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artus® HBV QS-RGQ Kit Handbook

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Σ 72 (catalog no. 4506366)

Version 1

IVD

Quantitative in vitro diagnostics

For use with QIAsymphony® SP/AS and Rotor-Gene® Q Instruments

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Contents

Intended Use

The *artus* HBV QS-RGQ Kit is an in vitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human EDTA plasma. This diagnostic test kit utilizes the polymerase chain reaction (PCR) and is configured for use with the QIAsymphony SP/AS and Rotor-Gene Q instruments. For more information about specific human biological samples with which the kit has been validated, see the Application Sheets, available online at www.qiagen.com/products/artushbvpcrkitce.aspx.

QIAGEN continues to develop and validate further applications for *artus* QS-RGQ Kits, such as use with additional sample types. The most current version of this handbook and associated Application Sheets are available online at www.qiagen.com/products/artushbvpcrkitce.aspx.

The *artus* HBV QS-RGQ Kit is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiviral treatment as measured by changes in human EDTA plasma HBV DNA levels. The *artus* HBV QS-RGQ Kit is not intended to be used as a screening test for HBV or as a diagnostic test to confirm the presence of HBV infection.

For more information about specific human biological samples with which the kit has been validated, see the Application Sheets, available online at www.qiagen.com/products/artushbvpcrkitce.aspx.

As QIAGEN continuously monitors the assay's performance and validates new claims, the users are required to ensure that they work with the latest revision of the instruction for use.

Check availability of new electronic labeling revisions at www.qiagen.com/products/artushbvpcrkitce.aspx before test execution.

All kits can be used with the respective instruction elements as long as the version number of the handbook and other labeling information matches with the kit version number. The version number is visible on each kit box label. QIAGEN ensures compatibility between all test kit lots under the same version number.

Summary and Explanation

The *artus* HBV QS-RGQ Kit constitutes a ready-to-use system for the detection of HBV DNA using polymerase chain reaction (PCR) on Rotor-Gene Q Instruments with sample preparation and assay setup using the QIAsymphony SP/AS instruments. The HBV RG/TM Master contains reagents and enzymes for the specific amplification of a 134 bp region of the HBV genome, and for the direct

detection of the specific amplicon in fluorescence channel Cycling Green of the Rotor-Gene Q.

In addition, the *artus* HBV QS-RGQ Kit contains a second heterologous amplification system to identify possible PCR inhibition. This is detected as an internal control (IC) in fluorescence channel Cycling Yellow of the Rotor-Gene Q. The detection limit of the analytical HBV PCR is not reduced. External positive controls (HBV RG/TM QS 1–5) are supplied, which allow the determination of the amount of viral DNA. For further information, see the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.

Pathogen information

Hepatitis B virus (HBV) is mainly transmitted via blood or blood products. However, sexual, oral, and perinatal infections are also possible. Following a general malaise, including appetite loss, vomiting, and abdominal problems, about 10–20% of patients develop fever, exanthema (skin rash), as well as rheumatoid joint and muscle problems. 2–14 days later jaundice develops, which may be accompanied by itching. Fulminant hepatitis occurs in about 1% of all infected patients and is frequently fatal. 5–10% of hepatitis B patients develop chronic liver inflammation, which can progress to cirrhosis of the liver or primary liver cell carcinoma.

Materials Provided

Kit contents

***artus* HBV QS-RGQ Kit**			**(24)**	**(72)**
Catalog no.			**4506363**	**4506366**
Number of reactions			**24**	**72**
Blue	HBV RG/TM Master		3 x 360 µl	7 x 360 µl
Red	HBV RG/TM QS 1* (1 x 10^5 IU/µl)	QS	200 µl	200 µl
Red	HBV RG/TM QS 2* (1 x 10^4 IU/µl)	QS	200 µl	200 µl
Red	HBV RG/TM QS 3* (1 x 10^3 IU/µl)	QS	200 µl	200 µl
Red	HBV RG/TM QS 4* (1 x 10^2 IU/µl)	QS	200 µl	200 µl
Red	HBV RG/TM QS 5* (1 x 10^1 IU/µl)	QS	200 µl	200 µl
Green	HBV RG/TM IC†	IC	1000 µl	2 x 1000 µl
White	Water (PCR grade)		1000 µl	1000 µl
	Handbook	HB	1	1

* Quantitation standard.

