Swab	0.25%
Terazol-3® Vaginal Cream	Swab	0.25%
Vagi gard® Povidone-Iodine Medicated Douche	Swab	0.25%
Vagi gard® Moisturizing Gel	Swab	0.25%
Vagisil® Anti-itch Creme	Swab	0.25%
Vagisil® Intimate Lubricant	Swab	0.25%
Yeast gard®	Swab	0.25%
Bilirubin	Urine	10 mg/mL
Glucose	Urine	10 mg/mL
pH 4 (acidic) Urine	Urine	N/A
pH 9 (alkaline) Urine	Urine	N/A
Protein: BGG	Urine	5%
Blood	Swab and Urine	5%
Leukocytes	Swab and Urine	1 x 10^6 cell/mL

Interference in the performance of the Abbott RealTi*me* CT/NG assay may be observed with the following substances:

- Talcum powder at concentrations greater than 0.1% in urine specimens.
- Phenazopyridine hydrochloride (the active ingredient in URISTAT) at concentrations greater than 3 mg/mL in urine specimens.
- Mucus at concentrations greater than 0.1% for urine specimens and 1% for swab specimens.

2.9 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 2.7 and 2.8, respectively.

Table 2.7

Precision Study: CT Results

Panel Member[a]	No. Tested[b]	No. Positive	Mean Delta Cycle	Within-Run Component SD[c]	Between-Run Component SD[c]	Between-Lot Component SD[c]	Between-Site Component SD[c]	Total SD[c,d]
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	3.12	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	0.637	0.000	0.192	0.000	0.665

[a] 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.
[b] Invalid replicates were excluded from the analysis.
[c] 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.
[d] The total variability contains within-run, between-run, between-lot, and between-site variability.

Table 2.8

Precision Study: NG Results

Panel Member[a]	No. Tested[b]	No. Positive	Mean Delta Cycle	Within-Run Component SD[c]	Between-Run Component SD[c]	Between-Lot Component SD[c]	Between-Site Component SD[c]	Total SD[c,d]
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	...	...	...	...	...	...
9	148	56	0.58	0.386	0.000	0.000	0.120	0.404

[a] NG concentrations were targeted approximately to 2000 CFU/assay in members 1 and 7; to 20 CFU/assay in members 2, 3, and 5. Member 9 was targeted to 0.1 CFU/assay, below the claimed assay LOD. Members 4, 6, and 8 did not contain any NG organisms.
[b] Invalid replicates were excluded from the analysis.
[c] The SD is based on positive replicates only. For member 9, analysis of all replicates with a cycle number (n=148), including those beyond the assay cutoff, resulted in a total SD of 0.978.
[d] The total variability contains within-run, between-run, between-lot, and between-site variability.

2.10 Summary of Clinical Studies

Performance characteristics of the Abbott RealTi*me* 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 RealTi*me* 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 reference NAATs reported negative results for all sample types. 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.

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.

Tables 2.9 through 2.28 summarize the clinical trial data.

Table 2.9

***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)

Table 2.10

***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)

Table 2.11

***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)

Table 2.12

***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)

Table 2.13

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)

Table 2.13 (Continued)

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)

Table 2.14

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)

Table 2.14 (Continued)

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)

Table 2.15

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.

Table 2.16

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.

Table 2.16 (Continued)

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

NAAT 1			NAAT 2		RealTi*me* 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.

Table 2.17

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.

Table 2.18

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.

Table 2.19

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.

Table 2.20

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.

Table 2.20 (Continued)

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.

Table 2.21

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.

Table 2.22

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.

Table 2.23

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

	Female Urine					
	% Prevalence (Number Positive/Number Tested)					
Site[a]	CT+/ NG+		CT+/ NG –[b]		CT –/ NG+[b]	
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)

[a] No evaluable results were available from Site 2.
[b] Does not include specimens that were positive for both CT and NG.

Table 2.24

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

	Clinician-Collected Vaginal Swab						Self-Collected Vaginal Swab					
	% Prevalence (Number Positive/Number Tested)						% Prevalence (Number Positive/Number Tested)					
Site[a]	CT+/ NG+		CT+/ NG –[b]		CT –/ NG+[b]		CT+/ NG+		CT+/ NG –[b]		CT –/ NG+[b]	
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)

[a] No evaluable results were available from Site 2.
[b] Does not include specimens that were positive for both CT and NG.

Table 2.25

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

	Urethral Swab					
	% Prevalence (Number Positive/Number Tested)					
Site[a,b]	CT+/ NG+		CT+/ NG –[c]		CT –/ NG+[c]	
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)

[a] Male specimens were not collected from Site 1.
[b] No symptomatic Male Urethral Swab specimens were available from site 2 and 11.
[c] Does not include specimens that were positive for both CT and NG.

Table 2.26

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

	Urine					
	% Prevalence (Number Positive/Number Tested)					
Site[a]	CT+/ NG+		CT+/ NG–[b]		CT –/ NG+[b]	
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)

[a] Male specimens were not collected from Site 1.
[b] Does not include specimens that were positive for both CT and NG.

Table 2.27

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

Prevalence Rate (%)	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
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

Table 2.28

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

Prevalence Rate (%)	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
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

2.11 Conclusion Drawn from Clinical Studies

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Paula Martin
Senior Manager, Regulatory and Clinical Affairs
Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018

JUL 10 2008

Re: k080739
Trade/Device Name:
Regulation Number: 21 CFR 866.3120/866.3390
Regulation Name: Chlamydia trachomatis reagents/Neisseria gonorrhoeae reagents,
Regulatory Class: Class I/II
Product Code: MKZ/LSL
Dated: March 12, 2008
Received: March 17, 2008

Dear Paula Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.0 Indications of Use Statement

510(k) Number K080739

Device Name: Abbott RealTi*me* CT/NG assay and

Abbott *m*ulti-Collect Specimen Collection Kit

The Abbott RealTi*me* 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.

The Abbott *m*ulti-Collect Specimen Collection Kit is intended for the collection and transportation of male and female swab and urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhea*e per instructions provided. Refer to the specimen collection procedure in the package insert for specimen collection instructions for specific sample types.

Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Abbott *m*ulti-Collect Specimen Collection Kit is not intended for home use.

Prescription Use X (Per 21 CFR 801.119) AND/OR Over-The-Counter Use_____ (Per 21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Page 1 of 1

(Posted November 13, 2003

Office of In Vitro Diagnostic Device Evaluation and Safety