Abbott RealTime CT/NG

IN VITRO TEST
REF 8L07-91
51-608362/R1

Customer Service: 1-800-553-7042

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

REF	List Number	CONTROL CO	Cutoff Control
LOT	Lot Number	INTERNAL CONTROL	Internal Control
IVD	*In Vitro* Diagnostic Medical Device	CONTROL –	Negative Control
-10°C	Store at -10°C or colder	AMPLIFICATION REAGENT PACK	Amplification Reagent Pack
15°C–30°C	Store at 15°C to 30°C		Manufacturer
	Consult instructions for use		Expiration Date

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

NAME

Abbott RealTime *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG)

INTENDED USE

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.

SUMMARY AND EXPLANATION OF THE TEST

The Abbott RealTime CT/NG assay uses PCR technology with homogeneous real-time fluorescence detection. The CT/NG assay is used for the dual detection of the sexually transmitted disease pathogens, *C. trachomatis* and *N. gonorrhoeae*. The assay detects *C. trachomatis* including the new variant strain recently discovered in Sweden (nvCT).[1]

Chlamydia

Chlamydia are non-motile, Gram-negative, obligate intracellular parasites of eukaryotic cells. They form inclusions in the cytoplasm of the host cell. *C. 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, cervicitis, ectopic pregnancies, and tubal factor infertility in women as well as nongonococcal urethritis and epididymitis in men.[2-5] The genital site most commonly affected in women is the cervix, but the infection often is asymptomatic and, if untreated, is likely to ascend to the uterus, the fallopian tubes, and the ovaries causing pelvic inflammatory disease (PID).[6] Neonates born of infected mothers can contract inclusion conjunctivitis, nasopharyngeal infections, and pneumonia due to *C. trachomatis*.[7] Infection by *C. trachomatis* in men is also often asymptomatic and, if untreated, may lead to epididymitis, a major complication.[4] Patients infected with *C. trachomatis* may be co-infected with *N. gonorrhoeae*, the causative agent of gonorrhea. Further, patients with treatment indications for gonorrhea but not chlamydia often harbor *C. trachomatis*.[7] Chlamydia infections may not respond well to recommended regimens for treating *N. gonorrhoeae*. Therefore, unless chlamydial infection has been ruled out in patients treated for gonorrhea, dual therapy for gonococcal and chlamydial infections is recommended.[6]

Cell culture used to detect *C. trachomatis*, has been replaced by more sensitive nucleic acid tests.[9] 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.[6]

Gonorrhea

N. gonorrhoeae is a Gram-negative, oxidase-positive diplococcus without flagellae.[10] In men, gonorrhea infection usually results in acute anterior urethritis accompanied by a purulent exudate.[11,12] 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 PID or acute salpingitis for women and epididymitis for men.[11,12] Rarely, disseminated gonococcal infection (DGI) may occur in untreated patients.[13]

Culture is commonly used for the detection of *N. 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 *N. gonorrhoeae* including sugar fermentation, fluorescent antibody staining, nucleic acid hybridization, and co-agglutination.[14,15] Nucleic acid tests are widely available for the sensitive detection of *N. gonorrhoeae*.[9]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

For the Abbott RealTime CT/NG assay, urine and swab specimens are collected using the Abbott multi-Collect Specimen Collection Kit. Specimens are stored and transported in the multi-Collect Specimen Transport Tube, which contains a buffer to stabilize DNA.

The Abbott RealTime CT/NG assay is performed on the Abbott *m2000* System which consists of the Abbott *m*2000*sp* and Abbott *m*2000*rt*. The *m*2000*sp* fully automates the extraction of the nucleic acid (DNA) from the specimen and then dispenses the extracted DNA, along with the PCR amplification mastermix, into a 96-well optical reaction plate. The user applies an optical adhesive cover which seals the plate which is then transferred to the *m*2000*rt* instrument. Real-time PCR takes place in the *m*2000*rt*. CT and NG target sequences, if present, are amplified and detected through the use of fluorescent-labeled oligonucleotide probes, without the need to open the sealed plate. The probes do not generate signal unless specifically bound to the amplified product. Assay results are reported on the *m*2000*rt*.

Sample Preparation

The purpose of sample preparation is to extract and concentrate the target DNA molecules, to make the target accessible for amplification and to remove potential inhibitors of amplification.

The automated Abbott *m*Sample Preparation System$_{DNA}$ uses magnetic particle technology to capture nucleic acids and washes the particles to remove unbound sample components. The bound nucleic acids are eluted and transferred to the Abbott 96 Deep-Well Plate. The nucleic acids are then ready for amplification. The Internal Control (IC) is taken through the entire sample preparation procedure along with the controls and specimens.

Reagent Preparation and Reaction Plate Assembly

The *m*2000*sp* automates the assembly of the PCR amplification master mix and then transfers aliquots to the Abbott 96-Well Optical Reaction Plate. Nucleic acid samples from the 96 Deep-Well Plate are then transferred into the 96-Well Optical Reaction Plate by the *m*2000*sp*. The plate is sealed by the user with an Abbott Optical Adhesive Cover and placed into the *m*2000*rt* instrument for PCR amplification and fluorescence detection.

Amplification

Analyte DNA is amplified using PCR. The amplification reagent contains specific sets of amplification primers for CT, NG, and IC. During PCR amplification, high temperature is used to separate the strands of double-stranded DNA. When the reaction is cooled to a temperature where DNA annealing can again occur, the analyte-specific, single-stranded DNA oligonucleotide primers bind to the analyte DNA. The primers are extended by DNA Polymerase, thereby making an exact copy of a short target strand of the analyte DNA. The DNA Polymerase enzyme is a thermophilic enzyme that has been modified in its active site by a molecule that renders it inactive. When the enzyme is heated prior to the initiation of PCR, the inhibitory molecule is cleaved from the enzyme allowing it to regain its activity. In this way, the enzyme is only active at temperatures where specific DNA-DNA interactions occur. This greatly reduces non-specific PCR artifacts such as primer dimers.