† Internal control

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.

- Pipets (adjustable)* and sterile pipet tips with filters
- Vortex mixer*
- Benchtop centrifuge* with rotor for 2 ml reaction tubes, capable of centrifugation at 6800 x *g*

For sample preparation

- QIAsymphony SP instrument (cat. no. 9001297)*
- QIAsymphony AS instrument (cat. no. 9001301)*

For PCR

- Rotor-Gene Q MDx 5plex HRM or Rotor-Gene Q 5plex HRM instrument*
- Rotor-Gene Q software version 2.1, or higher
- Optional: Rotor-Gene AssayManager† version 1.0, or higher

Note: Additional information about materials required for specific applications is contained in the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.

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

† Rotor-Gene AssayManager is planned to be available by the end of 2012.

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.

For safety information for the purification kit used, see the relevant kit handbook. For safety information regarding instruments, see the relevant instrument user manual.

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

General precautions

Always pay attention to the following:

- Use sterile pipet tips with filters.
- During manual steps, keep tubes closed when possible and avoid contamination.
- 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. Ensure that no foam or bubbles are present in the reagent tubes.
- Do not mix components from kits with different lot numbers.
- Make sure that the required adapters are precooled to 2–8°C.
- Work quickly and keep PCR reagents on ice or in the cooling block before loading.
- Proceed continuously from one part of the workflow to the next. Do not exceed 30 minutes of transfer time between each module (QIAsymphony SP to QIAsymphony AS to Rotor-Gene Q).

Reagent Storage and Handling

The components of the *artus* HBV QS-RGQ 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 performance.

Specimen Handling and Storage

Information about specimen handling and storage for specific applications is contained in the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.

Procedure

Getting started on the QIAsymphony SP/AS instruments

Close all drawers and the hoods.

Switch on the QIAsymphony SP/AS instruments, and wait until the "Sample Preparation" screen appears and the initialization procedure has finished.

Log into the instrument (drawers will unlock).

Viral DNA purification

The *artus* HBV QS-RGQ Kit has been validated with a viral DNA purification step performed on the QIAsymphony SP using a QIAsymphony DSP Virus/Pathogen Kit. See the *QIAsymphony DSP Virus/Pathogen Handbook* for all the information on how to prepare the reagent cartridge for the sample purification step on the QIAsymphony SP.

Using an internal control and carrier RNA (CARRIER)

Using QIAsymphony DSP Virus/Pathogen Kits in combination with the *artus* HBV QS-RGQ Kit requires introduction of the internal control (HBV RG/TM IC) into the purification procedure to monitor the efficiency of sample preparation and downstream assay. In addition, QIAsymphony DSP Virus/Pathogen Kits may require the preparation of carrier RNA (CARRIER). For specific information regarding the internal control and the use of carrier RNA (CARRIER), see the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.

Assay Control Sets and Assay Parameter Sets

Assay Control Sets are the combination of a protocol plus additional parameters, such as internal control, for sample purification on the QIAsymphony SP. A default Assay Control Set is preinstalled for each protocol.

Assay Parameter Sets are the combination of an assay definition with additional parameters defined, such as replicate count and number of assay standards, for assay setup on the QIAsymphony AS.

For integrated runs on the QIAsymphony SP/AS, the Assay Parameter Set is directly linked to an upfront Assay Control Set specifying the associated sample purification process.

Yields of nucleic acids

Eluates prepared with carrier RNA (CARRIER) may contain much more carrier RNA (CARRIER) than target nucleic acids. We recommend using quantitative amplification methods to determine yields.

