

# Rotor-Gene AssayManager® v2.1 Gamma MDx Plug-in User Manual

August 2016



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# Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual

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# 1 Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual

Welcome to the *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual*.

## 1.1 Safety Information

The user-friendly Rotor-Gene AssayManager v2.1 software has been specifically developed for use with up to 4 different Rotor-Gene® Q MDx instruments. Before using Rotor-Gene AssayManager v2.1 software, it is essential that you carefully read this user manual and *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*, paying particular attention to the "Safety Information" chapter. The instructions and safety information must be followed to ensure safe operation of the cyclers and to maintain the instrument in a safe condition.

*Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* does not provide detailed information about Rotor-Gene Q MDx instrument hardware and maintenance. The user manual only describes the functionality of the Rotor-Gene AssayManager v2.1 software in combination with Rotor-Gene Q MDx instruments.

## 1.2 Introduction

Thank you for choosing Rotor-Gene AssayManager v2.1. We are confident it will become an integral part of your laboratory.

Rotor-Gene AssayManager v2.1 is a software for routine testing in combination with Rotor-Gene Q MDx instruments. Rotor-Gene AssayManager v2.1 is able to read in sample information, set up experiments, control up to 4 different Rotor-Gene Q MDx cyclers, acquire data from these instruments, automatically analyze results and create reports.

Rotor-Gene AssayManager v2.1 consists of different components that work together. The core application is complemented by different plug-ins that provide assay-type specific analysis and visualization of the results. The core application is mandatory for working with Rotor-Gene AssayManager v2.1. Optionally, additional plug-ins can be installed. At least one plug-in must be installed. Not all plug-ins may be available in all countries. Refer to ► [www.qiagen.com/Products/Rotor-GeneAssayManager\\_v2\\_1.aspx](http://www.qiagen.com/Products/Rotor-GeneAssayManager_v2_1.aspx) to find out more about our continuously expanding range of plug-ins.

**Note**

The screenshots shown in this user manual are examples only and may differ from assay to assay.

### 1.2.1 Provided User Manuals

The core application, and every available plug-in, has its own user manual with specific information about the functionality of the different Rotor-Gene AssayManager v2.1 components. When installing additional plug-ins, the corresponding user manuals that are provided on the installation CD can be accessed, read and printed as \*.pdf files.

**Rotor-Gene AssayManager v2.1 MDx Core Application User Manual** Provides a description of the software and describes functions that are common to the core application and all plug-ins. Information about troubleshooting is also provided.

**Rotor-Gene AssayManager v2.1 MDx Plug-in user manuals** Provide details on how to use the assay-type specific plug-ins and describe their functionalities.

### 1.2.2 About this User Manual

This user manual provides information about the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in, version 1.0.x (where x is greater than or equal to 0) in the following sections:

1.2 ▶ Introduction

1.3 ▶ Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in specific tasks and procedures

### 1.2.3 General Information

#### **Policy Statement**

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time.

In an effort to produce useful and appropriate documentation, we would appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

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## Version Management

This document is the *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual*, version 1.0, which provides information about the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in, version 1.0.x (where x is greater than or equal to 0). The Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in can only be installed with the Rotor-Gene AssayManager Core Application, version 2.1.

### 1.3 Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in Specific Tasks and Procedures

Tasks and procedures specific for the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in are described in this section. For a general description, refer to the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

#### **Installing the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in**

The Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in can be installed with the Rotor-Gene AssayManager Core Application, version 2.1. A general step-by-step procedure on how to install Rotor-Gene AssayManager v2.1 plug-ins is provided in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*. Please refer to "Installing Core Application and Plug-ins" for details.

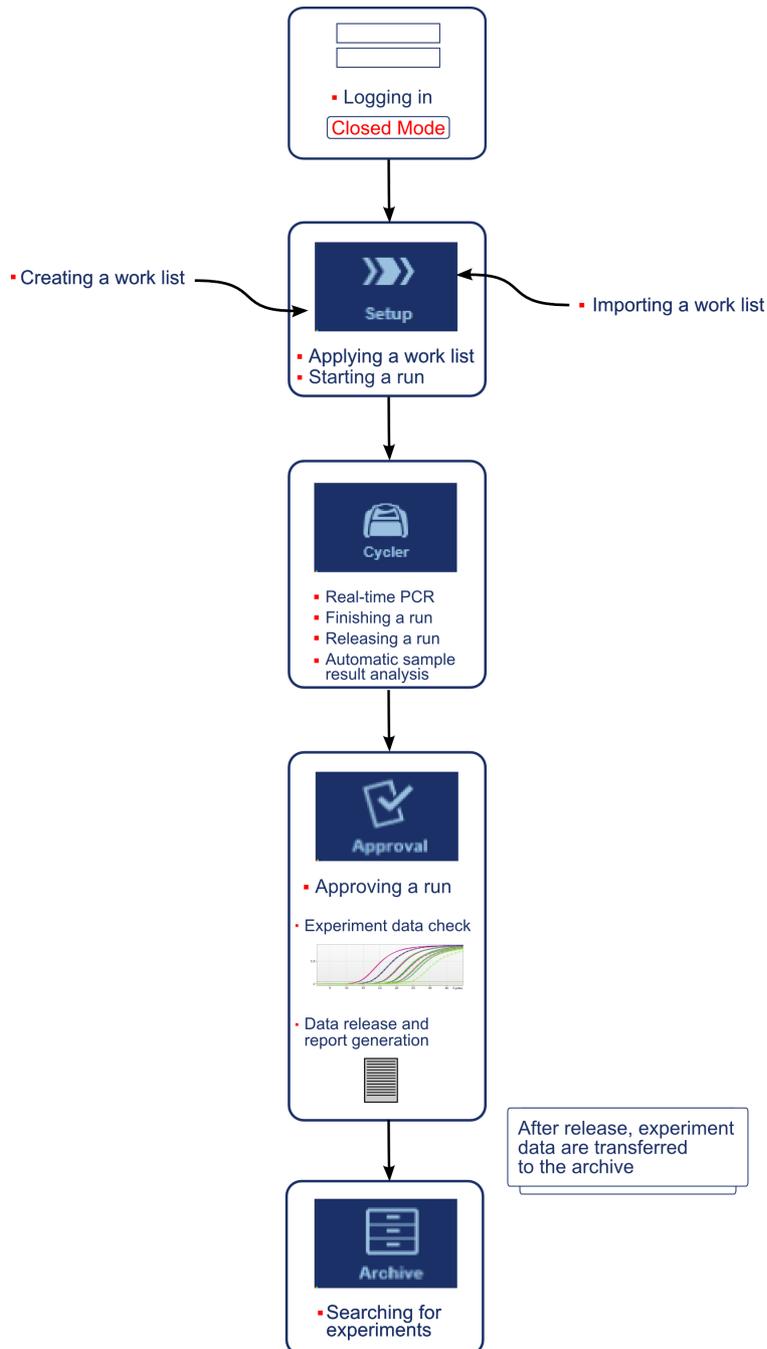
#### **Importing assay profiles for the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in**

To run and analyze polymerase chain reaction (PCR) kits with the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in, specific assay profiles need to be imported into the database. For a detailed description of how to import assay profiles, refer to "Managing Assay Profiles" in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

The information about which assay profile is needed for a specific PCR kit is provided in the corresponding kit instructions for use supplied with the kit.

