510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K202408

B Applicant

Roche Molecular Systems, Inc.

C Proprietary and Established Names

cobas CTNG for use on cobas 6800/8800 systems

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QEP	Class II	21 CFR 866.3393 - Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections	MI - Microbiology
MKZ	Class I, reserved	21 CFR 866.3120 - Chlamydia serological reagents	MI - Microbiology
LSL	Class II	21 CFR 866.3390 - Neisseria spp. direct serological test reagents	MI - Microbiology
OOI	Class II	21 CFR 862.2570 - Instrumentation for clinical multiplex test systems	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

To expand the indications for use to include oropharyngeal and anorectal swab specimens to the intended use. There have been no changes made to the device to accommodate this claim expansion. The technical characteristics and performance of the cobas CT/NG for use on the cobas 6800/8800 systems are the same as the device cleared under K173887.

B Measurand:

Chlamydia trachomatis and *Neisseria gonorrhoeae* DNA

C Type of Test:

Nucleic acid extraction, purification and amplification assay (real-time polymerase chain reaction)

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The cobas CT/NG for use on the cobas 6800/8800 system is an automated, qualitative in vitro nucleic acid diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in male and female urine, clinician-instructed self-collected vaginal swab specimens (collected in a clinical setting), and clinician-collected vaginal swab specimens, endocervical swab specimens, oropharyngeal (throat) swab specimens and anorectal swab specimens all collected in cobas PCR Media (Roche Molecular Systems, Inc.), and cervical specimens collected in PreservCyt solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.

Ancillary Collection Kits:

The cobas PCR Media Dual Swab Sample Kit is used to collect and transport endocervical and vaginal swab specimens. The cobas PCR Media serves as a nucleic acid stabilizing transport and storage medium.

Note: This kit has been validated for use with the following tests:

- cobas CT/NG v2.0 Test (for use on cobas 4800 System)
- cobas CT/NG for use on cobas 6800/8800 Systems
- cobas TV/MG for use on the cobas 6800/8800 Systems

The cobas PCR Media Uni Swab Sample Kit is used to collect and transport human specimens. The cobas PCR Media serves as a nucleic acid stabilizing transport and storage medium.

Note: This kit has been validated for use with the following tests:

- cobas CT/NG v2.0 Test (for use on cobas 4800 System)
- cobas CT/NG for use on cobas 6800/8800 Systems
- cobas TV/MG for use on the cobas 6800/8800 Systems

- cobas Cdiff Test for use on the cobas 4800 System

The cobas PCR Urine Sample Kit is used to collect and transport urine specimens. The cobas PCR Media serves as a nucleic acid stabilizing transport and storage medium. Use this collection kit only with the following tests:

- cobas CT/NG v2.0 Test (for use on cobas 4800 System)
- cobas CT/NG for use on cobas 6800/8800 Systems
- cobas TV/MG for use on the cobas 6800/8800 Systems

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

cobas 6800/8800

IV Device/System Characteristics:

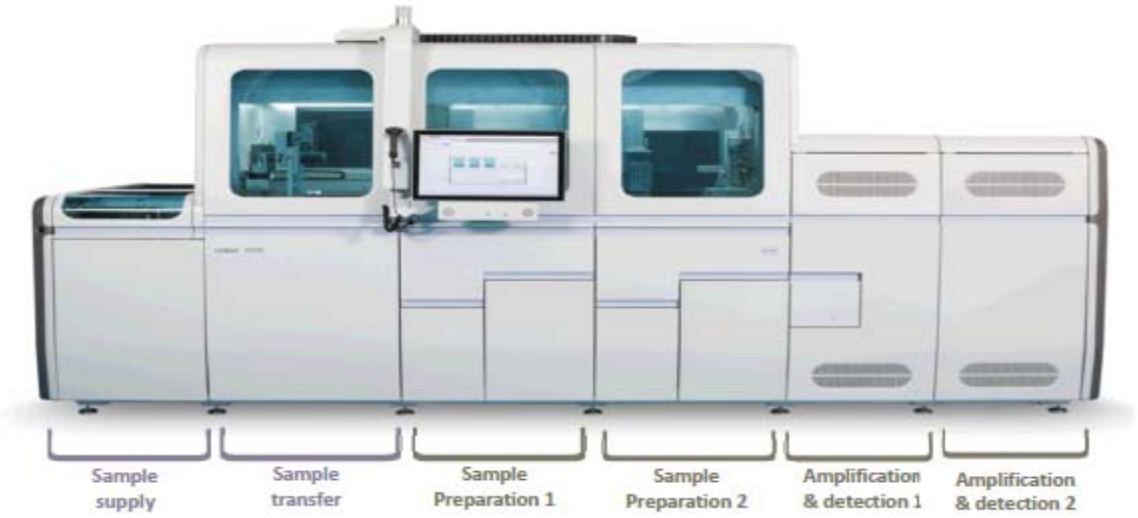
A Device Description:

The cobas CT/NG assay is a fully automated, qualitative real-time PCR assay performed on the cobas 6800 System and cobas 8800 System. cobas CT/NG enables the detection of CT/NG DNA in urogenital and extragenital specimens. Target-specific primers and two probes are used to detect but not discriminate between the CT cryptic plasmid and the ompA gene. Additionally, target-specific primers and two probes are used to detect but not discriminate between two conserved sequences in the NG DR-9 region. The DNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing.

There have been no changes made to the device, since 510(k) cleared under K173887, to accommodate this claim expansion to include oropharyngeal and anorectal swab specimens.

cobas 6800 System Instrument

cobas 8800 System Instrument



B Principle of Operation:

The cobas CT/NG assay is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The cobas 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data management is performed by the cobas 6800/8800 software which assigns test results for all tests as positive, negative, or invalid. Results can be reviewed directly on the system screen, exported, or printed as a report.

Nucleic acids from patient samples and internal control DNA (DNA-IC), added into the specimens to monitor for inhibition of nucleic acid isolation and amplification, are simultaneously extracted. In summary, bacterial nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acids bind to the silica surface of added

magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors, are removed with subsequent wash steps and purified nucleic acids are eluted from the magnetic glass particles with elution buffer at elevated temperature.

Selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers selected from highly conserved plasmid and genomic regions of CT and NG. A region on the CT cryptic plasmid and the ompA gene (dual target) and two conserved sequences of the NG DR-9 region are amplified. Selective amplification of DNA-IC is achieved by the use of sequence-specific forward and reverse primers which have no homology with either the CT or NG target regions. A thermostable DNA polymerase enzyme is used for PCR amplification. The target and DNA-IC sequences are amplified simultaneously utilizing a universal PCR amplification profile with predefined temperature steps and number of cycles.

