SELF-COLLECTED SAMPLES ARE LIKELY TO BECOME PART OF SCREENING, POST-VACCINATION MONITORING AND EPIDEMIOLOGICAL PROGRAMS

Both cervicovaginal and urine self-sampling have been proven effective in increasing participation and screening coverage of target populations.1,2

Several studies show that HPV DNA can be detected in urine samples using analytically sensitive HPV DNA assays.3,4,5,6,7

The INNO-LiPA HPV Genotyping Extra II assay has been widely demonstrated to generate sensitive and specific results for 32 genotypes of HPV using cervical swab samples (liquid-based cytology)8 and paraffin-embedded tissue (FFPE).9 The SPF10 PCR target used in the INNO-LiPA test can genotype infections with low viral load, “masked” HPV types, and mixed HPV infections.8,9,10

The newly validated urine protocol offers the possibility to perform full HPV genotyping on UCM-preserved first void urine samples.

Using a standardized urine collection and storage method is important to ensure good quality and a sufficient amount of DNA for extraction.

The urine sample for analysis preferably consists of first-void urine as it contains a larger amount of HPV DNA compared to random or midstream sampling, enabling a more accurate detection of cervical HPV2.

The Colli-Pee™ device, for example, is especially designed for first-void urine collection. It captures the first 20mL of a urine sample efficiently and with low effort from the user. The collection tube of the Colli-Pee™ device contains a UCM (Urine Conservation Medium) buffer for a general preservation of the urine during storage and transport.
Evaluation of the INNO-LiPA HPV Genotyping Extra II on UCM-preserved first-void urine

The high analytical sensitivity of the INNO-LiPA HPV Genotyping Extra II assay allows reduction of the sample volume to only 200µL and eliminates the need for a concentration step before DNA extraction.

First-void UCM-preserved urine is collected using a Colli-Pee™ device, followed by a convenient spin-column based DNA extraction step (QIAamp DNA Mini kit adapted extraction procedure, Qiagen).

Extracted DNA is amplified using the ready-to-use mastermix, followed by the INNO-LiPA HPV Genotyping Extra II line probe assay using identical protocols for both sample types.

With the optimized and standardized pre-analytical handling protocol an almost equivalent performance of the INNO-LiPA HPV Genotyping Extra II is achieved on both cervical and first-void urine samples.

INNO-LiPA HPV Genotyping Extra II results on paired cervical and UCM-preserved first-void urine samples showed 94% concordance. A concordant result means that identical results were obtained with both sample types for at least one of the high risk or potential high risk HPV genotypes11.

Colli-Pee is a trademark of Novosanis.

REFERENCES:

11. Instructions for Use INNO-LiPA HPV Genotyping Extra II kit