### 1.3.1 General Work Flow

The following graphic summarizes the work flow in Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in. Refer to the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* for details.



### 1.3.2 Setting up a Run

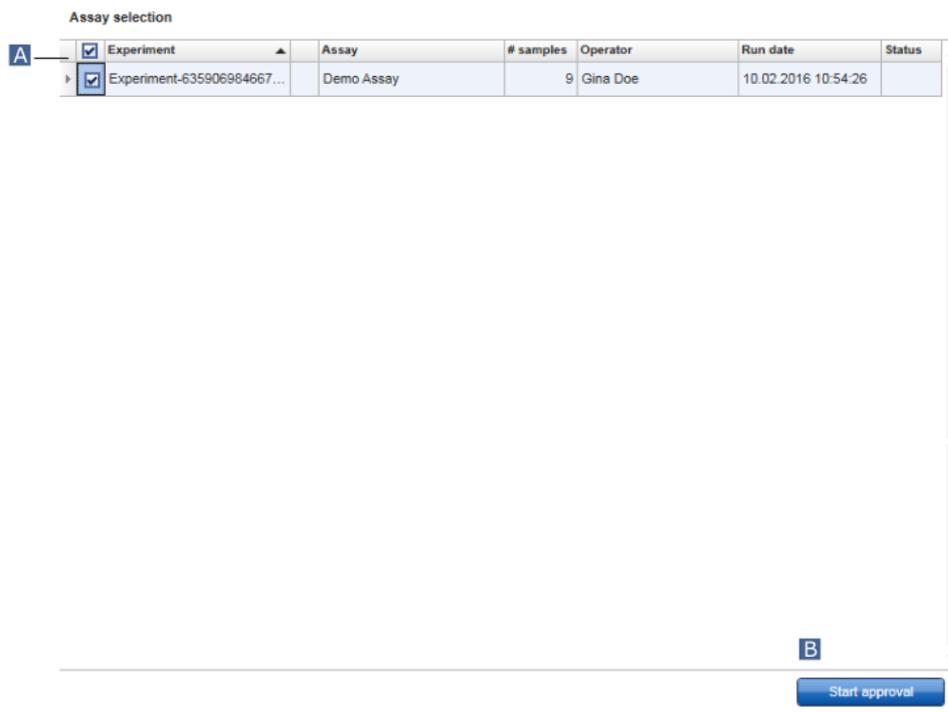
The overall functionalities of the "Setup" environment and of "Creating/Editing a Work List" are described in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

### 1.3.3 Releasing Samples

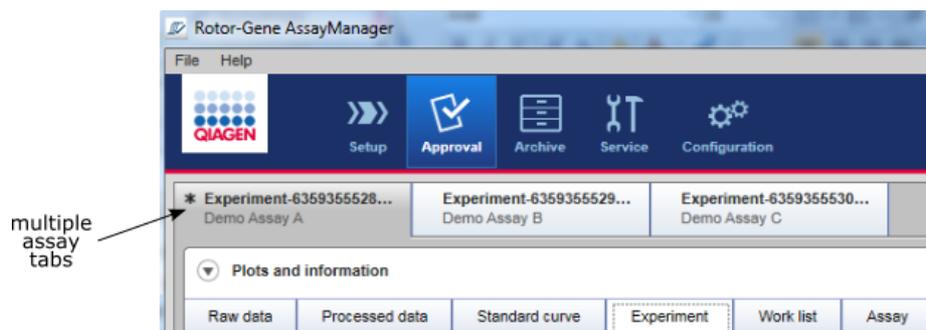
The general functionality of the "Approval" environment is described in *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*. In *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual*, only the functionality dedicated to the Gamma MDx Plug-in is described.

#### 1.3.3.1 Starting the Release Process in the Approval Environment

To start the release process in the "Approval" environment, the assays to be released can be selected by checking the corresponding check box (A) in the "Assay selection" area and clicking the "Start approval" button (B). For a general description of the "Approval" environment, refer to the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.



After starting the release process in the "Approval" environment, a screen is opened that is split in two main areas: "Plots and information" and "Results". If multiple assays were selected, all the selected assays will be listed in the tab list.



Depending on the assay type, experiment information can be reviewed in eight different tabs in the "Plots and information" area:

1. "Raw data"	}	<b>Graphic</b> focused: Shows amplification plots of raw and processed data as well as the standard curve, respectively.
2. "Processed data"		
3. "Standard curve"		
4. "Experiment"	}	<b>Data</b> focused: Shows detailed data about the experiment, the used work list and the assay.
5. "Work list"		
6. "Assay"		
7. "Audit trail"		Shows all actions that are recorded in the audit trail.
8. "Calibrator"		If the experiment contains at least one sample of type "Calibrator" (= "CAL"), mandatory information (yellow background) about the calibrator needs to be entered in the "Calibrator" tab before samples can be finally approved.

## Note

The "Calibrator" tab is only visible for quantitative assays that use a calibrator for calculation of final results.

By default the "Experiment" tab is opened upon starting the approval process.

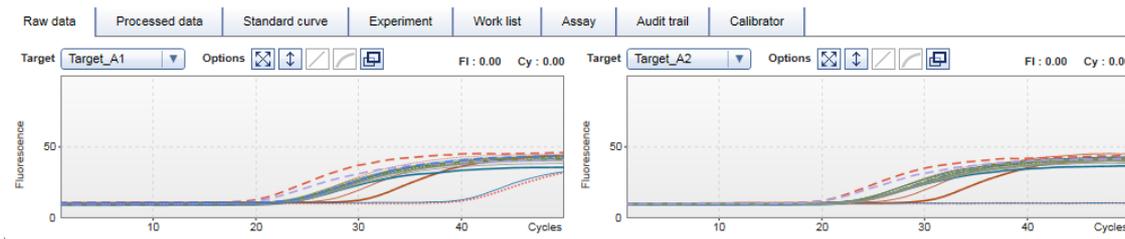
## Experiment

The "Experiment" tab provides detailed information about the experiment.

