



POSTER 823

Comparison of Copan UriSponge™ to Colli-Pee™ for the collection of Urine for HPV detection with molecular assays

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Background

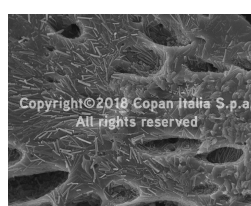
Urine specimen collection is non-invasive and better accepted by patients for HPV and STI screening. Copan's UriSponge™, a Liquid Based Microbiology device, can be used for urine collection for both culture and/or molecular assays. It consists of a leak-proof tube with a screw cap containing a plastic stick with sponges attached that absorb and retain the urine sample during transport preventing bacterial overgrowth.

Objective

The objective of this study was to compare UriSponge™ and Colli-Pee™ (Novosanis) urine devices for self-collection of first void urine (FVU) for the detection of HPV using the Seegene AnyplexII™ HPV28 assay. Clinician-collected cervical samples from the same patients were used as "gold standard".

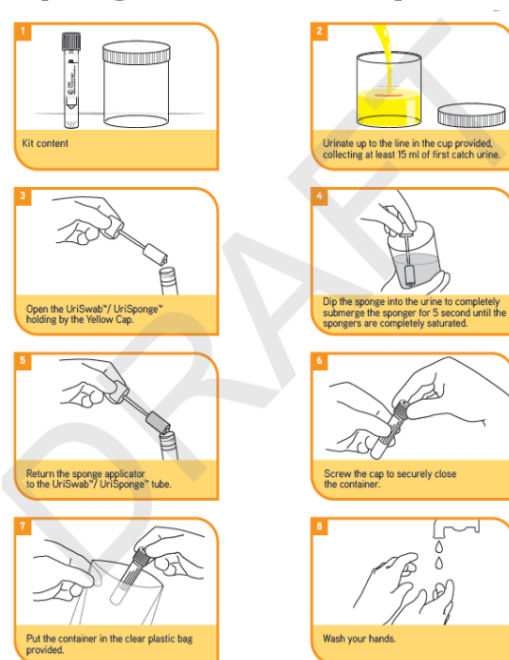
Materials

UriSponge™



Sponge Electronic Microscopy image containing salts

UriSponge™ collection procedure



Colli-Pee™ urine collection device



Seegene real-time PCR detection system

Methods

- First void urine samples were collected from 85 patients, with a recent diagnosis of cervical dysplasia, attending the Colposcopy clinic.
- 20 ml of first-void urine were collected using Colli-Pee™ and an additional aliquot of urine was collected in sterile containers to saturate UriSponge™.
- Cervical samples were collected by the clinician using L-Shaped Endo/Esocervical FLOQSwab (Copan) prior to colposcopy.
- The UriSponge™ samples were centrifuged (5 min at 3000 rpm) obtaining 3 ml of urine.
- Colli-Pee™ samples were processed directly for nucleic acid extraction, as recommended by manufacturer.
- Nucleic acids was extracted from 1 mL of each sample type by NucliSENS easyMAG (bioMérieux) and eluted in 40 µl and 100 µl for urine and cervical samples respectively.
- HPV detection was performed using AnyplexII™ HPV28 Assay.
- Sample cellularity was evaluated by means of a quantitative real-time PCR detecting human CCR5 gene.
- Cervical swabs results were used as a reference

