

# Rotor-Gene® Q and *artus*® PCR Kits — Pure Pathogen Detection

Molecular Diagnostics



Sample & Assay Technologies

# Guaranteed performance with *artus* real-time PCR kits

Successful real-time PCR requires amplification and detection under optimal conditions. Both the reaction composition and the thermal cycler used can affect the results. *artus* PCR Kits provide ready-to-use molecular detection kits for real-time PCR with guaranteed performance on the Rotor-Gene Q.

The kits provide all necessary reagents optimized for rapid and sensitive detection of pathogens from a broad range of sample materials with highly accurate quantification. In addition, all *artus* real-time PCR Kits contain a second heterologous amplification system to identify possible PCR inhibition. This internal control (IC) is detected in a separate fluorescence channel of the Rotor-Gene Q.



Figure 1. The *artus* HI Virus-1 RG RT-PCR Kit.

**Table 1. *artus* real-time PCR kits validated and CE-IVD-marked for use on the Rotor-Gene Q**

Pathogen	Detection targets	Page
HIV-1	Group M, subtypes A–H	3
HBV	Genotypes A–H	4
CMV	Cytomegalovirus	5
EBV	Epstein-Barr virus	6
<i>C. trachomatis</i>	<i>Chlamydia trachomatis</i> , serovars A–K	7
<i>M. tuberculosis</i>	<i>Mycobacterium tuberculosis</i> complex	8

## *artus* real-time PCR kits provide:

- High sensitivity with optimized components
- High specificity
- High reliability due to the internal control (IC)
- Quantitative results for reliable determination of pathogen load
- Ease of use
- Fully licensed and CE-marked for in vitro diagnostics

## Reliable results for your peace of mind

The Rotor-Gene Q is a precision instrument with outstanding performance. *artus* RG PCR Kits are designed and validated for optimal performance on Rotor-Gene instruments.

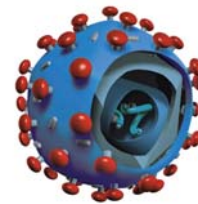
The combination of QIAGEN's Rotor-Gene Q thermal cycler and *artus* real-time PCR kits gives you the complete analytical solution for pathogen detection. Kits for detection of important pathogens (Table 1) provide the tools you need to properly diagnose and monitor patients. All kits are CE-IVD-marked for in vitro diagnostic use on the Rotor-Gene Q. The proven combination provides guaranteed performance and reliable results for your peace of mind.

# Quantitative detection of HIV-1 specific RNA

The *artus* HI Virus-1 RG RT-PCR Kit is a ready-to-use molecular detection kit for real-time RT-PCR on Rotor-Gene Q/6000 and Rotor-Gene 3000 instruments. The kit provides all necessary reagents optimized for rapid and sensitive detection of HIV-1 RNA from human plasma samples with highly accurate quantitation.

## The *artus* HI Virus-1 RG RT-PCR Kit provides:

- Highly sensitive detection of as few as 66.9 IU/ml
- Specific detection of HIV-1 genotypes A to H
- High reliability using the internal control
- Accurate quantitation of viral load over a very broad range
- Compliance with EU IVD Directive 98/79/EC

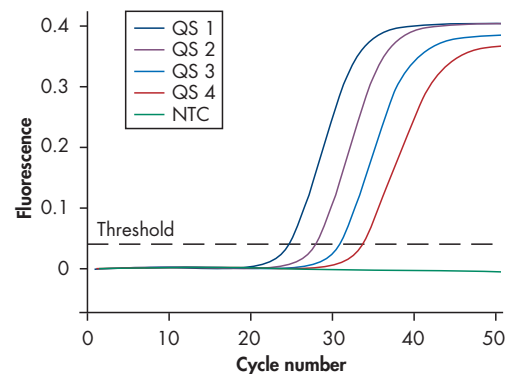


## Reliable HIV-1 diagnostics using real-time PCR

The *artus* HI Virus-1 RG RT-PCR Kit is based on the amplification and simultaneous detection of a highly conserved region within the HIV-1 genome using real-time PCR. The kit provides 4 HIV-1 quantitation standards, calibrated against the HIV-1 RNA International Standard (WHO 97/656) (Figure 2). Use of the standards enables accurate quantitation of viral load, as required to monitor the therapeutic success of highly active antiretroviral therapy (HAART).