In addition to its chromosomal DNA, *C. trachomatis* harbors a cryptic plasmid, which is found in all serovars at approximately 7 to 10 copies per organism.[16] The amplification reagent contains two sets of CT PCR primers that target two different regions of the plasmid. Both primer sets target short sequences that are highly conserved among all serovars of *C. trachomatis* but are not found in other species.[17,18] The first set of CT PCR primers target 102 base pairs within this plasmid. A new variant strain of *C. trachomatis* (nvCT)[1] has been characterized and contains a 377 base pair deletion in the cryptic plasmid within the region targeted by the first primer set. A second set of PCR primers targets 140 base pairs located outside this deleted region. The NG PCR primers target a region of the Opa gene of *N. gonorrhoeae*. The 122 base pair sequence was selected as the target DNA because it is conserved in all strains of *N. gonorrhoeae* studied, and is not found in non-STD *Neisseria*.[19] Up to 11 copies of the Opa gene are found per cell.[20,21] The IC PCR primers target 136 bases of a sequence unrelated to the CT and NG analyte sequences.

Detection

During each round of PCR amplification, the fluorescent probes anneal to the amplified target DNA, if present. The probes are labeled with different fluorescent molecules allowing CT, NG and IC to be distinguished from each other. The probes are single-stranded, linear DNA oligonucleotides modified with a fluorescent moiety covalently linked to one end of the probe and a quenching moiety to the other end. In the absence of target sequences, the probes adopt a conformation that brings the quencher close enough to the excited fluorophore to absorb its energy before it can be fluorescently emitted. When the probe binds to its complementary sequence in the target, the fluorophore and the quencher are held apart, allowing fluorescent emission and detection. Since this fluorescence occurs during every cycle, the PCR reaction can be read in real-time.

Assay Results

The Abbott RealTime CT/NG assay is a qualitative assay. Results for NG are reported as positive or negative. Results for CT are reported as positive, negative, or indeterminate. Refer to the "**RESULTS**" section of this package insert for further details.

REAGENTS

The Abbott RealTime CT/NG assay consists of two reagent kits:

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

Abbott RealTime CT/NG Amplification Reagent Kit (List No. 8L07-91)

1. INTERNAL CONTROL Abbott RealTime CT/NG Internal Control
   (4 vials, 0.53 mL per vial)
   Less than 0.01% noninfectious linearized DNA plasmid in a buffer solution with carrier DNA. Preservatives: Sodium azide and 0.15% ProClin® 950.
2. AMPLIFICATION REAGENT PACK Abbott RealTime CT/NG Amplification Reagent Pack
   (4 packs, 48 tests/pack)
   - 1 bottle (0.078 mL) DNA Polymerase. (5.4 to 5.9 Units/µL) in a buffered solution with stabilizers.
   - 1 bottle (0.696 mL) Amplification Reagent. Less than 0.1% synthetic oligonucleotides (8 primers and 4 probes) and less than 0.1% dNTPs in a buffered solution with a reference dye. Preservatives: Sodium azide and 0.15% ProClin 950.
   - 1 bottle (0.778 mL) Activation Reagent. 38mM magnesium chloride in a buffered solution. Preservatives: Sodium azide and 0.15% ProClin 950.

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

1. CONTROL – Abbott RealTime CT/NG Negative Control
   (8 vials, 0.5 mL per vial)
   Buffered solution with carrier DNA. Preservatives: Sodium azide and 0.15% ProClin 950.
2. CONTROL CO Abbott RealTime CT/NG Cutoff Control
   (16 vials, 0.5 mL per vial)
   Less than 0.01% noninfectious linearized DNA plasmids with CT and NG sequences in buffered solution with carrier DNA. Preservatives: Sodium azide and 0.15% ProClin 950.

WARNINGS AND PRECAUTIONS

IVD ***In Vitro* Diagnostic Medical Device.**

- For *In Vitro* Diagnostic Use Only.

Safety Precautions

Refer to the Abbott *m*2000*sp* and Abbott *m*2000*rt* Operations Manuals, Hazards Section, for instructions on safety precautions.

- There are no human sourced materials in any of the Abbott RealTi*m*e CT/NG amplification reagents or controls.
- This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices. Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.
- The Abbott RealTi*m*e CT/NG Control Kit, Internal Control, Amplification Reagent, and Activation Reagent contain 2-methyl-4-isothiazolin-3-one (which is a component of ProClin) and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:

R43 May cause sensitization by skin contact.

S24 Avoid contact with skin.

S35 This material and its container must be disposed of in a safe way.

S37 Wear suitable gloves.

S46 If swallowed, seek medical advice immediately and show this container or label.

Specimen Collection and Handling Precautions

- The Abbott *m*ulti-Collect Specimen Collection Kit must be used to collect swab specimens from the male urethra, the endocervix, or the vagina, or urine specimens from males and females.
- Do not use the *m*ulti-Collect Specimen Collection Kit beyond its expiration date.
- Do not use the *m*ulti-Collect Specimen Collection Kit if the packaging is damaged, the seal is broken, or if buffer has leaked from the tube. Discard unused, damaged, or leaking kits in accordance with local, state, and federal regulations.
- Use only the orange shaft swab provided in the *m*ulti-Collect Specimen Collection Kit for collecting male urethral, endocervical, or vaginal specimens and processing on the *m*2000*sp*. The swab must remain in the Transport Tube after specimen collection. Do not place multiple swabs or a combination of swab and urine in the Transport Tube. A new specimen should be collected if a swab specimen is received without a swab or with multiple swabs.
- For urine specimens, the liquid level in the specimen transport tube must fall within the fill window on the tube label, or a new specimen must be collected. If a urine specimen arrives in the laboratory transported in a urine specimen collection cup, transfer the urine to a specimen transport tube.
- The *m*ulti-Collect Specimen Collection Kit Transport Buffer contains guanidine thiocyanate, a chaotropic salt. Samples collected with the *m*ulti-Collect Specimen Collection Kit must be processed with the *m*Sample Preparation System$_{DNA}$.
- The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays. The effects of other factors such as vaginal discharge, use of tampons, douching, or specimen collection variables have not been determined.

