

ASSURANCE® GDS  
ROTOR-GENE® Q USER MANUAL




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# Safety


Before using the Assurance® GDS Rotor-Gene® Q, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition. The following types of safety information appear throughout this manual.

|   |  |
|---|--|
| <b>WARNING</b><br> | The term <b>WARNING</b> is used to inform you about situations that could result in <b>personal injury</b> to you or other persons.<br>Details about these circumstances are given in a box like this one. |
|---|--|


|   |  |
|---|--|
| <b>CAUTION</b><br> | The term <b>CAUTION</b> is used to inform you about situations that could result in <b>damage to the instrument</b> or other equipment.<br>Details about these circumstances are given in a box like this one. |
|---|--|


The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.


## Proper Use

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|---|---|
| <b>WARNING</b><br> | <b>Risk of personal injury and material damage</b> [W1]<br>Improper use of the Rotor-Gene Q may cause personal injuries or damage to the instrument.<br>The Rotor-Gene Q must only be operated by qualified personnel who have been appropriately trained.<br>Servicing of the Rotor-Gene Q must only be performed by QIAGEN Field Service Specialists. |
|---|---|






Perform the maintenance as described in Section 5. BioControl Systems charges for repairs that are required due to incorrect maintenance.

|   |  |
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| <b>WARNING</b><br> | <b>Risk of personal injury and material damage</b> [W2]<br>Rotor-Gene Q is a heavy instrument. To avoid personal injury or damage to the instrument, take care when lifting. |
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| <b>WARNING</b><br> | <b>Risk of personal injury and material damage</b> [W3]<br>Do not attempt to move the Rotor-Gene Q during operation. |
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| <b>CAUTION</b><br> | <b>Damage to the instrument</b> [C1]<br>Avoid spilling water or chemicals onto the Rotor-Gene Q.<br>Damage caused by water or chemical spillage will void your warranty. |
|---|--|


In case of emergency, switch off the Rotor-Gene at the power switch at the back of the instrument and unplug the power cord from the power outlet.

|   |   |
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| <p><b>WARNING</b></p>  | <p><b>Risk of personal injury and material damage</b> <span style="float: right;">[W4]</span></p> <p>Do not try to open the lid during an experiment, or while the Rotor-Gene Q is spinning. Otherwise, if you overcome the lid lock and reach inside, you risk contact with parts that are hot, electrically live, or moving at high speed, and you may injure yourself and damage the instrument.</p> |
| <p><b>WARNING</b></p>  | <p><b>Risk of personal injury and material damage</b> <span style="float: right;">[W5]</span></p> <p>If you need to stop an experiment quickly, turn off the power to the instrument, then open the lid. Let the chamber cool before reaching inside. Otherwise you risk injury by touching parts that are hot.</p>   |
| <p><b>WARNING</b></p>  | <p><b>Risk of personal injury and material damage</b> <span style="float: right;">[W6]</span></p> <p>If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.</p>  |
| <p><b>WARNING</b></p>  | <p><b>Risk of personal injury and material damage</b> <span style="float: right;">[W7]</span></p> <p>Loose paper underneath the Rotor-Gene Q interferes with instrument cooling. It is recommended that the area beneath the instrument is kept free of clutter.</p>  |
| <p><b>CAUTION</b></p>  | <p><b>Damage to the instrument</b> <span style="float: right;">[C2]</span></p> <p>Always use a locking ring on the rotor. This stops caps from coming off tubes during an experiment. If caps come off during an experiment, they may damage the chamber.</p>   |

If you touch the Rotor-Gene during an experiment, while you are charged with static electricity, in severe cases the Rotor-Gene may reset. However, the software will restart the Rotor-Gene and continue the experiment.

## Electrical Safety

Disconnect the line power cord from the power outlet before servicing.


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| <p><b>WARNING</b></p>  | <p><b>Electrical hazard</b> <span style="float: right;">[W8]</span></p> <p>Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.</p> <p>Intentional interruption is prohibited.</p> <p><b>Lethal voltages inside the instrument</b></p> <p>When the instrument is connected to line power, terminals may be live, and opening covers or removing parts is likely to expose live parts.</p> |
|---|--|


To ensure satisfactory and safe operation of the Rotor-Gene, follow the advice below:


- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, disconnect it from the power outlet, and contact Bellevue Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it, and contact Technical Services at [BioMTS@milliporesigma.com](mailto:BioMTS@milliporesigma.com); the instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.


|   |  |
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| <b>WARNING</b>  | <b>Electrical hazard</b> <span style="float: right;">[W9]</span>   |
|  | The instrument has an electrical compliance label which indicates the voltage and frequency of the power supply as well as fuse ratings. The equipment should only be operated under these conditions. |


|   |  |
|---|--|
| <b>WARNING</b>  | <b>Electrical hazard</b> <span style="float: right;">[W10]</span>  |
|  | Voltage selection may only be changed by your sales distributor or authorized personnel. Users should not attempt to change voltage selection. Doing so may void the warranty. |


|   |  |
|---|--|
| <b>WARNING</b>  | <b>Electrical hazard</b> <span style="float: right;">[W11]</span>  |
|  | Do not change the voltage selector switch setting while the instrument is connected to the mains, as doing so may cause damage to the instrument and/or blow the fuse. |

## Environment

### Operating Conditions

|   |  |
|---|--|
| <b>WARNING</b>  | <b>Explosive atmosphere</b> <span style="float: right;">[W12]</span> |
|  | The Rotor-Gene Q is not designed for use in an explosive atmosphere. |

|   |  |
|---|--|
| <b>WARNING</b>  | <b>Risk of explosion</b> <span style="float: right;">[W13]</span>  |
|  | The Rotor-Gene Q is intended for use with reagents and substances supplied with QIAGEN kits. Use of other reagents and substances may lead to fire or explosion. |


|   |   |
|---|---|
| <b>CAUTION</b>  | <b>Damage to the instrument</b> <span style="float: right;">[C3]</span>   |
|  | Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.<br>The Rotor-Gene Q must be located out of direct sunlight. |

## Biological safety


Specimens and reagents containing materials from biological sources should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as *Biosafety in Microbiological and Biomedical Laboratories*, HHS ([www.cdc.gov/od/ohs/biosfty/biosfty.htm](http://www.cdc.gov/od/ohs/biosfty/biosfty.htm)).

## Samples

Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store, and dispose of such samples according to the required safety regulations.

|   |  |
|---|--|
| <p><b>WARNING</b></p>  | <p><b>Samples containing infectious agents</b> [W14]</p> <p>Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.</p> <p>Always wear safety glasses, 2 pairs of gloves, and a lab coat.</p> <p>The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Material Safety Data Sheets (MSDSs) or OSHA,* ACGIH,† or COSHH‡ documents.</p> <p>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p> |
|---|--|


## Chemicals

|   |  |
|---|--|
| <p><b>WARNING</b></p>  | <p><b>Hazardous chemicals</b> [W15]</p> <p>Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run.</p> <p>Always wear safety glasses, gloves, and a lab coat.</p> <p>The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Material Safety Data Sheets (MSDSs) or OSHA,* ACGIH,† or COSHH‡ documents.</p> <p>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p> |
|---|--|

\* OSHA: Occupational Safety and Health Administration (United States of America).

† ACGIH: American Conference of Government Industrial Hygienists (United States of America).

‡ COSHH: Control of Substances Hazardous to Health (United Kingdom).

|   |   |
|---|---|
| <p><b>WARNING</b></p>  | <p><b>Risk of fire</b> <span style="float: right;">[W16]</span></p> <p>When cleaning the Rotor-Gene Q with alcohol-based disinfectant, leave the Rotor-Gene Q door open to allow flammable vapors to disperse.</p> <p>Only clean the Rotor-Gene Q when worktable components have cooled down.</p> |
|---|---|

### Toxic fumes


If working with volatile solvents or toxic substances, you must provide an efficient laboratory ventilation system to remove vapors that may be produced.


### Waste disposal

Used consumables and plastic ware may contain hazardous chemicals or infectious agents. Such wastes must be collected and disposed of properly according to local safety regulations.

### Mechanical hazards


The lid of the Rotor-Gene must remain closed during operation of the instrument.


|   |  |
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| <p><b>WARNING</b></p>  | <p><b>Moving parts</b> <span style="float: right;">[W17]</span></p> <p>To avoid contact with moving parts during operation of the Rotor-Gene Q, the instrument must be operated with the lid closed.</p> |
|---|--|


|   |   |
|---|---|
| <p><b>WARNING</b></p>  | <p><b>Risk of personal injury and material damage</b> <span style="float: right;">[W18]</span></p> <p>Open and close the lid of the Rotor-Gene Q carefully to avoid trapping fingers or clothing.</p> |
|---|---|

### Rotor


Make sure that the rotor and locking ring are installed correctly. If the rotor or locking ring show signs of mechanical damage or corrosion, do not use the Rotor-Gene; contact Bellevue Technical Services.


|   |   |
|---|---|
| <p><b>CAUTION</b></p>  | <p><b>Damage to the instrument</b> <span style="float: right;">[C4]</span></p> <p>The Rotor-Gene Q must not be used if the lid is broken or if the lid lock is damaged.</p> <p>Make sure that the rotor and locking ring are installed correctly.</p> <p>Only use rotors, locking rings, and consumables designed for use with the Rotor-Gene Q. Damage caused by use of other consumables will void your warranty.</p> |
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|   |  |
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| <p><b>WARNING</b></p>  | <p><b>Moving parts</b> <span style="float: right;">[W19]</span></p> <p>In case of breakdown caused by power failure, remove the power cord and wait 10 minutes before attempting to manually open the lid.</p> |
|---|--|

|   |   |
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| <b>WARNING</b><br> | <p><b>Risk of overheating</b> <span style="float: right;">[W20]</span></p> <p>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the Rotor-Gene Q.</p> <p>Slits and openings that ensure the ventilation of the Rotor-Gene Q must not be covered.</p> |
|---|---|



### Heat hazard

|   |  |
|---|--|
| <b>WARNING</b><br> | <p><b>Hot surface</b> <span style="float: right;">[W21]</span></p> <p>The Rotor-Gene Q chamber can reach temperatures above 120°C (248°F). Avoid touching it when it is hot.</p> |
|---|--|

|   |  |
|---|--|
| <b>WARNING</b><br> | <p><b>Hot surface</b> <span style="float: right;">[W22]</span></p> <p>When pausing a run, the Rotor-Gene Q will not be cooled completely to room temperature. Exercise caution before handling the Rotor or any tubes in the instrument.</p> |
|---|--|

### Symbols on the Rotor-Gene

The following symbols may appear on the instrument:

| Symbol  | Location  | Language | Description  |
|---|---|----------|--|
|  | Near the mains voltage selection switch           | EN       | General danger symbol — before using the Rotor-Gene Q for the first time, make sure the mains setting is correct, see Section 4.4. |
|  | Near the sample chamber, visible when lid is open | EN       | Hot surface warning  |

# Introduction

---

The Assurance® GDS Rotor-Gene® Q (RGQ) is an automated nucleic acid amplification system (thermocycler) for the detection of pathogenic organisms in foods, ingredients, and environmental samples. The instrument is intended for use by professional users, such as quality or laboratory technicians and microbiologists.

