
December 2017

QIAasymphony[®] SP Protocol Sheet

PC2500_HC2_V1_DSP protocol

This document is the PC2500_HC2_V1_DSP *QIAasymphony SP Protocol Sheet*, R2, for QIAasymphony DSP HPV Media Kit, version 1.

General information

The QIAAsymphony DSP HPV Media Kit is intended for in vitro diagnostic use.

This protocol was developed for use with cervical specimens stored in PreservCyt® Solution using the QIAAsymphony SP and the QIAAsymphony DSP HPV Media Kit. Sample extracts prepared with this protocol are ready for testing with the *digene* HC2 High-Risk HPV DNA Test using the Rapid Capture® System (RCS).

Important: Read *QIAAsymphony DSP HPV Media Kit Handbook* and the *digene* HC2 High-Risk HPV DNA Test instructions for use before using this protocol, paying attention to the safety information provided.

Overview

Kit	QIAAsymphony DSP HPV Media Kit (cat. no. 937358)
Sample material	Liquid-based cytology cervical specimens stored in PreservCyt Solution
Protocol name	PC2500_HC2_V1_DSP
Default assay control set	ACS_PC2500_HC2_V1_DSP
Sample volume*	3 ml required sample volume 2.5 ml processed sample volume
Sample extract volume	Approximately 90 µl
Required software version	Version 4.0 or higher

* The QIAAsymphony SP aspirates 2.5 ml of sample from the bottom of the sample tube. At least 3 ml of sample volume is required for a "valid" flagged sample. Samples with less than 3 ml of sample volume, but greater than 1.6 ml sample volume, will result in an "unclear" flagged sample. Samples with less than 1.6 ml sample volume will result in an "invalid" flagged sample. Neither an "unclear" nor "invalid" flagged sample is acceptable for testing with the *digene* HC2 High-Risk HPV DNA Test.

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.

Plasticware loaded on QIASymphony SP

	One batch, 24 samples*	Two batches, 48 samples*	Three batches, 72 samples*	Four batches, 88 samples*
Disposable filter-tips, 1500 µl†	63	123	183	227
Sample prep cartridges	6	12	18	22
8-Rod Covers	3	6	9	11

* Performing more than one inventory scan requires additional disposable filter-tips. Use of fewer than 24 samples per batch decreases the number of disposable filter-tips required per run.

† The number of required filter-tips includes filter-tips for one inventory scan per reagent cartridge (RC).

Note: The numbers of filter-tips given may differ from the numbers displayed on the touchscreen depending on the settings. QIAGEN recommends loading the maximum possible number of tips.

Additional materials

Refer to *QIASymphony DSP HPV Media Kit Handbook* for additional information on the following materials:

- 14 ml, 17 x 100 mm polystyrene round-bottom tubes available from BD (cat. no. 352051)
- Hybridization Microplates available from QIAGEN (cat. no. 6000-1203)
- Microplate Lids available from QIAGEN (cat. no. 6000-5001)
- Tip Disposal Bags available from QIAGEN (cat. no. 9013395)
- Cooling Adapter, MTP, RB, Qsym available from QIAGEN (cat. no. 9018085)
- Vortexer

Specimen Handling and Storage

Specimens should be stored according to the manufacturer's instructions.

Following collection, store PreservCyt specimens for up to 3 months at 2–30°C prior to sample preparation for the *digene* HC2 High-Risk HPV DNA Test. PreservCyt specimens cannot be frozen.

