SPECIAL 510(k): Device Modification
OIR Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K140887

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:
   Roche cobas CT/NG v2.0 Test (K132270) and cobas CT/NG Test (K110923)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

   The labeling for this modification to the subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification.

3. A description of the device **MODIFICATIONS:**

   This change was for new modularized software architecture. The changes to the software include consolidation of different platforms into one architecture, result view and report layout changes, and the method of implementation for the calculation of results (no changes to the results determination algorithm); update OS to Windows 7, remove redundancy in work order creation, automate sample processing parameters based on sample type, improve tip tracking and specimen removal function, expand allowable run size options, improve recovery from unexpected error (graceful recovery), and improvements to the LIS functions to support the HL7 communication standard.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**

5. **Comparison Information** (similarities and differences):

   Similarities

	Predicate devices CT/NG v2.0 Test (K132270)	**Modified device CT/NG v2.0 Test (K140887)**
Intended Use	The cobas® CT/NG v2.0 Test is an automated, in vitro nucleic acid amplification test for the qualitative detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected 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	Same

	chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals. Ancillary Collection Kits The cobas® PCR Female 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 for gynecological specimens. Use this collection kit only with either the cobas® CT/NG Test or the cobas® CT/NG v2.0 Test. 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 for urine specimens. Use this collection kit only with either the cobas® CT/NG Test or the cobas® CT/NG v2.0 Test.	
Symptomatic Status	Asymptomatic and symptomatic	Same
Sample Preparation Procedure	Semi-automated	Same
CT Analyte Targets	CT cryptic plasmid DNA CT *ompA* gene	Same
NG Analyte Targets	NG genomic DNA	Same
Amplification Technology	Real-time PCR	Same
Specimen Types	Male Urine Female Urine Endocervical swabs Clinician-collected vaginal swabs Patient-collected vaginal swabs Cervical specimens in PreservCyt® Solution	Same
Specimen Collection Devices	cobas PCR Urine Sample Kit cobas PCR Female Sample Kit PreservCyt® Solution	Same

	Predicate devices CT/NG Test (K110923)	**Modified device CT/NG Test (K140887)**
Intended Use	The cobas® CT/NG Test is an in vitro nucleic acid amplification test that utilizes the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the qualitative detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA to aid in the diagnosis	Same

	of chlamydial and gonococcal disease. The test may be used with vaginal swab specimens self-collected in a clinical setting and male urine from both symptomatic and asymptomatic individuals. Specimens to be tested should be collected in cobas® PCR Media. Ancillary Collection Kits: The cobas® PCR Female Swab Sample Kit is used to collect and transport self-collected vaginal swab specimens in a clinical setting. The cobas® PCR Media serves as a nucleic acid stabilizing transport and storage medium for gynecological specimens. Use this collection kit only with the cobas® CT/NG Test. NOTE: This collection kit should not be used for collection of alternative gynecological specimens. The cobas® PCR Urine Sample Kit is used to collect and transport male urine specimens. The cobas® PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens. Use this collection kit only with the cobas® CT/NG Test. NOTE: This collection kit should not be used for collection of female urine specimens.	
Symptomatic Status	Asymptomatic and symptomatic	Same
Sample Preparation Procedure	Semi-automated	Same
CT Analyte Targets	CT cryptic plasmid DNA CT *ompA* gene	Same
NG Analyte Targets	NG genomic DNA	Same
Amplification Technology	Real-time PCR	Same
Specimen Types	Male urine Patient-collected vaginal swabs	Same
Specimen Collection Devices	cobas PCR Urine Sample Kit cobas PCR Female Sample Kit	Same

Differences

The changes to the software include consolidation of different platforms into one architecture, automate sample processing parameters based on sample type, and the method of implementation for the calculation of results (no changes to the results determination algorithm); update OS to Windows 7, remove redundancy in work order creation, improve tip tracking, improve specimen removal function, expand allowable run size options, result view and report layout changes, improve

recovery from unexpected error (graceful recovery), and improvements to the LIS functions to support the HL7 communication standard.

6. **Design Control Activities Summary**:

   a) The detailed risk management plans for the cobas 4800 system and the cobas CT/NG and cobas CT/NG v2.0 products are provided in the following documents in the attachments " cobas 4800 System Release 2.1: Risk Management Plan" (DH-309-009A) and **"**cobas 4800 System Release 2.1: CT/NG and CT/NG v2.0 Risk Management Plan" (DH-252-022A). Final risk assessments were performed for the cobas 4800 system and CT/NG tests after hazard analysis and risk mitigations were completed. Various causes were considered in the risk analysis including human factors, hardware/software failures, installation/integration failures, and environmental. All remaining risks were identified to be As Low As Reasonably Possible (ALARP) in the final risk assessments and the rationale for risk acceptance was documented in the Risk Management Report.

   b) The validation plan stated that the hardware components of the cobas x 480 (sample prep), cobas z 480 (analyzer), and assay reagents have not changed and therefore no validation was recommended. The changes to the cobas 4800 software were validated at the unit, component, and system level. The scope of the system level testing encompassed verification that product requirements were successfully implemented and that observed anomalies were either corrected or accepted as known issues with no adverse impact on system performance. Product requirements were tested to demonstrate that risks had been mitigated. If a particular product requirement passed testing, then the risk was deemed successfully mitigated. System level risk mitigation testing was captured within the plans and reports completed for each testing campaign. All planned system level testing for the cobas 4800 System Core Software Release 2.1 and the cobas CT/NG and CT/NG v2.0 Analysis Packages was completed successfully.

   c) Anomaly reports "cobas 4800 System Release 2.1: Core Anomaly Summary Report" and cobas 4800 System Release 2.1: CT/NG Anomaly Summary Report" identify that anomalies within each configuration of the cobas 4800 system were acceptable and presented minimal risk to user, process, or product function. A "Known Issues" list will be distributed to system Users to address minor anomalies relevant to the user operation of the system.

      Rare instances of a channel shift anomaly are reported. This anomaly causes errors in the results generated by cobas z480 due to a camera anomaly which causes image data to be incorrectly assigned an optical channel. The mechanism of the channel shift was confirmed to be an extra image in the camera memory buffer. The cobas z480 Instrument Control (IC) software and the cobas z480 service software (zSSW) have been updated to detect and prevent creation and accumulation of extra images in the cobas z480 camera buffer. All test items for the system verification activities related to the channel shift anomaly are acceptable as presented in "cobas 4800 System Release 2.1: Channel Shift System Verification Report."

   d) Traceability between requirements, identified hazards, and verification and validation testing has been established using several trace matrices. Gap analysis was performed on each trace matrix to ensure that each higher-level requirement or specification traces to the next lower level requirement or specification, and that each requirement or specification also traces to a verification or validation activity. Identified hazards that are mitigated by implementation of requirements are traced from the identified risk to the mitigating requirement. The traceability matrices are updated and maintained throughout the development lifecycle of the cobas 4800 system.

   e) The Firm has provided a design control activities summary including the risk management files for the identification of risk analysis methods used to assess the impact of the modification on the

devices and their components, and the results of the analysis. The deviations and anomalies reported in the verification report for the core system were acceptable. The design verification and validation report (DVVR) for CT/NG v2.0 and CT/NG system verification summary report were acceptable.

A declaration of conformity with design controls was submitted including:

i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and

ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

7. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.