The cobas CT/NG master mix contains two detection probes specific for the CT target sequences, two detection probes specific for the NG target sequences and one for the DNA-IC. The probes are labeled with target specific fluorescent reporter dyes allowing simultaneous detection of CT targets, NG targets, and DNA-IC in three different channels. When not bound to the target sequence, the fluorescent signal of the intact probes is suppressed by a quencher dye. During the PCR amplification step, hybridization of the probes to the specific single-stranded DNA template results in cleavage of the probe by the 5' to 3' exonuclease activity of the DNA polymerase resulting in separation of the reporter and quencher dyes and the generation of a fluorescent signal. With each PCR cycle, increasing amounts of cleaved probes are generated and the cumulative signal of the reporter dye increases concomitantly. Real-time detection and discrimination of PCR products is accomplished by measuring the fluorescence of the released reporter dyes for the CT and NG targets and DNA-IC, respectively.

C Instrument Description Information:

1. Instrument Name:

   cobas 6800/8800

2. Specimen Identification:

   cobas 6800/8800 analyzer supports multiple types of barcodes. Loaded samples are automatically moved for barcode scanning and processing.

3. Specimen Sampling and Handling:

   Specimens are collected using the appropriate ancillary kits (cobas PCR Media Dual Swab Sample Kit, cobas PCR Media Uni Swab Sample Kit, or cobas PCR Urine Sample Kit) or PreservCyt Solution as per defined instructions. Swab specimens containing a single swab in the cobas PCR Media tube can be directly processed on the cobas 6800/8800 Systems, or the swab may be removed prior to loading onto the instrument. Urine specimens must show a liquid level between two black indicator lines on the cobas PCR Media tube to proceed to testing. Cervical specimens in PreservCyt Solution are to be aliquoted into barcoded cobas PCR Secondary tubes for processing. Only racks of uncapped tubes may be loaded into the

Sample Supply Module of the cobas 6800/8800 Systems for testing. Specimen processing is fully automated.

4. Calibration:

No calibration is required by the user.

5. Quality Control:

Quality Controls are provided as an accessory and must be used in daily operation according to each laboratory's operating procedures.

V Substantial Equivalence Information:

A Predicate Device Name(s):

cobas CT/NG for use on cobas 6800/8800 systems

B Predicate 510(k) Number(s):

K173887

C Comparison with Predicate(s):

Device & Predicate Device(s):	**K202408**	**K173887**
Device Trade Name	cobas CT/NG for use on the cobas 6800/8800 systems	cobas CT/NG for use on the cobas 6800/8800 systems
General Device Characteristic Similarities		
Intended Use/Indications for Use	The cobas CT/NG for use on the cobas 6800/8800 system is an automated, qualitative in vitro nucleic acid diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in male and female urine, clinician-instructed self-collected vaginal swab specimens (collected in a clinical setting), and clinician-collected vaginal swab specimens,	The cobas CT/NG for use on the cobas 6800/8800 system is an automated, qualitative in vitro nucleic acid diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in male and female urine, clinician instructed self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected

		endocervical swab specimens, oropharyngeal (throat) swab specimens and anorectal swab specimens all collected in cobas PCR Media (Roche Molecular Systems, Inc.), and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.	vaginal swab specimens, and endocervical swab specimens, all collected in cobas PCR Media (Roche Molecular Systems, Inc.), and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.
Ancillary Sample Collection Kits		Same	The cobas PCR Media Dual Swab Sample Kit is used to collect and transport endocervical and vaginal swab specimens. The cobas PCR Media serves as a nucleic acid stabilizing transport and storage medium. The cobas PCR Media Uni Swab Sample Kit is used to collect and transport human specimens. The cobas PCR Media serves as a nucleic acid stabilizing transport and storage medium. The cobas PCR Urine Sample Kit is used to collect and transport urine specimens. The cobas PCR Media serves as a nucleic acid stabilizing transport and storage medium.
Analytical Targets	**CT**	Same	CT cryptic plasmid DNA CT ompA gene
	NG	Same	NG genomic DNA
Sample Preparation		Same	Automated extraction and purification of nucleic acids
Technology		Same	Real-Time PCR

Instrument	Same	cobas 6800/8800 systems
General Device Characteristic Differences		
Sample Types	1. Male and female urine, 2. Self-collected/clinician-collected vaginal swab specimens in cobas PCR Media, 3. Endocervical swab specimens in cobas PCR Media, 4. Cervical specimens in PreservCyt® solution 5. Oropharyngeal (throat) swab specimens in cobas PCR Media, 6. Anorectal swab specimens in cobas PCR Media,	1. Male and female urine, 2. Self-collected/clinician-collected vaginal swab specimens in cobas PCR Media, 3. Endocervical swab specimens in cobas PCR Media, 4. Cervical specimens in PreservCyt® solution

VI Standards/Guidance Documents Referenced:

None.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Note: Only results for oropharyngeal and anorectal specimens are shown in this section. For performance data pertaining to urogenital specimens, refer to K173887.

1. Precision/Reproducibility:

See K173887.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Cross-reactivity/Microbial interference

Potential cross-reactivity of the cobas CT/NG assay with microorganisms which may be present in patients' specimens at the oropharyngeal and anorectal collection sites was evaluated by testing 178 bacteria, fungi, protozoa and viruses in the respective clinical matrices. Multiple strains were tested for several organisms, including 20 representatives of non-*gonorrhoeae Neisseria* strains. Each negative matrix was created by pooling individual specimens (i.e., oropharyngeal swabs collected in cobas PCR media and anorectal swabs collected in cobas PCR media) that had tested negative for both CT and NG with the cobas CT/NG Test. The matrix pools were divided into two separate batches, where one batch was set aside as the negative background to be spiked with the cross-reactants, to evaluate specificity. The potentially cross-reacting microorganisms were spiked into each matrix to a concentration level of 10^6 units/mL (EB or CFU/mL) for bacteria and yeast, and 10^5 units/mL (as cells/mL for protozoa or as determined by $TCID_{50}$ Endpoint Dilution Assay for viruses). The other portion was used to spike with CT serovar D at 6 EB/mL and NG strain 2948 at 0.6 CFU/mL, followed by spiking with the same organism stocks (interferents) to evaluate potential microbial interference.

The analysis of the generated Ct values for the low positive samples (i.e., the difference between the baseline Ct values and the Ct values generated after the potential cross reactant was added) showed no evidence of microbial interference. The data also showed that there was no evidence of cross-reactivity with the microbial strains tested where all negative samples returned negative results after the addition of the potential cross-reactants. In summary, all tests returned expected results.

