



GAME-CHANGING SAMPLING DEVICES

TOWARDS A WORLD WITHOUT CERVICAL CANCER

Cervical cancer remains a global challenge, leading to 275,000 deaths annually, worldwide.

[“Cervical cancer is still the 4th most common cancer in women despite proven efficacy of screening programs”]¹

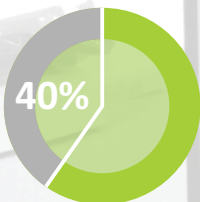
Despite availability of safe and effective vaccines for young girls, many women are still fully dependent on screening programs.

Public screening programs must achieve high compliance to be effective and efficient, yet participation is low in many countries despite standard invitations and recall systems.

Reasons mentioned for non-attendance are the relative invasive character of cervical sampling, ethnicity and culture, lack of time and the need to visit a clinician.

Importantly, especially young women are often reluctant to have a PAP smear.

NON-ATTENDEES
ACROSS EUROPE



50 MILLION WOMEN TO BE SCREENED
20 MILLION NOT PARTICIPATING



275,000 WOMEN DIE YEARLY
FROM CERVICAL CANCER



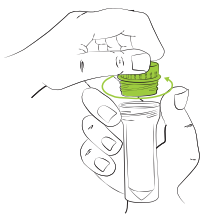
HPV DNA TESTING
IN FIRST-VOID URINE



COLLI-PEE™ An innovative approach to increase cervical cancer screening participation

The mucus and debris from exfoliated superficial cell layers of a cervix carcinoma are washed away by the first urine that passes.² This first-void urine combined with a preservative to prevent HPV DNA breakdown by DNA nucleases contains a significantly higher number of HPV DNA copies.³

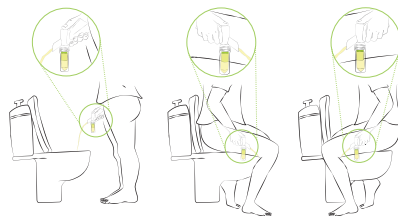
- Guaranteed and standardized first-void urine collection
- Allows hygienic and non-invasive self-sampling (at home)
- No need to interrupt the urine flow
- Collector tube prefillable with preservative
- Not interfering with the natural history of the infection ⁴
- First void-urine is useful for post-vaccination HPV surveillance ⁵



1. Uncap



2. Assemble



3. Collect first-void urine



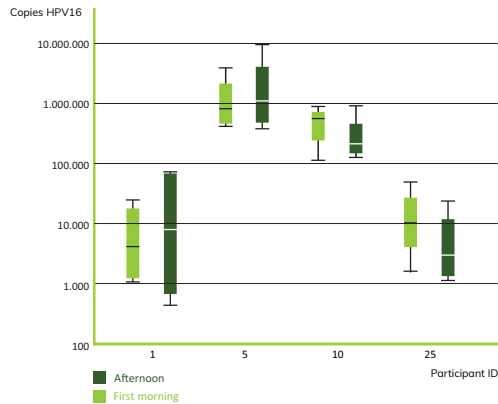
4. Disassemble



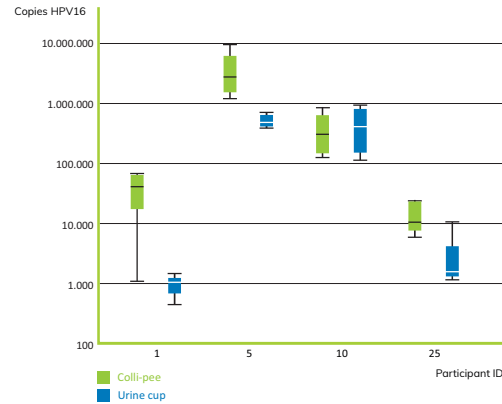
5. Recap

COLLI-PEE™ Enabling higher analytical sensitivity for HPV DNA detection in urine

Studies performed by A. Vorsters et al, in which participants with a self-reported HPV infection provided first-void urine samples, confirm that when an appropriate preservative and DNA extraction method is used, urine is a reliable and reproducible sample for HPV DNA testing. Samples collected by the Colli-Pee™ device yielded a significantly higher number of copies of hDNA and HPV DNA compared to regular urine collector devices, independent whether the first-void is taken from the first urine of the day or from urine provided later in the day.⁶



Average copies of HPV DNA per participant and per HPV genotype found in first morning FV and afternoon FV urine.



Average copies of HPV DNA per participant and per HPV genotype found in Colli-Pee™ and urine cup collected first void urine.

Compared to a standard urine collection cup, the use of Colli-Pee™ resulted in a higher analytical sensitivity.

Proof of concept studies with commercially available diagnostic assays for automated screening (Roche Cobas® HPV, BD Onclarity™ HPV, Aptima® HPV Hologic Panther), point of care testing (Cepheid Xpert® HPV) or genotyping (Genefirst Papilloplex™ HR-HPV, Anyplex™ II HPV HR Seegene, Fujirebio Innolipa™) confirm HPV DNA detection in first-void urine is feasible.^{7 to 15}

“I am convinced that the non-invasive character of urine sampling, with option of home collection, will definitely help to enroll underserved women in cervical cancer screening and follow-up programs across the world.”

