Sampling of Human Papilloma Viruses and Chlamydia trachomatis: Novel Flocked Swabs Increase Detection Rates significantly.

Thomas Krech[1] (thomas.krech@labor.ch) Santina Castriciano[2] (santina.castriciano@copanitalia.com) and Max Chernesky[3]

[1]Institute for laboratory medicine, Labor Prof. Krech and Partner AG, Kreuzlingen/Switzerland. [2]Copan Innovation, Brescia/Italy , [3]St. Joseph's Healthcare/McMaster University, Hamilton, ON, Canada.

Revised ABSTRACT

Background: Several studies have shown equal sensitivity and specificity for vaginal swabs compared to endocervical swabs and first voided urine for the detection of sexually transmitted viruses and bacteria, like human papillomaviruses (HPV) and Chlamydia trachomatis (Ct).. The novel flocked swabs promise higher sensitivity compared to conventional swabs

Aims: We compared the detection rates of HPV and Chlamydia trachomatis vaginal and endocervical swabs by using a special dual flocked/Rayon swab .

Method: A total of 1252 samples from 494 asymptomatic patients where tested from vaginal dual swabs taken by the gynecologist during routine visits. In 119 of them also an endocervical dual swab was taken. The dual swab consisted of a normal rayon swab and a novel flocked nylon swab. After the sample was taken, the swabs were separated and each one was transferred in an individual dry tube for transportation to the laboratory. There 1 ml of 0.9% sodium chloride was added to the tubes before extraction for Polymerase Chain Reaction (PCR). Extraction was done from 0.5 ml, 0.5 ml was stored frozen. Detection of HPV high risk types was done by the Digene® HPV Test*, using Hybrid Capture® 2 (hc2) technology. Detection of Chlamydia trachomatis was done by an in-house real-time PCR decribed elsewhere.

Results: 494 asymptomatic patients were tested for Human papillomavirus with both swab types. The flocked swabs detected from vaginal samples 68 positive HPV, while the Rayon swab detected 38, missing 30 of them. For C.trachomatis the flocked swabs from vaginal samples detected 13 positives, the rayon swabs detected 9 missing 4 of them.

Among the 119 paired vaginal/endocervical samples, the flocked swabs (in brackets rayon swabs) detected 20 (14) positive for HPV from vaginal samples and 10 (6) positive from endocervical samples. For C.trachomatis the corresponding figures are 6 (4) from vaginal swabs and 5 (3) from endocervical swabs.

The HPV positive rate from vaginal flocked swabs 14.1% with an average of 141 RLU/CO and 7.9% with an average of 70 RLU/CO for the Rayon swabs. The C.trachomatis positive rate from vaginal flocked swabs was 2.7% with an average of 51'869 DNA-Copies/ml and 1.9% with an average of 9178 DNA-Copies/ml for the Rayon swabs. Sampling with flocked swabs doubled the positive rate for Human Papillomavirus detection from vaginal swabs compared to conventional Rayon swabs. Vaginal sampling gave 30% more positive results for HPV than traditional endocervical sampling. For C.trachomatis vaginal sampling was also more sensitive than endocervical sampling.

The genotypes of HPV detected in vaginal samples were the same as detected from endocervical swabs.

Conclusions: Sampling with novel flocked swabs doubled the positive rate for Human Papillomavirus detection from vaginal swabs compared to conventional Rayon swabs. Furthermore vaginal sampling gave significantly more positive HPV results than traditional endocervical sampling. C.trachomatis was also more often detected with flocked swabs than with conventional Rayon swabs and vaginal swabs gave also more positive results than endocervical sampling.

Flocked swabs provide also higher sensitivity than conventional rayon swabs with regard to DNA-copy numbers.

BACKGROUND

•Several studies have shown equal sensitivity and specificity for vaginal swabs compared to endocervical swabs and first voided urine for the detection of sexually transmitted viruses and bacteria, like human papillomaviruses (HPV) and Chlamydia trachomatis (Ct).

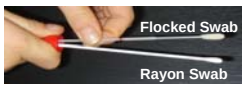
AIM

•Comparison of flocked swabs with conventional Rayon swabs for detection of human papillomaviruses (HPV) and Chlamydia trachomatis (Ct).

•Comparison of sensitivities in vaginal swabs compared to traditional endocervical swabs.

