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QIASymphony[®] DSP Virus/Pathogen Kit Instructions for Use (Handbook)

 192 (catalog no.937036)

 96 (catalog no. 937055)

Version 1

IVD

QIASymphony DSP Virus/Pathogen Mini Kit

QIASymphony DSP Virus/Pathogen Midi Kit

CE

REF 937036, 937055



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Sample & Assay Technologies

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Contents

| | |
|---|-----------|
| Intended Use | 4 |
| Summary and Explanation | 4 |
| Principle of the Procedure | 5 |
| Materials Provided | 6 |
| Kit contents | 7 |
| Materials Required but not Provided | 8 |
| Warnings and Precautions | 9 |
| Reagent Storage and Handling | 12 |
| Specimen Handling and Storage | 12 |
| Procedure | 13 |
| Automated purification on the QIA Symphony SP | 13 |
| Protocol: | |
| ■ General Purification Protocol | 19 |
| Troubleshooting Guide | 23 |
| Quality Control | 26 |
| Limitations | 26 |
| Symbols | 27 |
| Contact Information | 28 |
| Ordering Information | 29 |

Intended Use

The QIA Symphony DSP Virus/Pathogen Mini Kit and QIA Symphony DSP Virus/Pathogen Midi Kit utilize magnetic-particle technology for automated isolation and purification of nucleic acids from biological specimens.

These products are intended to be used by professional users, such as technicians and physicians who are trained in molecular biological techniques.

The QIA Symphony DSP Virus/Pathogen system is intended for in vitro diagnostic use.

Summary and Explanation

QIA Symphony DSP Virus/Pathogen Kits are intended to be used only in combination with the QIA Symphony SP. QIA Symphony DSP Virus/Pathogen Kits provide reagents for fully automated and simultaneous purification of viral nucleic acids. The kits can be used to purify nucleic acids from a broad range of DNA and RNA viruses as well as bacterial DNA from Gram-negative and Gram-positive bacteria. However, performance characteristics for every virus or bacteria species have not been established and must be validated by the user. Magnetic-particle technology enables purification of high-quality nucleic acids that are free of proteins, nucleases, and other impurities. The purified nucleic acids are ready for direct use in downstream applications, such as amplification or other enzymatic reactions. The QIA Symphony SP performs all steps of the purification procedure. Up to 96 samples, in batches of up to 24, are processed in a single run.

Principle of the Procedure

QIASymphony technology combines the speed and efficiency of silica-based nucleic acid purification with the convenient handling of magnetic particles (Figure 1). The purification procedure is designed to ensure safe and reproducible handling of potentially infectious samples, and comprises 4 steps: lyse, bind, wash, and elute (see flowchart, page 6). The user can choose between different elution volumes.

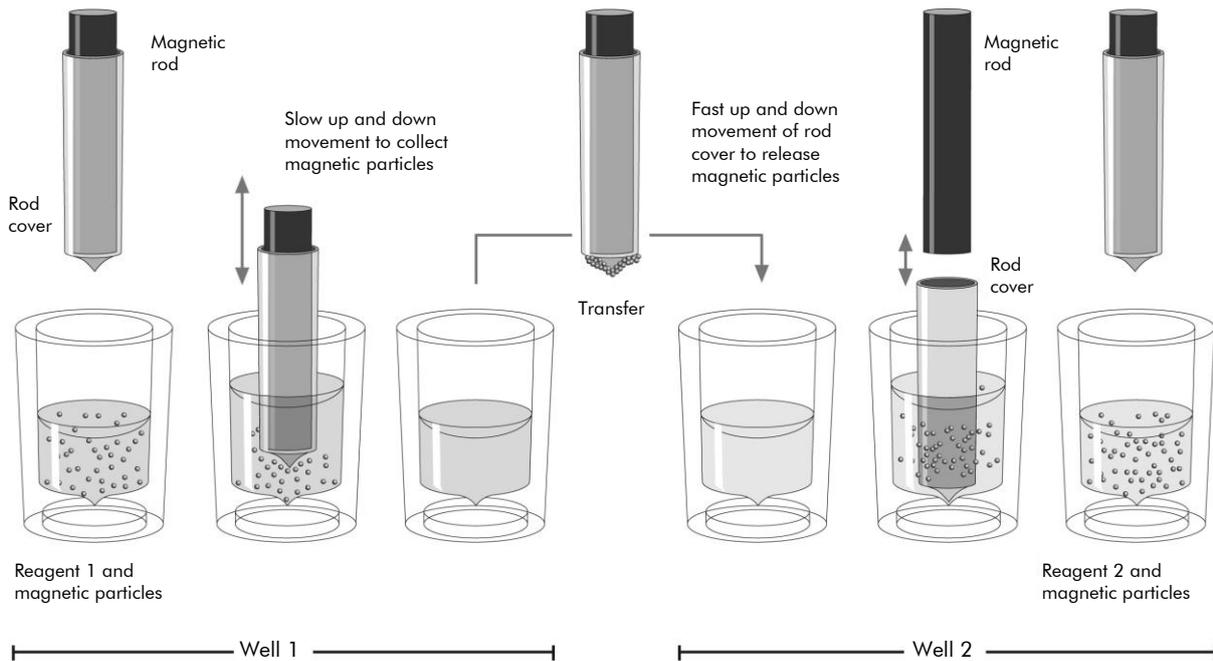
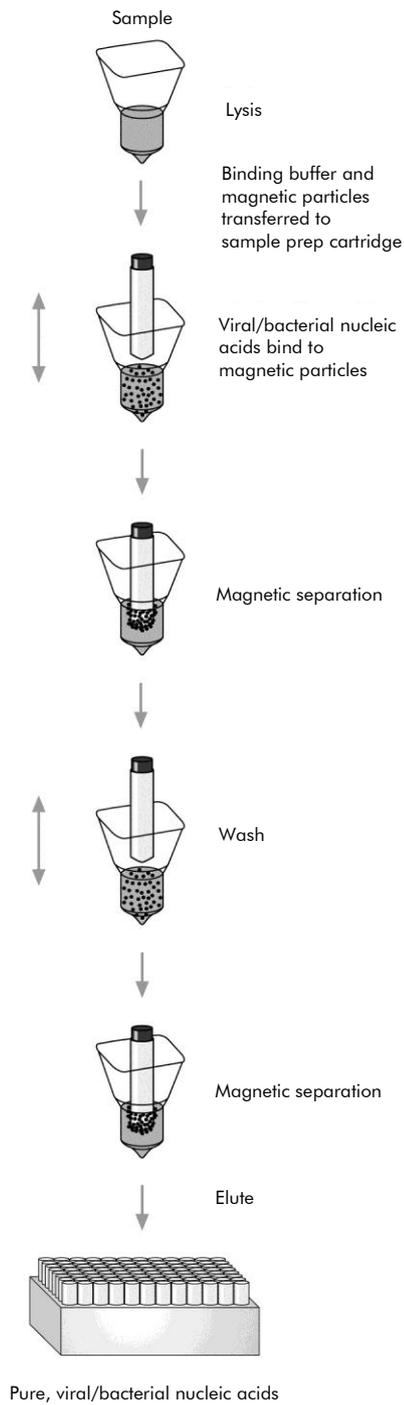


