510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k113319

B. Purpose for Submission:

Clearance of Rotor-Gene Q MDx

C. Manufacturer and Instrument Name:

QIAGEN GmbH

Rotor-Gene Q MDx

D. Type of Test or Tests Performed:

Real-Time PCR

E. System Descriptions:

1. Device Description:

The Rotor-Gene Q MDx is a real-time PCR analyzer designed for thermal cycling and real-time detection of PCR amplicons. The Rotor-Gene Q MDx ("RGQ") uses a centrifugal rotary design for thermal cycling where each tube spins in a chamber of moving air, intended to keep samples at a uniform temperature. Detection is performed as each tube aligns with the detection optics, where the sample is optically excited and the resulting fluorescent signal is collected from a single optical pathway. Software version 2.1.0 or higher has been validated for use with the *artus*® Infl A/B RG RT-PCR assay.

The *artus*® Infl A/B RG RT-PCR assay is being submitted separately, but concurrent with this RGQ instrument submission. Please refer to the *artus*® Infl A/B RG RT-PCR assay 510(k) submission (k113323) for the *artus*® Infl A/B RG RT-PCR assay analytical and clinical testing which includes limit of detection, limit of blank, reactivity, cross-reactivity, interference, precision, carry-over / cross-contamination, multi-center reproducibility, and testing of prospectively collected and banked specimens. The instrument has six sets of excitation and emission channels available to induce and measure fluorescence at specified wavelengths. Only excitation and emission channels referred to as "red" "crimson" and "green" have been validated for *in vitro* diagnostic use.

2. Principles of Operation:

Samples tubes are provided in groups of connected tubes and caps. Capped and hand labeled tubes are placed into a position labeled ring shaped holder which fits onto a spindle inside the instrument. The inside of the instrument acts as a low-mass–forced air oven. Heating is achieved by a nickel-chrome element in the lid and the chamber is cooled by venting the air out through the top of the chamber while ambient air is blown up through the base. The RGQ rotary format employs a centrifugal process where samples spin continually at 400 rpm during a run. Centrifugation promotes thermal uniformity between samples, prevents condensation and removes air bubbles, but does not pellet DNA.

During centrifugation each tube passes by an optical excitation source and detection zone where a fluorescence signal is simultaneously excited and detected. Samples are excited from the bottom of the chamber by a light-emitting diode. Energy is transmitted through the thin walls at the base of the tube. Emitted fluorescence passes through emission filters on the side of the chamber and is then collected by a photomultiplier. There are six excitation sources and six detection filters which require no calibration or compensation. Each assay specified dye is compatible with only one set of excitation/emission filter pairs. The optical path length is fixed for all excitation wavelengths; this precludes the use of an internal reference dye.

3. Modes of Operation:

The RGQ software utilizes assay packages to control the *in vitro* diagnostic workflow. Selecting an assay specific locked analysis template switches the software to an assay specific mode. This forces the loading of a restricted graphical user interface (GUI), which removes access to menus, menu items, quick launch buttons, etc. that are not required for the assay specific workflow. The assay specific locked analysis template includes, as applicable to the individual assay, the required parameters for cycling, data acquisition, data analysis, quantitation standards, acceptance of controls, reporting, etc. The assay package also includes a report template that specifies the format of the assay report. Each *in vitro* diagnostic application using the RGQ will require at least one assay specific locked analysis template file.

The RGQ instrument is also capable of performing laboratory-defined (user-validated) applications including high-resolution melting analysis, end-point thermal cycling, protein analysis, and enzyme kinetics. The FDA is not reviewing, clearing or approving any of the open-mode/laboratory-defined functionalities and requires documentation and evidence that these functionalities do not interfere with IVD functionalities.

4. Specimen Identification:

Samples are manually transferred into samples tubes; each tube has a cap with

sufficient space to include a hand written unique identifier or barcode. Tubes are placed in a ring shaped holder that locks the caps in place and has uniquely identified locations. In the software, the user matches the unique sample ID with the holder location ID. The keyed ring containing the sample tubes is placed into the instrument and the run is started. If the lid is opened at anytime during a run, results are not reported.

5. Specimen Sampling and Handling:

   Specimen sampling and handling is performed manually following user laboratory SOPs and the *artus*® Infl A/B RG RT-PCR user manual.

