



## HPV PCR

# Testing to detect individual high risk HPV genotypes enabling better patient management.

- Able to identify specific high risk HPV genotypes.
- HPV PCR test is more sensitive than current screening methods.
- Potential to reduce false negative results.
- The test has been validated to National Pathology Accreditation Advisory Council (NPAAC) standards.

### LOW RISK AND HIGH RISK HPV TYPES

Low risk HPV types, most commonly HPV 6 and 11, are associated with benign genital warts and benign cervical lesions, with no significant oncogenic potential. On the other hand, high risk HPV types, notably HPV 16, 18, 31 and 45 have the potential to cause high grade cervical intraepithelial neoplasia (CIN) and cervical carcinoma.

### HUMAN PAPILLOMAVIRUS INFECTION AND CERVICAL CANCER

Studies show that more than 95% of all cervical cancers are associated with human papillomavirus (HPV) infection. There are about 40 known sexually transmitted HPV types, of which 14 (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) have been established as having oncogenic (high risk) potential. Of these, HPV type 16 alone causes more than 50% of cervical cancers and HPV 18 causes 10% to 15%, followed by HPV 45 (around 7%) and HPV 31 (approx 3%). The ability to detect individual types of HPV viruses in cervical cytology specimens is, therefore, of considerable clinical value.

### HPV TEST USING PCR TECHNOLOGY

Our Molecular Biology Department in conjunction with Genera Biosystems has jointly developed a sensitive molecular test for the presence of HPV that also allows identification of any individual high risk genotypes. The assay uses the polymerase chain reaction (PCR) and a specific probe labelled silica bead hybridisation technique which enables the presence of one or more of the 14 oncogenic genotypes as well as other (so called low risk) types to be detected. The assay being PCR based is more sensitive than a hybrid capture assay which does not have an amplification step.

It also has internal controls that allow confirmation of adequate material in the sample, and detection of any substances inhibitory to the PCR step. These are both very important in preventing potential false negative results. The assay has been validated to National Pathology Accreditation Advisory Council (NPAAC) standards and requires either a liquid-based cervical cytology sample (ThinPrep or SurePath), or a plain (dry) cervical swab.

# HPV PCR

An innovative new test to detect individual high risk HPV genotypes enabling better patient management.

**The assay will determine and report the genotype of the HPV detected.**

**For example, if a high risk genotype is detected, the molecular biology report may be as follows:**

HUMAN PAPILLOMAVIRUS (High risk Genotypes)	DETECTED
Genotypes Identified	16, 18

The assay will also detect other (low risk) types of HPV, if present. The presence of low risk HPV will be reported, but not genotyped.

The advantage of this PCR based assay, unlike the other currently available assays, is that it is able to report the actual genotype of the HPV detected, rather than simply issue a broad statement such as “high risk type detected”.

## CLINICAL APPLICATIONS OF HPV TESTING

The presence of an infection with a high risk HPV type would serve to triage women needing close cervical smear and/or colposcopic follow up, particularly in the following circumstances:

1. Patients with equivocal cytology and/or histology results such as minor squamous abnormalities, non-specific squamous changes and equivocal HPV infection/CIN I.

2. Patients with low grade abnormalities, such as HPV infection and/or CIN I, reported on cytology and/or histology.
3. Patients with high grade CIN reported on cervical smears, who turn out to have normal findings or low grade abnormalities on colposcopy and/or histology.
4. Post treatment follow up of patients with high grade CIN.

**Patients who have a high risk HPV result should be referred for gynaecological assessment.**

HPV testing can be performed alone, or as an adjunct to the routine Pap smear, either by direct request, or by ‘reflex testing’ of a liquid-based sample.

Reflex testing is where the requesting doctor wishes HPV testing to subsequently proceed on the basis of abnormal cytology findings on a current liquid based sample.

The assay may be used, on request specifically to detect HPV genotypes 6 and 11 that are commonly associated with genital/venerual warts in both men and women. A plain swab moistened in water should be used to sample the affected area.