SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
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HOW TO FACILITATE AND IMPROVE SCREENING OF SEXUALLY-TRANSMITTED INFECTIONS IN WOMEN POPULATION

Obs-Gyne & Women's Health

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Introduction

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.** Aim of this study was to evaluate performance of a new Home–based Self Vaginal FLOQSwab® (HBSVF, COPAN Italia, Brescia) in combination with a commercially available real-time PCR assay, Anyplex™ II STI-7 (Seegene, Seoul, Korea) which detects seven pathogens in a single reaction (*Chlamydia trachomatis* CT, *Neisseria gonorrhoeae* NG, *Trichomonas vaginalis* TV, *Mycoplasma hominis* MH, *Mycoplasma genitalium* MG, *Ureaplasma urealyticum* UU, and *Ureaplasma parvum* UP) Figure 1.

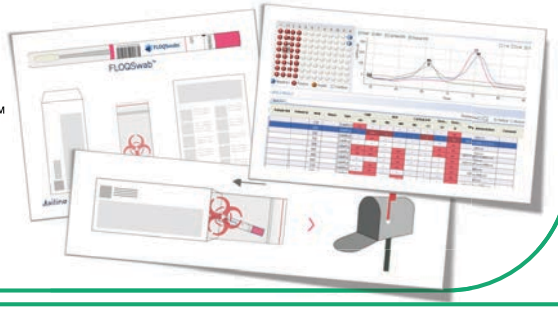


Figure 1. Anyplex™ II STI-7 & Home–based Self Vaginal FLOQSwab®

Methods

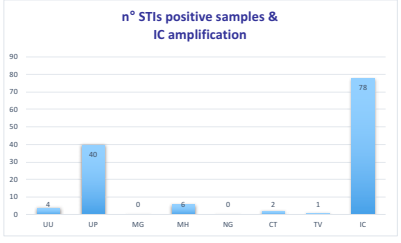
78 asymptomatic employees of a private industry (aged 18 to 45 years) were voluntarily enrolled to STIs screening. The subjects answered to a standardized anonymous questionnaire regarding the ease of use of self collection. The swab was collected in a domestic context by following the detailed "how to use" instructions. After collection, swabs were shipped at room temperature to the laboratory in Pievesestina and processed within five weeks. The threshold cycle value (Ct) of a human genomic target (internal control, IC) and Ct of pathogens (CT, NG, TV, MH, MG, UU, UP) were taken as parameters to assess respectively, the efficiency of self-sampling and presence of any inhibitor effects and the stability of nucleic acids on dry swabs (Figure 2)

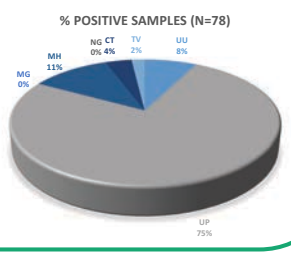
Figure 2 . Samples workflow in Pievesestina Laboratory

Results

No failure results were observed, the IC of all samples was amplified (average Ct 30). The real time PCR assay was able to identify 2/78 CT, 4/78 UU, 40/78 UP, 6/78 MH, 1/78 TV positive patients. No MG and NG positive patients were detected. Women reported self-collection with HBSVF was easy and comfortable (100%) (Figure 3).

Figure 3. Percentage of positive samples distributed between pathogens (*Chlamydia trachomatis* CT, *Neisseria gonorrhoeae* NG, *Trichomonas vaginalis* TV, *Mycoplasma hominis* MH, *Mycoplasma genitalium* MG, *Ureaplasma urealyticum* UU, and *Ureaplasma parvum* UP) detected by Anyplex™ II STI-7 (Seegene assay). IC: amplification of internal control (human genomic target)





Conclusions

HBSVF device showed excellent recovery and stability of nucleic acid of STI pathogens up to 5 weeks at room temperature. The HBSVF is suitable for screening of STIs with real-time PCR assay.

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