Figure 1. Schematic of the QIASymphony SP principle. The QIASymphony SP processes a sample containing magnetic particles as follows: A magnetic rod protected by a rod cover enters a well containing the sample and attracts the magnetic particles. The magnetic rod cover is positioned above another well and the magnetic particles are released. The QIASymphony SP uses a magnetic head containing an array of 24 magnetic rods, and can therefore process up to 24 samples simultaneously. Steps 1 and 2 are repeated several times during sample processing.

QIAsymphony Virus/ Pathogen Procedure



Fully automated nucleic acid purification on the QIAsymphony SP

Materials Provided

Kit contents

| QIAasymphony DSP Virus/Pathogen Kit | | | Mini | Midi |
|--|------------------------------------|--------------------------------------|---------------|---------------|
| Catalog no. | | | 937036 | 937055 |
| Number of preps* | | | 192 | 96 |
| RC | Reagent Cartridge [†] | REAG CART [¶] | 2 | 2 |
| ER | Enzyme Rack | | 2 | 2 |
| PL | Piercing Lid | | 2 | 2 |
| AVE | Buffer AVE (20 ml) [‡] | ELU BUF [¶] | 2 | 2 |
| AVE | Buffer AVE (2 ml) [‡] | ELU BUF [¶] | 2 | 2 |
| CARRIER | Carrier RNA | CAR RNA [¶] | 2 x 1350 µg | 2 x 1350 µg |
| RSS | Reuse Seal Set [§] | | 2 | 2 |
| | Instructions for Use (Handbook) | | 1 | 1 |

* Number of preps depends on the protocol used.

[†] Contains guanidine salts. Not compatible with disinfectants containing bleach. See page 9 for safety information.

[‡] Contains sodium azide as a preservative.

[§] A Reuse Seal Set (RSS) contains 8 Reuse Seal Strips.

[¶] See page 27 for symbols list with definitions.

Materials Required but not Provided

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) available from the product supplier.

- Sample Prep Cartridges, 8-well (cat. no. 997002)
- 8-Rod Covers (cat. no. 997004)
- Filter-Tips, 200 μ l and 1500 μ l (cat. nos. 990332 and 997024)
- Sample tubes, see the relevant protocol sheet available at www.qiagen.com/goto/dsphandbooks
- Vortexer

For pathogen complex protocols

- Buffer ATL (cat. no. 939016)

For using internal controls

- Sample tubes, 14 ml 17 x 100 mm polystyrene, round-bottom tubes from Corning (cat. no. 352051, www.corning.com)

Note: BD was the previous supplier of cat. no. 352051 and Corning, Inc. is the new supplier.

- Sample tubes, 2 ml sample tubes, with screw caps or without screw caps, from Sarstedt (e.g., cat. nos. 72.693 and 72.694, www.sarstedt.com)

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.



CAUTION: DO NOT add bleach or acidic solutions directly to the sample preparation waste.

