Evaluation of UCM® preservative robustness — enabling HPV DNA preservation in first-void urine collected with various Colli-Pee® device formats

Kyle MacDonald[1], Cameron Wood[1], Melissa Richer[1], Nette Meers[2], Koen Beyers[2], Tara Crawford Parks[1]

[1]DNA Genotek, Ottawa, Canada [2]Novosanis NV, Wijnegem, Belgium

Introduction

The ability to detect human papillomavirus (HPV) in first-void urine (FVU) offers exciting opportunities to expand cervical cancer screening and diagnosis programs, but it is dependent on proper collection. The Novosanis Colli-Pee® device enables convenient, user-friendly self-collection of a volumetric FVU sample. In addition, prefilled Colli-Pee devices with liquid UCM® preservative (1:3 preservative-to-sample ratio) are available to preserve urine samples post-collection and prevent degradation of HPV DNA.

Understanding the effective UCM preservative-to-sample ratio range for HPV DNA preservation is important to support multiple volume variants of the Colli-Pee device and collection of FVU samples for HPV detection.

Methods

FVU samples were collected from healthy female and male donors (n = 9) using the Colli-Pee device without preservative (FV-5020), then mixed post-collection with UCM preservative at various ratios (1:4–1:1.7), or left unpreserved (Figure 1). Samples were spiked with HPV-16 plasmid DNA (~500,000 cps/mL) and then held at room temperature (20°C-26°C) for 8 days.

At baseline (T0) and endpoint (T8), DNA was extracted (QIAGEN QIAamp® DNA Mini Kit) from a whole urine aliquot (200 µL) of each sample, followed by HPV-specific qPCR (internally developed assay) to evaluate HPV DNA detectability and preservation in the samples.
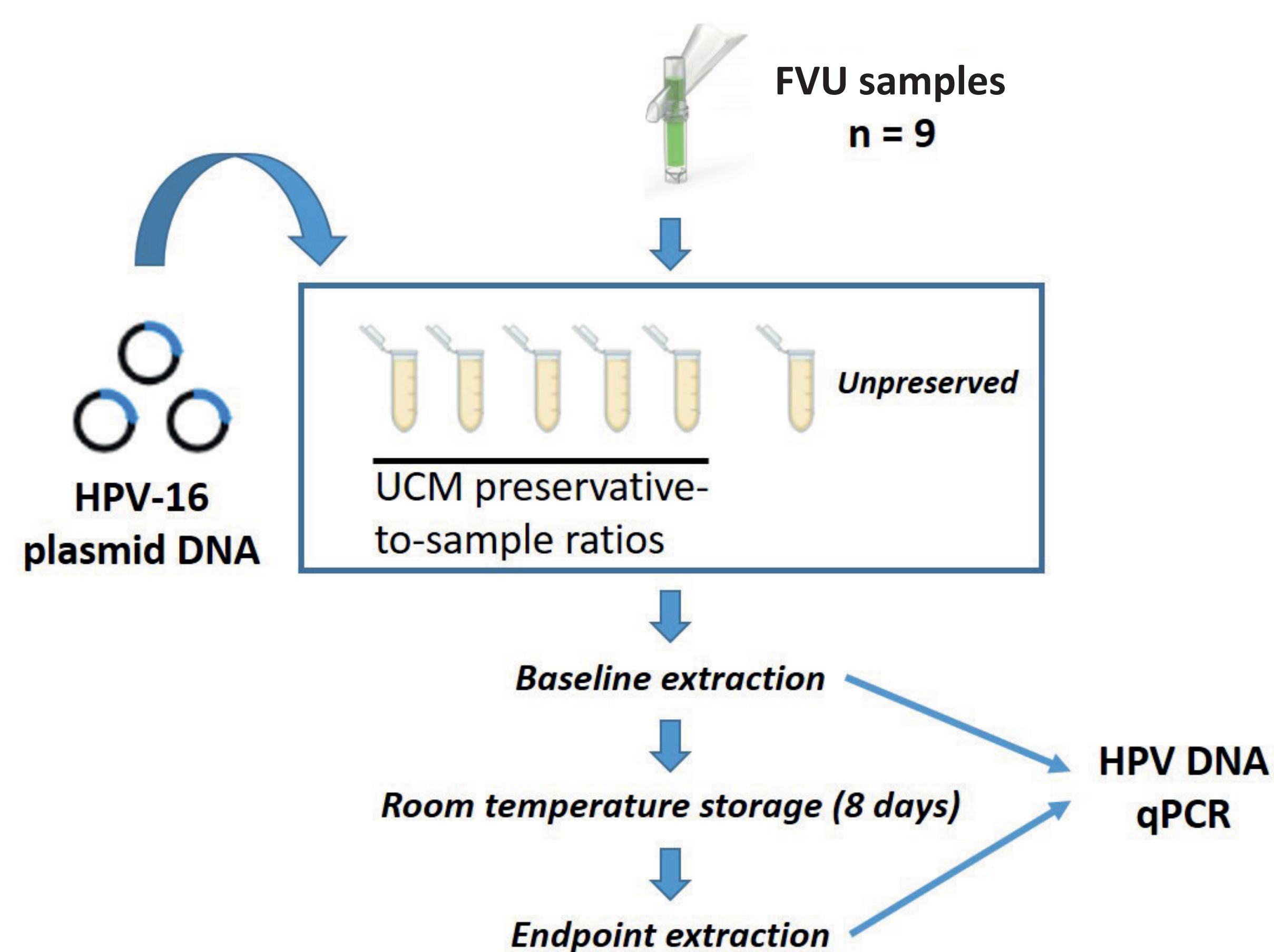