Procedure

Important points before starting procedure

- Refer to the user manuals supplied with the QIASymphony SP for additional instructions on operating the instrument.
- Do not process a sample tube more than once, even if it contains sufficient sample volume for sample preparation. Discard the remaining sample volume in the sample tube; do not retain the samples. Cells in liquid-based cytology specimens quickly sediment. The QIASymphony SP aspirates an enriched sample fraction from the 3 ml specimen input volume by aspirating 2.5 ml from the bottom of the sample tube.
- The user must reserve the first column of the Hybridization Microplate on the QIASymphony SP for the calibrators and quality controls provided with the *digene* HC2 High-Risk HPV DNA Test.
- Do not use a plate ID with the QIASymphony SP that was already used with the *digene* HC2 System Software. If the plate ID already exists in the *digene* HC2 System Software, the *digene* HC2 System Software will prompt for a new input or require the user to cancel the plate map import.
- Do not use a plate ID greater than 20 characters in length or a specimen ID greater than 30 characters in length. If either input is greater than the specified maximum characters, the *digene* HC2 System Software, during plate map import, will prompt for a new input or require the user to cancel the plate map import.
- When creating the specimen or plate ID, adhere to the following requirements to ensure compatibility with the *digene* HC2 System Software:
 - Do not use a space before or after the ID
 - Do not use case-sensitive characters to differentiate IDs
 - Only use alphanumeric characters, hyphens, and spaces to create an ID
- If testing a specimen as part of the retest algorithm, the specimen ID must be exactly the same as the original specimen ID that was tested. If the specimen ID is not exactly the same, during plate map import the *digene* HC2 System Software will not assign the specimen ID properly from the unassigned specimen list.
- If using a quality control ID, as defined in the *digene* HC2 System Software, as a specimen ID on the QIASymphony SP, the flagging of the sample (such as "valid", "unclear", or "invalid") and all comments from the QIASymphony SP will not transfer during the plate map import. The flagging and comments of the QIASymphony SP processing must be entered manually into the *digene* HC2 System Software.

- If the “Eluate” drawer is opened when a batch is running (e.g., if the Hybridization Microplate that contains the sample extracts is removed), the run will be paused and the user must perform an inventory scan of the “Eluate” drawer. Make sure to complete the “Eluate” drawer scan before continuing with the protocol.

Loading the QIASymphony SP

1. Close all drawers and the hood.
2. Power ON the QIASymphony SP, and wait until the initialization procedure has finished.

Note: The power switch is located at the bottom, left corner of the QIASymphony SP.
3. Log in to the instrument.
4. Prepare the “Waste” drawer according to the following table.

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, make sure that the box spacer has been removed.

Unit box holder 1–4	Empty unit boxes
Waste bag holder	Waste bag (replace the waste bag if necessary)
Liquid waste bottle holder	Empty liquid waste container
Tip chute holder	Tip chute
Tip park station	Empty tip park station

5. Perform an inventory scan of the “Waste” drawer, including the tip chute and liquid waste.
6. Load the required reagent cartridge(s) (RC) and consumables into the “Reagents and Consumables” drawer according to the following table.

See “Plasticware loaded on QIASymphony SP,” page 3, for more information about the number of consumables to load.

Important:

- Do not refill tip racks or unit boxes with consumables remaining. The QIASymphony SP can use partially used tip racks and unit boxes.
- Make sure not to touch the disposable filter-tips to the instrument drawer to prevent contamination.

If using new sample prep cartridges or 8-Rod Covers, invert the unit box holders while holding a hand over the opening, and slide the materials in the unit box holders up and down to make sure the materials are properly aligned in the unit box holders.

Position A1 and/or A2	Reagent cartridge (RC)
Position B1	Empty
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

7. Perform an inventory scan of the “Reagents and Consumables” drawer.

Notes:

- Initiate a new scan of the reagent cartridge (RC) after processing 88 specimens.
- Avoid scanning the reagent cartridge (RC) in short intervals (e.g., after additional loading of consumables or after running a batch of 24 specimens).

Loading the “Eluate” drawer

1. Place the Hybridization Plate into the Cooling Adapter, MTP, RB, Qsym with the A1 microplate well aligned with the adapter corner labeled “A1”.

2. Open the “Eluate” drawer.

The “Eluate Drawer/Elution Slot” screen appears.

3. Use the handheld bar code scanner to select slot 1. Alternatively, press the corresponding slot button on the touchscreen.

The “Eluate Drawer/Elution Slot/Change Rack 1” screen appears.

4. Use the handheld bar code scanner to input the rack ID. Alternatively, press the “Rack ID” button and enter the rack ID using the keyboard displayed on the screen.

The entered elution rack ID is displayed.

5. Place the Hybridization Microplate with the adapter in the “Eluate” drawer in slot 1 (the cooling position). Make sure the Hybridization Microplate is oriented with the A1 microplate well in the upper left corner.

Important: The Hybridization Microplate with the adapter must be oriented with the A1 microplate well in the upper left corner for proper use with the *digene* HC2 High-Risk HPV DNA Test and the RCS.

