

lune 2022

QlAsymphony® DSP DNA Kit Instructions for Use (Handbook)





Version 2



For In Vitro Diagnostic Use For use with QIAsymphony DSP DNA Mini Kit and QIAsymphony DSP DNA Midi Kit



REF 937236, 937255

QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY

1127540

Contents

Intended Use	4
Intended User	4
Description and Principle	5
Summary and explanation	5
Principles of the procedure	6
Materials Provided	8
Kit contents	8
Components of the kit	9
Materials Required but Not Provided	10
Additional reagents	10
Consumables	10
Equipment	11
Protocol and labware	11
Warnings and Precautions	12
Safety information	12
Precautions	13
Disposal	15
Reagent Storage and Handling	16
In-use stability	16
Specimen Collection, Storage, and Handling	17
Procedure	18
Automated purification on QIAsymphony SP	18

Protocol: Purification of DNA	. 23
Limitations	. 27
Performance Characteristics	. 28
Troubleshooting Guide	. 29
Symbols	. 31
Contact Information	. 33
Appendix: Quantification and Determination of Purity of DNA	. 34
Ordering Information	. 36
Document Revision History	. 38

Intended Use

The QIAsymphony DSP DNA Mini Kit and QIAsymphony DSP DNA Midi Kit utilize magnetic-particle technology for automated isolation and purification of DNA from biological specimens.

The QIAsymphony DSP DNA system is intended for in vitro diagnostic use.

Intended User

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

Description and Principle

Summary and explanation

The QIAsymphony DSP DNA Kits are intended to be used only in combination with the QIAsymphony SP instrument. The QIAsymphony DSP DNA Kits provide reagents for fully automated purification of total DNA from human whole blood, buffy coat, tissues and formalin-fixed, paraffin-embedded (FFPE) tissues, as well as simultaneous purification of viral DNA from human whole blood. However, performance characteristics for every virus, tissue, or FFPE tissue types 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. Purified nucleic acids are ready for direct use in downstream applications, such as amplification or other enzymatic reactions. The QIAsymphony SP performs all steps of the purification procedure. Up to 96 samples, in batches of 24, can be processed in a single run. Tissue and FFPE tissue protocols require manual sample pretreatment.

Principles 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, below). 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 the flowchart, page 7). The user can choose between different elution volumes.

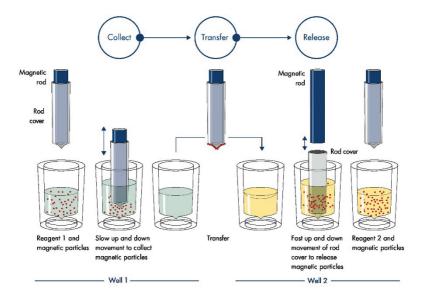
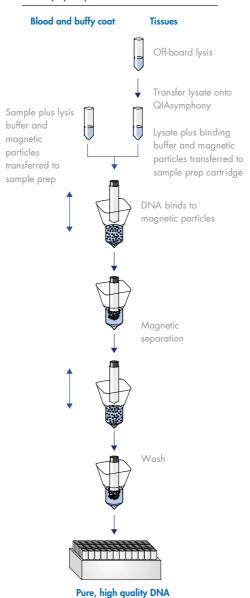


Figure 1. Schematic of the QIAsymphony SP principle. The QIAsymphony SP processes a sample containing magnetic particles as follows: A magnetic rod protected by a rod cover enters a well containing the sample and attracts the magnetic particles. The magnetic rod cover is positioned above another well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

QIAsymphony DSP DNA Procedure



Materials Provided

Kit contents

QIAsymphony DSP DNA Kit		Mini	Midi	
Catalog no. Number of reactions		937236	937255 96*	
		192		
Abbreviations	Identity		Quo	antity
P.C	Paggant Cartridget	DEAG CAPT	2	2

Abbreviations	Identity		Que	antity
RC	Reagent Cartridge [†]	REAG CART	2	2
ER	Enzyme Rack		2	2
PL	Piercing Lid		2	2
ATE	Buffer ATE‡	ELU BUF	20 ml	20 ml
RSS	Reuse Seal Set§		2	2
	Instructions for Use (Handbook)		1	1

^{*} For 96 x 1000 μl preps or 144 x 400 μl preps.