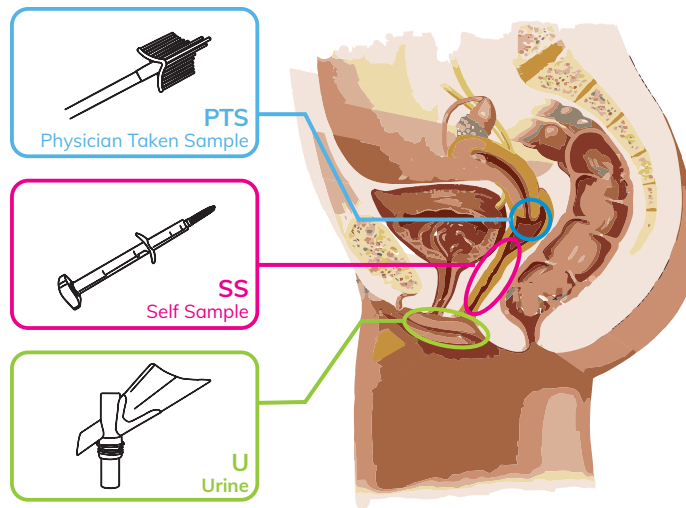
Alex Vorsters
PhD and Project Group Leader HPV VAXINFECTIO (University of Antwerp)

COLLI-PEE™ A first-void urine collection device suitable for self-sampling

Self-sampling can increase the screening coverage and reduce cervical cancer rates in populations that would otherwise not be screened.¹⁶

Physician-taken smears, brush-based self-sampling and first-void urine are equally sensitive to detect CIN2+ using two different hrHPV tests (the highly sensitive SPF10 LiPA 25, version 1 assay or the clinically validated GP5+/6+ based luminex assay). None of the samples or assays missed CIN3.¹⁷

Colli-Pee™ was equally sensitive in detection of CIN2+ as physician-taken smears



Sensitivity and specificity of hrHPV testing for CIN2+ detection in physician taken smear (PTS), self-sample (SS), morning first-void urine (FVU1) and first-void urine from later during the day (FVU2) tested with SPF10 and GP5+/6+

Sample	SPF10				GP5+/6+			
	Sensitivity		Specificity		Sensitivity		Specificity	
	%	95% CI	%	95% CI	%	95% CI	%	95% CI
PTS	100	83-100	33	24-45	95	75-99	39	28-50
SS	100	83-100	35	25-46	95	75-99	43	32-55
FVU1	95	75-99	32	22-43	95	75-99	42	31-53
FVU2	100	83-100	29	20-41	95	75-99	42	31-53



**GUARANTEED
FIRST-VOID**



**STANDARDIZED
SELF-SAMPLING**



**USER
FRIENDLY**



BHUTAN & RWANDA Urine testing to monitor the impact of HPV vaccination

Bhutan (2010) and Rwanda (2011) were the first African and Asian countries to implement national human papilloma virus (HPV) vaccination programs in primary schools.

The Colli-Pee™ device was enrolled in the study to check for the presence of hrHPV DNA genotypes 16 and 18 and to monitor the impact of HPV vaccination programs. A total of 1885 girls used the Colli-Pee™ device.

Prevalence of HPV6/11/16/18 was lower in vaccinated than unvaccinated students in both Rwanda and Bhutan.

This study supports the feasibility of urine surveys to monitor HPV vaccination as well as the effectiveness of the quadrivalent vaccine in women after pre-adolescence.¹⁸

1. Stewart, B et al World Cancer Report 2014
2. Van Keer et al Eur J Obstet Gynecol Reprod Biol., 2017, 216, 1-11
3. Vorsters et al Eur J Clin Microbiol Inf Dis, 2014, 33 (11) 2005-2014
4. Vorsters et al. Human Vaccines and Immunodeficiencies, 2015;11(2):350-2.
5. Pathak N et al BMJ. 2014;349 g5264.
6. Vorsters et al. 30th IPV Conference, 2015, Lisbon, PT, Poster #421
7. Vorsters et al. 30th IPV Conference, 2015, Lisbon, PT, Poster #422
8. Vorsters et al. Eurogin 2016, Salzburg, AT, Poster #12-16
9. Vorsters et al. Eurogin 2016, Salzburg, AT, Poster #12-17

10. Vorsters et al. Eurogin 2016, Salzburg, AT, Poster #12-21
11. Vorsters et al HPV2017, Capetown, SA, poster #HPV17-0542
12. Van Keer et al HPV2017, Capetown, SA, poster #HPV17-0667
13. Pattyn et al HPV2017, Capetown, SA, poster #HPV17-0411
14. Pattyn et al. EUROGIN 2017, Amsterdam, NL (oral presentation)
15. Vorset et al. EUROGIN 2017, Amsterdam, NL, Poster
16. Wentzensen N. et al. 2016;12.040
17. Leeman A. et al. BJOG. 2017;124(9):1356-1363
18. Franceschi S et al. Int J Cancer. 2016;139(3):518-26.

COLLI-PEE™ For customized standardized first-void urine collection

As a trusted partner of diagnostic companies, Novosanis develops customized versions of Colli-Pee™ for improved diagnostic accuracy and patient comfort. Bespoke tube design allows high-throughput processing, centrifugation and workflow optimization.



*Successful automation
starts with sampling*



*Successful automation
starts with sampling*



UCM-Preservative