Pilot study on the use of INNO-LiPA® HPV Genotyping Extra II with Colli-Pee™ collected UCM preserved urine

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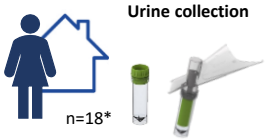
Introduction and objective

The use of urine as liquid biopsy for HPV DNA testing was shown to be very promising because of the high correlations between urinary and cervical HPV DNA. Performance of the INNO-LiPA® HPV Genotyping Extra II assay (Fujirebio, Belgium) has been demonstrated on cervical scrapes, but no data are currently available regarding HPV DNA detection in FV urine. The aim of this pilot study is to determine whether the INNO-LiPA® HPV Genotyping Extra II is compatible with DNA extractions from Colli-Pee™ collected, UCM preserved urine samples, using the Real-Time Riatol genotyping assay as reference.

Methods

**16 HPV pos and 2 HPV neg samples (identified with the Riatol assay) were randomly chosen from a previous conducted trial*

Urine collection

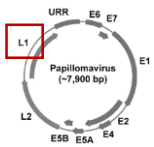


18 Colli-Pee™ collected, preserved (UCM), urine samples were collected at home and returned at ambient temperature to the CEV laboratory by postal mail.

Amicon filtration & DNA extraction

4 mL of urine/UCM mixture was concentrated on an ultrafiltration membrane (Amicon Ultra Centrifugal filters) and the DNA extraction was done by EasyMAG® (BioMérieux)

INNO-LiPA® HPV Genotyping Extra II



This assay can individually detect 32 HPV genotypes, generally used primers are located within the LI region

Reference assay: **Real-Time Riatol genotyping assay** can individually detect 18 HPV genotypes, used primers are located within the E6/E7 region

Only common HPV genotypes were considered for comparison: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 53, 66, 67, 6, 11

Results

The INNO-LiPA® HPV Genotyping Extra II assay was able to successfully detect results from 17/18 samples as shown in Figure 1. One vial was invalid because of an error during processing (opened vial in the PCR instrument). Two samples were HPV DNA negative as found by Riatol qPCR HPV genotyping assay. By both assays, this study detected 14 samples with at least one (probable/possible) high-risk HPV type *(shown in Figure 1 in bold).* Among the high risk HPV types, INNO-LIPA® confirmed those detected by Riatol but also detected others.

Figure 1. HPV genotype results per woman

ID	INNO-LiPA	Riatol assay
1	**16**	**16**
2	44	67
3	Invalid	**18**
4	**52, 58, 68**,70	**58**
5	**16,31,53**	**16,31,53**
6	Negative	Negative
7	**33**	**33**
8	Negative	Negative
9	**35, 53**,62	**35,53**,67
10	**16,33,58**	**16**
11	**35,45,**70	**35**
12	**31**	**31**
13	**66**,70	**66**
14	**52**,70,44	**52**
15	**35**,53,82,40	**35**
16	**58**	**58**
17	**33**,66,61	**33**
18	**16,39**,40	**16,39**,67

Figure 2. HPV genotype(s) detected per woman
(by both essays in yellow, only by INNO-LiPA® in red and only by Riatol in blue).

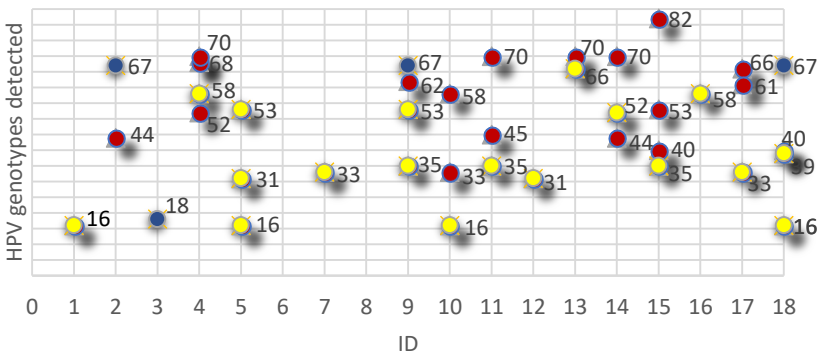
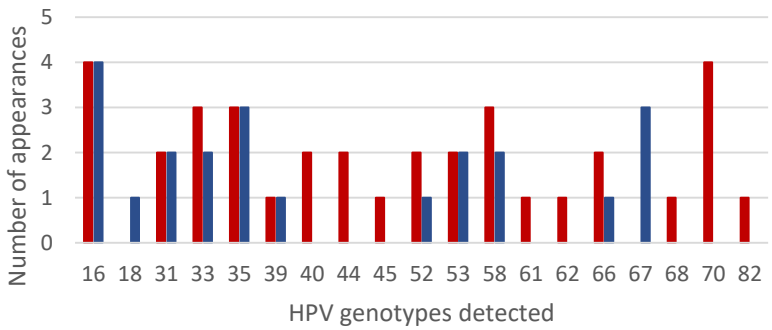


Figure 3. Number of appearances of each HPV genotype (Red: detected by INNO-LiPA®; Blue: detected by Riatol)



Conclusions

These preliminary results confirm that the INNO-LiPA® HPV Genotyping Extra II assay is compatible with self-collected, preserved, FV urine. The general comparability of the two assays (using the same DNA extract) was shown. Confirmation of performance by testing larger series in a clinical setting is warranted.

Please note that this was based on the slides of the oral presentation given by Jade Pattyn at EUROGIN 2017 in Amsterdam.

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Disclosure: VA, VV, BK and VDP are co-founders and board members of Novosanis