Raw data	Processed data	Standard curve	Experiment	Work list	Assay	Audit trail	Calibrator
Experiment name Demo_Assay_Run_1		Reaction volume 25 µl	Rotor type 72-Well Rotor	Run comment		Messages	
Run start 14.03.2016 09:36	End of run 14.03.2016 09:38	Run on SW version 2.1.0.6	Cycler serial no. 0409102				
Run operator Gina Doe (su)		Run released by System (automatically)					

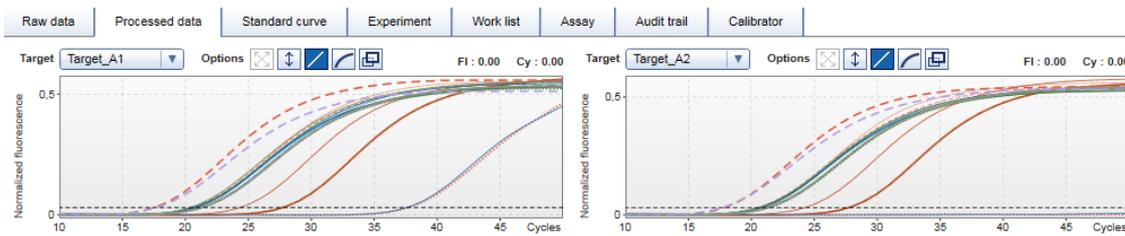
## Raw data

The "Raw data" tab displays amplification plots of the raw fluorescence data.



## Processed data

The "Processed data" tab displays amplification plots of the processed fluorescence data.



## Standard curve

The "Standard curve" tab displays the standard curve if the assay is quantitative.



## Work list

The "Work list" tab provides detailed information about the used work list.

Raw data	Processed data	Standard curve	Experiment	Work list	Assay	Audit trail	Calibrator
Work list name Demo_Assay_Run_1			QIASymphony software version		QIASymphony AS result file		
Work list created 14.03.2016 09:34	Work list last changed 14.03.2016 09:35	Work list source Manual	QIASymphony SP serial no.		QIASymphony kit information		
Work list changed by su	Work list read-only no	External order ID	QIASymphony AS serial no.		Material number	Kit lot number	Expiry date

## Assay

The "Assay" tab provides detailed information about the selected assay.

Raw data	Processed data	Standard curve	Experiment	Work list	Assay	Audit trail	Calibrator
Assay profile name Demo Assay		# standards and controls 14		Material number 7654321			
Short name Demo		# test samples 5		Kit expiry date 09.01.2018			
Version 1.0.0		Reserved rotor positions 56		Kit lot number 123456			

## Audit trail

The "Audit trail" tab contains detailed information about any substantial events of the experiment.

Raw data	Processed data	Standard curve	Experiment	Work list	Assay	Audit trail	Calibrator
Date and Time	User	Message ID	Message	Signed			
16.02.2016 10:44:20	Gina Doe (su)	420029	Run started for the experiment Demo_Assay_RUN_1 using work list Demo_Assay_Run_1 and cycler Berlin.				
16.02.2016 10:47:05	Gina Doe (su)	420028	Run for the experiment Demo_Assay_RUN_1 using work list Demo_Assay_Run_1 and cycler Berlin finished successfully.				

## Calibrator

The "Calibrator" tab, contains two options: "Use calibrator" and "Do not use calibrator". If you use a calibrator, select the "Use calibrator" button, and enter the corresponding calibrator value (found on the calibrator tube or certificate). You must enter this value twice in the fields "Enter calibrator value" and "Reenter calibrator value". After confirming the entered values by pressing the "Apply" button, the results are updated. If no calibrator is used, select the "Do not use calibrator" button and confirm your choice by selecting the check box "Confirm to only report non-calibrated results". It depends on the assay and the corresponding assay profile if the "Calibrator" tab is required and visible. For further information on the calibrator value refer to the respective assay kit manual.

Raw data	Processed data	Standard curve	Experiment	Work list	Assay	Audit trail	Calibrator
<input type="radio"/> Use calibrator	<input type="radio"/> Do not use calibrator	<input type="checkbox"/> Confirm to only report non-calibrated results		<b>Messages</b>			
Enter calibrator value <input type="text"/>							<input checked="" type="checkbox"/> Select whether calibrator value shall be used to obtain normalized results. (2270300)
Reenter calibrator value <input type="text"/>							
<input type="button" value="Apply"/>							

### Note

Once at least one sample is released, the calibrator value cannot be changed any more.

### 1.3.3.2 Reviewing Assay Data

#### Step-by-step procedure to review the amplification plots using the "Raw data" and the "Processed data" tabs

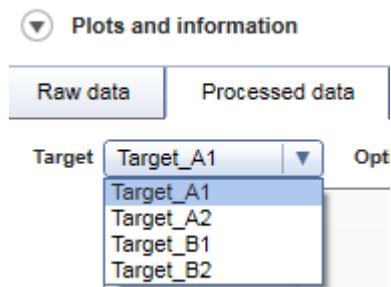
1. By default, all samples of an assay are selected. To display only the amplification curves of specific samples, first click the "Column select" icon in the header of the results table to deselect all samples. Click the "Sample selector" check box of the samples whose amplification curve you would like to have displayed.

Pos.	<input checked="" type="checkbox"/>	Style	Sample ID	Type	Sample comment	Overall sample result	Output
37	<input checked="" type="checkbox"/>	.....	Sample 1	Test		Valid	Target_B1
38	<input checked="" type="checkbox"/>						Target_B2
39	<input checked="" type="checkbox"/>						Target_A1
40	<input checked="" type="checkbox"/>						Target_A2
							mean_Ct_Target_A
							Delta_Ct_Target_B
							mean_Ct_Target_B
41	<input checked="" type="checkbox"/>	---	Sample 2	Test		Valid	Target_B1
42	<input checked="" type="checkbox"/>						Target_B2
43	<input checked="" type="checkbox"/>						Target_A1
44	<input checked="" type="checkbox"/>						Target_A2
							mean_Ct_Target_A
							Delta_Ct_Target_B
							mean_Ct_Target_B

#### Note

The result presentation shown in this user manual is an example only and may differ from assay to assay.