## Assurance® GDS System Overview

**Enrichment:** Each sample must be enriched via the appropriate Assurance® GDS assay protocol per the Directions for Use, prior to amplification and detection with the Assurance® GDS Rotor-Gene® Q.

**Sample Preparation:** Following enrichment, target organisms, if present, are concentrated and separated from the enriched sample via the Assurance® GDS PickPen® device.

**Amplification and Detection:** The concentrated sample is transferred to amplification tubes containing polymerase enzyme and lyophilized reagents specific for the detection of the target organism. If present, amplified nucleic acid sequences specific to the target organism generate a fluorescent signal which is read and interpreted by the Assurance® GDS Rotor-Gene® Q to determine test results.

## Standard Equipment

The Assurance® GDS Rotor-Gene® Q includes the following components:

- Assurance® GDS Rotor-Gene® Q thermocycler
- USB cable
- 36-well rotor and locking ring
- International power cord set (USA, UK, EU, Switzerland, and AUS/NZ)
- Gel cooling block set (2/cs)

Additional specific instrumentation and disposables are required to perform Assurance® GDS assays and must be purchased separately, see below. All instrumentation and disposables are available from [www.sigmaaldrich.com](http://www.sigmaaldrich.com).

- Assurance® GDS Rotor-Gene® Q laptop
- Assurance® GDS PickPen® II 8M
- Assurance® GDS PickPen® II tips
- Assurance® GDS Sample wells and bases
- Resuspension PCR plates
- Assurance® GDS Adhesive film strips and sheets
- Vortex Mixer with plate holder
- Micropipettes (repeat, variable single-channel, variable multi-channel) and tips
- General lab equipment (incubator, stomacher, autoclave)

The additional instrumentation used with the RGQ system must be designated for use exclusively with the Assurance® GDS system. Use of any of these instruments for general microbiology work may lead to contamination of samples and or reagent solutions.

For part numbers, refer to [Appendix A, Parts List](#).

## Documentation

The following documents are included with the Assurance® GDS Rotor-Gene® Q:

- User Manual (55342/ MK\_TN5775EN, MS\_TN5775EN)
- Qiagen Declaration of Conformity

## Technical Specifications

| <b>Technical Specification</b>  | <b>Definition</b>  |
|---------------------------------|--|
| <b>Communications</b>           | USB, Serial  |
| <b>Connections</b>              | One USB port, one serial port, one power supply port   |
| <b>Dimensions &amp; Weight</b>  | Door Closed W 37 X D 42 X H 27.5 cm (14.6 X 10.8 X 16.5 in)<br>Door Open W 37 X D 42 X H 56 cm (14.6 X 10.8 X 22 in)<br>12 kg (26.5 lb)  |
| <b>Environmental Conditions</b> | Indoor use<br>Altitude: Up to 2,000 m (6,500 ft)<br>Air Temperature range: Transportation -25 °C – 60 °C (-13 °F – 140 °F) in manufacturer's package; Storage 15 °C – 30 °C (59 °F – 86 °F) in manufacturer's package<br>Humidity: Maximum relative humidity 75% (noncondensing)<br>Environmental class: Transportation 2K2 (IEC 60721-3-2); Storage 1K2 (IEC 60721-3-1)   |
| <b>Power Requirements</b>       | <b>External Power Supply</b><br><b>Voltage</b><br>Frequency: 50 to 60 Hz<br>Voltage: 100 – 240 V AC<br>Peak: 520 VA<br>Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages.<br>RGQ should be grounded, it is equipped with a 3-conductor AC power cord and should only be operated from an AC power outlet that has a ground (earth) connection.<br>Idle power consumption: 8 VA<br>Fuse: F5a 250 V<br><b>Heat dissipation/thermal load</b><br>Average: 0.183 kW (632 BTU/h)<br>Peak: 0.458 kW (1578 BTU/h) |
| <b>Thermal Specifications</b>   | Temperature range: Ambient to 99 °C<br>Temperature accuracy: ±0.25 °C (type, measured 30 s after clock start)<br>Temperature resolution: ±0.02 °C (smallest programmable increment)<br>Temperature uniformity: ±0.01 °C<br>Ramp rate: > 15 °C/s heating<br>(peak ramp rates, air): > 20 °C/s cooling   |
| <b>Optical Specifications</b>   | Excitation sources: High energy light-emitting diodes<br>Detector: Photomultiplier<br>Acquisition time: 4 s  |
| <b>Laptop Requirements</b>      | Operating system: Microsoft® Windows® 10<br>Processor: Pentium® IV or higher, 2 GHz<br>Main memory: 512 MB RAM<br>Hard disk space: 10 GB HDD   |
| <b>Rotor Capacity</b>           | Black rotor – 36 wells for use with 0.2 mL amplification tubes<br>Blue rotor – 72 wells (sold separately) for use with 0.1 mL amplification tubes  |

# Setup/Operation

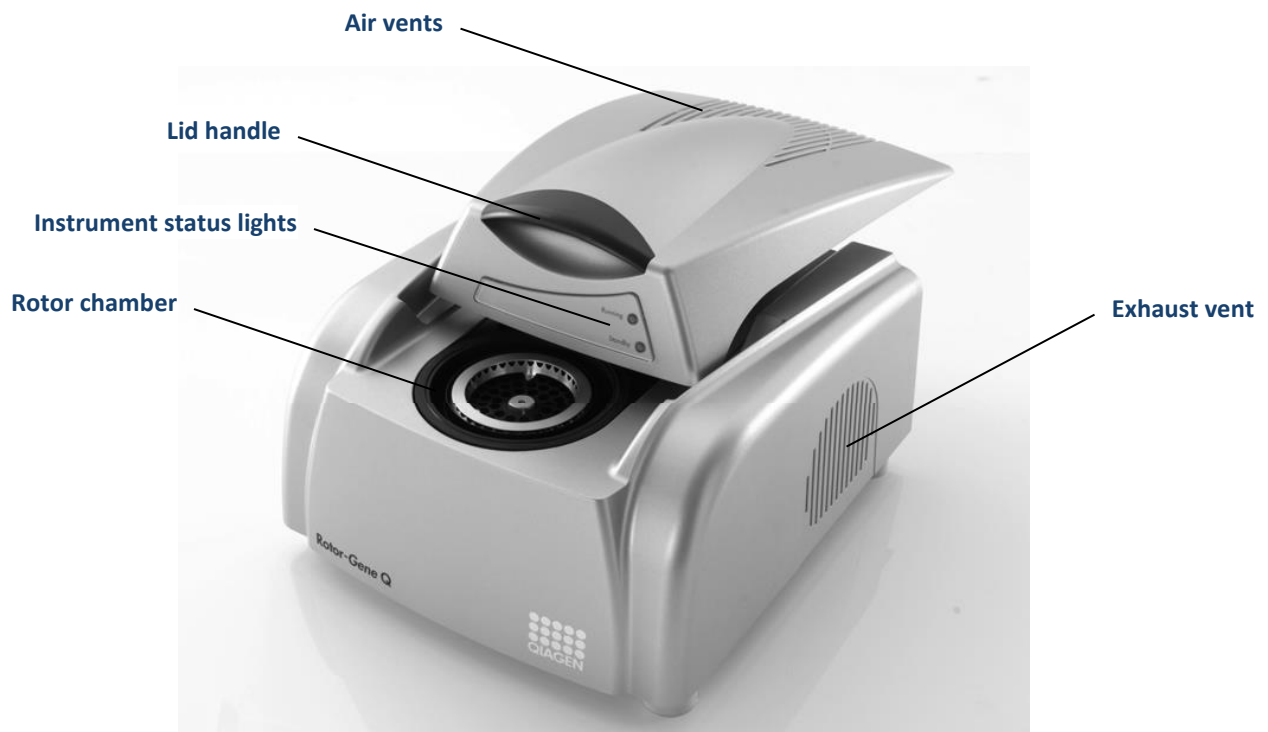
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To install the Assurance® GDS Rotor-Gene® Q, remove it from its packing materials and place it on a secure bench top. Connect the power cable to a suitable line conditioner and battery backup (i.e. APC Back-UPS RS, 600 watts/1000VA, Input 120V/Output 120V and Tripp Lite LC1200 Line Conditioner or equivalent) connected to a grounded electrical outlet.

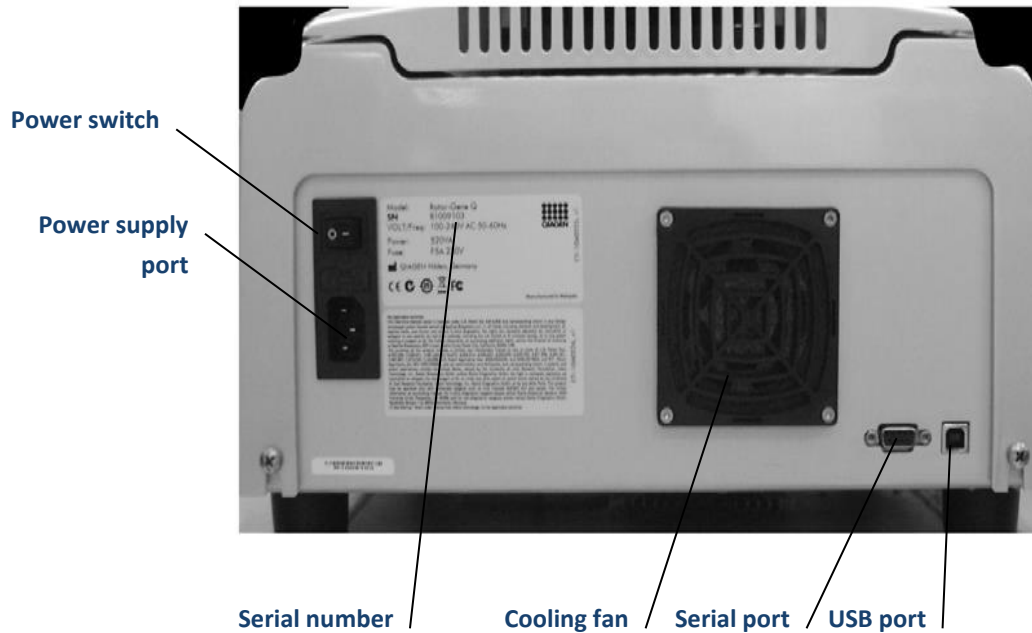
The Assurance® GDS Rotor-Gene® Q can be connected to the communications port of the Assurance® GDS Q laptop via the USB cable included with the instrument. It is important to only use the authorized laptop provided, use of other laptops may cause software errors.

NOTE: The side exhaust vent and the air intake vent on the bottom of the unit must remain unobstructed to ensure suitable air flow and proper operation of the RGQ.

## Rotor-Gene Q (Front View)



## Rotor-Gene Q (Rear View)



## Power On and Start Up

To start the Assurance® GDS Rotor-Gene® (RGQ):

- 1 Make sure that the RGQ is connected to a power source. The RGQ software will only recognize the RGQ if the RGQ is powered on.
- 2 Turn the RGQ power on using the MAINS power switch located on the rear panel (O is off, I is on). The standby indicator light on the front panel will illuminate blue.
- 3 Connect the Q laptop to the RGQ via the USB cable and power it on.
- 4 Select the appropriate user access level and enter the password.