Buffers in the reagent cartridge (RC) contain guanidine salts, which can form highly reactive compounds when combined with bleach. If liquid containing these buffers is spilt, clean with suitable laboratory detergent and water. If the spilt liquid contains potentially infectious agents, clean the affected area first with laboratory detergent and water, and then with 1% (v/v) sodium hypochlorite.

The following hazard and precautionary statements apply to components of QIAAsymphony DSP Virus/Pathogen Kits.

Buffer QSB1



Contains: Brij 58; guanidine thiocyanate; isopropanol. Danger! May be harmful if swallowed or in contact with skin. Causes severe skin burns and eye damage. May cause drowsiness or dizziness. Harmful to aquatic life with long lasting effects. Highly flammable liquid and vapor. Contact with acids liberates very toxic gas. Dispose of contents/container to an approved waste disposal plant. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Store in a well-ventilated place. Keep container tightly closed. Wear protective gloves/protective clothing/eye protection/face protection.

MBS

Warning! Causes mild skin irritation. If skin irritation occurs: Get medical advice/attention.

Proteinase K



Contains: Proteinase K. Danger! Causes mild skin irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Avoid breathing dust/fume/gas/mist/vapors/spray. Dispose of contents/container to an approved waste disposal plant. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Wear respiratory protection.

QSL2



Contains: Brij 58; guanidine thiocyanate. Danger! Harmful if swallowed. May be harmful in contact with skin or if inhaled. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Dispose of contents/container to an approved waste disposal plant. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician. Store locked up. Wear protective gloves/protective clothing/eye protection/face protection.

QSW1



Contains: ethanol; guanidine hydrochloride; lithium chloride. Warning! May be harmful if swallowed. Causes skin irritation. Causes serious eye irritation. Flammable liquid and vapor. Dispose of contents/container to an approved waste disposal plant. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Store in a well-ventilated place. Keep cool. Wear protective gloves/protective clothing/eye protection/face protection.

QSW2



Contains: ethanol. Danger! Causes serious eye irritation. Highly flammable liquid and vapor. Dispose of contents/container to an approved waste disposal plant. If eye irritation persists: Get medical advice/attention. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Store in a well-ventilated place. Keep cool. Wear protective gloves/protective clothing/eye protection/face protection.

QSW5



Contains: ethanol; guanidine hydrochloride. Danger! May be harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation. Highly flammable liquid and vapor. Dispose of contents/container to an approved waste disposal plant. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Store in a well-ventilated place. Keep cool. Wear protective gloves/protective clothing/eye protection/face protection.

Reagent Storage and Handling

The QIASymphony DSP Virus/Pathogen Kits should be stored at room temperature (15–25°C). The magnetic particles in the reagent cartridges (RC) remain active when stored at this temperature. Do not store reagent cartridges (RC) at temperatures below 15°C.

Store lyophilized carrier RNA (CARRIER) and Buffer AVE (AVE) at room temperature.

QIASymphony DSP Virus/Pathogen Kits contain ready-to-use proteinase K solution that can be stored at room temperature.

When stored properly, the kit is stable until the expiration date on the kit box.

Partially used reagent cartridges (RC) can be stored for a maximum of 4 weeks, enabling cost-efficient reuse of reagents and more flexible sample processing. If a reagent cartridge (RC) is partially used, replace the cover of the trough containing the magnetic particles and seal the reagent cartridge (RC) with the provided Reuse Seal Strips immediately after the end of the protocol run to avoid evaporation.

Running batches with low sample numbers (<24) will potentially reduce the total number of sample preparations possible per cartridge.

To avoid reagent evaporation, the reagent cartridge (RC) should be open for a maximum of 15 hours (including run times) at a maximum environmental temperature of 30°C.

Avoid exposure of the reagent cartridges (RC) to UV light (e.g., used for decontamination) as exposure may cause accelerated aging of the reagent cartridges (RC) and buffers.

Note: The label on the QIASymphony DSP Virus/Pathogen Kit box displays the expiration date of the kit. The result file documents the expiration dates for only the reagent cartridge (RC) and Buffer ATL (if required).

Specimen Handling and Storage

Prevent formation of foam in or on the samples. Depending on the starting material, sample pretreatment may be required. Samples should be equilibrated to room temperature (15–25°C) before starting the run.

For more information about the automated procedure (including information about sample tubes that can be used with specific protocols) and specific sample pretreatments, see the relevant protocol sheet available at www.qiagen.com/goto/dsphandbooks.

Procedure

Automated purification on the QIASymphony SP

The QIASymphony SP makes automated sample preparation easy and convenient. Samples, reagents and consumables, and eluates are separated in different drawers. Simply load samples, reagents provided in special cartridges, and preracked consumables in the appropriate drawer before a run. Start the protocol and remove purified nucleic acids from the “Eluate” drawer after processing. Refer to the user manuals supplied with your instrument for operating instructions.

Note: Optional maintenance is not mandatory for instrument function, but is highly recommended to reduce risk of contamination.

The range of protocols available is continually expanding, and additional QIAGEN protocols can be downloaded free of charge at www.qiagen.com/goto/dsphanbooks.

