



- EN** Please note that the QIAGEN® kit packed with this Important Note can be stored at -15 to -30°C , including all components, even if not explicitly stated on every component label.
- CS** Nezapomeňte, že sada QIAGEN, k níž je přibaleno toto Důležité oznámení, může být uchovávána při -15 až -30°C , a to včetně všech součástí, pokud není výslovně uvedeno jinak na štítku každé součásti.
- DA** Vær opmærksom på, at QIAGEN-kittet, som indeholder denne vigtige meddelelse, kan opbevares ved -15 til -30°C . Dette gælder alle komponenterne, også selvom dette ikke er udtrykkeligt angivet på den enkelte komponentetiket.
- DE** Bitte beachten Sie, dass der QIAGEN-Kit, inklusive aller Komponenten, der diesen wichtigen Hinweis enthält, bei einer Temperatur zwischen -15 bis -30°C gelagert werden muss, auch wenn dies nicht explizit in jedem Komponentenlabel erwähnt wird.
- EL** Παρακαλούμε σημειώστε ότι το kit QIAGEN που είναι συσκευασμένο με αυτήν τη Σημαντική σημείωση μπορεί να φυλαχθεί σε θερμοκρασία -15 έως -30°C , συμπεριλαμβανομένων όλων των συστατικών, ακόμα και αν δεν δηλώνεται ρητά στην επισήμανση του κάθε συστατικού.
- ES** Le informamos de que el kit QIAGEN que se le entrega con esta Nota importante se puede conservar entre -15 y -30°C , incluidos todos sus componentes, incluso aunque esta información no aparezca mencionada en cada una de las etiquetas de los componentes.



- FR** Veuillez noter que le kit QIAGEN emballé avec cette note importante peut être conservé à une température de -15 à -30 °C, y compris tous ses composants, même si cela n'est pas explicitement spécifié sur l'étiquette de chaque composant.
- IT** Si prega di notare che il kit QIAGEN che riporta la dicitura Nota Importante, deve essere conservato, inclusi tutti i suoi componenti, tra i -15 e i -30 °C, anche se non esplicitamente dichiarato sull'etichetta di ciascun componente.
- NO** Legg merke til at QIAGEN-settet som kommer med denne viktige beskjeden, kan oppbevares ved -15 til -30 °C. Dette omfatter alle komponentene, selv når dette ikke er uttrykkelig angitt på komponentetikettene.
- PL** Należy zauważyć, że zestaw QIAGEN z niniejszą ważną informacją w opakowaniu można przechowywać w temperaturze -15 do -30 °C, łącznie ze wszystkimi komponentami, nawet jeśli nie jest to wyraźnie podane na etykietach poszczególnych komponentów.
- PT** Por favor, note que o kit QIAGEN embalado com a presente "Nota Importante" pode ser armazenado entre -15 a -30 °C, incluindo todos os componentes, mesmo que não explicitamente declarado em cada etiqueta do componente.
- SV** Observera att QIAGEN-kitet som är förpackat med detta viktiga meddelande kan förvaras vid -15 till -30 °C, inklusive alla komponenter, även om detta inte uttryckligen anges på varje komponentetikett.

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May 2012

artus[®] HCV QS-RGQ Kit Handbook

 24 (catalog no. 4518363)

 72 (catalog no. 4518366)

Version 1

IVD

Quantitative in vitro diagnostics

For use with QIAasymphony[®] SP/AS and Rotor-Gene[®] Q Instruments

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Intended Use

The *artus* HCV QS-RGQ Kit is an in vitro nucleic acid amplification test for the quantitation of hepatitis C virus (HCV) RNA in human EDTA plasma. This diagnostic test kit utilizes the reverse transcription polymerase chain reaction (RT-PCR) and is configured for use with the QIA Symphony 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/artushcsvgpckitce.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/artushcsvgpckitce.aspx.

The *artus* HCV 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 HCV RNA levels. The *artus* HCV QS-RGQ Kit is not intended to be used as a screening test for HCV or as a diagnostic test to confirm the presence of HCV 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/artushcsvgpckitce.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/artushcsvgpckitce.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* HCV QS-RGQ Kit constitutes a ready-to-use system for the detection of HCV RNA using polymerase chain reaction (PCR) on Rotor-Gene Q Instruments with sample preparation and assay setup using the QIA Symphony SP/AS instruments. The Hep. C Virus RG Master A and B contain reagents and enzymes for the specific amplification of a 240 bp region of the HCV genome,

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

In addition, the *artus* HCV 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 Orange of the Rotor-Gene Q. The detection limit of the analytical HCV PCR is not reduced. External positive controls (Hep. C Virus RG QS 1–4) are supplied, which allow the determination of the amount of viral RNA. For further information, see the relevant Application Sheet at www.qiagen.com/products/artushcivrpgpckitce.aspx.