[†] Contains quanidine salts. Not compatible with disinfectants containing bleach. See page 12 for Safety information.

[‡] Contains sodium azide as a preservative.

[§] A Reuse Seal Set contains 8 Reuse Seal Strips.

[¶] See page 31 for symbols list with definitions.

Components of the kit

The principal components of the kit containing active ingredients are explained below.

Reagent	Components	Concentration (w/w) [%]
RC (Reagent Cartridge)	Maleic acid	≥0.1 to <1
	Guanidine hydrochloride	≥30 to <50
	Nonionic detergent	≥1 to <25
	Ethanol	≥10 to <90
	Isopropanol	≥30 to <50
	Lithium chloride	≥1 to <10
	Guanidinium thiocyanate	≥20 to <30
ER (enzyme rack)	Proteinase K	≥1 to <10

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.

Additional reagents

- Phosphate-buffered saline (PBS, may be required for diluting samples)
- Optional: DNase-free RNase A (to minimize RNA content)
- Buffer ATL (4 x 50 ml, cat. no. 939016) for use with QIAsymphony Tissue protocols
- Deparaffinization Solution (1 x 50 ml, cat. no. 939018) for use with QIAsymphony FFPE Tissue protocols

Consumables

- Sample Prep Cartridges, 8-well cartridges (cat. no. 997002)
- 8-Rod Covers (cat. no. 997004)
- $\bullet~$ Filter-Tips, 200 µl and 1500 µl (cat. nos. 990332 and 997024)
- Sample tubes. For compatible primary and secondary tube formats, see the labware list
 which can be found under the resource tab of the product page on www.qiagen.com.
- Internal Control Tubes for use with QIAsymphony Virus Blood protocol: For compatible tube formats, see the labware list which can be found under the resource tab of the product page on www.qiagen.com.
- Elution tubes or plates. For compatible elution tube and plate formats, see the labware list
 which can be found under the resource tab of the product page on www.qiagen.com.

Equipment*

- QIAsymphony SP (cat. no. 9001297)
- Vortexer
- ThermoMixer® or shaker-incubator (if needed)
- Centrifuge (if needed)

Protocol and labware

Table 1. Protocol overview

Sample	Sample volume (µl)	Elution volume (µl)	Kit	QIAsymphony SP protocol
Whole blood	200	50, 100, 200	Mini	Blood 200 DSP
	400	100, 200, 400	Midi	Blood 400 DSP
	1000	200, 400, 500	Midi	Blood 1000 DSP
Buffy coat	200	200, 300, 400	Mini	DNA Buffy Coat 200 DSP
	400	200, 400	Midi	DNA Buffy Coat 400 DSP
Virus blood	200	60, 85, 110, 165	Mini	VirusBlood200 DSP
Tissue	200	50, 100, 200,400	Mini	Tissue LC 200 DSP
	200	100, 200, 400	Mini	Tissue HC 200 DSP

Next to the handbook, the protocol sheets and labware list can be found under the resource tab of the product page on **www.qiagen.com**.

^{*} Prior to use, ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

Warnings and Precautions

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

For in vitro diagnostic use.

Read all instructions carefully before using the kit.

Please be aware of following remaining risks:

When using secondary tubes, please ensure that the sample IDs are not mixed up during transfer of sample ID from primary to secondary tube.

Sample IDs can also be entered manually (for details, refer to the *QIAsymphony SP User Manual*). If wrong ID data are entered manually, wrong correlation between sample and patient can occur.

Safety information

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.

 All chemicals and biological materials are potentially hazardous. Specimens and samples are potentially infectious and must be treated as biohazardous materials.

Emergency information

CHEMTREC
USA & Canada 1-800-424-9300
Outside USA & Canada +1 703-527-3887

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.

Precautions

The following hazard and precautionary statements apply to components of QIAsymphony DSP DNA Kits.