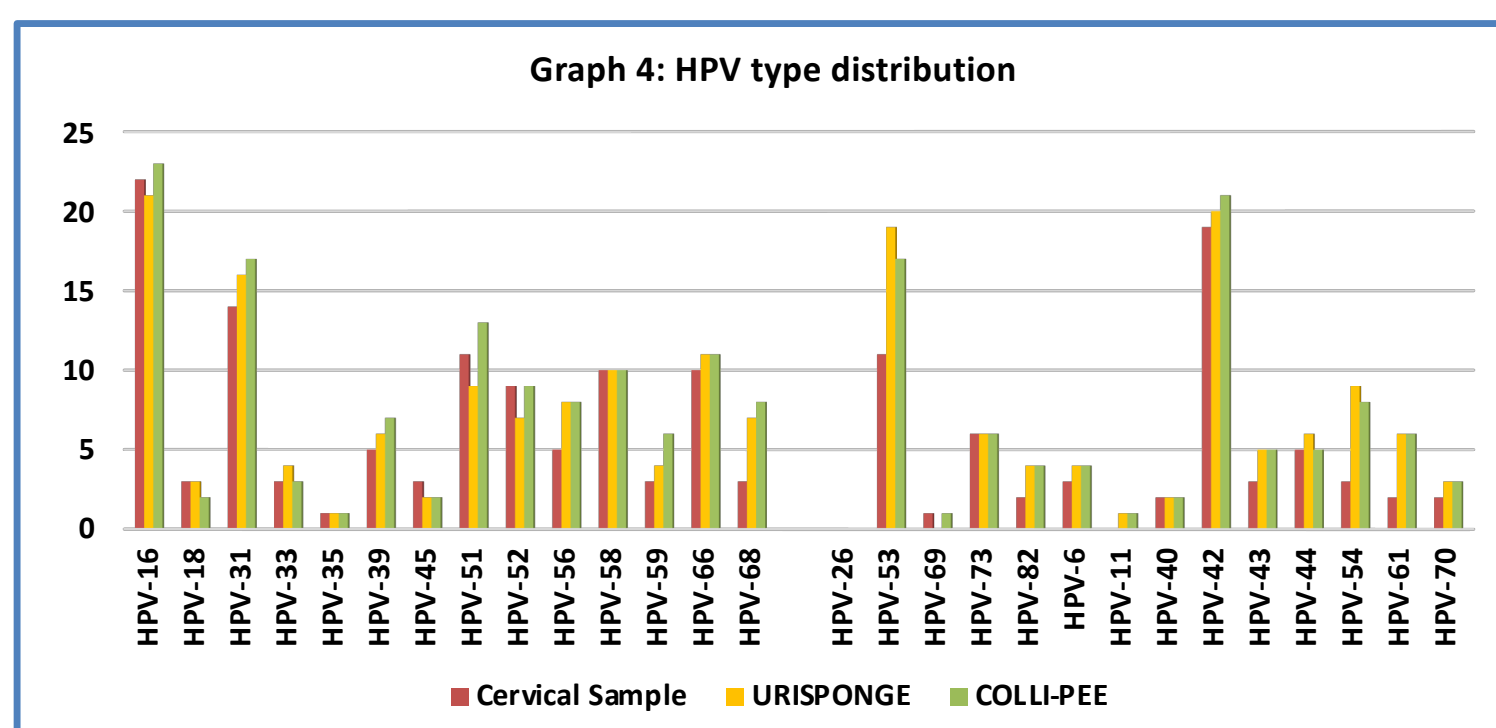
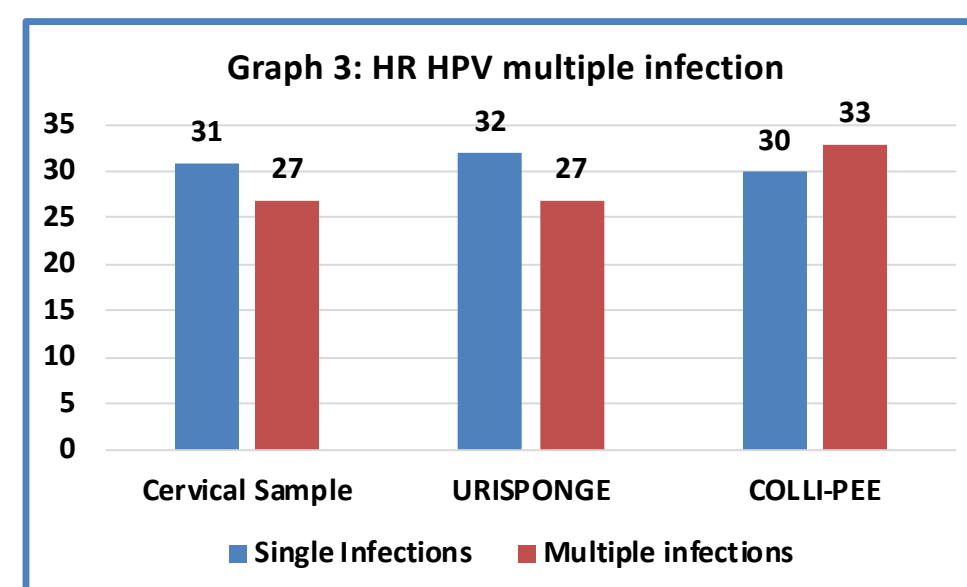
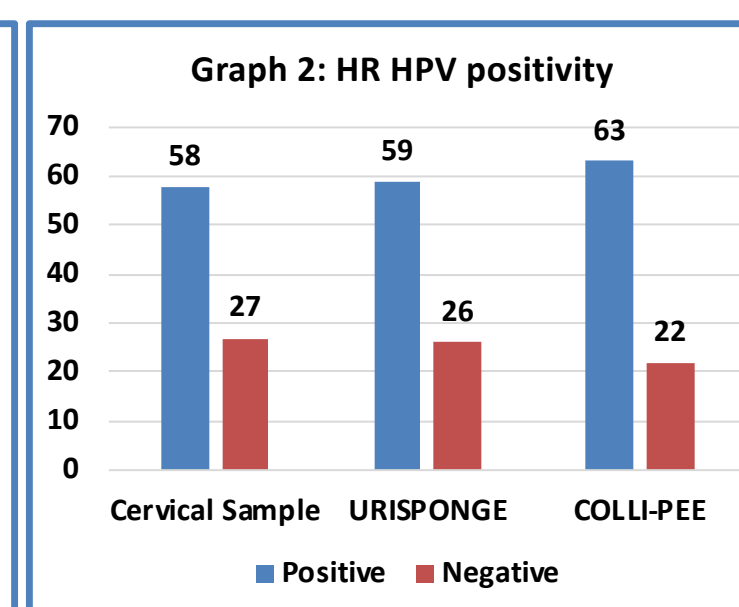
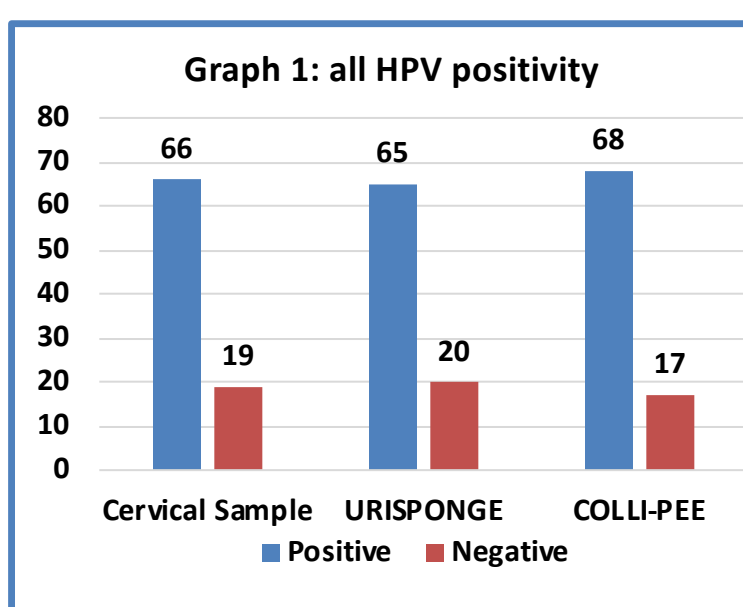
Results

