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# Rotor-Gene AssayManager Epsilon Plug-in User Manual



Rotor-Gene AssayManager



Sample & Assay Technologies



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# **Rotor-Gene AssayManager Epsilon Plug-in User Manual**

# 1 Rotor-Gene AssayManager Epsilon Plug-in User Manual

Welcome to the *Rotor-Gene AssayManager Epsilon Plug-in User Manual*.

## 1.1 Safety Information

The user-friendly Rotor-Gene AssayManager® software has been specifically developed for use with up to 4 different Rotor-Gene® Q instruments. Before using Rotor-Gene AssayManager software, it is essential that you carefully read this user manual and *Rotor-Gene AssayManager 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 Core Application User Manual* does not provide detailed information about Rotor-Gene Q instrument hardware and maintenance. The user manual only describes the functionality of the Rotor-Gene AssayManager software in combination with Rotor-Gene Q instruments.

### Note

The terms "Rotor-Gene Q" and "Rotor-Gene Q instrument", used in this manual, apply to all Rotor-Gene Q and Rotor-Gene Q MDx instruments (not available in all countries) unless otherwise specified.

## 1.2 Introduction

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

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

Rotor-Gene AssayManager 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. 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.aspx](http://www.qiagen.com/Products/Rotor-GeneAssayManager.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 components. The user manuals provide a context-sensitive online help that can be started by simply pressing the "F1" key.

When installing additional plug-ins, the corresponding user manuals are automatically added to the existing help system. Alternatively, the user manuals can be downloaded from the QIAGEN website at ► [www.qiagen.com/Products/Rotor-GeneAssayManager.aspx](http://www.qiagen.com/Products/Rotor-GeneAssayManager.aspx)

**Rotor-Gene AssayManager 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 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 Epsilon 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 Epsilon 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.

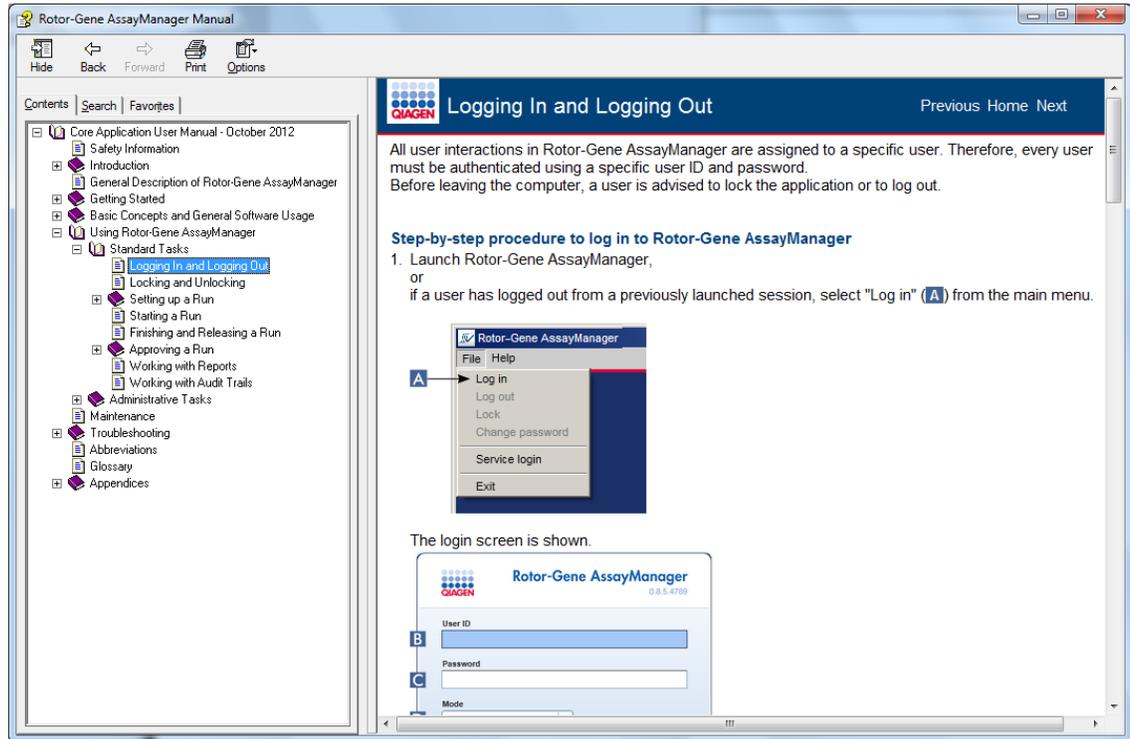
In an effort to produce useful and appropriate documentation, we would appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

**Version Management**

This document is the *Rotor-Gene AssayManager Epsilon Plug-in User Manual*, version 1.0, which provides information about the Rotor-Gene AssayManager Epsilon Plug-in, version 1.0.x (where x is greater than or equal to 0).