Figure 1. Study design overview.

Results

After room temperature storage, HPV DNA was detected in all FVU samples with UCM preservative (Table 1). There were no significant differences (paired t-test) in HPV DNA preservation (average qPCR ΔCt) between the UCM preservative at the nominal ratio (-0.41 ± 0.25 SD) and any of the evaluated UCM preservative-to-sample ratios (1:4; 0.00 ± 0.25 SD, 1:1; -0.35 ± 0.32 SD) (Figure 2). In contrast, unpreserved FVU samples experienced significant (p < 0.001) HPV DNA loss (9.83 ± 3.54 SD).

Donor	UCM preservative-to-sample ratio					% of samples with detectable HPV DNA
	1:1.7	1:2.1	1:3.0 (Nominal)	1:3.7	1:4.0	
F1	+	+	+	+	+	100%
F2	+	+	+	+	+	100%
F3	+	+	+	+	+	100%
F4	+	+	+	+	+	100%
F5	+	+	+	+	+	100%
M1	+	+	+	+	+	100%
M2	+	+	+	+	+	100%
M3	+	+	+	+	+	100%
M4	+	+	+	+	+	100%

Table 1. HPV DNA detectability in UCM preserved samples after 8 days at room temperature. ("+": T8 qPCR Ct < Ct of the no template control).
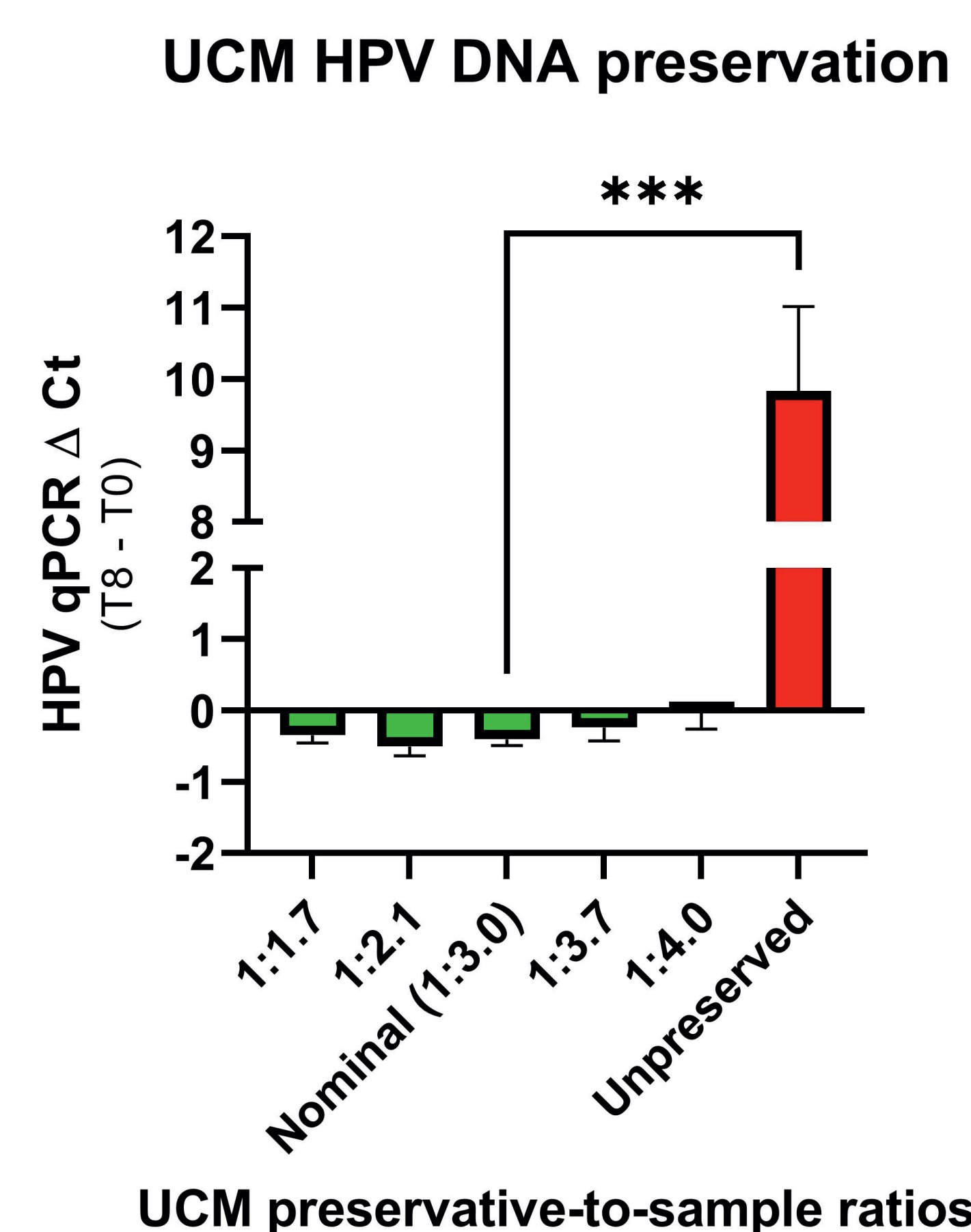