## User Levels

The Assurance® GDS Rotor-Gene® Q software is equipped with three different user access levels:

- The **“GDS Administrator”** user level provides IT professionals or administrators with the ability to set up new users, assign individual passwords, and configure the computer’s operational settings. This login is intended for use by qualified IT personnel only and is password protected.
- The **“GDS Analyst”** user level provides Quality and Laboratory Managers with the ability to analyze data in greater detail. Analysts have the ability to generate a report that can be saved to a file, printed, or e-mailed directly from the GDS Rotor-Gene® Q software and is password protected.
- The **“GDS Operator”** is the default access level (no password needed) that allows the user to enter sample information and provides a convenient results table. Operators have the ability to generate a report that can be saved to a file, printed, or e-mailed directly from the GDS Rotor-Gene® Q software.

Necessary passwords can be obtained by contacting Technical Services at [BioMTS@milliporesigma.com](mailto:BioMTS@milliporesigma.com).

## Loading the Assurance® GDS Rotor-Gene® Q

Turn on the Assurance® GDS Rotor-Gene® Q.

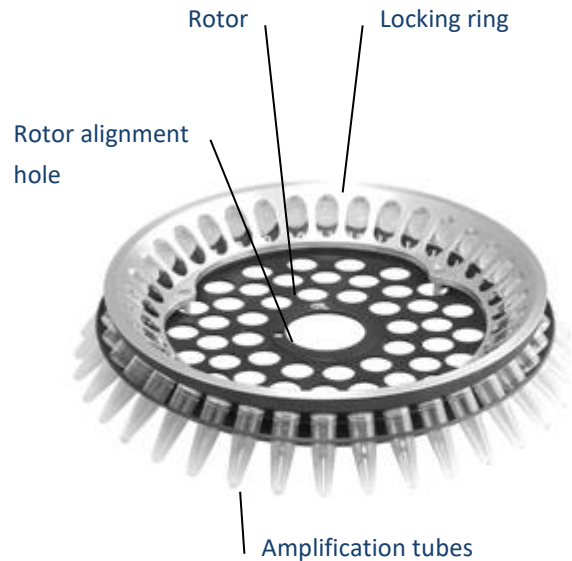
Open the Assurance® GDS Rotor-Gene® Q by pushing the cover back.

Ensure that the **rotor** is correctly positioned in the Rotor-Gene® rotor chamber by aligning the hole in the center circle of the rotor with the alignment pin on the Rotor-Gene® Q. Press down firmly on the rotor, when installed properly the rotor will snap in place.

Load the first amplification tube containing prepared sample (see Assurance® GDS kit directions for use) into the rotor position labeled as #1. Follow in a consecutive pattern around the rotor until all amplification tubes are loaded. Each amplification tube should snap into place and sit flat in the rotor.

Place **locking ring** over the top of the tubes. Snap the ring into place, by aligning the pins at the bottom of the ring with the holes in the rotor. The domed caps of the tubes should sit in the open slots of the locking ring.

Close the Rotor-Gene® Q.



## Unloading the Assurance® GDS Rotor-Gene® Q

When the Rotor-Gene® Q run is finished, open the instrument by pushing the cover back. Remove the locking ring.

⊗ **DO NOT attempt to remove used amplification tubes while rotor is in the Rotor-Gene® Q.**

To remove the rotor push down on the spring-loaded button in the center of area of the rotor. Inspect the amplification tubes for signs of leaking or open lids. If leaking has occurred, see [Decontamination](#) section of this user manual. Invert the rotor containing the amplification tubes over a sealable, disposable bag and gently push on the bottom of the amplification tubes to pop them out of the rotor. The bag should be sealed and placed into another bag for disposal. The double bagged tubes should be disposed of outside of the lab, after each run and following all applicable local and/or national regulations on disposal of wastes. Used amplification tubes should never be opened or transported throughout the laboratory.

An additional disposal option is to place used amplification tubes into a sealable bag with enough 10% bleach solution to cover the tubes. The bag should be disposed of outside of the lab, at the end of the day and following all applicable local and/or national regulations on disposal of wastes.

⊗ **DO NOT open used amplification tubes.**

⊗ **DO NOT autoclave used amplification tubes.**



### Important Technique

After working with the Assurance® GDS Rotor-Gene® Q technicians should remove and dispose of their gloves before moving into any other work zone.

## Launching Software

To launch the Assurance® GDS Rotor-Gene® Q software double-click on the RGQ icon shortcut found on the laptop computer desktop. If using the black 36 well rotor, choose the icon with 36 in the right corner, if using the blue 72 well rotor, choose the icon with 72 in the right corner.



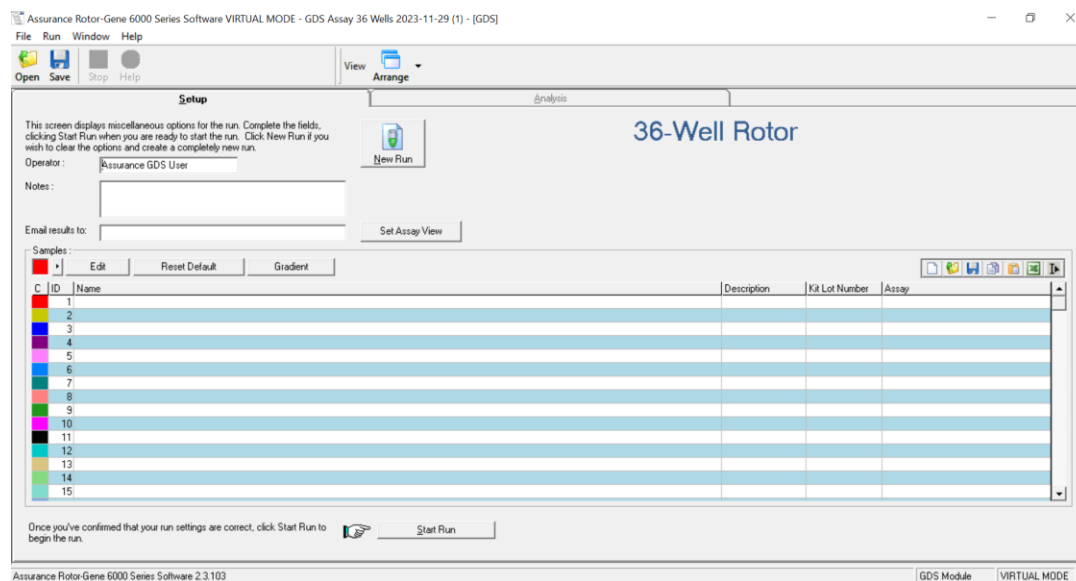
**NOTE:** If the RGQ software is launched while the computer is disconnected from the RGQ or if the RGQ is not powered on, a warning screen will appear giving the user the option to operate the software in “Demo Mode”. Demo mode is intended to allow users to familiarize themselves with the use of the software or to demonstrate its use. If the software is operating in Demo mode it will not control the RGQ.

RGQ software is offered in multiple languages: English, French, Spanish, Chinese (simplified).

**NOTE:** The language must be selected when installing the software on the laptop. Laptops should have their Windows setting change to the corresponding RGQ software language ensuring all characters display correctly.

## Entering Sample Information

The RGQ software opens to the ‘classic’ Setup menus shown below. A new run is automatically opened each time the RGQ software is launched.



| ID | Name | Description | Kit Lot Number | Assay |
|----|------|-------------|----------------|-------|
| 1  |      |             |                |       |
| 2  |      |             |                |       |
| 3  |      |             |                |       |
| 4  |      |             |                |       |
| 5  |      |             |                |       |
| 6  |      |             |                |       |
| 7  |      |             |                |       |
| 8  |      |             |                |       |
| 9  |      |             |                |       |
| 10 |      |             |                |       |
| 11 |      |             |                |       |
| 12 |      |             |                |       |
| 13 |      |             |                |       |
| 14 |      |             |                |       |
| 15 |      |             |                |       |

**Operator:** Enter name of user. *(optional field)*

**Notes:** Enter comments or other description of run. *(optional field)*

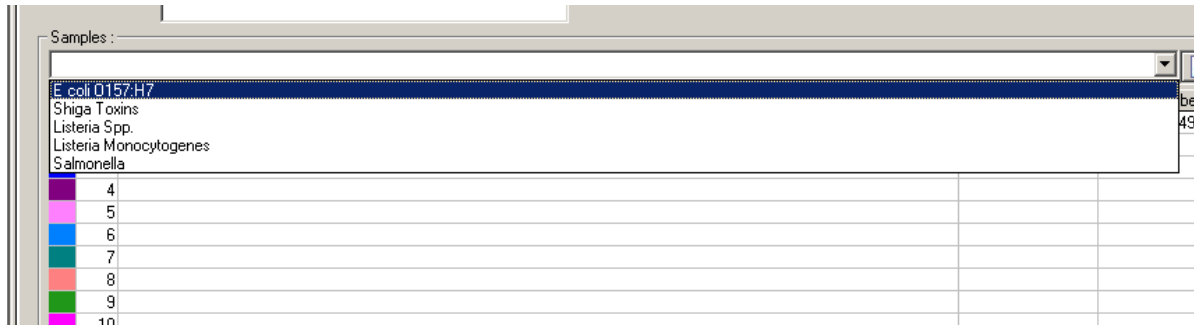
**Email results to:** Not currently functional

**Name:** Click in the desired cell to enter sample names. No results will be reported for any sample that is not identified with a name in the setup screen. *(required field)*

**Description:** Enter description of sample matrix to be analyzed. *(optional field)*

**Kit lot number:** Enter lot number from kit label. *(required field)*

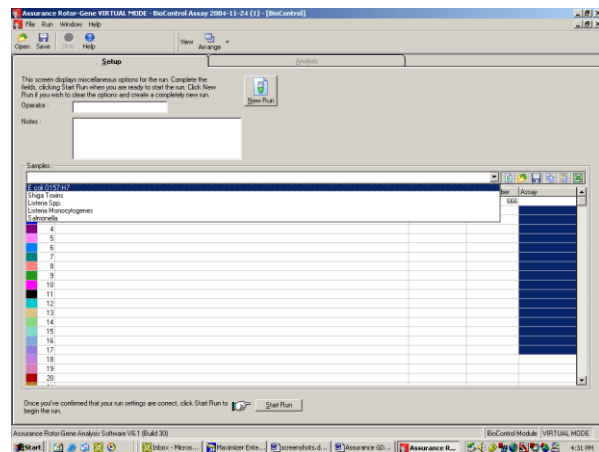
**Assay:** To select an assay, position your cursor in the Assay column. Click on the down arrow in the “Samples:” window. Click to select the appropriate assay. **(required field)**



After entering sample data, review all entries to ensure they are correct. Once a run has started changes to the sample information will not be allowed.

**NOTE:** To select the same assay type, lot number, or description for multiple samples:

- Click the first cell within the corresponding column.
- Drag the pointer or use shift+arrow key to highlight the desired cells.
- Type in the description or lot number for this series or for assay type, select the desired assay type from the drop-down menu.
- The software will automatically fill all cells in the selected series.



