510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number
K260917

B Applicant
Roche Molecular Systems, Inc.

C Proprietary and Established Names
cobas CT/NG for use on the cobas 5800/6800/8800 systems
cobas TV/MG for use on the cobas 5800/6800/8800 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	Microbiology

II Submission/Device Overview:

A Purpose for Submission:
To modify the Warnings and Precautions, and additional materials section in the package inserts of the cobas CT/NG and the cobas TV/MG for use on the 5800/6800/8800 systems to include Colli-Pee•Dx Urine Collection Kit (K254121). No changes were made to the respective cobas assay designs, hardware or software.

B Measurand:
Chlamydia trachomatis and *Neisseria gonorrhoeae* DNA
Trichomonas vaginalis and *Mycoplasma genitalium* 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:
cobas CT/NG for use on the cobas 5800/6800/8800 systems

cobas CT/NG for use on the cobas 5800/6800/8800 systems 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.

cobas TV/MG for use on the cobas 5800/6800/8800 systems

cobas TV/MG for use on the cobas 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens, all collected in cobas PCR Media (Roche Molecular Systems, Inc.). cobas TV/MG also detects TV DNA in cervical specimens collected in PreservCyt solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. This test is intended as an aid in the diagnosis of TV and MG infections in individuals suspected to have TV or MG infection.

A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher sensitivity compared to endocervical swabs and urine. For males, urine is the preferred specimen type due to higher sensitivity compared to meatal swabs. If vaginal swab or male urine is not used and MG testing is negative, further testing with the preferred specimen type may be indicated if *M. genitalium* infection is strongly suspected.

C Special Conditions for Use Statement(s)
Rx - For Prescription Use Only

D Special Instrument Requirements:
cobas 5800/6800/8800 systems

IV Device/System Characteristics:

A Device Description:
cobas CT/NG for use on the cobas 5800/6800/8800 systems
The cobas CT/NG for use on the cobas 5800/6800/8800 systems is a fully automated, qualitative real-time PCR assay. cobas CT/NG enables the detection of CT/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. The DNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing.

cobas TV/MG for use on the cobas 5800/6800/8800 systems
cobas TV/MG for use on the cobas 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test for the direct detection of TV/MG DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens collected in cobas PCR Media. cobas TV/MG also detects TV DNA in cervical specimens collected in PreservCyt Solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. The DNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing. In addition, the test utilizes external controls (low titer positive control and a negative control).

B Principle of Operation:

cobas CT/NG for use on the cobas 5800/6800/8800 systems
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 5800/6800/8800 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 5800/6800/8800 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 specimens 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.

cobas TV/MG for use on the cobas 5800/6800/8800 systems

cobas TV/MG is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The cobas 5800/6800/8800 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 5800/6800/8800 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 acid from patient specimens and added internal control DNA (DNA-IC) molecules are simultaneously extracted. In summary, nucleic acid is released by addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the 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 acid is eluted from the magnetic glass particles with elution buffer at elevated temperature. External controls (positive and negative) are processed in the same way with each cobas TV/MG run.

Selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers for TV and MG which are selected from highly-conserved regions within the respective target organism. TV is detected by one selective set of primers and a probe, while MG is detected by using two sets targeting separate regions (dual-target). Selective amplification of DNA IC is achieved using sequence-specific forward and reverse primers which are selected to have no homology with either the TV or MG 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 master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythymidine triphosphate (dTTP), which is incorporated into the newly synthesized DNA amplicon. Any contaminating amplicon from previous PCR runs is eliminated by the AmpErase enzyme, which is included in the PCR master mix, during the first thermal cycling step. However, newly formed amplicons are not eliminated since the AmpErase enzyme is inactivated once exposed to temperatures above 55°C.

The cobas TV/MG master mix contains one detection probe specific for the TV target sequence, two detection probes specific for the MG target sequences and one for the DNA-IC. The probes are labeled with target specific fluorescent reporter dyes allowing simultaneous detection of TV target, MG target, 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 TV and MG targets and DNA-IC, respectively.

C Instrument Description Information:

1. Instrument Name:
   cobas 5800/6800/8800 systems

2. Specimen Identification:
   cobas 5800/6800/8800 analyzer supports multiple types of barcodes. Loaded samples are automatically moved for barcode scanning and processing.

3. Specimen Sampling and Handling:
   As per cobas 5800 system or the cobas 6800/8800 systems User Assistance guidance, specimens contained in either primary or secondary sample tubes are loaded into the Sample Supply Module of the cobas 5800/6800/8800 systems for testing. Specimen processing is fully automated.

4. Calibration:
   No calibration is required by the user.

5. Quality Control:
   See K173887, K202408 and K190433 for quality control information.

V Substantial Equivalence Information:

A Predicate Device Name(s):
cobas CT/NG for use on the cobas 5800/6800/8800 systems
cobas TV/MG for use on the cobas 5800/6800/8800 systems

B Predicate 510(k) Number(s):
K202408 - cobas CT/NG for use on the cobas 5800/6800/8800 systems
K190433 - cobas TV/MG for use on the cobas 5800/6800/8800 systems

C Comparison with Predicate(s):

A comparison of the cobas CT/NG (K260917) and the cobas CT/NG (K202408) is summarized in Table 1 below.