## Diagnostic evaluation and correlation with reference method

Comparison of the *artus* HI Virus-1 RG RT-PCR Kit with a reference method (COBAS® TaqMan® HIV-1 Test, Roche) shows very close correlation over a broad concentration range (Figure 3).



**Figure 2. Detection of the quantitation standards.**

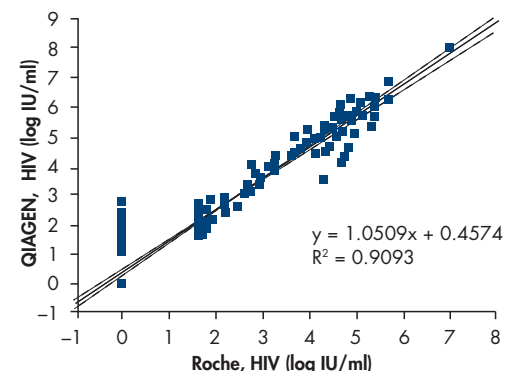
The quantitation standards (HI Virus-1 RG QS 1–4) are detected in fluorescence channel Cycling Green of the Rotor-Gene Q. NTC: no template control (negative control).

**Table 2. Specifications of the *artus* HI Virus-1 RG RT-PCR Kit**

Analytical sensitivity*	66.9 IU/ml
Linear range	120 to 10 <sup>8</sup> IU/ml
Specificity	HIV-1 genotypes A–H
Amplicon	93 bp region of the HIV-1 genome

\* In consideration of the purification (QIAamp DSP Virus Kit), detection on the Rotor-Gene 6000.

**Figure 3. Close correlation of quantitative results with a reference method.** Comparison of the *artus* HI Virus-1 RG RT-PCR Kit (QIAGEN; purification using the QIAamp® DSP Virus Kit) with the COBAS TaqMan HIV-1 Test (Roche; purification using the COBAS AmpliPrep system) showed high correlation of quantitative results from both test systems as analyzed by linear regression. The results from both kits are shown in an XY (scatter) plot with log-log scale.

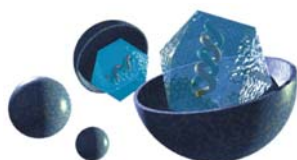


# Quantitative detection of hepatitis B virus specific DNA

The *artus* HBV RG PCR Kit is a ready-to-use molecular detection kit for real-time PCR on Rotor-Gene Q/6000 and Rotor-Gene 3000 instruments. The kit provides all necessary reagents optimized for rapid and sensitive detection of HBV DNA from human plasma samples with highly accurate quantitation.

CE

IVD



## The *artus* HBV RG PCR Kit provides:

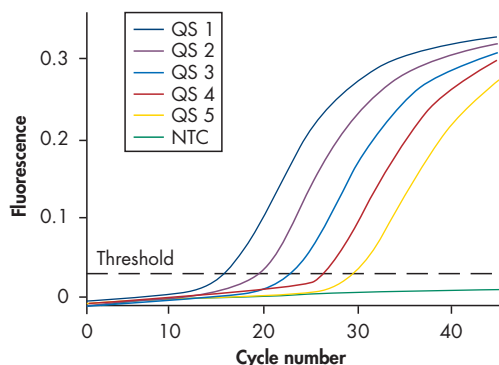
- Highly sensitive detection of as few as 3.8 IU/ml
- Specific detection of HBV genotypes A to H
- High reliability using the internal control
- Accurate quantitation of viral load over a very broad range
- Compliance with EU IVD Directive 98/79/EC

## Reliable HBV detection using real-time PCR

The *artus* HBV RG PCR Kit is based on the amplification and simultaneous detection of a 134 bp region of the HBV genome using real-time PCR. The kit provides 5 HBV quantitation standards (Figure 4). Use of the standards enables accurate quantitation of viral load.