UCM HPV DNA preservation

Figure 2. HPV DNA preservation in evaluated UCM preservative-to-sample ratios after 8 days at room temperature. Bars represent the HPV DNA qPCR average Δ Ct (average Ct T8 minus average Ct T0, within each sample) ± SD. The unpreserved urine samples had a significantly higher average HPV qPCR Δ Ct than the nominal UCM preservative-to-sample ratio. ***p < 0.001

Conclusions

These results demonstrate the robustness of UCM to preserve HPV DNA in FVU samples across a wide range of UCM preservative-to-sample ratios. Importantly, this permits UCM preservative incorporation in multiple Colli-Pee device volume variants, including FV-5004 (4 mL), FV-5010 (10 mL) and FV-5020 (20 mL) formats (Figure 3), allowing device selection based on sample volume, high-throughput processing and/or postal delivery needs.
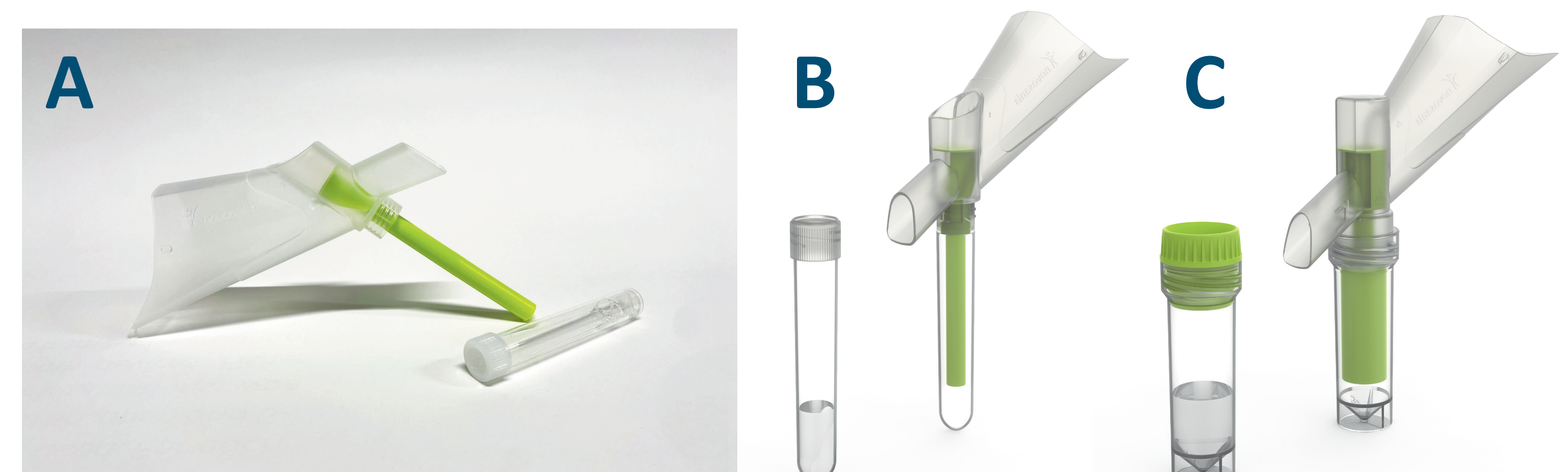

Figure 3. Testing conducted in this study supports the effectiveness of UCM to preserve HPV DNA in FVU samples collected with various Colli-Pee device volume variants, including FV-5004 (A), FV-5010 (B) and FV-5020 (C).