QSB1



Contains: guanidine thiocyanate and isopropanol. Danger! May be harmful if swallowed or in contact with skin. May be harmful if swallowed and enters airways. Causes severe skin burns and eye damage. May cause drowsiness or dizziness. Flammable liquid and vapor. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do NOT induce vomiting. Wash contaminated clothing before reuse. Store in a well-ventilated place. Store locked up. Dispose of contents/container to an approved waste disposal plant.

MBS

Warning! Causes mild skin irritation. Wear protective gloves/protective clothing/eye protection/face protection.

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. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. IF exposed or concerned: Call a POISON CENTER or doctor/physician. Remove person to fresh air and keep comfortable for breathing. Dispose of contents/container to an approved waste disposal plant.

QSL₁



Contains: guanidine hydrochloride and maleic acid. Warning! May be harmful if swallowed or if inhaled. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. Wear protective gloves/protective clothing/eye protection/face protection.

QSW1





Contains: ethanol, guanidine hydrochloride, and lithium chloride. Warning! May be harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation. Flammable liquid and vapor. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Wear protective gloves/protective clothing/eye protection/face protection. Call a POISON CENTER or doctor/physician if you feel unwell. Take off contaminated clothing and wash before reuse. Store in a well-ventilated place. Dispose of contents/container to an approved waste disposal plant.

QSW2





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

Disposal

The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed properly. Refer to your local safety regulations for proper disposal procedures.

For more information, please consult the appropriate safety data sheets (SDSs). These are available online in PDF format at www.qiagen.com/safety where you can find, view, and print the SDS for each QIAGEN kit and kit component.

Reagent Storage and Handling

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

The QIAsymphony DSP DNA Kits should be stored upright at room temperature ($15-25^{\circ}$ C). The magnetic particles in the reagent cartridges (RC) remain active when stored at this temperature. When stored properly, the kit is stable until the expiration date on the kit box.

The QIAsymphony DSP DNA Kits contain ready-to-use proteinase K solution that can be stored at room temperature.

Note: The label on the QIAsymphony DSP DNA Kit box displays the expiration date of the kit. The result file documents the expiration dates for only the reagent cartridge (RC).

In-use stability

Partially used reagent cartridges (RC) can be stored for a maximum of 4 weeks, upright at room temperature (15–25°C), 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.

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 32°C.

Running batches with low sample numbers (<24) will increase both the time that the reagent cartridge (RC) is open and the required buffer volumes, potentially reducing the total number of sample preparations possible per cartridge.

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.

Specimen Collection, Storage, and Handling

For more information about the automated procedure (including information about sample tubes that can be used with specific protocols), sample collection, storage, handling, and specific sample pretreatments, see the relevant protocol sheets and labware list that can be found under the resource tab of the product page on www.qiagen.com.

Procedure

Automated purification on 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 pre-racked consumables in the appropriate drawer before a run. Start the protocol and remove purified DNA 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**.

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

Reagents for purification of DNA are contained in an innovative reagent cartridge (RC) (Figure 2, page 19). 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 (RSS) for later reuse, which avoids generation of waste due to leftover reagents at the end of the purification procedure.

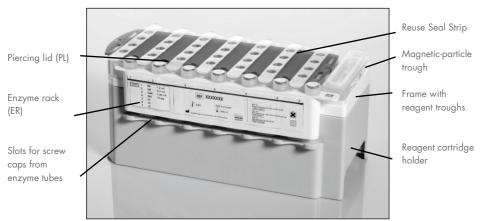


Figure 2. QIAsymphony reagent cartridge (RC). The reagent cartridge (RC) contains all reagents required for the protocol run.

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 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 2, above).

Note: The piercing lid (PL) 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.

Partially used reagent cartridges (RC) can be stored until needed again, see "Reagent Storage and Handling", page 16.

Loading plasticware into the "Reagents and Consumables" drawer

Sample prep cartridges, 8-Rod Covers (both pre-racked in unit boxes), and disposable filtertips (200 µl tips provided in blue racks and 1500 µl tips provided in gray racks) are loaded into the "Reagents and Consumables" drawer.