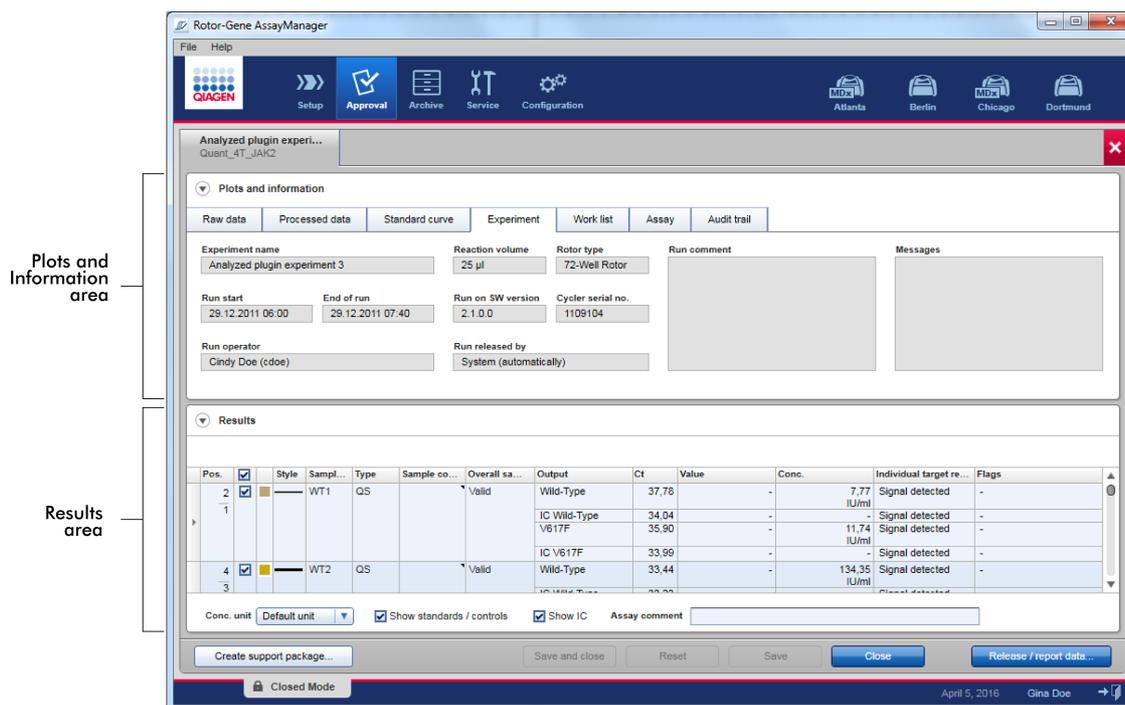
2. Select the target which shall be displayed from the "Target" drop-down list.



3. Review the individual amplification curves.

### 1.3.3.3 General Information about Releasing Samples

The results of all samples determined by Rotor-Gene AssayManager v2.1 are shown in the "Results" area of the "Approval" environment.



Depending on the assay profile settings, the "Results" table in the "Results" area may include the following detailed information about the individual samples:

Field	Content
"Pos." (Position)	The tube position of the target.
"Checkbox" <input type="checkbox"/>	Sample select check box.
"Color"	Color of the target plot.
"Style"	Style of the target plot.
"Sample ID"	The sample ID of the external control or test sample.

"Type"	The type of sample. Possible values are "Test" (Test Sample), "NTC" (Non-template Control), "PC" (Positive Control), "EC+" (Positive Extraction Control), "EC-" (Negative Extraction Control), "FPC+" (Positive Full Process Control), "FPC-" (Negative Full Process Control), "CAL" (Calibrator), and "QS" (Quantification Standard).
"Sample comment"	This field contains a comment about the sample entered by the operator or approver.
"Overall sample result"	The overall sample result from analysis of the external control or test sample. Possible values are "Valid", "Invalid" or an assay specific overall sample result.
"Output"	All targets relating to the external control or test sample. Each target is displayed in a separate row and appears in the order defined in the assay profile.
"Ct"	The $C_T$ value detected for the target.
"Value"	The value for the target defined in "Output"; determined according to calculations defined in the assay profile.
"Conc." (Concentration)	The concentration of the target if quantitative.
"Individual target result"	This field displays the analysis result as "Signal detected", "No signal", "INVALID", or as an assay specific target result.
"Flags"	The flags resulting from the analysis of external controls or test samples displayed as a comma-separated list. If no flags are applicable, a dash is displayed.

## Result table options

Below the "Results" table the following options can be used:

Conc. unit   Show standards / controls  Show IC

A B C D

	Option	Explanation
A	Conc. unit <input type="text" value="Default unit"/>	Choose from default and alternative concentration units (defined in the assay profile).  <b>Note:</b> This function is only available for quantitative assays.
B	<input checked="" type="checkbox"/> Show standards / controls	Check the box to display standards and controls in the "Results" table.  <b>Note:</b> By default, this box is checked.
C	<input checked="" type="checkbox"/> Show IC	Check the box to display the results of the internal control (IC) in the "Results" table.  <b>Note:</b> By default, this box is checked if an assay contains an internal control target.
D	Assay comment <input type="text"/>	Enter a comment about the assay.  <b>Note:</b> Comment must not exceed 256 characters. After the assay has been released, the comment cannot be changed.

#### 1.3.3.4 Target Results

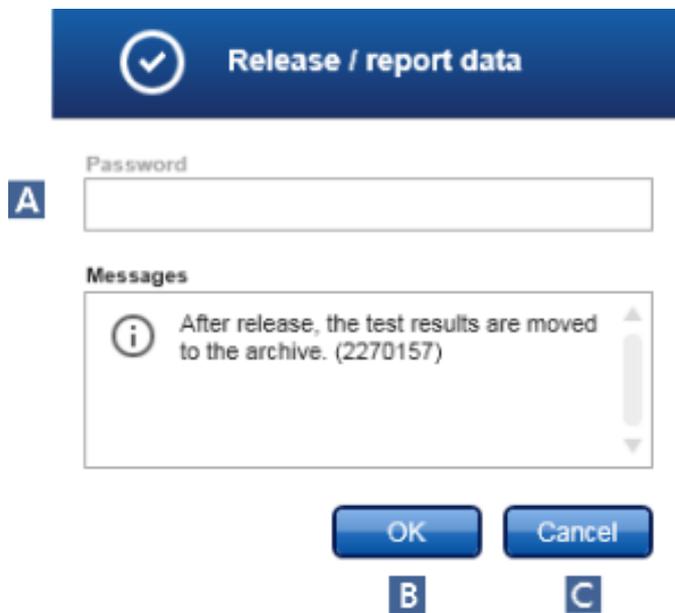
Rotor-Gene AssayManager v2.1 determines the result of a target by combining all relevant analysis results according to core analysis algorithms such as normalization, automatic data scan (AUDAS) and sample and assay rules defined in the corresponding assay profile. The following results could be assigned to an individual target:

Individual target result	Description
Signal detected	<ul style="list-style-type: none"><li>• A target gets the result "Signal detected" if a <math>C_T</math> value is detected within a predefined valid range.</li><li>• A target gets the result "Signal detected" if the value of a calculated target could be calculated.</li></ul>
No signal	<ul style="list-style-type: none"><li>• A target gets the result "No signal" if no <math>C_T</math> value is detected or if the <math>C_T</math> is outside of a predefined valid range.</li><li>• A target gets the result "No signal" if the value of a calculated target could not be calculated for any reason, e.g., an input value (like the calibrator value) is missing.</li></ul>
INVALID	<ul style="list-style-type: none"><li>• A target gets the result "INVALID" if one or more flags are assigned to the sample during analysis by Rotor-Gene AssayManager v2.1 that are defined to set the target result to "INVALID". If the check box "Enable processing of unclear samples" in the configuration settings is deactivated, results of samples with the upstream flag "UNCLEAR" (e.g., flagged by QIASymphony® AS) are also set to "INVALID".</li></ul>
Assay specific target result	<ul style="list-style-type: none"><li>• The target gets an assay specific result string if defined in the assay profile.</li></ul>

### 1.3.3.5 Step-by-step procedure to release data

The following steps shall be performed to release data:

1. After approving the sample results, click "Release / report data..." in the button bar. The following dialog will be open:



2. If the release must be signed, enter the Rotor-Gene AssayManager v2.1 login password in the "Password" field (A). This option is set by the administrator in the "Configuration" environment under: Settings ▶ Global settings ▶ Finish run. For a general description of the "Configuration" environment, refer to the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.
3. To release the data, click "OK" (B). To cancel and go back to the "Results" table click "Cancel" (C).

## Note

The release process is managed via the following buttons:



Button	Explanation
	<ul style="list-style-type: none"><li>• Saves all changes.</li><li>• Closes this screen, if only one experiment is open and returns to the "Assay selection" screen. If more than one experiment is open, the next open experiment is displayed.</li></ul>
	<ul style="list-style-type: none"><li>• Cancels all changes.</li><li>• Reverts to the previously saved approval status; amplification plots and result table options are not reset.</li></ul>
	<ul style="list-style-type: none"><li>• Saves all changes.</li></ul>
	<ul style="list-style-type: none"><li>• Discards all changes and returns to the previously saved approval status.</li><li>• Closes this screen, if only one experiment is open and returns to the "Assay selection" screen. If more than one experiment is open, the next open experiment is displayed.</li></ul>
	<ul style="list-style-type: none"><li>• Opens a dialog to release test results and automatically create a report.</li><li>• The status of the assay is set to "Fully released".</li><li>• Exports the results to LIMS in the following folder if defined in the "Configuration" environment, under: Settings ▶ Local Settings ▶ Default data export directories ▶ LIMS output folder.</li><li>• Saves the *.pdf report file in the folder defined in the "Configuration" environment, under: Settings ▶ Local Settings ▶ Default data export directories ▶ Report folder.</li><li>• Closes this screen, if only one experiment is open and returns to the "Assay selection" screen. If more than one experiment is open, the next open experiment is displayed.</li></ul>

### 1.3.3.6 Flags

The following flags may be assigned to individual targets or samples during analysis by Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in. Depending on the settings of a specific assay profile, not all flags may be applicable. Additionally, other assay specific flags may be reported which are not listed in the table below. Depending on the assay profile settings, flags are either displayed individually for each target or are reported on sample level in the following format: <flag>@<target name>. Refer to the kit instructions for use for a detailed listing of the flags and their specific behavior for the different assay profiles.

The appearance of flags in Rotor-Gene AssayManager v2.1 is associated with an invalidation of the corresponding target for a test sample, control or quantification standard.

Flag	Description
ANALYSIS_FAILED	Assay is set to invalid because the analysis has failed. Contact QIAGEN Technical Services.
ASSAY_INVALID	The assay is invalid because at least one external control is invalid.
CONSECUTIVE_FAULT	Target that was used for calculation of this target is invalid.
CURVE_SHAPE_ANOMALY	The raw data amplification curve shows a shape that deviates from the established behavior for this assay. There is a high likelihood of incorrect results or misinterpretation of results.
FLAT_BUMP	The raw data amplification curve shows a shape like a flat bump deviating from the established behavior for this assay. There is a high likelihood of incorrect results or misinterpretation of results (e.g., wrong $C_T$ value determination).
IC_INVALID	The internal control is invalid. Target and internal control share the same tube.

IC_NO_SIGNAL	No internal control signal detected. Target and internal control share the same tube.
INVALID_CALCULATION	Calculation for this target failed.
MULTIPLE_THRESHOLD_CROSSING	The amplification curve crosses the threshold more than once. An unambiguous $C_T$ cannot be determined.
NO_BASELINE	No initial baseline has been found. The subsequent analysis cannot be performed.
OTHER_IC_INVALID	The internal control is invalid. Target and internal control are in different tubes.
OTHER_IC_NO_SIGNAL	No internal control signal detected. Target and internal control are in different tubes.
OTHER_TARGET_INVALID	Another target for the same sample is invalid.
OUT_OF_COMPUTATION_RANGE	The calculated concentration for this sample exceeds the technical limit.
RUN_FAILED	Assay is set to invalid due to a problem with the cycler or the cycler connection.
RUN_STOPPED	Assay is set to invalid because the run has been stopped manually.
SATURATION	The raw data fluorescence is saturating strongly before the inflection point of the amplification curve.
SPIKE	A spike in the raw data fluorescence is detected in the amplification curve but outside the region where the $C_T$ is determined.
SPIKE_CLOSE_TO_CT	A spike is detected in the amplification curve close to the $C_T$ .