## Diagnostic evaluation and correlation with reference method

Comparison of the *artus* HBV RG PCR Kit with a reference method (COBAS TaqMan HBV Assay, Roche) shows very close correlation over a broad concentration range (Figure 5).

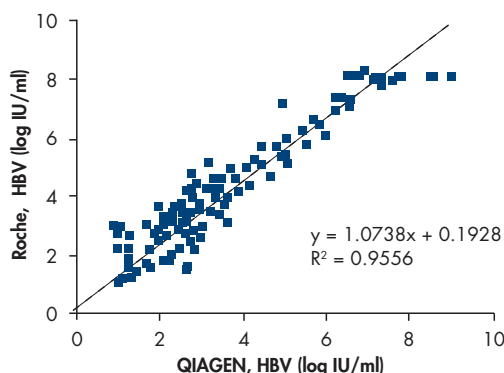


**Figure 4. Detection of the quantitation standards.** The quantitation standards (HBV RG/TM QS 1–5) are detected in fluorescence channel Cycling Green of the Rotor-Gene Q. **NTC:** no template control (negative control).

**Table 3. Specifications of the *artus* HBV RG PCR Kit**

Analytical sensitivity*	3.8 IU/ml
Linear range	0.02 to 10 <sup>8</sup> IU/μl
Specificity	HBV genotypes A–H
Amplicon	134 bp region of the HBV genome

\* In consideration of the purification (QIAamp DSP Virus Kit), detection on the Rotor-Gene 3000. Equivalence between the Rotor-Gene 3000 and the Rotor-Gene Q/6000 was shown on the basis of technical specifications confirmed by analytical performance comparison.



**Figure 5. Close correlation of quantitative results with a reference method.** Comparison of the *artus* HBV RG PCR Kit (QIAGEN; purification using the QIAamp DSP Virus Kit) with the COBAS TaqMan HBV Assay (Roche; purification using the High Pure system) showed high correlation of quantitative results from both test systems as analyzed by linear regression. The results from both kits are shown in an XY (scatter) plot with log-log scale.

# Quantitative detection of cytomegalovirus specific DNA

The *artus* CMV RG PCR Kit is a ready-to-use molecular detection kit for real-time PCR on Rotor-Gene Q/6000 and Rotor-Gene 3000 instruments. The kit provides all necessary reagents optimized for rapid and sensitive detection of CMV DNA from human plasma samples with highly accurate quantitation.

## The *artus* CMV RG PCR Kit provides:

- Highly sensitive detection of as few as 57.1 copies/ml
- High reliability using the internal control
- Accurate quantitation of viral load over a very broad range
- Compliance with EU IVD Directive 98/79/EC

## Reliable CMV detection using real-time PCR

The *artus* CMV RG PCR Kit is based on the amplification and simultaneous detection of a 105 bp region of the CMV genome using real-time PCR. The kit provides 4 CMV quantitation standards (Figure 6). Use of the standards enables accurate quantitation of viral load.

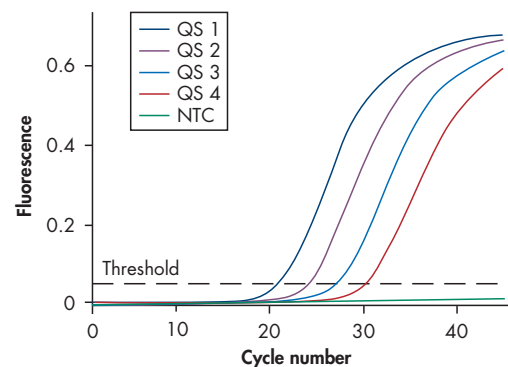
## Diagnostic evaluation and correlation with reference method

Comparison of the *artus* CMV RG PCR Kit with a reference method (COBAS AMPLICOR® CMV MONITOR® Test, Roche) shows close correlation (Table 4). If the results of the COBAS AMPLICOR CMV MONITOR Test are taken as reference, the diagnostic sensitivity of all samples of the *artus* CMV RG PCR Kit is 100%, and the diagnostic specificity is 84.8%. Further testing of the 22 discordant samples confirmed the results of the *artus* CMV RG PCR Kit. Therefore it can be assumed that the discrepancy is based on the higher sensitivity of the *artus* CMV RG PCR Kit.