Laboratory Precautions

- During preparation of samples, compliance with good laboratory practices is essential to minimize the risk of cross-contamination between samples as well as the inadvertent introduction of nucleases into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with DNA.
- Work areas and instrument platforms must be considered potential sources of contamination. Change gloves after having contact with potential contaminants (such as DNases, specimens, eluates, and/or amplified product) before handling unopened reagents, negative controls, cutoff controls, or specimens. Refer to the Abbott *m*2000*sp* and *m*2000*rt* Operations Manuals for instructions on instrument cleaning procedures.
- Wear appropriate personal protective equipment at all times.
- Use powder-free gloves.
- Change gloves after having contact with potential contaminants (DNases, samples, and/or amplified product).
- To reduce the risk of nucleic acid contamination due to aerosols formed during manual pipetting, pipettes with aerosol barrier tips must be used for all reagent pipetting. The length of the tip should be sufficient to prevent contamination of the pipette barrel. While pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Change aerosol barrier pipette tips between ALL manual liquid transfers.
- Clean and disinfect spills of specimens and reagents as stated in the *m*2000*sp* and *m*2000*rt* Operations Manuals.

Contamination Precautions

- Amplification reactions such as PCR are sensitive to accidental introduction of product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the RealTi*m*e reagents used in the sample preparation or amplification steps become contaminated by accidental introduction of even a few molecules of amplification product. Measures to reduce the risk of contamination in the laboratory include physically separating the activities involved in performing PCR in compliance with good laboratory practices.
- The use of two dedicated areas within the laboratory for performing the Abbott RealTi*m*e CT/NG assay is recommended.
  - The Sample Preparation Area is dedicated to processing samples (specimens and Abbott RealTi*m*e CT/NG Controls) and to adding processed samples and controls to the 96-Well Optical Reaction Plate. All reagents used in the Sample Preparation Area should remain in this dedicated area at all times. Laboratory coats, pipettes, pipette tips, and vortexers used in the Sample Preparation Area must remain in this area and not be moved to the Amplification Area. Do not bring amplification product into the Sample Preparation Area.
  - The Amplification Area is dedicated to the amplification and detection of amplified product. Laboratory coats and equipment used in the Amplification Area must remain in this area and not be moved to the Sample Preparation Area.
- In the rare event that a swab is removed from the transport tube during *m*2000*sp* sample aspiration, cross-contamination may occur.
- If the *m*2000*sp* sample extraction run is aborted, dispose of all commodities and reagents according to the Abbott *m*2000*sp* Operations Manual. If the *m*2000*sp* master mix addition protocol is aborted after amplification reagents are added to the 96-Well Optical Reaction Plate, seal the 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott *m*2000*sp* Operations Manual, Hazards Section, along with the gloves used to handle the plate.
- For all completed runs or if the *m*2000*rt* run is interrupted or aborted, dispose of the 96-Well Optical Reaction Plate in a sealable plastic bag according to the Abbott *m*2000*rt* Operations Manual along with the gloves used to handle the plate.
- **Autoclaving the sealed Reaction Plate will not degrade the amplified product and may contribute to the release of the amplified product by opening the sealed plate. The laboratory area can become contaminated with amplified product if the waste materials are not carefully handled and contained.**
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[22,23] All materials should be handled in a manner that minimizes the chance of potential contamination of the work area.

REAGENT STORAGE AND HANDLING INSTRUCTIONS

Note: Care must be taken to separate the Abbott RealTi*m*e CT/NG Amplification Reagent Pack that is in use from direct contact with specimens and Abbott RealTi*m*e CT/NG Control Kit reagents.

Abbott RealTi*m*e CT/NG Amplification Reagent Kit (List No. 8L07-91)

- The Abbott RealTi*m*e CT/NG Amplification Reagent Pack and Internal Control vials must be stored at −10°C or colder when not in use.
- Reagents are shipped on dry ice.

Abbott RealTi*m*e CT/NG Control Kit (List No. 8L07-80)

- The Abbott RealTi*m*e CT/NG Negative and Cutoff Controls must be stored at −10°C or colder.
- Reagents are shipped on dry ice.

INSTRUMENTS

The Abbott RealTi*m*e CT/NG assay is performed on the *m*2000 System, consisting of the *m*2000*sp* and *m*2000*rt*. Refer to the Abbott *m*2000*sp* and *m*2000*rt* Operations Manuals for detailed instrument operating procedures.

The Abbott RealTi*m*e CT/NG application file must be installed on the *m*2000*sp* and *m*2000*rt* from the Abbott *m*2000 System *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Application CD-ROM (List No. 6L98) prior to performing the assay. For detailed information on application file installation, refer to the Abbott *m*2000*sp* and *m*2000*rt* Operations Manuals, Operating Instructions section.

SPECIMEN COLLECTION AND HANDLING INSTRUCTIONS

Specimens must be collected using the *m*ulti-Collect Specimen Collection Kit (List No. 9K12). Refer to the *m*ulti-Collect package insert for detailed sample collection instructions.

