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**Performance of a new home-based self-vaginal device for diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae***Sonia Allibardi<sup>1</sup>, Squassina A<sup>1</sup> and Rubessa S<sup>2</sup><sup>1</sup>Copan Italia, Italy<sup>2</sup>Spedali Civili Hospital, Italy

**Background & Aim:** 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 flocked swab (FLOQSwab™, Copan) developed for home collection.

**Methodology:** 80 donors (18-45) performed a double self-vaginal sampling (n=160) using a certified flocked self-vaginal point of care collection (POC) device as a reference method (Copan), a new home-based self-vaginal flocked swab 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<sup>®</sup> assay (Cepheid). 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 oC and +30 oC, 54 negative home collected samples were inoculated with a suspension of CT and GC ATCC (VR880-43069) at 1 and 10x LOD of molecular assay.

**Findings:** 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 oC and at 30 oC all spiked samples were detected.

**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.

**Biography**

Sonia Allibardi is a molecular biologist with a specialization degree in Biochemistry Science. Her professional life started in a research Cardiovascular Physiology laboratory at San Raffaele Scientific Institute, Milan Italy, where she worked for more than 10 years and she published scientific papers on International Journals. The objective of her research was the evaluation of myocardial metabolism in hypoxic and ischemic heart. In 2011, thanks to the "Mad Cow Disease", she started a new job in Biorad Company. She spent three wonderful years as a scientific product specialist in life science division for Italy and Southern Europe (Spain, Greece, and Portugal). She had the possibility to work in Cepheid Europe for five years and her main topics were: Women's Health, Hospital Acquired Infection and Tuberculosis. Currently she is working in a Scientific Team of COPAN laboratory collaborating with scientific KOL in Italy and Europe

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