Loading reagent cartridges (RC) into the “Reagents and Consumables” drawer

Reagents for purification of DNA are contained in an innovative reagent cartridge (RC) (see Figure 2). Each trough of the reagent cartridge (RC) contains a particular reagent, such as magnetic particles, lysis buffer, wash buffer, or elution buffer. Partially used reagent cartridges (RC) can be reclosed with Reuse Seal Strips for later reuse, which avoids generation of waste due to leftover reagents at the end of the purification procedure.

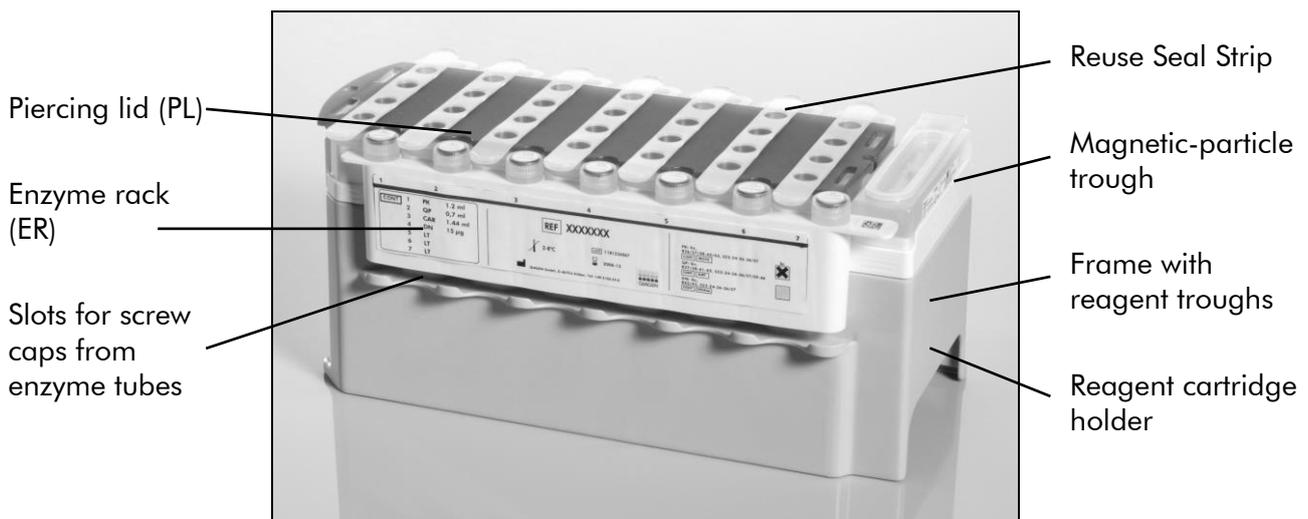


Figure 2. QIASymphony reagent cartridge (RC). The reagent cartridge (RC) contains all reagents required for the protocol run.

Before starting the procedure, ensure that the magnetic particles are fully resuspended. Remove the magnetic-particle trough from the reagent cartridge

frame, vortex it vigorously for at least 3 minutes, and replace it in the reagent cartridge frame before the first use. Place the reagent cartridge (RC) into the reagent cartridge holder. Place the empty enzyme rack (ER) into the reagent cartridge holder. Before using a reagent cartridge (RC) for the first time, place the piercing lid (PL) on top of the reagent cartridge (RC) (Figure 3).

Note: The piercing lid is sharp. Take care when placing it onto the reagent cartridge (RC). Make sure to place the piercing lid (PL) onto the reagent cartridge (RC) in the correct orientation.

After the magnetic-particle trough cover is removed and the enzyme rack tubes are opened (screw caps can be stored in dedicated slots, see Figure 2 above), the reagent cartridge (RC) is subsequently loaded into the “Reagents and Consumables” drawer.

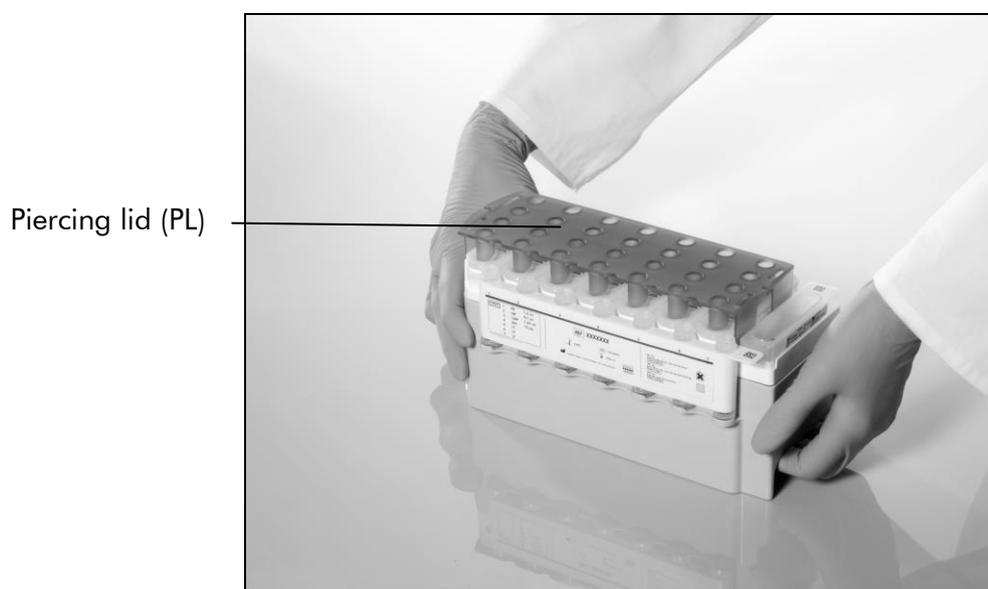


Figure 3. Easy worktable setup with reagent cartridges (RC).