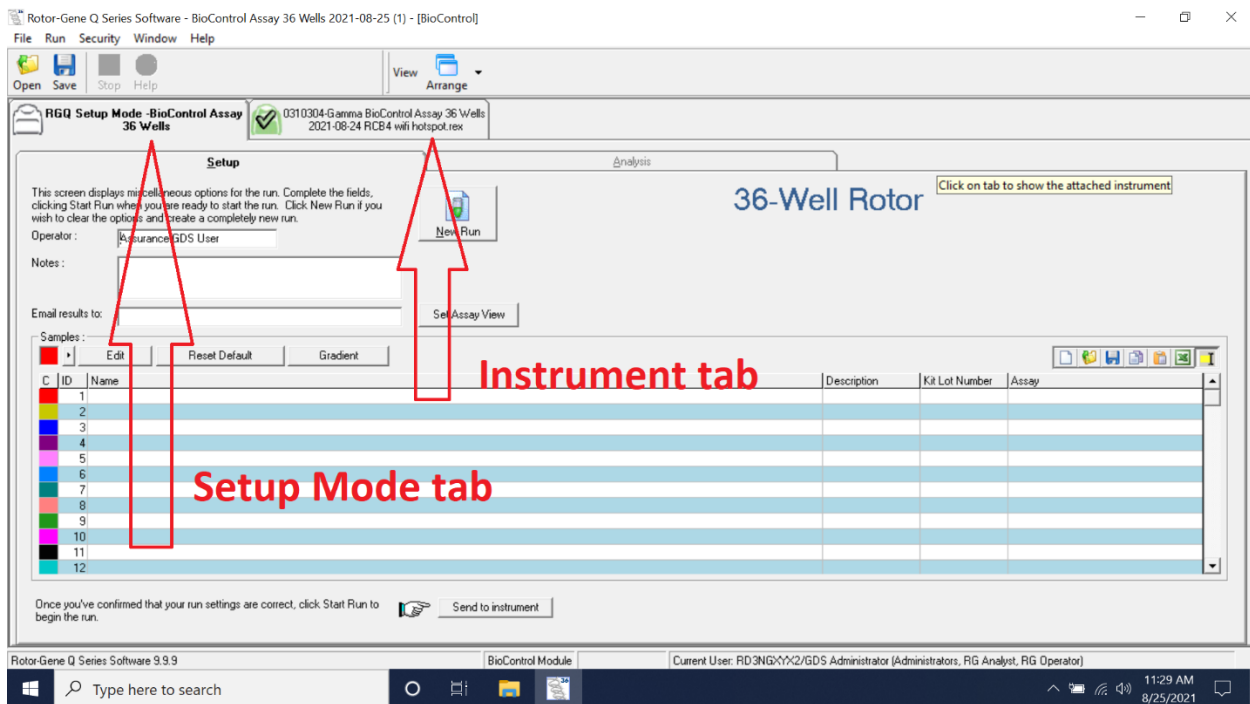
After entering sample data, review all entries to ensure they are correct prior to starting run. Once a run has started, changes to the sample information will not be allowed.

After confirming sample information, select **Start Run**. You will be prompted to save the run. Select the desired folder and type in the desired file name. The default file name is “BioControlassay<date>”.

Select **Save** to begin the run.

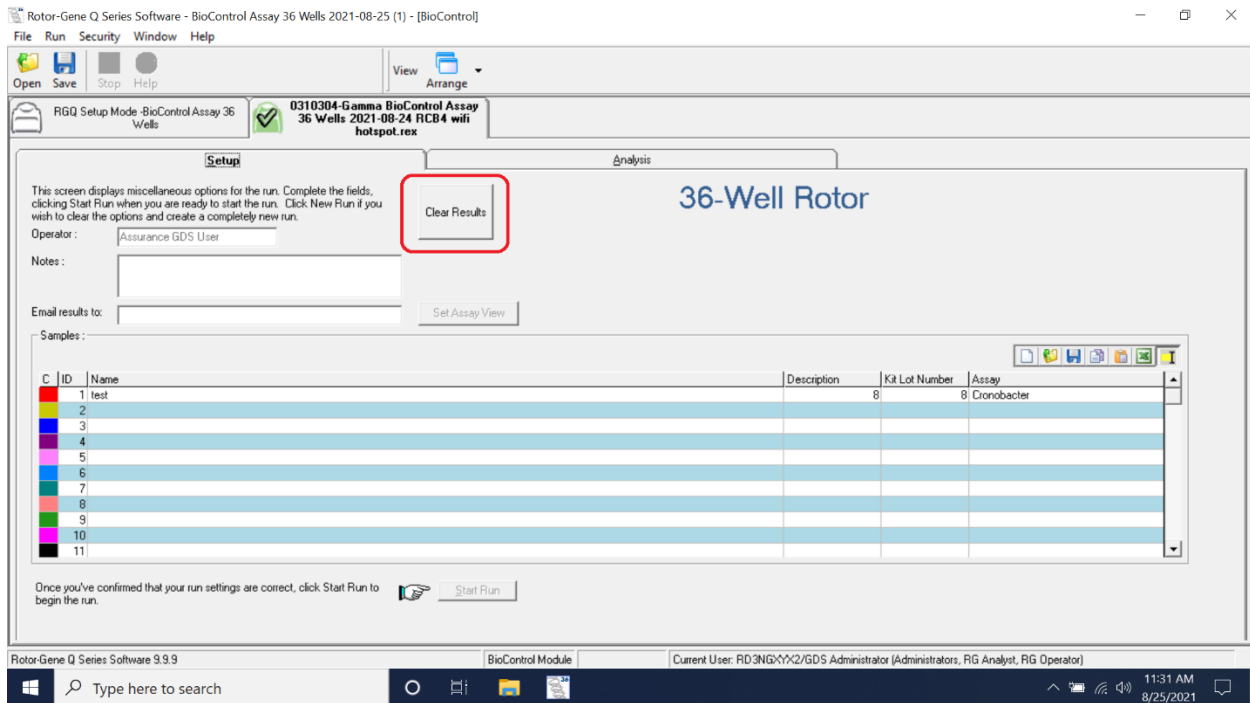
**IMPORTANT:** If using **GDS Adaptor Boxes with the RGQ**, the user interface has a tab-style system to accommodate the expansion of multiple instruments linked to a single laptop (up to 6 tabs). One tab is designated the “setup mode” tab and up to 5 instrument tabs can be added. See below.

**NOTE:** Instrument tabs will only populate if instruments have been configured to the laptop [if only 1 instrument is configured to the laptop, only 1 instrument tab will populate].

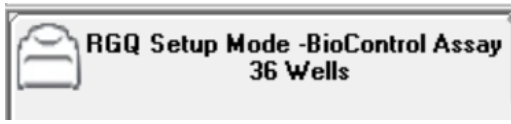


**IMPORTANT:** The user must use the “setup mode” tab to set up new runs. Runs can be pushed to “open” instruments once the run is created in the “setup mode” tab.

**NOTE:** An instrument must be open, indicated by a blue icon, before a run can be pushed to the instrument. Instruments can be cleared of exiting run information through the “clear run” button on the corresponding instrument’s tab under the “Setup” subtab, as shown below.

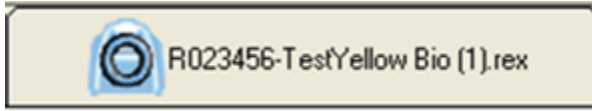


Integrated into the ‘adaptor box’ user interface are color coded status icons [see images below for icon example and description].



= Setup Mode Tab | Used for setting up new runs to be sent to open instruments. Can also be used to read run files.

**NOTE:** the virtual mode tab is always present.



= Empty Instrument | Instrument cleared and ready to receive new run file. Note: instruments must be cleared before a new run can be sent to the instrument.



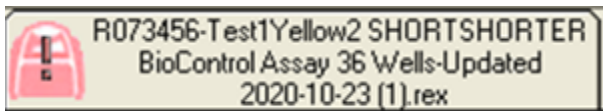
= Run Complete | Run has finished, and results are ready to be read, saved, exported, etc.



= Connection Lost | Connection to the adaptor box or RGQ has been broken and must be established before further action.



= Run in Progress | Run has been initiated and instrument is taking readings.

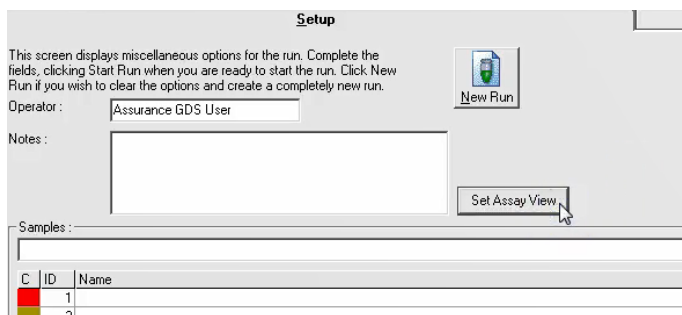


= Instrument Error | problem with instrument.

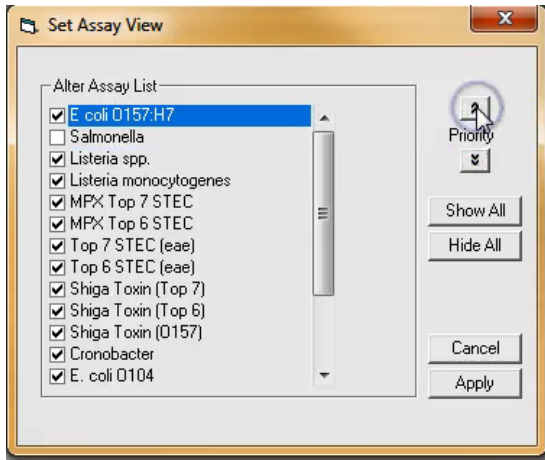
Seek technical assistance.

## Software Setup Options

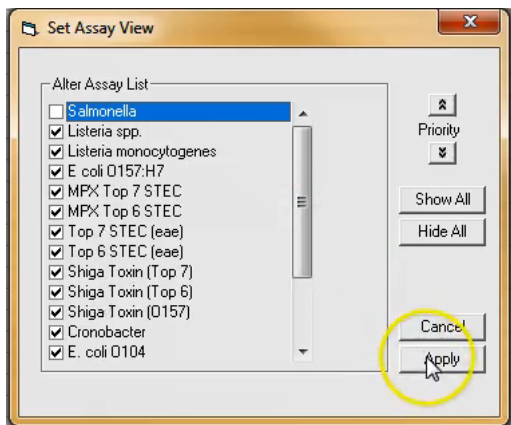
“Most used” assays can be ordered to the top of the assay list by selecting Set Assay View in the Setup tab.



The window below will open, choose the assay (it will highlight) and click on the priority arrows to move the assay up or down in the list.



Assays may also be hidden from the list by unchecking the box and selecting “Apply”. To have all assays appear again, select “Show All” and “Apply”.