6. Calibration:

   Optical Temperature Verification (OTV) is a method that verifies the in-tube temperature in the Rotor-Gene Q MDx. While it is not required for the Rotor-Gene Q MDx, calibration of in-tube temperature can be a laboratory requirement. The OTV procedure provides a means for users to comply with potential site specific calibration interval requirements. OTV is performed using a Rotor-Disc® OTV Kit.

   OTV uses the optical properties of three thermochromatic liquid crystals (TLC) as absolute temperature references. When heated, TLCs change from opaque to transparent at very precise temperatures (50°C, 75 °C, and 90 °C). TLCs are not inherently fluorescent; therefore, it is necessary to cover the excitation source with a fluorescent insert so that the TLC transition points can be detected by the Rotor-Gene Q MDx optical system. TLCs that are below their transition temperature are opaque and reflect light. A portion of the reflected light scatters towards the detector and is measured as an increase in fluorescence. When the in-tube temperature reaches the TLC transition point, the TLC becomes transparent, and light passes through the sample rather than being reflected toward the detector, resulting in a decrease in fluorescence. The change in fluorescence is used to determine the precise transition temperature of each TLC. The transition temperature is compared with the temperature reported by the factory calibration file for the OTV Rotor-Disc to verify whether the Rotor-Gene Q MDx is within temperature specification.

7. Quality Control:

   Assay quality control is addressed for each separately cleared specific assay to be run on the instrument. The quality system used during software and hardware development was adequately described. The quality system documents which were reviewed include:
   - Design history file including design verification plans, reports, and deviations
   - Software requirements specifications
   - Software and firmware design specifications

- Software architecture design, development and maintenance plan
- Software test case analysis
- Risk and hazard analysis
- Traceability matrix

The electromagnetic compatibility and safety verification of the Rotor-Gene Q instrument, which encompasses the Rotor-Gene Q MDx model, was found to be in conformance with the following standards:

CAN/CSA – C22.2 No. 61010-1-4 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part I: General Requirements

CAN/CSA-C22.2 No. 61010-2-010-04 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials

CAN/CSA-C22.2 No. 61010-2-081-04 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

CAN/CSA-C22.2 No. 61010-2-101-04 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

UL Std. No. 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part I: General Requirements

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes____X____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.2570 Instrumentation for clinical multiplex test system.

2. Classification:

   Class II

3 Product code:

OOI

4. Panel:

Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

The Rotor-Gene Q MDx instrument with Rotor-Gene Q software version 2.1.0 or higher is a real-time nucleic acid amplification and detection system which measures nucleic acid signals from amplified DNA using fluorescent detection.

The Rotor-Gene Q MDx instrument is intended for *in vitro* diagnostic use with FDA cleared or approved nucleic acid tests in clinical laboratories.

2. Special Conditions for Use Statement(s): None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Abbott Molecular Inc. m2000rt™ System (k092705)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	The Rotor-Gene Q MDx instrument with Rotor-Gene Q software version 2.1.0 or higher is a real-time nucleic acid amplification and detection system which measures nucleic acid signals from amplified DNA using fluorescent detection. The Rotor-Gene Q MDx instrument is intended for	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*rt* is an automated system for performing fluorescence-

Similarities		
Item	Device	Predicate
	in vitro diagnostic use with FDA cleared or approved nucleic acid tests in clinical laboratories.	based PCR to provide quantitative and qualitative detection of nucleic acid sequences.
Assay Format	Homogeneous, closed tube PCR	Homogeneous, closed tube PCR
Degree of Automation	Automated control of amplification, detection, and data analysis	Automated control of amplification, detection, and data analysis
Primary Operational Amplification and Detection	Integrated thermocycler and microvolume fluorimeter for walk away PCR amplification and detection	Integrated thermocycler and microvolume fluorimeter for walk away PCR amplification and detection
Detection Chemistries	Fluorescence labeled, target-specific probes	Fluorescence labeled, target-specific probes
User Interface	PC with instrument-specific software	PC with instrument-specific software