Note: Make sure 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 QIAsymphony SP worktable can be filled with either type of tip rack. The QIAsymphony 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**. For plasticware ordering information, see page 36.

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: Make sure 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 at the latest 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 at the latest after a maximum of 96 samples have been processed.

Loading the "Eluate" drawer

Load the required elution rack into the "Eluate" drawer. As long-term storage of eluates in the "Eluate" drawer may lead to evaporation of eluates, the cooling position must be used. Only use "Elution slot 1" with the corresponding cooling adapter.

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

The QIAsymphony DSP DNA Kits are designed for automated purification of total DNA from human whole blood, buffy coat, tissues, and FFPE tissues, as well as viral DNA from human whole blood (Table 1, page 11).

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. Tissue and FFPE tissue protocols require manual sample pretreatment. 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 and labware list available at www.giagen.com.

Yield of purified DNA

DNA yields depend on the sample type, number of nucleated cells in the sample, the quality of the starting material, and the protocol used for isolation of DNA. Elution in smaller volumes increases the final DNA concentration in the eluate but slightly reduces overall DNA yield. We recommend using an elution volume appropriate for the intended downstream application. The QIAsymphony DSP DNA Kits copurify RNA and DNA if both are present in the sample. To minimize RNA content in the sample, add RNase A to the sample in the step indicated in the respective pretreatment protocol. For more information, refer to protocol sheets available at www.giagen.com.

Storing DNA

Storage conditions and duration of the purified nucleic acid depends on the sample material used. More information are given in the relevant protocol sheets available at **www.qiagen.com**.

Note: Eluate stability highly depends on various factors and relates to the specific downstream application. It has been established for the QIAsymphony DSP DNA Kits in conjunction with exemplary downstream applications. It is the responsibility of the user to consult the instructions for use of the specific downstream application used in their laboratory and/or validate the whole workflow to establish appropriate storage conditions.

Protocol: Purification of DNA

The following is a general protocol for using the QIAsymphony DSP DNA Kits. Detailed information for each protocol, including volumes and tubes, is provided in protocol sheets that can be downloaded at **www.qiagen.com**.

Important points before starting

- Make sure that you are familiar with operating the QIAsymphony 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.
- Before beginning the procedure, read "Principles of the procedure" starting on page 6.
- Make sure you are familiar with the protocol sheet corresponding to the procedure you
 want to use (available at www.qiagen.com).
- Before using a reagent cartridge for the first time, check that Buffers QSL1 and QSB1 do
 not contain any precipitates. If necessary, remove the troughs containing Buffers QSL1
 and QSB1 from the reagent cartridge and incubate for 30 minutes at 37°C with
 occasional shaking to dissolve precipitates. Make sure to replace the troughs in the
 correct positions. If the reagent cartridge is already pierced, make sure that the troughs
 are sealed with Reuse Seal Strips and incubate the complete reagent cartridge 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.

Things to do before starting

 Before starting the procedure, make sure that the magnetic particles are fully resuspended. Vortex the trough containing the magnetic particles vigorously for at least 3 minutes before first use.

- Make sure that the piercing lid is placed on the reagent cartridge and the lid of the
 magnetic-particle trough has been removed or if using a partially used reagent cartridge,
 make sure the Reuse Seal Strips have been removed.
- Make sure to open the enzyme tubes.
- 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 labware list (available at www.qiagen.com).
- For information about minimum sample volumes for samples in primary and secondary tubes for a certain protocol, see the corresponding labware list (available at www.qiagen.com). This information also indicates which tubes can be used for different protocols.

Procedure

- 1. Close all drawers and the hood.
- 2. Power 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 on to the instrument.
- 4. Make sure that the "Waste" drawer is properly prepared 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.

Do not load a 96-well plate onto "Elution slot 4".

"Elution slot 1", with the corresponding cooling adapter, must be used.

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) and consumables into the "Reagents and Consumables" drawer.
- 7. Perform an inventory scan of the "Reagents and Consumables" drawer.
- 8. Place the samples into the appropriate sample carrier, and load them into the "Sample" drawer.

Note: To ensure correct liquid level detection, push the tubes down to the bottom of the tube carrier or insert, if inserts are used.