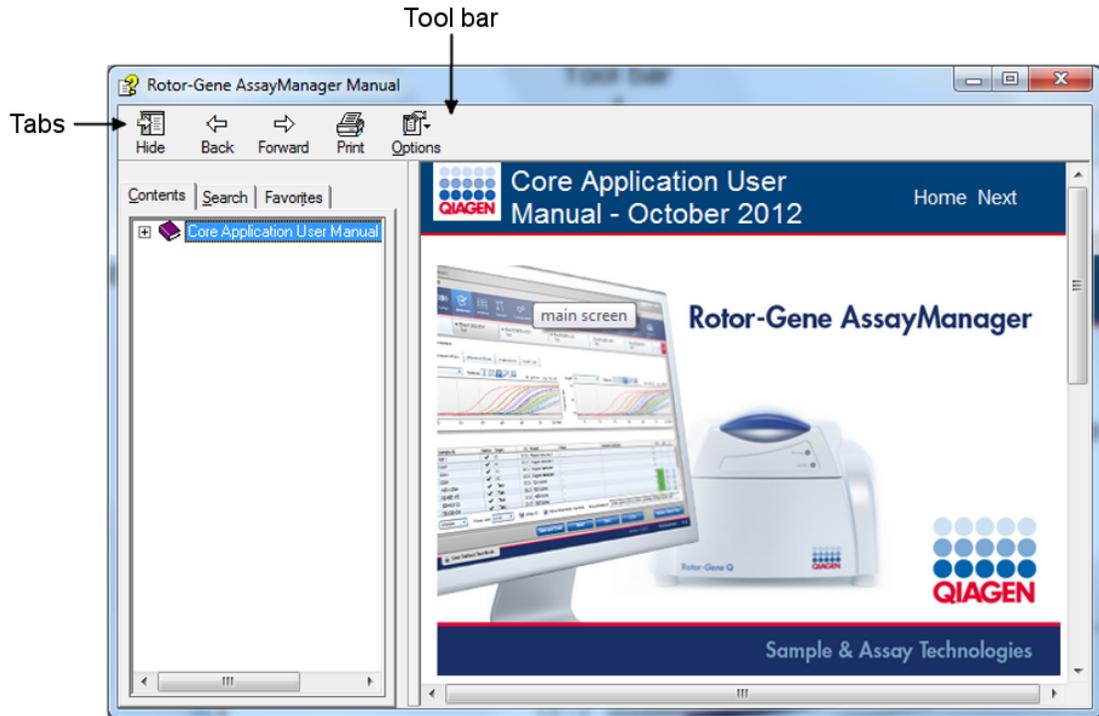
## 1.2.4 Getting Help

Rotor-Gene AssayManager comes with a detailed help system. Help is provided as a \*.pdf user manual or via the online help. For example, the following screenshot shows the help page that corresponds to the login screen:



Rotor-Gene AssayManager has a context-sensitive help system. Press the "F1" key in dialog boxes to display a context-sensitive help page.

## Using Rotor-Gene AssayManager Help

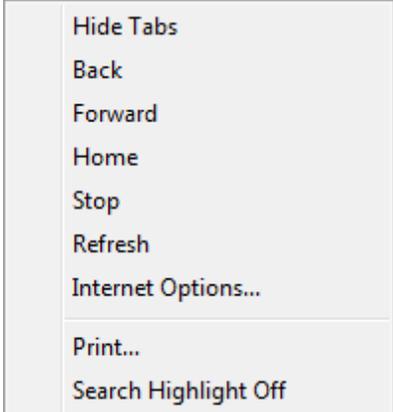


The help file contains two functional areas:

- Tool bar
- Tabs

The tool bar includes the following buttons:

Name	Icon	Description
"Hide" or "Show"		Hides the left-hand side navigation tab. To display the navigation tab again, click "Show". This button appears instead of "Hide".
"Back"		Returns to the previous screen.
"Forward"		Returns to the screen displayed before using the "Back" button.

"Print"		The user can choose to: 1) Print the selected topic. 2) Print the selected heading and all subtopics. Select one option and confirm with "OK", or select "Cancel" to go back.
"Options"		Opens the options menu with the following entries:
		

The navigation tab includes the following tabs.

Name	Description
"Contents"	In the "Contents" tab, the help content can be browsed by topic.
"Search"	Specific help topics can be found by entering search terms.
"Favorites"	Shortcuts to individual help topics can be added and managed.

### 1.3 Rotor-Gene AssayManager Epsilon Plug-in Specific Tasks and Procedures

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

#### Installing the Rotor-Gene AssayManager Epsilon Plug-in

A general step-by-step procedure detailing how to install Rotor-Gene AssayManager plug-ins is provided in the *Rotor-Gene AssayManager Core Application User Manual*. Please refer to "Installing Core Application and Plug-ins" in the *Rotor-Gene AssayManager Core Application User Manual*.

### **Importing assay profiles for the Rotor-Gene AssayManager Epsilon Plug-in**

To analyze results from a run of a specific assay with the Rotor-Gene AssayManager Epsilon 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 Core Application User Manual*.

Information about which assay profile is needed for each assay is provided in the handbook supplied with the kit.

## **1.3.1 Approving Samples**

The general functionality of the "Approval" environment is described in *Rotor-Gene AssayManager Core Application User Manual*. In the *Rotor-Gene AssayManager Epsilon Plug-in User Manual*, only the functionality relating to the Rotor-Gene AssayManager Epsilon Plug-in is described.

### **1.3.1.1 Reviewing Assay Data**

#### **Step-by-step procedure to review data from a specific assay**

After starting the approval process, a screen is displayed which is divided into 2 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 may be reviewed in 7 different sub tabs:

- "Raw data"
- "Processed data"
- "Standard curve"
- "Experiment"
- "Assay"
- "Audit trail"
- "Calibrator"

All sub tabs except for the "Calibrator" sub tab are described in the *Rotor-Gene AssayManager Core Application User Manual*. By default, the "Experiment" sub tab is opened upon starting the approval process. 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" sub tab before samples can be finally approved.

