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artus® BK Virus RG PCR Kit Handbook

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Σ 96 (catalog no. 4514265)

Version 1

IVD

Quantitative in vitro diagnostics

For use with Rotor-Gene® Q Instruments

CE

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Intended Use

The *artus* BK Virus PCR Kit is an in vitro nucleic acid amplification test for the quantitation of BK virus DNA in human plasma or urine. This diagnostic test kit utilizes the polymerase chain reaction (PCR) and is configured for use with Rotor-Gene Q Instruments.

Note: The *artus* BK Virus RG PCR Kit may not be used with Rotor-Gene Q 2plex Instruments.

Summary and Explanation

The *artus* BK Virus RG PCR Kit constitutes a ready-to-use system for the detection of BK virus DNA using polymerase chain reaction (PCR) on Rotor-Gene Q Instruments. The BK Virus RG Master contains reagents and enzymes for the specific amplification of a 274 bp region of the BK virus genome, and for the direct detection of the specific amplicon in fluorescence channel Cycling Green of the Rotor-Gene Q MDx, Rotor-Gene Q, or Rotor-Gene 6000.

In addition, the *artus* BK Virus RG PCR Kit contains a second heterologous amplification system to identify possible PCR inhibition. This is detected as an internal control (IC) in fluorescence channel Cycling Orange of the Rotor-Gene Q MDx, Rotor-Gene Q, or Rotor-Gene 6000. The detection limit of the analytical BK Virus PCR (see "Analytical sensitivity", page 22) is not reduced. External positive controls (BK Virus RG QS 1–4) are supplied, which allow the determination of the amount of viral DNA. For further information, see "Interpretation of Results", page 18.

Pathogen information

BK virus (BKV) is a DNA virus belonging to the polyomaviruses. Primary infection occurs mainly during childhood and is usually asymptomatic. The seroprevalence in adults is up to 90%. After primary infection, BKV remains latent in kidney cells and can be reactivated under immune deficiency conditions, such as transplantation.

BKV infection can be correlated with tubulointerstitial nephritis and ureteric stenosis in renal transplant recipients as well as hemorrhagic cystitis in bone marrow transplant recipients. It has also been associated with disease patterns for vasculopathy, pneumonitis, encephalitis, retinitis, and even multi-organ failure.

Persistent high-level BKV replication is the typical characteristic of polyomavirus-associated nephropathy (PAN) in renal transplantation patients. Clinically relevant infections are mostly limited to immunosuppressed individuals.

Principle of the Procedure

Pathogen detection by the polymerase chain reaction (PCR) is based on the amplification of specific regions of the pathogen genome. In real-time PCR the amplified product is detected via fluorescent dyes. These are usually linked to oligonucleotide probes that bind specifically to the amplified product. Monitoring the fluorescence intensities during the PCR run (i.e., in real-time) allows the detection and quantitation of the accumulating product without having to re-open the reaction tubes after the PCR run.*

Materials Provided

Kit contents

***artus* BK Virus RG PCR Kit**			**(24)**	**(96)**
Catalog no.			**4514263**	**4514265**
Number of reactions			**24**	**96**
Blue	BK Virus RG Master		2 x 12 reactions	8 x 12 reactions
Yellow	BK Virus RG Mg-Sol†	**Mg-Sol**	400 µl	400 µl
Red	BK Virus RG QS 1‡ (1 x 10^4 copies/µl)	**QS**	200 µl	200 µl
Red	BK Virus RG QS2‡ (1 x 10^3 copies/µl)	**QS**	200 µl	200 µl
Red	BK Virus RG QS3‡ (1 x 10^2 copies/µl)	**QS**	200 µl	200 µl
Red	BK Virus RG QS4‡ (1 x 10^1 copies/µl)	**QS**	200 µl	200 µl
Green	BK Virus RG IC§	**IC**	1000 µl	2 x 1000 µl
White	Water (PCR grade)		1000 µl	1000 µl
	Handbook	HB	1	1

† Magnesium solution.

‡ Quantitation standard.

§ Internal control.

* Mackay, I.M. (2004) Real-time PCR in the microbiology laboratory. Clin. Microbiol. Infect. **10**, 190.

Materials Required but Not Provided

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, consult the appropriate safety data sheets (SDSs), available from the product supplier.

Reagents

- DNA isolation kit (see "DNA isolation", page 9)

Consumables

- Sterile pipet tips with filters
- Strip Tubes and Caps, 0.1 ml, for use with 72-well rotor (cat. no. 981103 or 981106)
- Alternatively: PCR Tubes, 0.2 ml, for use with 36-well rotor (cat. no. 981005 or 981008)

Equipment

- Pipets (adjustable)*
- Vortex mixer*
- Benchtop centrifuge* with rotor for 2 ml reaction tubes
- Rotor-Gene Q MDx, Rotor-Gene Q, or Rotor-Gene Instrument*† with fluorescence channels for Cycling Green and Cycling Orange
- Rotor-Gene Q MDx/Rotor-Gene Q software version 1.7.94 or higher (Rotor-Gene 6000 software version 1.7.65)
- Cooling block (Loading Block 72 x 0.1 ml Tubes, cat. no. 9018901, or Loading Block 96 x 0.2 ml Tubes, cat. no. 9018905)

Warnings and Precautions

For in vitro diagnostic use

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at www.qiagen.com/safety where you can find, view, and print the SDS for each QIAGEN® kit and kit component.

Discard sample and assay waste according to your local safety regulations.

* Ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

† The *artus* BK Virus RG PCR Kit may not be used with Rotor-Gene Q 2plex Instruments.

General precautions

The user should always pay attention to the following:

- Use sterile pipet tips with filters.
- Store and extract positive materials (specimens, positive controls, and amplicons) separately from all other reagents, and add them to the reaction mix in a spatially separated facility.
- Thaw all components thoroughly at room temperature (15–25°C) before starting an assay.
- When thawed, mix the components (by pipetting repeatedly up and down or by pulse vortexing) and centrifuge briefly.
- Work quickly and keep components on ice or in the cooling block (72/96-well loading block).

Reagent Storage and Handling

The components of the *artus* BK Virus PCR Kit should be stored at –15°C to –30°C and are stable until the expiration date stated on the label. Repeated thawing and freezing (>2 x) should be avoided, as this may reduce assay sensitivity. If the reagents are to be used only intermittently, they should be frozen in aliquots. Storage at 2–8°C should not exceed a period of 5 hours.