**Table 5. Specifications of the *artus* CMV RG PCR Kit**

Analytical sensitivity*	57.1 copies/ml
Specificity	CMV (human herpesvirus 5)
Amplicon	105 bp region of the CMV genome

\* In consideration of the purification (QIAamp DSP Virus Kit), detection on the Rotor-Gene 3000. Equivalence between the Rotor-Gene 3000 and the Rotor-Gene Q/6000 was shown on the basis of technical specifications confirmed by analytical performance comparison.



**Figure 6. Detection of the quantitation standards.**

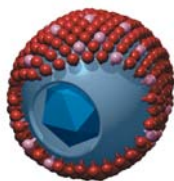
The quantitation standards (CMV QS 1–4) are detected in fluorescence channel Cycling Green of the Rotor-Gene Q. NTC: no template control (negative control).

**Table 4. Results of the comparative validation study**

		COBAS AMPLICOR CMV MONITOR Test		Total
		+	–	
<i>artus</i> CMV RG PCR Kit	+	11	22	33
	–	0	123	123

# Quantitative detection of Epstein-Barr virus specific DNA

The *artus* EBV RG PCR Kit is a ready-to-use molecular detection kit for real-time PCR on Rotor-Gene Q/6000 and Rotor-Gene 3000 instruments. The kit provides all necessary reagents optimized for rapid and sensitive detection of EBV DNA from human plasma, serum, CSF, or blood cells with highly accurate quantitation.

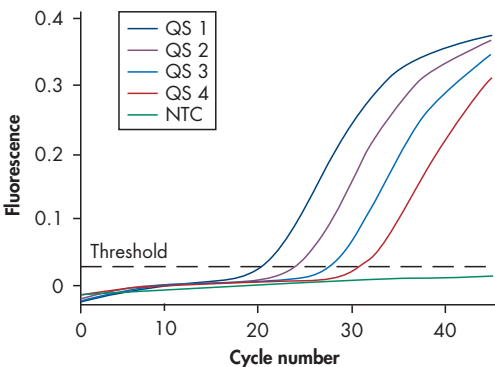


**The *artus* EBV RG PCR Kit provides:**

- Highly sensitive detection of as few as 1.02 copies/ $\mu$ l
- High reliability using the internal control
- Accurate quantitation of viral load over a very broad range
- Compliance with EU IVD Directive 98/79/EC

**Reliable EBV detection using real-time PCR**

The *artus* EBV RG PCR Kit is based on the amplification and simultaneous detection of a 97 bp region of the EBV genome using real-time PCR. The kit provides 4 EBV quantitation standards (Figure 7). Use of the standards enables accurate quantitation of viral load.



**Figure 7. Detection of the quantitation standards.**  
The quantitation standards (EBV RG QS 1–4) are detected in fluorescence channel Cycling Green of the Rotor-Gene Q.  
**NTC:** no template control (negative control).

**Table 6. Specifications of the *artus* EBV RG PCR Kit**

Analytical sensitivity	1.02 copies/ $\mu$ l
Specificity	EBV (human herpesvirus 4)
Amplicon	97 bp region of the EBV genome

# Detection of *C. trachomatis* specific DNA

The *artus C. trachomatis* Plus RG PCR Kit is a ready-to-use molecular detection kit for real-time PCR on Rotor-Gene Q/6000 and Rotor-Gene 3000 instruments. The kit provides all necessary reagents optimized for rapid and sensitive detection of *C. trachomatis* DNA from human urine, swab (eye, endocervical, or urethral), or semen samples.