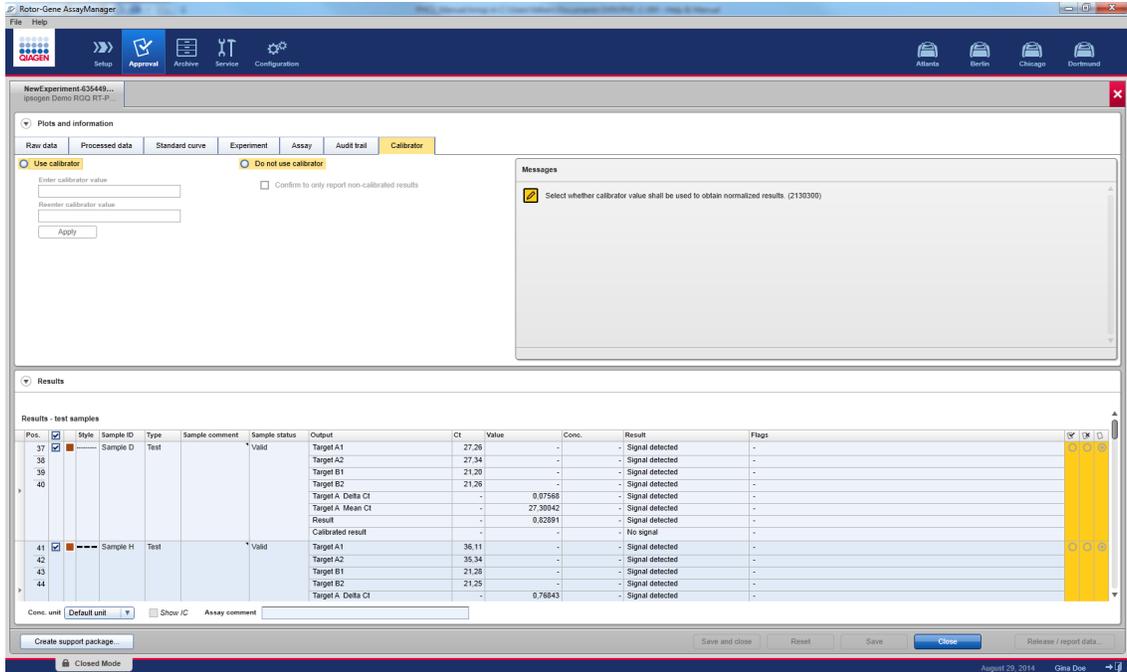
#### **"Calibrator" sub tab**

In the "Calibrator" sub tab, you must select if a calibrator is used or not. 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".

### Note

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



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

1. By default all samples of an assay are selected. To display only the amplification curves of specific samples:
  - a) Click the "Column select" icon in the header of the results table to deselect all samples.
  - b) Then click the "Sample selector" check box of the samples whose amplification curve should be displayed.

Results

Pos.	<input checked="" type="checkbox"/>	Style	Sample ID	Type	Sample comment	Sample status	Output	Ct	Value
2	<input checked="" type="checkbox"/>	■	QS 1	QS		Valid	Target A1	33,86	-
							Target A2	33,89	-
							Delta Ct	-	0,02380
3	<input checked="" type="checkbox"/>	■	QS 2	QS		Valid	Target A1	29,91	-
4	<input checked="" type="checkbox"/>						Target A2	30,24	-
							Delta Ct	-	0,33447
5	<input checked="" type="checkbox"/>	■	QS 3	QS		Valid	Target A1	26,48	-
6	<input checked="" type="checkbox"/>						Target A2	26,64	-
							Delta Ct	-	0,15869
7	<input checked="" type="checkbox"/>	■	QS 4	QS		Valid	Target A1	19,94	-
8	<input checked="" type="checkbox"/>						Target A2	19,80	-
							Delta Ct	-	0,14343
9	<input checked="" type="checkbox"/>	■	QS 5	QS		Valid	Target A1	16,80	-
10	<input checked="" type="checkbox"/>						Target A2	16,89	-
							Delta Ct	-	0,09033

Column selector

Sample selector

- Select the target from the "Target" drop-down list.

Plots and information

Raw data | Processed data

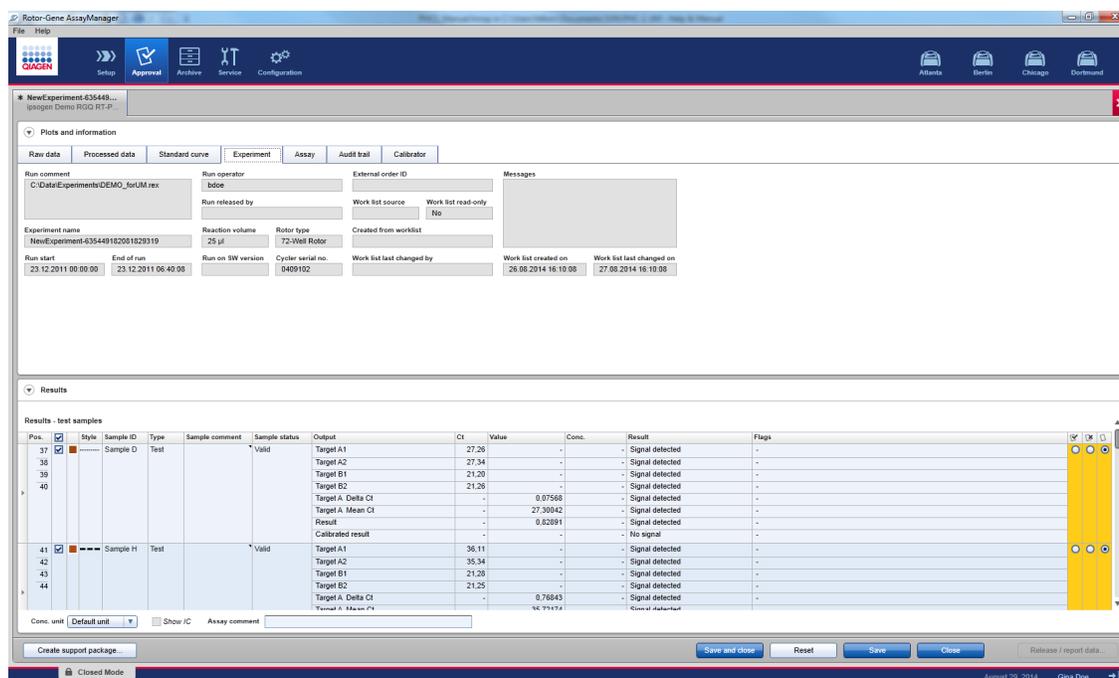
Target  Option

Target B1  
Target B2  
Target A1  
Target A2

- Review the individual amplification curves.

### 1.3.1.2 General Information About Approving Samples

The results of all samples must be approved (accepted or rejected) in the "Results" area of the "Approval" screen.