Procedure

DNA isolation

The EZ1 DSP Virus Kit (QIAGEN, cat. no. 62724)* is validated for viral nucleic acid purification from human plasma or urine, for use with the *artus* BK Virus RG PCR Kit. Carry out the viral DNA purification according to the instructions in the *EZ1 DSP Virus Kit Handbook*, with a starting sample size of 400 µl.

Note: The *artus* BK Virus RG PCR Kit should not be used with phenol-based isolation methods.

Note: The use of carrier RNA is critical for extraction efficiency and, consequently, for DNA/RNA yield. Add the appropriate amount of carrier RNA to each extraction following the instructions in the *EZ1 DSP Virus Kit Handbook*.

Note: The internal control of the *artus* BK Virus RG PCR Kit can be used directly in the isolation procedure (see "Internal control", page 9).

Note: We strongly recommend to use the purified viral nucleic acids for PCR immediately after extraction using the EZ1 DSP Virus Kit. Alternatively, eluates can be stored for up to 3 days at 4°C before PCR analysis.

Internal control

An internal control (BK Virus RG IC) is supplied. This allows the user both to control the DNA isolation procedure and to check for possible PCR inhibition. For this application, add the internal control to the isolation at a ratio of 0.1 µl per 1 µl elution volume. For example, using the EZ1 DSP Virus Kit, if the viral nucleic acids are eluted in 60 µl Elution Buffer (AVE), then 6 µl of the internal control should be added initially.

Note: The internal control and carrier RNA (see "DNA isolation", page 9) should be added only to the mixture of lysis buffer and sample material or directly to the lysis buffer.

The internal control must not be added to the sample material directly. If added to the lysis buffer, note that the mixture of internal control and lysis buffer–carrier RNA has to be prepared freshly and used immediately (storage of the mixture at room temperature or in the fridge for only a few hours may lead to internal control failure and a reduced extraction efficiency).

Note: Do not add the internal control and the carrier RNA to the sample material directly.

* The EZ1 DSP Virus Kit is also available as CE-IVD-marked EASY*artus*® BK Virus RG PCR Kits, combined with the *artus* BK Virus RG PCR Kit (see page 29 for ordering information).

The internal control can optionally be used exclusively to check for possible PCR inhibition. For this application, add the internal control directly to the mixture of BK Virus RG Master and BK Virus RG Mg-Sol, as described in step 2b of the protocol (page 12).

Protocol: PCR and data analysis

Important points before starting

- Take time to familiarize yourself with the Rotor-Gene Q Instrument before starting the protocol. See the instrument user manual.
- Make sure that at least one quantitation standard as well as one negative control (Water, PCR grade) are included per PCR run. To generate a standard curve, use all 4 quantitation standards supplied (BK Virus RG QS 1–4) for each PCR run.

Things to do before starting

- Make sure that the cooling block (accessory of the Rotor-Gene Q Instrument) is precooled to 2–8°C.
- Before each use, all reagents need to be thawed completely, mixed (by repeated up and down pipetting or by quick vortexing), and centrifuged briefly.

Procedure

1. **Place the desired number of PCR tubes into the adapters of the cooling block.**
2. **If you are using the internal control to monitor the DNA isolation procedure and to check for possible PCR inhibition, follow step 2a. If you are using the internal control exclusively to check for PCR inhibition, follow step 2b.**

2a. **The internal control has already been added to the isolation (see "Internal control", page 9). In this case, prepare a master mix according to Table 1.**

The reaction mix typically contains all of the components needed for PCR except the sample.

Table 1. Preparation of master mix (internal control used to monitor DNA isolation and check for PCR inhibition)

Number of samples	1	12
BK Virus RG Master	7 µl	84 µl
BK Virus RG Mg-Sol	3 µl	36 µl
BK Virus RG IC	0 µl	0 µl
Total volume	**10 µl**	**120 µl**

2b. The internal control must be added directly to the mixture of BK Virus RG Master and BK Virus RG Mg-Sol. In this case, prepare a master mix according to Table 2.

The reaction mix typically contains all of the components needed for PCR except the sample.

Table 2. Preparation of master mix (internal control used exclusively to check for PCR inhibition)

Number of samples	1	12
BK Virus RG Master	7 µl	84 µl
BK Virus RG Mg-Sol	3 µl	36 µl
BK Virus RG IC	1.5 µl	18 µl
Total volume	**11.5 µl***	**138 µl***

* The volume increase caused by adding the internal control is neglected when preparing the PCR assay. The sensitivity of the detection system is not impaired.

3. Pipet 10 µl of the master mix into each PCR tube. Then add 15 µl of the eluted sample DNA (see Table 3). Correspondingly, 15 µl of at least one of the quantitation standards (BK Virus RG QS 1–4) must be used as a positive control and 15 µl of water (Water, PCR grade) as a negative control.

Table 3. Preparation of PCR assay

Number of samples	1	12
Master mix	10 µl	10 µl each
Sample	15 µl	15 µl each
Total volume	**25 µl**	**25 µl each**

4. **Close the PCR tubes. Make sure that the locking ring (accessory of the Rotor-Gene Instrument) is placed on top of the rotor to prevent accidental opening of the tubes during the run.**
5. **For the detection of BK virus DNA, create a temperature profile according to the following steps.**

Setting the general assay parameters	**Figures 1, 2, 3**
Initial activation of the hot-start enzyme	**Figure 4**
Amplification of the DNA	**Figure 5**
Adjusting the fluorescence channel sensitivity	**Figure 6**
Starting the run	**Figure 7**

All specifications refer to the Rotor-Gene Q MDx/Rotor-Gene Q software version 1.7.94 and Rotor-Gene 6000 software version 1.7.65. Please find further information on programming Rotor-Gene Instruments in the instrument user manual. In the illustrations these settings are framed in bold black. Illustrations are included for Rotor-Gene Q Instruments.