Partially used reagent cartridges (RC) can be stored until needed again, see “Reagent Storage and Handling” page 12.

Loading plasticware into the “Reagents and Consumables” drawer

Sample prep cartridges, 8-Rod Covers (both preracked in unit boxes), and disposable filter-tips (200 μ l tips provided in blue racks, 1500 μ l tips provided in gray racks) are loaded into the “Reagents and Consumables” drawer.

Note: Ensure that the covers of the unit boxes are removed before loading the unit boxes into the “Reagents and Consumables” drawer.

Note: Tips have filters to help prevent cross-contamination

Tip rack slots on the QIAAsymphony SP worktable can be filled with either type of tip rack. The QIAAsymphony SP will identify the type of tips loaded during the inventory scan.

Note: Do not refill tip racks or unit boxes for sample prep cartridges or 8-Rod Covers before starting another protocol run. The QIASymphony SP can use partially used tip racks and unit boxes.

For the consumables required, see the relevant protocol sheet available at www.qiagen.com/goto/dsphandbooks. For plasticware ordering information, see page 29.

Loading the “Waste” drawer

Sample prep cartridges and 8-Rod Covers used during a run are re-racked in empty unit boxes in the “Waste” drawer. Make sure that the “Waste” drawer contains sufficient empty unit boxes for plastic waste generated during the protocol run.

Note: Ensure that the covers of the unit boxes are removed before loading the unit boxes into the “Waste” drawer. If you are using 8-Rod Cover boxes for collecting used sample prep cartridges and 8-Rod Covers, ensure that the box spacer has been removed.

A bag for used filter-tips must be attached to the front side of the “Waste” drawer.

Note: The presence of a tip disposal bag is not checked by the system. Make sure that the tip disposal bag is properly attached before starting a protocol run. For more information, see the user manuals provided with your instrument. Empty the tip bag after a maximum of 96 samples have been processed to avoid a tip jam.

A waste container collects liquid waste generated during the purification procedure. The “Waste” drawer can only be closed if the waste container is in place. Dispose of the liquid waste according to your local safety and environment regulations. Do not autoclave the filled waste bottle. Empty the waste bottle after a maximum of 96 samples have been processed.

Loading the “Eluate” drawer

Load the required elution rack into the “Eluate” drawer. Use “Elution slot 1” with the corresponding cooling adapter. As long-term storage of eluates in the “Eluate” drawer may lead to evaporation of eluates, we strongly recommend using the cooling position.

Inventory scan

Before starting a run, the instrument checks that sufficient consumables for the queued batch(es) have been loaded into the corresponding drawers.

Preparation of sample material

QIASymphony DSP Virus/Pathogen Kits are suitable for use with a wide range of sample types, including plasma, serum, CSF, and respiratory and urogenital samples. Prevent formation of foam in or on the samples. Depending on the

starting material, sample pretreatment may be required. Samples should be equilibrated to room temperature (15–25°C) before starting the run.

For more information about the automated procedure (including information about sample tubes that can be used with specific protocols) and specific sample pretreatments, see the relevant protocol sheet available at www.qiagen.com/goto/dsphandbooks.

Preparing carrier RNA (CARRIER)–Buffer AVE (AVE) mixtures

Note: We strongly recommend use of carrier RNA (CARRIER). If carrier RNA (CARRIER) is not added, recovery of nucleic acids may be significantly reduced.

To prepare a carrier RNA (CARRIER) stock solution, add 1350 μ l Buffer AVE (AVE) (provided in 2 ml vials) to the tube containing 1350 μ g lyophilized carrier RNA (CARRIER) to obtain a solution of 1 μ g/ μ l. Dissolve the carrier RNA (CARRIER) thoroughly, divide it into conveniently sized aliquots, and store at 2–8°C for up to 4 weeks.

For volumes of carrier RNA (CARRIER) required for specific protocols see the relevant protocol sheet available at www.qiagen.com/goto/dsphandbooks.

Calculating the volume of carrier RNA (CARRIER) mixture per tube

The minimum volume of carrier RNA (CARRIER)–Buffer AVE (AVE) mixture must include sufficient additional volume to take into account liquid loss due to pipetting and evaporation. Compatible tube formats including minimum volume of carrier RNA (CARRIER)–Buffer AVE (AVE) mixtures are listed at www.qiagen.com/goto/dsphandbooks.

Tubes containing carrier RNA (CARRIER)–Buffer AVE (AVE) mixtures are placed in a tube carrier. The tube carrier containing the carrier RNA (CARRIER)–Buffer AVE (AVE) mixture(s) must be placed in slot A of the sample drawer. Up to 8 tubes of the mixture can be used per batch and up to 24 tubes can be used per run of 4 batches.