STEEP_BASELINE	A steeply rising baseline for the raw data fluorescence is detected in the amplification curve.
STRONG_BASELINE_DIP	A strong drop in the baseline for the raw data fluorescence is detected in the amplification curve.
STRONG_NOISE	Strong noise is detected outside the growth phase of the amplification curve.
STRONG_NOISE_IN_GROWTH_PHASE	Strong noise is detected in the growth (exponential) phase of the amplification curve.
UPSTREAM	Sample status was set to "Invalid" or "Unclear" by an upstream process (e.g., QIASymphony).
WAVY_BASE_FLUORESCENCE	Wavy baseline for the raw data fluorescence detected in the amplification curve.

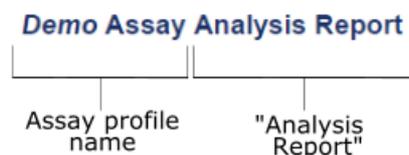
#### 1.3.4 Reporting

The Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in automatically generates PDF report files that summarize result data for an assay run performed on a Rotor-Gene Q MDx instrument.

After the run has finished, the generated report is first saved as a PDF according to the configured file path. Directly after saving the PDF, the report is displayed with the system PDF viewer. The report layout and content are fixed and described in more detail below.

#### Report Title

The report title consists of the name of the assay profile followed by "Analysis Report", e.g.:



Depending on the settings in the assay profile used, the report may comprise the following sections:

Section	Content
"Assay information"	A table listing general information about the assay.
"RGQ run information"	A table listing general information about the corresponding Rotor-Gene Q MDx run.
"Upstream process details"	A table listing general information about the corresponding QIASymphony upstream process.
"Standard Curve"	Plot(s) displaying the standard curve(s) of a quantitative assay.
"Standard Curve Details"	A table listing statistical parameters for the standard curves of a quantitative assay.
"Results"	A table listing results, flags and statuses for all external controls and test samples.
"Comments"	Blank rows for hand-written comments about the run including 2 rows for the signatures of the operator and a reviewer.

**Note**

Depending on the assay profile settings, the section "Results" may be separated into 2 sections: "External controls" and "Test samples".

The following sections show example screenshots of a PDF report and include a more detailed description of the individual report sections.

#### 1.3.4.1 "Assay information" Table

The "Assay Information" table provides the following information:

Field	Content
"Assay profile"	Name and version of the assay profile.
"Plug-in"	Name and version of the used Rotor-Gene AssayManager v2.1 plug-in.
"Kit(s)"	List of material numbers, lot numbers and expiry dates of all used kits.
"Calibrator value"	Numeric value of the calibrator used (entered by the operator in the "Approval" environment) or the entry "not used" if no calibrator was used.  <b>Note:</b> This row only appears for assays with a calibrator defined in the assay profile.
"Assay status"	This field displays the assay status as "Successful", "Failed" or "Imported". Reasons for a failed assay status can be "run failed", "run stopped", "analysis failed" (in case of unexpected error) or "assay invalid" (according to failed analysis rules). The assay status is set to "Imported" if an experiment was imported in the "Archive" environment.
"Assay comment"	This field contains a comment about the assay entered by the operator or approver.

Example of the "Assay information" table:

#### Assay information

Assay profile	Demo Assay (1.0.0)
Plug-in	Gamma MDx 1.0.0 (Closed)
Kit(s)	Material no.: 3333337, Expiry date: 30.03.2018 (not expired), Lot no.: 654321
Calibrator value	Not used
Assay status	Successful
Assay comment	-

#### 1.3.4.2 "RGQ run information" Table

The "RGQ run information" table provides the following information:

Field	Content
"Run name"	Name of the experiment as defined previously in the "Setup" environment.
"Run information"	<ol style="list-style-type: none"><li>1. Start and end time of the run.</li><li>2. Run operator and software version of the application.</li><li>3. Run comment as entered by the operator during the run.</li><li>4. Errors that may have occurred during the run.</li><li>5. Experiment release information.</li></ol>
"Work list"	<ol style="list-style-type: none"><li>1. Name and source of the work list from which the experiment was created. The work list source can be "manual", "QIASymphony" or "QIALink\LIMS".</li></ol> <p><b>Note:</b> If the work list is locked then it is mentioned as "(read-only)" together with the work list name.</p> <ol style="list-style-type: none"><li>2. Creator of the work list.</li><li>3. Last modifier of the work list.</li></ol>
"Used cycler"	<ol style="list-style-type: none"><li>1. Serial number of the cycler.</li><li>2. Rotor type.</li><li>3. Reaction volume.</li></ol>

Example of the "RGQ run information" table:

### RGQ run information

<b>Run name</b>	Demo_Assay_Run_1
<b>Run information</b>	From 14.03.2016, 09:36 +01:00 UTC to 14.03.2016, 09:38 +01:00 UTC Operated by Gina Doe (su) on Rotor-Gene AssayManager version 2.1.0 No comment No errors Run automatically released by the system on 14.03.2016, 09:38 +01:00 UTC
<b>Work list</b>	Demo_Assay_Run_1 Work list created manually Created by Gina Doe (su) on 14.03.2016, 09:34 +01:00 UTC Last changed by Gina Doe (su) on 14.03.2016, 09:35 +01:00 UTC
<b>Used cycler</b>	Cycler serial no.: 0409102 (RGQ) Rotor type: 72-Well Rotor Reaction volume: 25 µl

#### 1.3.4.3 "Upstream process details" Table

The "Upstream process details" table is optional and provides the following information if a QIAAsymphony work list was used:

Field	Content
"QS Software version"	Version of the QIAAsymphony software.
"Operator ID"	Name(s) of the operator(s) who started the run on QIAAsymphony SP and AS.
"Extraction time"	Start and end date of the run on QIAAsymphony SP.
"SP Serial number"	Serial number of QIAAsymphony SP.
"Assay setup time"	Start and end date of the run on QIAAsymphony AS.
"AS Serial number"	Serial number of QIAAsymphony AS.
"AS Result file"	Name of the imported QIAAsymphony AS Result file.
"Sample preparation kit(s)"	List of material numbers, lot numbers and expiry dates of all used sample preparation kits.