Storing nucleic acids

For short-term storage of up to 24 hours, we recommend storing purified nucleic acids at 2–8°C. For long-term storage of over 24 hours, we recommend storage at –20°C.

Protocol: DNA isolation and assay setup on the QIAsymphony SP/AS

The following description is a general protocol for using QIAsymphony DSP Virus/Pathogen Kits. Detailed information for a specific application, including volumes and tubes, is provided in the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.

Important points before starting

- Ensure that you are familiar with operating the QIAsymphony SP/AS instruments. Refer to the user manuals supplied with your instruments and the most current versions available online at www.qiagen.com/products/qiasymphonyrgq.aspx for operating instructions.
- Before using a reagent cartridge (RC) for the first time, check that Buffers QSL2 and QSB1 in the cartridge (RC) do not contain a precipitate. If necessary, remove the troughs containing Buffers QSL2 and QSB1 from the reagent cartridge (RC) and incubate for 30 minutes at 37°C with occasional shaking to dissolve precipitate. Make sure to replace the troughs in the correct positions. If the reagent cartridge (RC) is already pierced, make sure that the troughs are sealed with Reuse Seal Strips and incubate the complete reagent cartridge (RC) for 30 minutes at 37°C with occasional shaking in a water bath.*
- Try to avoid vigorous shaking of the reagent cartridge (RC) otherwise foam may be generated, which can lead to liquid-level detection problems.
- Work quickly and keep PCR reagents on ice or in the cooling block before loading.
- The reagent volumes are optimized for 24 or 72 reactions per kit per run (cat. nos. 4506363 and 4506366 respectively).
- Before each use, all reagents need to be thawed completely, mixed (by repeated up and down pipetting or by quick vortexing), and centrifuged for at least 3 seconds at 6800 x *g*. Avoid foaming of the reagents.
- Eluates from the sample preparation and all components of the *artus* HBV QS-RGQ Kit have been shown to be stable onboard the instrument for at least the normal time required for sample purification for 96 samples and assay setup of 72 assays, including up to 30 minutes transfer time from the QIAsymphony SP to the QIAsymphony AS and up to 30 minutes transfer time from the QIAsymphony AS to the Rotor-Gene Q.

* Ensure that instruments have been checked, maintained, and calibrated regularly according to the manufacturer's instructions.

Things to do before starting

- Prepare all required mixtures. If needed, prepare mixtures containing carrier RNA (CARRIER) and internal controls just before starting. For more information, see the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.
- Before starting the procedure, ensure that the magnetic particles are fully resuspended. Vortex the trough containing the magnetic particles vigorously for at least 3 minutes before first use.
- Before loading the reagent cartridge (RC), remove the cover from the trough containing the magnetic particles and open the enzyme tubes. Make sure that the enzyme rack has been equilibrated to room temperature (15–25°C).
- Make sure that the piercing lid (PL) is placed on the reagent cartridge (RC) and the lid of the magnetic-particle trough has been removed or, if using a partially used reagent cartridge (RC), make sure the Reuse Seal Strips have been removed.
- If samples are bar coded, orient samples in the tube carrier so that the bar codes face the bar code reader within the "Sample" drawer at the left side of the QIAsymphony SP.

Procedure

Viral DNA purification on the QIAsymphony SP

1. **Close all drawers and the hoods of the QIAsymphony SP/AS instruments.**
2. **Switch on the instruments, and wait until the "Sample Preparation" screen appears and the initialization procedure has finished.**
   The power switch is located at the bottom, left corner of the QIAsymphony SP.
3. **Log in to the instruments.**
4. **Prepare the following drawers according to the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.**
   - "Waste" drawer; when prepared, perform an inventory scan.
   - "Eluate" drawer; when prepared, perform an inventory scan.
   - "Reagents and Consumables" drawer; when prepared, perform an inventory scan.
   - "Sample" drawer

5. **Using the "Integrated run" setup on the QIAsymphony touchscreen, enter the required information for each batch of samples to be processed. Select an Assay Parameter Set for the run, and assign it and the corresponding AS batch to the samples.**

   Information about the Assay Parameter Set and preselected elution volume is provided on the relevant Application Sheet.

