COLLI-PEE® Urine testing allows to monitor the impact of HPV vaccination

A vaccine impact study conducted by the World Health Organization (WHO) and International Agency for Research on Cancer (IARC) in Bhutan and Rwanda demonstrated first-void urine is a very well-accepted liquid biopsy source that can be easily and non-invasively collected with minimal requirements for trained staff[15].

Follow-up of HPV prevalence through repeated surveys in these populations show that vaccine-targeted HPV types decreased significantly. These findings highlight the high acceptability of urine as a sample type, and feasibility for home-based collection in combination with accessible delivery points in low- and middle-income countries[16].

Additionally, a vaccine impact study by the WHO-IVI is also ongoing in Thailand to detect high risk HPV strains in urine collected with Colli-Pee. HPV detection in urine showed good sensitivity and specificity when compared to clinician-collected cervical swabs[17].

"I am convinced that the clinical and diagnostic information present in a first-void urine sample still is greatly underestimated. We confirmed that first-void urine is an interesting sample to monitor HPV vaccination programs; possibilities in cervical cancer screening programs are being explored. 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)

STANDARDIZED **FIRST-VOID**

VOLUMETRIC **SELF-SAMPLING**

USER **FRIENDLY**

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

The Colli-Pee® platform offers improved diagnostic accuracy and patient comfort. It consists of variants and stabilization solutions for different application purposes.* To facilitate high-throughput screening, Novosanis developed Colli-Pee® Small Volumes. The combination of the new funnel and standard 4 mL and 10 mL tubes allows immediate processing by fully automated systems.

Colli-Pee®

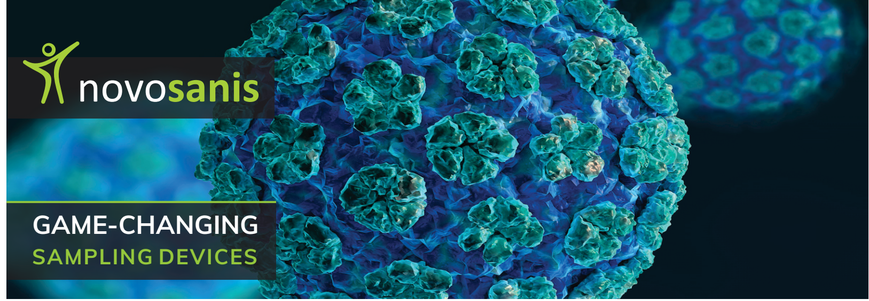
Successful automation starts with sampling

UCM-Preservative For improved preservation of urine sample

Colli-Pee® (10 mL and 20 mL) devices can be prefilled with non-toxic Novosanis proprietary Urine Conservation Medium (UCM), which allows the preservation of urine during storage and transport. First-void urine collected in the Colli-Pee® device prefilled with UCM can be transported by postal mail at room temperature[9].

*Some products are in development or not available in all geographic regions.

www.novosanis.com **Version 2021-02A-EN** **Subsidiary of OraSure Technologies Inc.**



TOWARDS A WORLD WITHOUT CERVICAL CANCER

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

Nearly all cervical cancers are caused by a persistent cervical infection with a high risk Human Papillomavirus (HPV). 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 for non-attendance are the relative invasive character of cervical sampling, ethnicity and culture, lack of time and the need to visit a clinician. Additionally, especially young women are often reluctant to have a PAP smear.

To reduce preventable cervical cancer deaths, methods to increase awareness through health education and improve HPV vaccination and cervical cancer screening uptake are needed. The Word Health Organization's (WHO) Global Strategy aims to accelerate the elimination of cervical cancer through improved uptake of vaccination and screening as well as timely treatment. Implementation of these methods could prevent more than 40% of new cases and 5 million related deaths by 2050[1].

