

# QIASymphony® DSP AXpH DNA Kit

The QIASymphony DSP AXpH DNA Kit is designed for fully automated purification of DNA from liquid-based cytology media using the QIASymphony SP. The QIASymphony DSP AXpH DNA Kit provides DNA eluates that are ready for direct use in downstream applications, such as hybridization-based assays or enzymatic reactions. The eluates should not be used in PCR. The QIASymphony SP performs all steps of the sample preparation procedure. Up to 96 samples, in batches of up to 24, are processed in a single run.

## Performance Characteristics

### Repeatability

The repeatability was determined in 2 independent experiments. DNA was purified from 7 dilutions of an HPV positive cell line (SiHa) in a negative cellular background in PreservCyt media using the QIASymphony DSP AXpH DNA Kit on the QIASymphony SP. Eluates were analyzed using the *digene*® HC2 High-Risk HPV Test (Figure 1).

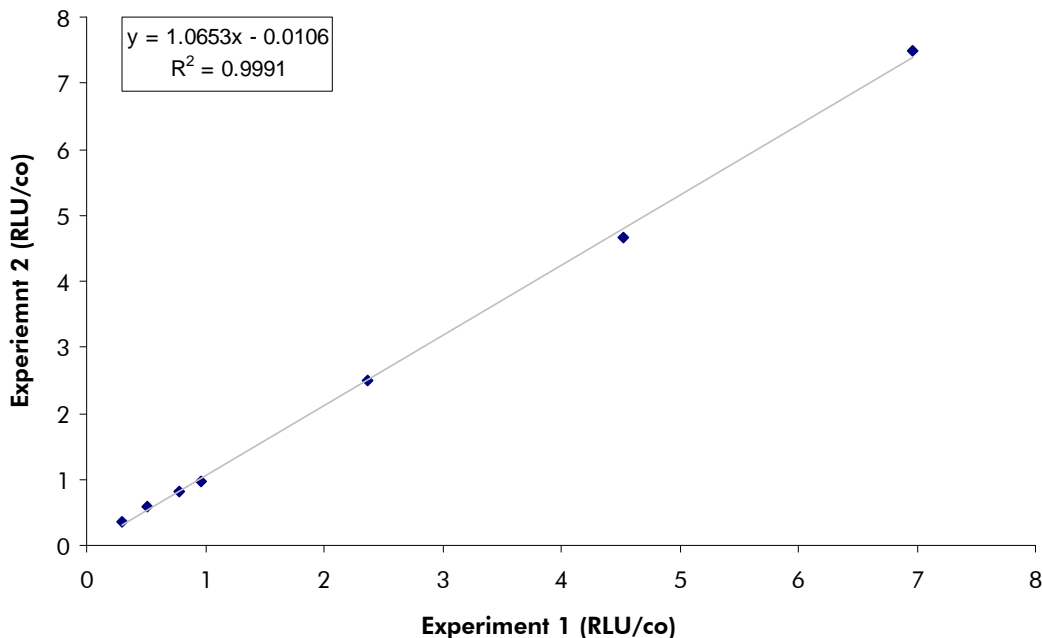


Figure 1. Mean RLU/co values from 2 independent experiments, where DNA was purified from 7 dilutions of an HPV positive cell line.