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)	Tube position of the target.
<input type="checkbox"/>	Sample select check box.
" " (Color)	Color of the target plot.
"Style"	Style of the target plot.
"Sample ID"	Sample ID of the external control or test sample.
"Type"	Type of sample. Possible values are "Test" (test sample), "NTC" (no-template control), "PC" (positive control), "EC+" (positive extraction control), "EC-" (negative extraction control), "CAL" (calibrator), and "QS" (quantitation standard).
"Sample comment"	Comment about sample.
"Sample status"	Sample status from analysis of the external control or test samples. Possible values are "Valid" or "Invalid".
"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"	C <sub>T</sub> value for the target.
"Value"	Value for the target defined in "Output"; determined according to calculations defined in the assay profile.
"Conc." (Concentration)	Concentration of the target if quantitative.
"Result"	Outcome of analysis. Possible values are "Signal detected", "No signal", "INVALID", or a specific string defined in the assay profile.
"Flags"	Flags resulting from the analysis of the external controls or test samples displayed as a comma-separated list. If no flags are applicable, a dash is displayed.

Sample results are approved by the user using 3 buttons at the right of the results list. As a visual aid, the background color of the approval bar changes according to the approval state. Initially, all test samples of a finished experiment have the status "Undefined" and are displayed with a yellow background. An "Accepted" sample changes to green. A "Rejected" sample changes to red.

Background color	Status of test sample
	Undefined
	Accepted
	Rejected

### Step-by-step procedure to approve samples

1. In the "Results" list, scroll to the sample to be approved. Every sample result to be approved has 3 buttons right of the results list.

Pos.	Style	Sample ID	Type	Sample comment	Sample status	Output	Ct	Value	Conc.	Result	Flags
45	✓	Sample E	Test		Valid	Target A1	30.82	-	-	Signal detected	
46	✓	Sample E	Test		Valid	Target A2	30.94	-	-	Signal detected	
47		Sample E	Test		Valid	Target B1	21.36	-	-	Signal detected	
48		Sample E	Test		Valid	Target B2	21.39	-	-	Signal detected	
					Valid	Target A Delta Ct	-	0.12268	-	Signal detected	
					Valid	Target A Mean Ct	-	30.88226	-	Signal detected	
					Valid	Result	-	0.08096	-	Signal detected	
					Valid	Calibrated result	-	-	-	No signal	
49	✓	Sample G	Test		Valid	Target A1	34.88	-	-	Signal detected	
50		Sample G	Test		Valid	Target A2	33.69	-	-	Signal detected	
51		Sample G	Test		Valid	Target B1	21.29	-	-	Signal detected	
52		Sample G	Test		Valid	Target B2	21.26	-	-	Signal detected	
					Valid	Target A Delta Ct	-	1.28235	-	Signal detected	

Approval Buttons

2. Either accept or reject the result of a sample.

	Click	Changes to
To <b>accept</b> a sample result, click the first button.		
To <b>reject</b> a sample result, click the second button.		

**Optional:** Enter a comment in the "Sample comment" column.

3. Repeat steps 1 and 2 for every sample until all sample results have either been accepted or rejected. To approve several sample results at once, highlight the dedicated rows using the row selector . To highlight adjacent rows, click the row selector of the first element, hold down the left mouse button, and move the cursor to the last element to be highlighted using the mouse wheel. All rows in between are highlighted. The same can be done by selecting the first row, holding the "Shift" key and selecting the last row to be highlighted. If you wish to select all rows in the table, mark any row and press "Ctrl" and "A" or click the header cell of the row selector column (upper left corner). The "Ctrl" keys can also be used to make multiple selections of non-adjacent rows.

A right-click in the highlighted rows opens the context menu below, which can be used to approve or reject all highlighted sample results at once:

Copy	Ctrl+C
<hr/>	
Show curves	
Hide curves	
Invert selection	
<hr/>	
Accept all non released	
Reject all non released	
Reset to undefined (all non released)	
<hr/>	
Cancel	

**Note**

It is also possible to approve only some of the sample results and to approve the remaining sample results later. The button bar provides the following buttons to manage the approval process:



Button	Explanation
	<ul style="list-style-type: none"> <li>▪ Saves all changes</li> <li>▪ Closes this screen and returns to the "Assay selection" screen</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 and returns to the "Assay selection" screen</li> </ul>
	<ul style="list-style-type: none"> <li>▪ Opens a dialog to release test results and optionally create a report</li> <li>▪ The status of the assay is set to: <ul style="list-style-type: none"> <li>▪ "Fully released" if all test samples were released and no test sample has the status "Undefined".</li> <li>▪ "Partially released" if at least one test sample is approved and released while at least one test sample still is not yet released.</li> </ul> </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>▪ Returns to the "Assay selection" screen</li> </ul>

### 1.3.1.3 Result

Rotor-Gene AssayManager determines the result of a target by combining all relevant analysis results according to normalization,  $C_T$  value calculation, Automatic Data Scan (AUDAS), and sample and assay rules defined in the corresponding assay profile. The target result can be "Signal detected", "No signal", "INVALID", or a specific string defined in the assay profile:

1. The target gets the result "Signal detected" if:
  - a) a  $C_T$  value is detected within a predefined valid range.
  - b) the value of a calculated target could be calculated.
  
2. The target gets the result "No signal" if:
  - a) no  $C_T$  value is detected or if the  $C_T$  is outside of a predefined valid range.
  - b) the value of a calculated target could not be calculated for any reason, e.g., an input value (like the calibrator value) is missing.
  
2. The target gets the result "INVALID" if one or more sample flags are assigned to the sample during analysis by Rotor-Gene AssayManager 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".
  
3. The target gets an assay specific result string if defined in the assay profile.

### 1.3.1.4 Concept of Approval Buttons in Rotor-Gene AssayManager Epsilon Plug-in

After clicking the "Start approval" button in the "Assay selection" screen, the "Approval" screen will be displayed. In the Rotor-Gene AssayManager Epsilon Plug-in, the AUDAS method is applied for assay analysis as defined in the corresponding assay profile. This means that the amplification curves of external controls, such as no-template controls (NTC), positive controls (PC), etc., as well as the amplification curves of the test samples, are automatically checked for anomalies by Rotor-Gene AssayManager.