The Abbott RealTi*m*e CT/NG assay is designed to detect the presence of CT and NG in clinician-collected endocervical swab, vaginal swab, and male urethral swab specimens; patient-collected vaginal swab specimens; and female and male urine specimens from symptomatic and asymptomatic individuals. Performance with specimens other than those collected with the *m*ulti-Collect Specimen Collection Kit has not been evaluated.

For swab specimen collections, use only the orange shaft swab provided in the Abbott *m*ulti-Collect Specimen Collection Kit. A transport tube containing multiple swabs, or a combination of swab and urine cannot be used in the Abbott RealTi*m*e CT/NG assay.

For urine specimen collections, ensure that the urine level falls within the clear window of the Specimen Transport Tube label.

After collection, specimens may be stored and transported at 2°C to 30°C for up to 14 days. If longer storage is needed, store at −10°C or colder for up to 90 days. Thaw specimens at 2°C to 30°C. Specimens should not undergo more than four freeze/thaw cycles.

Time and temperature conditions for storage must be adhered to during transport.

It is recommended that each tube be placed in an individual sealable bag prior to transport.

For domestic shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

Note: Validation of specimens not collected, transported, and stored per the instructions in this package insert is the responsibility of the user.

ASSAY PROCEDURE

Materials Provided

- Abbott RealTi*m*e CT/NG Amplification Reagent Kit (List No. 8L07-91)

Materials Required But Not Provided

- Abbott RealTi*m*e CT/NG Control Kit (List No. 8L07-80)
- Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12)
- Abbott *m*2000 System *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Application CD-ROM (List No. 6L98)

*m*2000*sp* Sample Preparation Area

- Abbott *m*2000*sp* instrument
- Abbott *m*Sample Preparation System$_{DNA}$ (List No. 6K12)
  Note: One kit is sufficient to complete 192 CT/NG sample preparations.
- 5 mL Reaction Vessels
- Calibrated Pipettes capable of delivering 20-1000 µL
- Aerosol Barrier Pipette Tips for 20-1000 µL Pipettes
- Bulk Solid Caps (List No. 4J71-95)
- Vortex Mixer
- USP Grade 190-200 Proof Ethanol (95%-100% Ethanol). Do not use ethanol that contains denaturants.
- Abbott Optical Adhesive Covers
- Abbott Adhesive Cover Applicators
- Abbott Splash-Free Support Base
- Master Mix Tube
- 200 mL Reagent Vessels
- Abbott 96 Deep-Well Plate
- Abbott 96-Well Optical Reaction Plate
- 13 mm Sample Racks

Amplification Area

- Abbott *m*2000*rt* Instrument
- Abbott *m*2000*rt* Optical Calibration Kit (List No. 4J71-93)

Other Materials

- Adhesive labels for sample identification information
- Sealable plastic bags
- DNase-free water†
- Cotton Tip Applicators (Puritan or equivalent)†

†These items are used in the procedure for **Monitoring the Laboratory for the Presence of Contamination**. Refer to the **"QUALITY CONTROL PROCEDURES"** section of this package insert.

Procedural Precautions

- Read the instructions in this package insert carefully before processing samples.
- Do not use kits or reagents beyond expiration date.
- Components contained within a kit are intended to be used together. Do not mix components from different kit lots. For example, do not use the negative control from control kit lot X with the cutoff controls from control kit lot Y.
- Amplification Reagents, Controls, and *m*Sample Preparation System$_{DNA}$ are for single-use only and should be discarded after use. Use new reagent vessels, new reaction vessles, and newly opened reagents for every new Abbott RealTi*m*e CT/NG assay run. At the end of each run, discard all remaining reagents from the Abbott *m*2000*sp* worktable as stated in the Abbott *m*2000*sp* Operations Manual.
- The Abbott RealTi*m*e CT/NG Controls must be processed with the specimens to be tested. The use of the Abbott RealTi*m*e CT/NG Controls is integral to the performance of the Abbott RealTi*m*e CT/NG assay. Refer to the "**QUALITY CONTROL PROCEDURES"** section in this package insert for details.
- Use only USP Grade 190-200 Proof Ethanol (95%-100% Ethanol) to prepare the *m*Wash 2$_{DNA}$ sample prep reagent. Do not use ethanol that contains denaturants.
- Use aerosol barrier pipette tips or disposable pipettes only one time when pipetting. To prevent contamination to the pipette barrel while pipetting, care should be taken to avoid touching the pipette barrel inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Replace any empty or partially used 200 µL and 1000 µL disposable tips on the *m*2000*sp* with full trays before every run.
- Monitoring procedures for the presence of amplification product can be found in the **"QUALITY CONTROL PROCEDURES"** section in this package insert.
- To reduce the risk of nucleic acid contamination, clean and disinfect spills of specimens, reagents, and controls by using a detergent solution followed by a tuberculocidal disinfectant such as 0.1% sodium hypochlorite or other suitable disinfectant.

ASSAY PROTOCOL

Refer to the "**WARNINGS AND PRECAUTIONS"** section of this package insert before preparing samples.

1. Remove the specimens from the refrigerator or thaw them if frozen.
   - If the urine or swab specimen is stored frozen, it must be completely thawed prior to sample preparation. Thaw tubes or vials at 2°C to 30°C. Once thawed, specimens can be stored closed at 2°C to 30°C for up to 14 days prior to being tested.
   - Use only the orange shaft swab provided in the *m*ulti-Collect Specimen Collection Kit for collecting endocervical, vaginal, and male urethral specimens and processing on the *m*2000*sp*. The swab must remain in the Transport Tube after specimen collection. Do not place multiple swabs or a combination of swab and urine in the Transport Tube. A new specimen should be collected if a swab specimen is received without a swab or with multiple swabs.
   - For urine specimens, the liquid level in the specimen transport tube must fall within the fill window on the tube label, or a new specimen must be collected. If a urine specimen arrives in the laboratory transported in a urine specimen collection cup, transfer the urine to a specimen transport tube.

