June 2022

QIAamp® DSP Virus Kit Instructions for Use (Performance Characteristics)

Version 2

IVD

For In Vitro Diagnostic Use

For use with QIAamp® DSP Virus Kit

CE

REF 60704

QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, Germany

R1

Performance Characteristics is available electronically and can be found under the resource tab of the product page on **www.qiagen.com**

Sample to Insight

Contents

General introduction

The QIAamp® DSP Virus Kit is intended for manual isolation and purification of viral nucleic acids from human plasma or serum samples. The QIAamp DSP Virus Kit utilizes silica-membrane technology (QIAamp technology) for isolation and purification of viral nucleic acids from human plasma or serum samples.

The QIAamp DSP Virus procedure comprises 4 steps (lyse, bind, wash, and elute) and is carried out using QIAamp MinElute® columns together with a vacuum manifold and a standard microcentrifuge. The procedure is designed to minimize the potential for sample-to-sample cross-contamination and allows safe handling of potentially infectious samples. The simple QIAamp DSP Virus procedure is suitable for simultaneous processing of multiple samples. The QIAamp DSP Virus Kit can be used for isolation of viral RNA and DNA from a broad range of RNA and DNA viruses.

In the following selected performance data for the different applications are shown.

Performance Characteristics

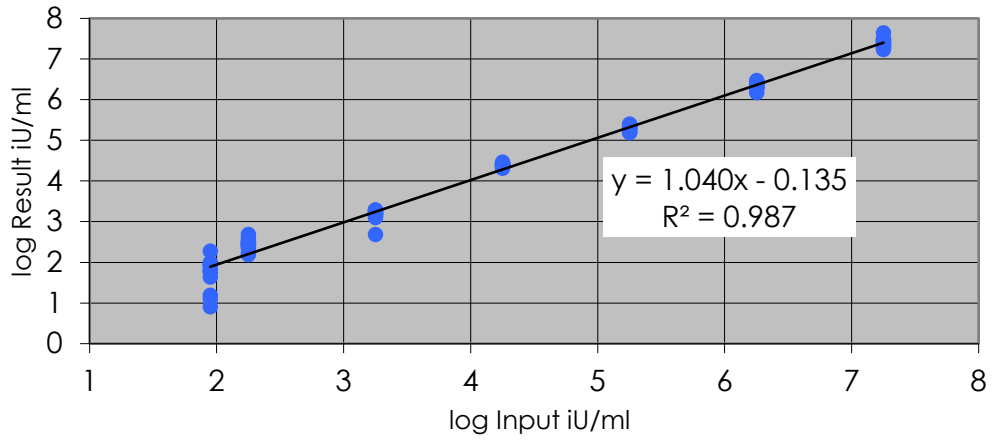
Note: Performance Characteristics highly depends on various factors and relates to the virus species and the specific downstream application. Performance characteristics have been established for the QIAamp DSP Virus Kit in conjunction with exemplary virus species and exemplary downstream applications. However, methods for isolating nucleic acids from biological specimen are used as a front-end for multiple downstream applications. Performance parameter e.g. cross contamination or run precision need to be established for any such workflow as part of the downstream application development. Therefore, it is the responsibility of the user to validate the whole workflow to establish appropriate performance parameters.

Kit performance is not guaranteed for each virus species and must be validated by the user. 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.

Basic performance and compatibility to different downstream applications

The performance for purification of viral nucleic acid using the QIAamp DSP Virus Kit was analyzed with human citrate plasma spiked with viral dilution series of HIV and HBV standard material. Dilution series with 6–7 different virus titers were tested, with 12 replicates each. Viral nucleic acids were purified from 500 µl samples and an elution volume of 60 µl. HIV and HBV standard material was detected by exemplary real-time PCR assays for HIV and HBV (Figure 1).

