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Rotor-Gene AssayManager Epsilon (US) Plug-in User Manual

For use with Rotor-Gene AssayManager Software version 1.0



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Rotor-Gene AssayManager Epsilon (US) Plug-in User Manual

1 Rotor-Gene AssayManager Epsilon (US) Plug-in User Manual

Welcome to the *Rotor-Gene AssayManager Epsilon (US) 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 MDx instruments. Before using Rotor-Gene AssayManager software, it is essential that you carefully read this user manual and the *Rotor-Gene AssayManager IVD (US) 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 IVD (US) 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 software in combination with Rotor-Gene Q MDx instruments.

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 MDx instruments. Rotor-Gene AssayManager 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 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 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. 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 IVD (US) 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 (US) 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 (US) 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 (US) Plug-in specific tasks and procedures

1.4 ▶ Error Messages and Error Codes

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

1.3 Rotor-Gene AssayManager Epsilon (US) Plug-in Specific Tasks and Procedures

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

Installing the Rotor-Gene AssayManager Epsilon (US) Plug-in

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

Importing assay profiles for the Rotor-Gene AssayManager Epsilon (US) Plug-in

To analyze results from a run of a specific assay with the Rotor-Gene AssayManager Epsilon (US) 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 IVD (US) 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 Releasing Samples

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

Note

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

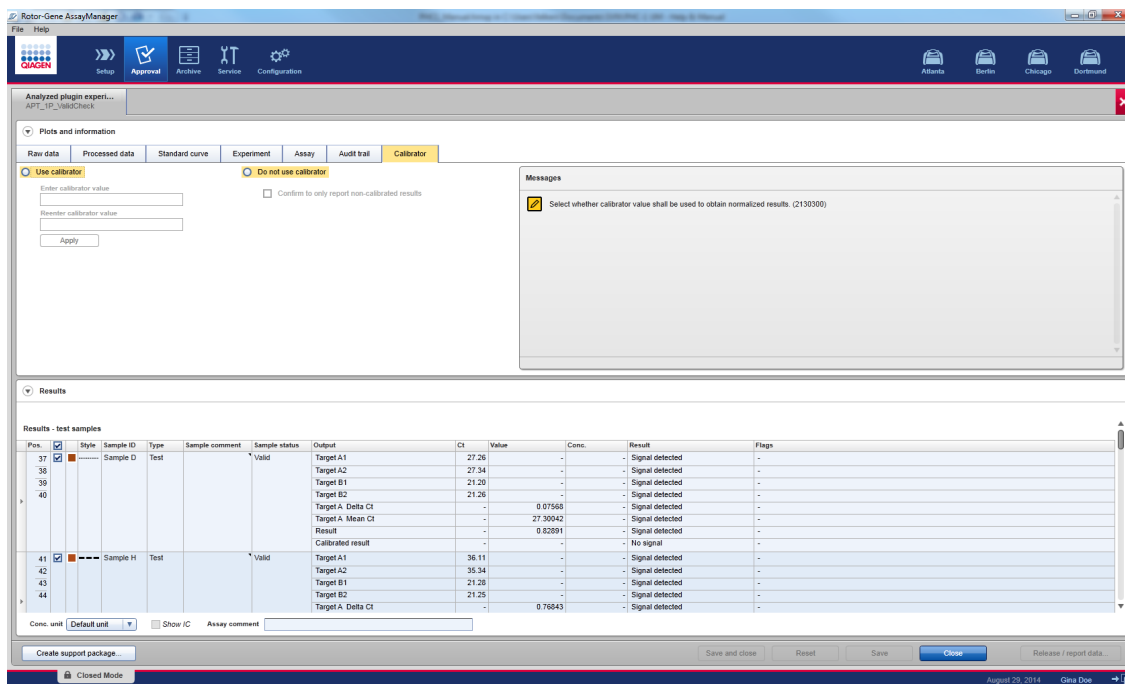
All sub tabs except for the "Calibrator" sub tab are described in the *Rotor-Gene AssayManager IVD (US) Core Application User Manual*. By default, the "Experiment" sub tab is opened upon starting the release process. If the experiment contains at least one sample of type "Calibrator" (= "CAL"), mandatory information (yellow background) about the calibrator needs to be entered in the "Calibrator" sub tab before samples can be finally released.