   For more information about integrated runs on the QIAsymphony SP/AS, see the instrument user manuals.

6. **When setting up an integrated run, check for correct assignment of sample labware, sample type (sample, EC+, and EC–), and volumes.**

   Information about consumables and components to load in each drawer is provided on the relevant Application Sheet.

7. **After information about all batches of the integrated run has been entered, click the "Ok" button to exit the "Integrated run" setup. The status of all batches within the overview of the integrated run changes from "LOADED" to "QUEUED". As soon as one batch is queued the "Run" button appears. Press the "Run" button to start the procedure.**

   All processing steps are fully automated.

Loading the QIAsymphony AS drawers for assay setup

8. **After queuing an integrated run, open the QIAsymphony AS drawers. The required components to be loaded are shown on the touchscreen.**
9. **Always make sure to do the following before the integrated run.**
   - Insert the tip chute
   - Discard the tip disposal bag
   - Install an empty tip disposal bag
10. **Define and load assay rack(s). Assay rack(s), in precooled adapter(s), are loaded onto the "Assay" slot(s). Information about the assay racks is provided on the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.**
11. **Check the temperature of the cooling positions.**

    When the target cooling temperatures are reached, the small asterisk next to each slot will appear green.

12. **Combine all tubes of HBV RG/TM Master in a single kit into one tube before use.**

    Note: Viscous reagents can be difficult to handle with manual pipets. Make sure to transfer the entire volume of the Master in the tube.

13. **Fill each reagent tube with the required volume of appropriate reagent according to the loading information given by the instrument software.**

    Note: Before each use, all reagents need to be thawed completely, mixed (by repeated up and down pipetting or by quick vortexing), and centrifuged for at least 3 seconds at 6800 x *g*. Avoid bubbles or foaming, which could cause detection errors. Work quickly and keep PCR components on ice or in the cooling block before loading.

14. **Load the reagent rack, and place the reagent tubes, without lids, into the appropriate positions of precooled adapters for reagents according to the relevant Application Sheet.**
15. **Load disposable filter-tips into the "Eluate and Reagents" and "Assays" drawers, according to the required number of each tip type indicated on the relevant Application Sheet.**
16. **Close the "Eluate and Reagents" and "Assays" drawers.**
17. **Upon closing each drawer, press "Scan" to start the inventory scan for each drawer.**

    The inventory scan checks the slots, adapters, filter-tips, and the tip chute, as well as the correct loading of specific reagent volumes. If required, correct any errors.

    The assay setup will start automatically after the purification step on the QIAsymphony SP is completed and the eluate racks are transferred to the QIAsymphony AS.

18. **After the run is finished, press "Remove" in the assay setup "Overview" screen. Open the "Assays" drawer and unload the assay rack(s).**
19. **Download the result and cycler files.**
20. **If multiple batches on the QIAsymphony AS are configured in an integrated run, reload the QIAsymphony AS drawers, starting at step 8.**
21. **Proceed to "Protocol: PCR on the Rotor-Gene Q", page 16.**
22. **Perform the regular maintenance of the QIAsymphony AS during the PCR run on the Rotor-Gene Q or later.**

    Since the workflow is an integrated operation, clean all instruments at the end of the completed workflow.

    Follow the maintenance instructions in the *QIAsymphony SP/AS User Manual — General Description*. Make sure to carry out maintenance regularly to minimize the risk of cross-contamination.

Protocol: PCR on the Rotor-Gene Q

Important points before starting

- Take time to familiarize yourself with the Rotor-Gene Q before starting the protocol. See the instrument user manual.
- For automatic interpretation of the PCR results, Rotor-Gene AssayManager* may be used instead of Rotor-Gene Q software.
- Make sure that at all 5 quantitation standards as well as at least one negative control (Water, PCR grade) are included per PCR run. To generate a standard curve, use all 5 quantitation standards supplied (HBV RG/TM QS 1–5) for each PCR run.