#### Approval of external controls

In the Rotor-Gene AssayManager Epsilon Plug-in, the amplification curves of all external controls are automatically analyzed, and a specific result for each target is determined. The results of external controls in this plug-in do not have to be approved because tailored analysis parameters and rules are applied to the raw data of samples and external controls. This ensures Rotor-Gene AssayManager detects any abnormal or invalid amplification curve behavior. Each lot of external controls is tested against predetermined specifications to ensure consistent product quality. Therefore, only the approval buttons for test samples are activated.

### Approval of test sample results

The results of the test samples are automatically analyzed and set by Rotor-Gene AssayManager, but have to be approved and released by the user logged in as the approver. This is because the results of test samples may, for example, be influenced by different sample materials, in contrast to the external controls that have a constant product quality. Since not all potential abnormalities in the raw data can be automatically detected, the test sample results still need to be approved manually.

#### Note

Use the "Accepted" button for test samples when you agree with the results for test samples given by Rotor-Gene AssayManager. Use the "Rejected" button when you do not agree with the results given by Rotor-Gene AssayManager for any reason.

<b>Rotor-Gene AssayManager analysis</b>	<b>Approver agrees with the test sample result</b>	<b>Expected behavior of the approver</b>
Sample result is valid and displayed ("Signal detected", "No signal", or a string defined in the assay profile).	Yes	Click "Accepted".
Sample result is "INVALID", justified by at least one corresponding flag.	Yes	Click "Accepted" and re-test the sample.
Sample result is valid and displayed ("Signal detected", "No signal", or a string defined in the assay profile).	No (e.g., an invalid result is not automatically detected by Rotor-Gene AssayManager)	Click "Rejected" and re-test the sample.
Sample result is "INVALID", justified by at least one corresponding flag.	No (e.g., the result of a test sample looking valid was set to invalid)	Click "Rejected" and re-test the sample.

#### Note

A result automatically set to "INVALID" by Rotor-Gene AssayManager cannot be subsequently converted to a valid result, even if the result is rejected.

## Result table options

The result table can be adjusted using 4 fields at the bottom of the "Results" area:

The image shows a horizontal row of four controls. From left to right: a dropdown menu labeled 'Conc. unit' with 'Default unit' selected; a checked checkbox labeled 'Show standards / controls'; a checked checkbox labeled 'Show IC'; and a text input field labeled 'Assay comment'. Below each control is a blue lettered label: A, B, C, and D respectively.

	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, the box is checked.
C	<input checked="" type="checkbox"/> Show IC	Check the box to display the results of the internal control from the "Results" table.  <b>Note:</b> By default, this box is checked if an assay contains an IC (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.

### 1.3.1.5 Flags

The flags in the table below may be assigned to targets during analysis by Rotor-Gene AssayManager. This is not a complete list of all flags that can occur when using the Rotor-Gene AssayManager Epsilon Plug-in. Additional flags may be defined for specific rules for the particular assay and sample analysis in the assay profile. These flags are described in the corresponding assay handbook.

Flags may result in an "INVALID" result in Rotor-Gene AssayManager, or they may be

a "warning" only. Flags that are designated "variable" in the table below will result in different behavior by Rotor-Gene AssayManager depending on the settings in the assay profile used. Refer to the assay handbook for a detailed description of the flags and their specific behavior for the different assay profiles.

Explanation of table row colors:

- Red denotes core analysis
- Blue denotes assay and sample analysis
- Green denotes AUDAS

Flag	Behavior	Description
ABOVE_ACCEPTED_RANGE	Variable	The target value is higher than the defined range. This can be a $C_T$ , endpoint-fluorescence, concentration, or calculated value, e.g., mean $C_T$ or delta $C_T$ .
ASSAY_INVALID	Invalid	The assay is invalid because at least one external control is invalid.
BELOW_ACCEPTED_RANGE	Variable	The target value is lower than the defined range. This can be a $C_T$ , endpoint-fluorescence, concentration, or calculated value, e.g., mean $C_T$ or delta $C_T$ .
CONSECUTIVE_FAULT	Invalid	Target that was used for calculation of this target is invalid.
CORRESPONDING_CONTROL_INVALID	Invalid	Target is set to "INVALID" because at least one corresponding external control is invalid.
CORRESPONDING_POSITIVE_CONTROL_TARGET_INVALID	Invalid	The target result is invalid because the corresponding positive

		control is invalid.
CURVE_SHAPE_ANOMALY	Invalid	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	Invalid	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	Invalid	The internal control is invalid. Target and internal control share the same tube.
IC_NO_SIGNAL	Invalid	No internal control signal detected. Target and internal control share the same tube.
INVALID_CALCULATION	Invalid	Calculation for this target failed.
LOW_FLUORESCENCE_CHANGE	Warning	The percentage fluorescence change for this sample relative to the sample tube with the largest fluorescence change is lower than a defined limit.

LOW_REACTION_EFFICIENCY	Warning	The reaction efficiency for this sample has not reached a defined limit.
MAX_CORRELATION_IN_STANDARD_CURVE_EXCEEDED	Variable	The upper limit for the correlation coefficient ( $R^2$ or R value) is exceeded.
MAX_EFFICIENCY_EXCEEDED	Variable	The upper limit for reaction efficiency is exceeded.
MAX_SLOPE_EXCEEDED	Variable	The upper limit of the slope is exceeded.
MULTIPLE_THRESHOLD_CROSSING	Invalid	The amplification curve crosses the threshold more than once. An unambiguous $C_T$ cannot be determined.
NO_CT_DETECTED	Variable	No $C_T$ is detected for this target.
NO_VALUE	Variable	The target has no value but it is expected to have one. This value does not have to be in certain range. This can be a $C_T$ endpoint-fluorescence, concentration, or calculated value, e.g., mean $C_T$ or delta $C_T$ .
NORM_FACTOR_ALTERATION	Warning	Deviation during the normalization procedure. The amplification curve is displayed with a default normalization; results should be manually checked for correctness.
OTHER_IC_INVALID	Invalid	The internal control is invalid. Target and internal control are in different tubes.