## Precision

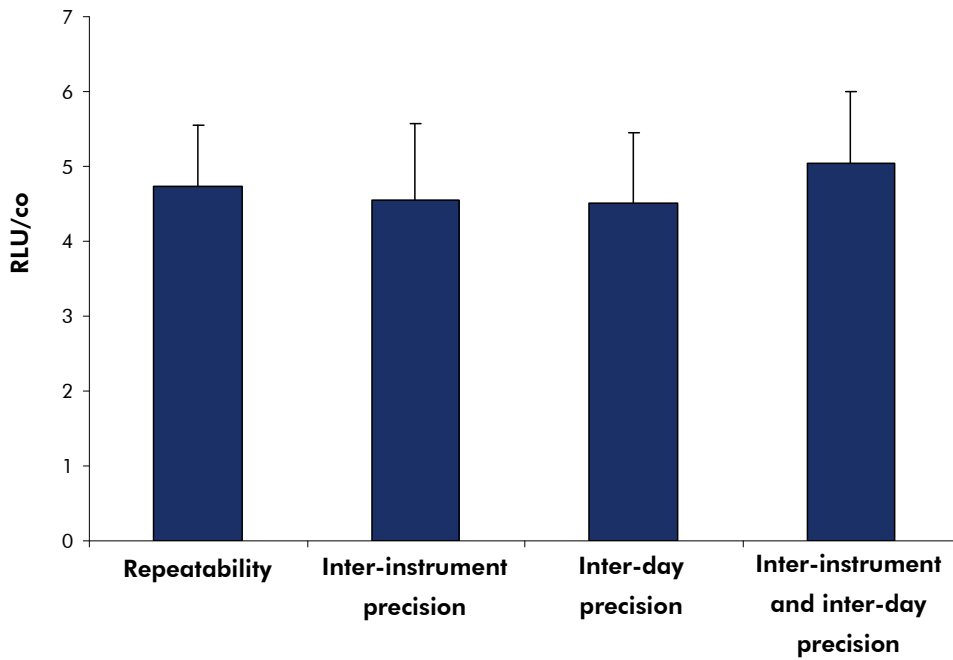
Inter-instrument precision and inter-day precision of DNA purification using the QIAAsymphony DSP AXpH Kit on the QIAAsymphony SP was determined on 3 different instruments (1–3) and on 3 different days (A–G) (Table 1). DNA was purified from HPV-positive cells (SiHa cell line) in a negative cellular background in PreservCyt media. The eluates were analyzed using the digene HC2 High-Risk HPV DNA Test (Table 2).

**Table 1. Strategy for determining inter-instrument and inter-day precision, where A–G indicate individual runs on the QIAAsymphony SP.**

Instrument	Day 1	Day 2	Day 3
Instrument 1	A1 + A2	D1	F1
Instrument 2	B1	E1	–
Instrument 3	C1	–	G1

**Table 2. Repeatability, inter-instrument precision, inter-day precision, and inter-instrument and inter-day precision.**

	Runs	Precision (%CV)
Repeatability	A1+A2	17.32
Inter-instrument precision	A1+B1+C1	22.28
Inter-day precision	A1+D1+F1	20.52
Inter-instrument and inter-day precision	A1+E1+G1	19.09