## The *artus C. trachomatis* Plus RG PCR Kit provides:

- Highly sensitive detection of as few as 300 target copies/ml
- High reliability using the internal control
- Unsurpassed specificity using 2 target genes for detection
- Compliance with EU IVD Directive 98/79/EC

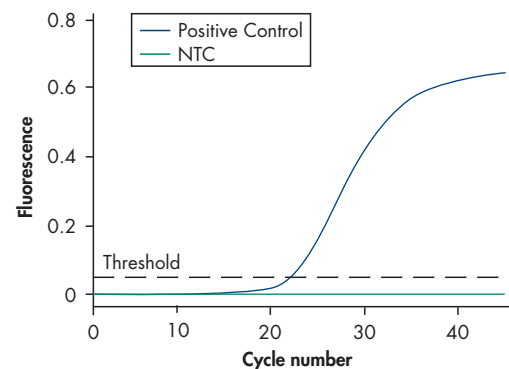


## Reliable *C. trachomatis* detection using real-time PCR

The *artus C. trachomatis* Plus RG PCR Kit is based on the amplification and simultaneous detection of two target genes of *C. trachomatis*, a region of the MOMP gene and of a region of the cryptic plasmid, using real-time PCR. The combined detection of two targets guarantees a highly sensitive and specific detection of all known *C. trachomatis* strains (including strains carrying deletions in the cryptic plasmid). The kit includes an external positive control (Figure 8).

## Diagnostic evaluation and correlation with reference method

Comparison of the *artus C. trachomatis* Plus RG PCR Kit with a reference method (COBAS Amplicor CT/NG Assay, Roche) shows close correlation (Table 7). For 65 tested prospective semen specimen, there was a 100% correlation of the *artus C. trachomatis* Plus RG PCR Kit compared with the COBAS Amplicor Assay. The inhibition rate was 0%. The diagnostic sensitivity was 100%. The diagnostic specificity of the *artus C. trachomatis* Plus RG PCR Kit was 100%.



**Figure 8. Detection of the positive control.** The positive control is detected in fluorescence channel Cycling Green of the Rotor-Gene Q. NTC: no template control (negative control).

**Table 8. Specifications of the *artus C. trachomatis* Plus RG PCR Kit**

Analytical sensitivity*	300 target copies/ml
Specificity	<i>C. trachomatis</i> , serovars A–K (including the Swedish variant with a 377 bp deletion in the cryptic plasmid)
Amplicons	106 bp region of the <i>C. trachomatis</i> MOMP gene, 111 bp region of the cryptic plasmid

\* In consideration of the purification (QIAamp DNA Mini Kit), detection on the Rotor-Gene 3000. Equivalence between the Rotor-Gene 3000 and the Rotor-Gene Q/6000 was shown on the basis of technical specifications confirmed by analytical performance comparison.

**Table 7. Results of the comparative validation study**

		COBAS Amplicor CT/NG Assay		Total
		+	–	
<i>artus C. trachomatis</i> Plus RG PCR Kit	+	16	0	16
	–	0	49	49



# Quantitative detection of DNA of all members of the *M. tuberculosis* complex

The *artus M. tuberculosis* RG PCR Kit is a ready-to-use molecular detection kit for real-time PCR on Rotor-Gene Q/6000 and Rotor-Gene 3000 instruments. The kit provides all necessary reagents optimized for rapid and sensitive detection of DNA of all members of the *M. tuberculosis* complex (*M. tuberculosis*, *M. africanum*, *M. bovis*, *M. bovis BCG*, *M. microti*, and *M. pinnipedi*) from sputum, bronchoalveolar lavage (BAL), bronchial secretion, CSF, stomach fluid, or peritoneal puncture.