The following organisms were evaluated for cross-reactivity and microbial interference with the cobas CT/NG Test.

Microorganisms Tested for Analytical Specificity/Cross-reactivity

Achromobacter xerosis	*Fusobacterium nucleatum*	Norovirus**††
Acinetobacter baumannii ††	*Gardnerella vaginalis*	*Pantoea agglomerans*
Acinetobacter calcoaceticus	*Gemella haemolysans*	*Paracoccus denitrificans*
Acinetobacter lwoffi	*Giardia lamblia††*	*Parvinomas micra†*
Actinomyces israelii	*Haemophilus ducreyi*	*Peptostreptococcus anaerobius*
Adenovirus†	*Haemophilus influenzae*	*Peptostreptococcus asaccharolyticus*
Aerococcus viridans	*Helicobacter pylori*	*Peptostreptococcus magnus*
Aeromonas hydrophila	Herpes simplex virus I	*Plesiomonas shigelloides*
Aggregatibacter actinomycetemcomitans††	Herpes simplex virus II **	*Porphyromonas gingivalis†*
Alcaligenes faecalis	HPV16 *	*Prevotella bivia†††*

Anaerococcus prevotii††	Human influenza virus A†	*Prevotella oralis†*
Arcanobacterium haemolyticum†	Human influenza virus B†	*Propionibacterium acnes*
Atopobium vaginae	Human metapneumovirus†	*Proteus mirabilis*
Bacillus subtilis	*Kingella dentrificans*	*Proteus penneri*
Bacteriodes fragilis	*Kingella kingae*	*Proteus vulgaris*
Bacteroides caccae	*Klebsiella oxytoca*	*Providencia rettgeri*
Bacteroides ureolyticus	*Klebsiella pneumoniae*	*Providencia stuartii*
Bergeriella denitrificans	*Lactobacillus acidophillus*	*Pseudomonas aeruginosa*
Bifidobacterium adolescentis	*Lactobacillus brevis*	*Pseudomonas fluorescens*
Bifidobacterium breve	*Lactobacillus crispatus*	*Pseudomonas putida*
Bifidobacterium longum	*Lactobacillus jensenii*	*Rahnella aquatilis*
Blautia producta	*Lactobacillus lactis*	*Respiratory syncytial virus†*
Bordetella pertussis†	*Lactobacillus leichmannii*	*Rhinovirus**†
Branhamella catarrhalis	*Lactobacillus oris*	*Rhizobium radiobacter*
Brevibacterium linens	*Lactobacillus parabuchnerri*	*Rhodospirillum rubrum*
Campylobacter coli	*Lactobacillus reuteri*	*Saccharomyces cerevisiae*
Campylobacter jejuni	*Lactobacillus vaginalis*	*Salmonella choleraesuis*
Campylobacter rectus†	*Lactococcus lactis cremoris*	*Salmonella minnesota*
Candida albicans	*Legionella pneumophila*	*Salmonella typhimurium*
Candida glabrata	*Leuconostoc paramensenteroides*	*Serratia denitrificans*
Candida parapsilosis	*Listeria monocytogenes*	*Serratia marcescens*
Candida tropicalis	*Micrococcus luteus*	*Shigella dysenteriae*
Chlamydophila pneumoniae	*Moraxella catarrhalis†*	*Shigella flexneri ††*
Chlamydophila psittaci	*Moraxella lacunata*	*Shigella sonnei ††*
Chromobacter violaceum	*Moraxella osloensis*	*Staphylococcus aureus*
Citrobacter freundii	*Morganella morganii*	*Staphylococcus epidermidis*
Clostridioides difficile	*Mycobacterium smegmatis*	*Staphylococcus saprophyticus*
Clostridium perfringens	*Mycoplasma pneumoniae†*	*Streptococcus agalactiae*
Coronavirus†	*Mycoplasma genitalium***	*Streptococcus anginosus*

Corynebacterium diphtheriae †	*Mycoplasma hominis*	*Streptococcus bovis*
Corynebacterium genitalium	*Neisseria cinerea*	*Streptococcus dysgalactiae*
Corynebacterium xerosis	*Neisseria elongata subsp. elongata*	*Streptococcus equinis*
Cryptococcus neoformans	*Neisseria elongata subsp. nitroreducens*	*Streptococcus mitis*
Cytomegalovirus **	*Neisseria flava*	*Streptococcus mutans*
Deinococcus radiodurans	*Neisseria flavescens*	*Streptococcus pneumoniae*
Derxia gummosa	*Neisseria kochi*	*Streptococcus pyogenes*
Eikenella corrodens	*Neisseria lactamica*	*Streptococcus salivarius*
*Entamoeba histolytica**††	*Neisseria macacae*	*Streptococcus sanguis*
Enterobacter aerogenes	*Neisseria meningitides Serogroup W135*	*Streptomyces griseinus*
Enterobacter cloacae	*Neisseria meningitidis Serogroup A*	*Tannerella forsythia†*
Enterococcus avium	*Neisseria meningitidis Serogroup B*	*Treponema denticola†*
Enterococcus casseliflavus	*Neisseria meningitidis Serogroup C*	*Trichomonas vaginalis*
Enterococcus faecalis	*Neisseria meningitidis Serogroup D*	*Trueperella pyogenes*
Enterococcus faecium	*Neisseria meningitidis Serogroup Y*	*Ureaplasma urealyticum*
Enterovirus**††	*Neisseria mucosa*	*Veillonela parvula*
Erysipelothrix rhusiopathiae	*Neisseria perflava*	*Vibrio cholerae*
Escherichia coli	*Neisseria polysaccharea*	*Vibrio parahaemolyticus*
Escherichia fergusonii	*Neisseria sicca*	*Yersinia enterocolitica*
Flavobacterium meningosepticum	*Neisseria subflava*	-
Fusobacterium necrophorum†	*Neisseria weaverii*	-

* HPV16 was tested as CaSki cells

** Organism was tested at a concentration of 1 x 10^4 Units/mL

*** Organism was tested at a concentration of 1 x 10^5 CFU/mL

† Tested in oropharyngeal swabs only

†† Tested in anorectal swabs only

††† Tested in oropharyngeal and anorectal swabs only

Analytical Interference

The interference studies (endogenous and exogenous interferents) included four test samples for each specimen type, oropharyngeal swabs and rectal swabs, each collected in cobas PCR media.

- CT/NG positive specimen matrix spiked with each interfering substance
- CT/NG negative specimen matrix spiked with each interfering substance
- CT/NG negative specimen matrix without interfering substance
- CT/NG positive specimen matrix without interfering substance

CT serovars D and I, and NG strains 2948 and 891 at 3x LoD concentrations were used to prepare the positive specimens in each matrix for this study.