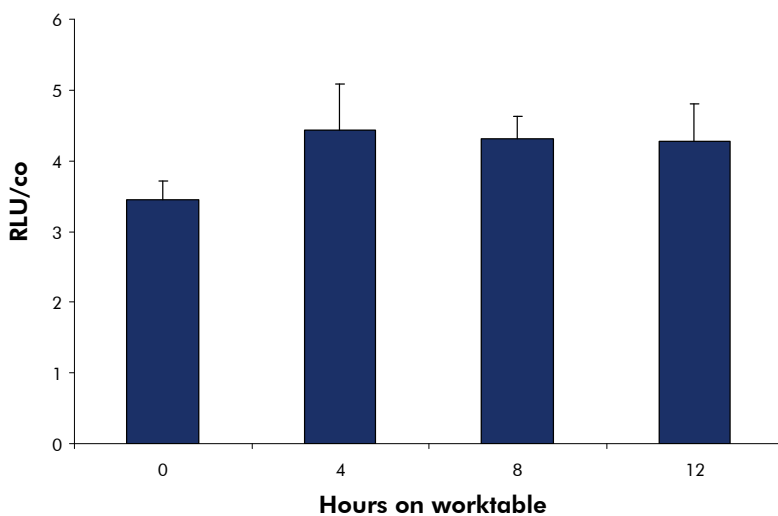


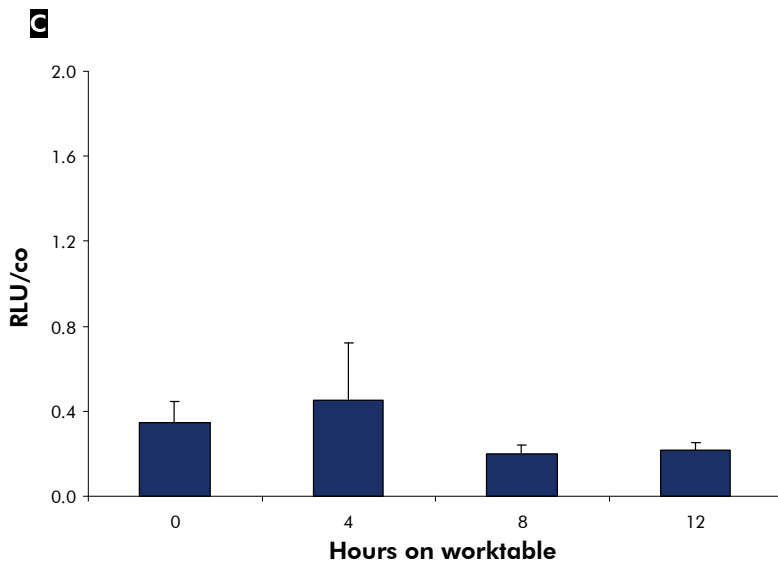
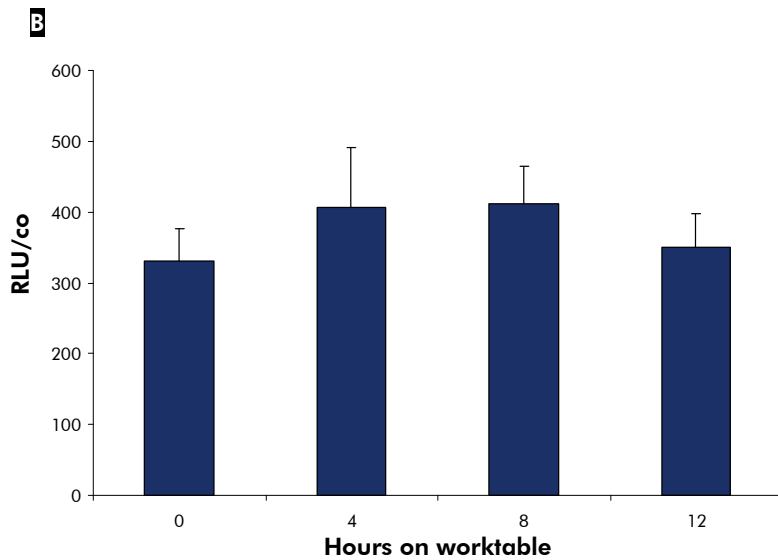
**Figure 2. Repeatability, inter-instrument precision, inter-day precision, and inter-instrument and inter-day precision.**

### Stability

HPV positive cellular, positive clinical, and negative cellular samples were aliquoted into 14 ml BD secondary primary tubes according to the defined time for the respective batch. Samples were stored at either  $5 \pm 3^\circ\text{C}$  or at  $30 \pm 3^\circ\text{C}$ . At 0, 4, 8, and 12 hour time points samples ( $n=11$ ) were removed from each temperature, defined as a batch (total number of samples = 22), and then processed immediately on the QIAAsymphony SP. The eluates were analyzed using the digene HC2 High-Risk HPV DNA Test (Figure 3).

