

QIAsymphony® DSP Virus/Pathogen Kit Instructions for Use (Protocol Sheet)

Cellfree500_V5_DSP protocol

Version 2



For In Vitro Diagnostic Use

For use with QIAsymphony DSP Virus/Pathogen Midi Kit



937055



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R1

The protocol sheet available electronically and can be found under the resource tab of the product page on www.qiagen.com.

General information

The QIASymphony DSP Virus/Pathogen Kit is intended for in vitro diagnostic use.

Kit	QIASymphony DSP Virus/Pathogen Midi Kit
Sample material	Plasma, serum, and CSF
Protocol name	Cellfree500_V5_DSP
Default Assay Control Set	ACS_Cellfree500_V5_DSP_default_IC
Editable	Eluate volume: 60, 85, and 110 µl
Required software version	Version 4.0 or higher
Required software configuration for IVD use	Default Profile 1

“Sample” drawer

Sample type	Plasma, serum, and CSF
Sample volume	Depends on type of sample tube used; for more information see the labware list which can be found under the resource tab of the product page on www.qiagen.com
Processed sample volume	See the labware list which can be found under the resource tab of the product page on www.qiagen.com for more information
Primary sample tubes	See the labware list which can be found under the resource tab of the product page on www.qiagen.com for more information
Secondary sample tubes	Depends on type of sample tube used; for more information see the labware list which can be found under the resource tab of the product page on www.qiagen.com
Inserts	Depends on type of sample tube used; for more information see the labware list which can be found under the resource tab of the product page on www.qiagen.com
Other	Carrier RNA–Buffer AVE mix required; use of internal control is optional

“Reagents and Consumables” drawer

Position A1 and/or A2	Reagent cartridge (RC)
Position B1	n/a
Tip rack holder 1–17	Disposable filter-tips, 200 µl
Tip rack holder 1–17	Disposable filter-tips, 1500 µl
Unit box holder 1–4	Unit boxes containing sample prep cartridges
Unit box holder 1–4	Unit boxes containing 8-Rod Covers

n/a = not applicable.

“Waste” drawer

Unit box holder 1–4	Empty unit boxes
Waste bag holder	Waste bag
Liquid waste bottle holder	Liquid waste bottle

“Eluate” drawer

Elution rack (we recommend using slot 1, cooling position)

For more information, see the labware list that can be found under the resource tab of the product page on www.qiagen.com.

Required plasticware

Plasticware	One batch 24 samples*	Two batches 48 samples*	Three batches 72 samples*	Four batches 96 samples*
Disposable filter-tips, 200 µl†‡	32	56	80	104
Disposable filter-tips, 1500 µl†‡	109	198	297	386
Sample prep cartridges§	21	42	63	84
8-Rod Covers¶	3	6	9	12

* Use of more than one internal control per batch and performing more than one inventory scan requires additional disposable filter-tips. Use of less than 24 samples per batch decreases the number of disposable filter-tips required per run.

† There are 32 filter-tips/tip rack.

‡ Number of required filter-tips includes filter-tips for 1 inventory scan per RC.

§ There are 28 sample prep cartridges/unit box.

¶ There are twelve 8-Rod Covers/unit box.

Note: Numbers of filter-tips given may differ from the numbers displayed on the touchscreen depending on settings. We recommend loading the maximum possible number of tips.

Selected elution volume

Selected elution volume (µl)*	Initial elution volume (µl)†
60	90
85	115
110	140

* The elution volume selected on the touchscreen. This is the minimum accessible volume of eluate in the final elution tube.

† The initial volume of elution solution required to ensure that the actual volume of eluate is the same as the selected volume.

Preparation of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture

Selected elution volume (µl)	Volume stock carrier RNA (CARRIER) (µl)	Volume internal control (µl)*	Volume Buffer AVE (AVE) (µl)	Final volume per sample (µl)
60	5	9	106	120
85	5	11.5	103.5	120
110	5	14	101	120

* The calculation of the amount of internal control is based on the initial elution volumes. Additional void volume depends on the type of sample tube used; see the labware list, which can be found under the resource tab of the product page on www.qiagen.com for more information.

Note: The values displayed in the table are for preparation of internal control–carrier RNA (CARRIER) mixture for a downstream assay that requires 0.1 µl internal control/µl eluate.

Tubes containing internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture are placed in a tube carrier. The tube carrier containing the internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture(s) must be placed in slot A of the sample drawer.

Depending on the number of samples to be processed, we recommend using 2 ml tubes (Sarstedt®, cat. no. 72.693 or 72.694) or 14 ml 17 x 100 mm polystyrene, round-bottom tubes (BD™, cat. no. 352051) for diluting the internal control, as described in the table below. The volume can be split into 2 or more tubes.