If less carrier RNA (CARRIER) has been shown to be better for your amplification system, adjust the volume of carrier RNA (CARRIER) accordingly. The use of a different concentration of carrier RNA (CARRIER) must be validated for each particular sample type and downstream assay.

If no carrier RNA (CARRIER) is used, the tubes loaded into slot A must contain Buffer AVE (AVE) only (120 μ l Buffer AVE (AVE) per sample).

Using an internal control

Using QIASymphony DSP Virus/Pathogen Kits in combination with amplification systems that use an internal control may require introduction of these internal controls into the purification procedure to monitor the efficiency of sample preparation and downstream assay.

Internal controls must be added with carrier RNA (CARRIER)–Buffer AVE (AVE) mixture, and the total volume of the internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture remains 120 μ l.

The amount of internal control added depends on the assay system and the elution volume chosen within the QIA Symphony SP protocol. Calculation and validation must be performed by the user. Refer to the manufacturer's instructions for the downstream assay to determine the optimal concentration of internal control. Using a concentration other than that recommended may lead to incorrect results, especially if the internal control is used for calculation of titers.

A mixture of internal controls can be used to analyze different parameters from a single eluate. Compatibility of different internal controls must be validated by the user.

When calculating the amount of internal control to use as well as the titer of the processed sample, it is necessary to take into consideration the actual volume of elution solution that is used for each sample. Since small amounts of liquid are lost during transfer and contact with the magnetic particles, the initial volume of elution solution must be larger than the selected volume to ensure that the final eluate is of the correct volume. The relevant protocol sheet, available at www.qiagen.com/goto/dsphanhandbooks, provides the initial elution volumes to allow accurate calculation for internal controls and titer. The protocol sheet also provides information for calculating the volume of internal control mixture according to the type of tube used. We recommend preparing fresh mixtures for each run just before use.

Assay Control Sets

Assay Control Sets are used for each protocol, even when no internal controls are used. A default Assay Control Set is preinstalled for each protocol. Creation of additional Assay Control Sets is described in the *QIA Symphony Management Console User Manual*.

Note: When using the default Assay Control Sets designed for working without internal control, the use of carrier RNA (CARRIER)–Buffer AVE (AVE) mixture is still required.

Handling RNA

Ribonucleases (RNases) are very stable and active enzymes that generally do not require cofactors to function. Since RNases are difficult to inactivate and only minute amounts are sufficient to destroy RNA, do not use any plasticware or glassware without first eliminating possible RNase contamination. Great care should be taken to avoid inadvertently introducing RNases into the RNA sample during or after the purification procedure.

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: General Purification Protocol

The following is a general protocol for using QIAasymphony DSP Virus/Pathogen Kits. Detailed information for each protocol, including volumes and tubes, is provided in protocol sheets that can be downloaded at www.qiagen.com/goto/dsphandbooks.

Note: Important points before starting

- Ensure that you are familiar with operating the QIAasymphony SP. Refer to the user manuals supplied with your instrument for operating instructions.
- Optional maintenance is not mandatory for instrument function, but is highly recommended to reduce risk of contamination.
- Ensure you are familiar with the protocol sheet corresponding to the procedure you want to use (available at www.qiagen.com/goto/dsphandbooks). In particular, note the initial elution volumes required for accurate calculation of internal controls and titer, as well as instructions for calculating the volume of internal control mixture according to the type of tube used. Also check if the protocol requires Buffer ATL.
- Before using a reagent cartridge (RC) for the first time, check that Buffers QSL2 and QSB1 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.
- Before starting a protocol that requires Buffer ATL, check whether precipitate has formed in Buffer ATL. If necessary, dissolve by heating at 70°C with gentle agitation in a water bath.* Aspirate bubbles from the surface of Buffer ATL.

* 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, including mixtures containing carrier RNA (CARRIER) and internal controls (optional) just before starting. For more information, see the corresponding protocol sheet (available at www.qiagen.com/goto/dsphandbooks), as well as “Preparing carrier RNA (CARRIER)–Buffer AVE (AVE) mixtures”, page 16, and “Using an internal control”, page 16.
- 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.
- 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 has been equilibrated to room temperature (15–25°C). Make sure that the piercing lid (PL) is placed on the reagent cartridge (RC) or, if using a partially used reagent cartridge, 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 at the left side of the QIASymphony SP.
- For information about sample tubes compatible with a certain protocol, see the corresponding protocol sheet (available at www.qiagen.com/goto/dsphandbooks).

For information about minimum sample volumes for samples in primary and secondary tubes for a certain protocol, see the corresponding protocol sheet (available at www.qiagen.com/goto/dsphandbooks). This information also indicates which tubes can be used for the different protocols.

Procedure

- 1. Close all drawers and the hood.**
- 2. Switch on the QIASymphony SP, 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 instrument.**
- 4. Ensure the “Waste” drawer is prepared properly, and perform an inventory scan of the “Waste” drawer, including the tip chute and liquid waste. Replace the tip disposal bag if necessary.**

5. Load the required elution rack into the “Eluate” drawer.

Use only “Elution slot 1” with the corresponding cooling adapter.

