



# Urine collected through Colli-Pee® offers potential for self-sampling at home for detection of sexually transmitted infections

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## INTRODUCTION

Sexually transmitted infections (STIs) continue to remain a global health problem. They can affect quality of life, as well as compromise an individual's sexual and reproductive health.

Annually 351 million new cases of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) are estimated among people aged 15 to 49 years. Further, human papillomavirus (HPV), the most common STI, is a major cause of cervical cancer and is responsible for an estimated 530,000 cases and 264,000 cervical cancer deaths each year<sup>1</sup>.

Routine screening is critical for prevention and control of STIs, particularly since many infections do not present symptoms<sup>2,3</sup>.

## LIMITATIONS OF CURRENT SCREENING METHODS

Traditional clinic-based sampling and conventional methods can be invasive, time intensive, and require a clinician to perform. Moreover, many individuals often feel embarrassed or uncomfortable to discuss their sexual activity and are reluctant to visit a clinic for testing<sup>2,3</sup>.

As a result, methods to detect STIs are underutilized and only detect a proportion of cases<sup>2</sup>.

## URINE AS AN ALTERNATIVE SOLUTION TO INCREASE PARTICIPATION IN STI AND CERVICAL CANCER SCREENING PROGRAMS

Due to limitations with current screening methods, self-sampling through non or minimally invasive techniques are gaining interest<sup>2</sup>.

Urine, in particular first-void/first-catch urine (first 20ml of urine flow) has shown great promise in STI screening. Infections including CT, NG, *Mycoplasma genitalium* (MG) and HPV can be detected in urine<sup>3,4</sup>.

## BENEFITS OF URINE SAMPLING

Urine sampling is attractive for many reasons<sup>5,6,7</sup>:

- Self-sampling potential
- Does not interfere with the natural history of the HPV infection
- Non-invasive
- User-friendly
- Private

## IMPORTANCE OF FIRST-VOID URINE COLLECTION

First-void urine contains a higher concentration of DNA than other fractions of urine<sup>8</sup>, improving diagnostic sensitivity of STIs.

However, collecting first-void urine in a regular urine container is not standardized and can be awkward, messy and inconvenient for the user.

Colli-Pee® Novosanis' first-void urine collection device, allows easy capture of first-void urine. Recent data by the Tropical Institute of Medicine in Antwerp, Belgium compared routine clinic-based urine collection through a regular urine cup with home-collected urine sampling using Colli-Pee®, among Men who have Sex with Men (MSM) Pre-exposure prophylaxis (PrEP) users<sup>4</sup>. A high correlation was found between clinic-based and home-collected urine samples for CT, NG, and MG,  $\kappa=0.75, 0.87$  and  $0.85$  respectively. TV was not detected in any of the samples.

Only one low positive CT and two positive MG infections were not detected in the home-collected urine samples. A total of 11 additional STIs (three CT, two NG and six MG infections) were detected in the home-collected samples using Colli-Pee®, and not found in the equivalent clinic-collected urine samples<sup>4</sup> (Figure 1), highlighting the importance of capturing first-void urine, rather than a random or midstream sample for improved accuracy.

CT		Clinic-collected urine cups		
Colli-Pee®		Positive	Negative	Total
	Positive	6	3	9
	Negative	1	454*	455
	<b>Total</b>	<b>7</b>	<b>457</b>	<b>464</b>

Figure 1a. Number of CT infections detected in home-collected samples and clinic-based urine samples. 3 additional infections were detected using Colli-Pee®. \*Two results were not-confirmed in the clinic-based sample

MG		Clinic-collected urine cups		
Colli-Pee®		Positive	Negative	Total
	Positive	25	6	31
	Negative	2	431	433
	<b>Total</b>	<b>27</b>	<b>437</b>	<b>464</b>

Figure 1b. Number of MG infections detected in home-collected samples and clinic-based urine samples. 6 additional infections were detected using Colli-Pee®.