"Calibrator" sub tab

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

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

Column selector

Sample selector

Results									
Pos.	<input checked="" type="checkbox"/>	Style	Sample ID	Type	Sample comment	Sample status	Output	Ct	Value
1	<input checked="" type="checkbox"/>	■	QS 1	QS		Valid	Target A1	33.86	-
2	<input checked="" type="checkbox"/>	■	QS 1	QS		Valid	Target A2	33.89	-
							Delta Ct	-	0.02360
3	<input checked="" type="checkbox"/>	■	QS 2	QS		Valid	Target A1	29.91	-
4	<input checked="" type="checkbox"/>	■	QS 2	QS		Valid	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"/>	■	QS 3	QS		Valid	Target A2	26.64	-
							Delta Ct	-	0.15669
7	<input checked="" type="checkbox"/>	■	QS 4	QS		Valid	Target A1	19.94	-
8	<input checked="" type="checkbox"/>	■	QS 4	QS		Valid	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"/>	■	QS 5	QS		Valid	Target A2	16.89	-
							Delta Ct	-	0.09033

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

Plots and information

Raw data Processed data

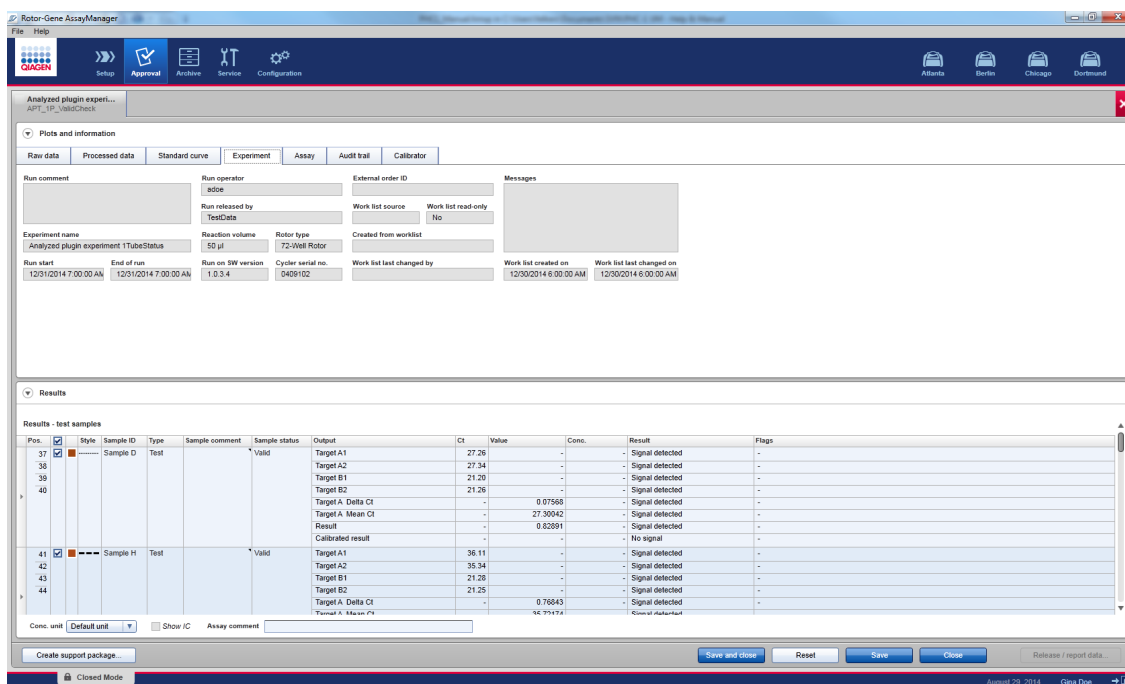
Target Target B1 Option

Target B1
Target B2
Target A1
Target A2

3. Review the individual amplification curves.

1.3.1.2 General Information About Releasing Samples

The results of all samples determined by Rotor-Gene AssayManager are shown 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".


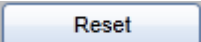

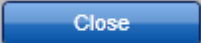

"Output"	All targets relating to the external control or test sample. Each target is displayed in a separate row and appears in the order defined in the assay profile.
"Ct"	C _T value for the target.
"Value"	Value for the target defined in "Output"; determined according to calculations defined in the 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.