6. **First, open the "New Run Wizard" dialog box (Figure 1). Check the "Locking Ring Attached" box and click "Next".**

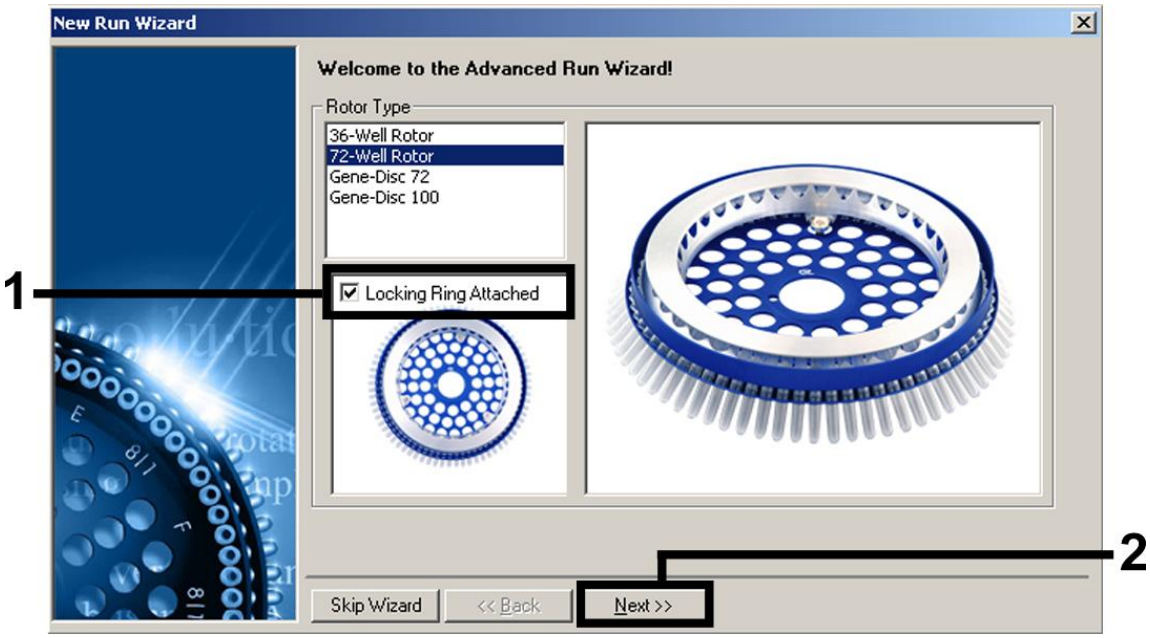

Figure 1. The "New Run Wizard" dialog box.

7. **Select *50* for the PCR reaction volume and click "Next" (Figure 2).**

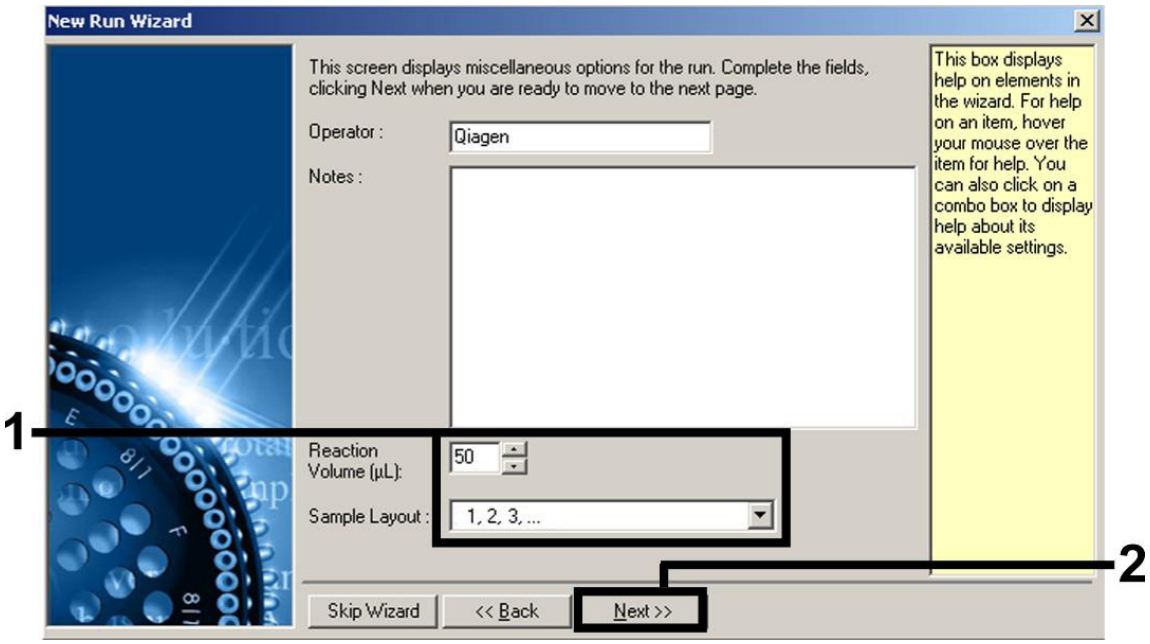

Figure 2. Setting the general assay parameters.

Note: Although the physical reaction volume is 25 µl, make sure to select *50* for the reaction volume in the Rotor-Gene software.

8. **Click the "Edit Profile" button in the next "New Run Wizard" dialog box (Figure 3), and program the temperature profile as shown in Figures 3–5).**

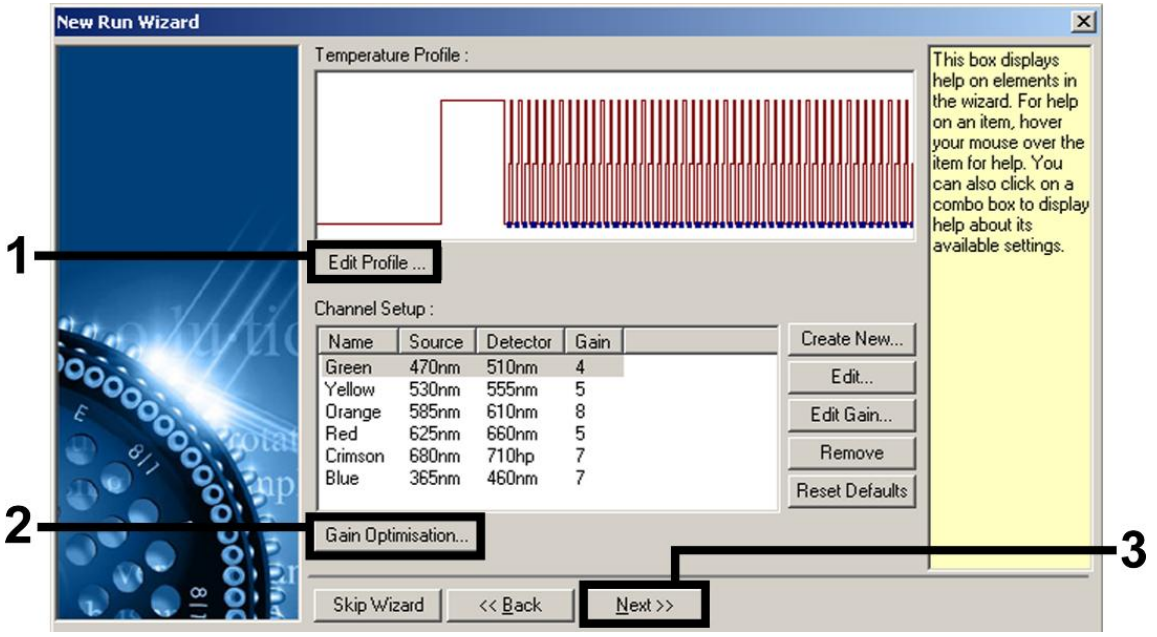

Figure 3. Editing the profile.

