Lot 10, Sistem RT-PCR

Rotor-Gene Q MDx 5plex HRM Platform, cu soft Rotor-Gene AssayManager 2.1

Qiagen GmbH, Malaesia

DM000308110 – numar inregistrare in calitate de DM

Parametri ceruti	Parametri oferiti
"Aplicare: Pentru analiza PCR în timp real validată IVD în aplicații clinice	"Aplicare: Pentru analiza PCR în timp real validată IVD în aplicații clinice Rotor-Gene AssayManager v2.1 software for QIAGEN IVD assays. For routine testing with Rotor-Gene Q MDx instruments Exemple: Oncology Assays Compatible with Rotor-Gene AssayManager v2.1 Therascreen BRAF V600E RGQ PCR Kit: Detects BRAF V600E mutations associated with various cancers. Therascreen KRAS RGQ PCR Kit: Identifies KRAS mutations relevant for colorectal cancer therapy. Therascreen EGFR RGQ PCR Kit: Detects EGFR mutations linked to non-small cell lung cancer. Therascreen PIK3CA RGQ PCR Kit: Identifies PIK3CA mutations associated with breast cancer. Therascreen FGFR RGQ RT-PCR Kit: Detects FGFR gene fusions relevant for cancer therapy. Ipsogen JAK2 RGQ PCR Kit: Detects JAK2 mutations associated with myeloproliferative neoplasms
Sistem optic: 5 canale + HRM (Green, Yellow, Orange, Red, Crimson, HRM) sau minim 5 canale cu lungimi de undă analogici culorilor indicate în intervalul 450 - 730 nm + analiza HRM.	Sistem optic: 5 canale + HRM (Green, Yellow, Orange, Red, Crimson, HRM)
Surse de excitare: diode emițătoare de lumină de înaltă energie sau LED filtrat	Surse de excitare: diode emițătoare de lumină de înaltă energie de tip LED
Detector: fotomultiplicator/fotodiodă	Detector: fotomultiplicator
Probe per run (debit): Tuburi 0,2 ml, 36 – 96 probe/run	Probe per run (debit): Tuburi 0,2 ml/0,1ml/0,03ml, 36 -72- 100 probe/run
Tehnologie: Ciclor PCR în timp real	Tehnologie: Ciclor PCR în timp real
Performanta termică: interval de temperatură, 35–99°C, acuratețea temperaturii, ± 0,5°C	Performanta termică: interval de temperatură, 35–99°C, acuratețea temperaturii, ± 0,5°C
Software: cu soft pentru analiză și interpretare a testelor IVD și soft pentru analiza HRM	Software: cu soft pentru analiză și interpretare a testelor IVD și soft pentru analiza HRM
Calculator (computer sau notebook) – da	Calculator (computer sau notebook) – da
Seturi pentru calibrare și verificare – da	Seturi pentru calibrare și verificare – da
Termen de garanție: minim 24 luni	Termen de garanție: 24 luni
Anul producerii – minim 2024	Anul producerii –2024

Instalare, darea in exploatare, instruirea de către participantul câștigător – obligatoriu Training pentru utilizatori la instalare și la solicitare - obligatoriu. Servicii de mentenanță preventivă pe perioada de garanție"	Instalare, darea in exploatare, instruirea de către participantul câștigător – obligatoriu Training pentru utilizatori la instalare și la solicitare - obligatoriu. Servicii de mentenanță preventivă pe perioada de garanție"

Rotor-Gene® Q — Pure Detection

Now with even more applications!

QIAGEN®

Sample & Assay Technologies

The Rotor-Gene Q — for your success

Quantitative, real-time PCR is a precision science that places high demands on the instrument, chemistry, and software. High thermal and optical uniformity, short equilibration times, and fast ramping rates are critical for precise and rapid quantitative analysis. Sensitivity, speed, and specificity are also highly dependent on the performance of the DNA polymerase and reaction components.

QIAGEN's real-time PCR cycler, the Rotor-Gene Q, combines multiple optimized design features to provide the outstanding performance and reliable results that your research demands. Together with optimized QIAGEN® kits for real-time PCR, the Rotor-Gene Q enables streamlined analysis for a wide range of applications.

Benefits of the Rotor-Gene Q:

- Outstanding thermal and optical performance due to rotary format
- An unmatched optical range spanning UV to infrared wavelengths
- Various state-of-the-art analyses supported by user-friendly software
- Low maintenance and maximum convenience due to robust design
- High performance in multiple applications with QIAGEN kits

Comprehensive application range

The Rotor-Gene Q combined with optimized QIAGEN kits addresses a wide range of real-time PCR and high-resolution melting (HRM™) applications:

- Gene expression analysis
- Pathogen detection
- DNA methylation analysis
- Genotyping
- Mutation analysis
- miRNA research

For details of applications, see page 8.

Visit www.qiagen.com/PCR-applications and navigate your way through the Rotor-Gene Q Virtual World. Experience more than 20 instrument and software animations!

Unique rotary design for outstanding performance

The unique centrifugal rotary design of the Rotor-Gene Q makes it the most precise and versatile real-time PCR cycler currently available (Figure 1). Each tube spins in a chamber of moving air, keeping all samples at precisely the same temperature during rapid thermal cycling. Detection is similarly uniform. When each tube aligns with the detection optics, the sample is illuminated and the fluorescent signal is rapidly collected from a single, short optical pathway. This thermal and optical uniformity results in sensitive, precise, and fast real-time PCR analysis (Figure 2). It also eliminates sample-to-sample variation and edge effects. These are unavoidable in traditional block-based instruments due to temperature gradients across the block and multiple, complex optical pathways.

The rotary design delivers:

- Well-to-well temperature variation below ±0.02°C
- Uniform detection eliminating the need for ROX reference dye
- Fast ramping and negligible equilibration times for short run times
- Complete confidence in your results!

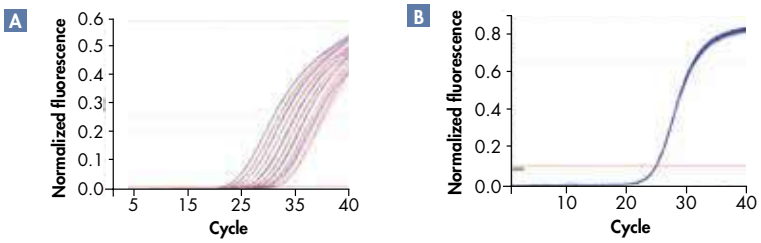


Figure 2. Precise real-time PCR analysis. A Twofold dilutions of human genomic DNA from 30 ng (10,000 copies) to 0.06 ng (20 copies) were used as template in real-time PCR. Five replicate reactions were run for each dilution using a self-designed TaqMan® assay for IL1R2 and the Rotor-Gene Probe PCR Kit on the Rotor-Gene Q. The average difference in the C_T values between all dilutions was 1.07 cycles. B Human genomic DNA was used as template in 72 replicate real-time PCRs using a self-designed TaqMan assay for BCL2 on the Rotor-Gene Q without ROX normalization. The average C_T value was 24.94 with a standard deviation of only 0.05, equivalent to a CV of 0.2%.

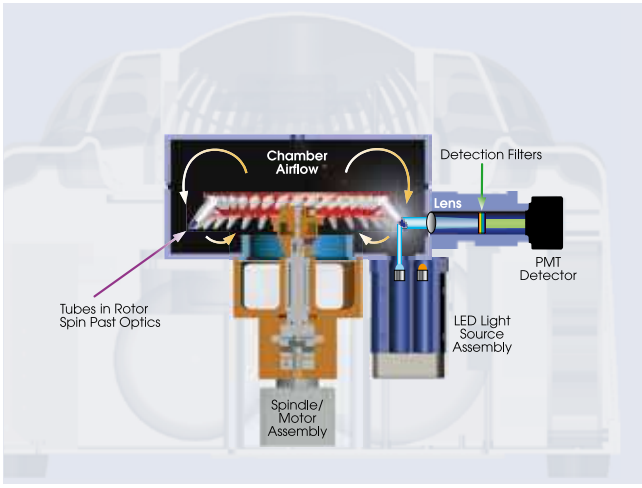


Figure 1. Cross-section of the Rotor-Gene Q. Heating/cooling is achieved by rapid airflow in the reaction chamber. Tubes spin past the excitation/detection optics every 150 milliseconds enabling high-speed data capture. Up to 6 separate LED light sources can be used in combination with 6 different detection filters and a highly sensitive photomultiplier detector.

Placing a 72-Well Rotor into the Rotor-Gene Q.

Unrivaled optical range enables multiple applications

Whether your assay is based on intercalating dyes such as SYBR® Green, probes such as hydrolysis (TaqMan), hybridization (FRET), or Scorpion probes, the Rotor-Gene Q meets your requirements. With up to 6 channels spanning UV to infrared wavelengths, the cycler delivers the widest optical range currently available (Table 1), and is highly suited for all multiplex applications. In addition, the software allows you to create new excitation/detection wavelength combinations, which means that the Rotor-Gene Q is compatible with dyes you may use in the future.

Table 1. Channels for optical detection

Channel	Excitation (nm)	Detection (nm)	Examples of fluorophores detected
Blue	365±20	460±20	Marina Blue®, Edans, Bothell Blue, Alexa Fluor® 350, AMCA-X
Green	470±10	510±5	FAM™, SYBR Green I, Fluorescein, EvaGreen®, Alexa Fluor 488
Yellow	530±5	557±5	JOE™, VIC®, HEX, TET™, MAX™, CAL Fluor®, Gold 540, Yakima Yellow®
Orange	585±5	610±5	ROX™, CAL Fluor Red 610, Cy®3.5, Texas Red®, Alexa Fluor 568
Red	625±5	660±10	Cy5, Quasar® 670, LightCycler®, Red640, Alexa Fluor 633
Crimson	680±5	712 high pass	Quasar 705, LightCycler Red705, Alexa Fluor 680
HRM	460±20	510±5	SYBR Green I, SYTO®9, LC Green®, LC Green Plus+, EvaGreen

Multiple PCR tube and Rotor-Disc formats.

Flexible formats match your workflows

The Rotor-Gene Q supports multiple PCR tube formats to suit a range of needs. Changing the format, by simply switching the snap-fit metal rotor that holds the tubes, takes just seconds.

As well as tubes, Rotor-Disc™ rotors are available, which offer accelerated setup and higher throughput. Rotor-Discs are circular plates of vertically-oriented reaction wells. The Rotor-Disc 100 is the equivalent of a 96-well plate with an additional 4 reference wells. These extra wells can be conveniently used for more reactions or additional controls. Rotor-Discs can be quickly and easily sealed with plastic film using a Rotor-Disc Heat Sealer.

You can perform manual reaction setup, or take advantage of QIAGEN's automated solutions for reaction setup. The QIAgility® is cost-effective and delivers rapid, high-precision PCR setup, while the QIAsymphony® AS is ideal for laboratories performing routine PCR tests on a day-to-day basis Both instruments perform automated reaction setup in Rotor-Gene formats, allow direct transfer of sample lists, and are supplied with verified protocols for real-time PCR master mixes.

Minimum maintenance, maximum convenience

The Rotor-Gene Q is engineered to reduce the need for maintenance and to maximize ease of use. This saves time and costs and allows you to focus on your research, not on keeping the cycler up and running. For example, highly stable excitation source LEDs are provided with a life-long guarantee, eliminating the need for frequent and time-consuming lamp replacement.

Features of the Rotor-Gene Q:

- Few moving parts and short, fixed optical path increase robustness
- No need for optical alignment, calibration, or lamp replacement
- Small, light instrument is easily transportable for flexibility in your lab

Easy routine verification

Laboratories may often want to verify thermal accuracy. For most cyclers, this requires interaction with a service engineer. With the Rotor-Gene Q, this is not necessary. Instead, the easy-to-use, cost-effective Rotor-Disc OTV (Optical Temperature Verification) Kit automates accuracy testing. The kit includes a specialized Rotor-Disc filled with temperature-sensitive liquid crystals and dedicated analysis software. The full procedure takes less than 30 minutes.