Procedure

1. **Close the PCR tubes, and place them in the 72-Well Rotor of the Rotor-Gene Q. Make sure to transfer the Rotor-Gene Q 4-strip tubes in the correct orientation, so that the position indices of the cooling adapter and the rotor match. 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.**
2. **Transfer the cycler file from the QIAsymphony AS to the Rotor-Gene Q computer.**
3. **For the detection of HBV DNA, create a temperature profile and start the run according to the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx. Software-specific information about programming the Rotor-Gene Q is provided in the relevant Protocol Sheet "Settings to run *artus* QS-RGQ Kits" at www.qiagen.com/products/artushbvpcrkitce.aspx.**

* Rotor-Gene AssayManager is planned to be available by the end of 2012.

Interpretation of Results

See the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx for detailed information about interpretation of results.

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
General handling	
Error message displayed in the touchscreen	If an error message is displayed during a protocol run, refer to the user manuals supplied with your instruments.
Precipitate in reagent trough of opened cartridge of the QIAsymphony DSP Virus/Pathogen Kit	
a) Buffer evaporation	Excessive evaporation may lead to increased salt concentration or decreased alcohol concentrations in buffers. Discard reagent cartridge (RC). Make sure to seal buffer troughs of a partially used reagent cartridge (RC) with Reuse Seal Strips when not being used for purification.
b) Storage of reagent cartridge (RC)	Storage of reagent cartridge (RC) under 15°C may lead to formation of precipitates. If necessary, remove the troughs containing Buffers QSL2 and QSB1 from the reagent cartridge (RC) and incubate in a water bath* at 37°C for 30 minutes with occasional shaking to dissolve precipitate. Make sure to replace the troughs in the correct positions. If the reagent cartridge (RC) is already pierced, make sure that the troughs are reclosed with Reuse Seal Strips and incubate the complete reagent cartridge (RC) in a water bath* at 37°C for 30 minutes with occasional shaking.

* Ensure that instruments have been checked, maintained, and calibrated regularly according to the manufacturer's instructions.

Comments and suggestions	
Low yield of nucleic acids	
a) Magnetic particles were not completely resuspended	Before starting the procedure, ensure that the magnetic particles are fully resuspended. Vortex for at least 3 minutes before use.
b) Frozen samples were not mixed properly after thawing	Thaw frozen samples with mild agitation to ensure thorough mixing.
c) Carrier RNA (CARRIER) not added	Reconstitute carrier RNA (CARRIER) in Buffer AVE (AVE) and mix with appropriate volume of Buffer AVE (AVE) as described in the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx. Repeat the purification procedure with new samples.
d) Degraded nucleic acids	Samples were stored incorrectly or subjected to too many freeze–thaw cycles. Repeat the purification procedure with new samples.
e) Incomplete sample lysis	Before use, check that Buffer QSL2 and QSB1 do not contain precipitates. If necessary, remove the troughs containing Buffers QSL1 and QSB1 from the reagent cartridge (RC) and incubate for 30 minutes at 37°C with occasional shaking to dissolve precipitate. If the reagent cartridge (RC) is already pierced, make sure that the troughs are reclosed with Reuse Seal Strips, and incubate the complete reagent cartridge (RC) for 30 minutes at 37°C with occasional shaking in a water bath.*
f) Clogging of pipet tip due to insoluble material	Insoluble material was not removed from the sample prior to starting the QIAsymphony purification procedure. To remove insoluble material for viral applications, centrifuge the sample at 3000 x *g* for 1 minute, and transfer the supernatant to a new sample tube.

* Ensure that instruments have been checked, maintained, and calibrated regularly according to the manufacturer's instructions.