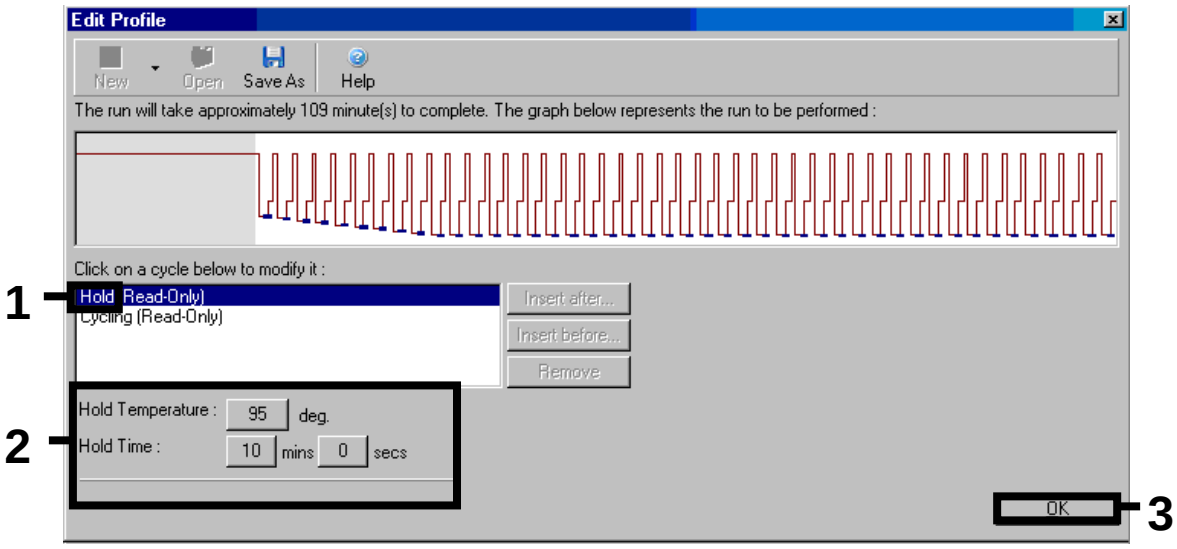

Figure 4. Initial activation of the hot-start enzyme.

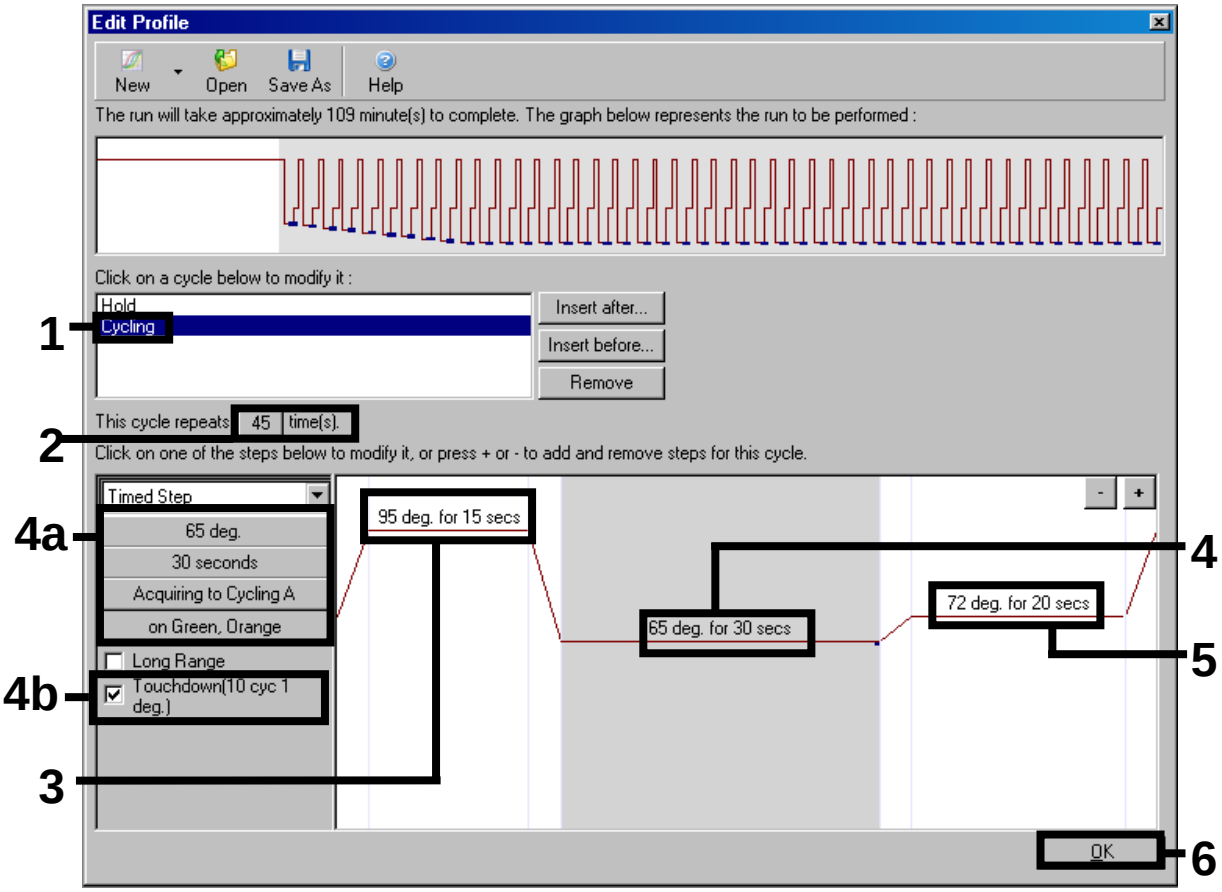

Figure 5. Amplification of the DNA. Make sure to activate the touchdown function for 10 cycles in the Annealing step.