Each sample was tested in five replicates with each interferent.

a. Endogenous Substances

Interference from the following endogenous substances, potentially present at the oropharyngeal and rectal sites of collection, was evaluated. No evidence of interference was noted with the following substances at the concentrations shown.

Endogenous Substances Tested for Interference in Oropharyngeal and Anorectal Samples

Interferent	Oropharyngeal Swab	Anorectal Swab
Mucus (% w/v)	1.0%	1.0%
Peripheral Blood Mononuclear Cells (PBMCs as cells/mL)	1.00E+06	1.00E+06
Saliva (% w/v)	2.0%	NT
Stool (% w/v)	NT	0.3%*
Whole Blood (% v/v)	10%	10%

*Stool caused interference at 0.4% (w/v) in anorectal swab specimens collected in cobas PCR Media
NT = Not Tested

b. Exogenous Substances

The performance of the cobas CT/NG Test was evaluated when testing oropharyngeal and rectal swabs in the presence of potentially interfering exogenous substances, e.g., over-the-counter products, that may be found at the respective sites of collection. The interferents were spiked at levels expected through typical product use. No evidence of interference was noted with the following substances at the concentrations shown.

Substances Tested for Interference in Oropharyngeal Samples

Product Name	Oropharyngeal Swabs (mg/mL)
Cepacol Maximum Strength Throat Drop Lozenges	7.5
Colgate Total Toothpaste	Residual *

Product Name	Oropharyngeal Swabs (mg/mL)
Robitussin Cough / Chest Congestion Cough Syrup	4.4
Listerine Ultra Clean Antiseptic Mouthwash	15.8
Scope Mouthwash	20.1
Sucrets Complete Lozenges	5.8
Vicks - Chloraseptic Sore Throat Spray Menthol	18.1
Zicam Oral Mist	12.2

* Amount of toothpaste present on a swab collected immediately following a subject's brushing of their teeth

Substances Tested for Interference in Anorectal Samples

Product Name	Anorectal Swabs (mg/mL)
ANUSOL® Plus Ointment	5.3
CB Fleet® Mineral Oil Enema	4.8
Doproct Suppositories/ Hemorrhoidal Treatment	4.9
K-Y Jelly	5.0
Lotrimin Antifungal Cream	4.2
Preparation H Hemorrhoidal Ointment	4.9
PREPARATION H Hemorrhoidal Suppositories	6.0
Driminate Generic for Dramamine Motion Sickness - Major Pharmaceuticals	0.6
Target – Triple Paste Diaper Rash Ointment	4.3
Tucks Medicated Cooling Hemorrhoidal Pads	35.6
Vaseline Original Petroleum Jelly	4.7

4. Assay Reportable Range:

Not applicable.

5. Sample Stability

The following specimen types were included in this study:

- Oropharyngeal swabs collected in cobas PCR media
- Anorectal swabs collected in cobas PCR media

For each matrix, individual specimens that had tested negative for both CT and NG with the cobas® 6800/8800 CT/NG Test were pooled to prepare test samples. Positive samples were prepared by spiking individual CT and NG positive specimens into the negative samples to produce Ct values of approximately 35 for both CT and NG, which correspond to concentrations of ~3X the limit of detection of the test. Five pools of positive samples and five pools of negative samples were prepared. Each sample pool was then split into two primary specimen containers which were filled to the volume of a freshly collected specimen, and placed into storage at 2-8°C

and 32°C. The samples (5 positive and 5 negative) were tested at time 0 (baseline), and then after 3 months, 6 months, and 12 months after storage. Each timepoint was tested at least one day beyond the scheduled test date within its calendar month. There was no evidence of deterioration in positive samples based on the Ct values generated over the period of 12 months, as compared to the Ct values generated at time 0. All negative specimens tested negative at all timepoints. The data showed that oropharyngeal and anorectal swab specimens may be stored up to 12 months at either 2-8°C or 32ºC prior to testing with the cobas CT/NG test.

6. Detection Limit:

The limit of detection of the cobas CT/NG assay, testing anorectal and oropharyngeal swabs was evaluated by testing 3 reagent lots, 3 sample dilution series and 4 cobas® 6800/8800 Systems. Testing included 23-30 replicates for each target positive level per reagent lot. The resulting data were analyzed to identify the lowest target concentration (Limit of Detection) that resulted in ≥ 95 % positive rate.

The following specimen types were included in this study:

- Oropharyngeal swabs collected in cobas PCR media
- Anorectal swabs collected in cobas PCR media

Negative background was prepared for each specimen type by pooling individual specimens that had tested negative for both CT and NG with the cobas® 6800/8800 CT/NG Test.

Quantified stocks of *Chlamydia trachomatis,* serovars D and I, and two strains of *Neisseria gonorrhoeae (*2948 (ATCC 19424) and 891) were used to produce panels in each specimen type. Each panel consisted of 5 target positive levels prepared from three independent dilution series.

Test Panels used in the Limit of Detection Study

Organism	Level 1		Level 2		Level 3		Level 4		Level 5	
CT Serovar D	12	EB/mL	4.0	EB/mL	2.0	EB/mL	1.0	EB/mL	0.40	EB/mL
NG #2948	1.2	CFU/mL	0.4	CFU/mL	0.2	CFU/mL	0.1	CFU/mL	0.04	CFU/mL
CT Serovar I	60	EB/mL	20	EB/mL	10	EB/mL	5.0	EB/mL	2.0	EB/mL
NG #891	0.48	CFU/mL	0.16	CFU/mL	0.08	CFU/mL	0.04	CFU/mL	0.016	CFU/mL

EB = Elementary Bodies
CFU = Colony Forming Unit

For each target, specimen type, and reagent lot, the LoD was calculated using Probit analysis and the LoD was confirmed by testing at least 23 replicates of each dilution with three lots of reagents.

The final LoD claimed is the lowest concentration level where the detection rate was ≥ 95%, as defined by the worst performing lot tested. The summary of results is shown below.

