June 2022

QIAsymphony® DSP DNA Mini Kit Instructions for Use (Protocol Sheet)

VirusBlood200_V5_DSP protocol

Version 2

IVD

For In Vitro Diagnostic Use

For use with QIAsymphony DSP DNA Mini Kit (192)

CE

REF 937236

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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 DNA Kit is intended for in vitro diagnostic use.

This protocol is for purification of viral DNA from fresh human whole blood using the QIAsymphony SP and the QIAsymphony DSP DNA Mini Kit. Viral DNA from released viruses as well as from cell-associated viruses is copurified with genomic DNA from blood cells.

Kit	QIAsymphony DSP DNA Mini Kit (cat. no. 937236)
Sample material	Human whole blood (EDTA or citrate anti-coagulated)
Protocol name	VirusBlood200_V5_DSP
Default Assay Control Set	ACS_VirusBlood200_V5_DSP_default IC
Editable	Elution volume: 60, 85, 110, and 165 µl
Required software version	Version 4.0 or higher
Required software configuration for IVD use	Default Profile 1

Materials required but not provided

For preparation of the internal control–Buffer ATE mixture

- 2 ml sample tube (Sarstedt® cat. no. 72.693, non-skirted)
- 2 ml sample tube (Sarstedt cat. no. 72.694, skirted)
- BD™ 14 ml Falcon polystyrene round-bottom tube (cat. no. 352051)

"Sample" drawer

Sample type	Human whole blood (EDTA, citrate, or heparin anti-coagulated)
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**.
Primary sample tubes	For more information, see the labware list which can be found under the resource tab of the product page on **www.qiagen.com**.
Secondary sample tubes	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	Internal control–Buffer ATE 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 or 1500 µl
Unit box holder 1–4	Unit boxes containing sample prep cartridges or 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	Empty 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†‡	26	50	74	98
Disposable filter-tips, 1500 µl†‡	98	188	278	368
Sample prep cartridges§	21	42	63	84
8-Rod Covers¶	3	6	9	12

* 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 in 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
165	195

* The elution volume selected in 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–Buffer ATE mixture

Using the VirusBlood200_V5_DSP protocol 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.

The amount of internal control that is added depends on the assay system and the elution volume chosen within the VirusBlood200_V5_DSP 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.

Internal controls must be added with the internal control–Buffer ATE (ATE) mixture in a total volume of 60 µl. 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. We recommend preparing fresh mixtures for each run just before use. If no internal control is used, the use of Buffer ATE is still required.

Selected elution volume (µl)	Initial elution volume (µl)	Volume internal control (µl)*	Volume Buffer ATE (ATE) (µl)	Final volume per sample (µl)
60	90	9	51	60
85	115	11.5	48.5	60
110	140	14	46	60
165	195	19.5	40.5	60

* 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 for IC mix; for details see the labware list available at **www.qiagen.com**.
Note: The values displayed in the table are for preparation of internal control–Buffer ATE mixture for a downstream assay that requires 0.1 µl internal control/µl eluate.

The tubes containing internal control–Buffer ATE mixtures are placed in a tube carrier. The tube carrier containing the internal control–Buffer ATE 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. nos. 72.693 and 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. It is possible to split the volume into 2 or more tubes.

Calculating the volume of internal control mixture

Tube type*	Name on QIAsymphony touchscreen	Calculation of internal control mixture volume per tube
2 ml with cap; microtube 2 ml, PP, skirted (Sarstedt, cat. no. 72.694)	SAR#72.694 T2.0 ScrewSkirt	(n x 60 µl) + 360 µl†
Microtube 2 ml with cap; microtube 2 ml, PP, non-skirted (Sarstedt, cat. no. 72.693)	SAR#72.693 T2.0 Screw	(n x 60 µl) + 360 µl†
Tube 14 ml, 17 x 100 mm polystyrene round-bottom (BD, cat. no. 352051)	BD#352051 FalconPP 17 x 100	(n x 60 µl) + 600 µl‡

* For the required insert(s) see the labware list that can be found under the resource tab of the product page on **www.qiagen.com**

† Use this equation to calculate the required volume of internal control mixture (*n* = number of samples; 60 µl = volume of internal control–Buffer ATE mixture; 360 µl = void volume required per tube). For example, for 12 samples (*n* = 12): (12 x 60 µl) + 360 µl = 1080 µl. Do not fill the tube with more than 1.92 ml (i.e., a maximum of 26 samples per tube). If more than 26 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–Buffer ATE mixture (*n* = number of samples; 60 µl = volume of internal control–Buffer ATE mixture; 600 µl = void volume required per tube). For example, for 96 samples (*n* = 96): (96 x 60 µl) + 600 µl = 6360 µl.

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.

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 shall be followed during sample preparation, storage, transport, and general handling.

Human whole blood

For isolation of viral DNA, we recommend using whole blood samples treated with EDTA or citrate. For short-term storage of up to 7 days, we recommend storage at 2–8°C. For longer storage, we recommend freezing aliquots at –20°C for up to 3 months or –80°C for up to 1 year.

Note: Sample stability highly depends on various factors and relates to the specific downstream application. It has been established for the QIAsymphony DSP DNA Mini Kit 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.

If using fresh blood samples in primary tubes, mix the blood samples thoroughly (e.g., by inverting the tubes several times) before loading them onto the QIAsymphony SP. Frozen samples should be thawed quickly in a 37°C water bath with mild agitation to ensure thorough mixing and then equilibrated to room temperature (15–25°C) before beginning the procedure. To ensure reliable sample transfer, avoid generating foam in sample tubes. Try to avoid blood clots in the samples and, if necessary, transfer the sample without clots to a fresh tube.

Storage of eluates

It is recommended to remove the eluate plate from the "Eluate" drawer immediately after the run has finished. Elution plates may be left in the QIAsymphony SP after the run is completed overnight (maximum 12 hours including run time; recommended environmental conditions: 18–26°C and 20–75% relative humidity). Depending on temperature and humidity, eluate may experience condensation or evaporation.

For short-term storage of eluates up to 7 days, we recommend storing of purified nucleic acid at 2–8°C. For long-term storage, we recommend storage at –20°C or –80°C.

Note: Eluate stability highly depends on various factors and relates to the specific downstream application. It has been established for the QIAsymphony DSP DNA Mini Kit 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.

Interfering substances

Blood samples with high concentrations of triglycerides (>30 g/l) may lead to reduced gDNA yield.

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 DNA Mini 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.

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 • Update to version 2 for compliance to IVD • Addition of Materials required but not provided section • Addition of Interfering substances section • Addition of Storage of eluates section • Addition of Symbols section • Update of Preparation of sample material 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.