Important: For VirusBlood200 applications the tube(s) containing the internal control-Buffer ATE mixture should be placed in slot A of the "Sample" drawer.

For more information about preparing the mixture and using an internal control, refer to the relevant protocol sheet (available at www.giagen.com).

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

Enter the following information:

- 9a. Sample information (depending on sample racks used)
- 9b. Protocol to be run (Assay Control Set)
- 9c. Elution volume and output position
- 9d. For VirusBlood200 applications: tube(s) containing internal control(s)

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.

10. 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".

- 11. Retrieve the elution rack containing the purified nucleic acids from the "Eluate" drawer.
- 12. The DNA is ready to use or can be stored. Details are given in the relevant protocol sheets available at www.qiagen.com.

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 QIAsymphony SP after the run is completed may experience condensation or evaporation.

In general, magnetic particles are not carried over into eluates. If carryover does occur, magnetic particles in eluates will not affect most downstream applications.

If magnetic particles need to be removed before performing downstream applications, tubes, or plates containing eluates should first be placed in a suitable magnetic rack and the eluates transferred to a clean tube (see the appendix, page 34).

Result files are generated for each elution plate.

13. If a reagent cartridge 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.

Note: For more information about storage of partially used reagent cartridges (RC), see "Reagent Storage and Handling", page 16.

- 14. Discard used sample tubes and waste according to your local safety regulations.
 See page 12 for Safety information.
- 15. Clean the QIAsymphony 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.

16. Close the instrument drawers and power OFF the QIAsymphony SP.

Limitations

System performance has been established in performance evaluation studies purifying total DNA from human whole blood, buffy coat, tissues and FFPE tissues, as well as viral DNA from human whole blood.

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.

Performance Characteristics

The applicable performance characteristics can be found under the resource tab of the product page on **www.qiagen.com**.

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/or protocols in this handbook or sample and assay technologies (for contact information, visit www.qiagen.com).

Comments and suggestions

General handling

Error message displayed on 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 the reagent cartridge (RC). Make sure to seal the 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 QSL1 and QSB1 from the reagent cartridge (RC) and incubate in a water bath * at 37°C for 30 min 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 min with occasional shaking.

Low DNA yield

 Magnetic particles were not completely resuspended Before starting the procedure, ensure that the magnetic particles are fully resuspended. Vortex for at least 3 min before use.

 Frozen blood or buffy coat samples were not mixed properly after thawing Thaw frozen blood or buffy coat samples with mild agitation to ensure thorough mixing.

^{*} Make sure that instruments have been checked, maintained, and calibrated regularly according to the manufacturer's instructions.

Comments and	suggestions
Committee and	. 309903110113

		Comments and soggestions
с)	Incomplete sample lysis	Before use, check that Buffer QSL1 and QSB1 do not contain precipitates. If necessary, remove the troughs containing Buffers QSL1 and QSB1 from the reagent cartridge (RC) and incubate in a water bath * for 30 min 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 min at 37°C with occasional shaking in a water bath. *
d)	Incomplete digestion of tissue samples	Ensure that the tissue is completely digested by extending the time of incubation with proteinase K.
e)	Clogging of pipette tip due to insoluble material	Insoluble material was not removed from the sample prior to starting the QIAsymphony purification procedure. 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 .
f)	Poor buffy coat preparation when using buffy coat protocol	Make sure that the leukocyte fraction is efficiently harvested.
g)	Low leukocyte count in the whole blood sample used as starting material for buffy coat preparation	If using the buffy coat protocol, increase volume of whole blood used and keep the volume of leukocytes harvested constant.
h)	Incomplete lysis of tissues	If the lysate contains insoluble material, extend the proteinase K incubation time.
i)	Pellet was lost during FFPE pretreatment with xylene/ethanol	Carefully observe samples during pretreatment.