Analytical Sensitivity (Limit of Detection) for Oropharyngeal and Anorectal Specimens

Matrix	Serovar D		Serovar I		NG 2948		NG 891	
	Mean Ct Value	EB/mL	Mean Ct Value	EB/mL	Mean Ct Value	CFU/mL	Mean Ct Value	CFU/mL
Oropharyngeal Swabs	37.3	2	36.5	40	38.0	0.2	37.3	0.08
Anorectal Swabs	37.2	2	37.2	20	37.0	0.2	37.2	0.08

EB = Elementary Body; CFU = Colony Forming Unit

7. Inclusivity

Inclusivity and verification of the LoD were performed for 14 additional CT serovars and an additional 43 independently isolated strains of NG using one lot of reagents. The following serovars were included in the study: A, B, Ba, C, E, F, G, H, j, K, LGV Type 1, LGV Type 2, LGV Type 3, and nvCT (the "Swedish variant"). Testing was performed using CT and NG cultures diluted into pools of negative specimens; each organism was tested in both, rectal and in oropharyngeal matrix. All CT serovars were tested at a concentration of 40 EB/mL, each in 20 replicates, and all tests generated positive results (100% positivity). Of the 43 NG strains tested, 39 were detected at 0.4 CFU/mL concentration in ≥19 out of 20 replicates in both matrices. Four NG strains were re-titered and re-tested at 1.0 CFU/mL, resulting in 100% detection rate.

8. Assay Cut-Off:

See K173887

9. Carry-Over:

See K173887

10. Matrix Comparison/Bridging Study

Because of the unique clinical study design, which included four manufacturers, where all specimens were collected in a common collection vial containing 10 mL PreservCyt medium, followed by aliquoting into each of the manufacturer's collection/transport tube, the sponsor compared analytical sensitivity of the cobas CT/NG when using swab samples collected in PreservCyt Solution and those collected with the cobas PCR Media Uni Swab Sample Kit. A bridging study was conducted to demonstrate that detection of low levels of CT and NG in extragenital swab samples collected with the cobas PCR Media Uni Swab Sample Kit was at least as sensitive as in swab samples collected in PreservCyt.

The following sample matrices were tested in this study:

- Oropharyngeal swabs collected and placed into PreservCyt Solution
- Oropharyngeal swabs collected using the cobas PCR Media Uni Swab Sample Kit
- Anorectal swabs collected and placed into PreservCyt Solution
- Anorectal swabs collected using the cobas PCR Media Uni Swab Sample Kit

Negative background for each sample matrix was prepared by pooling individual specimens that had tested negative for both CT and NG with the cobas 6800/8800 CT/NG Test. Quantified stocks of *Chlamydia trachomatis* serovar D and *Neisseria gonorrhoeae* strain 2948 (ATCC 19424) were spiked concurrently into each sample matrix. Each matrix panel consisted of 5 target positive levels and one negative level as shown in the table below. Each sample was tested in 20 replicates.

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CT and NG Concentrations (each matrix panel)

Organism	Level 1 (10x LOD)	Level 2 (5x LOD)	Level 3 (2.5x LOD)	Level 4 (1.25x LOD)	Level 5 (0.625x LOD)	Level 6 (Negative)
CT	20 EB/mL (3 IFU/mL)	10 EB/mL (1.5 IFU/mL)	5 EB/mL (0.75 IFU/mL)	2.5 EB/mL (0.38 IFU/mL)	1.25 EB/mL (0.19 IFU/mL)	Not spiked
NG	2 CFU/mL	1 CFU/mL	0.5 CFU/mL	0.25 CFU/mL	0.13 CFU/mL	Not spiked

The lowest concentration which resulted in ≥95% detection rate (≥19/20) for each sample type in each collection medium is shown below.

Summary of results: Limit of Detection in Oropharyngeal and Anorectal Swabs

Organism	Oropharyngeal				Rectal	
	PCR Media	PreservCyt			PCR Media	PreservCyt
	≥95% Detection Level				≥95% Detection Level	
CT	2.5 EB/mL (0.38 IFU/mL)	10 EB/mL (1.5 IFU/mL)			2.5 EB/mL (0.38 IFU/mL)	20 EB/mL (3 IFU/mL)
NG	0.25 CFU/mL	1 CFU/mL			0.5 CFU/mL	2 CFU/mL

The study showed that the cobas CT/NG assay is more sensitive for the detection of CT and NG when testing extragenital swab samples (oropharyngeal/throat and anorectal/rectal) collected with the cobas PCR media as compared to those collected in PreservCyt solution. The superior sensitivity of the assay when using cobas PCR media rather than the PreservCyt collection media indicates no risk of a lower sensitivity for detection of CT and NG in a clinical setting than was demonstrated in the clinical study.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See Clinical Studies section below.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

The clinical performance of the cobas CT/NG test for the detection of *C. trachomatis* and *N. gonorrhoeae* in oropharyngeal (throat) and anorectal (rectum) swab specimens was established in a multi-site, prospective collection. The clinical study was uniquely designed, in collaboration and agreement between academic institutions and FDA, to facilitate the evaluation of assay performance for the detection of CT and NG infections in extragenital specimens by simultaneous comparison of the performance among four previously FDA-cleared NAATs for the detection of CT and NG in urogenital specimens.

Eight diverse clinic sites (STD, HIV, Family Planning, and STD Research), located at geographically distributed locations, were utilized for sample collection. There were 2390 subjects available for testing, representing sexually active men and women, ranging in age from 15 to 77 years old. The study population consisted of 1256 males, 1108 females, and 26 transgender individuals. Both symptomatic and asymptomatic individuals were included in the study population following informed consent.

Specimens were tested for CT and NG using cobas CT/NG and three commercially available NAATs. All tests were run according to the respective manufacturers' Instructions for Use. For each subject enrolled in the study, three swab specimens were collected from each anatomic site (rectum and throat) using the Specimen Collection Swab from the Abbott *m*ulti-Collect™ Specimen Collection Kit. Swabs from each anatomical site were subsequently placed into a common collection vial containing 10 mL PreservCyt medium. Samples were sent to a central aliquoting laboratory, where they were vortexed and transferred into each of the four manufacturer's collection/transport tube prior to being transported to a testing laboratory.

The clinical performance of cobas CT/NG testing oropharyngeal and rectal specimens was determined by comparing the results obtained with the cobas CT/NG Test to a site-specific Infection Status (IS) derived by algorithm of results from the three comparator NAATs. The anatomic site was considered to be infected if at least two of the three comparator assays, were positive (2/3 rule). The three comparator NAATs, referred to as A, B, and C in this document, were identified in the marketing submission to FDA.

Comparator Algorithm for Determination of Infection Status for Each Specimen Type

NAAT A	NAAT B	NAAT C	IS Interpretation
+	+	+	+
+	+	-	+
+	-	+	+
-	+	+	+
U	+	+	+
+	U	+	+
+	+	U	+
+	-	-	-

NAAT A	NAAT B	NAAT C	IS Interpretation
-	+	-	-
-	-	+	-
-	-	-	-
+	+	+	+
+	+	-	+
+	-	+	+
-	+	+	+
+	-	-	-
-	+	-	-
-	-	+	-
-	-	-	-
U	-	-	-
-	U	-	-
-	-	U	-
+	U	-	U
+ or -	U	U	U

IS = Infection status; U = Uninterpretable test result.
+ denotes Positive; - denotes Negative;

Note: Uninterpretable test results occurred when retesting of invalid or equivocal results failed to yield a positive or negative result.