Note: A maximum of 96 reactions can be performed per run.
For up to 48 reactions use: two tubes of Cutoff Control, one tube of Negative Control, one vial of IC, one amplification reagent pack, and one set (one bottle each) of *m*Sample Preparation System reagents.
For 49 to 96 reactions use: two tubes of Cutoff Control, one tube of Negative Control, one vial of IC, two amplification reagent packs, and two sets of *m*Sample Preparation System reagents WITH THE EXCEPION of *m*LYSIS BUFFER and *m*MICROPARTICLES. USE ONLY ONE BOTTLE of *m*LYSIS BUFFER and ONE BOTTLE OF *m*MICROPARTICLES for 49 to 96 reactions.

2. Thaw two tubes of the CT/NG Cutoff Control, one tube of the CT/NG Negative Control, and one vial of CT/NG Internal Control at 2°C to 30°C.
   - Once thawed, the controls and the IC can be stored closed at 15°C to 30°C for up to 8 hours or at 2°C to 8°C for up to 7 days prior to use.
3. Thaw amplification reagents at 2°C to 30°C.
   - Thaw one pack of amplification reagents to support up to 48 reactions, and two packs to support 49 to 96 reactions.
   - Once thawed, the amplification reagents can be stored closed at 15°C to 30°C for up to 8 hours or at 2°C to 8°C for up to 7 days prior to use.
4. Mix specimen thoroughly to ensure uniformity. The CT/NG assay requires a minimum 500 µL of each specimen per individual specimen transport tube to ensure that 400 µL is transferred to the reaction vessel.

Note: A maximum of two 400 uL sample preparations can be performed from a swab specimen collected in the specimen transport tube.

5. Place two replicates of the CT/NG Cutoff Control, one replicate of the CT/NG Negative Control, and the patient specimens in the *m*2000*sp* sample rack.

CAUTION: Use only 13 mm sample racks. Do NOT skip any positions in a sample rack. Load specimens and controls into the 13 mm sample racks in consecutive positions, starting with the first position in the first sample rack. Fill all positions in each sample rack without skipping any positions before loading specimens into the next sample rack.
Insert specimen and control tubes into sample racks carefully to avoid splashing. If used, bar codes on tube labels must face right for scanning. Ensure that each tube is placed securely in the sample rack so that the bottom of the tube reaches the inside bottom of the rack.
Load filled sample racks on to the *m*2000*sp* in consecutive sample rack positions, with the first rack farthest to the right on the worktable, and any additional racks progressively to the left of the first rack.

6. Ensure all caps have been removed from specimens and controls prior to starting the *m*2000*sp* run. Do not remove swabs from specimen transport tubes. Swabs do not interfere with the ability of the *m*2000*sp* to aspirate samples.
7. Open the *m*Sample Preparation System reagent pack. Mix the IC by vortexing three times for 2 to 3 seconds each. Using a calibrated precision pipette dedicated for IC use only, add 250 µL of IC to the bottle of mLysis Buffer. Swirl the container 20 to 30 times or mix gently by inversion, but minimize foaming.
8. Prepare the *m*Wash 2 by adding 70ml of USP Grade 190-200 proof Ethanol (95%-100% Ethanol) to the *m*Wash 2 bottle as described in the *m*Sample Preparation System product information. Do not use ethanol that contains denaturants. Gently invert each reagent bottle to ensure a homogenous solution and pour the contents into the appropriate reagent vessels per the Abbott *m*2000*sp* Operations Manual, Operating Instructions. If crystals are observed in any of the reagent bottles upon opening, allow the reagent to equilibrate at room temperature until the crystals disappear. Do not use the reagents until the crystals have dissolved.

Note: Before pouring the *m*Microparticles into the 200 mL reagent vessels, vigorously mix or vortex until the *m*Microparticles are fully resuspended. Only one bottle of *m*Microparticles is needed for up to 96 reactions. Initiate the *m*2000*sp* sample extraction protocol as described in the Abbott *m*2000*sp* Operations Manual, Operating Instructions.

9. Initiate the *m*2000*sp* sample extraction protocol as described in the Abbott *m*2000*sp* Operations Manual, Operating Instructions.
10. While the *m*2000*sp* is performing sample preparation, switch on and initialize the *m*2000*rt*. The *m*2000*rt* requires a 15-minute warm-up prior to starting a run. Refer to the Abbott *m*2000*rt* Operations Manual, Operating Instructions.
11. After sample preparation is complete, check the *m*2000*sp* deck to ensure all specimens have been processed correctly. In the rare event that a swab has been removed from the transport tube and is found on the *m*2000*sp* deck, cross-contamination of samples may have occurred.

Note: Once sample preparation is completed, the master mix protocol should be started within one hour.

12. Load the amplification reagents and the master mix tube on the *m*2000*sp* worktable.
    - Prior to opening the amplification reagents, ensure that the contents of the Amplification Reagent Pack are at the bottom by tapping the Amplification Reagent Pack in an upright position on the bench to bring the liquid to the bottom of the vials.
    - Remove and discard caps.
    - Amplification reagents are stable for up to 6 hours on board the *m*2000*sp*.
13. Initiate the *m*2000*sp* master mix addition protocol as described in the Abbott *m*2000*sp* Operations Manual, Operating Instructions.
14. After the *m*2000*sp* instrument has completed addition of samples and amplification reagents, seal the 96-Well Optical Reaction Plate according to the instructions in the Abbott *m*2000*sp* Operations Manual.
    - Contamination of the bottom of the 96-Well Optical Reaction plate with fluorescent materials could potentially interfere with the CT/NG assay. It is recommended that the Splash-Free Support Base is used to hold or transport the 96-Well Optical Reaction Plate to minimize contamination.