Overall out of 85 cervical samples tested, 19 (22%) were found to be HPV negative and 66 (78%) HPV positive: 32 HR+LR (49%), 26 HR (39%) and 8 LR (12%). UriSponge™ detected 20 (24%) HPV negative and 65 (76%) HPV positive samples: 40 HR+LR (62%), 19 HR (29%) and 6 LR (9%). Colli-Pee™ detected 17 (20%) HPV negative and 68 (80%) HPV positive samples: 39 HR+LR (57%), 24 HR (35%) and 5 LR (8%). A good concordance for the detection of HR-HPV types was demonstrated in urine samples collected using both devices, with HPV 16, 31 and 51 being the most frequent detected genotypes. Comparable cellularity was demonstrated in samples collected using Colli-Pee™ and UriSponge™ (mean values: 6.25E+04 vs 6.37E+04 cells/mL).

Results

Table 1: Cellularity	Average (n. cells/sample)	Minimum (n. cells/sample)	Maximum (n. cells/sample)
Cervical Sample (20 ml)	1,09E+06	4,65E+01	2,65E+06
Urine (20 ml)	1,25E+06	8.58E+01	3,62E+07
Urisponge (3 ml)	3,82E+05	8,58E+01	1,34E+07

Table 2: Agreement	Colli-Pee™		UriSponge™	
HPV Type	k value (95%CI)	Agreement	k value (95%CI)	Agreement
At least one HR HPV	0.800 (0.660 - 0.940)	very good	0.804 (0.665 - 0.943)	very good
HPV-16	0.849 (0.721 - 0.977)	very good	0.816 (0.675 - 0.957)	very good



Conclusions

Data obtained in this study demonstrate that Copan's UriSponge™ has a very good HR-HPV detection concordance and good cellularity compared to the cervical swab and to Novosanis' Colli-Pee™, using Seegene Anyplex™ II HPV28 assay.

UriSponge™ is easy to use for urine self-collection, it's not bulky and can be conveniently shipped by mail at a relatively low cost. In conclusion, the use of UriSponge™ can be advocated for both point of care or home-collection of urine samples in HPV screening programs.

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