A total of 2,439 subjects were consented to participate in this study, however, a total of 49 subjects were excluded, based on exclusion/inclusion criteria, that led to a total subject enrollment of 2,390.

Of the 2,390 subjects contributing specimens, there were 2365 rectal swabs and 2382 oropharyngeal swabs submitted for testing (rectal specimens from 25 subjects and oropharyngeal swabs from 8 subjects were either not collected or not aliquoted).

A total of 4794 tests were initially performed on the cobas instruments. Among those, there were 22 specimens that yielded no results in the initial run. Of those, 20 samples were re-tested of which 19 returned valid results. There were four final invalid results due to processing errors. Therefore, in total, 4814 tests were performed on the cobas instruments. The rate of invalid results observed in the study was 0.48% (23/4814, with 95% CI of 0.32%-0.72%).

1. *Chlamydia trachomatis*: Clinical Performance of the cobas CT/NG Test in Extragenital Specimens.

Of the 2365 anorectal (rectal) swabs submitted for testing, 12 samples were excluded from final data analysis due to protocol deviations and 18 subjects had uninterpretable comparator results, leaving 2,335 evaluable samples for inclusion in data analysis.

Similarly, of the 2382 oropharyngeal swabs submitted for testing, 11 samples were excluded from final data analysis due to protocol deviations, three oropharyngeal swabs were excluded due to the lack of final valid results from the cobas CT/NG test, and 23 subjects had uninterpretable comparator results, leaving 2,345 evaluable samples for inclusion in data analysis.

***Chlamydia trachomatis*: Summary of Infection Status Interpretation for Anorectal and Oropharyngeal Specimens**

Specimen Type[a]	NAAT A	NAAT B	NAAT C	IS[b] Interpretation	cobas CT/NG	SS[c] Symp[d]	SS[c] Asymp[d]	SS[c] Unkn[d]	Total
AR	Inv	+	+	Positive	+	1	3	0	4
AR	-	+	+	Positive	-	0	3	0	3
AR	-	+	+	Positive	+	4	12	0	16
AR	+	-	+	Positive	-	0	1	0	1
AR	+	+	-	Positive	+	1	0	0	1
AR	+	+	+	Positive	-	2	1	0	3
AR	+	+	+	Positive	+	47	68	0	115
AR				**Total Positive**		**55**	**88**	**0**	**143**
AR	Inv	-	-	Negative	-	29	45	1	75
AR	-	NA	-	Negative	-	7	2	3	12
AR	-	NA	-	Negative	+	0	1	0	1
AR	-	Inv	-	Negative	-	3	3	0	6
AR	-	-	Inv	Negative	-	0	1	0	1
AR	-	-	Inv	Negative	+	1	0	0	1
AR	-	-	-	Negative	-	635	1,411	13	2,059
AR	-	-	-	Negative	+	5	2	0	7
AR	-	-	+	Negative	-	4	12	0	16
AR	-	-	+	Negative	+	0	6	0	6
AR	-	+	-	Negative	-	1	5	0	6
AR	-	+	-	Negative	+	1	1	0	2
AR				**Total Negative**		**686**	**1,489**	**17**	**2,192**
OP	Inv	+	+	Positive	+	0	1	0	1
OP	-	+	+	Positive	+	1	2	0	3
OP	+	+	-	Positive	+	0	1	0	1
OP	+	+	+	Positive	+	8	15	0	23
OP				**Total Positive**		**9**	**19**	**0**	**28**
OP	Inv	-	-	Negative	-	32	46	1	79
OP	-	NA	-	Negative	-	5	7	2	14
OP	-	Inv	-	Negative	-	1	6	0	7
OP	-	-	Inv	Negative	-	1	0	0	1
OP	-	-	-	Negative	-	679	1,486	14	2,179
OP	-	-	-	Negative	+	2	0	0	2
OP	-	-	+	Negative	-	13	16	0	29
OP	-	+	-	Negative	-	1	1	0	2
OP	-	+	-	Negative	+	0	2	0	2
OP	+	-	-	Negative	-	1	1	0	2
OP				**Total Negative**		**735**	**1,565**	**17**	**2,317**

[a]AR = Anorectal; OP=Oropharyngeal
[b] IS = Infection Status.
[c]SS = Symptom Status;
[d]Symp = Symptomatic, Asymp = Asymptomatic, Unkn = Unknown symptom status.

Note: NA = Not available, Inv = Invalid.

Note: Infection Status (IS) is determined for each specimen type. The IS of a sample was established by the concordance results from at least 2 out of 3 comparator assays (NAAT A, NAAT B, NAAT C). If one of the comparator assays is Uninterpretable/Invalid/Failed, the two remaining assays must be concordant to define the IS as Positive (+) or Negative (-). Any other combination of Uninterpretable/Invalid/Failed and valid results are excluded from the analyses.

Note: Of the 2,365 contributing subjects for Rectum, 18 subjects had CT uninterpretable IS (3 samples were discordant between the two available comparator assay results). Similarly, of the 2,382 contributing subjects for Oropharyngeal, 23 subjects had CT uninterpretable IS (7 samples were discordant between the two available comparator assay results).
Note: Any IS interpretation that is Uninterpretable/Invalid/Failed/Protocol deviations are excluded from performance analyses.

The overall point estimate sensitivity of cobas CT/NG for CT detection in anorectal specimens was 95.1% with a 95% CI of 90.2% to 97.6%. The overall point estimate specificity of cobas CT/NG for CT detection in anorectal specimens was 99.2% with a 95% CI of 98.8% to 99.5%.

***C. trachomatis* Clinical Performance in Anorectal Specimens**

CT in Rectal Swabs		Infection Status (composite algorithm)	
		Positive	Negative
Cobas CT/NG Test	Positive	136	17
	Negative	7	2175
	Total	143	2192
Sensitivity: 95.1% (136/143; 95% CI: (90.2%-97.6%)			
Specificity: 99.2% (2175/2192); 95% CI: (98.8%-99.5%)			

The overall point estimate sensitivity of cobas CT/NG for CT detection in oropharyngeal specimens was 100% with a 95% CI of 87.9% to 100%. The overall point estimate specificity of cobas CT/NG for CT detection in oropharyngeal specimens was 99.8% with a 95% CI of 99.6% to 99.9%.