Calculating the volume of internal control mixture

Tube type	Name on QIAasymphony touchscreen	Calculation of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture volume per tube
Microtube 2 ml with cap; microtube 2 ml, PP, skirted (Sarstedt, cat. no. 72.694)	SAR#72.694 T2.0 ScrewSkirt	$(n \times 120 \mu\text{l}) + 360 \mu\text{l}^*$
Microtube 2 ml with cap; microtube 2 ml, PP, non-skirted (Sarstedt, cat. no. 72.693)	SAR#72.693 T2.0 Screw	$(n \times 120 \mu\text{l}) + 360 \mu\text{l}^*$
Tube 14 ml, 17 x 100 mm polystyrene round-bottom (BD [§] , cat.no. 352051)	BD#352051 FalconPP 17x100	$(n \times 120 \mu\text{l}) + 600 \mu\text{l}^\dagger$

* Use this equation to calculate the required volume of internal control mixture (n = number of samples; $120 \mu\text{l}$ = volume of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture; $360 \mu\text{l}$ = void volume required per tube). For example, for 12 samples ($n = 12$): $(12 \times 120 \mu\text{l}) + 360 \mu\text{l} = 1800 \mu\text{l}$. Do not fill the tube with more than 1.9 ml (i.e., a maximum of 12 samples per tube). If more than 12 samples will be processed, use additional tubes, ensuring that the void volume is added per tube.

† Use this equation to calculate the required volume of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture (n = number of samples; $120 \mu\text{l}$ = volume of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture; $600 \mu\text{l}$ = void volume required per tube). For example, for 96 samples ($n = 96$): $(96 \times 120 \mu\text{l}) + 600 \mu\text{l} = 12120 \mu\text{l}$.

§ BD was the previous supplier of this tube and Corning Inc. is now the new supplier.

For required inserts, see the labware list which can be found under the resource tab of the product page on www.qiagen.com.

Preparation of sample material

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

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.

Note: Sample stability highly depends on various factors and relates to the specific downstream application. It has been established for the QIAasymphony DSP Virus/Pathogen 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.

For general collection, transport, and storage recommendations refer to the approved CLSI guideline MM13-A “Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods”. Furthermore, the manufacturer’s instructions for the selected sample collection device/kit shall be followed during sample preparation, storage, transport, and general handling.

Plasma, serum, and CSF samples

The purification procedure is optimized for use with plasma, serum, or CSF samples. Blood samples treated with EDTA or citrate as anticoagulant can be used for plasma preparation. Samples can be either fresh or frozen, provided that they have not been frozen and thawed more than once. After collection and centrifugation, plasma and serum can be stored at 2–8°C for up to 6 hours.

For longer storage, we recommend freezing aliquots at –20°C or –80°C. Frozen plasma or serum must not be thawed more than once. Repeated freeze–thawing leads to denaturation and precipitation of proteins, resulting in a potential reduction in viral titers and, therefore, reduced yields of viral nucleic acids. If cryoprecipitates are visible in the samples, centrifuge at 6800 x *g* for 3 minutes, transfer the supernatants to fresh tubes without disturbing the pellets, and start the purification procedure immediately. Centrifugation at low *g*-forces does not reduce viral titers.

Limitations and interfering substances

Blood samples treated with serum clot activator may cause reduced yields of viral nucleic acids. Do not use Greiner Bio-One® Vacuette® Blood Collection Tubes containing Z Serum Clot Activator.

No further significant negative impact of potential interfering substances was observed (for details see the applicable Performance Characteristics document that can be found under the resource tab of the product page on www.qiagen.com).

Note: Testing was done using exemplary downstream applications for an assessment of the quality of the extracted nucleic acids. However, different downstream applications may have different requirements with respect to purity (i.e., absence of potential interfering substances), so the identification and testing of relevant substances also needs to be established as part of the downstream application development for any workflow involving the QIA Symphony DSP Virus/Pathogen Kits.

Note: According to ISO 20186-2:2019(E), heparin from blood collection tubes may impact the purity of the isolated nucleic acids and possible carryover into eluates could cause inhibitions in some downstream applications. Therefore, we recommend usage of blood samples treated with EDTA or citrate as anticoagulant for plasma preparation.





Storage of eluates

Note: Eluate stability highly depends on various factors and relates to the specific downstream application. It has been established for the QIA Symphony DSP Virus/Pathogen 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.

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.

Symbols

The following symbols appear in this document. For a full list of symbols used in the instructions for use or on the packaging and labeling, please refer to the handbook.

Symbol	Symbol definition
	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
	In vitro diagnostic medical device
	Catalog number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Manufacturer

Revision history

Revision	Description
R1, June 2022	Version 2, Revision 1 <ul style="list-style-type: none">• Update to version 2 for compliance to IVDR• Extension of Preparation of sample material section• Addition of Limitations and interfering substances section• Addition of Storage of eluates section• Addition of Symbols section

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