C

DNA does not perform well in downstream applications				
a)	Insufficient DNA used in downstream application	Quantify the purified DNA by spectrophotometric measurement of the absorbance at 260 nm (see the appendix, page 34).*		
b)	Excess DNA used in downstream application	Excess DNA can inhibit some enzymatic reactions. Quantify the purified DNA by spectrophotometric measurement of the absorbance at 260 nm (see the appendix, page 34).*		

A₂₆₀/A₂₈₀ ratio for purified DNA is low

Absorbance reading at 320 nm was not subtracted from the absorbance readings at 260 and 280 nm

To correct for the presence of magnetic particles in the eluate, an absorbance reading at 320 nm should be taken and subtracted from the absorbance readings obtained at 260 and 280 nm (see the appendix, page 34).*

^{*} Make sure that instruments have been checked, maintained, and calibrated regularly according to the manufacturer's instructions.

Symbols

The following symbols appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol definition
\\\ < N>	Contains reagents sufficient for <n> reactions</n>
\square	Use by
C€	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
IVD	In vitro diagnostic medical device
REF	Catalog number
LOT	Lot number
MAT	Material number (i.e., component labeling)
COMP	Components
CONT	Contains
NUM	Number
GTIN	Global Trade Item Number

Symbol	Symbol definition
Rn	R is for revision of the Instructions for Use and n is the revision number
*	Temperature limitation
	Manufacturer
	Consult instructions for use
类	Keep away from sunlight
\triangle	Warning/caution
PROTK	Proteinase K
WELL	Well number (i.e., reagent cartridge well)
REAG CART	Reagent cartridge
ЕЮН	Ethanol
UDI	Unique device identifier

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**).

Appendix: Quantification and Determination of Purity of DNA

The concentration of DNA should be determined by measuring the absorbance at 260 nm (A_{260}) in a spectrophotometer. Absorbance readings at 260 nm should fall between 0.1 and 1.0 to be accurate. An absorbance of 1 unit at 260 nm corresponds to 50 μ g of DNA per milliliter ($A_{260} = 1 = 50 \ \mu$ g/ml).

Use Buffer ATE to dilute the samples and to calibrate the spectrophotometer.

The ratio between the absorbance values at 260 and 280 nm gives an estimate of DNA purity. Purity is determined by calculating the ratio of corrected absorbance at 260 nm to corrected absorbance at 280 nm, that is, $(A_{260} - A_{320})/(A_{280} - A_{320})$.

Measure the absorbance at 320, 280, and 260 nm. Subtract the absorbance reading obtained at 320 nm from the readings obtained at 260 and 280 nm to correct for the potential presence of background reading.

Use the following formula to calculate DNA concentration and yield:

Concentration of DNA sample = 50 $\mu g/ml \times (A_{260} - A_{320}) \times dilution factor$

Total amount of DNA purified = concentration x volume of sample in milliliters

In case magnetic particles were carried over in the eluate and might affect downstream application (e.g., purified DNA is to be analyzed by fluorescent capillary sequencing), the tube containing the eluate should first be applied to a suitable magnetic separator and the eluate transferred to a clean tube.

If a suitable magnetic separator is not available, centrifuge the tube containing the DNA for 1 minute at full speed in a microcentrifuge to pellet any remaining magnetic particles.

Note: For accurate quantification of DNA by absorbance at 260 nm, we recommend diluting the sample in the corresponding elution buffer. Dilution of the sample in water may lead to inaccurate values. Elution buffer has high absorbance at 220 nm, which can lead to high background absorbance levels if the spectrophotometer is not properly zeroed. Evaporation of eluates potentially increases the risk of impact on the measurement especially when low amounts of eluates are used undiluted. Extra elution buffer to blank the spectrophotometer is provided in a separate bottle with the QIAsymphony DSP DNA Kits.