9. **The detection range of the fluorescence channels has to be determined according to the fluorescence intensities in the PCR tubes. Click "Gain Optimisation" in the "New Run Wizard" dialog box (see Figure 3) to open the "Auto-Gain Optimisation Setup" dialog box. Set the calibration temperature to *65* to match the annealing temperature of the amplification program (Figure 6).**

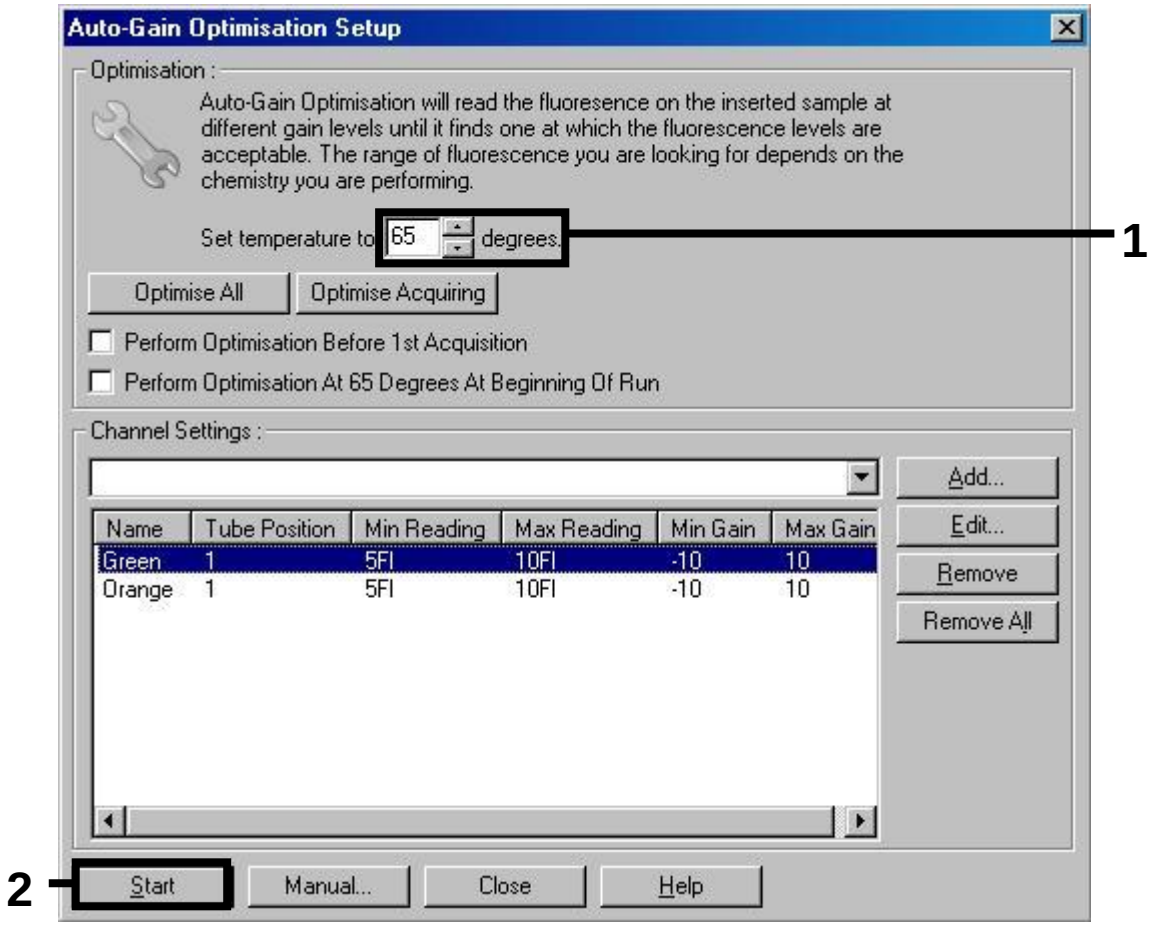

Figure 6. Adjusting the fluorescence channel sensitivity.

10. **The gain values determined by the channel calibration are saved automatically and are listed in the last menu window of the programming procedure (Figure 7). Click "Start Run".**

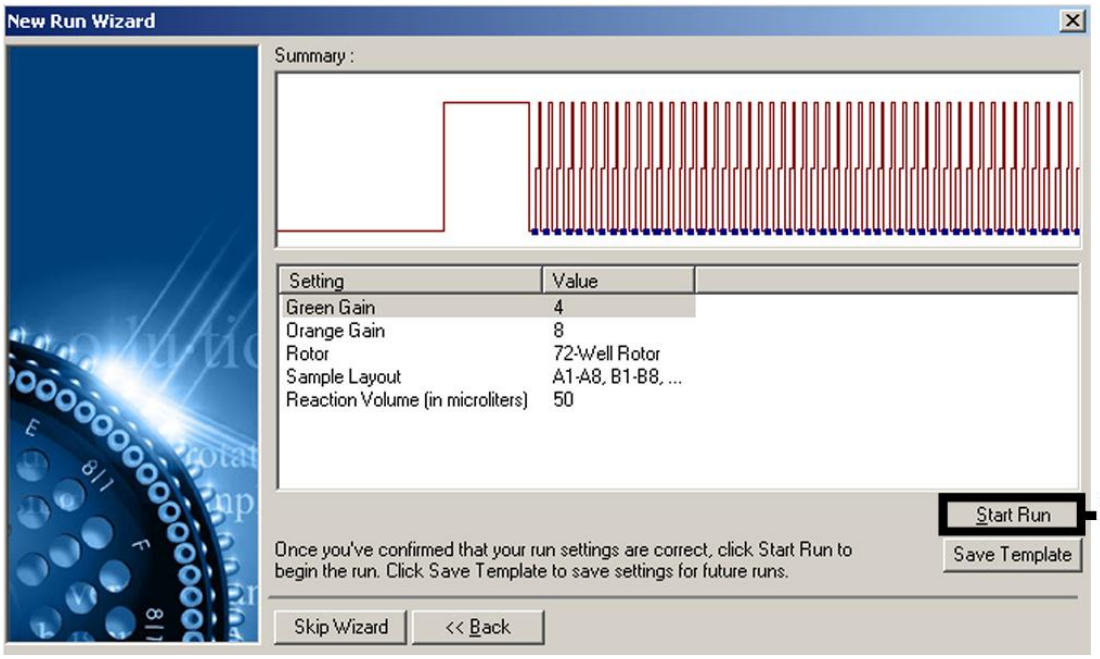

Figure 7. Starting the run.

