

# Performance evaluation of a new home-based self-vaginal collection device for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

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## Background

Sexually Transmitted Infections (STIs) are increasing worldwide. Innovative approaches are required to eliminate barriers to STIs testing such as **home-based self-sampling for patients that are difficult to reach**. Self vaginal sampling is a new collection approach for detection of Sexually Transmitted Infections and is able to guarantee privacy and comfort during the collection. The aim of the study was to evaluate **usability, vaginal cells collection efficiency and ability to preserve nucleic acids** stability of a new self vaginal nylon flocked swab (FLOQSwab®, Copan) developed for home collection (Figure 1).



Figure 1: nylon flocked swab FLOQSwab®

## Methods

80 donors (aged 18 to 45 years) performed a double self-vaginal sampling (n=160) using:

- 1. Certified flocked self-vaginal point of care collection (POC) device** as a reference method (Copan);
- 2. New home-based self-vaginal flocked swab (SVF)** by following the kit instructions. Patients received a questionnaire to assess the usability of the new device. Home-based and POC swabs were processed using Xpert CT/NG® assay (Cepheid, Figure 2).

The threshold cycle value (Ct) of a human genomic target, Ct of pathogens (*Chlamydia trachomatis* CT and *Neisseria gonorrhoeae* GC2-GC4) and extraction and amplification control (*Bacillus globigii* spores) were considered to compare performance between the two devices. To evaluate the stability of the nucleic acids at time 0 and after 4 weeks of storage at 4°C and 30°C, 54 negative home collected samples were inoculated with a suspension of CT and GC ATCC (VR880-43069) at 1 and 10xLOD of molecular assay.



Figure 2: GeneXpert® Platform

## Results

100% of overall agreement was obtained comparing the two devices: 77/80 negative and 3/80 CT positive patients were detected. No failure results were observed. The survey reported a better appreciated home-based collection (80%) with respect to the POC sampling. After 4 weeks of storage at 4°C and at 30°C all spiked samples were detected (Figure 3). The efficiency of cells collection is comparable between SVF and POC devices (Figure 4.).

DNA stability on SVF at +30°C (1xLOD)

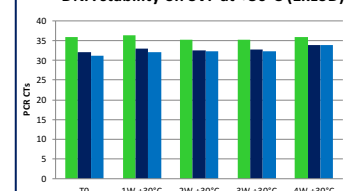


Figure 3. Stability of the targets gene (CT and NG) after 4 weeks of storage at RT.

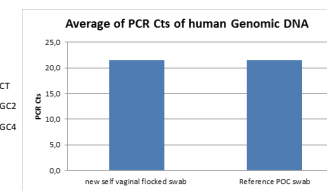


Figure 4. Performance recovery of vaginal cells: comparison between new self vaginal FLOQSwab® and Reference POC swab.

## Conclusions

The new home-based device has shown the same performance of the reference swab, demonstrating an efficient recovery of vaginal cells, stability of CT and GC nucleic acids up to 4 weeks and excellent acceptability by women.

## Bibliography

- Lunny C et al. 2015 Self-Collected versus Clinician-Collected Sampling for Chlamydia and Gonorrhoea Screening: A Systemic Review and Meta-Analysis. PLoS One. 10
- Van Rooijen (2016) et al. Young Low-Risk Heterosexual Clients Prefer a Chlamydia Home Collection Test to a Sexually Transmitted Infection Clinic Visit in Amsterdam, the Netherlands, A Cross-Sectional Study. Sex Transm Dis. 43(11):710-716.