K092705

MAY 28 2010

Abbott® *m*2000™ System

510(k) Summary

Table of Contents

A summary of the Abbott® *m*2000™ System as required by Section 807.92(c) is provided below.

1.0 Submitted By:

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3.0 Date of Preparation

August 2009

4.0 Name of Device

Trade Name:	Abbott® *m*2000™ System	
	Components:	Model Numbers:
	Abbott® *m*2000*sp*™	9K14-01 (G-Series) 9K14-02 (E-Series)
	Abbott ® *m*2000*rt*™	9K15-01
Common Name:	Automated sample preparation and batch analyzer system for nucleic acid amplification and detection.	
	Components: The *m*2000*sp* is an automated sample preparation system. The *m*2000*rt* is an automated batch analyzer for nucleic acid amplification and detection.	
Classification Name and Regulation:	The *m*2000*sp* is classified as a "Clinical sample concentrator" as described in 21CFR §862.2310 (Class I, Procode JJH). The *m*2000*rt* is classified as "Instrumentation for clinical multiplex test systems" as described in 21CFR §862.2570 (Class II, Procode OOI).	

5.0 Predicate Devices

Roche COBAS® TaqMan® Analyzer (K012966)

6.0 Device Description

The Abbott *m*2000 System is an instrument platform that automates steps to perform nucleic acid amplification assays from sample processing through amplification, detection, and data reduction.

The Abbott *m*2000 System comprises the *m*2000*sp* and *m*2000*rt* instruments, which are operated with separate System Control Center (SCC) workstations. Each instrument contains an independent software application; one for the *m*2000*sp* and a second for the *m*2000*rt*.

The *m*2000*sp* instrument is a floor standing, automated sample preparation system. The three main components of the *m*2000*sp* are the:

- Instrument
- Cabinet
- System Control Center (SCC)

The m 2000rt instrument is a real-time PCR thermal cycler/reader instrument system. The two main components of the *m*2000*rt* are the:

- Instrument
- System Control Center (SCC)

The Abbott *m*2000 System software processes sample preparation and amplification/detection protocols based on pre-determined, assay-specific parameters that are contained in individual assay application specification files that are installed on the SCC. The Abbott *m*2000*sp* reads and processes bar coded primary sample tubes and processes up to 96 specimens, controls, and calibrators in batch mode. The *m*2000 System is capable of processing samples from various matrices, depending on the specific assay application, including plasma, serum, endocervical swabs, urethral swabs, vaginal swabs, and urine. At the completion of the automated sample preparation protocol, the operator seals and manually transfers the PCR plate to the Abbott *m*2000*rt* for nucleic acid detection. Bar code and *m*2000*sp* data is transferred to the *m*2000*rt* electronically.

7.0 Intended Use of the Device

The Abbott *m*2000 system is intended for in vitro diagnostic use in performing FDA cleared and approved nucleic acid testing in clinical laboratories. It comprises the Abbott *m*2000*sp* and the Abbott *m*2000*rt* instruments.

The Abbott *m*2000*sp* is an automated system for performing sample preparation for nucleic acid testing.

The Abbott *m*2000*rt* is an automated system for performing fluorescence-based PCR to provide quantitative and qualitative detection of nucleic acid sequences.

8.0 Technological Characteristics of the Device as Compared to the Predicate(s)

The Abbott *m*2000 System is substantially equivalent to the currently marketed predicate device Roche COBAS TaqMan Analyzer (510(k) K012966.

These devices are similar in that they are designed to amplify, detect and report results of DNA or RNA qualitative and/or quantitative assays. The primary similarities and differences between the *m*2000 System and the predicate device are shown in Table 1 in the attachment (the differences are shown in underlined italics in the table).

Because the Abbott RealTi*me* CT/NG assay 510(k) is being submitted at the same time as this 510(k), it should be noted that the CT/NG assay, which is used on the Abbott *m*2000*rt*, is shown to be substantially equivalent to the Gen-Probe Combo-2 Assay (K043224). The Abbott RealTi*me* CT/NG assay is also shown to be substantially equivalent to the Becton Dickinson ProbeTec ET *Chlamydia trachomatis /Neisseria gonorrhoeae* Amplified DNA Assay (K012351). Please refer to the Abbott RealTi*me* CT/NG assay 510(k) submission for more information.

9.0 Summary of Non-Clinical Testing

9.1 Analytical Sensitivity

The Limit of Detection (LOD) claim for the Abbott 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 107 NG target DNA copies per assay, or 1 x 107 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.

9.2 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 1×10^7 copies/assay. HBV DNA and HCV RNA were added directly into the PCR reaction at approximately 4×10^5 and 6×10^6 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 RealTi*m*e e 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 106 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.

9.3 Evaluation of Potentially Interfering Substances

The potential for interference in the Abbott RealTi*m*e CT/NG assay was assessed with substances that may be found in swab and/or urine specimens. Substances were spiked

into a swab and/or urine matrix containing 320 copies of CT and NG target DNA per assay, and into a swab and/or urine matrix without CT or NG DNA.

No interference in the performance of the Abbott RealTi*m*e CT/NG assay was observed in the presence of the substances listed in Table 3.

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

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

9.4 Precision Study

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. 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 Table 4 and Table 5, respectively.

9.5 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 10^7 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%.

10.0 Summary of Clinical Testing

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) were reported. For CT, female subjects with positive results on urine and negative results on 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 were reported. If the reference NG culture assay result was positive, the subject was categorized as infected regardless of NAAT results.

A female subject was categorized as not infected with CT or NG if at least one of the reference NAATs reported negative results for all sample types 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.

Tables 6 through 24 summarize the clinical trial data.

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 6 and 7, respectively. Sensitivity and specificity for NG for female subjects and male subjects are presented in Tables 8 and 9, 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 10 and 11, and for infected and non-infected male subjects in Tables 12 and 13. NG results for infected and non-infected female subjects are presented in Tables 14 and 15, and for infected and non-infected male subjects in Tables 16 and 17.

The prevalence of CT and NG in this study was dependent on several factors including age, gender, clinic type, 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 18, for clinician-collected and self-collected vaginal swab specimens is presented in Table 19; for female urine specimens in Table 20; and for male urethral swab and male urine specimens in Tables 21 and 22, 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 23 for CT and Table 24 for NG.

11.0 Conclusions for Non-clinical and Clinical Testing

Based on the results of the studies summarized above, the Abbott *m*2000 System, in conjunction with the Abbott RealTi*m*e CT/NG assay, has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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MAY 2 8 2010

Re: k092705

Trade/Device Name:	Abbott m2000 system
Regulation Number:	21CFR §862.2570
Regulation Name:	Instrumentation for clinical multiplex test systems
Regulatory Class:	Class II
Product Code:	OOI, JJH
Dated:	May 21, 2010
Received:	May 24, 2010

Dear Ms. Martin:

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

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the

1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number (if known): K092705

Device Name: Abbott *m*2000 System

Indications for Use:

The Abbott *m*2000 system is intended for in vitro diagnostic use in performing FDA cleared and approved nucleic acid testing in clinical laboratories. It comprises the Abbott *m*2000*sp* and the Abbott *m*2000*rt* instruments.

The Abbott *m*2000*sp* is an automated system for performing sample preparation for nucleic acid testing.

The Abbott *m*2000*rt* is an automated system for performing fluorescence-based PCR to provide quantitative and qualitative detection of nucleic acid sequences.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092705