Example of the "Upstream process details" table:

### Upstream process details

<b>QS Software version:</b>	5.0.1 (RC)
<b>Operator ID:</b>	Developer
<b>Extraction time:</b>	Start: 28.10.2014, 13:21, End: 28.10.2014, 13:57
<b>SP Serial number:</b>	qssp6605
<b>Assay setup time:</b>	Start: 28.10.2014, 13:51, End: 28.10.2014, 14:23
<b>AS Serial number:</b>	qsas8162
<b>AS Result file:</b>	ResultFile_20141028_135136_3000928_ClosedMode.xml
<b>Sample preparation kit(s):</b>	Material no.: 8090045, Expiry date: 01.01.2015, Lot no.: 0145051380

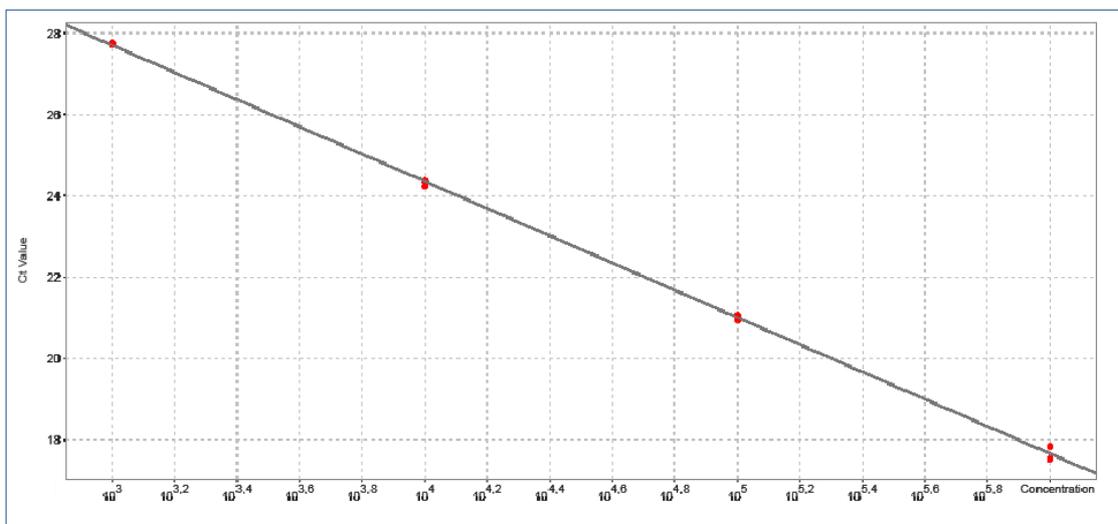
For further details about the upstream QIASymphony run (e.g. reason for "UPSTREAM" flag), refer to the AS result file listed in the table above.

#### 1.3.4.4 "Standard Curve" Section

The "Standard Curve" section displays the standard curves for the quantification standards as a result of plotting the  $C_T$  values on the y-axis against the expected concentrations of the standards on the x-axis.

Example of the "Standard Curve" section:

#### Standard Curve Target\_A



### 1.3.4.5 "Standard Curve Details" Table

The "Standard Curve Details" table provides the following statistical information about the standard curve:

Field	Content
"R"	Root extracted from R <sup>2</sup>
"R <sup>2</sup> "	The correlation coefficient R <sup>2</sup> is a statistical parameter to measure the fit of the data points to the regression line.
"M"	Curve slope
"B"	Curve offset
"Efficiency"	Amplification efficiency of the PCR reaction.

Example of the "Standard Curve Details" table:

#### Standard Curve Details

	R	R <sup>2</sup>	M	B	Efficiency
Target_A	0,99969	0,99938	-3,347	37,747	0,990
Target_B	0,99933	0,99867	-3,398	36,999	0,969

#### 1.3.4.6 "Results" Table

The "Results" table may comprise the following columns depending on assay profile settings:

Field	Content
"Pos." (Position)	The tube position of the target.
"Sample ID"	The sample ID of the external control or test sample.
"Type"	The type of sample. Possible values are "Test" (Test Sample), "NTC" (Non-template Control), "PC" (Positive Control), "EC+" (Positive Extraction Control), "EC-" (Negative Extraction Control), "FPC+" (Positive Full Process Control), "FPC-" (Negative Full Process Control), "CAL" (Calibrator) and "QS" (Quantification Standard).
"Sample comment"	This field contains a comment about the sample entered by the operator or approver.
"Overall sample result"	The overall sample result from analysis of the external control or test sample. Possible values are "Valid", "Invalid" or an assay specific overall sample result.
"Output"	All targets relating to the external control or test sample. Each target is displayed in a separate row and appears in the order defined in the assay profile.
"Ct"	The C <sub>T</sub> value detected for the target.
"Value"	The value for the target defined in "Output"; determined according to calculations defined in the assay profile.
"Conc." (Concentration)	The concentration of the target if quantitative.
"Individual target result"	This field displays the analysis result as "Signal detected", "No signal", "INVALID" or an assay specific target result.
"Flags"	The flags resulting from the analysis of external controls or test samples displayed as a comma-separated list. If no flags are applicable, a dash is displayed.

Example of the "Results" table:

### Test Samples

Pos.	Sample ID	Type	Sample comment	Overall sample result	Output	Ct	Value	Conc.	Individual target result	Flags
37, 38, 39, 40	Sample 1	Test		Valid	Target_B1	27,26	-	-	Signal detected	-
					Target_B2	27,34	-	-	Signal detected	-
					Target_A1	21,20	-	-	Signal detected	-
					Target_A2	21,26	-	-	Signal detected	-
					mean_Ct_Target_A	-	21,22986	-	Signal detected	-
					Delta_Ct_Target_B	-	0,07568	-	Signal detected	-
					mean_Ct_Target_B	-	27,30042	-	Signal detected	-
41, 42, 43, 44	Sample 2	Test		Valid	Target_B1	36,11	-	-	Signal detected	-
					Target_B2	35,34	-	-	Signal detected	-
					Target_A1	21,28	-	-	Signal detected	-
					Target_A2	21,25	-	-	Signal detected	-
					mean_Ct_Target_A	-	21,26740	-	Signal detected	-
					Delta_Ct_Target_B	-	0,76843	-	Signal detected	-
					mean_Ct_Target_B	-	35,72174	-	Signal detected	-
45, 46, 47, 48	Sample 3	Test		Valid	Target_B1	30,82	-	-	Signal detected	-
					Target_B2	30,94	-	-	Signal detected	-
					Target_A1	21,36	-	-	Signal detected	-
					Target_A2	21,39	-	-	Signal detected	-
					mean_Ct_Target_A	-	21,37512	-	Signal detected	-
					Delta_Ct_Target_B	-	0,12268	-	Signal detected	-
					mean_Ct_Target_B	-	30,88226	-	Signal detected	-

### Note

Depending on the assay profile settings, the "Results" table may be separated into two individual tables, one for "External Controls", another one for "Test Samples".