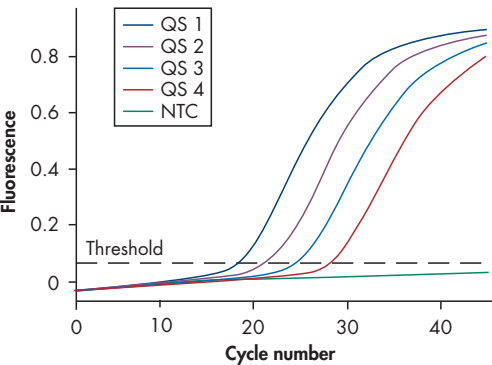


**The *artus M. tuberculosis* RG PCR Kit provides:**

- Highly sensitive detection of as few as 0.23 copies/μl
- High reliability using the internal control
- Accurate quantitation of pathogen load over a very broad range
- Compliance with EU IVD Directive 98/79/EC

**Reliable detection of DNA of all members of the *M. tuberculosis* complex using real-time PCR**

The *artus M. tuberculosis* RG PCR Kit is based on the amplification and simultaneous detection of a 159 bp region of the mycobacterial genome using real-time PCR. The kit provides 4 *M. tuberculosis* quantitation standards (Figure 9). Use of the standards enables accurate quantitation of pathogen load.



**Figure 9. Detection of the quantitation standards.**  
The quantitation standards (*M. tuberculosis* RG/TM QS 1–4) are detected in fluorescence channel Cycling Green of the Rotor-Gene Q. **NTC**: no template control (negative control).

**Table 9. Specifications of the *artus M. tuberculosis* RG PCR Kit**

Analytical sensitivity	0.23 copies/μl
Specificity	All members of the <i>M. tuberculosis</i> complex ( <i>M. tuberculosis</i> , <i>M. africanum</i> , <i>M. bovis</i> , <i>M. bovis BCG</i> , <i>M. microti</i> , and <i>M. pinnipedi</i> )
Amplicon	159 bp region of the mycobacterial genome



# The Rotor-Gene Q — designed for molecular diagnostics

QIAGEN's real-time PCR cycler, the Rotor-Gene Q, combines multiple optimized design features to provide the outstanding performance and reliable results that molecular diagnostics demand. Fluorescence channels span a wide optical range from UV to infrared wavelengths, and the Rotor-Gene Q can be used with various PCR assays, including assays based on intercalating dyes, hydrolysis or hybridization probes, or multiplex chemistries. Together with optimized *artus* real-time PCR kits, the Rotor-Gene Q enables streamlined analysis for molecular diagnostics workflows.

## Benefits of the Rotor-Gene Q:

- Outstanding thermal and optical performance due to rotary format
- An unmatched optical range spanning UV to infrared wavelengths
- Low maintenance and maximum convenience due to robust design
- High performance in pathogen detection with *artus* real-time PCR kits

## 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 10). Each tube spins in a chamber of moving air, keeping all samples at precisely the same temperature. When each tube aligns with the detection optics, the sample is illuminated and the fluorescent signal is rapidly collected. This results in sensitive, precise, and fast real-time PCR analysis and eliminates sample-to-sample variations and edge effects. These are unavoidable in traditional block-based instruments due to temperature gradients across the block and multiple, complex optical pathways.

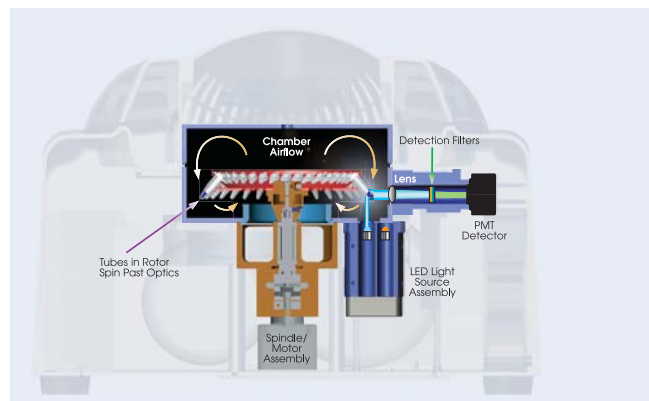
## The rotary design delivers:

- Well-to-well variation below  $\pm 0.01^{\circ}\text{C}$  (20 times less than block cyclers)
- Uniform detection eliminating the need for ROX reference dye
- Fast ramping and negligible equilibration times for short run times
- Complete confidence in your results!