***C. trachomatis* Clinical Performance in Oropharyngeal Specimens**

CT in Throat Swabs		Infection Status (composite algorithm)	
		Positive	Negative
Cobas CT/NG Test	Positive	28	4
	Negative	0	2313
	Total	28	2317
Sensitivity: 100.0% (28/28); 95% CI: (87.9%-100.0%)			
Specificity: 99.8% (2313/2317); 95% CI: (99.6%-99.9%)			

The cobas CT/NG clinical performance for *C. trachomatis*, by sample type and symptom status, is shown below.

***Chlamydia trachomatis*: Clinical Performance in Extragenital Specimens, by Sample Type and Symptom Status**

Sample Type[a]	Symptom Status[b]	Total (N)	SENS	95% Score CI	SPEC	95% Score CI
AR	Symp	741	96.4% (53/55)	(87.7%, 99.0%)	99.0% (679/686)	(97.9%, 99.5%)
AR	Asymp	1,577	94.3% (83/88)	(87.4%, 97.5%)	99.3% (1479/1489)	(98.8%, 99.6%)
AR	Unknown	17	NE	NE	100.0% (17/17)	(81.6%, 100.0%)
AR	Overall	2,335	95.1% (136/143)	(90.2%, 97.6%)	99.2% (2175/2192)	(98.8%, 99.5%)
OP	Symp	744	100.0% (9/9)	(70.1%, 100.0%)	99.7% (733/735)	(99.0%, 99.9%)
OP	Asymp	1,584	100.0% (19/19)	(83.2%, 100.0%)	99.9% (1563/1565)	(99.5%, 100.0%)
OP	Unknown	17	NE	NE	100.0% (17/17)	(81.6%, 100.0%)
OP	Overall	2,345	100.0% (28/28)	(87.9%, 100.0%)	99.8% (2313/2317)	(99.6%, 99.9%)

[a]AR = Anorectal; OP=Oropharyngeal

[b]Symp = Symptomatic, Asymp = Asymptomatic, Unkn = Unknown symptom status

Note: CI = Confidence Interval NE = Non-estimable

2. *Neisseria gonorrhoeae*: Clinical Performance of the cobas CT/NG Test in Extragenital Specimens.

Of the 2365 anorectal (rectal) swabs submitted for testing, 12 samples were excluded from final data analysis due to protocol deviations and 15 subjects had uninterpretable comparator results, leaving 2,338 evaluable samples for inclusion in data analysis.

Similarly, of the 2382 oropharyngeal swabs submitted for testing, 11 samples were excluded from final data analysis due to protocol deviations, three oropharyngeal swabs were excluded due to the lack of final valid results from the cobas CT/NG test, and 19 subjects had uninterpretable comparator results, leaving 2,349 evaluable samples for inclusion in data analysis.

Neisseria gonorrhoeae: Summary of Infection Status Interpretation for Anorectal and Oropharyngeal Specimens

Specimen Type[a]	NAAT A	NAAT B	NAAT C	IS[b] Interpretation	cobas CT/NG	SS[d] Symp[c]	SS[d] Asymp[c]	SS[d] Unkn[c]	Total
AR	Inv	+	+	Positive	+	2	0	0	2
AR	-	+	+	Positive	-	1	0	0	1
AR	-	+	+	Positive	+	3	4	0	7
AR	+	NA	+	Positive	+	0	1	0	1
AR	+	Inv	+	Positive	+	0	1	0	1
AR	+	-	+	Positive	+	0	1	0	1
AR	+	+	+	Positive	+	37	50	1	88
AR				**Total Positive**		**43**	**57**	**1**	**101**
AR	Inv	-	-	Negative	-	27	50	1	78
AR	Inv	-	-	Negative	+	1	0	0	1
AR	-	NA	-	Negative	-	7	2	3	12
AR	-	Inv	-	Negative	-	3	2	0	5
AR	-	-	-	Negative	-	646	1,461	12	2,119
AR	-	-	-	Negative	+	3	3	0	6
AR	-	-	+	Negative	-	5	0	0	5
AR	-	-	+	Negative	+	6	1	0	7
AR	-	+	-	Negative	-	0	2	0	2
AR	+	-	-	Negative	-	0	1	0	1
AR	+	-	-	Negative	+	1	0	0	1
AR				**Total Negative**		**699**	**1,522**	**16**	**2,237**
OP	Inv	+	+	Positive	+	1	1	0	2
OP	-	+	+	Positive	+	9	8	0	17
OP	+	NA	+	Positive	+	0	1	0	1
OP	+	Inv	+	Positive	+	0	1	0	1
OP	+	-	+	Positive	+	1	2	0	3
OP	+	+	-	Positive	+	0	1	0	1
OP	+	+	+	Positive	+	41	30	0	71
OP				**Total Positive**		**52**	**44**	**0**	**96**
OP	Inv	-	-	Negative	-	30	53	1	84
OP	-	NA	-	Negative	-	5	6	2	13
OP	-	Inv	-	Negative	-	0	5	0	5
OP	-	-	Inv	Negative	-	2	0	0	2
OP	-	-	Inv	Negative	+	1	0	0	1
OP	-	-	-	Negative	-	631	1,452	13	2,096
OP	-	-	-	Negative	+	6	7	1	14
OP	-	-	+	Negative	-	4	3	0	7
OP	-	-	+	Negative	+	4	4	0	8
OP	-	+	-	Negative	-	5	15	0	20
OP	-	+	-	Negative	+	0	1	0	1
OP	+	-	-	Negative	-	1	0	0	1
OP	+	-	-	Negative	+	0	1	0	1
OP				**Total Negative**		**689**	**1,547**	**17**	**2,253**

[a]AR = Anorectal; OP = Oropharyngeal.
[b]IS= Infection Status
[c]Symp =Symptomatic, Asymp = Asymptomatic, Unkn = Unknown symptom status.
[d]SS=Symptom Status

Note: NA = Not available, Inv = Invalid.

Note: Infection Status (IS) is determined for each specimen type. The IS of a sample was established by the concordance results from at least 2 out of 3 comparator assays (NAAT A, NAAT B, NAAT C). If one of the comparator assays is Uninterpretable/Invalid/Failed, the two remaining assays must be concordant to define the IS as Positive (+) or Negative (-). Any other combination of Uninterpretable/Invalid/Failed and valid results are excluded from the analyses.

Note: Of the 2,365 contributing subjects for Rectum, 15 subjects had NG uninterpretable IS. Similarly, of the 2,382 contributing subjects for Oropharyngeal, 19 subjects had NG uninterpretable IS (4 samples were discordant between the two available comparator assay results).