Interpretation of Results

Quantitation

The enclosed quantitation standards (BK Virus RG QS 1–4) are treated as previously purified samples and the same volume is used (15 µl). To generate a standard curve on Rotor-Gene Q Instruments, all 4 quantitation standards should be used and defined in the "Edit Samples" dialog box as standards with the specified concentrations (see the instrument user manual).

Note: The quantitation standards are defined as copies/µl. The following equation has to be applied to convert the values determined using the standard curve into copies/ml of sample material:

$$\text{Result (copies/ml)} = \frac{\text{Result (copies/µl)} \times \text{Elution Volume (µl)}}{\text{Sample Volume (ml)}}$$

As a matter of principle the initial sample volume should be entered in the equation above. This has to be considered when the sample volume has been changed prior to the nucleic acid extraction (e.g., reducing the volume by centrifugation or increasing the volume by adding to the volume required for the isolation).

Results

Examples of positive and negative PCR reactions are given in Figure 8 and Figure 9.

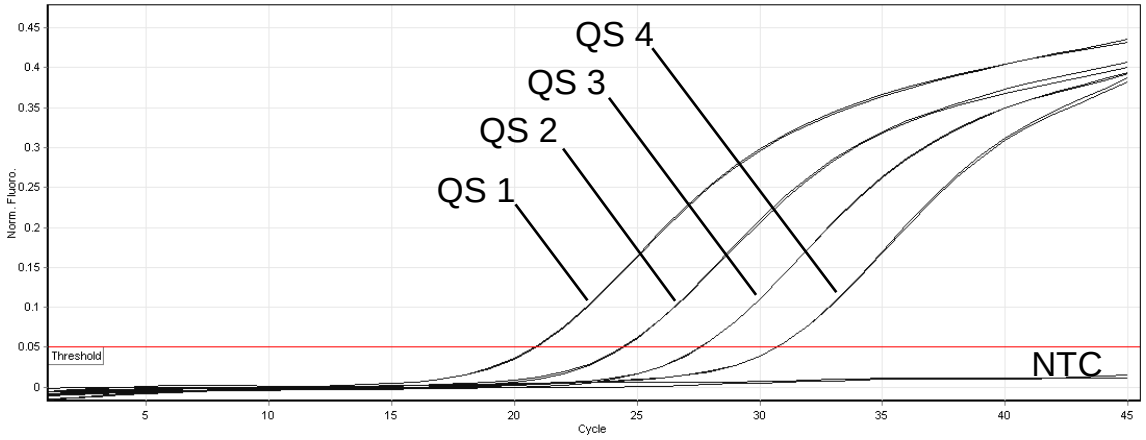

Figure 8. Detection of the quantitation standards (BK Virus RG QS 1–4) in fluorescence channel Cycling Green. NTC: No template control (negative control).

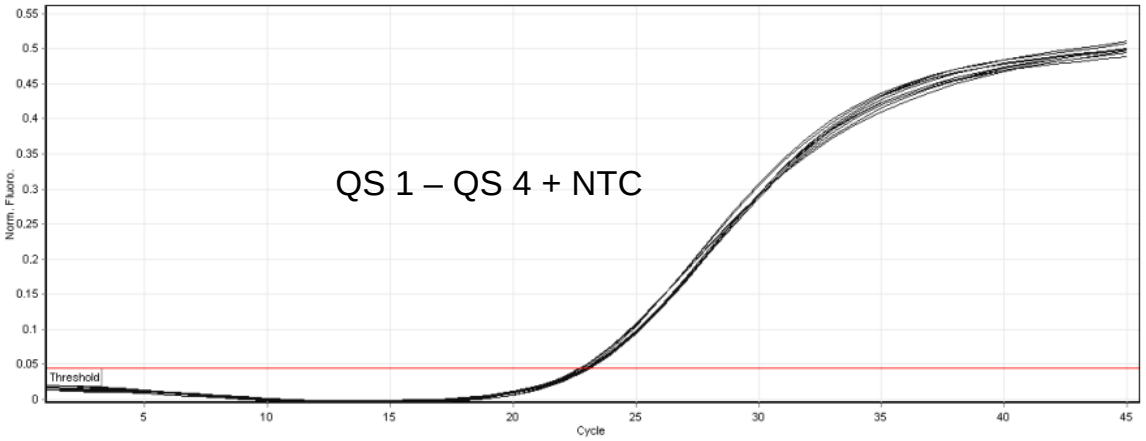

Figure 9. Detection of the internal control (IC) in fluorescence channel Cycling Orange with simultaneous amplification of the quantitation standards (BK Virus RG QS 1–4). NTC: No template control (negative control).

A signal is detected in fluorescence channel Cycling Green. The result of the analysis is positive: the sample contains BK virus DNA.

In this case, the detection of a signal in the Cycling Orange channel is dispensable, since high initial concentrations of BK virus DNA (positive signal in the Cycling Green channel) can lead to a reduced or absent fluorescence signal of the internal control in the Cycling Orange channel (competition).

In fluorescence channel Cycling Green no signal is detected. At the same time, a signal from the internal control appears in the Cycling Orange channel.
In the sample no BK virus DNA is detectable. It can be considered negative.

In the case of a negative BK Virus PCR, the detected signal of the internal control rules out the possibility of PCR inhibition.

No signal is detected in the Cycling Green or in the Cycling Orange channels.
No result can be concluded.

Information regarding error sources and their solution can be found in "Troubleshooting guide", below.

Troubleshooting guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: www.qiagen.com/FAQ/FAQList.aspx. The scientists in QIAGEN Technical Services are always happy to answer any questions you may have about either the information and protocols in this handbook or sample and assay technologies (for contact information, see back cover or visit www.qiagen.com).

	Comments and suggestions
No signal with positive controls (BK Virus RG QS 1–4) in fluorescence channel Cycling Green	
a) The selected fluorescence channel for PCR data analysis does not comply with the protocol	For data analysis select the fluorescence channel Cycling Green for the analytical BK Virus PCR and the fluorescence channel Cycling Orange for the internal control PCR.
b) Incorrect programming of the temperature profile of the Rotor-Gene Instrument	Compare the temperature profile with the protocol. See "Protocol: PCR and data analysis", page 11.
c) Incorrect configuration of the PCR	Check your work steps by means of the pipetting scheme, and repeat the PCR, if necessary. See "Protocol: PCR and data analysis", page 11.