When using a 96-well plate, make sure that the plate is in the correct orientation, as incorrect placement may cause sample mix-up in downstream analysis.

When using the Elution Microtubes CL rack, remove the bottom by twisting the rack until the bottom comes off.

6. Load the required reagent cartridge(s) (RC) and consumables into the “Reagents and Consumables” drawer.

7. If using a protocol that does not require Buffer ATL, continue with step 8. If using a protocol that requires Buffer ATL, press the “R+C” button in the touchscreen to open the screen that shows the consumables status (“Consumables/8-Rod Covers/Tubes/ Filter-Tips/Reagent Cartridges”). Press the “Scan Bottle” button to scan the bar code of the bottle of Buffer ATL with the handheld bar code scanner. Press “OK”.

Ensure that the bottle of Buffer ATL is scanned, opened, and placed into the position specified in the touchscreen before starting the inventory scan.

Otherwise the inventory scan must be repeated after scanning, opening, and placing the bottle of Buffer ATL into the “Reagents and Consumables” drawer.

8. Perform an inventory scan of the “Reagents and Consumables” drawer.

9. Place the samples into the appropriate sample carrier, and load them into the “Sample” drawer.

10. Place the tube(s) containing the carrier RNA (CARRIER)–Buffer AVE (AVE) mixture (including optional internal control) into the tube carrier and load into slot A of the “Sample” drawer.

For more information about preparing the mixture, see the corresponding protocol sheet (available at www.qiagen.com/goto/dsphandbooks), as well as “Preparing carrier RNA (CARRIER)–Buffer AVE (AVE) mixtures”, page 16, and “Using an internal control”, page 16.

11. Using the touchscreen, enter the required information for each batch of samples to be processed.

Enter the following information:

- Sample information (depending on sample racks used).
- Protocol to be run (“Assay Control Set”).
- Elution volume and output position.
- Tubes containing the carrier RNA (CARRIER)–Buffer AVE (AVE) mixture (including optional internal control).

After information about the batch has been entered, the status changes from "LOADED" to "QUEUED". As soon as one batch is queued, the "Run" button appears.

12. Press the "Run" button to start the purification procedure.

All processing steps are fully automated. At the end of the protocol run, the status of the batch changes from "RUNNING" to "COMPLETED".

13. Retrieve the elution rack containing the purified nucleic acids from the "Eluate" drawer.

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 purified nucleic acids at –20°C.

We recommend removing the eluate plate from the "Eluate" drawer immediately after the run has finished. Depending on temperature and humidity, elution plates left in the QIA Symphony SP after the run is completed may experience condensation or evaporation.

Result files are generated for each elution plate.

Note: Ensure that the correct eluate volume is used for the downstream applications.

14. If a reagent cartridge (RC) is only partially used, seal it with the provided Reuse Seal Strips and close tubes containing proteinase K with screw caps immediately after the end of the protocol run to avoid evaporation. If Buffer ATL was used, close the bottle and store at 15–25°C.

Note: For more information about storage of partially used reagent cartridges (RC), see "Reagent Storage and Handling", page 12.

15. Discard used sample tubes, plates, and waste according to your local safety regulations.

See page 9 for safety information.

16. Clean the QIA Symphony SP.

Follow the maintenance instructions in the user manuals supplied with your instrument. Make sure to clean the tip guards regularly to minimize the risk of cross-contamination.

17. Close the instrument drawers, and switch off the QIA Symphony SP.

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 instrument. |
|--|--|

Precipitate in reagent trough of opened cartridge

| | |
|-----------------------|---|
| a) Buffer evaporation | Excessive evaporation may lead to increased salt concentration 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) below 15°C may lead to formation of precipitates. If necessary, remove the troughs containing Buffer 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 trough in the correct position. If the reagent cartridge (RC) is already pierced, make sure that the trough is reclosed with a Reuse Seal Strip 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 "Preparing carrier RNA (CARRIER)–Buffer AVE (AVE) mixtures" starting on page 16. 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 QSL2 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.* |

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

Comments and suggestions

- f) Clogging of pipet tip due to insoluble material
- Insoluble material was not removed from the sample prior to starting the QIA Symphony 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. If required, use pretreatment procedures as described in the corresponding protocol sheets, for example, for viscous sample materials. Protocol sheets are available at www.qiagen.com/goto/dsphandbooks.

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAasymphony DSP Virus/Pathogen Kit is tested against predetermined specifications to ensure consistent product quality.

Limitations

The system performance has been established in performance evaluation studies purifying viral DNA and RNA from human serum, plasma, or cerebrospinal fluid (CSF) and purifying viral DNA and RNA as well as bacterial DNA from respiratory and urogenital samples. Blood samples treated with serum clot activator may result in reduced yields of viral nucleic acids. Do not use Greiner Bio-One® VACUETTE® Blood Collection Tubes containing Z Serum Clot Activator.

It is the user's responsibility to validate system performance for any procedures used in their laboratory that are not covered by the QIAGEN performance evaluation studies.

To minimize the risk of a negative impact on the diagnostic results, adequate controls for downstream applications should be used. For further validation, the guidelines of the International Conference on Harmonisation of Technical Requirements (ICH) in *ICH Q2 (R1) Validation of Analytical Procedures: Text and Methodology* are recommended.