Reliable support for your peace of mind

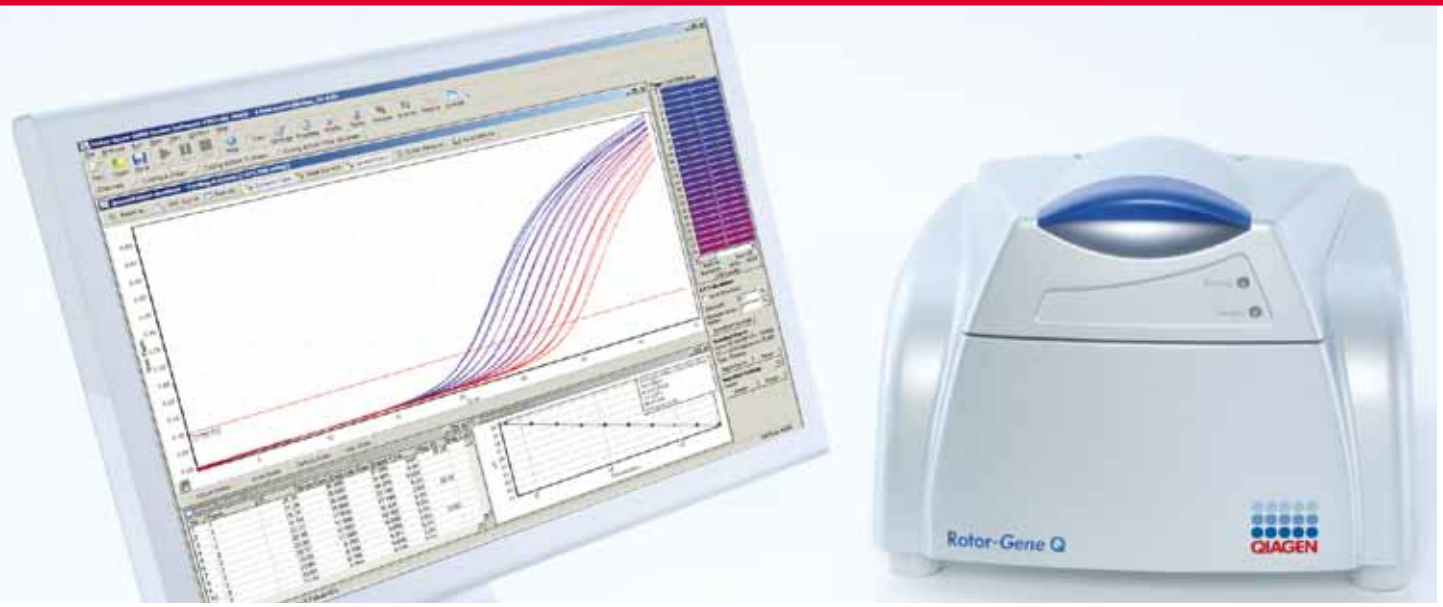
In the unlikely event of any service issues with your Rotor-Gene Q, QIAGEN Instrument Service provides comprehensive support services to ensure the continued success of your PCR applications. QIAGEN Instrument Service offers a wide range of flexible Service Support products, giving you peace of mind and letting you enjoy complete coverage and cost control. Our Application Services and Training Programs give you the freedom and flexibility to adapt your system to specific or changing research needs. With ISO 9001/ISO 13485 certification and an international team of highly qualified and experienced Support Specialists, we deliver the high-quality service that you deserve and that your applications demand.

Specifications of the Rotor-Gene Q

View the outstanding technical features of the Rotor-Gene Q (Table 2).

Table 2. Rotor-Gene Q specifications

Dimensions and weight	Width 370 mm (14.6 in.) x Depth 420 mm (16.5 in.) x Height 286 mm (11.3 in.)
	Depth (door open): 538 mm (21.2 in.)
	Weight: 12.5 kg (27.6 lb)
Thermal performance	Temperature uniformity: ±0.02°C (Standard deviation)
	Temperature accuracy: ±0.5°C
	Temperature resolution: ±0.02°C
	Temperature range: 35 – 99°C
Optical system	Up to 6 separate channels (365–680 nm excitation, 460–750 nm detection)
	Fixed optical path, separate high-power excitation LEDs and emission filters per channel
	Highly sensitive photomultiplier (PMT) detector with gain setting (sensitivity control)
	Dynamic range: 10 orders of magnitude (assay dependent)
Rotor and well configurations	Rotor-Disc 100: 30 µl x 100 wells, 15–25 µl recommended reaction volume
	Rotor-Disc 72: 0.1 ml x 72 wells, 20–25 µl recommended reaction volume
	Strip Tubes 0.1 ml: 0.1 ml x 72 wells, 10–50 µl recommended reaction volume, strips of 4 tubes and caps
	PCR Tubes 0.2 ml: 0.2 ml x 36 wells, 20–50 µl recommended reaction volume, individual tubes with caps
Typical run time	40 cycles in 45–60 minutes with QIAGEN Rotor-Gene Kits (detection method dependent)
Electrical requirements	100–240 V AC, 50/60 Hz; 560 VA (peak)
Warranty	1 year on instrument; lifetime guarantee on excitation LEDs



Software enables quantification and enhances data security

The comprehensive Rotor-Gene Q software package supports all current state-of-the-art real-time analysis procedures with basic to advanced algorithms. This provides complete freedom to analyze your valuable experimental data and increases the reliability of your results. Data security is assured and process steps are trackable from starting the run to exporting the results.

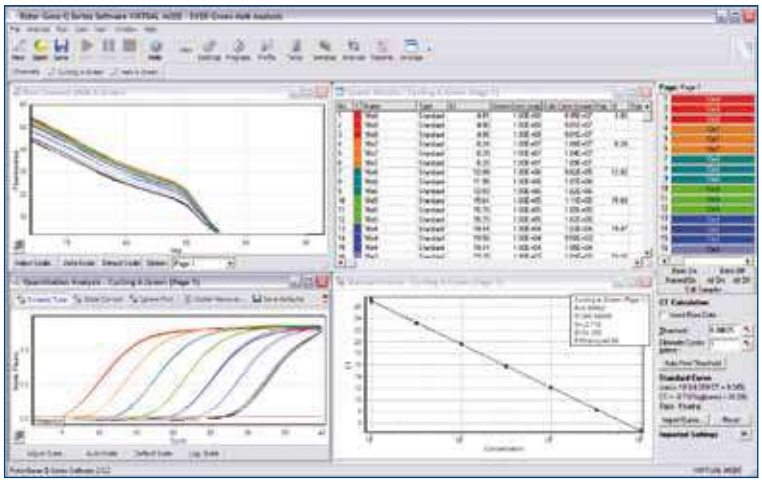
Analysis procedures supported by Rotor-Gene Q software

- Absolute quantification
  - Standard curve quantification
- relative quantification
  - 2 standard curves
  - $\Delta\Delta C_T$ relative quantification
  - Comparative quantification
  - Export to LinRegPCR (assumption-free analysis)
  - REST (Relative Expression Software Tool)
- Analysis of genetic differences
  - Allelic discrimination
  - Scatter plot analysis
  - Melt analysis
  - HRM analysis
  - Rotor-Gene Screen Clust HRM Software†
- Other analysis tools
  - End-point analysis
  - Concentration analysis

* REST employs differing PCR efficiencies and multiple reference genes for normalization, available free of charge at www.qiagen.com/rest † Software available separately

The easy-to-use software provides:

- Unlimited user licenses and individual user management
- A digital signature for every result file
- Audit trails to track changes made to experiment files
- Various result reports and export functions
- Raw data export for validation purposes



Expand your research with HRM

High-resolution melting analysis (HRM) is a closed-tube, post-PCR analysis that has raised enormous scientific interest. HRM characterizes double-stranded PCR products based on their dissociation (melting) behavior. It is similar to classical melting curve analysis, but provides far more information for a wider range of applications. PCR products can be discriminated according to sequence, length, GC content, or strand complementarity, down to single base-pair changes. Previously unknown and even complex sequence variations can be readily detected and characterized in a robust and straightforward way. The Rotor-Gene Q is ideal for HRM applications due to its outstanding temperature and fluorescence precision for every well.

The HRM option for the Rotor-Gene Q features:

- A specially tuned high-intensity optical HRM channel
- Thermal resolution down to 0.02°C
- High data acquisition rates
- Comprehensive HRM software

HRM on the Rotor-Gene Q is capable of deciphering minute genetic differences such as difficult A/T class IV SNPs with melting point differences below 0.2°C (Figure 3 and 4).

Harness the power of HRM for applications such as:

- Genotyping
- Pathogen typing
- Gene scanning
- Quantitative methylation analysis

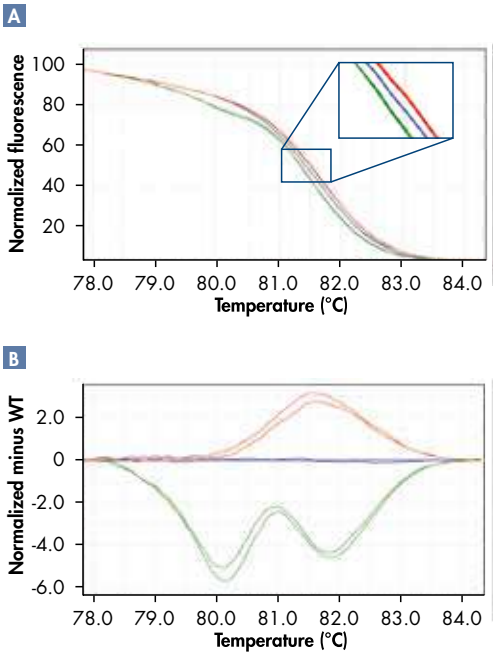


Figure 3. Successful genotyping of an A/T Class IV SNP. Typing the SNP (rs2270938) in the human GYS1 gene using the Type-it HRM PCR Kit results in highly reproducible and accurate results. The normalized melting curve and difference plot show successful and reliable discrimination of all 3 genotypes (Blue: wild-type; Green: heterozygous; Red: mutant). A normalized melt curve. B difference plot normalized to wild type samples.

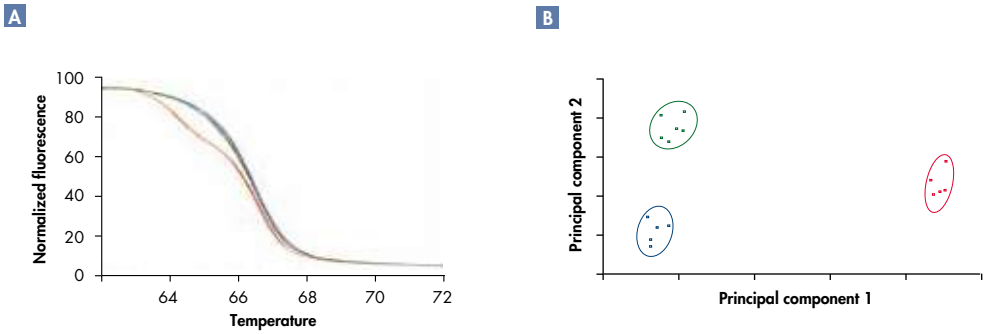


Figure 4. HRM Analysis of a class IV SNP with less than 0.1°C difference between homozygote alleles. A human A/T SNP in the AHRR gene was analyzed using genomic DNA from wild-type (blue), homozygous mutant (green), and heterozygous (red) samples. Experiments were performed using the Type-it HRM PCR Kit, Rotor-Gene Q HRM instrument, and Rotor-Gene ScreenClust HRM Software. A Normalized melting curves: homozygote curves are almost identical. B ScreenClust HRM cluster plot: all pseudo-unknowns including homozygous alleles were unambiguously clustered according to the correct genotype.

Optimized reagents for all your applications

A range of QIAGEN kits for the Rotor-Gene Q enables reliable quantification in your real-time PCR applications without the need for optimization of reaction and cycling conditions (Table 3).

Features and benefits of QIAGEN's kits for real-time PCR

Highly specific amplification is assured through a balanced combination of $NH4^+$ and K^+ ions that minimizes nonspecific primer annealing. Fast cycling without compromising performance is achieved using Q-Bond, a proprietary PCR additive that enables cycler run times of as low as 45 minutes. For multiplex PCR applications, synthetic Factor MP allows different amplicons in the same reaction to all be amplified with the same high efficiency. Factor MP, an innovative PCR additive, increases the local concentration of primers at the template and stabilizes specifically bound primers, allowing efficient primer extension by DNA polymerase.