Note: Within one hour of starting the mastermix protocol, the sealed PCR plate should be transferred to the *m*2000*rt* to begin amplification detection.

15. Place the 96-Well Optical Reaction Plate in the *m*2000*rt* and initiate the Abbott RealTi*m*e CT/NG assay protocol as described in the Abbott *m*2000*rt* Operations Manual. The *m*2000*rt* completes the run in approximately 2 hours and 15 minutes. At the completion of the run, assay results are reported on the *m*2000*rt*. Refer to the "**RESULTS**" section of this package insert for further details.
16. After the *m*2000*rt* instrument has completed the amplification and detection protocol, remove the 96-Well Optical Reaction Plate and dispose according to the instructions in the **Contamination Precautions** section of this insert. Place the 96-Well Optical Reaction Plate in a sealable plastic bag and dispose according to the Abbott *m*2000*rt* Operations Manual along with the gloves used to handle the plate.

Post Processing Procedures

1. Upon completion of sample preparation, the specimens should be recapped using new, unused caps and can be stored closed at 2°C to 30°C for up to 14 days. If longer storage is needed, store at –10°C or colder for up to 90 days.
2. At the end of each run, remove and discard all remaining reagents from the *m*2000*sp* worktable as stated in the Abbott *m*2000*sp* Operations Manual.
3. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[22,23]
4. Clean the Splash-Free Support Base before next use, according to the Abbott *m*2000*rt* Operations Manual.

QUALITY CONTROL PROCEDURES

Abbott *m*2000*rt* Optical Calibration

Optical calibration of the *m*2000*rt* instrument is required for the accurate measurement and discrimination of dye fluorescence during the Abbott RealTi*m*e CT/NG assay.

The following *m*2000*rt* Optical Calibration Plates are used to calibrate the *m*2000*rt* instrument for the Abbott RealTi*m*e CT/NG assay:

- FAM™ Plate (Carboxyfluorescein)
- VIC® Plate (Proprietary dye)
- NED™ Plate (ABI proprietary dye)
- ROX™ Plate (Carboxy-X-rhodamine)

For a detailed description of how to perform an *m*2000*rt* Optical Calibration, refer to the Calibration Procedures section in the Abbott *m*2000*rt* Operations Manual.

Detection of Inhibition

A defined, consistent quantity of IC nucleic acid is introduced into each specimen and control at the beginning of sample preparation and measured on the *m*2000*rt* to demonstrate proper specimen processing and assay validity. The IC is composed of a DNA sequence unrelated to the CT and NG target sequences. An error control flag is displayed when a specimen or control fails to meet this specification.

Negative and Cutoff Controls

A negative control and a minimum of two replicates of the cutoff control are required for every *m*2000 System run to verify that the specimen processing, the amplification, and the detection steps are performed correctly. The Abbott RealTi*m*e CT/NG controls need to be prepared with the specimens prior to running the amplification portion of the assay.

If the controls are out of their expected range, all of the specimens and controls from that run must be reprocessed beginning with sample preparation. Refer to the Abbott *m*2000*rt* System Operations Manual for an explanation of the corrective actions for the error control flag.

Contamination may be introduced into the negative control from other samples or amplified product during sample preparation or preparation of the 96-Well Optical Reaction Plate. To remove contamination, clean the *m*2000*sp* and *m*2000*rt* instruments according to the Abbott *m*2000*sp* and *m*2000*rt* Operations Manuals. Following cleaning, repeat the sample processing for controls and specimens following the assay protocol outlined in this insert.

Monitoring the Laboratory for the Presence of Contamination

It is recommended that the following procedure be done at least once a month to monitor laboratory surfaces and equipment for contamination. It is very important to test all areas that may have been exposed to processed specimens and controls and/or amplification product. This includes pipettes, *m*2000*sp* and *m*2000*rt* function keys, bench surfaces and other equipment that may be present in the work areas.

1. Add 0.8 mL DNase-free water to an empty Master Mix Tube.
2. Saturate the cotton tip of an applicator (Puritan or equivalent) in the DNase-free water from the Master Mix Tube.
3. Using the saturated cotton tip of the applicator, wipe the area to be monitored using a sweeping motion. Place the applicator into the Master Mix Tube.
4. Swirl the cotton tip in DNase-free water 10 times, then press the applicator along the inside of the tube so that the liquid drains back into the solution at the bottom of the Master Mix Tube. Discard the applicator.
5. Cap the Master Mix Tube and vortex.
6. Remove the caps from the Master Mix Tubes and test the sample according to the appropriate assay procedure section of this package insert.
7. Contamination is indicated by the presence of CT or NG amplification even after the assay cutoff.
8. If contamination is detected on the equipment, follow the cleaning and decontaminating guidelines given in that equipment's operations manual. If CT or NG DNA is detected on surfaces, clean the contaminated areas with 0.1% (v/v) sodium hypochlorite solution, followed by 70% ethanol.

Note: Chlorine solutions may pit equipment and metal. Use sufficient amounts or repeated applications of 70% ethanol until chlorine residue is no longer visible.

9. Repeat testing of the contaminated area by following Steps 1 through 6.
10. If the presence of contamination is detected again, repeat Steps 8 and 9 until no CT or NG DNA amplification is detected.