**A**

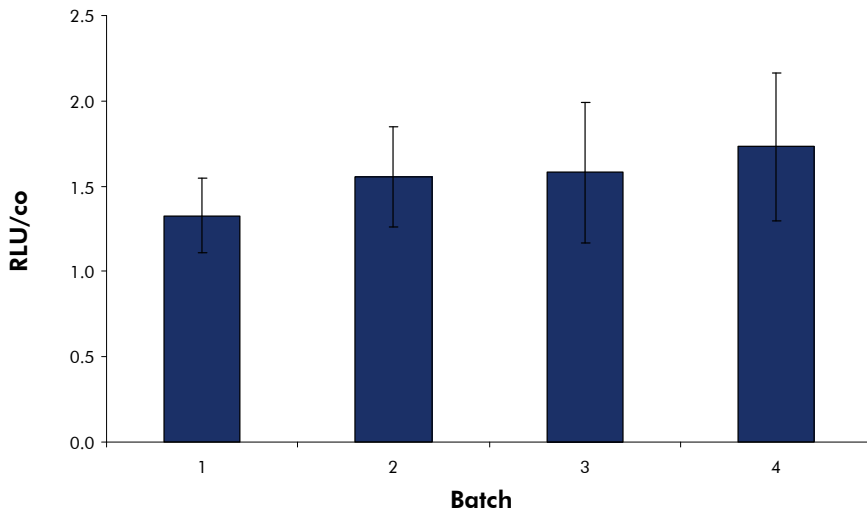




**Figure 3. Stability of **A** positive cellular, **B** positive clinical, and **C** negative cellular samples after 0, 4, 8, and 12 hours at 30°C on the worktable.**

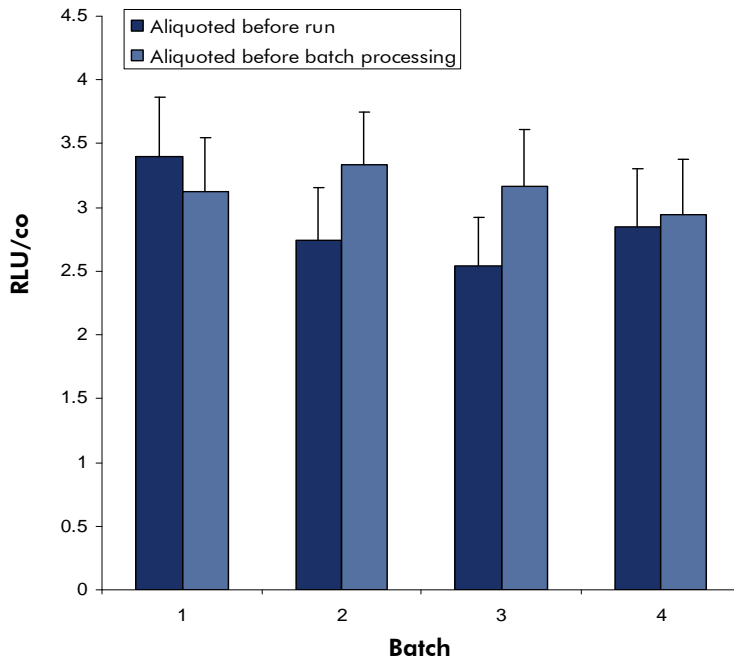
### Inter-batch variability

DNA from 4 batches of 11 positive clinical pool samples (cervical swabs stored in PreservCyt medium) was purified using the QIASymphony DSP AXpH Kit on the QIASymphony SP. Eluates were analyzed using the digene HC2 High-Risk HPV DNA Test (Figure 4). No significant change in RLU/co was observed for the different batches, indicating that there was no significant inter-batch variability.



**Figure 4. Inter-batch variability of positive clinical pool samples purified on the QIAAsymphony SP using the QIAAsymphony DSP AXpH Kit.**

DNA from 8 batches of 24 HPV positive cell line samples (SiHa cells in PreservCyt medium) was purified on the QIAAsymphony SP using the QIAAsymphony DSP AXpH Kit. Four batches were aliquoted before the run was started and 4 batches were aliquoted immediately before each batch was processed. Eluates were analyzed using the digene HC2 High-Risk HPV DNA Test (Figure 5). When samples were aliquoted immediately before the batch was processed, no significant change in RLU/co was observed. Samples that were aliquoted at the start of the run show a decrease in RLU/co signal. Therefore cellular samples that are processed on the QIAAsymphony SP using the QIAAsymphony DSP AXpH Kit should be aliquoted immediately before processing.



**Figure 5. Inter-batch variability of cellular clinical pool samples purified on the QIAAsymphony SP using the QIAAsymphony DSP AXpH Kit.**

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