OTHER_IC_NO_SIGNAL	Invalid	No internal control signal detected. Target and internal control are in different tubes.
OTHER_TARGET_INVALID	Invalid	Another target for the same sample is invalid.
OUT_OF_COMPUTATION_RANGE	Invalid	The calculated concentration for this sample exceeds the technical limit.
SATURATION	Invalid	The raw data fluorescence is saturating strongly before the inflection point of the amplification curve.
SATURATION_IN_PLATEAU	Warning	The raw data fluorescence is saturating in the plateau phase of the amplification curve.
SPIKE	Variable	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	Invalid	A spike is detected in the amplification curve close to the $C_T$ .
STEEP_BASELINE	Invalid	A steeply rising baseline for the raw data fluorescence is detected in the amplification curve.
STRONG_BASELINE_DIP	Invalid	A strong drop in the baseline for the raw data fluorescence is detected in the amplification curve.
STRONG_NOISE	Invalid	Strong noise is detected

		outside the growth phase of the amplification curve.
STRONG_NOISE_IN_GROWTH_PHASE	Invalid	Strong noise is detected in the growth (exponential) phase of the amplification curve.
TOO_LESS_CORRELATION_IN_STANDARDS_CURVE	Variable	A lower limit for the correlation coefficient ( $R^2$ or R value) is not reached.
TOO_LESS_EFFICIENCY	Variable	A lower limit for reaction efficiency is not reached.
TOO_LESS_SLOPE	Variable	A lower limit for the slope is not reached.
TOO_MANY_QUANTIFICATION_STANDARDS_INVALID	Variable	The number of valid targets which are used for calculation of the standard curve is not sufficient.
UNCERTAIN	Variable	Results from the AUDAS are conflicting with results from the core analysis. An unambiguous automatic assessment of data validity is not possible.
UNEXPECTED_CT_DETECTED	Variable	A $C_T$ value is detected for a target that should not amplify.
UNEXPECTED_VALUE	Variable	The target has a value, but it is not expected to have one. This can be a $C_T$ , endpoint-fluorescence, concentration, or calculated value, e.g., mean $C_T$ or delta $C_T$ .

UPSTREAM	Variable	Sample status was set to "Invalid" or "Unclear" by an upstream process (e.g., QIASymphony). <b>Note:</b> For samples that are flagged as unclear, the behavior of Rotor-Gene AssayManager is defined in the "Configuration" environment of the AssayManager software. "Invalid" flags from upstream processes always result in an invalid corresponding sample in Rotor-Gene AssayManager.
WAVY_BASE_FLUORESCENCE	Invalid	Wavy baseline for the raw data fluorescence detected in the amplification curve.

### 1.3.2 Reporting

The Rotor-Gene AssayManager Epsilon Plug-in automatically generates \*.pdf report files that summarize result data for an assay run performed on a Rotor-Gene Q instrument.

After the run has finished, the report is saved as a \*.pdf file in the configured file directory. Then the report is displayed in read-only mode 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 long name of the assay profile followed by "Analysis Report". Below the report title, the report creation date and time are shown followed by the name of the operator and associated user ID, e.g.,:

## *ipsogen* Demo RGQ RT-PCR Analysis Report

Created on 29.08.2014, 15:34:12 +02:00 UTC by Gina Doe (su)

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.
"Run information"	A table listing general information about the run.
"Results"	A table listing results, flags, and statuses for all external controls and test samples. Depending on the assay profile settings, the table may have 12 columns: "Position", "Sample ID", "Type", "Sample comment", "Sample status", "Approval status", "Output", "Ct", "Value", "Conc.", "Result", and "Flags". See below for detailed descriptions.
"Standard Curve Details"	A table listing statistical parameters for the standard curves of a quantitative assay if quantitation standards are used.
"Standard Curve Plots"	Plot(s) displaying the standard curve(s) of a quantitative assay if quantitation standards are used.
"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 section describes the individual report sections in more detail, including example screenshots of a \*.pdf file.

**1.3.2.1 "Assay Information" Table**

The "Assay Information" table may provide the following information:

Field	Content
"Assay Profile:"	Name and version of the assay profile.
"Assay Kit:"	1. Material number of the assay kit. 2. Lot number of the assay kit. 3. Expiration date of the assay kit.
"Calibrator value:"	Numeric value of the calibrator used (entered by the operator in the "Approval" environment) or the entry "not used" if no

"Assay Status:"	<p>calibrator was used.</p> <p><b>Note:</b> This row only appears for assays with a calibrator defined in the assay profile.</p> <p>This field displays the assay status as "Successful" or "Failed". Possible reasons for a failed assay status include "run failed", "run stopped", "analysis failed" (in case of unexpected error), or "assay invalid" (according to failed analysis rules).</p> <p><b>Note:</b> The assay status is also "successful" if the run operator decided to allow the usage of an assay kit material number that deviates from the one defined in the assay profile.</p>
"Assay Comment:"	Comments about the assay entered by the operator.

Below the "Assay Information" table, the method by which the work list was generated is described. A work list can either be generated automatically or manually.

Example of the "Assay Information" table:

<b>Assay Information</b>	
Assay Profile:	ipsogen Demo RGQ RT-PCR (1.0.0)
Assay Kit:	Material number: 3333337, Lot number: 4567890, Expiration date: 29.04.2015 (not expired)
Calibrator Value:	Not used
Assay Status:	Successful
Assay Comment:	No comment
The work list was generated manually.	