Table 3. Pure detection for all your applications

Application	Detection method	Procedure	QIAGEN kit	Data
Gene expression analysis	SYBR Green	PCR and 2-step RT-PCR	Rotor-Gene SYBR Green PCR Kit	Table 4
	SYBR Green	1-step RT-PCR	Rotor-Gene SYBR Green RT-PCR Kit	Fig. 5
	SYBR Green	2-step RT-PCR array	Pathway-Focused RT² Profiler PCR Arrays	Fig. 9
	Probe (singleplex)	PCR and 2-step RT-PCR	Rotor-Gene Probe PCR Kit	Fig. 2
	Probe (singleplex)	1-step RT-PCR	Rotor-Gene Probe RT-PCR Kit	
	Probe (multiplex)	PCR and 2-step RT-PCR	Rotor-Gene Multiplex PCR Kit	Fig. 7
	Probe (multiplex)	1-step RT-PCR	Rotor-Gene Multiplex RT-PCR Kit	Fig. 8
	Probe (duplex)	2-step RT-PCR and 1-step RT-PCR	QuantiFast Probe Assays and Kits	Fig. 6
miRNA detection	SYBR Green	Two-step RT-PCR	miScript SYBR Green PCR Kit	Fig. 10
Pathogen detection	Probe (multiplex)	PCR, 2-step RT-PCR, and 1-step RT-PCR	QuantiTect® Virus +ROX Vial Kit	
	Probe (duplex)	PCR or 1-step RT-PCR incl. universal internal control	QuantiFast Pathogen +IC Kits	Fig. 11
Food safety testing	Probe	Real-time PCR assays	*mericon*™ food testing portfolio	Fig. 12
Pathogen typing	EvaGreen	HRM	Type-it HRM PCR Kit	Fig. 13
Genotyping	Probe	PCR	Type-it Fast SNP Probe PCR Kit	Fig. 14
	EvaGreen	HRM	Type-it HRM PCR Kit	Fig. 15, 3
Methylation analysis	Probe	PCR	EpiTect® MethyLight PCR Kit	Table 5
	EvaGreen	HRM	EpiTect HRM PCR Kit	Fig. 16

Gene expression analysis

The combination of Rotor-Gene SYBR Green Kits, QuantiTect Primer Assays, and the Rotor-Gene Q provides a complete, ready-to-run solution for gene expression analysis. QuantiTect Primer Assays are predesigned primer sets for any gene from human, mouse, rat, and many other species. Assays can be easily ordered online at the GeneGlobe® Web portal (www.qiagen.com/GeneGlobe). When the assays are used together with Rotor-Gene SYBR Green Kits, highly sensitive quantification of specific PCR products is achieved without the need for optimization (Figure 5 and Table 4).

Table 4. Superior performance in RT-PCR with SYBR Green

	QIAGEN		Supplier A_{II}	
	C_T	Mean deviation	C_T	Mean deviation
BAX (BCL2-associated X protein)	24.84	0.05	29.57	0.46
BCL2 (apoptosis gene)	26.96	0.05	32.83	0.29
MYC (proto-oncogene)	28.42	0.21	35.26	0.72
β-Actin (housekeeping gene)	20.24	0.03	24.39	0.12

Human leukocyte cDNA (1 ng) was used as template in SYBR Green-based real-time two-step RT-PCR. Triplicate reactions were run using QuantiTect Primer Assays for 4 different targets: BAX, BCL2, MYC, and β-Actin. The Rotor-Gene Q and Rotor-Gene SYBR Green PCR Kit provided highly sensitive detection, indicated by lower C_T values and lower mean deviations compared to an instrument and kit from Supplier A_{II}.

For gene expression analysis using probe detection, QuantiFast Probe Assays, containing a premixed primer pair and dual-labeled probe (TaqMan-based probe), can be used in combination with dedicated master mix kits on the Rotor-Gene Q for fast and sensitive quantification. QuantiFast Probe Assays are designed using a proprietary algorithm to enable amplification and detection of RNA and cDNA targets less than 100 bp in size with high efficiency and reliability. They are highly suited for use with degraded starting material such as formalin-fixed, paraffin-embedded (FFPE) analytes. (Figure 6).

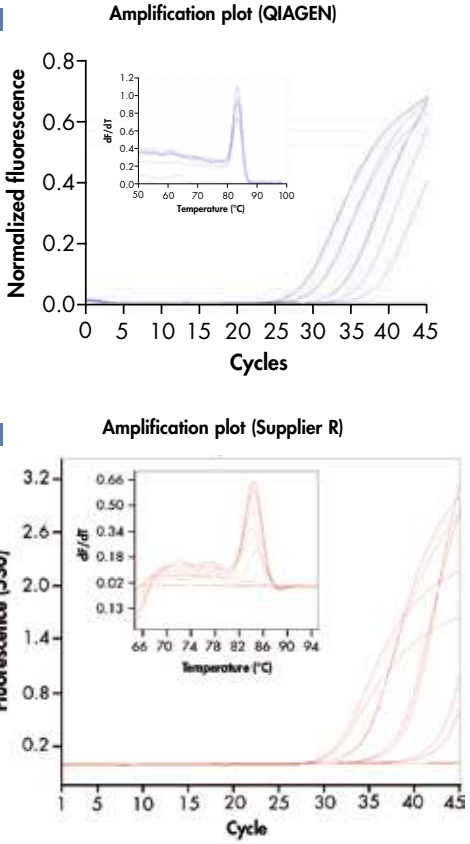


Figure 5. Specific and sensitive detection using SYBR Green. Tenfold dilutions of human leukocyte RNA (100 ng to 10 pg) were used as template in SYBR Green-based real-time one-step RT-PCR. Duplicate reactions were run using the QuantiTect Primer Assay for BCL2 (B-cell CLL/lymphoma 2). A The Rotor-Gene Q and Rotor-Gene SYBR Green RT-PCR Kit provided sensitive detection from 10 pg RNA and amplification of specific PCR product (melting curve shown in inset). B In contrast, an instrument and kit from Supplier R provided detection only after optimization of Mg^{2+} concentration. However, the limit of detection was 100 pg RNA and coamplification of nonspecific products was observed (melting curve shown in inset).

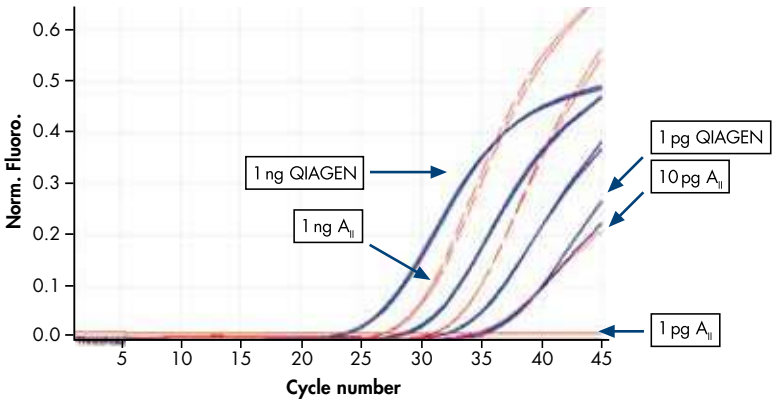


Figure 6. Highly efficient real-time RT-PCR detection using RNA from FFPE samples. Total RNA (1 ng, 100 pg, 10 pg, and 1 pg) was purified from a breast tissue FFPE sample using the RNeasy FFPE Kit. Transcripts of the human MUC1 gene were amplified and detected on the Rotor-Gene Q cycler using the QuantiFast Probe RT-PCR Plus Kit and the QuantiFast Probe Assay (blue curves) or a predesigned assay from Supplier A_{II} (red curves). Results from the QuantiFast Probe Assay showed lower C_T values and higher sensitivity compared to results using the assay from Supplier A_{II}. As low as 1 pg template was detectable using the QuantiFast Probe Assay (1 pg was undetectable using the assay from Supplier A_{II}).

The ultimate solution for fast and reliable gene expression analysis is provided by the combination of the Rotor-Gene Multiplex PCR and RT-PCR Kits and the Rotor-Gene Q. Up to 4 cDNA targets can be simultaneously and rapidly quantified in the same tube, increasing throughput and saving precious sample material (Figures 7 and 8). Genes with different expression levels are all amplified in the same tube with the same high efficiency, enabling reliable relative quantification of gene expression.

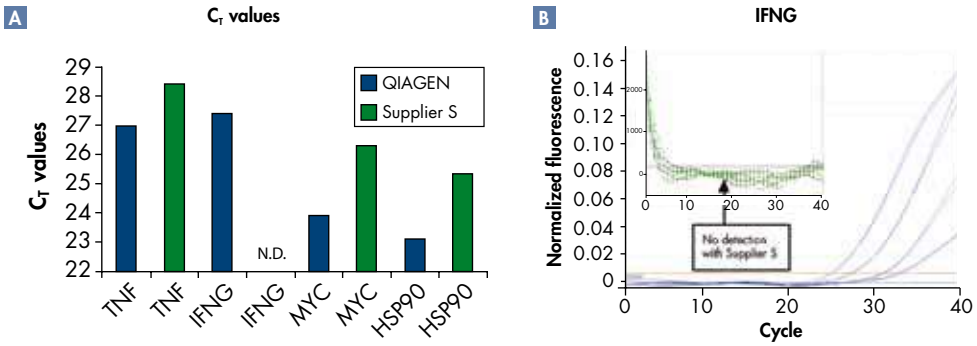


Figure 7. Reliable multiplex analysis. Tenfold dilutions of human leukocyte cDNA (10 ng to 10 pg) were used as template in 4-plex, real-time PCR. Reactions were run in triplicate using either the Rotor-Gene Q and Rotor-Gene Multiplex PCR Kit or an instrument and kit from Supplier S. Target genes: TNF (tumor necrosis factor), IFNG (interferon, gamma), MYC (v-myc myelocytomatosis viral oncogene homolog [avian]), HSP90AA1 (heat shock protein 90 kDa alpha [cytosolic], class A member 1). A C_T values obtained for all 4 targets (instrument and kit from Supplier S did not successfully detect IFNG; **N.D.**). Lower C_T values on the Rotor-Gene Q demonstrate detection with greater sensitivity. B Amplification plots for IFNG (plots for Supplier S in inset).

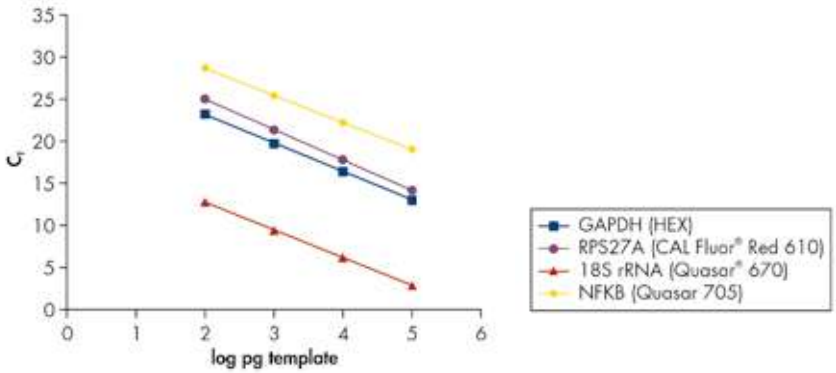


Figure 8. Highly efficient 4-plex analysis. 4-plex, real-time one-step RT-PCR was performed using the Rotor-Gene Multiplex RT-PCR Kit and self-designed TaqMan assays for the indicated targets. Reactions were run on the Rotor-Gene Q using 100, 10, 1, or 0.1 ng RNA from HeLa cells. The plots of C_T value versus log template amount were parallel, indicating all 4 targets were amplified with the same high efficiency. GAPDH: glyceraldehyde-3-phosphate dehydrogenase; RPS27A: ribosomal protein S27a; NFKB: nuclear factor of kappa light polypeptide gene enhancer in B-cells.

Pathway- and disease-focused PCR arrays

Pathway-focused RT² Profiler PCR Arrays are exeptionally reliable tools for analyzing the expression of a focused panel of genes. Each 100-well Rotor-Disc PCR Array includes SYBR Green-optimized (laboratory-tested) primer assays for a thoroughly researched panel of relevant, pathway- or disease-focused genes on the Rotor-Gene Q. RT² profiler PCR Arrays can also be customized to contain a panel of genes tailored to your specific research interests. Our high-quality primer design and master mix formulation enable the RT² profiler PCR Array to amplify 96 different gene-specific products simultaneously under uniform cycling conditions. This combination provides the RT² profiler PCR Array with the specificity and the high amplification efficiencies required for accurate real-time SYBR Green results (see Figure 9).* The simplicity of RT² profiler PCR Arrays makes them accessible for routine use in every research laboratory.