The sample results have to be released. By pressing the "Release / report data..." button, the sample results are released, and a report is generated as a *.pdf file. If a LIMS export is configured, the LIMS export file will also be generated.

Note

The button bar provides the following buttons to manage the release process:



Button	Explanation
	<ul style="list-style-type: none">• Saves all changes• Closes this screen and returns to the "Assay selection" screen
	<ul style="list-style-type: none">• Discards all unsaved changes• Reverts to the previously saved status; amplification plots and result table options are not reset
	<ul style="list-style-type: none">• Saves all changes; remains in this dialog
	<ul style="list-style-type: none">• Discards all changes and returns to the previously saved status• Closes this screen and returns to the "Assay selection" screen
	<ul style="list-style-type: none">• Opens a dialog to release test results and optionally create a report• The status of the assay is set to "Fully released".• Saves the *.pdf report file in the folder defined in the "Configuration" environment, under:<ul style="list-style-type: none">• Settings ▶ Local Settings ▶ Default data export directories ▶ Report folder• Returns to the "Assay selection" screen

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, optionally quantification, Automatic Data Scan (AUDAS), and sample & 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.
3. 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". Results of samples with the upstream flag "UNCLEAR" (e.g., flagged by QIAasymphony® AS) are also set to "INVALID".
4. The target gets an assay specific result string if defined in the assay profile.

1.3.1.4 Concept of Buttons in Rotor-Gene AssayManager Epsilon (US) Plug-in

Release of Assay

After clicking "Start Approval" in the "Assay selection" screen, the "Approval" screen will be displayed. In the Rotor-Gene AssayManager Epsilon (US) Plug-in, the automatic data scan (AUDAS) method is applied for assay analysis as defined in the corresponding assay profile. All amplification curves are automatically checked for anomalies by Rotor-Gene AssayManager and analyzed according to tailored analysis parameters and rules. A specific result for each target is determined.

Result table options

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

The diagram illustrates the result table options interface. It consists of four fields labeled A, B, C, and D, each with a corresponding label above it. Field A is labeled 'Conc. unit' and contains a dropdown menu with 'Default unit' selected. Field B is labeled 'Show standards / controls' and contains a checked checkbox. Field C is labeled 'Show IC' and contains a checked checkbox. Field D is labeled 'Assay comment' and contains a text input field.

Option	Explanation
Conc. unit <input type="text" value="Default Unit"/> ▼	Choose from default and alternative concentration units (defined in the assay profile). Note: This function is only available for quantitative assays.
<input checked="" type="checkbox"/> Show standards / controls	Check the box to display standards and controls in the "Results" table. Note: By default, the box is checked.
<input checked="" type="checkbox"/> Show IC	Check the box to display the results of the internal control from the "Results" table. Note: By default, this box is checked if an assay contains an IC (internal control target).
Assay comment <input type="text"/>	Enter a comment about the assay. Note: 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 (US) 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.

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

- Blue denotes assay and sample analysis
- Green denotes AUDAS (curve check) analysis
- Red denotes core analysis

Flag	Description
ABOVE_ACCEPTED_RANGE	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	The assay is invalid because at least one external control is invalid.
AUDAS_CONFLICT	Results from the automatic data scan (AUDAS) are in conflict with results from the core analysis. An unambiguous automatic assessment of data validity is not possible.
BELOW_ACCEPTED_RANGE	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	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.
MAX_CORRELATION_IN_STANDARD_CURVE_EXCEEDED	The upper limit for the correlation coefficient (R^2 or R value) is exceeded.
MAX_EFFICIENCY_EXCEEDED	The upper limit for reaction efficiency is exceeded.
MAX_SLOPE_EXCEEDED	The upper limit of the slope is exceeded.
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.
NO_CT_DETECTED	No C_T is detected for this target.
NO_VALUE	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 .
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.
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.
TOO_LESS_CORRELATION_IN_STANDARD_CURVE	A lower limit for the correlation coefficient (R^2 or R value) is not reached.
TOO_LESS_EFFICIENCY	A lower limit for reaction efficiency is not reached.
TOO_LESS_SLOPE	A lower limit for the slope is not reached.
UNEXPECTED_CT_DETECTED	A C_T value is detected for a target that should not amplify.

UNEXPECTED_VALUE	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	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.