QIAsymphony AS detects insufficient Master

Not all of the Master transferred to tube	Combine all tubes of HBV RG/TM Master in a single kit into one tube before use. Viscous reagents can be difficult to handle with manual pipets. Make sure to transfer the entire volume of the Master in the tube. For viscous reagents, we recommend aspirating an extra volume of 5% when using manual pipets (e.g., adjust the pipet to 840 µl for an 800 µl volume). Alternatively, after slowly dispensing the liquid and performing a blowout at the target tube's wall, remove the tip from the liquid, release the pipet plunger, and wait for an additional 10 seconds. Residual liquid will flow down the tip and can be blown out by pressing the pipet plunger a second time. The use of PCR grade filter-tips labeled as "low retention" can improve the recovery of liquid.

No signal with positive controls (HBV RG/TM QS 1–5) 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 HBV PCR and the fluorescence channel Cycling Yellow 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 the relevant Application Sheet and Protocol Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.
c) Incorrect configuration of the PCR	Make sure that assay setup was performed correctly and that the correct Assay Parameter Set was used. Repeat the PCR, if necessary. See the relevant Application Sheet at www.qiagen.com/products/artushbvpcrkitce.aspx.

	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* HBV QS-RGQ 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 sample subjected to purification using the QIAsymphony DSP Virus/Pathogen Kit in fluorescence channel Cycling Yellow 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 validated isolation method (see "Protocol: DNA isolation and assay setup on the QIAsymphony SP/AS", page 12) and closely follow the instructions.
c) DNA was lost during extraction	An absent signal of the internal control can indicate the loss of DNA during the extraction. Make sure that you use the validated isolation method (see "Protocol: DNA isolation and assay setup on the QIAsymphony SP/AS", page 12) and closely follow the instructions. See also "Low yield of nucleic acids", above.
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* HBV QS-RGQ 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 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* HBV QS-RGQ Kit is tested against predetermined specifications to ensure consistent product quality.

Limitations

All reagents may exclusively be used in in vitro diagnostics.

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

See www.qiagen.com/products/artushbvpcrkitce.aspx for performance characteristics of the *artus* HBV QS-RGQ Kit.

References

QIAGEN maintains a large, up-to-date online database of scientific publications utilizing QIAGEN products. Comprehensive search options allow you to find the articles you need, either by a simple keyword search or by specifying the application, research area, title, etc.

For a complete list of references, visit the QIAGEN Reference Database online at www.qiagen.com/RefDB/search.asp or contact QIAGEN Technical Services or your local distributor.

Symbols

 <N>	Contains reagents sufficient for <N> reactions
	Use by
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number
	Components
	Contains
	Number
	Global Trade Item Number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Caution

Contact Information

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/Support, call 00800-22-44-6000, or contact 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 HBV QS-RGQ Kit (24)	For 24 reactions: Master, 5 Quantitation Standards, Internal Control, Water (PCR grade)	4506363
artus HBV QS-RGQ Kit (72)	For 72 reactions: Master, 5 Quantitation Standards, Internal Control, Water (PCR grade)	4506366
QIAsymphony RGQ system		
QIAsymphony RGQ, System	QIAsymphony SP, QIAsymphony AS, Rotor-Gene Q MDx 5plex HRM, required accessories and consumables, installation and training	9001850

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.

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The purchase of this product allows the purchaser to use it for the performance of diagnostic services for human in vitro diagnostics. No general patent or other license of any kind other than this specific right of use from purchase is granted hereby.

Trademarks: QIAGEN®, QIAsymphony®, *artus*®, Rotor-Gene® (QIAGEN Group).

The *artus* HBV QS-RGQ Kit is a CE-marked diagnostic kit according to the European In Vitro Diagnostic Directive 98/79/EC. Not available in all countries.

Limited License Agreement

Use of this product signifies the agreement of any purchaser or user of the *artus* HBV QS-RGQ Kit to the following terms:

1. The *artus* HBV QS-RGQ Kit may be used solely in accordance with the artus *HBV QS-RGQ Kit Handbook* and for use with components contained in the Kit only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this Kit with any components not included within this Kit except as described in the artus *HBV QS-RGQ Kit Handbook* and additional protocols available at www.qiagen.com.
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