	Comments and suggestions
d) The storage conditions for one or more kit components did not comply with the instructions given in "Reagent Storage and Handling" (page 8)	Check the storage conditions and the expiration date (see the kit label) of the reagents and use a new kit, if necessary.
e) The *artus* BK Virus RG PCR Kit has expired	Check the storage conditions and the expiration date (see the kit label) of the reagents and use a new kit, if necessary.

Weak or no signal of the internal control of a negative plasma or urine sample subjected to purification using the *artus* BK Virus RG PCR Kit in fluorescence channel Cycling Orange and simultaneous absence of a signal in channel Cycling Green

a) The PCR conditions do not comply with the protocol	Check the PCR conditions (see above) and repeat the PCR with corrected settings, if necessary.
b) The PCR was inhibited	Make sure that you use the recommended isolation method and closely follow the manufacturer's instructions.
c) DNA was lost during extraction	If the internal control was added to the extraction, an absent signal of the internal control can indicate the loss of DNA during the extraction. Make sure that you use the recommended isolation method (see "DNA isolation", page 9) and closely follow the manufacturer's instructions.
d) The storage conditions for one or more kit components did not comply with the instructions given in "Reagent Storage and Handling" (page 8)	Check the storage conditions and the expiration date (see the kit label) of the reagents and use a new kit, if necessary.
e) The *artus* BK Virus RG PCR Kit has expired	Check the storage conditions and the expiration date (see the kit label) of the reagents and use a new kit, if necessary.

	Comments and suggestions
Signals with the negative controls in fluorescence channel Cycling Green of the analytical PCR	
a) Contamination occurred during preparation of the PCR	Repeat the PCR with new reagents in replicates. If possible, close the PCR tubes directly after addition of the sample to be tested. Make sure to pipet the positive controls last. Make sure that work space and instruments are decontaminated at regular intervals.
b) Contamination occurred during extraction	Repeat the extraction and PCR of the sample to be tested using new reagents. Make sure that work space and instruments are decontaminated at regular intervals.

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of *artus* BK Virus RG PCR Kit is tested against predetermined specifications to ensure consistent product quality.

Limitations

The product is to be used by personnel specially instructed and trained in the in vitro diagnostics procedures only.

Strict compliance with the user manual is required for optimal PCR results.

Attention should be paid to expiration dates printed on the box and labels of all components. Do not use expired components.

Although rare, mutations within the highly conserved regions of the viral genome covered by the kit's primers and/or probe may result in underquantitation or failure to detect the presence of the virus in these cases. Validity and performance of the assay design are revised at regular intervals.

Performance Characteristics

Analytical sensitivity

To determine the analytical sensitivity of the *artus* BK Virus RG PCR Kit, a standard dilution series was set up from 10 to nominal 0.001 copy equivalents/µl and analyzed on the Rotor-Gene 6000 in combination with the *artus* BK Virus RG PCR Kit. Testing was carried out on 3 different days on

8 replicates. The results were determined by a probit analysis. A graphical illustration of the probit analysis on the Rotor-Gene 6000 is shown in Figure 10. The analytical detection limit of the *artus* BK Virus RG PCR Kit in combination with the Rotor-Gene Q MDx/Q/6000 is 0.195 copies/µl (p = 0.05). This means that there is a 95% probability that 0.195 copies/µl will be detected.

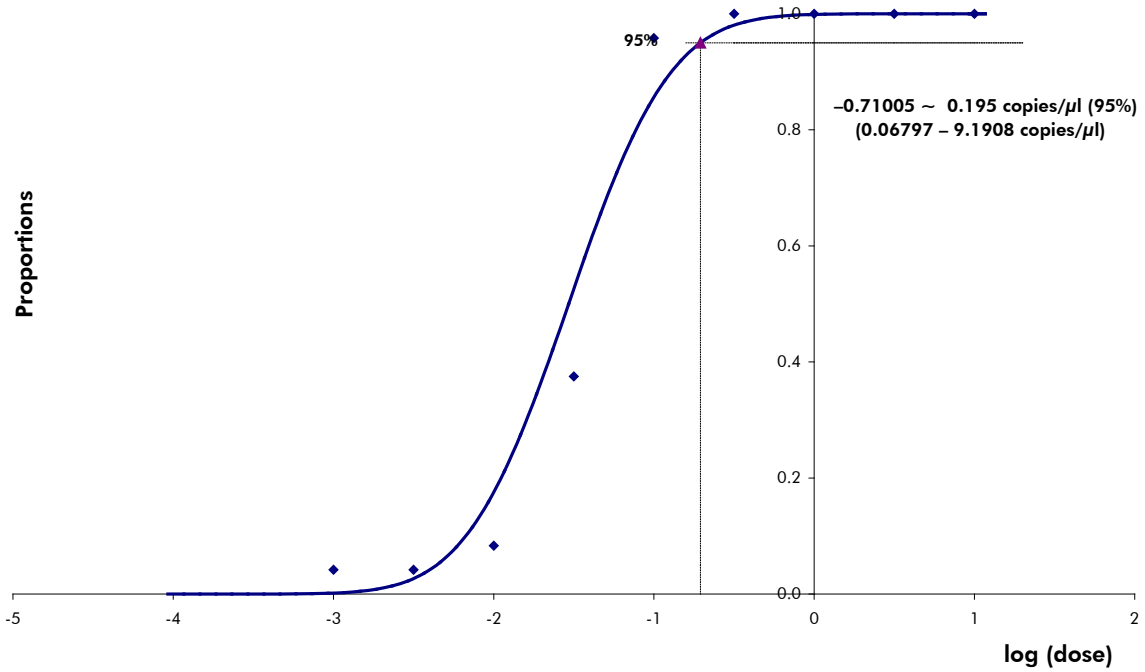

Figure 10. Probit analysis: BK Virus (Rotor-Gene 6000). Analytical sensitivity of the *artus* BK Virus RG PCR Kit on the Rotor-Gene 6000.

Specificity

The specificity of the *artus* BK Virus PCR Kit is first and foremost ensured by the selection of the primers and probes, as well as the selection of stringent reaction conditions. The primers and probes were checked for possible homologies to all published sequences in gene banks by sequence comparison analysis. The detectability of all relevant strains has thus been ensured by a database alignment and by a PCR run on Rotor-Gene Instruments with the following strains (see Table 4).

Table 4. Testing of the specificity of relevant strains

Virus	Strain	Source	BK Virus (Cycling Green)	Internal control (Cycling Orange)
BK virus	Dunlop	ATCC*	+	+
BK virus	Gardner	ATCC	+	+
BK virus	AB269822	Geneart	+	+
BK virus	S72390	Geneart	+	+

* American Type Culture Collection.

