

COLLI-PEE: A new device to collect first-void urine at home for molecular detection of STIs

EVALUATION & ACCEPTABILITY BY MSM IN A PREP STUDY IN BELGIUM

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INTRODUCTION

The CE-labeled Colli-Pee™ device efficiently captures first-void urine without interruption of the urine stream and is suited for postal delivery of the urine sample. We aimed to evaluate the use of Colli-Pee collected urine mailed by regular post for sexually transmitted infection (STI) detection among Men who have Sex with Men (MSM) who participated in a Belgian HIV prevention study.

METHODS

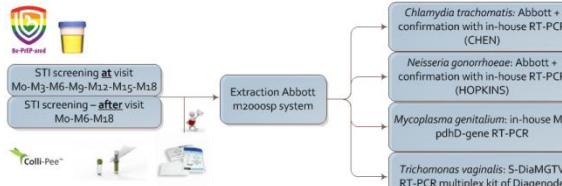


Fig 1: Molecular assays used to detect CT/NG/MG/TV

RT-PCR = Real-Time PCR

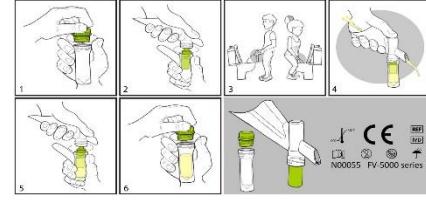


Fig 2: Instructions how to use the Colli-Pee™ device

- Be-PrEP-ared: 200 MSM followed up for 18 months while using Truvada as Pre-exposure prophylaxis (PrEP) at the Institute of Tropical Medicine (ITM), Antwerp, Belgium.
- Three-monthly screening Sexually Transmitted Infections (STI) (CT/NG; MG/TV) using anal & pharyngeal swabs and first-void urine (sterile container)
- At the first visit, 6 and 18 months participants were instructed (after consent) to use the Colli-Pee™ device at home and to send the container to the clinic by mail, the next day for STI testing. Time & date of sampling were recorded.
- Agreement of the results of the molecular assays by both sampling methods was assessed by Cohen's kappa statistic (κ).
- Additionally, a survey completed during the next visit asked about experiences in using and willingness to use the Colli-Pee™ device

RESULTS OF BASELINE AND MONTH 6 VISIT

338 Colli-Pees were sent from all over Belgium, on average collected 2 days after specimen collection at clinic visit. Date of collection was missing for 27,2% of the samples. Samples were on route for an average of $4,4 \pm 2,2$ days.

5 samples gave inhibition and are not included. (n = 333). No sample was positive for TV.

CT	POS	NEG	TOTAL	NG	POS	NEG	TOTAL	MG	POS	NEG	TOTAL
Colli-Pee	routine			Colli-Pee	routine			Colli-Pee	routine		
	POS 5	1	6		POS 5	2	7		POS 20	4	24
	NEG 0	327	327		NEG 0	326	326		NEG 1	308	309
	TOTAL 5	328	333		TOTAL 5	328	333		TOTAL 21	312	333
K = 0,908				K = 0,830				K = 0,881			

A very good agreement between colli-pee and routine sample for CT/NG/MG detection!

Results survey at baseline (n=164)

90%	Found it easy to mail the Colli-Pee
89%	Would order an online STI test
88%	Found Colli-Pee easy to very easy to use
82%	Would use the Colli-Pee for an STI test

Ease of use – 55%	Nothing – 47%
No interruption of urine stream – 16%	Not recyclable – 15%
Hygienic – 12%	Not hygienic – 10%
Home test (private) – 11%	Too large – 6%

CONCLUSIONS

- Only one MG infection was missed but 7 additional STIs (1 CT – 2 NGs and 4 MGs) were detected. We can however not exclude that participants became positive after the clinic visit.
- This research shows that the Colli-Pee™ device is a feasible and for some a more convenient way to collect urine at home for STI testing. This may be particularly relevant for populations that need frequent STI testing (e.g. PrEP users) and patients who prefer home-testing.

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