Evaluation of a New Home-Based Self-Vaginal Collection Device for Detection of Chlamydia Trachomatis and Neisseria Gonorrhoeae

**Abstract**

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.

Methods 80 donors (age 18 to 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 self-vaginal swabs have been processed using Xpert CT/NG assay (Cepheid). The threshold cycle value (Ct) of a human genomic target (sample adequacy control), Ct of pathogens assay (Cepheid). The threshold cycle value (Ct) of a human genomic target (sample adequacy control), Ct of pathogens 

Results All 54 spiked samples have been correctly detected. 54 negative home collected self vaginal samples have been inoculated with a suspension of CT and GC ATCC (VR880-43069) at 1 and 10xLOD of molecular assay.

Conclusion The produced antibodies will be used to study the pathogenesis of Gardnerella vaginalis during the development of BV.

**Methods**

Three New Zealand rabbits were immunised for 8 weeks using as antigen the strain ATCC 14018 of G. vaginalis and the complete and incomplete Freund’s adjuvants. The immune response was evaluated at weeks 0, 4th and 7th by indirect ELISA. At the 8th week the rabbits were sacrificed and blood serum was obtained, purification was performed using the Protein A antibody purification kit (Sigma). For the characterisation of the polyclonal antibody we perform Indirect ELISA, Dot Blot, Western Blot and inhibition of haemagglutination.

**Results**

Two polyclonal antibodies against G. vaginalis were obtained. The first was obtained from Rabbit 1 (A.ka. Gv1) and the second one is a Pool (Gv2) from the serum of rabbits 2 and 3. Both antibodies recognise the strain ATCC 14018 of G. vaginalis at titers greater than 1: 2000 and proteins with molecular weights of approximately 38, 50, 65, 75 and 90 kDa, in addition the antibodies are capable of inhibiting lysis of vaginolysin.

**Conclusion**

The produced antibodies will be used to study the pathogenesis of Gardnerella vaginalis during the development of BV.

**Introduction**

Bacterial Vaginosis (BV) is the most frequent vaginal infection. It is characterised by a decrease in the number of Lactobacilli and an increase of anaerobic bacteria. Gardnerella vaginalis is the main etiological agent, this bacteria has multiple virulence factors such as the production of biofilm, sialidase and vaginylisin, which can cause the degradation of cervical mucus, adhesion and lysis of epithelial cells. The production of antibodies against this microorganism will allow understanding their role in the development of BV.

**Methods**

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**Introduction**

Individuals receiving the human papillomavirus (HPV) vaccine develop high levels of circulating neutralising antibodies. However, data about antibody responses in the cervix are limited.

**Methods**

This study was designed to describe the course of IgA/ IgG responses in cervical secretions and in serum after intramuscular administration of the HPV16/18 AS04-adjuvant vaccine. An enzyme linked immunosorbent assay for detection of IgA and IgG anti–HPVVLP was developed for this purpose.

**Results**

Immunoglobulin G seroconversion after the second dose was observed in 100% of the participants and remained 1 month after the third dose. Regarding IgG reactivity in cervical secretions, conversion was observed in 85% of women after the final dose. Immunoglobulin A seroconversion was observed in 76.7% of women after the third dose. Lower levels of IgA were detected in the cervical mucus (28.3%) and decreased to 23.3% after the last dose. Comparing local and systemic IgG responses, positivity in both serum and cervical samples was observed in 85%, whereas in 15% only, the serum was IgG antibody positive. A weak agreement between local and systemic IgA responses was observed. Only 18.3% of participants were local and systemic IgA positive, 58.4% were positive only in serum, 5% were positive only in the cervical mucus.