6. In the “Available rack types:” drop-down list, press the “Micro Plate” button.

A list of available microplates displays.

7. Press the “QIA#6000-1203 *MTP96 RB” button from the available microplates listed.

The “Reserved Columns” option becomes available after a rack type has been selected. The first column on the left side of the Hybridization Microplate must be reserved.

8. Use the “+” and “-” to reserve “1” column of the Hybridization Microplate.

9. Close the “Eluate” drawer.

10. Press the “OK” button.

The QIASymphony SP performs an inventory scan of the “Eluate” drawer. Sample processing pauses, and the robotic arm moves to the “Eluate” drawer to check that selected elution slots contain an elution rack.

Preparing the samples

Equilibrate the specimens to room temperature (15–30°C) prior to preparing the samples. Transfer the specified specimen volume to a sample tube just before starting the run.

1. For each specimen, label a 14 ml 17 x 100 mm polystyrene, round-bottom tube. Alternately, place a bar code on the tube.
2. In the applicable tube carrier, place the sample tubes in the order in which they will be placed onto the Hybridization Microplate. Orient the bar codes to the left so that they can be read by the bar code reader, as applicable.

3. Handling one specimen at a time, shake the PreservCyt specimen vial vigorously by hand for 5–10 seconds. Alternately, mix with a vortexer at maximum speed for 5–10 seconds.

4. Immediately, as cells settle quickly, remove the lid of the PreservCyt specimen vial, and pipet 3 ml of specimen into the bottom of the corresponding sample tube in the tube carrier.

Pipetting into the bottom of the sample tube minimizes cellular material adhering to the inside of the sample tube.

Make sure of reliable sample transfer by not generating foam.

5. Replace the lid on the PreservCyt specimen vial.
6. Repeat for each additional specimen, as applicable.
7. Load the sample carrier in the “Sample” drawer.

Running the QIASymphony SP

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

Enter the following information:

- Sample IDs
- Sample tube type: “BD#352051 FalconPP 17x100”
- Protocol to be run: “PC2500_HC2_V1_DSP”
- Output position: “Elution slot 1”

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2. Press "Queue".

The status of the batch changes from "LOADED" to "QUEUED". As soon as one batch is queued, the "Run" button appears.

3. Press the "Run" button to start the QIASymphony SP protocol run.

All steps of the protocol run are fully automated. At the end of the protocol run, the status of the batch changes from "RUNNING" to "COMPLETED".

The Hybridization Microplate should be removed from the "Eluate" drawer immediately after the protocol run has finished. Depending on temperature and humidity, leaving the Hybridization Microplate in the QIASymphony SP after the protocol run is completed may cause condensation or evaporation.

4. Open the "Eluate" drawer.

5. On the touchscreen, press "Slot 1" and press "Remove".

A message appears asking if you want to remove the rack.

6. Press the "Yes" button.

7. Remove the Hybridization Microplate containing the sample extracts from the "Eluate" drawer. See "Storage of sample extracts", page 9, for additional information.

Important: Avoid splashing the sample extracts when handling the Hybridization Microplate. Cover the Hybridization Microplate with a microplate lid after removing it from the "Eluate" drawer and keep the Hybridization Microplate covered whenever possible.

8. Press "OK".

The QIASymphony SP scans the "Eluate" drawer.

Result files are generated for each Hybridization Microplate.

9. Visually inspect the sample extracts. Exclude from further testing any sample extract without a visible amount of magnetic particles.

10. Remove the reagent cartridge(s) (RC). If the reagent cartridge (RC) is only partially used, seal it with the provided Reuse Seal Strips immediately after the protocol run to avoid evaporation.

11. Visually inspect the sample tubes. Exclude from further testing any sample that was not transferred during the protocol run.

12. Discard the used sample tubes and waste according to national and local safety regulations.

13. Clean the QIASymphony SP.

Follow the maintenance instructions in the user manuals supplied with your instrument.

14. Close the instrument drawers, and power OFF the QIASymphony SP.

Storage of sample extracts

Make sure the Hybridization Microplate is covered with a microplate lid and store. The sample extracts may be stored for 5 days at 2–8°C covered with a microplate lid.

Revision history

Document revision history	
R2 12/2017	Update for QIASymphony Software version 5.0

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