A



B

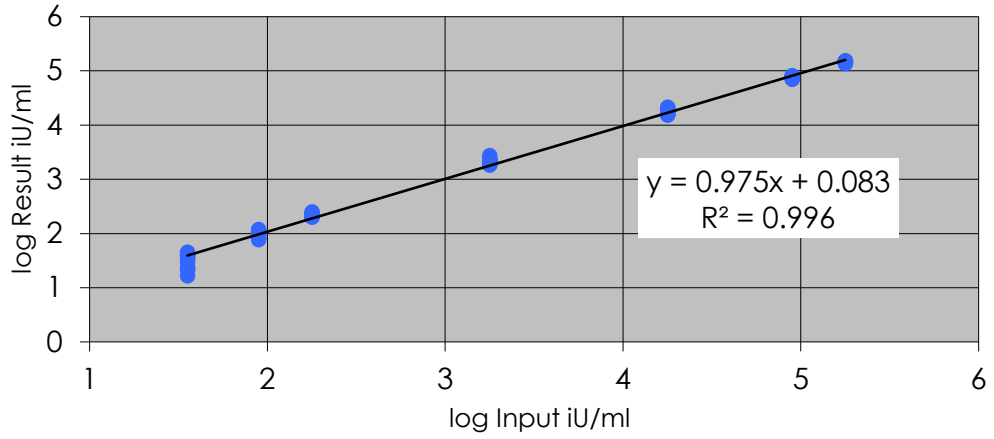


Figure 1. Virus titers determined by exemplary real-time PCR assays for (A) HIV and (B) HBV after using the QIAamp DSP Virus Kit for viral nucleic acid isolation from citrate plasma spiked with viral dilution series of HIV and HBV standard material and an elution volume of 60 µl.

Sample Input/Eluate Output Range

The starting sample volume for purification of viral nucleic acids from human plasma and serum samples using the QIAamp DSP Virus Kit is 500 µl. Elution volumes of 20 and 60 µl can be used which were both analyzed with various exemplary real-time PCR assays for HBV, HCV, and HIV.

Precision

Coefficients of variations (CVs) were determined within a reproducibility study using the QIAamp DSP Virus Kit for isolation of viral nucleic acid from human EDTA plasma spiked with HVB standard material (2,000.00 IU/ml) and using an elution volume of 60 µl. Virus titers were determined using a real-time PCR assays for HBV.

Repeatability (intra-run variability within one purification run) and total precision were determined. The precision data are shown in Table 1.

Table 1. Analysis of precision estimates

Precision	CV (%)
Repeatability	4.95%
Total precision	5.55%

Eluate Stability

Note: Eluate stability highly depends on various factors and relates to the specific downstream application. Data for eluate stability have been generated with the QIAamp DSP Virus 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. Eluate stability for the QIAamp DSP Virus Kit was evaluated using 500 µl EDTA plasma samples spiked with HBV and HCV standard material ($1x10^4$ IU/ml for both) and a 60 µl elution volume. Stability of the nucleic acid was determined with real-time PCR assays for HBV and HCV. Eluate stability at 2–8°C was not affected by duration of the storage up to 2 weeks. However, for storage times of over 24 hours we recommend to store purified nucleic acids for up to 6 months at –20°C and for up to 12 months at –80°C.

Interfering Substances

Different potential exogenous and endogenous interfering substances present in patient blood were spiked into EDTA plasma with virus standard material to test their impact on exemplary downstream assays after purification of viral nucleic acids with the QIAamp DSP Virus Kit.

Common relevant potential interfering substances for haemolysis (human hemoglobin), lipemia (triglycerides) and jaundice (bilirubin unconjugated) were evaluated in exemplary downstream assays. No negative impact was observed for these potential interferents and for over 30 additional potential interferents such as drugs typically used e.g. for treatment of relevant viral infections or other opportunistic infections and, thus, likely to be found in patient samples.

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 or concentration of potential interfering substances), so the identification and testing of relevant substances and respective concentration also needs to be established as part of the downstream application development for any workflow involving the QIAamp DSP Virus Kit.

However, interference was detected in a real-time PCR assay for heparinized plasma. This is in line with ISO 20186-2:2019(E), that suggests that heparin from blood collection tubes may impact the purity of the isolated nucleic acids and possible carryover into eluates may cause inhibitions in some downstream applications. Therefore, we recommend usage of blood samples treated with EDTA or citrate as anticoagulant for plasma preparation.

Any potential interfering substances (e.g. drugs) and corresponding concentration is very specific to the downstream application and possible previous medical treatments of a patient and needs to be investigated during verification of such downstream application using the QIAamp DSP Virus Kit.

Cross Contamination

The risk of cross contamination was analyzed using the QIAamp DSP Virus Kit on the QIAvac 24 system for viral nucleic acid isolation from citrate plasma spiked with 9.07E+04 copies/ml HBV virus. The test included three-checker board pattern runs with 24 sample (positive and negative samples alternating) and two negative samples runs in between. A potential contamination of the negative samples during the extraction was evaluated by subsequent analysis of the eluates using a real-time PCR assay. No cross-contamination was detected for sample to sample or run to run carry over.

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
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Important note

Document Revision History

Revision	Description
R1, June 2022	Version 2, Revision 1 ● Update to Version 2 for compliance to IVDR ● Transfer and update of performance characteristics from kit handbook to this document ● Addition of the following sections: ○ Basic performance and compatibility to different downstream applications ○ Sample input/eluate output range ○ Precision ○ Eluate stability ○ Interfering substances ○ Cross contamination ○ Symbols ○ Document Revision History

Limited License Agreement for QIAamp® DSP DNA Blood Mini Kit

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 Instructions for Use 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 Instructions for Use, 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**.