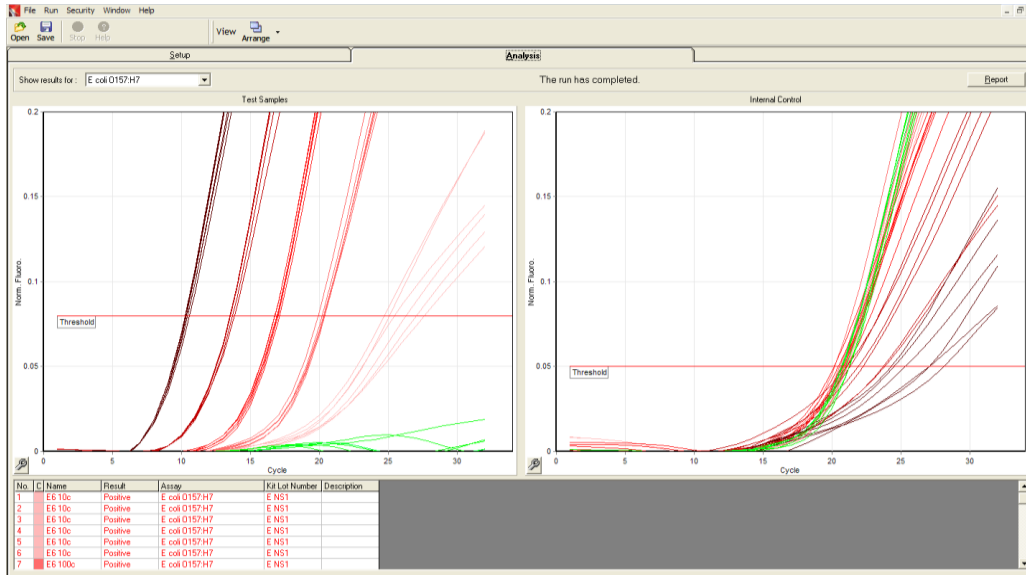
## Viewing Results

When logged in as a “GDS Operator” the Assurance® GDS Rotor-Gene® Q software will display results in the table format only.

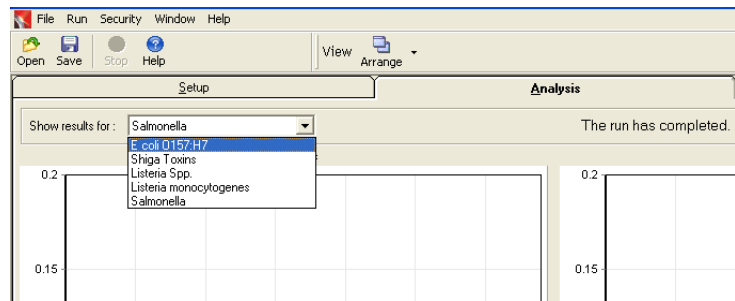
| No. | C | Name    | Result   | Assay          | Kit Lot Number | Description |
|-----|---|---------|----------|----------------|----------------|-------------|
| 1   |   | E6 10c  | Positive | E coli O157:H7 | E NS1          |             |
| 2   |   | E6 10c  | Positive | E coli O157:H7 | E NS1          |             |
| 3   |   | E6 10c  | Positive | E coli O157:H7 | E NS1          |             |
| 4   |   | E6 10c  | Positive | E coli O157:H7 | E NS1          |             |
| 5   |   | E6 10c  | Positive | E coli O157:H7 | E NS1          |             |
| 6   |   | E6 10c  | Positive | E coli O157:H7 | E NS1          |             |
| 7   |   | E6 100c | Positive | E coli O157:H7 | E NS1          |             |

When logged in as a “GDS Analyst” the Assurance® GDS Rotor-Gene® Q software will display amplification curves for the “Test Samples” and “Internal Control” for each tube. The graph will begin to display the fluorescence signal for each sample after a number of cycles have been completed to generate baseline signal. At that point the

established Threshold lines will appear in the Test Sample and Internal Control windows. A run consists of a total of 32 cycles and will take roughly 80 min to complete. Although it is possible to view the curves in real-time, users will need to wait until the end of the run to report results.

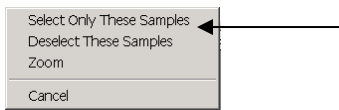


Multiple assays can be run simultaneously on the Assurance® GDS Rotor-Gene®. Results for all assays appear in the results table by sample number. To enhance readability, the graphic representation of these results is by assay type. To change assay type select the desired assay from the “Show results for” drop down menu.



During or upon completion of a run, samples can be viewed individually or in groups. To select a range of samples, click on the graph near the first sample and draw a box around the samples of interest. When you release the mouse button, a menu will appear.

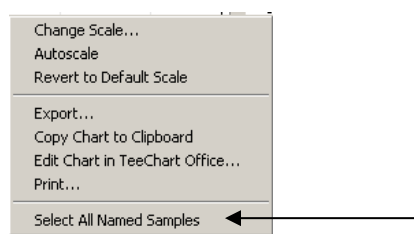
Clicking **Select Only These Samples** will only show those samples selected.



**Deselect These Samples** will show all samples except those that have been selected.

To return to a view of all samples right-mouse-click on the graph. A menu will appear.

**Select All Named Samples.**



## Interpreting Results

When logged in as a “GDS Analyst” the Assurance® GDS Rotor-Gene® Q software will display amplification curves for the “Target(s)” and “Internal Control” for each sample. The graph will begin to display the fluorescence signal for each sample. Once the run has been completed all samples and their determination will appear in the Results table. The table shows the determination of test results for each sample. Results can be Positive, Negative, or invalid as a result of no amplification (No Amp).

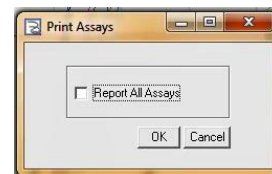
**Positive:** Sample tests positive for the target organism and internal control is positive or samples test positive for target organism and internal control is negative (in the case of strong positives the amplification of the target may use all reaction resources not leaving any for the internal control).

**Negative:** Samples test negative for target organism and internal control is positive.

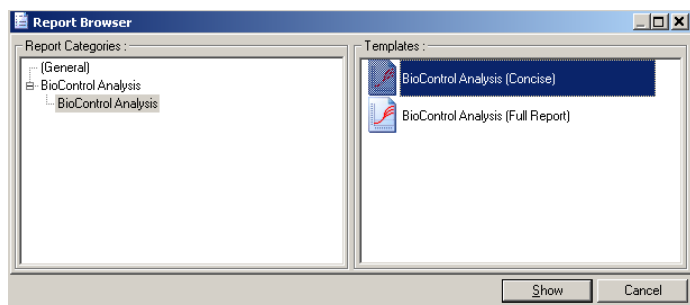
**No Amp:** Sample tests negative for target organism and internal control is negative. This means that amplification did not occur. User should go back to enriched sample and re-run assay. If problem persists, contact Technical Services at [BioMTS@milliporesigma.com](mailto:BioMTS@milliporesigma.com).

## Reports

Upon completion of the run, the **Report** button located at the top right of the Analysis Screen becomes selectable. Selecting the Reports button opens the screen shown. By checking the box, a user will have a report that includes all the assays completed during a run, if the box is left unchecked then the report generated will only show the assay results for the assay displayed on the screen.



After selecting OK the screen below will appear.



BioControl Analysis (Concise) – This report generates a results table for each assay.

BioControl Analysis (Full Report) – This report generates a results table and amplification curves for each assay – Analyst level users only.

**Using the buttons on the top, the reports can be printed, saved, emailed or exported to Word.**



The report contains a table showing all run information including operation, date, time, and valid signature.

The **Run Signature** is a non-reversible key which is regenerated every time the file is changed. If any section of the file is modified outside of the software, the signature and the file will no longer match. Using the signature, you can ensure that the data has not been modified. The signature also protects against non-malicious corruption, such as file-system errors.

## Virtual Mode/Analysis Only Mode

The Rotor-Gene® Q software can be run independent of the RGQ instrument for demonstration purposes or to view results from past runs. This mode of operation is termed “Virtual Mode” or “Analysis Only Mode”. During this mode of operation, no data is actually acquired from the Rotor-Gene® Q. If a run is initiated in Virtual Mode, all named samples will be reported as No Amp. When a run is started in Virtual Mode the file name at the top of the screen will begin with "Analysis-Only Assurance Rotor-Gene VIRTUAL MODE", the “running” status light will remain dark, and no sound will be emitted by the RGQ.

Virtual Mode and Analysis Only Mode can be accessed by launching the Assurance® GDS Software while the Rotor-Gene® Q is powered off or disconnected from the laptop.

NOTE: The above will be in the ‘classic’ user interface, if a user wishes to demo the ‘adaptor box’ user interface, please contact Technical Services for further instructions.

## Additional Software on Networked Laptops

Assurance® GDS Rotor-Gene® Q software manages time-critical processes during the PCR run and the data acquisition process. For this reason, it is important to ensure that no other processes use significant system resources and thus slow down the RGQ software. It is particularly important to pay attention to the points listed below. System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it. Additionally, to prevent communication issues between the RGQ and laptop, it is recommended that all Assurance® GDS laptops be shut down at least **once per day**.

### *Virus scanners*

We are aware of the threat that viruses cause to any computer that exchanges data with other computers. RGQ software is primarily installed in environments where local policies exist to minimize this threat. These policies usually require use of a particular anti-virus tool. Due to the sheer number of anti-virus tools available, it is not possible to predict the possible impact on the RGQ software if such a tool is active during a PCR run. In order to get consistent results, system administrators should therefore ensure that during performance of a PCR run:

- File access is not intercepted by a virus scanner
- Updates to the virus database are not performed
- File scans are not performed

We strongly recommend disabling virus scanner activity during real-time PCR data acquisition. The critical virus scanner tasks described above can only be safely carried out without running the risk of impacting the performance of the instrument when the RGQ software is not running. Otherwise there is a risk of adverse impact on the performance of the instrument.

### *System tools*

Many system tools may use significant system resources even without any user interaction...these should be disabled. Typical examples of such tools are as follows:

- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the internet
- Remote monitoring and management tools
- Power saving options

Please be aware that due to the dynamic nature of the IT world, this list may not be complete, and tools may be released that are not known at the time of writing. It is important that system administrators take care that such a tool is not active during a PCR run.

### *Operating system updates*

We strongly recommend turning off any automatic update processes of the operating system on the computer that is used for data acquisition on the RGQ.

### *Wireless and remote access software*

We strongly recommend Wi-Fi and remote access software (such as TeamViewer) not be used on RGQ computers, as these programs can interfere with communication between the computer and RGQ.

## Using the GDS Adaptor Box to link Multiple RGQ to 1 Laptop

The Assurance® GDS Adaptor Box can be used to link up to 5 RGQ to one laptop. For installation guidance, please refer to the GDS Adaptor Box Directions for Use. Note: Installation will require site IT.

# Troubleshooting

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For technical assistance or questions about the Assurance® GDS Rotor-Gene® Q please contact Technical Services at [BioMTS@milliporesigma.com](mailto:BioMTS@milliporesigma.com).

Locate the serial numbers of the RGQ and laptop prior to contacting technical support. To help us serve you quickly and efficiently, please refer to [Appendix B. Before Calling Us](#).