New developments in PCR array technology enable optimal performance of RT² Profiler PCR Arrays using RNA prepared from regular samples (0.1–5 µg RNA), FFPE samples, and small samples (1–100 ng RNA). See the PCR Array Protocol Guide to learn more.

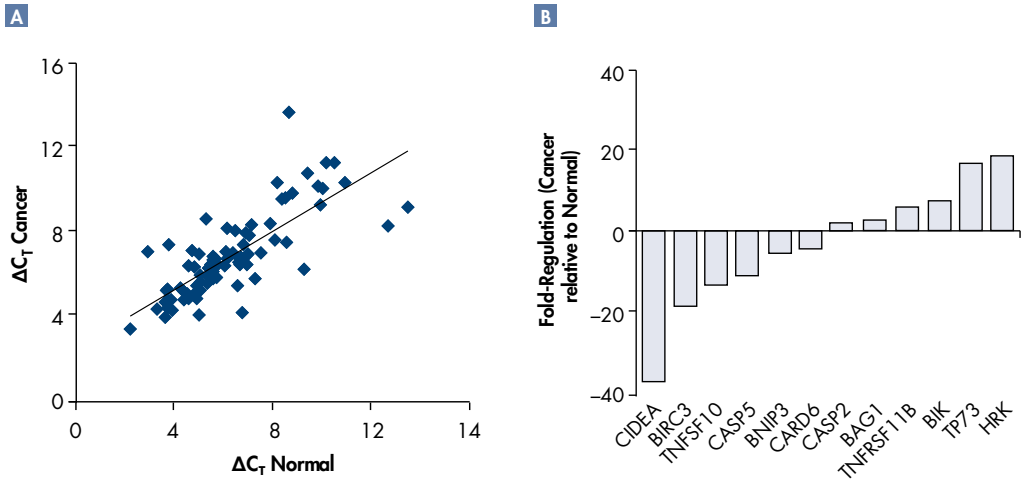


Figure 9. Gene expression profiling of normal and cancerous colon tissue. Using the Human Apoptosis RT² Profiler PCR Array, gene expression analysis of both normal (adult ascending colon) and cancer (adult colon adenocarcinoma) colon was performed using the Rotor-Gene Q. A ΔC_T values (data normalized to the geometric mean of 5 housekeeping genes) were plotted for both the normal and cancer tissue. B The fold-changes for selected targets that underwent significant (greater than 2-fold) changes in expression (cancer relative to normal) were plotted. Altogether, a total of 36 genes had a differential expression pattern in the cancer versus normal tissue, with 30 genes showing down-regulation and 6 genes showing up-regulation. Collectively, these data demonstrate the power of RT² Profiler PCR Arrays performed on the Rotor-Gene Q to profile differential gene expression patterns in cancer versus normal tissue.

* Data analysis software for pathway-focused RT² Profiler PCR Arrays is available free of charge at www.sabiosciences.com/pcarraydataanalysis.php

miRNA detection

miRNAs play an important role in many diverse biological processes. Dysregulation of miRNA expression is associated with several cancers and other diseases. For this exciting, emerging research area, QIAGEN offers the miScript PCR System, a three-component system that covers all steps of conversion of miRNA, mRNA, and other noncoding RNAs into cDNA and their subsequent detection of miRNAs by SYBR Green-based real-time PCR. Fast and easy reverse transcription using the miScript Reverse Transcription Kit is followed by sensitive and specific miRNA detection using the miScript SYBR Green PCR Kit and a miScript Primer Assay on the Rotor-Gene Q. Using appropriate assays, it is possible to detect either mature miRNA or precursor miRNA (Figure 10). For more information on the miScript PCR System, visit www.qiagen.com/miRNA.

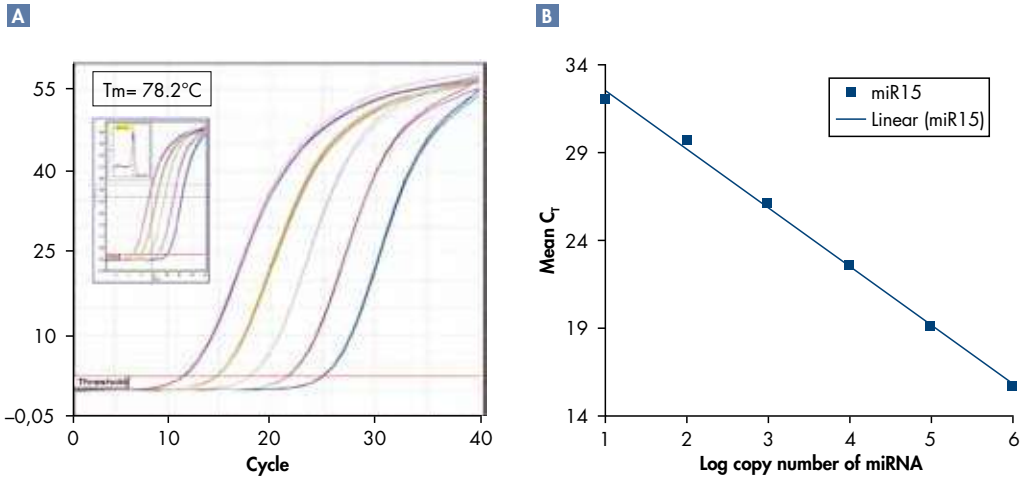


Figure 10. Quantification of miR-15 and RNU6B using the miScript PCR System on the Rotor-Gene Q. A Sensitive, specific quantification for a wide range of template amounts. The miScript Reverse Transcription Kit was used to generate cDNA from HeLa S3 cells. A range of cDNA amounts from 1 pg to 10 ng was used in real-time PCR with the miScript PCR System and a miScript Primer Assay for RNU6B. Real-time PCR was performed on the Rotor-Gene Q cycler. The amplification plot shows sensitive, accurate quantification from low to high cDNA template amounts. The melting curve (inset) shows a single peak indicating specific detection. B Accurate detection of as low as 10 miRNA copies. Synthetic miR-15 was used to generate cDNA using the miScript Reverse Transcription Kit. A range of amounts from 10 copies to 10^6 copies of this cDNA was used in real-time PCR using the miScript PCR System. Real-time PCR was performed on the Rotor-Gene Q cycler. The resultant C_T values decreased linearly with increasing miRNA copy number, indicating sensitive detection from a wide range of template amounts. The resultant C_T values were plotted against the log copy numbers, showing sensitive and linear detection from a wide range of template amounts.

Pathogen detection and food safety testing

Regardless of the pathogen or the material being examined, standard pathogen testing typically begins with a screening assay to simply assess presence or absence of a target. If results from the screening assay indicate presence of pathogens, further typing of the pathogen may be beneficial. Real-time PCR is the method of choice for accurate and reliable detection of pathogens and QIAGEN technologies and assays greatly facilitate this screening process. To streamline detection workflows, QIAGEN offers verified, ready-to-use assays as well as QuantiTect Virus Kits and QuantiFast Pathogen +IC RT-PCR Kits that enable multiplex qPCR for the detection of multiple targets in a single run.

Highly sensitive detection of viral RNA and/or DNA

The combination of the QuantiTect Virus +ROX Vial Kit and the Rotor-Gene Q provides highly sensitive and rapid detection of up to 4 viral DNA and RNA targets simultaneously. A concentrated master mix allows larger volumes of template to be added to assays, lowering the limit of detection. Viral nucleic acid targets can be individually detected in singleplex assays or detected together with internal controls in multiplex assays.

QuantiFast Pathogen +IC Kits show the same performance as QuantiTect Virus Kits, but are also delivered with a universal internal control to enable high process safety through correct interpretation of negative results e.g., by detecting PCR inhibition. In combination with the Rotor-Gene Q, the QuantiFast Pathogen +IC Kits enable simultaneous detection of viral RNA or DNA targets plus internal control over a wide linear range without loss of sensitivity when duplexing (Figure 11).

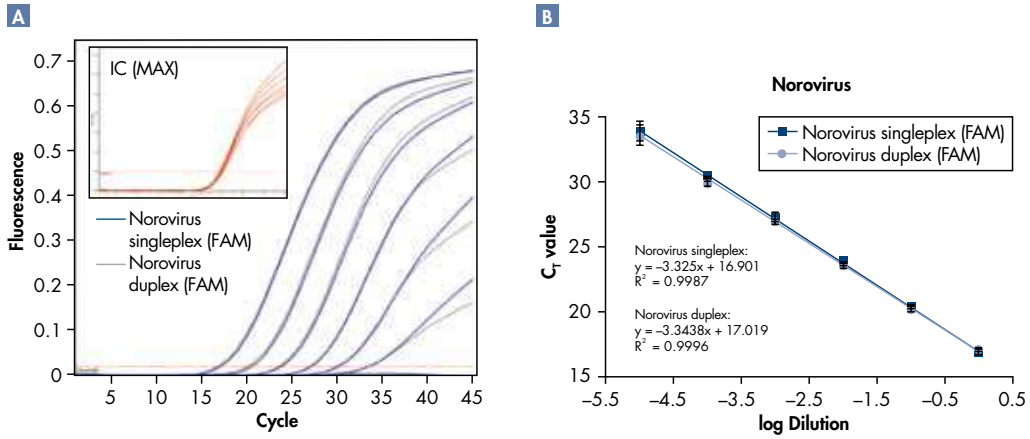


Figure 11. Sensitive and precise detection of Norovirus on the Rotor-Gene Q. A Norovirus transcript was serially diluted and detected by either singleplex real-time RT-PCR or by duplex real-time RT-PCR in parallel with the QIAGEN international control. Real-time RT-PCR was carried out using the QuantiFast Pathogen +IC RT-PCR Kit on the Rotor-Gene Q without any PCR optimization. The duplex reactions contained a fixed amount of IC template. Each dilution was analyzed in triplicate, one replicate per dilution is shown. B A 6-log range of both Norovirus RNA singleplex detection and Norovirus/IC duplex detection shows high precision and linearity. Error bars each represent ±1 SD of 3 real-time RT-PCR replicates.

Rapid identification of animal pathogens with the Rotor-Gene Q

QIAGEN provides everything you need for pathogen identification and genotyping — reagents, enzymes, and instruments. *cador* real-time PCR reagents are developed for sensitive identification of specific animal pathogens (viral and bacterial) using PCR on the Rotor-Gene Q. For example, *cador* TKP PCR Reagent contains reagents and enzymes for simultaneous multiplex amplification of highly conserved regions of *Taylorella equigenitalis*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* genomes. The amplicons are detected in one tube by measuring the green, orange, and crimson fluorescence on a Rotor-Gene Q. An internal control is included in the same tube, to monitor DNA extraction and/or the presence of PCR inhibitors. QIAGEN is one of the few companies with a worldwide PCR license for animal testing, without additional licensing costs for the user.

Complete workflow solutions for food safety testing

The *mericon*™ food testing portfolio is a complete system of sample preparation and assay kits that meet the increasing demands of food research and monitoring. The assays, with detection by real-time PCR, enable sensitive and accurate detection of a broad range of pathogens, genetically-modified organisms, and plant and animal matter in food, animal feed, or pharmaceutical products. The entire workflow for food safety testing using *mericon* sample preparation kits and *mericon* PCR Assays has been validated. *mericon* PCR Assays perform optimally on the Rotor-Gene Q (Figure 12).

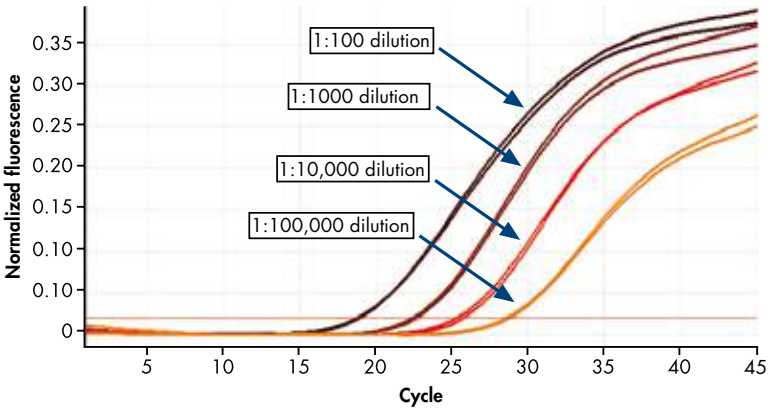


Figure 12. Highly sensitive pathogen detection, even in difficult food matrices such as peanut butter. Peanut butter was homogenized in buffered peptone water, spiked with < 5 cfu of Salmonella, and enriched for 20 h at 37°C. DNA was extracted from serially diluted samples of the enrichment culture using the *mericon* DNA Bacteria Kit and then tested with the *mericon* Salmonella Kit on the Rotor-Gene Q. Although the original inoculation was small, Salmonella was still reliably detected at a dilution factor of 1:100,000.