"Cervical cancer is still the 4th most common cancer in women despite proven efficacy of screening programs"[2]

Global recommended targets to achieve by 2030[1]

90%
GIRLS VACCINATED WITH HPV VACCINES BY AGE 15

70%
WOMEN SCREENED USING HIGH-PERFORMANCE TESTS AT AGE 35 AND 45

90%
WOMEN WITH CERVICAL DISEASE RECEIVE TREATMENT

COLLI-PEE® An innovative approach to test high risk HPV and biomarkers in the same sample[3]

The mucus and debris from exfoliated superficial cell layers of a cervix carcinoma are washed away by the first urine that passes.[4]
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.[4]

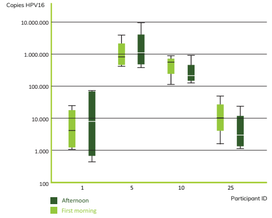
- Volumetric and standardized first-void urine collection
- Allows hygienic and non-invasive self-sampling (at home)
- No need to interrupt the urine flow
- Collector tube prefillable with preservative
- Not interfering with the natural history of the infection[5]
- Useful for post-vaccination HPV surveillance[6]

1. Uncap 2. Assemble 3. Collect first-void urine 4. Disassemble 5. Recap

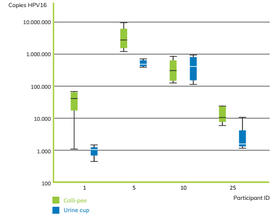
COLLI-PEE® Enabling higher analytical sensitivity for HPV DNA detection in urine

Studies performed by A. Vorsters et al, confirm that when an appropriate preservative and DNA extraction method is used, first-void 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.[7]

Pattyn et al provided further evidence that when an appropriate preservative and DNA extraction method in combination with a PCR-based HPV test is used, first-void urine is a reliable sample for HPV DNA testing. Colli-Pee® collected samples showed higher HPV concentrations than cup collected samples[8].



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.

Colli-Pee® collected samples show higher HPV concentration than cup collected samples[8]

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™, High+Low Papillomastrip Operon) confirm HPV DNA detection in first-void urine is feasible[9].

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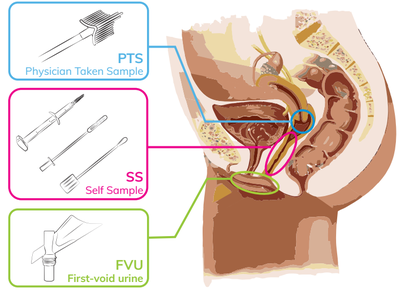
COLLI-PEE® Empowering higher cervical cancer screening participation

Self-sampling can increase the screening coverage and reduce cervical cancer rates in populations that would otherwise not be screened.[11] A study in France highlighted that urinary HPV testing may be useful to reach women who do not regularly have cervical Pap smears done to find high-grade cervical lesions[12].

The **EVAH** study showed that 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[13].

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



The **Predictors 5.1** study compared 5 different sampling methods through vaginal self-sampling devices and urine for HPV testing among a population of women. Similar positivity rates and sensitivities for CIN2+ and CIN3+ were seen for flocked swab, dacron swab and urine but women found urine easiest to collect, and were more confident they had taken the sample correctly[14].

Methods: **620 women** referred for colposcopy were invited to provide an initial stream urine sample collected with the Colli-Pee® device and take two vaginal self-samples[14]

Usability data collected from five clinical studies revealed 91% find Colli-Pee® was easy or very easy to use[9].

371 PARTICIPANTS IN 5 STUDIES

186 185

46% CP-2000

54% FV-5000

92% would like to use Colli-Pee® for screening purposes

91% rated Colli-Pee® 'easy' or 'very easy' to use

"Self-collected urine, through a first-void urine collection device, has the potential to increase uptake of cervical cancer screening. Urine collection can be more comfortable and more socially acceptable for some women who are reluctant to perform a vaginal examination"

Professor Clementina Cocuzza,
of the Department of Medicine and Surgery, University of Milan-Bicocca, Italy