RESULTS

Calculation

The RealTi*m*e CT/NG assay is a qualitative assay. A minimum of one replicate of the Negative Control, also designated by the software as the "control", and two replicates of the Cutoff Control, designated by the software as the "calibrator", are required with each run. For each assayed analyte (CT or NG), the software will calculate the mean target cycle number (CN) of the Cutoff Controls and then add a predetermined number of cycles to this average to generate the decision cycle (assay cutoff or assay CO). If the tested sample generates a cycle number less than or equal to the assay CO, a "Positive" interpretation and a numerical result greater than or equal to zero will be reported. The numerical result (Delta Cycle or DC) corresponds to the difference in cycle number between the CO and the sample CN. A higher number in DC is indicative of a greater amount of analyte present in the assayed sample. No DC calculation is performed for samples with a cycle number greater than the assay CO, or for samples with no cycle number determination.

At least two valid Cutoff Control results must be generated in a run to calculate and report an assay CO value. Runs that lack two valid Cutoff Controls will not produce results or interpretations for any samples.

The Negative Control serves to verify that CT or NG DNA contamination of the Negative Control did not occur during the sample preparation and set-up of the amplification reaction. If the Negative Control is not run, the flag NNC (No Negative Control) is indicated next to all sample results for that run. If the Negative Control generates a positive result for either analyte, the flag, –QC (Negative Control out of range), is displayed next to all sample results for the run. Samples with the –QC flag may have been similarly contaminated with analyte during processing.

The Internal Control (IC) in each sample serves to confirm that each sample was processed correctly and to indicate whether inhibitors of amplification are present. If the IC is out of range but the analyte(s) in that sample generate(s) a cycle number less than or equal to the assay CO, the sample will still yield a positive interpretation. An IC flag ("IC") will be reported next to the positive result. If the IC is out of range and the analyte does not produce a cycle number less than or equal to the assay CO, no results will be reported for the analyte and an error code will be generated.

For more information about error codes and flags, refer to the Abbott *m*2000*rt* Operations Manual, Section 10 Troubleshooting and Diagnostics.

Results Reporting

CT samples with a cycle number less than or equal to the assay CO are interpreted as "Positive."
CT samples with a cycle number beyond the assay CO are interpreted as "Equivocal."
CT samples with no evidence of amplification are interpreted as "Negative."

Note: A sample with an initial interpretation of "Equivocal" for CT is required to be retested.

- If retest interpretation is "Positive," report sample as Positive.
- If retest interpretation is "Equivocal", report sample as Indeterminate. A new sample should be collected.
- If retest interpretation is "Negative," report sample as Negative.

NG samples with a cycle number less than or equal to the assay CO are interpreted as "Positive." NG samples with no evidence of amplification or with a cycle number that is greater than the assay CO are interpreted as "Negative." An "Equivocal" interpretation does not apply to NG samples.

LIMITATIONS OF THE PROCEDURE

- **FOR *IN VITRO* DIAGNOSTIC USE ONLY.**
- Optimal performance of this test requires appropriate specimen collection, handling, and storage (refer to the **SPECIMEN COLLECTION and SPECIMEN TRANSPORT TO TEST SITE AND STORAGE** sections of this package insert). The assay should be performed only on swab samples from the vagina, the endocervix, the male urethra, or on urine from males and females. The use of specimens other than those listed has not been validated.
- Use of the Abbott RealTi*m*e CT/NG assay is limited to personnel who have been trained on the use of the *m*2000*sp* and *m*2000*rt*.
- The instruments and assay procedures reduce the risk of contamination by amplification product. However, nucleic acid contamination from the controls, specimens, and amplification product must be controlled by good laboratory practice and careful adherence to the procedures specified in this package insert.
- A negative result does not exclude the possibility of infection because results are dependent on appropriate specimen collection and absence of inhibitors. The presence of PCR inhibitors may cause invalid results with this product.
- The Abbott RealTi*m*e CT/NG assay will not detect plasmid-free variants of *C. trachomatis*.
- Therapeutic success or failure should not be determined as analyte nucleic acids may persist after appropriate antimicrobial therapy.
- The Abbott RealTi*m*e CT/NG assay for male and female urine testing must be performed on first-catch urine specimens (defined as the first 20-30 mL of the urine stream). The effects of other variables such as first-catch vs. mid-stream, post douching, etc. have not been determined.
- The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays. The effects of other factors such as vaginal discharge, use of tampons, douching, or specimen collection variables have not been determined.
- The Abbott RealTi*m*e CT/NG assay is not intended to replace culture and other methods (e.g., cervical exam) for diagnosis of urogenital infection. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- Use of the Abbott RealTi*m*e CT/NG assay is not approved for the evaluation of suspected sexual abuse contact tracings nor for other medico-legal indications.
- As with any diagnostic test, results from the Abbott RealTi*m*e CT/NG assay should be interpreted in conjunction with other clinical and laboratory findings.
- The Abbott RealTi*m*e CT/NG assay has not been validated for use with vaginal swab specimens collected by patients at home.
- The patient-collected vaginal swab specimen application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.

SPECIFIC PERFORMANCE CHARACTERISTCS

Analytical Sensitivity

The Limit of Detection (LOD) claim for the RealTi*m*e 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 RealTi*m*e 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 RealTi*m*e 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 10^7 NG target DNA copies per assay, or 1 x 10^7 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 RealTi*m*e 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 RealTi*m*e 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 Potentially Interfering Substances

The potential for interference in the Abbott RealTime CT/NG assay was assessed with substances that may be found in swab and/or urine specimens. Substances were diluted 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.

There was no assay interference observed in the presence of the substances listed in Table 1.

Table 1: 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

Assay interference may be observed in the presence of 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% in urine specimens and 1% in swab specimens.