### 1.3.2.2

#### "Run Information" Table

The "Run Information" table provides the following information:

Field	Content
"Run:"	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 comments 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 of the work list from which the experiment was created. <b>Note:</b> If the work list is locked then "(read-only)" is displayed together with the work list name.</li> <li>2. Creator of the work list.</li> <li>3. Last modifier of the work list.</li> </ol>
"Cycler:"	<ol style="list-style-type: none"> <li>1. Serial number of the cycler and rotor type.</li> <li>2. Reaction volume.</li> </ol>

Example of the "Run Information" table:

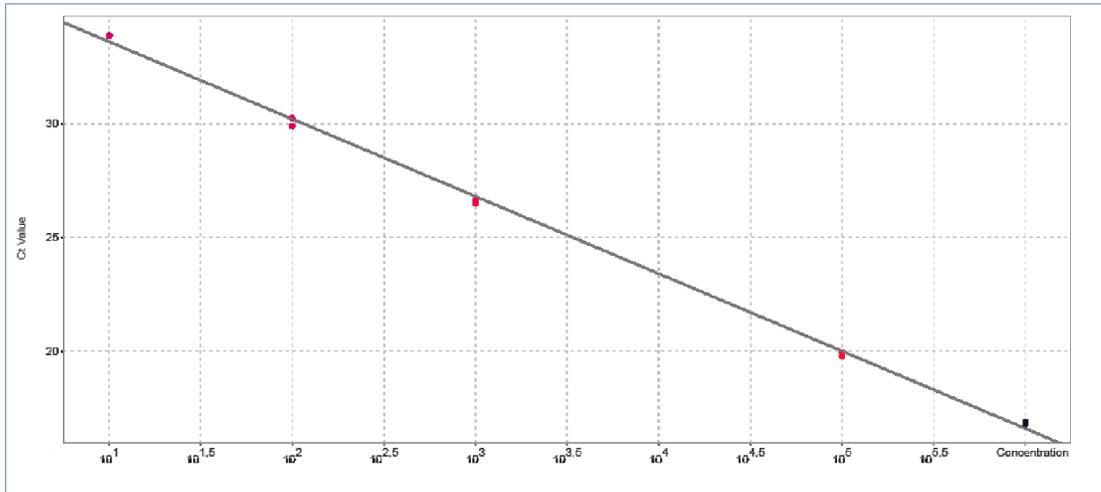
Run Information	
<b>Run:</b>	Demo_20140909_1452
<b>Run Information:</b>	From 09.09.2014, 2:52 +02:00 UTC to 09.09.2014, 2:55 +02:00 UTC Operated by Gina Doe (su) on Rotor-Gene AssayManager version 1.0.3.5 using Epsilon plug-in version 1.0.0 No comment No errors Run automatically released by the system on 09.09.2014, 2:55 +02:00 UTC
<b>Work List:</b>	WL_20140909_1452_su Created by Gina Doe (su) on 09.09.2014, 2:52 +02:00 UTC Last changed by Gina Doe (su) on 09.09.2014, 2:52 +02:00 UTC
<b>Cycler:</b>	0409102, Rotor type 72-Well Rotor 25 µl Reaction Volume

### 1.3.2.3 "Standard Curve Plots" Section

The "Standard Curve Plots" section displays the standard curves for the quantitation 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 Plots" section:

Standard Curve Target A



#### 1.3.2.4 "Standard Curve Details" Table

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

Field	Content
"R"	Root extracted from $R^2$
"R <sup>2</sup> "	The correlation coefficient $R^2$ 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 B	0,99969	0,99938	-3,347	37,747	0,990
Target A	0,99933	0,99867	-3,398	36,999	0,969

### 1.3.2.5 "Results" Table

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

Field	Content
"Pos." (Position)	Tube position of the target.
"Sample ID"	Sample ID of the external control or test sample.
"Type"	Type of sample. Possible values are "Test" (test sample), "NTC" (no-template control), "PC" (positive control), "EC+" (positive extraction control), "EC-" (negative extraction control), "CAL" (calibrator), and "QS" (quantitation standard).
"Sample comment"	Comment about sample.
"Sample status"	Sample status from analysis of the external control or test samples. Possible values are "Valid" or "Invalid".
"Approval status"	For external controls, the approval status is "Approved automatically". For test samples, the approval status is either "Accepted" or "Rejected".
"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"	C <sub>T</sub> value for the target.
"Value"	Value for the target defined in "Output"; determined according to calculations defined in the assay profile.
"Conc." (Concentration)	Concentration of the target if quantitative.
"Result"	Outcome of analysis. Possible values are "Signal detected", "No signal", "INVALID", or a specific string defined in the assay profile.
"Flags"	Flags resulting from the analysis of the 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	Sample status	Approval status	Output	Ct	Value	Conc.	Result	Flags
37, 38, 39, 40	Sample D	Test		Valid	Accepted	Target A1	27,26	-	-	Signal detected	-
						Target A2	27,34	-	-	Signal detected	-
						Target B1	21,20	-	-	Signal detected	-
						Target B2	21,26	-	-	Signal detected	-
						Target A Delta Ct	-	0,07568	-	Signal detected	-
						Target A Mean Ct	-	27,30042	-	Signal detected	-
						Result	-	0,82891	-	Signal detected	-
						Calibrated result	-	-	-	No signal	-
41, 42, 43, 44	Sample H	Test		Valid	Accepted	Target A1	36,11	-	-	Signal detected	-
						Target A2	35,34	-	-	Signal detected	-
						Target B1	21,28	-	-	Signal detected	-
						Target B2	21,25	-	-	Signal detected	-
						Target A Delta Ct	-	0,76843	-	Signal detected	-
						Target A Mean Ct	-	35,72174	-	Signal detected	-
						Result	-	0,00293	-	Signal detected	-
						Calibrated result	-	-	-	No signal	-
45, 46, 47, 48	Sample E	Test		Valid	Accepted	Target A1	30,82	-	-	Signal detected	-
						Target A2	30,94	-	-	Signal detected	-
						Target B1	21,36	-	-	Signal detected	-
						Target B2	21,39	-	-	Signal detected	-
						Target A Delta Ct	-	0,12268	-	Signal detected	-
						Target A Mean Ct	-	30,88226	-	Signal detected	-
						Result	-	0,08096	-	Signal detected	-
						Calibrated result	-	-	-	No signal	-

#### Note

Depending on the assay profile settings, the "Results" table may be separated into 2 individual tables, one for "External Controls", another one for "Test Samples".