To send software run or .rex files to technical support, follow the procedure below:

- Left click on **Help**, located on the top toolbar
- Select **Send Support Email...**
- Choose the support folder (file name may not correspond to run name, choose most recent dated folder)
- Select **Save As**, save to a USB drive and email to technical support from a computer with internet access or email directly from the laptop if networked

## Warranty

Units that are under warranty will be repaired and returned to the user at no charge. If you have any questions about applicability, contact your local sales representative. For out-of-warranty repairs, contact your local sales representative who will discuss service options with you.

## Instrument Return Procedure

Contact Technical Services at [BioMTS@milliporesigma.com](mailto:BioMTS@milliporesigma.com) to obtain authorization before returning any Assurance® GDS equipment. To help us serve you quickly and efficiently, please refer to [Appendix B. Before Calling Us](#). To return a piece of equipment:



- Carefully pack the RGQ unit and laptop in original container to prevent damage in transit. Check with Technical Services regarding proper method of shipment. No responsibility is assumed for damage caused by improperly packaged instruments. Indicate the return authorization on the carton and on the packing slip.
- Always insure for the replacement value of the unit.

## Preventative Maintenance

To ensure proper performance of the Assurance® GDS Rotor-Gene® Q the following routine cleaning and lubrication procedures should be performed on a regular basis. It is recommended that these procedures be carried out **at least monthly**. However, based on the specific laboratory environment and number of runs per day, it may be necessary to complete procedures more often.

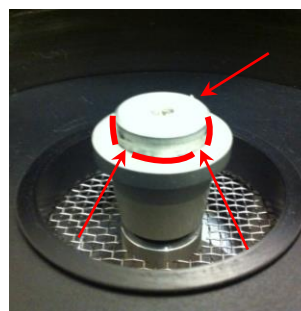
### Optics Cleaning

Optical performance of the RGQ is maintained by ensuring that the lenses, located at both the emission and detection source, are clean. This is achieved by gently wiping a cotton tip applicator, moistened with 70% isopropyl alcohol, over the lenses.

### Rotor Locking Mechanism Adjustments & Lubrication

For optimum performance of the rotor, the spring-loaded rotor locking mechanism should be rotated to prevent the bearings from wearing grooves in the inner circle of the rotor. Proceed as follows:

- Hold the main hub of the spring-loaded rotor locking mechanism and turn the center piece 1/8<sup>th</sup> of a turn to change the position of the ball bearings.
- Fit a rotor into the instrument and then remove to test the smooth action of the quick release. If the center piece sticks in position, lubricate with silicone oil or a [dry Teflon based lubricant](#).
  - Do not spray directly onto the button. Instead spray the lubricant into a container and use an eye dropper, small syringe, or applicator to apply a very small amount to the three ball bearings. Work the lubricant into the bearings by depressing the center piece several times.
- After confirming the smooth action, wipe away any excess.
- Silicone oil can be sourced from Sigma Aldrich [Silicone Oil, viscosity 10 cSt, Part No. 378321].



Keep the bench area clean and free from dust and sheets of paper. There are two air inlets on the RGQ; one is at the bottom and one is on the right side. Do not block these inlets. Loose material such as paper or dust may compromise performance.

## Performance Verification

The OTV (Optical Temperature Verification) Insert (Qiagen Part No.981400) provides automated performance verification of the RGQ. It is recommended that the OTV be run **annually** to verify the GDS RGQ performance.

The OTV system uses the chemical properties of thermochromic liquid crystals (TLCs) as an absolute temperature reference. When heated, a TLC changes from opaque to transparent at a very precise temperature. The Rotor-Gene® can measure this precise temperature transition point and, by comparing the measured in-tube thermal transition point to the known calibrated value the OTV software verifies that the Rotor-Gene® is within specification. If necessary, the OTV software allows the user to automatically recalibrate the instrument with a simple push of a button. A printable post-run report documents each test and any necessary recalibration.

Users should purchase the following part numbers directly from Qiagen to run the OTV:

| Part Number | Description                |
|-------------|----------------------------|
| 981400      | Rotor-Disc OTV Kit         |
| 9018899     | Rotor-Disc 72              |
| 9018900     | Rotor-Disc 72 Locking Ring |

### OTV Test Procedure

- (a) Launch **Rotor-Gene Verification** application from desktop shortcut.
- (b) Install the appropriate OTV Optical Filter in the Rotor-Gene detector well and click the check-box on the screen to verify the installation.  
**NOTE:** There are two filters included, the smaller green circular filter fits the Rotor-Gene 3000; the larger green filter with a flat edge fits the Rotor-Gene Q. Please use the latter for the GDS RGQ.
- (c) Place the OTV Rotor (9018899) in the Rotor-Gene Q. Ensure that the rotor is correctly positioned by aligning the hole in the center circle of the rotor with the alignment pin on the Rotor-Gene Q.
- (d) Load OTV Insert (981400) into the OTV Rotor. Verify that the insert alignment tab is correctly positioned in the rotor.  
**NOTE:** Inspect OTV Insert wells to ensure contents are in the bottom of well. If necessary, shake Insert with a snapping motion to move contents to bottom of wells.
- (e) Enter the serial number found on the top of the OTV insert. (i.e. "OTV-...").
- (f) Install the OTV rotor locking ring (9018900).
- (g) Select "Start" and proceed as directed to perform the Optical Temperature Verification of the Rotor-Gene Q.



## OTV Results

Upon completion of the OTV, the software will automatically determine if any adjustments are necessary.

- (a) No Adjustment required – select the “Report...” function to produce an automated report with the results of the Optical Temperature Verification.
- (b) Adjustment Recommended – select “Apply Adjustment...” to apply an automated correction. Repeat the OTV procedure to verify that no further corrections are necessary.
- (c) If the performance of the Rotor-Gene cannot be verified, contact Technical Services.

## OTV Storage

Store the OTV Insert in a dark, dry, location, at room temperature (18-25°C).

Avoid exposure to direct sunlight; UV light will degrade the OTV liquid crystals.

Do not freeze the OTV insert.

The OVT Insert may be used within the expiration date printed on the insert or for 30 verification runs, whichever comes first.

# Contamination Prevention

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Assurance® GDS is a highly sensitive and specific test based on the principles of DNA amplification and detection. Due to the sensitive nature of this assay certain precautions must be taken to avoid potential sample contamination and produce accurate test results.

Contamination can be caused by live organisms (from samples, positive controls, and the environment) or from amplified DNA produced by a positive Assurance® GDS reaction. The amplification reaction produces billions of copies of DNA, allowing highly sensitive detection of specific target sequences. Microscopic volumes of amplified reactions have the potential to cause cross contamination if spread by contact or aerosols. Improper workflow and handling of used Assurance® GDS amplification tubes may result in DNA contamination of laboratory work surfaces and equipment.

## Recommended Lab Organization and Workflow

To help avoid contamination of reagents and samples it is highly recommended that 3 distinct work zones be established within the laboratory for performing various aspects of the GDS assay.

### ***Work Zone 1 – Reagent Preparation***

Work Zone 1 should be an area where bacterial cultures and food samples are not handled or stored. All handling and preparation of Assurance® GDS reagents should be performed in this area including:

- Addition of concentration reagent, wash solution, and media to the sample block
- Addition of resuspension buffer to the resuspension plate
  
- Loading the gel cooling block with amplification tubes
- Refilling of PickPen® tip boxes

Laboratory personnel should wear new gloves upon entering Work Zone 1. The same gloves may be worn when moving forward into higher work zones (e.g. Work Zone 1 to Work Zone 2).



### **Important Technique**

Before entering Work Zone 1 and handling GDS reagents, technicians should put on clean gloves and a clean lab coat.

#### ***Work Zone 2 - Sample Preparation***

This area should conform to typical specifications for a microbiological work station. All handling and processing of samples and enrichments should be conducted in this area including:

- Transfer of enriched sample to prepared sample block
- PickPen® transfers of concentrated samples to prepared resuspension plate
- Transfer of resuspended sample to amplification tubes



### **Important Technique**

To avoid potential contamination, clean gloves should be worn when opening amplification tubes for the sample transfer.

#### ***Work Zone 3 – Amplification & Detection***

This area should contain a suitable work surface and power source for the RGQ and laptop workstation. No cultures, food samples or disposable supplies should be stored or prepared in this area.

All used amplification tubes should be appropriately double bagged and disposed of daily outside of the laboratory (see [Unloading the Assurance® GDS Rotor-Gene® Q](#)). Do not autoclave used amplification tubes. Used amplification tubes should never be opened or transported throughout the laboratory.

Rotor-Gene® Q software should be setup for the run first, prior to preparing the samples for the run.

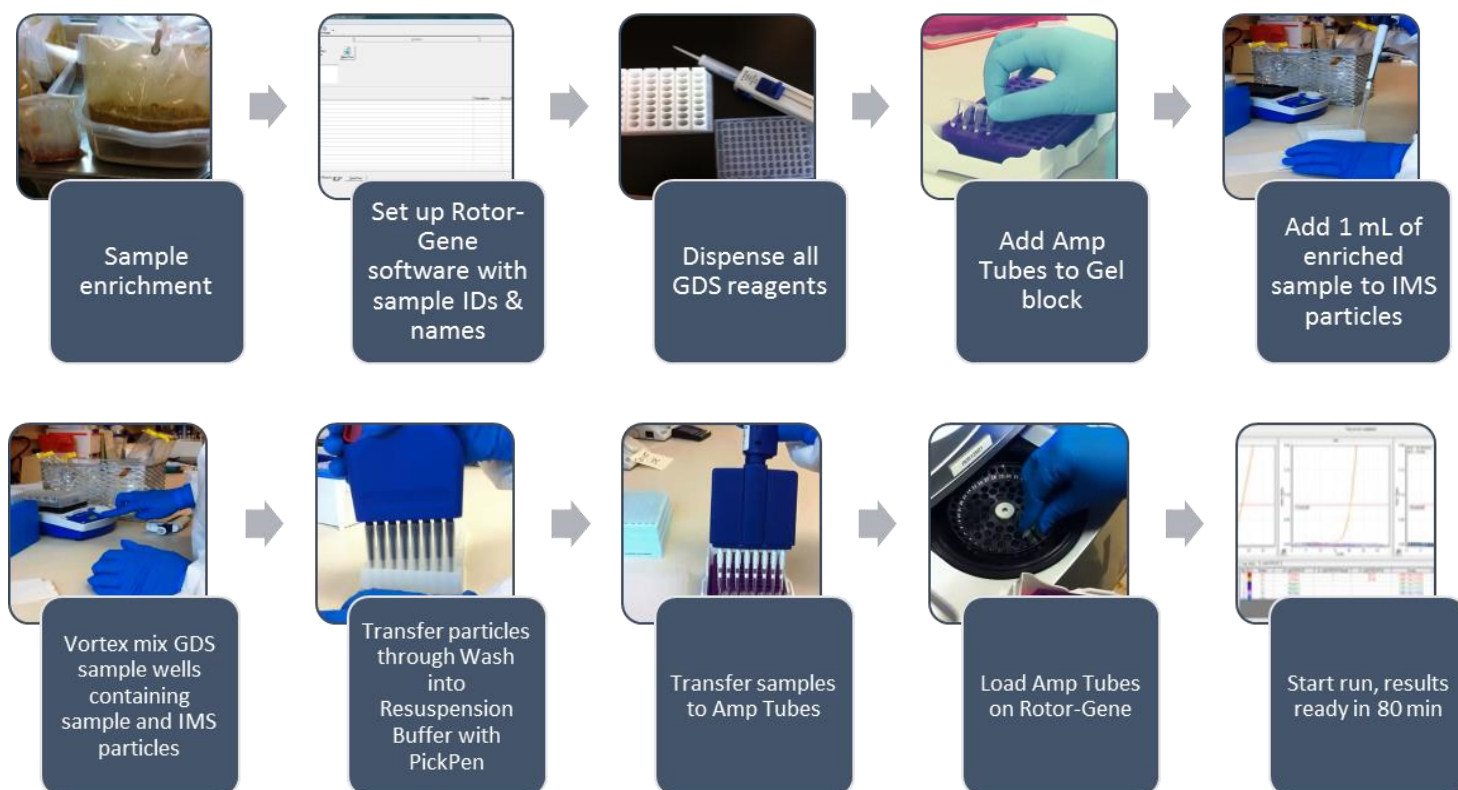


### **Important Technique**

Lab coats used in Work Zone 3 should not be used in any other lab areas. All gloves worn in Work Zone 3 should be removed before moving to other areas of the lab.