Note: Any IS interpretation that is Uninterpretable/Invalid/Failed/Protocol deviations are excluded from performance analyses.

The overall point estimate sensitivity of cobas CT/NG for NG detection in anorectal specimens was 99.0% with a 95% CI of 94.6% to 99.8%. The overall point estimate specificity of cobas CT/NG for NG detection in anorectal specimens was 99.3% with a 95% CI of 98.9% to 99.6%.

***N. gonorrhoeae* Clinical Performance in Anorectal Specimens**

NG in Rectal Swabs		Infection Status (composite algorithm)	
		Positive	Negative
Cobas CT/NG Test	Positive	100	15
	Negative	1	2222
Total		101	2237
Sensitivity: 99.0% (100/101); 95% CI: (94.6%-99.8%)			
Specificity: 99.3% (2222/2237); 95% CI: (98.9%-99.6%)			

The overall point estimate sensitivity of cobas CT/NG for NG detection in oropharyngeal specimens was 100% with a 95% CI of 96.2% to 100%. The overall point estimate specificity of cobas CT/NG for NG detection in oropharyngeal specimens was 98.9% with a 95% CI of 98.4% to 99.3%.

***N. gonorrhoeae* Clinical Performance in Oropharyngeal Specimens**

NG in Throat Swabs		Infection Status (composite algorithm)	
		Positive	Negative
Cobas CT/NG Test	Positive	96	25
	Negative	0	2228
Total		96	2253
Sensitivity: 100.0% (96/96); 95% CI: (96.2%-100.0%)			
Specificity: 98.9% (2228/2253); 95% CI: (98.4%-99.3%)			

The cobas CT/NG clinical performance for *N. gonorrhoeae*, by sample type and symptom status, is shown below.

***N. gonorrhoeae*: Clinical Performance in Extragenital Specimens, by Sample Type and Symptom Status**

Sample Type[a]	Symptom Status[b]	Total (N)	SENS	95% Score CI	SPEC	95% Score CI
AR	Symp	742	97.7% (42/43)	(87.9%, 99.6%)	98.4% (688/699)	(97.2%, 99.1%)
AR	Asymp	1,579	100.0% (57/57)	(93.7%, 100.0%)	99.7% (1518/1522)	(99.3%, 99.9%)
AR	Unknown	17	100.0% (1/1)	(20.7%, 100.0%)	100.0% (16/16)	(80.6%, 100.0%)
AR	Overall	2,338	99.0% (100/101)	(94.6%, 99.8%)	99.3% (2222/2237)	(98.9%, 99.6%)
OP	Symp	741	100.0% (52/52)	(93.1%, 100.0%)	98.4% (678/689)	(97.2%, 99.1%)
OP	Asymp	1,591	100.0% (44/44)	(92.0%, 100.0%)	99.2% (1534/1547)	(98.6%, 99.5%)
OP	Unknown	17	NE	NE	94.1% (16/17)	(73.0%, 99.0%)
OP	Overall	2,349	100.0% (96/96)	(96.2%, 100.0%)	98.9% (2228/2253)	(98.4%, 99.2%)

[a]AR = Anorectal; OP=Oropharyngeal
[b]Symp = Symptomatic, Asymp = Asymptomatic, Unkn = Unknown symptom status
Note: CI = Confidence Interval, NE = Non-estimable

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The observed positivity rate for *C. trachomatis* during the clinical study, as determined by the cobas CT/NG Test, was 1.4% and 6.6% for oropharyngeal and anorectal swabs, respectively. The positivity rate for CT for each site and overall is shown below.

CT Positivity Rate as Determined by cobas CT/NG for Oropharyngeal and Anorectal Specimens

Collection Site ID	OP[a] No. of Samples Tested with cobas valid results (N)	OP[a] No. of Positive Results by cobas CT/NG (n)	OP[a] Positivity Rate (%)[c] (n/N)	AR[b] No. of Samples Tested (N)	AR[b] No. of Positive Results by cobas CT/NG (n)	AR[b] Positivity Rate (%)[c] (n/N)
10	170	2	1.2%	170	6	3.5%
11	90	1	1.1%	89	4	4.5%
12	388	6	1.5%	385	49	12.7%
13	171	1	0.6%	170	3	1.8%
14	259	2	0.8%	256	18	7.0%

Collection Site ID	OP[a] No. of Samples Tested with cobas valid results (N)	OP[a] No. of Positive Results by cobas CT/NG (n)	OP[a] Positivity Rate (%)[c] (n/N)	AR[b] No. of Samples Tested (N)	AR[b] No. of Positive Results by cobas CT/NG (n)	AR[b] Positivity Rate (%)[c] (n/N)
15	433	10	2.3%	426	36	8.5%
16	394	6	1.5%	395	19	4.8%
17	457	5	1.1%	456	21	4.6%
Total	2362	33	1.4%	2347	156	6.6%

a OP= Oropharyngeal / Throat specimen type.
b AR= Anorectal specimen type.
c Positivity Rate (%) = (Number of valid Positive cobas results/Total number of cobas valid results) x100.

Similarly, the observed positivity rate for *N. gonorrhoeae,* as determined by the cobas CT/NG test, was 5.2% and 4.9% for oropharyngeal and anorectal swabs, respectively. The positivity rate for NG for each site and overall is shown below.

NG Positivity Rate as Determined by cobas CT/NG for Oropharyngeal and Anorectal Specimens

Collection Site ID	OP[a] No. of Samples Tested with cobas valid results (N)	OP[a] No. of Positive Results by cobas CT/NG (n)	OP[a] Positivity Rate (%)[c] (n/N)	AR[b] No. of Samples Tested (N)	AR[b] No. of Positive Results by cobas CT/NG (n)	AR[b] Positivity Rate (%)[c] (n/N)
10	170	6	3.5%	170	4	2.4%
11	90	7	7.8%	89	4	4.5%
12	388	51	13.1%	385	48	12.5%
13	171	0	0 %	170	3	1.8%
14	259	21	8.1%	256	18	7.0%
15	433	14	3.2%	426	15	3.5%
16	394	10	2.5%	395	8	2.0%
17	457	14	3.1%	456	15	3.3%
Total	2362	123	5.2%	2347	115	4.9%

a OP= Oropharyngeal / Throat specimen type.
b AR= Anorectal specimen type.
c Positivity Rate (%) = (Number of valid Positive cobas results/Total number of cobas valid results) x100.

F Other Supportive Instrument Performance Characteristics Data:

Refer to K173887 for details on the instrument operation and the applicable software.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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