Beyond pathogen detection — pathogen typing using HRM technology

In pathogen research, categorization of various pathogen subtypes is often required. This pathogen typing enables identification of different strains, for instance drug-resistant mutations or highly pathogenic variants. The resolution and flexibility of HRM in combination with the Type-it HRM PCR Kit on the Rotor-Gene Q, makes it the method of choice for pathogen typing in many application areas (Figure 13).

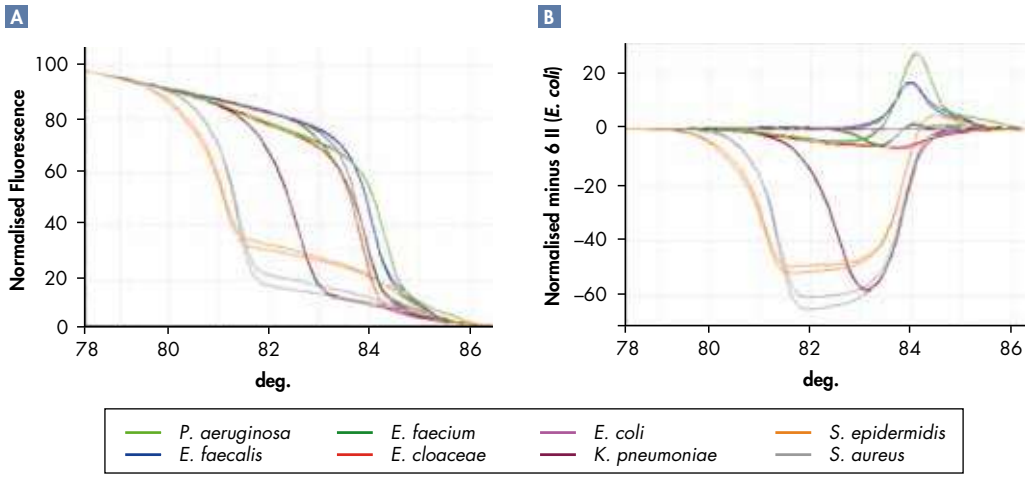


Figure 13. Pathogen typing using robust HRM detection. HRM primers were designed to recognize and differentiate the 16S ribosomal DNA of 8 different bacterial strains. Microbial DNA (10 pg) from each strain was used as template and amplified using the Type-it HRM PCR Kit. PCR products were sequenced to confirm the results and the robustness of the HRM detection method for this application.

Genotyping

The analysis of differences in DNA between individuals has become increasingly important in all areas of biological and medical research. The term "genotyping" is used as a synonym for a wide range of applications associated with human, animal, plant, microbial, or viral samples. QIAGEN has developed highly specific and accurate PCR solutions and versatile detection methods to address the requirements of genotyping studies for accuracy, speed, reliability, and standardization.

PCR-based genotyping analysis

The Type-it Fast SNP Probe PCR Kit provides accurate SNP genotyping using the Rotor-Gene Q, even for difficult templates or SNPs and low template amounts. Outstanding separation and tight allele clustering, together with the allelic discrimination or scatter plot analysis functions of the Rotor-Gene Q software, ensure high call rates and accurate, reproducible, and reliable genotyping results (Figure 14). The kit is functionally validated with commercially available SNP genotyping assays and is compatible with TaqMan MGB probes as well as custom assays consisting of TaqMan MGB, TaqMan, or other dual-labeled probes.

Accurate genotyping with the Type-it HRM PCR Kit

The optimized Type-it HRM PCR Kit ensures accurate resolution of sequence variations and is an unmatched tool for unambiguous allelic discrimination using HRM technology. Together with the Rotor-Gene Q, the Type-it HRM PCR Kit requires no optimization in the development of new HRM assays. Due to the unique master mix chemistry and optimized HRM buffer, specific amplification products and reliable results are consistently ensured, even when analyzing Class IV SNPs (Figures 3 and 4). Unlike HRM kits from other suppliers, the unique features of the Type-it HRM PCR Kit enable amplification of the most challenging subtle sequence differences, even in difficult gene mutations in cancer-related genes (Figure 15).

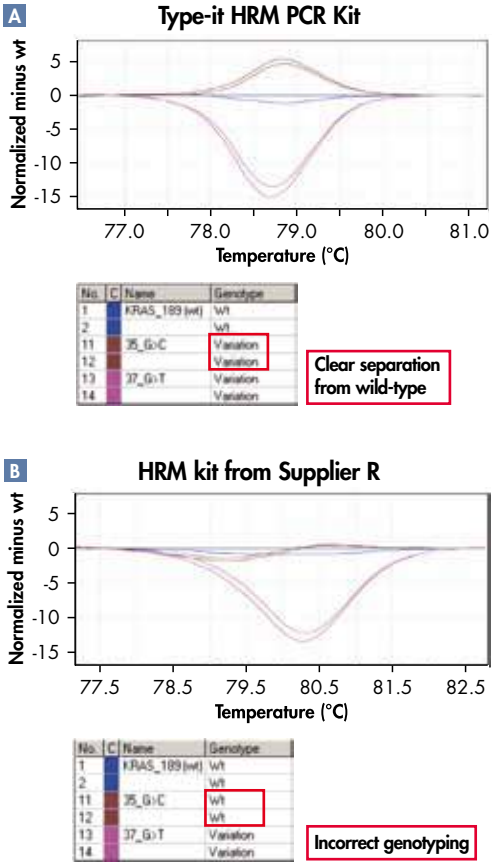


Figure 15. Successful typing of gene mutations in the human KRAS gene using the Type-it HRM PCR Kit. A Difference plot showing reliable discrimination between the wild-type sequence (blue), the c.35 G>C mutation (brown), and the c.37G>T mutation (pink). Reproducible discrimination with high confidence was obtained without the need for optimization. B The c.35 G>C mutation could not be resolved from the wild-type even after extensive optimization of Mg^{2+} concentration and cycling parameters when using the HRM master mix from Supplier R. The mutation affects the amino acid in position 12, resulting in p.G12A and in position 13, resulting in p.G13C.

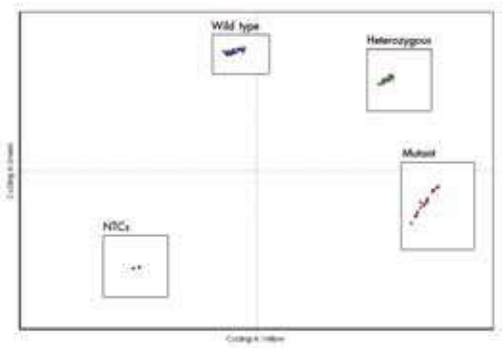


Figure 14. Reliable SNP genotyping even with low template amounts. Allelic discrimination plot analysis was performed with a panel of 70 different genomic DNAs (1 ng each) using the Type-it Fast SNP Probe PCR Kit. PCR was performed on the Rotor-Gene Q with a TaqMan SNP genotyping assay for rs 951134 and two no template controls (NTCs). **Black**: NTCs. **Green**: heterozygous samples. **Red**: homozygous for VIC fluorescence (A allele). Even using low amounts of template, tight clustering and reliable genotyping results were observed.

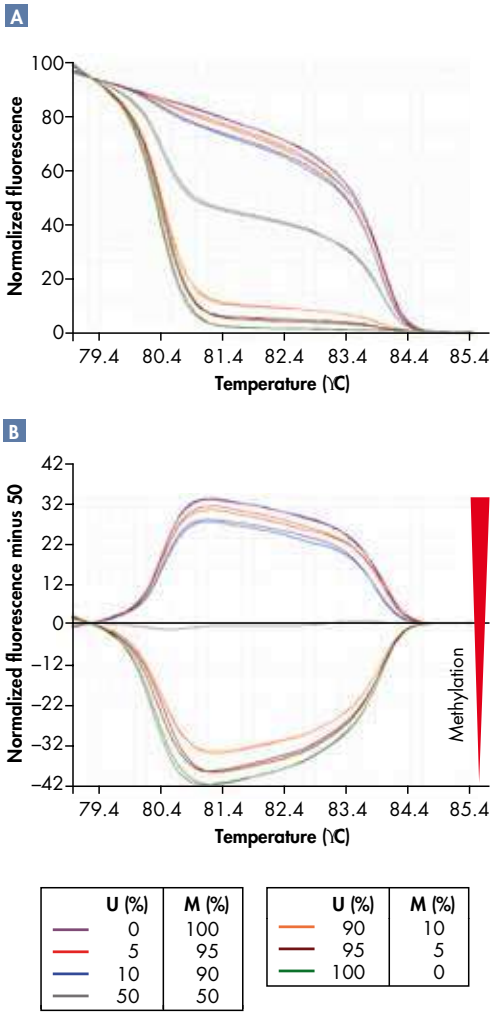


Figure 16. Highly sensitive results — detection of even low percentages of methylated DNA. Mixtures of methylated and unmethylated DNA of varying ratios were used as template. A CpG island from the promoter region of the APC gene (adenomatosis polyposis coli) was amplified and the degree of methylation was determined by HRM methylation analysis on the Rotor-Gene Q using the EpiTect HRM PCR Kit. A A standard normalized melt curve and B a difference plot normalized to the 50% methylated sample are shown.

DNA methylation analysis

EpiTect HRM PCR Kit — for reliable screening of changes in methylation status by HRM analysis

The EpiTect HRM PCR Kit uses high-resolution melting (HRM) technology for fast screening and accurate detection of changes in the CpG methylation status of bisulfite-converted DNA.

The EpiTect HRM PCR Kit offers:

- Highly specific PCR amplification without the need for optimization
- Distinct melting curves due to EvaGreen fluorescent dye
- Convenient master mix format and optimized protocol
- Fast and easy development of new HRM methylation assays

For CpG methylation analysis by HRM, the DNA has to undergo complete bisulfite conversion before the melting behavior of DNA can be measured by HRM analysis. Unknown samples can be compared to a standard control based on their melting characteristics. The sensitivity ensured by the EpiTect HRM PCR Kit together with the Rotor-Gene Q means that even low amounts of methylated DNA can be detected (Figure 16).

EpiTect MethyLight PCR Kits — for quantitative, real-time probe-based PCR analysis of methylation status

Once methylation sites have been identified using HRM, probe-based techniques can be used for sensitive quantification of CpG sites. Using the EpiTect MethyLight PCR Kit with the Rotor-Gene Q allows sensitive and reliable analysis of methylation status using TaqMan or other dual-labeled probes. Highly accurate quantitative methylation analysis is achieved when the kit is used together with probe-based Methylation assays (such as EpiTect MethyLight Assays). EpiTect MethyLight Assays consist of PCR primers and 2 probes — one methylation-specific, the other nonmethylation-specific — which can be used in a single reaction to simultaneously detect methylated and unmethylated sites (Table 5).