#### 1.3.4.7 "Comments" Section

Three blank lines in the "Comments" section enable the operator to write comments about the run.

Two additional lines are provided so that the report may be signed by the operator and a reviewer. These lines display the following text:

"Operator:", "Print Name", "Signature", "Date"

"Reviewer:", "Print Name", "Signature", "Date"

Example of the "Comments" section:

##### Comments

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Operator:

\_\_\_\_\_

Print Name

\_\_\_\_\_

Signature

\_\_\_\_\_

Date

Reviewer:

\_\_\_\_\_

Print Name

\_\_\_\_\_

Signature

\_\_\_\_\_

Date

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at [www.qiagen.com](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.

## 1.4 Online Documentation

Rotor-Gene AssayManager v2.1 uses plug-ins to increase its functionality. In order to have a clear distinction between the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* and the *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual* and to keep the documentation short and focused, general topics are explained in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

Providing you with the best information depends on the environment you are currently in, especially for the following items:

- ▶ Help for "Plots and information" table
- ▶ Help for "Results" table

### 1.4.1 Help for "Plots and information" Table

The help information for the "Plots and information" table is available either in the *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual* or in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

The table below shows — depending on the current environment — where to find more information.

Environment	Help file and topic
"Approval"	<p><b><i>Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual (i.e., this manual)</i></b></p> <p>Topic:</p> <ul style="list-style-type: none"><li>▶ General information about releasing samples</li></ul>
"Archive"	<p><b><i>Rotor-Gene AssayManager v2.1 MDx Core Application User Manual</i></b></p> <p>Topics:</p> <ul style="list-style-type: none"><li>• Basic Concepts and General Software Usage → Environments → "Archive" Environment</li><li>• Using Rotor-Gene AssayManager → Administrative Tasks → Managing Archives</li></ul>

In case the information is referenced to the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*, open the help file using the Microsoft® Windows® Start menu:

Start → Programs → QIAGEN → Rotor-Gene AssayManager

#### 1.4.2 Help for "Results" Table

The help information for the "Results" table is available either in the *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual* or in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

The table below shows — depending on the current environment — where to find more information.

Environment	Help file and topic
"Approval"	<p><b><i>Rotor-Gene AssayManager v2.1 MDx Core Application User Manual</i></b></p> <p>Topic:</p> <ul style="list-style-type: none"><li>• Using Rotor-Gene AssayManager → Standard Tasks → Approving a Run</li></ul>
"Archive"	<p><b><i>Rotor-Gene AssayManager v2.1 MDx Core Application User Manual</i></b></p> <p>Topic:</p> <ul style="list-style-type: none"><li>• Using Rotor-Gene AssayManager → Administrative Tasks → Managing Archives</li></ul>

In case the information is referenced to the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*, open the help file using the Microsoft Windows Start menu:

Start → Programs → QIAGEN → Rotor-Gene AssayManager

## 1.5 Error Messages and Error Codes

Error messages and warnings are displayed when a problem occurs during the operation of Rotor-Gene AssayManager v2.1. All messages have an error ID, which is displayed at the end of the error message. It is possible that several errors are combined in only one message. Refer to the error IDs listed in this section and in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual* if an error message or warning appears. If error messages or warnings appear that are not listed here or if the error cannot be resolved, note the error ID, the error text and the steps leading to the error. Then contact QIAGEN Technical Services.

### Note

The error ID is unique and helps QIAGEN Technical Services to clearly identify the error message.

If there are problems with a specific experiment, create a support package and send it to QIAGEN Technical Services.

The following list provides all error messages that might occur during operation of Rotor-Gene AssayManager v2.1 in combination with the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in:

Error ID	Error Text
2240009	Analysis - The analysis of assay {0} was not performed because the run was not successful.
2240025	Could not release experiment. The user {0} was deactivated because the wrong password was entered too many times. The session will be terminated.
2240034	Archiving of the experiment "{0}" failed.
2240035	Creation of the archiving scripts for {0} plugin failed.
2270000	The Quantification Standard {0} does not have a result object.
2270001	No sample with the name {0} was found. Check the sample configuration and retry.
2270002	The plug-in key of the provided assay does not match the plug-in key of this plug-in.

2270003	The provided curve is invalid.
2270004	Raw data input was zero.
2270005	Precision is too low.
2270006	Raw data input was too small.
2270007	The parameter 'IgnoreFirst' must not be set if 'DynamicTube' option is deactivated. Check Rotor-Gene .qut-file and retry.
2270008	No local maximums found. Reason: 'Ignore First'- {0} value is higher than NumberOfCycles {1}.
2270009	Slope correction cannot be performed without activation of 'DynamicTube' option. Check Rotor-Gene .qut-file and retry.
2270010	Provide a regression line.
2270011	The provided cycle threshold value is zero. Check Rotor-Gene .qut-file and retry.
2270012	The slope of the provided regression line is zero.
2270013	The provided data collections are too small.
2270014	LIMS export failed. Reason: {0}
2270016	All arguments must have the same size.
2270038	No target profile with the name {0} was found.
2270039	The parameter value 'Ignore First' is higher than the number of cycles. Lower the parameter value 'Ignore First' in the Rotor-Gene .qut-file.
2270043	Shorten the sample comment to max. 256 characters.
2270044	Shorten the assay comment to max. 256 characters.
2270080	The user has no rights to save to the folder of the network drive. (Access is denied.)
2270083	The access to the path of destination folder (network drive) is lost due to network issues. (Path could not be found.)
2270152	No target analysis profile for the target profile with the name {0} was found.

2270159	Enter a valid password.
2270160	This user is deactivated. Contact your local administrator.
2270161	Enter your password to sign your approval electronically.
2270162	Initialize dialog first.
2270163	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
2270168	Could not release experiment. The user {0} was deactivated because the wrong password was entered too many times. The session will be terminated.
2270170	The release was not performed.
2270173	The report was not created.
2270174	The release was not performed but data was saved.
2270210	The report was not created.
2270296	The entered calibrator values are not the same. Check and enter the correct values.
2270301	The entered calibrator value is not within the required range between {0} and {1}. Check the entered values.
2270304	Failed to create file {0}.

The numbers in curly brackets are placeholders for variable terms, names or specific error information that are not listed here.

Further information about troubleshooting and error codes can be found in the "Troubleshooting" chapter in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

## 1.6 Appendix

The appendix contains the Liability Clause and the License Terms for the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in.

### Note

Further information, such as a glossary, can be found in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

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