## Software enables quantification and enhances data security

### 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



**Figure 10. 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.

## 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 only a couple of 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 and compare to those of alternative cyclers (Table 10).

**Table 10. Rotor-Gene Q specifications**

Dimensions and weight	Width 370 mm (14.6 in.) x Depth 420 mm (16.5 in.) x Height 275 mm (10.8 in.)
	Depth (door open): 560 mm (22 in.)
	Weight: 14 kg (31 lb.)
Thermal performance	Temperature uniformity: $\pm 0.01^{\circ}\text{C}$
	Temperature accuracy: $\pm 0.25^{\circ}\text{C}$
	Temperature resolution: $\pm 0.02^{\circ}\text{C}$
	Temperature range: Ambient to $99^{\circ}\text{C}$
	Temperature equilibration time: Zero seconds
Optical system	Peak ramp rate (air): $>15^{\circ}\text{C}/\text{second}$ heating; $>20^{\circ}\text{C}/\text{second}$ cooling
	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 $\mu\text{l}$ x 100 wells, 15–25 $\mu\text{l}$ recommended reaction volume
	Rotor-Disc 72: 0.1 ml x 72 wells, 15–25 $\mu\text{l}$ recommended reaction volume
	Strip Tubes 0.1 ml: 0.1 ml x 72 wells, 10–30 $\mu\text{l}$ recommended reaction volume, strips of 4 tubes and caps
	PCR Tubes 0.2 ml: 0.2 ml x 36 wells, 15–50 $\mu\text{l}$ 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

## Ordering Information

Product	Contents	Cat. no.
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*	Inquire
Rotor-Gene Q 5plex HRM	Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories, 1-year warranty on parts and labor*	Inquire
Rotor-Gene Q 6plex	Real-time PCR instrument with 6 channels (blue, green, yellow, orange, red, crimson), including laptop computer, software, accessories, 1-year warranty on parts and labor*	Inquire
<i>artus</i> HI Virus-1 RG RT-PCR Kit (24) <sup>†</sup>	For 24 reactions on Rotor-Gene Q instruments: 2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4513263
<i>artus</i> HBV RG PCR Kit (24) <sup>†</sup>	For 24 reactions on Rotor-Gene Q instruments: Master, 5 Quantitation Standards, Internal Control, Water (PCR grade)	4506263
<i>artus</i> CMV RG PCR Kit (24) <sup>†</sup>	For 24 reactions on Rotor-Gene Q instruments: Master, Mg-Solution, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4503263
<i>artus</i> EBV RG PCR Kit (24) <sup>†</sup>	For 24 reactions on Rotor-Gene Q instruments: Master, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4501263
<i>artus</i> C. trachomatis Plus RG PCR Kit (24) <sup>†</sup>	For 24 reactions on Rotor-Gene Q instruments: Master, Mg-Solution, Positive Control, Negative Control, Water (PCR grade)	4559263
<i>artus</i> M. tuberculosis RG PCR Kit (24) <sup>†</sup>	For 24 reactions on Rotor-Gene Q instruments: Master, Mg Solution, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4555263

\* Warranty PLUS 2 Basic (cat. no. 9241780) recommended: 3-year warranty, 5-working day response time, all labor, travel, and repair parts.

<sup>†</sup> 96-prep kits also available; please inquire.

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

**Find out more about the Rotor-Gene Q at [www.qiagen.com/goto/Rotor-GeneQ!](http://www.qiagen.com/goto/Rotor-GeneQ!)**



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For applicable countries:

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**China** ■ Orders 86-21-3865-3865 ■ Fax 86-21-3865-3965 ■ Technical 800-988-0325

**Denmark** ■ Orders 80-885945 ■ Fax 80-885944 ■ Technical 80-885942

**Finland** ■ Orders 0800-914416 ■ Fax 0800-914415 ■ Technical 0800-914413

**France** ■ Orders 01-60-920-920 ■ Fax 01-60-920-925 ■ Technical 01-60-920-930

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