Moreover, the specificity was validated with 30 different BK virus negative plasma samples. These did not generate any signals with the BK virus specific primers and probes, which are included in the BK Virus RG Master.

A potential cross-reactivity of the *artus* BK Virus RG PCR Kit was tested using the control group listed in Table 5. None of the tested pathogens has been reactive. No cross-reactivities appeared with mixed infections.

Table 5. Testing the specificity of the kit with potentially cross-reactive pathogens

Control group	BK virus (Cycling Green)	Internal control (Cycling Orange)
Cytomegalovirus	–	+
Epstein-Barr virus	–	+
Human herpesvirus 1 (herpes simplex virus 1)	–	+
Human herpesvirus 2 (herpes simplex virus 2)	–	+
Human herpesvirus 3 (varicella-zoster virus)	–	+
Human herpesvirus 6	–	+
JC virus	–	+
Simian virus 40	–	+
Candida albicans	–	+

Precision

The precision data of the *artus* BK Virus RG PCR Kit have been collected by means of Rotor-Gene Instruments and allow the determination of the total variance of the assay. The total variance consists of the intra-assay variability (variability of multiple results of samples of the same concentration within one experiment), the inter-assay variability (variability of multiple results of the assay generated on different instruments of the same type by different operators within one laboratory) and the inter-batch variability (variability of multiple results of the assay using various batches). The data obtained were used to determine the standard deviation, the variance and the coefficient of variation for the pathogen specific and the internal control PCR.

Precision data of the *artus* BK Virus RG PCR have been collected using the quantitation standard of the lowest concentration (QS 4; 1 x 10^1 copies/µl). Testing was performed with 8 replicates. The precision data were calculated on basis of the C_T values of the amplification curves (C_T: threshold cycle, see Table 6). Based on these results, the overall statistical spread of any given sample with the mentioned concentration is 2.11% (C_T), and 3.59% (C_T) for the

detection of the internal control. These values are based on the totality of all single values of the determined variabilities.

Table 6. Precision data on basis of the C_T values

	C_T value	Standard deviation	Coefficient of variation (%)
Intra-assay variability: BK Virus RG QS 4	29.45	0.17	0.56
Intra-assay variability: Internal control	24.31	0.12	0.49
Inter-assay variability: BK Virus RG QS 4	29.42	0.25	0.85
Inter-assay variability: Internal control	23.30	0.77	3.30
Inter-batch variability: BK Virus RG QS 4	30.31	0.64	2.10
Inter-batch variability: Internal control	22.53	0.40	1.78
Total variance: BK Virus RG QS 4	29.80	0.63	2.11
Total variance: Internal control	23.12	0.83	3.59

Robustness

The verification of the robustness allows the determination of the total failure rate of the *artus* BK Virus RG PCR Kit. 30 BK virus negative samples were spiked with 1 copy/µl elution volume of BK virus control DNA (approximately fivefold concentration of the analytical sensitivity limit). After extraction using the EZ1® DSP Virus Kit (see "DNA isolation", page 9), these samples were analyzed with the *artus* BK Virus RG PCR Kit. For all 30 samples the failure rate was 0%. In addition, the robustness of the internal control was assessed by purification and analysis of 30 BK virus negative samples. The total failure rate was 0%. Inhibitions were not observed. Thus, the robustness of the *artus* BK Virus RG PCR Kit is ≥99%.

Reproducibility

Reproducibility data permit a regular performance assessment of the *artus* BK Virus RG PCR Kit as well as an efficiency comparison with other products. These data are obtained by the participation in established proficiency programs.

Diagnostic evaluation

Currently, the *artus* BK Virus RG PCR Kit is undergoing a series of evaluation studies.

References

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Symbols

 <N>	Contains reagents sufficient for <N> tests
	Use by
IVD	In vitro diagnostic medical device
REF	Catalog number
LOT	Lot number
MAT	Material number
COMP	Components
CONT	Contains

Number

Global Trade Item Number

Temperature limitation

Manufacturer

Consult instructions for use

Contact Information

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/Support or call one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit www.qiagen.com).

Ordering Information

Product	Contents	Cat. no.
artus BK Virus RG PCR Kit (24)	For 24 reactions: Master, 4 Quantitation Standards, Internal Control, Magnesium Solution, Water (PCR grade)	4514263
artus BK Virus RG PCR Kit (96)	For 96 reactions: Master, 4 Quantitation Standards, Internal Control, Magnesium Solution, Water (PCR grade)	4514265
EASY*artus* BK Virus RG PCR Kits — for fully CE-IVD-compliant integrated automated sample purification and pathogen detection		
EASY*artus* BK Virus RG PCR Kit 1	For 48 viral nucleic acid preps and 24 assays: 1 x EZ1 DSP Virus Kit, 1 x *artus* BK Virus RG PCR Kit (24)	EA11423
EASY*artus* BK Virus RG PCR Kit 2	For 48 viral nucleic acid preps and 48 assays: 1 x EZ1 DSP Virus Kit, 2 x *artus* BK Virus RG PCR Kit (24)	EA11424
EZ1 DSP Virus Kit — for automated, simultaneous purification of viral DNA and RNA from 1–14 human plasma, serum, or CSF samples		
EZ1 DSP Virus Kit (48)	For 48 viral nucleic acid preps: Prefilled Reagent Cartridges, Disposable Tip Holders, Disposable Filter-Tips, Sample Tubes, Elution Tubes, Buffers, Carrier RNA	62724
Rotor-Gene Q MDx and accessories		
Rotor-Gene Q MDx 5plex Platform	Real-time PCR cycler with 5 channels (green, yellow, orange, red, crimson), laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training not included	9002022

Product	Contents	Cat. no.
Rotor-Gene Q MDx 5plex System	Real-time PCR cycler with 5 channels (green, yellow, orange, red, crimson), laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training	9002023
Rotor-Gene Q MDx 5plex HRM Platform	Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training not included	9002032
Rotor-Gene Q MDx 5plex HRM System	Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training	9002033
Rotor-Gene Q MDx 6plex Platform	Real-time PCR instrument with 6 channels (blue, green, yellow, orange, red, crimson), including laptop comptuer, software, accessories: includes 1-year warranty on parts and labor, installation and training not included	9002042
Rotor-Gene Q MDx 6plex System	Real-time PCR instrument with 6 channels (blue, green, yellow, orange, red, crimson), including laptop computer, software, accessories: includes 1-year warranty on parts and labor, installation and training	9002043
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 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

Product	Contents	Cat. no.
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
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 10,000 reactions	981008

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