Table 5. Sensitive detection of small changes in methylation

Defined experimental methylation degree	Mean $C_{T(CG)}$ value (FAM probe)	Mean $C_{T(TG)}$ value (VIC probe)	Calculated methylation degree in % per sample
0% methylation	45	30.37	0.004
10% methylation	34.62	30.72	6.278
50% methylation	31.27	31.67	56.887
90% methylation	30.52	33.43	88.258
100% methylation	30.05	45	99.997

Ordering Information

Product	Contents	Cat. no.
Rotor-Gene Q 2plex	Real-time PCR cycler with 2 channels (green, yellow), laptop computer, software, accessories, 1-year warranty on parts and labor, optional installation and training	Inquire
Rotor-Gene Q 2plex HRM	Real-time PCR cycler and HRM instrument with 2 channels (green, yellow) plus HRM channel, laptop computer, software, accessories, 1-year warranty on parts and labor, optional installation and training	Inquire
Rotor-Gene Q 5plex	Real-time PCR cycler with 5 channels (green, yellow, orange, red, crimson), laptop computer, software, accessories, 1-year warranty on parts and labor, optional installation and training	Inquire
Rotor-Gene Q 5plex HRM	Real-time PCR cycler and HRM instrument with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories, 1-year warranty on parts and labor, optional installation and training	Inquire
Rotor-Gene Q 6plex	Real-time PCR cycler with six channels (blue, green, yellow, orange, red, crimson), laptop computer, software, accessories, 1-year warranty on parts and labor, optional installation and training	Inquire
Warranty PLUS 1 Basic, Rotor-Gene Q	2-year warranty, all labor, travel, and parts	9241779
Rotor-Disc 100 Starter Kit	Kit includes: 2 Rotor-Disc 100 packs, Rotor-Disc Heat Sealer, Rotor-Disc Heat Sealing Film, Rotor-Disc 100 Rotor and Locking Ring, Rotor-Disc 100 Loading Block, Rotor-Disc Pipetting Aid	Inquire
Rotor-Disc 100 (30)	Pack of 30 individually wrapped discs for 3000 reactions	981311
Rotor-Disc 72 Starter Kit	Kit includes: 3 Rotor-Disc 72 packs, Rotor-Disc Heat Sealer, Rotor-Disc Heat Sealing Film, Rotor-Disc 72 Rotor and Locking Ring, Rotor-Disc 72 Loading Block, Rotor-Disc Pipetting Aid	Inquire
Rotor-Gene Probe PCR Kit (400)*	For 400 x 25 µl reactions: 2x Master Mix, RNase-Free Water	204374
Rotor-Gene Probe RT-PCR Kit (400)	For 400 x 25 µl reactions: 2x Master Mix, RT Mix, RNase-Free Water	204574
QuantiFast Probe Assay (400)*	For 400 x 25 µl reactions: dual-labeled, probe-based, predesigned 20x lyophilized assays; includes master mix and reagents for real-time one-step or two-step RT-PCR	Varies
Rotor-Gene Multiplex PCR Kit (400)*	For 400 x 25 µl reactions: 2x Master Mix, RNase-Free Water	204774
Rotor-Gene Multiplex RT-PCR Kit (400)*	For 400 x 25 µl reactions: 3 x 1.7 ml 2x Rotor-Gene Multiplex RT-PCR Master Mix, 100 µl Rotor-Gene RT Mix, 2 x 2 ml RNase-Free Water	204974
QuantiTect Primer Assay (200)*	For 200 x 50 µl reactions: 10x QuantiTect Primer Assay (lyophilized)	Varies

* Various kit sizes available; please inquire.

Ordering Information

Product	Contents	Cat. no.
QuantiTect Reverse Transcription Kit (50)*	For 50 x 20 µl reactions: Buffers, Quantiscript® Reverse Transcriptase, RT Primer Mix, RNase-Free Water	205311
miScript SYBR Green PCR Kit (200)*†	For 200 x 50 µl reactions: 2x Master Mix, Universal Primer, RNase-Free Water	218073
QuantiTect Virus +ROX Vial Kit (200)*	For 200 x 50 µl reactions: 5x Master Mix, RT Mix, RNase-Free Water, Nucleic Acid Dilution Buffer	211033
QuantiFast Pathogen PCR +IC Kit (400)*	For 400 x 25 µl reactions: Master Mix, lyophilized Internal Control Assay, lyophilized Internal Control DNA, ROX Dye Solution, High-ROX Dye Solution, RNase-Free Water, Nucleic Acid Dilution Buffer, Buffer TE	211354
QuantiFast Pathogen RT-PCR +IC Kit (400)*	For 400 x 25 µl reactions: Master Mix, RT Mix, lyophilized Internal Control Assay, lyophilized Internal Control RNA, ROX Dye Solution, High-ROX Dye Solution, RNase-Free Water, Nucleic Acid Dilution Buffer, Buffer TE	211454
Type-it Fast SNP Probe PCR Kit (800)*	For 800 x 25 µl reactions: 2x Master Mix, RNase-Free Water, Q-Solution®	206045
EpiTect MethyLight PCR Kit (200)*	For 200 x 50 µl reactions: 2x Master Mix, RNase-Free Water	59436
EpiTect HRM PCR Kit (100)	For 100 x 25 µl reactions: 2x Master Mix, RNase-Free Water	59445
Type-it HRM PCR Kit (100)	For 100 x 25 µl reactions: 2x Master Mix, RNase-Free Water	206542
Pathway-Powered RT² Profiler PCR Arrays	PCR Array includes SYBR Green-optimized primer assays for a panel of relevant pathway- or disease-focused genes	330231
Custom RT² Profiler PCR Arrays	Custom PCR Arrays containing any set of human, mouse, rat, dog, rhesus macaque, or fruit fly genes	330131
RT² SYBR Green ROX FAST Mastermix	For 200 x 20 µl reactions: 2x SYBR Green ROX FAST qPCR Mastermix, HotStart DNA Taq Polymerase, dNTP mix, dyes	330520

* Various kit sizes available; please inquire. † The kit is part of the miScript PCR System; for details, visit www.qiagen.com/miRNA.

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 or can be requested from QIAGEN Technical Services or your local distributor.

Discover more about the Rotor-Gene Q at www.qiagen.com/pure-detection

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Brazil ▪ Orders 0800-557779 ▪ Fax 55-11-5079-4001 ▪ Technical 0800-557779

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Spain ▪ Orders 91-630-7050 ▪ Fax 91-630-5145 ▪ Technical 91-630-7050

Sweden ▪ Orders 020-790282 ▪ Fax 020-790582 ▪ Technical 020-798328

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Sample & Assay Technologies

Rotor-Gene® Q accessories

Accessories that can be used with the Rotor-Gene® Q are listed below.

Product	Contents	Cat. no.
36-Well Rotor 	For holding PCR Tubes, 0.2 ml; requires 36-Well Rotor Locking Ring	9018907
36-Well Rotor Locking Ring 	For locking PCR Tubes, 0.2 ml, in the 36-Well Rotor	9018906
72-Well Rotor 	For holding Strip Tubes and Caps, 0.1 ml; requires Locking Ring 72-Well Rotor	9018903
Locking Ring 72-Well Rotor 	For locking Strip Tubes and Caps, 0.1 ml in the 72-Well Rotor	9018904
Rotor-Disc® 72 Rotor 	For holding Rotor-Disc 72 discs in the Rotor-Gene Q; requires Rotor-Disc 72 Locking Ring	9018899

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Rotor-Disc 72 Locking Ring 	For locking a Rotor-Disc 72 in the Rotor-Disc 72 Rotor	9018900
Rotor-Disc 100 Rotor 	For holding Rotor-Disc 100 discs in the Rotor-Gene Q; requires Rotor-Disc 100 Locking Ring	9018895
Rotor-Disc 100 Locking Ring 	For locking a Rotor-Disc 100 in the Rotor-Disc 100 Rotor	9018896
Rotor-Disc Pipetting Aid 	Aid for marking well during manual reaction setup on a Rotor-Disc Loading Block	9018897
Rotor-Disc 72 Starter Kit (115V)	3 Rotor-Disc 72 packs, Rotor-Disc Heat Sealer, Rotor-Disc Heat Sealing Film, Rotor-Disc 72 Rotor and Locking Ring, Rotor-Disc 72 Loading Block, Rotor-Disc Pipetting Aid	9001600
Rotor-Disc 72 Starter Kit (230V)	3 Rotor-Disc 72 packs, Rotor-Disc Heat Sealer, Rotor-Disc Heat Sealing Film, Rotor-Disc 72 Rotor and Locking Ring, Rotor-Disc 72 Loading Block, Rotor-Disc Pipetting Aid	9001601
Rotor-Disc 100 Starter Kit (115V)	2 Rotor-Disc 100 packs, Rotor-Disc Heat Sealer, Rotor-Disc Heat Sealing Film, Rotor-Disc 100 Rotor and Locking Ring, Rotor-Disc 100 Loading Block, Rotor-Disc Pipetting Aid	9001602
Rotor-Disc 100 Starter Kit (230V)	2 Rotor-Disc 100 packs, Rotor-Disc Heat Sealer, Rotor-Disc Heat Sealing Film, Rotor-Disc 100 Rotor and Locking Ring, Rotor-Disc 100 Loading Block, Rotor-Disc Pipetting Aid	9001603
Rotor-Disc Heat Sealer 110V 	Heat sealing instrument for use with Rotor-Discs; requires Rotor-Disc 72 or 100 Loading Block	9018898

Rotor-Disc Heat Sealer 230V 	Heat sealing instrument for use with Rotor-Discs; requires Rotor-Disc 72 or 100 Loading Block	9019725
Loading Block 72 x 0.1 ml Tubes 	Aluminum block for manual reaction setup with a single-channel pipet in 72 x 0.1 ml tubes	9018901
Loading Block 72 x 0.1 ml Multi-channel 	Aluminum block for reaction set-up with multichannel pipets in 72 x 0.1 ml tubes 9018902	
Loading Block 96 x 0.2 ml Tubes 	Aluminum block for manual reaction set-up in a standard 8 x 12 array using 96 x 0.2 ml tubes	9018905
Rotor Holder 	Metal free-standing holder for assembling tubes and Rotor-Discs into rotors	9018908
Rotor-Disc 72 Loading Block 	Aluminum block for manual and automated reaction setup in Rotor-Disc 72 discs	9018910

Rotor-Disc 100 Loading Block 	Aluminum block for manual and automated reaction setup in Rotor-Disc 100 discs	9018909

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Sample & Assay Technologies

Rotor-Gene® Q consumables

Consumables that can be used with the Rotor-Gene® Q are listed below.

Product	Contents	Cat. no.
PCR Tubes, 0.2 ml (1000) 	1000 thin-walled tubes for 1000 reactions	981005
PCR Tubes, 0.2 ml (10000) 	10 x 1000 thin-walled tubes for 1000 reactions	981008
Strip Tubes and Caps, 0.1 ml (250) 	250 strips of 4 tubes and caps for 1000 reactions	981103
Strip Tubes and Caps, 0.1 ml (2500) 	10 x 250 strips of 4 tubes and caps for 10,000 reactions	981106

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Sample & Assay Technologies

Rotor-Disc® 72 (24) 	24 individually wrapped discs for 1728 reactions	981301
Rotor-Disc 72 (240) 	10 x 24 individually wrapped discs for 17,280 reactions	981303
Rotor-Disc 100 (30) 	30 individually wrapped discs for 3000 reactions	981311
Rotor-Disc 100 (300) 	10 x 30 individually wrapped discs for 30,000 reactions	981313
Rotor-Disc Heat Sealing Film (60)	60 films for sealing Rotor-Disc 100 or Rotor-Disc 72 discs	981601
Rotor-Disc Heat Sealing Film (600)	10 x 60 films for sealing Rotor-Disc 100 or Rotor-Disc 72 discs	981604

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

August 2016

Sample to Insight

QIAGEN®

Contents

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

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 cycler 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 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.

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.

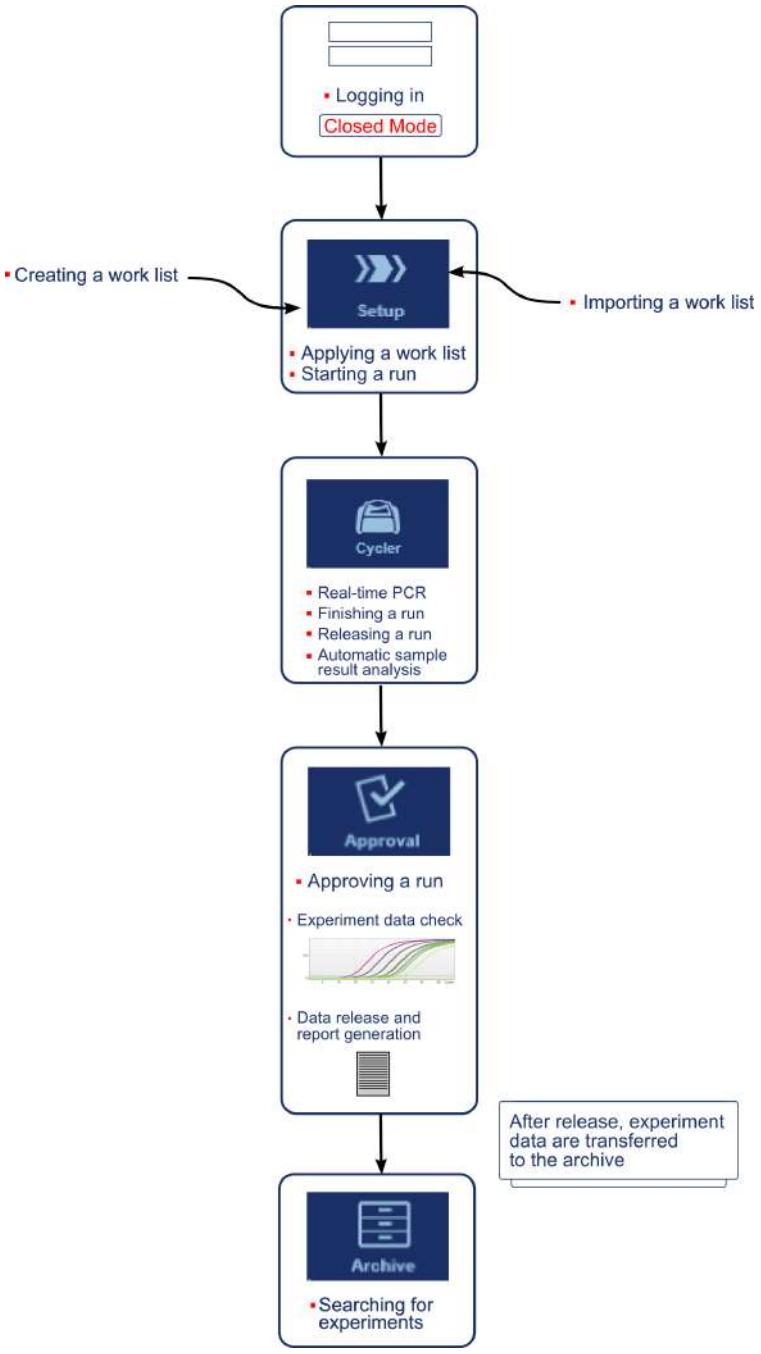
Importing assay profiles for the Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in