### 1.3.2.6 "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

---



---



---

Operator:

---

 Print Name

---

 Signature

---

 Date

Reviewer:

---

 Print Name

---

 Signature

---

 Date

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## 1.4 About the Online Documentation

Rotor-Gene AssayManager uses plug-ins to increase its functionality. To make a clear distinction between the core application manual and the plug-in manuals, and to keep the documentation short and focused, general topics are explained in the core application manual.

Appropriate help for the "Plots and information" table and the "Results" table depends on which software environment you are currently working in. For more information, see below.

- ▶ 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 Epsilon Plug-in User Manual* or in the *Rotor-Gene AssayManager Core Application User Manual*.

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

Environment	Help file and topic
"Approval"	<b><i>Rotor-Gene AssayManager Epsilon Plug-in User Manual (i.e., this manual)</i></b>

Environment	Help file and topic
"Archive"	<p>Topic:</p> <ul style="list-style-type: none"> <li>▶ General information about approving samples</li> </ul> <p><b><i>Rotor-Gene AssayManager 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>

If the information references the *Rotor-Gene AssayManager Core Application User Manual*, open the help file using the 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 Epsilon Plug-in User Manual* or in the *Rotor-Gene AssayManager 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 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 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>

If the information references the *Rotor-Gene AssayManager Core Application User Manual*, open the help file using the 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. 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 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.

The following list provides all error messages that might occur during operation of Rotor-Gene AssayManager in combination with the Rotor-Gene AssayManager Epsilon Plug-in:

### Note

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

Error ID	Error Text
2120019	Approval: Experiment {0} assay {1} assay comment set from {2} to {3}.
2120020	Approval: Experiment {0} assay {1} sample {2} in tube position {3} state set from {4} to {5}.
2120021	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} state set from {5} to {6}.
2120022	Approval: Experiment {0} assay {1} sample {2} in tube position {3} comment set from {4} to {5}.
2120023	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} comment set from {5} to {6}.
2120024	Approval: Experiment {0} assay {1} was released.
2120025	Could not release experiment. The user {0} was deactivated because the wrong password was entered too many times. The session will be terminated.
2120029	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} was released and exported.
2120030	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} was released.

2120031	Approval: Experiment {0} assay {1} sample {2} in tube position {3} was released and exported.
2120032	Approval: Experiment {0} assay {1} sample {2} in tube position {3} was released.
2120033	Approval: Experiment {0} assay {1} partially released.
2120037	Approval: Experiment {0} assay {1} calibrator state set from 'Do not use calibrator' to 'Use calibrator' with calibrator value {2}.
2120038	Approval: Experiment {0} assay {1} calibrator state set to 'Do not use calibrator'.
2120039	Approval: Experiment {0} assay {1} calibrator value set from {2} to {3}.
2120040	Approval: Experiment {0} assay {1} calibrator state set from 'Use calibrator' with calibrator value {2} to 'Do not use calibrator'.
2120041	Approval: Experiment {0} assay {1} calibrator state set to 'Use calibrator' with calibrator value '{2}'
2130017	The run template does not contain any cycling parameters.
2130018	The run profile must only contain "Cycling" and "Hold" steps. Check the run profile and the assay profile for consistency.
2130019	Enter a valid value for {0} of target {1} ({2}-{3}).
2130020	The {0} of target {1} has an incorrect format.
2130047	{0} (report generation failed)
2130122	The default AUDAS parameters for this target have been restored.
2130135	AUDAS is not enabled for target {0}
2130151	Run profile must contain at least 7 cycles in the "Cycling" entries.
2130157	After release, the test results are moved to the archive.
2130158	After release, the approval state of data cannot be changed.
2130159	Enter a valid password.
2130160	This user is deactivated. Contact your local administrator.
2130161	Enter your password to sign your approval electronically.

2130163	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
2130168	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
2130169	The release was performed successfully.
2130170	The release was not performed.
2130171	The LIMS output was saved.
2130172	The report {0} was stored in the folder {1}.
2130173	The report was not created.
2130174	The release was not performed but data was saved.
2130206	The export of the QIALink/LIMS result file failed. Please check the LIMS export configuration settings.
2130208	The LIMS output was not saved.
2130209	The LIMS output was saved.
2130210	The report was not created.
2130211	The report {0} was stored in the folder {1}.
2130217	AUDAS is temporarily disabled for the target. It has to be enabled before the assay is finalized.
2130278	The exported .rex file contains data from all assays of experiment: {0}
2130280	Unsaved changes in the currently active assay will be discarded.
2130282	The .rex file is not included in the support package.
2130283	Report generation failed. Reason: {0}
2130284	The report is not included in the support package.
2130286	The audit trail report is not included in the support package.
2130288	Failed to create support package. Reason: {0}
2130289	The time interval audit trail report is not included in the support package.

2130291	The QIAGEN-Hardware.log was not included in the support package. Reason: The run was performed on a different machine.
2130292	Not all log files for the related time period could be found.
2130293	The log file is not included in the support package.
2130294	Failed to create log file. Reason: {0}
2130295	Rex file export failed. Reason: {0}
2130296	The entered calibrator values are not the same. Check and enter the correct values.
2130297	Confirm to only report non-calibrated results.
2130298	Enter a calibrator value.
2130299	Reenter the calibrator value.
2130300	Select whether calibrator value shall be used to obtain normalized results.
2130301	The entered calibrator value is not within the required range between {0} and {1}. Check the entered values.

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

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

## 1.6 Appendix

The appendix contains the Liability Clause and the License Terms for the Rotor-Gene AssayManager Epsilon Plug-in.

### Note

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

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### **Rotor-Gene AssayManager Epsilon Plug-in Software License Agreement**

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- delay,
- compensation due to defect,
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