Differences		
Item	Device	Predicate
Heating Method for Amplification	Air (low-mass-forced air oven) with rotor	Peltier device with sample block
Amplification Reaction Volume	10-50 µL in 0.1 ml tubes with 72-well rotor	25–100 µL in 96-well PCR plates
Sample preparation	No automated sample processing instrument offered in conjunction with the Rotor-Gene Q MDx	Pairing with the m2000sp instrument provides automated sample processing

I. Special Control/Guidance Document Referenced:

Class II Special controls guidance document: Instrumentation for Clinical Multiplex Test Systems:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077819.htm

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Accuracy:

   Accuracy was assessed during clearance of the assay (k113323) and will be addressed for each assay to be run on the system.

   b. Precision/Reproducibility:

   Precision and reproducibility was assessed during clearance of the assay (K113323) and will be addressed for each assay to be run on the system.

   c. Linearity:

   Not applicable.

   d. Carryover:

   Carryover was assessed during clearance of the assay (k113323) and will be addressed for each assay to be run on the system.

   e. Interfering Substances:

   Interfering substances were assessed during clearance of the assay (k113323) and will be addressed for each assay to be run on the system.

2. Other Supportive Instrument Performance Data Not Covered Above:

   Optical detection verification
   Performance requirements for optical detection are stated in the verification report (VER-0000002-B). These requirements include:

   LED spot size of 3mm +/- 1mm sufficient for optical excitation covering the reaction volume. (PS-TCH-11)

   Optical cross talk of <4% in adjacent Yellow on Green channel. (PS-TCH-020)

   Optical cross talk of <10% in adjacent Green on Yellow channel. (PS-TCH-021)

   Optical cross talk of <15% in adjacent Red on Orange channel. (PS-TCH-022)

   Optical cross talk of <1% in adjacent Crimson on Orange channel. (PS-TCH-023)

   Optical cross talk of <10% in adjacent Orange on Red channel. (PS-TCH-024)

Optical cross talk of <8% in adjacent Crimson on Red channel. (PS-TCH-025)

Optical cross talk of <1% in adjacent Orange on IR channel. (PS-TCH-026)

Optical cross talk of <8% in adjacent Red on IR channel. (PS-TCH-027)

All emission and detection wavelengths are specified. (PS-PHY-003 to PS-PHY-009)

Lens materials compatible with cleaning solutions listed in the User Manual. (PS-ENV-001 and PS-ENV-002)

Satisfaction of these requirements was demonstrated by performance testing and documented in the submitted verification test reports.

Environmental and transport simulation

Environment and transport simulation studies were performed and results were in accordance with the following standards.

Climatic Stationary Use: EN 60721-3-3 - Class 3K2
15 - 30°C, 10 – 75% RH

Climatic Transport Conditions: EN 60721-3-2 – Class 2K2
Temperature ramped from -25°C to 60°C and from 60°C to -25°C, <75% RH

Mechanical Transport Conditions: EN 60721-3-2 – Class 2M2
Vibration – 3 mm, 2-500 Hz; Random 10-2000 Hz

Shock – positive & negative half sinus 100 m/s2 impulse, 11 ms duration, 3 axes, 3 repetitions for a total of 18 shocks

Climatic Longtime Storage: EN 60721-3-1 – Class 1K2
5 - 40°C, 5 – 85% RH, 4 days

Endurance testing

The endurance of the RGQ instrument was assessed by subjecting an instrument to repetitive simulated use were each use cycle consists of opening the lid, closing the lid, running a model PCR cycle, acquiring fluorescence data during the run (fluorescent beads are loaded in the tubes), opening the lid, closing the lid, and waiting five minutes to allow the instrument to cool. The cycle was repeated at least 2250 times, which is the estimated number of cycles expected in a five year period assuming 225 work days and two runs per day. The endurance testing was executed and successfully completed (VER-00000024).

Thermal cycler performance testing

Functional design verification testing demonstrated that the Rotor-Gene Q MDx

design satisfies its design input requirements for the required ramp rate of 1.25°C/s and 1.38°C/s for thermal ramp-up and ramp-down rates respectively. The input requirement for temperature uniformity can not be measured in a specific test setup due to physical limitations. Thermal accuracy and uniformity will be validated during assay specific testing. The centrifuge speed was verified to meet the design input requirement of 400 RPM within the specified tolerance.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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