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

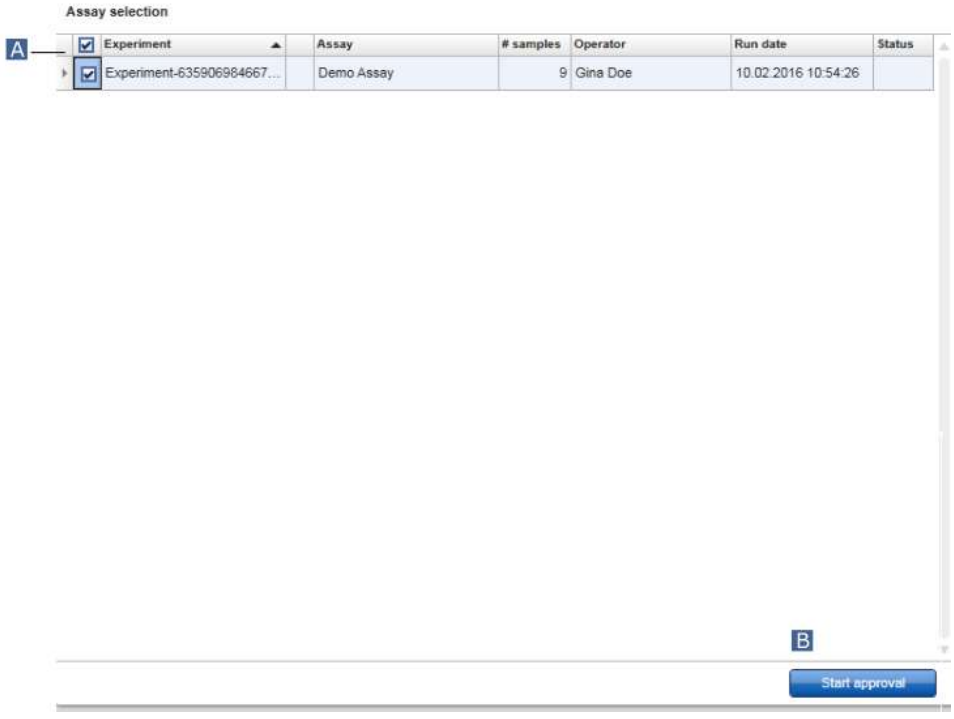
The overall functionalities of the "Setup" environment and of "Creating/Editing a Work List" are described in the *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*.

1.3.3 Releasing Samples

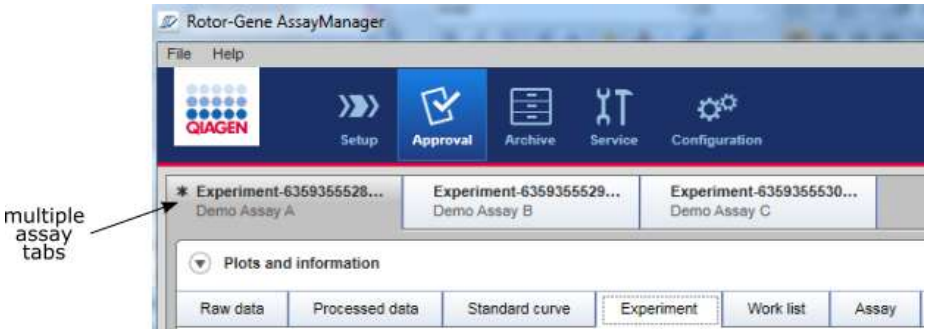
The general functionality of the "Approval" environment is described in *Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*. In *Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual*, only the functionality dedicated to the Gamma MDx Plug-in is described.

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"** 2. **"Processed data"** 3. **"Standard curve"**	**Graphic** focused: Shows amplification plots of raw and processed data as well as the standard curve, respectively.
4. **"Experiment"** 5. **"Work list"** 6. **"Assay"**	**Data** focused: Shows detailed data about the experiment, the used work list and the 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.

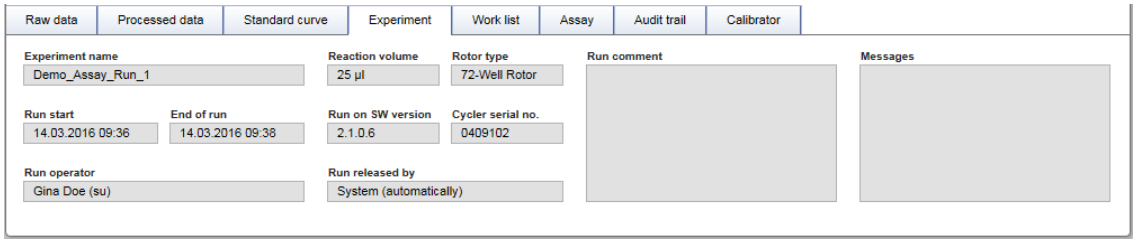
Note

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.

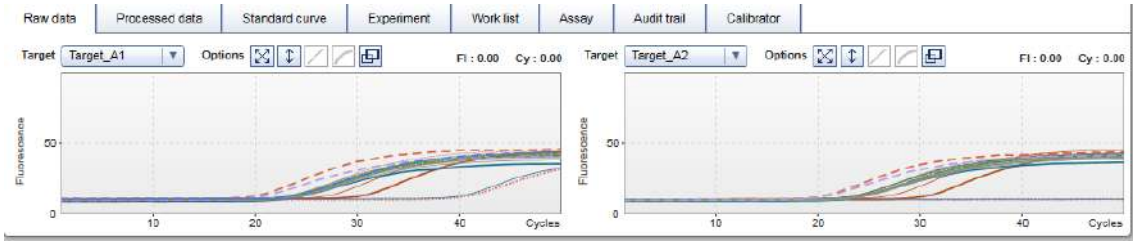
Experiment

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



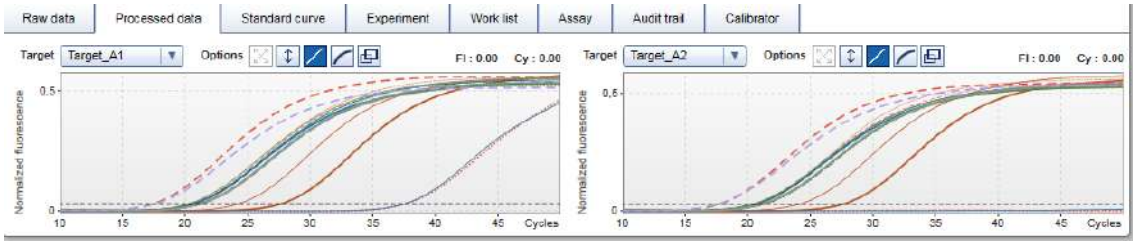
Raw data

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



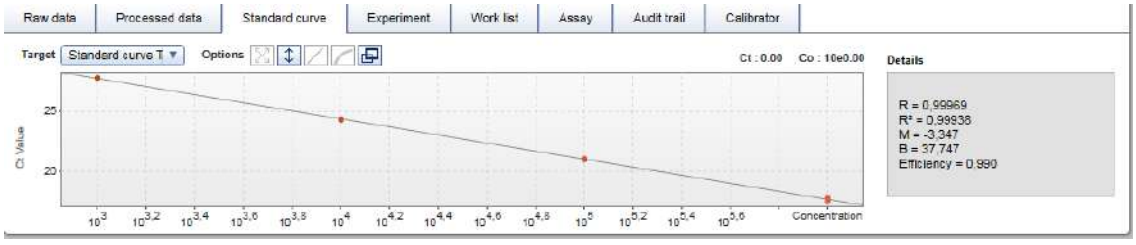
Processed data

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



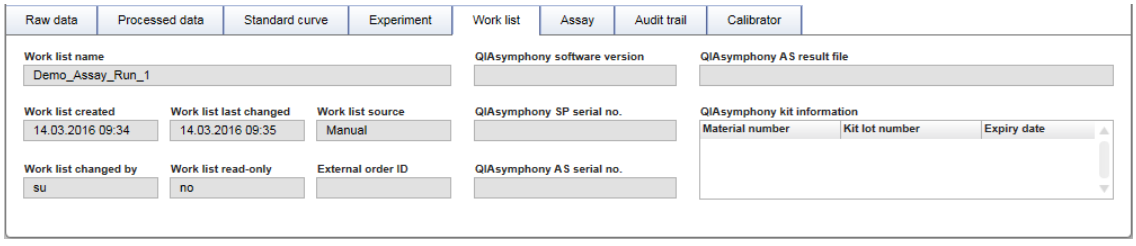
Standard curve

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



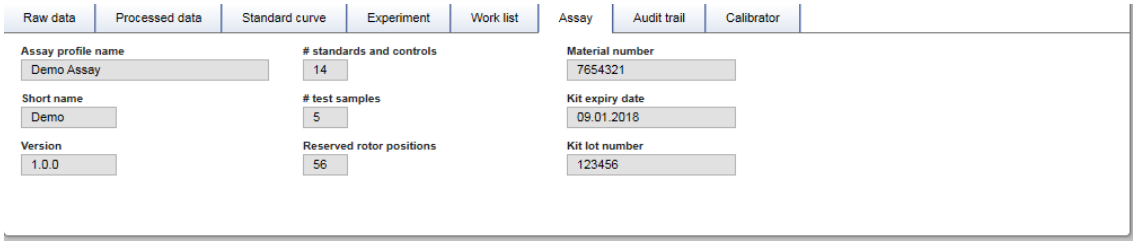
Work list

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



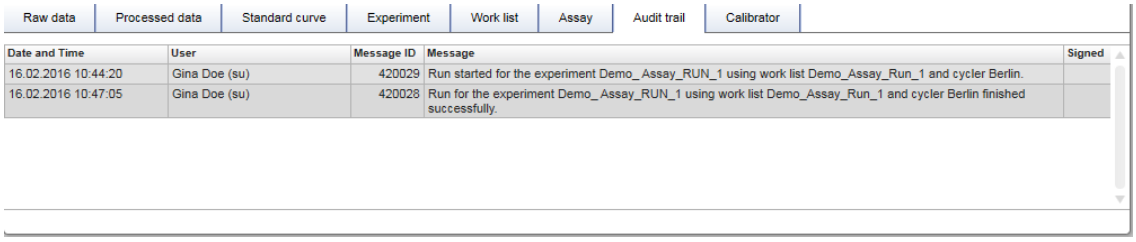
Assay

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



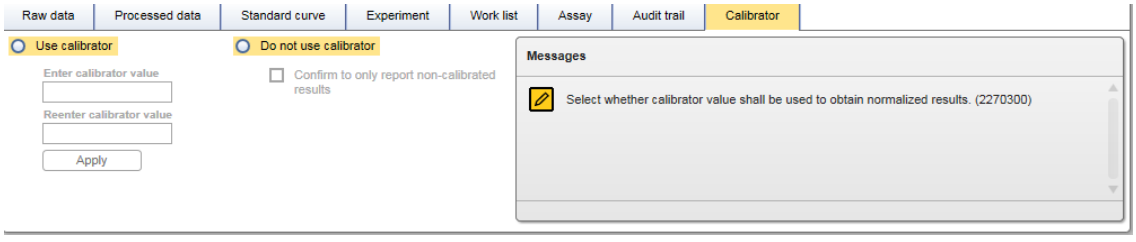
Audit trail

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



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.