METHODS

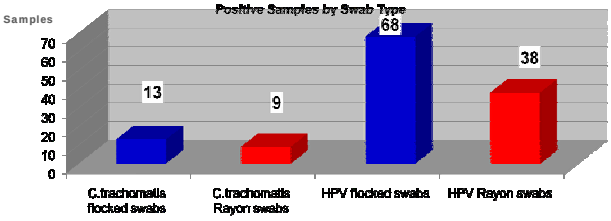
- 494 asymptomatic patients where tested from vaginal dual swabs taken by the gynecologist during routine visits. From 129 of the patients also endocervical swabs were taken.
- The dual swab collection kit consisted of a normal rayon swab and a novel flocked nylon swab as shown in picture.
- A specimen collection protocol was prepared for the use the of the dual rayon/flocked swab kit as follows:
  - Open the package and take out the two tubes.
  - Open the plastic tube containing the two swabs holding them by the red handle, **Note:** Do not discard the long plastic tube.
  - Collect the specimen as per specimen collection procedure.
  - After the specimen is collected with the dual swabs, holding the swabs by the red handle with one hand, use the other hand to remove the white shafted swab from the handle, making sure that the swab is held above the breaking point.
  - Place the green shafted swab left in the red handle in the long plastic tube
  - Still holding the white shafted swab in your hand, open the small plastic tube with the green top.
  - Aseptically unscrew and remove the cap from the tube.
  - Place the white shafted swab (flocked) in the small tube, bend and break the swab at the breaking point marked on the swab shaft.
  - Replace the white cap on the small tube and secure tightly
  - Write patient identification and collection date on both tube labels.
  - Place both tubes containing the swab in a biohazard bag and send to the laboratory
- Samples collected with flocked swabs and rayon swabs were processed as follows:
- One ml of 0.9% normal saline was added to each sample, tubes were vortexed to release sample material from the swabs. O.5 ml of each sample was used for nucleic acid extraction, the remainder of the sample was stored frozen.
- Detection of HPV high risk types was done using the Digene® HPV Test*, with the Hybrid Capture® 2 (hc2) technology as per manufacturer procedure.
- Detection of C.trachomatis was done by an in-house real-time PCR on Light-Cycler Roche (Poster: Development and Validation of Fourteen LightCycler™ Real-Time PCR Assays for the Quantification or Qualitative Detection of Common Viral and Bacterial Infections in Various Specimen Types. T. Krech[1], S. Chong[3], X. Song[3], T. Bruderer[1], D. Jang[2,3], J.B. Mahony[2,3], A.K. Petrich[2,3], K. Luinstra[3], S. Castriciano[3], M. Smieja[2,3], M. Chernesky [2,3]Labor Prof. Krech und Partner AG, Kreuzlingen, Switzerland[1], Dept. of Pathology and Molecular Medicine[2], St. Joseph's Hospital[3], Hamilton, Ontario, Canada)

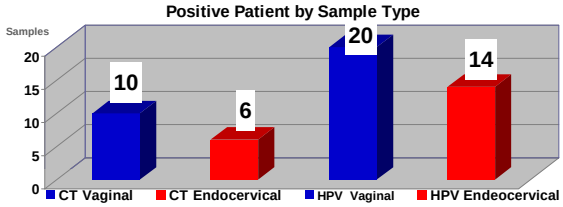


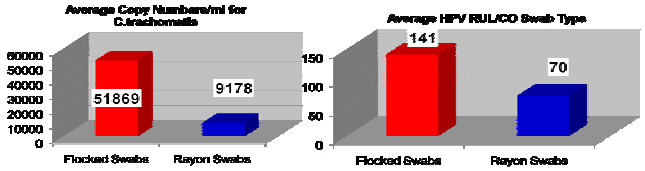
Copan Specially Designed Dual Swab

Dry transportation in separate tubes

RESULTS







HPV Genotypes in Vaginal and endocervical Samples

Patient		16	33	51	53	56	58	61	71	CP6108
1	Vaginal		■	■		■		■		
	endocervical		■	■				■		
2	Vaginal	■				■	■		■	
	endocervical	■			■	■	■	■	■	
3	Vaginal			■						■
	endocervical			■						■
4	Vaginal	■		■						
	endocervical			■						

494 asymptomatic patients were tested for C. trachomatis and Human papillomavirus with both swabs type.

- The flocked swabs detected from vaginal samples 68 positive HPV, while the Rayon swabs detected 38 positive, missing 30 positive HPV

•For C.trachomatis the flocked swabs from vaginal samples detected 13 positives, the rayon swabs detected 9 positive missing 4 of them

•All samples positive by Rayon swabs were also detected by flocked swabs.

•Among the 119 paired vaginal/endocervical samples, the flocked swabs (in brackets rayon swabs) detected 20 (14) positive for HPV from vaginal samples and 10 (6) positive from endocervical samples. For C.trachomatis the corresponding figures are 6 (4) from vaginal swabs and 5 (3) from endocervical swabs.

•The HPV positive rate from vaginal swabs was 14.1% with an average of 141 RLU/CO for the flocked swabs and 7. 9% with an average of 70 RLU/CO for the Rayon swabs.

• The C.trachomatis positive rate from vaginal swabs) was 2.7% with an average of 51'869 DNA-Copies/ml for the flocked swabs and 1.9% with an average of 9178 DNA-Copies/ml for the Rayon swabs.

•Sampling with flocked swabs doubled the positive rate for Human Papillomavirus detection from vaginal swabs compared to conventional Rayon swabs

CONCLUSIONS

Sampling with novel flocked swabs doubled the positive rate for Human Papillomavirus detection from vaginal swabs compared to conventional Rayon swabs.

Furthermore vaginal sampling gave significantly more positive HPV results than traditional endocervical sampling.

C.trachomatis was also more often detected with flocked swabs than with conventional Rayon swabs and vaginal swabs gave also more positive results than endocervical sampling.

Flocked swabs provide also higher sensitivity than conventional rayon swabs with regard to DNA-copy numbers.

•This opens a wide range of self-testing applications (see also www.self-testing.com) that can be offered to everybody for prophylaxis and diagnosis of diseases.