When leaving Work Zone 3 all gloves should be removed before moving to any other part of the laboratory including Work Zones 1 and 2.

The general procedure workflow for Assurance® GDS is as follows for non-multiplex Assurance GDS assays:



For multiplex assays (i.e. MPX, HET, and ID assays), it is recommended that the amplification tubes be added to the frozen gel block after PickPen® IMS, once the samples have been transferred to the Resuspension plate.

If running 0.1 mL HT amp tubes, follow **Application Note: Utilizing New Manual Tools to run GDS HT Non-Multiplex Assays (MK\_AN6591EN, MS\_AN6591EN)** or **Application Note: Utilizing the PPMX to run GDS High Throughput Non-Multiplex Assays (MK\_AN6589EN, MS\_AN6589EN)**.

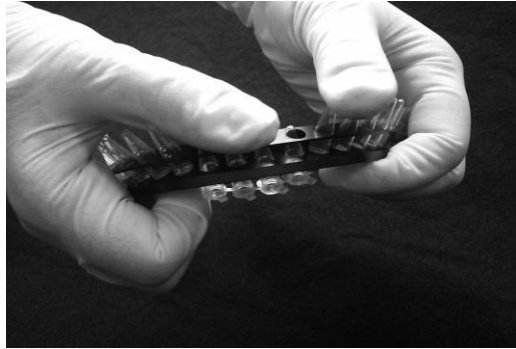
## Recommended Lab Practices

The equipment used with the RGQ must be designated for use with Assurance® GDS assays only. Use of any of these instruments including pipettes for other general microbiology work may lead to contamination of samples and/or reagent solutions.

To help prevent contamination of pipettes, aerosol barrier tips must be used for all pipetting steps.

Observe vortex mixing action. During the vortex mixing steps, media within the sample wells should not vortex up to within ½ inch of well opening. If the vortex action is causing droplets of media to splash up and adhere to the underside of the adhesive strips, turn down the rpm speed setting.

**Never open tubes after amplification.** To avoid accidental tube opening, do not attempt to remove tubes from the rotor by pulling tubes out from the top. To safely remove amplification tubes, invert the rotor containing the amplification tubes over a sealable, disposable bag and gently push on the bottom of the amplification tubes to pop them out of the rotor. The bag should be sealed and placed into another bag for disposal. The double bagged tubes should be disposed of outside of the lab, after each run to minimize contamination risk and following all applicable local and/or national regulations on disposal of wastes. An additional disposal option is to place used amplification tubes into a sealable bag with enough 10% bleach solution to cover the tubes. The bag should be disposed of outside of the lab, at the end of the day to minimize contamination risk and following all applicable local and/or national regulations on disposal of wastes.



Do not track materials from the RGQ to the amplification tube preparation area. Maintain separation between the RGQ and the amplification tube preparation area.

## Routine Cleaning

It is recommended that the following cleaning procedure be carried out **at least weekly**:

To clean the RGQ rotor chamber, remove the rotor and locking ring. Lightly spray a 10% bleach solution onto a low lint wipe (i.e. Kimwipes®) and gently clean the chamber surface to disinfect. Repeat the procedure with a 70% isopropyl alcohol solution to remove potentially corrosive residues. Locking mechanism may need to be lubricated after cleaning to prevent sticking.

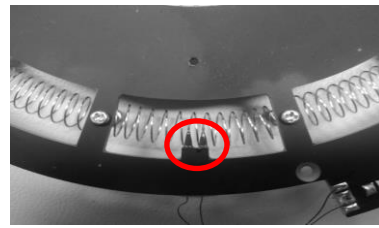
*Note: To prepare 10% bleach solution add 10 mL of commercially available bleach containing 5% sodium hypochlorite to 90 mL of deionized water. The minimum final concentration of sodium hypochlorite in the bleach solution should be 0.5%. The bleach solution is stable for 7 days from preparation. To prepare 70% isopropyl alcohol solution add 70 mL of isopropyl alcohol to 30 mL of deionized water.*

**Do not** spray any solutions directly into the rotor chamber or under the chamber lid.

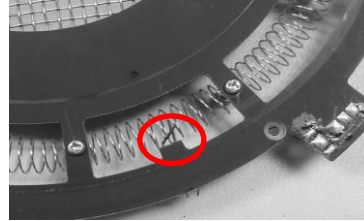
Care should be taken during rotor chamber cleaning to prevent damage to the thermistor, which is located on the heater plate assembly under the rotor chamber lid. **Do not** let low lint wipe catch on the thermistor's two prongs as it is important that they retain the proper parallel orientation. If the thermistor becomes damaged, the heater plate assembly will not heat properly which can cause the software to report 'No Amp' results.



Thermistor located to the front of the heater assembly on Rotor-Gene Q instruments



Functional thermistor



Damaged thermistor

It is recommended that the following cleaning procedures be carried out **at least weekly**:

- Clean gel cooling blocks and high throughput aluminum block with a paper towel sprayed with 10% bleach solution, rinse with a 70% isopropyl alcohol solution and dry by tapping to remove any remaining liquid from the wells. Be sure to let the block dry completely and store upside down.
- Clean the rotor and locking ring with a paper towel sprayed with 10% bleach solution, repeat the procedure with a 70% isopropyl alcohol solution to remove any potentially corrosive residues.
- Clean outside of RGQ instrument with a paper towel sprayed with 70% isopropyl alcohol solution.

It is recommended that the following cleaning procedures be carried out **after each Assurance® GDS run**:

- Clean the PickPen® by spraying a paper towel with 70% isopropyl alcohol solution and gently wiping the outside of the device. Avoid introducing any liquid into the openings at the end of the carrier sleeves. Exposure of the magnets or the inside of the carrier sleeves to moisture may result in corrosion, preventing the device from operating properly.  
Do not spray any solutions directly on the PickPen®. Do not autoclave.
- Clean bench work surfaces, sample well base(s), all GDS pipettes, all pipette tip boxes, vortex mixer, and high throughput variable spacing amp tube block + lid with a paper towel sprayed with 70% isopropyl alcohol solution.
- To clean the laptop, wipe the screen and keyboard with a low lint cloth designed for electronics.  
*Note: Do not use pre-moistened alcohol or bleach wipes to clean the laptop screen.*

For a maintenance log, please refer to [Appendix C. Maintenance Log](#).

## Use of Vapor-Lock with Positive Controls

- Vapor-Lock or mineral oil is a hydrophobic, low viscosity PCR encapsulation barrier that can be added to positive control reactions to help minimize the potential for release of the amplified DNA into the laboratory environment. The procedure for using Vapor-Lock (mineral oil) with positive control samples is detailed below and is also available in **Application Note: Vapor Lock (MK\_AN4583EN, MS\_AN4583EN)**.
  1. Remove Amplification Tubes Tq from foil pouch and place them in a gel cooling block. Reseal pouch.
  2. Transfer 40 µL of Vapor-Lock (Part No. 73074BC) or mineral oil (Mineral oil for PCR, Fisher Bioreagents BP26291) to the positive control Amplification Tube. Vapor-Lock is intended for use with positive control samples only.
  3. Transfer 30 µL of sample from resuspension plate well into each Amplification Tube using a multi-channel pipette and filter barrier tips.

4. Transfer 30 µL of positive control to the appropriate Amplification Tube containing Vapor-Lock (mineral oil).
5. Firmly press down on each Amplification Tube lid to close. Visually inspect each tube to ensure that the cap is securely sealed.
6. Prior to placing in rotor, invert Amplification Tubes and shake with a snapping motion to thoroughly mix contents.

## Decontamination

---

Improper handling and disposal of used Assurance® GDS amplification tubes may result in DNA amplicon contamination of laboratory work surfaces and equipment. It is recommended that labs have the following onsite in case of a contamination event:

|         |  |      |
|---------|--|------|
| 34726BC | Assurance® GDS DNA Swab Resuspension Buffer Tq                 | 6 mL |
| 34746BC | Assurance® GDS <i>Listeria</i> DNA Swab Resuspension Buffer Tq | 6 mL |

Approved Sample Collection Swabs:

- Fisher brand Sterile Polyester Swab, Fisher Cat. No 14-959-90
- Texwipe CleanTip Swab, Fisher Cat. No 18-385
- Berkshire BCR Clean Room Swab, Fisher Cat. No 18-999-17

If an open amp tube is observed in the RGQ after amplification & detection process has finished, carefully hold the tube closed and remove the rotor. Immerse the rotor and all tubes in 10% bleach solution for 15 min. Dispose of the tubes as described in the [Recommended Practices for Contamination Control](#) section above. Clean all work areas and equipment using a 10% bleach solution, allowing the solution to remain on the surface for 15 min. Follow with a 70% isopropyl alcohol solution as described in the [Routine Cleaning and Decontamination](#) section above. Also change lab coats and gloves. All opened or partially used disposable items (pipettes, tips, test kits, reagents, plates, etc...) should be quarantined and tested. If contaminated, they should be disposed of appropriately. Send .rex file(s) to Technical Services as described in the [Troubleshooting](#) section above for review. For more information see **Application Note: Environmental Decontamination Checklist (MK\_AN4548EN, MS\_AN4548EN)**.

After decontamination, work surfaces and equipment in each zone can be sampled via the following protocol. Any area or piece of equipment still exhibiting contamination should be re-cleaned and tested until negative test results are obtained.

### Environmental Sampling for DNA Contamination

As a preventative measure, it is recommended to perform periodic sampling for DNA contamination. The information below is also located in **Application Note: Environmental Sampling for DNA Contamination (MK\_AN4549EN, MS\_AN4549EN)**.

1. Add 1 mL of sterile deionized water to each of the required number of Assurance® GDS sample wells (1 well/sample).
2. Moisten the tip of a dry Dacron, polyurethane or polyester swab by dipping it into the corresponding well containing the sterile deionized water.