Ordering Information

Product	Contents	Cat. no.
QIAsymphony DSP DNA Mini Kit (192)	For 192 preps of 200 µl each: Includes 2 reagent cartridges and enzyme racks and accessories	937236
QIAsymphony DSP DNA Midi Kit (96)	For 96 preps of 1000 µl each or 144 preps of 400 µl each: Includes 2 reagent cartridges and enzyme racks and accessories	937255
Related products		
Buffer ATL (4 x 50 ml)	4 x 50 ml lysis buffer for use in purification of nucleic acids using QlAsymphony DSP Virus/Pathogen Kits and the QlAsymphony DSP DNA Mini Kit	939016
Deparaffinization Solution (1 x 50 ml)	1 x 50 ml Deparaffinization Solution	939018
Accessory Trough (10)	Accessory troughs for use with the QIAsymphony SP	997012
Reagent Cartridge Holder (2)	Reagent cartridge holder for use with the QIAsymphony SP	997008
Tube Insert, 2 ml, v2, sample carrier, Qsym	Secondary tube adapter (for 2 ml screw-cap tubes) for use with the QIAsymphony tube carrier	9242083
Tube Insert, 11 mm, Revision, sample carrier, Qsym	Primary tube adapter (11 mm, with tube insert 2A) for use with the QIAsymphony SP tube carrier (all software versions)	9242057

Tube Insert, 13 mm, sample carrier, Qsym	Primary tube adapter (13 mm, with tube insert 1A) for use with the QIAsymphony SP tube carrier (all software versions)	9242058
Cooling Adapter, 2 ml, v2, Qsym (24)	Cooling adapter for 2 ml screw-cap tubes; for use with the QIAsymphony SP/AS instruments (software version 3.1 or higher)	9020674
Cooling Adapter, EMT, v2, Qsym	Cooling adapter for EMT racks; for use with the QIAsymphony SP/AS instruments (software version 3.1 or higher)	9020730
Sample Prep Cartridges, 8-well (336)	8-well sample prep cartridges for use with the QIAsymphony SP	997002
8-Rod Covers (144)	8-Rod Covers for use with the QIAsymphony SP	997004
Filter-Tips, 200 µl (1024)	Disposable Filter-Tips, racked; (8 x 128). For use with the QIAcube® and the QIAsymphony SP/AS instruments	990332
Filter-Tips, 1500 µl (1024)	Disposable Filter-Tips, racked; (8 x 128). For use with the QIAsymphony SP/AS instruments	997024
Tip Disposal Bags (15)	Tip disposal bags for use with the QIAsymphony SP/AS instruments	9013395
Reuse Seal Set (20)	Reuse seal sets for sealing QIAsymphony reagent cartridges	997006

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.

Document Revision History

Revision

Description

R1, June 2022 Version 2, Revision 1

- Update to version 2 for compliance to IVDR
- Update of Intended Use and Limitations section
- Update of Description and Principle section
- Update of Materials Provided (addition of active ingredients)
 and Material Required but Not Provided sections
- Update of Warnings and Precautions (Addition of residual risks, emergency, and disposal information) sections
- Update of Reagent Storage and Handling section
- Update of Specimen Collection, Storage, and Handling section
- Update of Procedure section
- Update of Performance Characteristics section
- Update of Symbols section
- Update of Ordering Information
- Update of Appendix: Quantification and Determination of Purity of DNA section

Limited License Agreement for QIAsymphony DSP DNA Mini/Midi Kits

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

- 1. The product may be used solely in accordance with the protocols provided with the product and this handbook and for use with components contained in the panel only, QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this panel with any components not included within this panel except as described in the protocols provided with the product, this handbook, and additional protocols available at www.qiagen.com. Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN neither guarantees them nor warrants that they do not infringe the rights of third-parties.
- 2. Other than expressly stated licenses, QIAGEN makes no warranty that this panel and/or its use(s) do not infringe the rights of third-parties.
- 3. This panel and its components are licensed for one-time use and may not be reused, refurbished, or resold.
- 4. QIAGEN specifically disclaims any other licenses, expressed or implied other than those expressly stated.
- 5. The purchaser and user of the panel agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. QIAGEN may enforce the prohibitions of this limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this limited License Agreement or any of its intellectual property rights relating to the panel and/or its components.

For updated license terms, see www.qiagen.com.

Trademarks: QIAGEN®, Sample to Insight®, QIAsymphony®, QIAcube® (QIAGEN Group); Eppendorf®; ThermoMixer® (Eppendorf AG). Jun-2022 HB-3029-001 1127540 © 2022 QIAGEN, all rights reserved.

