June 2022

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

Cellfree200_V7_DSP protocol

Version 2

IVD

For In Vitro Diagnostic Use

For use with QIAsymphony DSP Virus/Pathogen Mini Kit

CE

REF 937036

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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**.

Sample to Insight

## General information

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

| | |
|---|---|
| **Kit** | QIAsymphony DSP Virus/Pathogen Mini Kit |
| **Sample material** | Plasma, serum, and CSF |
| **Protocol name** | Cellfree200_V7_DSP |
| **Default Assay Control Set** | ACS_Cellfree200_V7_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†‡ | 30 | 54 | 78 | 102 |
| Disposable filter-tips, 1500 µl†‡ | 101 | 182 | 271 | 354 |
| 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 | 2.5 | 9 | 108.5 | 120 |
| 85 | 2.5 | 11.5 | 106 | 120 |
| 110 | 2.5 | 14 | 103.5 | 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 QIAsymphony 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<br>T2.0 ScrewSkirt | (n x 120 µl) + 360 µl* |
| Microtube 2 ml with cap; microtube 2 ml, PP, non-skirted (Sarstedt, cat. no. 72.693) | SAR#72.693<br>T2.0 Screw | (n x 120 µl) + 360 µl* |
| Tube 14 ml, 17 x 100 mm polystyrene round-bottom (BD§, cat.no. 352051) | BD#352051<br>FalconPP 17x100 | (n x 120 µl) + 600 µl† |

* Use this equation to calculate the required volume of internal control mixture (*n* = number of samples; 120 µl = volume of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture; 360 µl = void volume required per tube). For example, for 12 samples (*n* = 12): (12 x 120 µl) + 360 µl = 1800 µl. 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 µl = volume of internal control–carrier RNA (CARRIER)–Buffer AVE (AVE) mixture; 600 µl = void volume required per tube). For example, for 96 samples (*n* = 96): (96 x 120 µl) + 600 µl = 12120 µl.

§ 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**.

## Using FIX labware

Using liquid-level detection (LLD) for sample transfer allows the use of primary and secondary tubes. However, this requires certain dead volumes in the respective tubes. To minimize dead volumes, secondary tubes should be used without liquid-level detection. Specific FIX labware is available (e.g., SAR_FIX_#72.694 T2.0 ScrewSkirt), which can also be selected on the touchscreen of the QIAsymphony SP. This tube/rack type imposes aspiration restrictions. The sample is aspirated at a particular height in the tube that is defined by the volume of sample to be transferred. Therefore, it is essential to make sure that the volume listed in the labware list is used. The labware list is available for download at **www.qiagen.com** under the resource tab of the product page.

Sample tubes that can be used with or without liquid-level detection and required sample volumes are also listed in the labware list available at **www.qiagen.com** under the resource tab of the product page. Do not use volumes greater or lower than the required volume because this may lead to errors during sample preparation.

Tubes for liquid-level detection and tubes that are not for liquid-level detection can be processed within one batch/run.

## 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 QIAsymphony 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 QIAsymphony 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 QIAsymphony 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 |
|---|---|
| CE | 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 |
| 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<br>• Update to version 2 for compliance to IVDR<br>• Extension of Preparation of sample material section<br>• Addition of Limitations and interfering substances section<br>• Addition of Storage of eluates section<br>• Addition of Symbols section |

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.