1.3.2 Reporting

The Rotor-Gene AssayManager Epsilon (US) 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 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 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.,:

APT_1P_ValidCheck Analysis Report

Created on 8/21/2015, 3:08:28 PM +00:00 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 up to 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 calibrator was used. Note: This row only appears for quantitative assays that use a calibrator to obtain final results.
"Assay Status:"	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).
"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:

Assay Information

Assay Profile:	APT_1P_ValidCheck (2.3.1)
Assay Kit:	Material number: 7654321 (deviating from assay profile), Lot number: 34567, Expiration date: 10/22/2015 (not expired)
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">1. Start and end time of the run.2. Run operator and software version of the application.3. Run comments as entered by the operator during the run.4. Errors that may have occurred during the run.5. Experiment release information.
"Work List:"	<ol style="list-style-type: none">1. Name of the work list from which the experiment was created. Note: If the work list is locked then "(read-only)" is displayed together with the work list name.2. Creator of the work list.3. Last modifier of the work list.
"Cycler:"	<ol style="list-style-type: none">1. Serial number of the cycler and rotor type.2. Reaction volume.

Example of the "Run Information" table:

Run Information

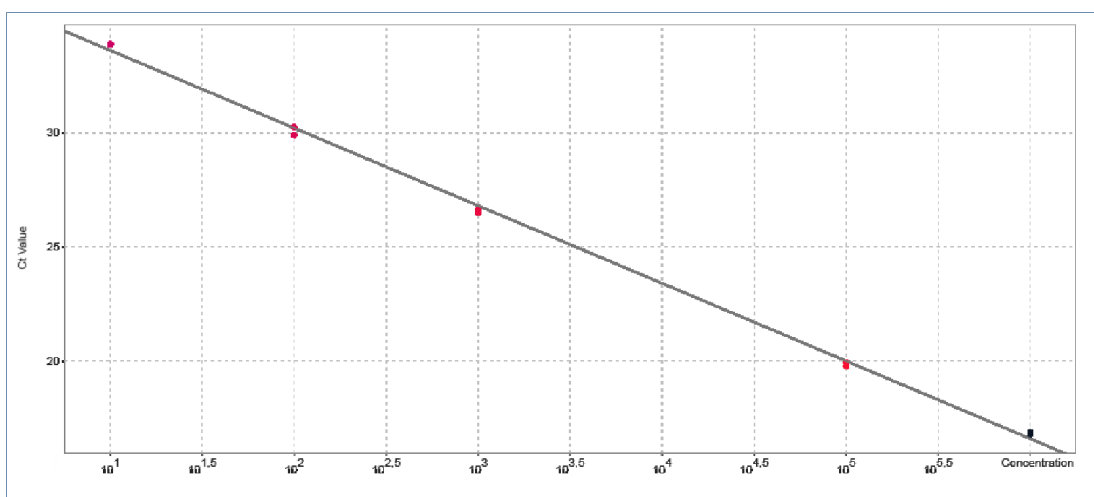
Run:	Analyzed plugin experiment 1
Run Information:	From 12/31/2014, 7:00 AM +00:00 UTC to 12/31/2014, 7:00 AM +00:00 UTC Operated by Andy Doe (adoe) on Rotor-Gene AssayManager version 1.0.3.4 using Epsilon (US) plug-in version 1.0.0 No comment No errors Run automatically released by the system on 8/21/2015, 1:56 PM +00:00 UTC
Work List:	<Not defined> Created by <Not defined> on 12/30/2014, 6:00 AM +00:00 UTC Last changed by <Not defined> on 12/30/2014, 6:00 AM +00:00 UTC
Cycler:	0409102, Rotor type 72-Well Rotor 50 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 ² "	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 ²	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".
"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 _T 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

"Flags"	<p>detected", "No signal", "INVALID", or a specific string defined in the assay profile.</p> <p>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.</p>
---------	--

Example of the "Results" table:

Test Samples

Pos.	Sample ID	Type	Sample comment	Sample status	Output	Ct	Value	Conc.	Result	Flags
37, 38, 39, 40	Sample D	Test		Valid	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	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	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 result table can display a different set of columns

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:

<hr/>	<hr/>	<hr/>
Print Name	Signature	Date

Reviewer:

<hr/>	<hr/>	<hr/>
Print Name	Signature	Date

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1.4 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 (US) Plug-in:

Note

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

Error ID	Error Text
2160019	Approval: Experiment {0} assay {1} assay comment set from {2} to {3}.
2160020	Approval: Experiment {0} assay {1} sample {2} in tube position {3} state set from {4} to {5}.
2160021	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} state set from {5} to {6}.
2160022	Approval: Experiment {0} assay {1} sample {2} in tube position {3} comment set from {4} to {5}.
2160023	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} comment set from {5} to {6}.
2160024	Approval: Experiment {0} assay {1} was released.
2160025	Could not release experiment. The user {0} was deactivated because the wrong password was entered too many times. The session will be terminated.
2160029	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} was released and exported.
2160030	Approval: Experiment {0} assay {1} sample {2} in tube positions {3} to {4} was released.
2160031	Approval: Experiment {0} assay {1} sample {2} in tube position {3} was released and exported.
2160032	Approval: Experiment {0} assay {1} sample {2} in tube position {3} was released.
2160033	Approval: Experiment {0} assay {1} partially released.
2160037	Approval: Experiment {0} assay {1} calibrator state set from 'Do not use calibrator' to 'Use calibrator' with calibrator value {2}.
2160038	Approval: Experiment {0} assay {1} calibrator state set to 'Do not use calibrator'.
2160039	Approval: Experiment {0} assay {1} calibrator value set from {2} to {3}.

2160040	Approval: Experiment {0} assay {1} calibrator state set from 'Use calibrator' with calibrator value {2} to 'Do not use calibrator'.
2160041	Approval: Experiment {0} assay {1} calibrator state set to 'Use calibrator' with calibrator value '{2}'
2165017	The run template does not contain any cycling parameters.
2165018	The run profile must only contain "Cycling" and "Hold" steps. Check the run profile and the assay profile for consistency.
2165019	Enter a valid value for {0} of target {1} ({2}-{3}).
2165020	The {0} of target {1} has an incorrect format.
2165047	{0} (report generation failed)
2165122	The default AUDAS parameters for this target have been restored.
2165135	AUDAS is not enabled for target {0}
2165151	Run profile must contain at least 7 cycles in the "Cycling" entries.
2165157	After release, the test results are moved to the archive.
2165158	After release, the approval state of data cannot be changed.
2165159	Enter a valid password.
2165160	This user is deactivated. Contact your local administrator.
2165161	Enter your password to sign your approval electronically.
2165163	Copying of the selected cells failed. Only adjacent cells can be copied. Copy and paste the selected cells individually.
2165168	This user was deactivated because the password was entered wrong too many times. Contact your local administrator. The current session will be closed.
2165169	The release was performed successfully.
2165170	The release was not performed.
2165171	The LIMS output was saved.
2165172	The report {0} was stored in the folder {1}.

2165173	The report was not created.
2165174	The release was not performed but data was saved.
2165206	The export of the QIALink/LIMS result file failed. Please check the LIMS export configuration settings.
2165208	The LIMS output was not saved.
2165209	The LIMS output was saved.
2165210	The report was not created.
2165211	The report {0} was stored in the folder {1}.
2165217	AUDAS is temporarily disabled for the target. It has to be enabled before the assay is finalized.
2165278	The exported .rex file contains data from all assays of experiment: {0}
2165280	Unsaved changes in the currently active assay will be discarded.
2165282	The .rex file is not included in the support package.
2165283	Report generation failed. Reason: {0}
2165284	The report is not included in the support package.
2165286	The audit trail report is not included in the support package.
2165288	Failed to create support package. Reason: {0}
2165289	The time interval audit trail report is not included in the support package.
2165291	The QIAGEN-Hardware.log was not included in the support package. Reason: The run was performed on a different machine.
2165292	Not all log files for the related time period could be found.
2165293	The log file is not included in the support package.
2165294	Failed to create log file. Reason: {0}
2165295	Rex file export failed. Reason: {0}

2165296	The entered calibrator values are not the same. Check and enter the correct values.
2165297	Confirm to only report non-calibrated results.
2165298	Enter a calibrator value.
2165299	Reenter the calibrator value.
2165300	Select whether calibrator value shall be used to obtain normalized results.
2165301	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 IVD (US) Core Application User Manual*.

1.5 Appendix

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

Note

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

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