Pathogen information

Hepatitis C is a liver inflammation caused by the virus of the same name. As opposed to the other hepatitis viruses A, B, D, or E, infection with the hepatitis C virus (HCV) leads, in a high number of cases, to chronic liver disease. An infection with HCV often produces no symptoms for a relatively long period of time. For this reason, most patients are not aware of their HCV infection. Therapy, however, is most effective in the earliest stages of the disease. Currently, interferon α (in combination with Ribavirin) is the only proven, effective treatment. However, it is also known that only some chronic hepatitis C patients respond to interferon therapy. Hence, under certain circumstances, this expensive patient treatment can be unfavorable and may have serious side effects such as a debilitation of the immune system, leading to exacerbations (e.g., lip herpes, shingles).

Materials Provided

Kit contents

artus HCV QS-RGQ Kit		(24)	(72)
Catalog no.		4518363	4518366
Number of reactions		24	72
Blue	Hep. C Virus RG Master A	4 x 144 µl	8 x 144 µl
Violet	Hep. C Virus RG Master B	4 x 216 µl	8 x 216 µl
Red	Hep. C Virus RG QS 1* (10 ⁴ IU/µl) QS	200 µl	200 µl
Red	Hep. C Virus RG QS 2* (10 ³ IU/µl) QS	200 µl	200 µl
Red	Hep. C Virus RG QS 3* (10 ² IU/µl) QS	200 µl	200 µl
Red	Hep. C Virus RG QS 4* (10 ¹ IU/µl) QS	200 µl	200 µl
Green	Hep. C Virus RG IC [†] IC	1000 µl	2 x 1000 µl
White	Water (PCR grade)	1000 µl	1000 µl
	Handbook 	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 material safety data sheets (MSDSs), 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/artushcivrpgpckitce.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 material safety data sheets (MSDSs). These are available online in convenient and compact PDF format at www.qiagen.com/support/MSDS.aspx where you can find, view, and print the MSDS 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.

24-hour emergency information

Emergency medical information in English, French, and German can be obtained 24 hours a day from:

Poison Information Center Mainz, Germany

Tel: +49-6131-19240

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* HCV QS-RGQ Kit should be stored at –20°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/artushcivrqpckitce.aspx.

Procedure

Getting started on the QIA Symphony SP/AS instruments

Close all drawers and the hoods.

Switch on the QIA Symphony 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 RNA purification

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

Using an internal control and carrier RNA (CARRIER)

Using QIA Symphony DSP Virus/Pathogen Kits in combination with the *artus* HCV QS-RGQ Kit requires introduction of the internal control (Hep. C Virus RG IC) into the purification procedure to monitor the efficiency of sample preparation and downstream assay. In addition, QIA Symphony 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/artushcvrgpckitce.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 QIA Symphony 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 QIA Symphony AS.

For integrated runs on the QIA Symphony 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: RNA isolation and assay setup on the QIA Symphony SP/AS

The following description is a general protocol for using QIA Symphony 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/artushcvrgpckitce.aspx.

Important points before starting

- Ensure that you are familiar with operating the QIA Symphony 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. 4518363 and 4518366, 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* HCV 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 QIA Symphony SP to the QIA Symphony AS and up to 30 minutes transfer time from the QIA Symphony 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/artushcivrqpckitce.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 RNA 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/artushcivrqpckitce.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/artushcvrgqpcrkitce.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 HCV RG Master A in a single kit into one tube before use. Combine all tubes of HCV RG Master B 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: RT-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: RT-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 4 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 4 quantitation standards supplied (Hep. C Virus RG QS 1–4) 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 HCV RNA, create a temperature profile and start the run according to the relevant Application Sheet at www.qiagen.com/products/artushcivrqpckitce.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/artushcivrqpckitce.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/artushcvrgpckitce.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.
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Precipitate in reagent trough of opened cartridge of the QIA Symphony 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/artushcvrgpckitce.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.

Comments and suggestions

QIA Symphony AS detects insufficient Master

Not all of the Master transferred to tube

Combine all tubes of HCV RG Master A in a single kit into one tube before use. Combine all tubes of HCV RG Master B 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 μ l for an 800 μ l 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 (Hep. C 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 HCV 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 the relevant Application Sheet and Protocol Sheet at www.qiagen.com/products/artushcvgpckitce.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/artushcvgpckitce.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 9) 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* HCV 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 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 validated isolation method (see "Protocol: RNA isolation and assay setup on the QIASymphony SP/AS", page 12) and closely follow the instructions.
- c) RNA was lost during extraction An absent signal of the internal control can indicate the loss of RNA during the extraction. Make sure that you use the validated isolation method (see "Protocol: RNA 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 9) 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* HCV 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* HCV 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/artushcvrgpckitce.aspx for performance characteristics of the *artus* HCV 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

	Contains reagents sufficient for <N> reactions
	Use by
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number
	Components
	Contains
	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.
<i>artus</i> HCV QS-RGQ Kit (24)	For 24 reactions: 2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4518363
<i>artus</i> HCV QS-RGQ Kit (72)	For 72 reactions: 2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)	4518366
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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