3. Swab the intended sample surface. Avoid surfaces grossly contaminated with particulate matter.
4. Return the swab to the corresponding sample block well and gently stir the swab tip in the water for 10 sec.
5. Gently press the swab tip against the inside well of the sample block to expel excess liquid and dispose of the swab as biohazard waste.
6. For all Assurance® GDS assays (except *Listeria*), transfer 10 µL of DNA Swab Resuspension Buffer Tq (Part No. 34726BC) to the appropriate amplification tubes. For Assurance GDS *Listeria* Tq assays, transfer 10 µL of *Listeria* DNA Swab Resuspension Buffer Tq (Part No. 34746BC) to the appropriate amplification tubes.
7. Transfer 20 µL of sample directly from sample block wells to the appropriate prepared Assurance® GDS amp tubes and proceed as indicated by Assurance® GDS kit directions for use.

# Appendix A

## Parts List

### Equipment

| <i>Part Number</i> | <i>Description</i>  |
|--------------------|---|
| 73070BC            | GDS ROTOR-GENE® Q (INCLUDES 36 WELL ROTOR/LOCK RING, GEL BLOCK SET, POWER CORDS-US/EU/GB, USB CABLE)                |
| 73071BC            | GDS ROTOR-GENE® Q LAPTOP (INCLUDES CHARGER + US POWER CORD)   |
| 73103BC            | ROTOR-GENE® Q LAPTOP POWER CORD FOR US + USB TYPE C FLAT CHARGER, 90W   |
|                    | <i>Laptop model Latitude 5430 Rugged</i>  |
| 73104BC            | ROTOR-GENE® Q LAPTOP POWER CORD FOR US + 7.4MM ROUND CHARGER, 90W   |
|                    | <i>older laptop model Latitude 5420 Rugged</i>  |
| 73068BC            | ROTOR-GENE® Q LAPTOP POWER CORD FOR US + 7.4MM ROUND CHARGER, 65W   |
|                    | <i>older laptop models, Latitude 5510, Latitude 5500, Latitude E5590, Latitude E5580, Latitude E5570</i>            |
| 73082EUBC          | ROTOR-GENE® Q LAPTOP POWER CORD FOR EU  |
| 73105UKBC          | ROTOR-GENE® Q LAPTOP POWER CORD FOR UK  |
| 73091BC            | GDS PICKPEN® II 8M  |
| 73063BC            | VORTEX MIXER WITH SAMPLE BASE HOLDER, US 115V   |
| 73060BC            | VORTEX MIXER POWER CONVERTER FOR EU   |
| 73083BC            | GEL COOLING BLOCK SET (2/CS)  |
| 73042BC            | INCUBATOR, US 115V (LISTERIA ONLY)  |
| 73074BC            | INCUBATOR, EU/UK 230V (LISTERIA ONLY)   |
| 73184BC            | GDS PICKPEN® II 8M STAND (HOLDS 3)  |
| 73076BC            | ROTOR-GENE® Q 72 WELL ROTOR (HT ONLY)   |
| 73084BC            | ROTOR-GENE® Q 72 WELL LOCKING RING (HT ONLY)  |
| 79134BC            | GDS VARIABLE SPACING AMP TUBE HOLDER, 72 WELL (HT ONLY)   |
| 79184BC            | GDS VARIABLE SPACING AMP TUBE HOLDER LID, 72 WELL (HT ONLY)   |
| 79132BC            | GDS AMP TUBE CAPPING TOOL (HT ONLY)   |
| 73093BC            | GDS ALUMINUM COOLING BLOCK, 72 WELL (HT ONLY)   |
| 79197BC            | GDS AMP TUBE CAP RACK, 72 WELL (HT ONLY)  |
| 73400BC            | GDS ADAPTOR BOX (INCLUDES POWER SUPPLY 110-220V, US POWER CABLE, ETHERNET CABLE) (USE FOR MULTIPLE RGQ TO 1 LAPTOP) |

### Reagents

| <i>BCS Part Number</i> | <i>Description</i>   |
|------------------------|--|
| 73074BC                | GDS VAPOR LOCK (1.2 ML, 30 REACTIONS)                              |
| 34726BC                | GDS DNA SWAB RESUSPENSION BUFFER TQ (6 ML, 100 REACTIONS)          |
| 34746BC                | GDS LISTERIA DNA SWAB RESUSPENSION BUFFER TQ (6 ML, 100 REACTIONS) |

|         |  |
|---------|--|
| 34761BC | GDS POSITIVE CONTROL FOR SALMONELLA                                |
| 34762BC | GDS POSITIVE CONTROL FOR LISTERIA                                  |
| 34760BC | GDS POSITIVE CONTROL FOR E. COLI O157:H7                           |
| 34791BC | GDS POSITIVE CONTROL FOR CRONOBACTER                               |
| 61031BC | GDS WASH SOLUTION KIT (4 X 250 ML) (HT & AUTOMATION ONLY)          |
| 61020BC | GDS TOP STEC WASH SOLUTION KIT (4 X 250 ML) (TOP STEC ONLY)        |
| 34724BC | GDS RESUSPENSION BUFFER TQ (70 ML) (HT & AUTOMATION ONLY)          |
| 34745BC | GDS LISTERIA RESUSPENSION BUFFER TQ (70 ML) (HT & AUTOMATION ONLY) |

Disposables

| <i>BCS Part Number</i> | <i>Description</i>   |
|------------------------|--|
| 73043BC                | GDS SAMPLE WELLS BASE (10/CS)                              |
| 73044BC                | GDS SAMPLE WELLS (200/CS)                                  |
| 73006BC                | GDS RESUSPENSION PLATES (120/CS)                           |
| 73026BC                | GDS ADHESIVE FILM STRIPS (200/CS)                          |
| 73087BC                | GDS PICKPEN® TIPS, RACKED (96/CS)                          |
| 73085BC                | GDS PICKPEN® TIPS, BULK (500/CS)                           |
| 73004BC                | ADHESIVE FILM SHEETS (100/CS) (LISTERIA & AUTOMATION ONLY) |

# Appendix B

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## Before You Call Us

Technical Services will be able to serve you more efficiently if you have the following information on hand:

- Serial number of the instrument(s) involved:
  - The serial number for the RGQ is located on the back of the unit.
  - The serial number for the PickPen® magnetic device is located on the underside of the handheld.
  - The serial number for the Q laptop is located on the underside of the unit.
- List of concise symptoms being exhibited by the instrument(s).
- List of operating procedures / protocols and conditions you were using when the problem arose.
- Be prepared to email the exported RGQ protocol that was running when the issue occurred, refer to the [Troubleshooting](#) section.
- List of all instruments in the configuration and the connections to those instruments.
- List of other electrical connections in the room.

# Appendix C

## Maintenance Log



### Assurance GDS Rotor-Gene Q Maintenance Log

| Laboratory:  | Instrument S/N: | Week No.: |         |           |          |        |          |        | Month/Year: |
|--|-----------------|-----------|---------|-----------|----------|--------|----------|--------|-------------|
|  |                 | Monday    | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |             |
| <b>RGQ Daily Maintenance Procedure</b><br>Save all run files and exit RGQ software |                 |           |         |           |          |        |          |        |             |
| Switch off the laptop and RGQ instrument   |                 |           |         |           |          |        |          |        |             |
| Visually inspect inside of Rotor-Gene chamber for any debris or foreign material   |                 |           |         |           |          |        |          |        |             |

| Laboratory:  | Instrument S/N: | Week No.: |         |           |          |        |          |        | Month/Year: |
|--|-----------------|-----------|---------|-----------|----------|--------|----------|--------|-------------|
|  |                 | Monday    | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |             |
| <b>RGQ Weekly Maintenance Procedure</b><br>Wipe down rotor and locking ring with bleach solution prepared as described in kit insert, follow with isopropyl alcohol. |                 |           |         |           |          |        |          |        |             |
| Wipe down the inside of the Rotor-Gene chamber with bleach solution prepared as described in kit insert, follow with isopropyl alcohol.                              |                 |           |         |           |          |        |          |        |             |
| Wipe down the outside of Rotor-Gene instrument and surrounding work surfaces with isopropyl alcohol prepared as described in kit insert                              |                 |           |         |           |          |        |          |        |             |

| Laboratory:   | Instrument S/N: | Month/Year: |          |       |       |     |      |      |        |           |         |          |          |  |  |  |  |
|---|-----------------|-------------|----------|-------|-------|-----|------|------|--------|-----------|---------|----------|----------|--|--|--|--|
|   |                 | January     | February | March | April | May | June | July | August | September | October | November | December |  |  |  |  |
| <b>RGQ Monthly Maintenance Procedure</b><br>Clean Rotor-Gene optics |                 |             |          |       |       |     |      |      |        |           |         |          |          |  |  |  |  |
| Rotate and lubricate Rotor-Gene rotor locking mechanism             |                 |             |          |       |       |     |      |      |        |           |         |          |          |  |  |  |  |

| Laboratory:  | Instrument S/N: | Week No.: |         |           | Month/Year: |
|--|-----------------|-----------|---------|-----------|-------------|
|  |                 | Monday    | Tuesday | Wednesday |             |
| <b>RGQ Annual Maintenance Procedures</b><br>Perform Optical Temperature Verification using Rotor-Gene OTV kit. |                 |           |         |           |             |
| Perform a backup of results  |                 |           |         |           |             |

\* For detailed information regarding specific maintenance procedures refer to Preventative Maintenance and Decontamination sections of the Assurance GDS Rotor-Gene Q User Manual.

Operator/Supervisor Signature: \_\_\_\_\_

## Appendix D

### Guard Bands for Time Sensitive Steps

|                 |  | <i>Time</i>               | <i>Temperature</i> |
|-----------------|--|---------------------------|--------------------|
| <b>Reagents</b> | GDS Test Kits  | Up to 3 weeks             | 25 °C              |
|                 |  | Long term storage         | 2 to 8 °C          |
|                 | Dispensed Concentration Reagent, Wash Solution, Resuspension Buffer or Sterile Media | 4 h                       | 15 to 30 °C        |
|                 |  | 24 h                      | 2 to 8 °C          |
|                 | Open Amplification Tubes (pellet only)   | 2 h in a frozen gel block | 15 to 30 °C        |
|                 | Closed Amplification Tubes (pellet only)   | 4 h in a frozen gel block | 15 to 30 °C        |

|                    |  | <i>Time</i>                  | <i>Temperature</i> |
|--------------------|--|------------------------------|--------------------|
| <b>Sample Prep</b> | After addition of sample to sample block       | 30 min*                      | 15 to 30 °C        |
|                    | After addition of sample to Resuspension plate | 1 h                          | 15 to 30 °C        |
|                    |  | 18 h                         | 2 to 8 °C          |
|                    | Amplification Tubes (after sample addition)    | 20 min in a frozen gel block | 15 to 30 °C        |

\*Excluding vortex mixing time

|                       |                                   | <i>Time</i>   | <i>Temperature</i> |
|-----------------------|-----------------------------------|---|--------------------|
| <b>Cooling Blocks</b> | Gel block (Pink)                  | Minimum of 6 h<br>(prior to 1 <sup>st</sup> time use) | -15 to -20 °C      |
|                       |                                   | Minimum of 2 h<br>(after each use)                    | -15 to -20 °C      |
|                       | PPMX Gel block (Pink)             | Minimum of 2 h  | -15 to -20 °C      |
|                       | Aluminum Transfer block (HT only) | Minimum of 20 min                                     | 2 to 8 °C          |

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