

University of Warwick Science Park, Venture Centre, Sir William Lyons Road, Coventry CV4 7EZ Website: www.micropathology.com E-mail: info@micropathology.com

## **HPV detection and genotyping**

The majority of Human Papilloma Virus (HPV) testing in the UK is performed as part of the cervical national screening program and is centred on the detection of HPV high-risk genotypes. This testing is undertaken as part of the national treatment guidelines [1]. Most commercial kits are designed for this specific purpose. Many assays do not provide a specific HPV genotype, but instead report on the presence or absence of HPV in a very limited range of sample types.

High risk HPV genotypes are associated with certain anal, oropharyngeal, vaginal, vulval and penile cancers. In addition, HPV can cause problematic cutaneous and conjunctival papillomas. Very limited or absent testing is provided for these sample sites by commercial manufacturers.

Micropathology Ltd offers two separate HPV assays, one of these utilises Sanger sequencing and has been used in our laboratory since 2001. It is unusual because it is designed to detect all known genotypes (over 170 HPV genotypes have been described). The test has been successfully applied in our laboratory on a wide range of sample types and, unlike most commercial kits, is valued as one of the few assays available for use with non-cervical specimens.

There is an increasing awareness of the prevalence of mixed-type HPV co-infection (>35% in cervical samples) [2]. The ability of our sequencing-based assay to deal with mixed infection is limited due to the nature of the sequencing technology that is used in this procedure. Therefore, in May 2016 we launched a second high-risk HPV subtype assay to run alongside our original sequencing-based assay. This assay utilises specific probes to determine the presence of certain high risk HPV genotypes even against a mixed background of other types. The assay has been verified for the detection of HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68a and 82 in genital swabs. Please note that type 68b is not detectable using this assay. In December 2023 we took the decision to perform both our sequencing-based genotyping assay and probe-based high-risk genotype assay on all samples referred to us for HPV testing as we felt that this would be in the best interests of the patients and clients whom we serve.

## Sample Types

Genital swabs are validated for use in this assay. Unvalidated sample types will usually be caveated to explain that the sample type is not validated. More information can be found in

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the latest version of our User Handbook, available on our website. Please note that our inhouse HPV genotyping assay is not currently UKAS accredited.

## References

1. "Cervical screening: professional guidance" Public Health England 24/10/19, <u>www.gov.uk</u>.

2. van Hamont, Dennis, et al. "Evaluation of the SPF10-INNO LiPA human papillomavirus (HPV) genotyping test and the roche linear array HPV genotyping test." *Journal of clinical microbiology* 44.9 (2006): 3122-3129.