Table 1: Comparison with Predicate:

Device & Predicate Device(s):	K260917	K202408 (Predicate)
Device Trade Name	cobas CT/NG for use on the cobas 5800/6800/8800 systems	cobas CT/NG for use on the cobas 5800/6800/8800 systems
Regulation Number	Same	21 CFR 866.3393
Regulation Name	Same	Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections
Regulatory Class	Same	Class II
Classification Product Code	Same	QEP
Subsequent Product Codes		MKZ, LSL, OOI
Intended Use	Same	cobas CT/NG for use on the cobas 5800/6800/8800 systems 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.
Sample Types	Same	• Male and female urine, • Vaginal swab specimens, • Endocervical swab specimens, • Oropharyngeal (throat) swab specimens, • Anorectal swab specimens, • Cervical specimens in PreservCyt Solution.
Subject Status	Same	Symptomatic and asymptomatic

Device & Predicate Device(s):	K260917	K202408 (Predicate)
Analyte Targets	same	CT cryptic plasmid DNA CT ompA gene NG genomic DNA
Sample Preparation	Same	Automated
Amplification Technology	Same	Real Time PCR
Detection Chemistry	Same	Paired reporter and quencher fluorescence labeled probes (TaqMan Technology) using fluorescence resonance energy transfer (FRET)
Controls used	Same	cobas CT/NG Positive Control Kit, cobas Buffer Negative Control Kit
Result Analysis	Same	PCR Cycle threshold analysis
Collection Devices	Same as predicate with the addition of Colli-Pee•Dx Urine Collection Kit.	cobas PCR Urine Sample Kit, cobas PCR Media Uni Swab Sample Kit, cobas PCR Media Dual Swab Sample Kit, ThinPrep Pap Test Physician's Kits.

A comparison of the cobas TV/MG (K260917) and the cobas TV/MG (K190433) is summarized in Table 2 below.

Table 2: Comparison with Predicate:

Device & Predicate Device(s):	K260917	K190433 (Predicate)
Device Trade Name	cobas TV/MG for use on the cobas 5800/6800/8800 systems	cobas TV/MG for use on the cobas 5800/6800/8800 systems
Regulation Numbers	Same	21 CFR 866.3393
Regulation Names	Same	Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections.
Regulatory Class	Same	Class II
Classification Product Code	Same	QEP

Device & Predicate Device(s):	K260917	K190433 (Predicate)
Intended Use	Same	cobas TV/MG for use on the cobas 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens, all collected in cobas PCR Media (Roche Molecular Systems, Inc.). cobas TV/MG also detects TV DNA in cervical specimens collected in PreservCyt solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. This test is intended as an aid in the diagnosis of TV and MG infections in individuals suspected to have TV or MG infection. A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher sensitivity compared to endocervical swabs and urine. For males, urine is the preferred specimen type due to higher sensitivity compared to meatal swabs. If vaginal swab or male urine is not used and MG testing is negative, further testing with the preferred specimen type may be indicated if *M. genitalium* infection is strongly suspected.
Sample Types	Same	• Male and female urine, • Penile meatal swabs for MG, • Vaginal swab specimens, • Endocervical swab specimens, • Cervical specimens in PreservCyt solution for TV
Subject Status	Same	Symptomatic and asymptomatic

Device & Predicate Device(s):	K260917	K190433 (Predicate)
Analyte Targets	same	5.8s ribosomal RNA gene (*T. vaginalis*). MgPar and MgpB genes (*M. genitalium*).
Sample Preparation	Same	Automated
Amplification Technology	Same	Real Time PCR
Detection Chemistry	Same	Paired reporter and quencher fluorescence labeled probes (TaqMan Technology) using fluorescence resonance energy transfer (FRET)
Controls used	Same	cobas TV/MG Positive Control Kit cobas Buffer Negative Control Kit
Result Analysis	Same	PCR Cycle threshold analysis
Collection Devices	Same as predicate with the addition of Colli-Pee•Dx Urine Collection Kit.	cobas PCR Urine Sample Kit, cobas PCR Media Uni Swab Sample Kit, cobas PCR Media Dual Swab Sample Kit, ThinPrep Pap Test Physician's Kits.

VI Standards/Guidance Documents Referenced:

None.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

See K173887, K202408, K190433 and K254121 for analytical performance information.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   See Clinical Studies section below.

2. Analytical equivalency of Collection Media and Collection Devices:
   See K254121 for analytical equivalency information.

C Clinical Studies:

See K173887, K202408, K190433 and K254121 for clinical performance information.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

See K173887, K202408, K190433 and K254121 for expected values/reference range information.

F Other Supportive Instrument Performance Characteristics Data:

See K173887, K202408 and K190433 for other supportive instrument performance information.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for these devices.

IX Conclusion:

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