NG		Clinic-collected urine cups		
Colli-Pee®		Positive	Negative	Total
	Positive	7	2	9
	Negative	0	455	455
	<b>Total</b>	<b>7</b>	<b>457</b>	<b>464</b>

Figure 1c. Number of NG infections detected in home-collected samples and clinic-based urine samples. 2 additional infections were detected using Colli-Pee®

TV		Clinic-collected urine cups		
Colli-Pee®		Positive	Negative	Total
	Positive	0	0	0
	Negative	0	464	464
	<b>Total</b>	<b>0</b>	<b>464</b>	<b>464</b>

Figure 1d. Number of TV infections detected in home-collected samples and clinic-based urine samples. No additional infections were detected using Colli-Pee®.



## POSTAL DELIVERY AND SELF-SAMPLING IN STI DETECTION

The results of the study performed by the Tropical Institute of Medicine also highlight that self-collection followed by postal delivery of urine samples did not influence STI detection. This methodology offers opportunities to reach a wider population, especially high-risk individuals or participants that are reluctant to access traditional STI health services<sup>3,4</sup>. Performing a test independently at home also means that results can be made available to a physician prior to consultation<sup>4</sup>.

Another study conducted in France also showed the potential of urine self-collection and postal delivery. Home-based urinary HPV sampling increased participation of women who did not traditionally attend cervical cancer screening clinics for a Pap smear by 13.7%. In the study, of the 687 samples analyzed, high-risk HPV was detected in urine samples of 29 women, of which 28 were then referred to a physician for further examination<sup>5</sup>.

## CHALLENGES WITH URINE COLLECTION AND METHODS TO OPTIMIZE RESULTS

There are challenges with urine sampling. Urine contains known inhibitors such as urea, nitrites as well as unknown polymerase chain reaction (PCR) inhibitors. Further, DNA quality in urine can be deteriorated by contamination. As a result, collection, transport, storage and detection methods are critical for optimum outcomes<sup>7</sup>.

## NEXT-GENERATION COLLI-PEE® OPTIMIZED FOR POSTAL DELIVERY AND HOME-BASED URINE COLLECTION

Novosanis has been working on an optimized next-generation Colli-Pee® suited for home-based urine collection and postal delivery. Live-testing was done in collaboration with living labs Happy Aging (Belgium) and Expertise Center for Innovative Care and Technology - EIZT (Netherlands).

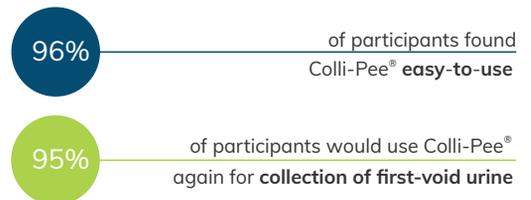
The usability of the next-generation Colli-Pee® was assessed in 84 healthy volunteers in Belgium and the Netherlands. Volunteers were asked to request a self-sampling urine collection kit online. The box contained user instructions, an identity tag, a Colli-Pee® device pre-filled with Novosanis' proprietary UCM preservative, allowing longer preservation of urine during transport, and a safety bag to place the urine sample after collection (Figure 2).

The samples were checked for return conditions, volume collected and leakage. Participants also had the opportunity to provide feedback on ease-of-use of the device and the process of self-sampling.

The results showed that Colli-Pee® is a reliable and valuable device to collect first-void urine and is suited for postal delivery.



Figure 2: Variants of the home-based Colli-Pee® sampling kit



All bags containing samples were intact once returned to the laboratory via postal delivery. On average the time between the sample collection and arrival at the laboratory was 3 days. Leakage was only observed in 3 samples on return across both regions, possibly due to tubes not being properly closed.

## CONCLUSION

Home-based urine collection and mail transport can improve STI detection, offering the opportunity to reach a wider population, improving patient flow and allowing for treatment to begin immediately.

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