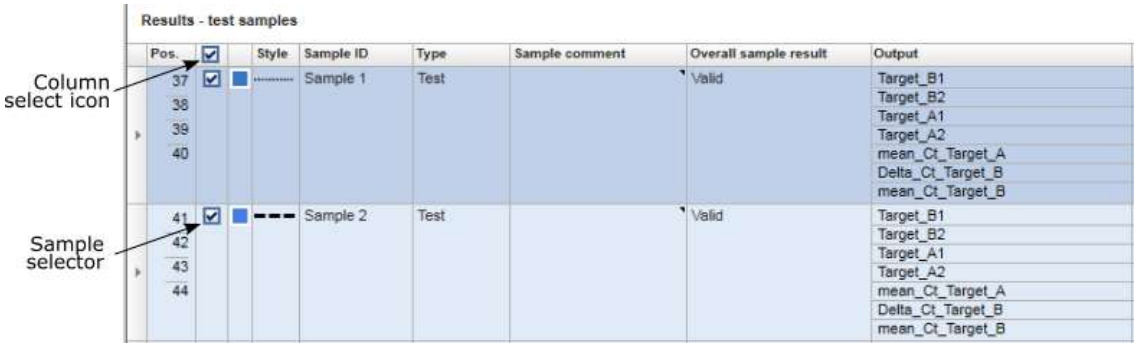
Note

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

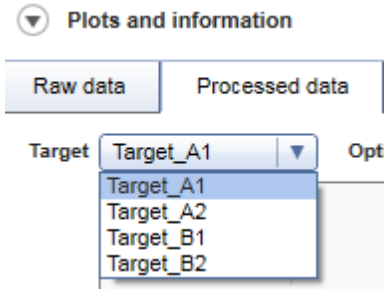
1. By default, all samples of an assay are selected. To display only the amplification curves of specific samples, first click the "Column select" icon in the header of the results table to deselect all samples. Click the "Sample selector" check box of the samples whose amplification curve you would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



Note

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

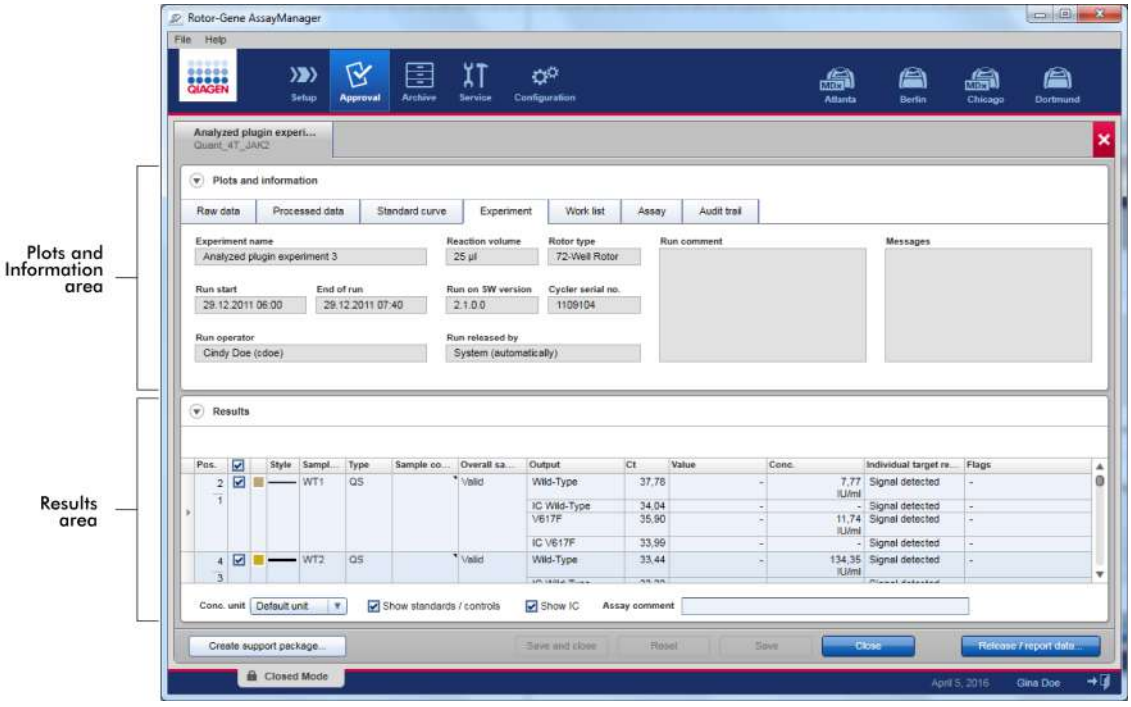
2. Select the target which shall be displayed from the "Target" drop-down list.



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.



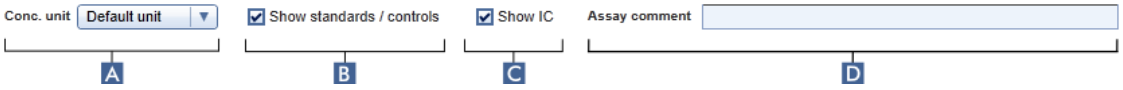
Depending on the assay profile settings, the "Results" table in the "Results" area may include the following detailed information about the individual samples:

Field	Content
"Pos." (Position)	The tube position of the target.
"Checkbox" ☐	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:



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

1.3.3.4 Target Results

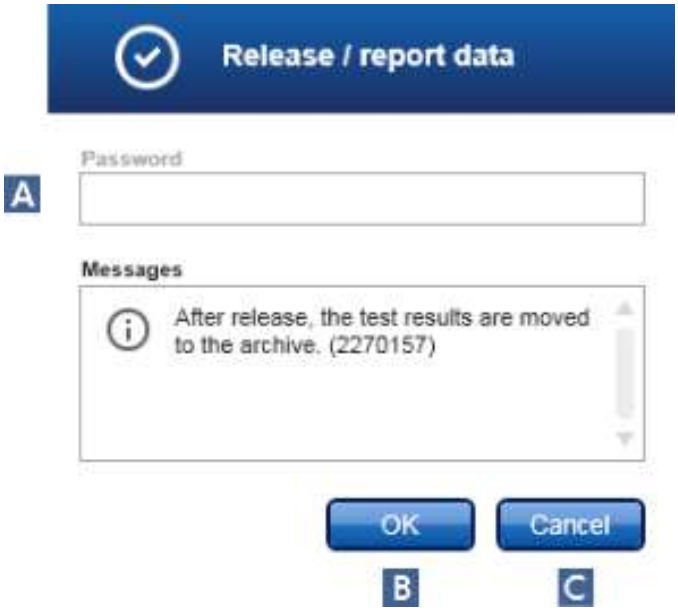
Rotor-Gene AssayManager v2.1 determines the result of a target by combining all relevant analysis results according to core analysis algorithms such as normalization, automatic data scan (AUDAS) and sample and assay rules defined in the corresponding assay profile. The following results could be assigned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

Individual target result	Description
Signal detected	• A target gets the result "Signal detected" if a C_T value is detected within a predefined valid range. • A target gets the result "Signal detected" if the value of a calculated target could be calculated.
No signal	• A target gets the result "No signal" if no C_T value is detected or if the C_T is outside of a predefined valid range. • 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.
INVALID	• 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".
Assay specific target result	• The target gets an assay specific result string if defined in the assay profile.

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
Save and close	• Saves all changes. • 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.
Reset	• Cancels all changes. • Reverts to the previously saved approval status; amplification plots and result table options are not reset.
Save	• Saves all changes.
Close	• Discards all changes and returns to the previously saved approval status. • 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.
Release / report data...	• Opens a dialog to release test results and automatically create a report. • The status of the assay is set to "Fully released". • 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. • Saves the *.pdf report file in the folder defined in the "Configuration" environment, under: Settings ▸ Local Settings ▸ Default data export directories ▸ Report folder. • 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.

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.

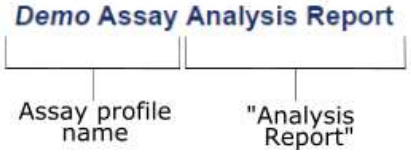
1.3.4 Reporting

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. **Note:** 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"	1. Start and end time of the run. 2. Run operator and software version of the application. 3. Run comment as entered by the operator during the run. 4. Errors that may have occurred during the run. 5. Experiment release information.
"Work list"	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". **Note:** If the work list is locked then it is mentioned as "(read-only)" together with the work list name. 2. Creator of the work list. 3. Last modifier of the work list.
"Used cycler"	1. Serial number of the cycler. 2. Rotor type. 3. Reaction volume.

Example of the "RGQ run information" table:

RGQ run information

Run name	Demo_Assay_Run_1
Run information	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
Work list	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
Used cycler	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 QIAsymphony work list was used:

Field	Content
"QS Software version"	Version of the QIAsymphony software.
"Operator ID"	Name(s) of the operator(s) who started the run on QIAsymphony SP and AS.
"Extraction time"	Start and end date of the run on QIAsymphony SP.
"SP Serial number"	Serial number of QIAsymphony SP.
"Assay setup time"	Start and end date of the run on QIAsymphony AS.
"AS Serial number"	Serial number of QIAsymphony AS.
"AS Result file"	Name of the imported QIAsymphony 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

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

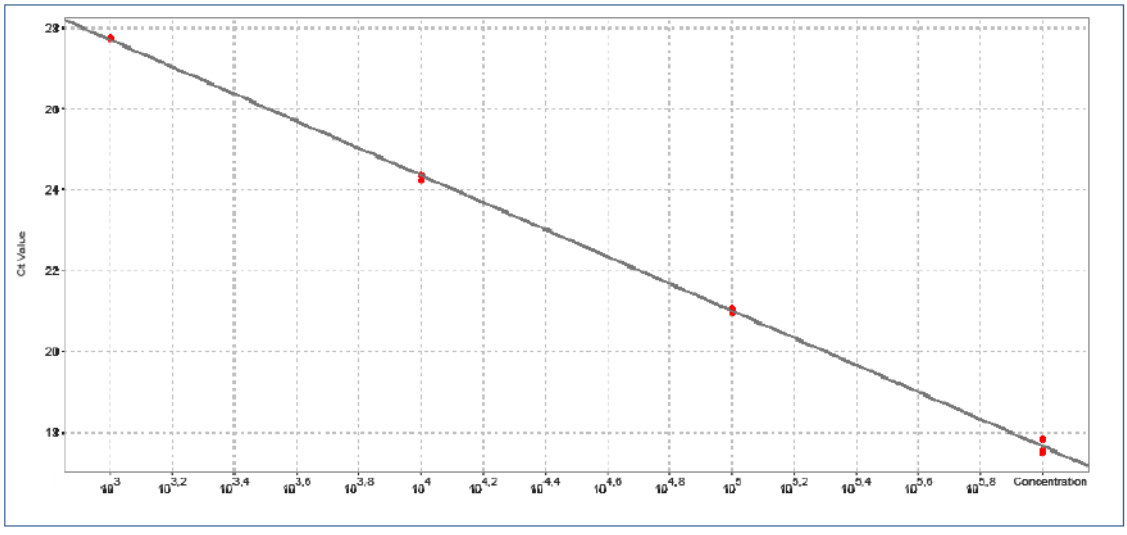
For further details about the upstream QIAsymphony run (e.g. reason for "UPSTREAM" flag), refer to the AS result file listed in the table above.

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^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	R²	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_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 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:

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"	***Rotor-Gene AssayManager v2.1 Gamma MDx Plug-in User Manual* (i.e., this manual)** Topic: ▸ General information about releasing samples
"Archive"	***Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*** Topics: • Basic Concepts and General Software Usage ➜ Environments ➜ "Archive" Environment • Using Rotor-Gene AssayManager ➜ Administrative Tasks ➜ Managing Archives

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"	***Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*** Topic: • Using Rotor-Gene AssayManager ➜ Standard Tasks ➜ Approving a Run
"Archive"	***Rotor-Gene AssayManager v2.1 MDx Core Application User Manual*** Topic: • Using Rotor-Gene AssayManager ➜ Administrative Tasks ➜ Managing Archives

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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1101306 08/2016 HB-2090-001