Any diagnostic results that are generated must be interpreted in conjunction with other clinical or laboratory findings.

Symbols

| | |
|---|--|
|  | Contains sufficient reagents for <N> sample preparations |
|  | Use by |
|  | In vitro diagnostic medical device |
|  | Catalog number |
|  | Lot number |
|  | Material number (i.e., component labeling) |
|  | Components (i.e., a list of what is included) |
|  | Number (i.e., vials, bottles) |
| Rn | R is the revision of the Instructions for Use (Handbook), n is the revision number |
|  | Volume |
|  | Guanidinium thiocyanate |
|  | Isopropanol |
|  | Guanidine hydrochloride |
|  | Ethanol |
|  | BRIJ 58 |
|  | Lithium chloride |
|  | Well number (i.e., reagent cartridge well) |
|  | Proteinase K |
|  | Caution |
|  | Reagent cartridge |
|  | Elution buffer (Buffer AVE) |
|  | Carrier RNA |
|  | Global Trade Item Number |
|  | Sharp edge |
|  | Temperature limitation |
|  | Manufacturer |
|  | Only for use with |

Contact Information

At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Service Departments are staffed by experienced scientists with extensive practical and theoretical expertise in sample and assay technologies and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the QIASymphony DSP Virus/Pathogen Mini Kit, QIASymphony DSP Virus/Pathogen Midi Kit, or QIAGEN products in general, please do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

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. |
|--|---|----------|
| QIAasymphony DSP Virus/Pathogen Mini Kit (192) | Includes 2 reagent cartridges and enzyme racks and accessories | 937036 |
| QIAasymphony DSP Virus/Pathogen Midi Kit (96) | Includes 2 reagent cartridges and enzyme racks and accessories | 937055 |
| Related products | | |
| Buffer ATL (4 x 50 ml) | Buffer 4 x 50 ml ATL for use with QIAasymphony SP pathogen complex protocols | 939016 |
| QIAGEN Proteinase K (2 ml) | 2 ml (>600 mAU/ml, solution) | 19131 |
| QIAGEN Proteinase K (10 ml) | 10 ml (>600 mAU/ml, solution) | 19133 |
| Sample Prep Cartridges, 8-well (336) | 8-well sample prep cartridges for use with the QIAasymphony SP | 997002 |
| 8-Rod Covers (144) | 8-Rod Covers for use with the QIAasymphony SP | 997004 |
| Reagent Cartridge Holder (2) | Reagent cartridge holder for use with the QIAasymphony SP | 997008 |
| Accessory Trough (10) | Accessory troughs for use with the QIAasymphony SP | 997012 |
| Tip Disposal Bags (15) | Tip disposal bags for use with the QIAasymphony SP | 9013395 |
| Sample Carrier, plate, Qsym | Plate carrier for sample input for use with the QIAasymphony SP | 9017660 |
| Cooling Adapter, MTP, RB, v2, Qsym | Cooling adapter for round-bottom microplates (MTP). For use with the QIAasymphony SP/AS instruments | 9020729 |
| Cooling Adapter, EMT, v2, Qsym | Cooling adapter for EMT racks. For use with the QIAasymphony SP/AS instruments | 9020730 |

| Product | Contents | Cat. no. |
|--|---|-----------------|
| Cooling Adapter, PCR, v2, Qsym | Cooling adapter for PCR plates. For use with the QIAAsymphony SP/AS instruments | 9020732 |
| Cooling Adapter, 2 ml, v2, Qsym | Cooling adapter for 2 ml screw-cap tubes. For use with the QIAAsymphony SP/AS instruments | 9020674 |
| Tube Insert, 2 ml, v2 sample carrier, Qsym | Secondary tube adapter (for 2 ml screw-cap tubes) for use with the QIAAsymphony tube carrier | 9242083 |
| Tube Insert, 11 mm, Revision, sample carrier, Qsym | Primary tube adapter (11 mm) for use with the QIAAsymphony tube carrier | 9242057 |
| Tube Insert, 13 mm, sample carrier, Qsym | Primary tube adapter (13 mm) for use with the QIAAsymphony tube carrier | 9242058 |
| Adapter, tubes, 2 ml, v2, Qsym | Adapter for 2 ml screw-cap tubes. For use in the QIAAsymphony "Eluate" drawer | 9021670 |
| Filter-Tips, 200 μ l (1024) | Disposable Filter-Tips, racked; (8 x 128). For use with the QIAcube and the QIAAsymphony SP | 990332 |
| Filter-Tips, 1500 μ l (1024) | Disposable Filter-Tips, racked; (8 x 128). For use with the QIAAsymphony SP | 997024 |
| Reuse Seal Set (20) | Reuse seal sets for sealing partly used QIAAsymphony reagent cartridges | 997006 |
| Elution Microtubes CL (24 x 96) | Nonsterile polypropylene tubes (0.85 ml maximum capacity, less than 0.7 ml storage capacity, 0.4 ml elution capacity); 2304 in racks of 96; includes cap strips | 19588 |
| QIAAsymphony SP | QIAAsymphony sample prep module, 1-year warranty on parts and labor | 9001297 |

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