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*m*e CT/NG assay (Table 2). 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 x 10^7 copies/assay. HBV DNA and HCV RNA were added directly into the PCR reaction at approximately 4 x 10^5 and 6 x 10^6 copies per reaction, respectively. All results were negative for both CT and NG.

Additionally, a total of 32 culture isolates were tested for potential cross reactivity in the Abbott RealTime assay. These included 27 organisms listed in Table 2, 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 10^6 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. Microorganisms / Viruses

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 enterica*
Bacteroides fragilis	*Human Papilloma Virus 18*	*Salmonella typhimurium*
Bacteroides ureolyticus	*Kingella denitrificans*	*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*
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.

Carryover

Potential carryover was determined by performing a study in which high copy CT positive samples were interspersed with negative samples arranged in a checkerboard pattern. The positive samples were CT DNA at a concentration of 107 copies/ml. The carryover rate is defined as the number of CT negative samples that are reported as positive or equivocal over the total number of CT-negative samples tested. Each run included 47 negative samples and 46 positive samples. A total of 14 runs were evaluated using two lots of the RealTi*m*e CT/NG amplification reagents on four *m*2000*sp* and *m*2000*rt* instrument pairs.

A total of 656 valid negative samples were evaluated for potential carryover effect. A total of 5 false positive and 1 equivocal results were observed. The carryover rate was 0.91%.

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.

Table 3: 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	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

[a] *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.
[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 0.960. 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.
[d] The total variability contains within-run, between-run, between-lot, and between-site variability.

Table 4: 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	13.32	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

[a] *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.
[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=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.
[d] The total variability contains within-run, between-run, between-lot, and between-site variability.

Clinical Study Results

Performance characteristics of the Abbott RealTi*m*e 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 RealTi*m*e 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 RealTi*m*e 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 RealTi*m*e 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 RealTi*m*e 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 RealTi*m*e 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.

Table 5: CT Clinical Sensitivity and Specificity (Female Specimens)

Specimen	Symptoms	n	True Positive	False Positive	True Negative	False Negative	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
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)

Table 6: CT Clinical Sensitivity and Specificity (Male Specimens)

Specimen	Symptoms	n	True Positive	False Positive	True Negative	False Negative	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
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)

Table 7: NG Clinical Sensitivity and Specificity (Female Specimens)

Specimen	Symptoms	n	True Positive	False Positive	True Negative	False Negative	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
Endocervical	Symptomatic	619	22	1	593	3	88.0 (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)

Table 8: NG Clinical Sensitivity and Specificity (Male Specimens)

Specimen	Symptoms	n	True Positive	False Positive	True Negative	False Negative	% Sensitivity (95% C.I.)	% Specificity (95% C.I.)
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)

Table 9: CT Analysis Per Patient Infected Status - **INFECTED FEMALE** Subjects

NAAT 1			NAAT 2		RealTi*m*e CT/NG				No. of Subjects		
									Symptomatic	Asymptomatic	
E	CCV	FU	E	FU	E	CCV	SCV	FU	(E/SCV/CCV/FU)	(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
+	+	+	–	+	+	+	+	+	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	+	+	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.

Table 10: CT Analysis Per Patient Infected Status - **NON-INFECTED FEMALE** Subjects

NAAT 1			NAAT 2		RealTi*me* 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.

Table 11: CT Analysis Per Patient Infected Status - **INFECTED MALE** Subjects

NAAT 1		NAAT 2	RealTi*me* 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.

Table 12: CT Analysis Per Patient Infected Status - **NON-INFECTED MALE** Subjects

NAAT 1		NAAT 2	RealTi*me* 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.

Table 13: NG Analysis Per Patient Infected Status - **INFECTED FEMALE** Subjects

Culture	NAAT 1			NAAT 2		RealTi*me* CT/NG				No. of Subjects		
E	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	+	+	+	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		
										Symptomatic	Asymptomatic	
E	E	CCV	FU	E	FU	E	CCV	SCV	FU	(E/SCV/CCV/FU)	(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.

Table 15: NG Analysis Per Patient Infected Status - **INFECTED MALE** Subjects

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
						Symptomatic	Asymptomatic	
MUS	MUS	MU	MU	MUS	MU	(MUS/MU)	(Urine Only)	Total
+	+	+	+	+	+	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

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

Table 16: NG Analysis Per Patient Infected Status - **NON-INFECTED MALE** Subjects

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
						Symptomatic	Asymptomatic	
MUS	MUS	MU	MU	MUS	MU	(MUS/MU)	(Urine Only)	Total
–	–	–	–	–	–	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.

Table 17: Prevalence of CT and/or NG By Collection Site: Symptomatic Female Endocervical Specimens

	Female Endocervical % Prevalence (# Positive / # Tested)					
Site[a]	CT+/NG+		CT+/NG–[b]		CT–/NG+[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)
ALL	2.3	(14/616)	7.6	(47/616)	1.6	(10/616)

[a] No evaluable results were available from Site 2.
[b] 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

	Clinician-Collected Vaginal Swab % Prevalence (# Positive / # Tested)						Self-Collected Vaginal Swab % Prevalence (# Positive / # Tested)					
Site[a]	CT+/NG+		CT+/NG–[b]		CT–/NG+[b]		CT+/NG+		CT+/NG–[b]		CT–/NG+[b]	
1	0.0	(0/40)	0.0	(0/40)	0.0	(0/40)	0.0	(0/41)	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)

[a] No evaluable results were available from Site 2.
[b] 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

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

[a] No evaluable results were available from Site 2.
[b] 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

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

[a] Male specimens were not collected from Site 1.
[b] No symptomatic male urethral swab specimens were available from Site 2 or 11.
[c] 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

	Urine % Prevalence (# Positive / # 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	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)

[a] Male specimens were not collected from Site 1.
[b] 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

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