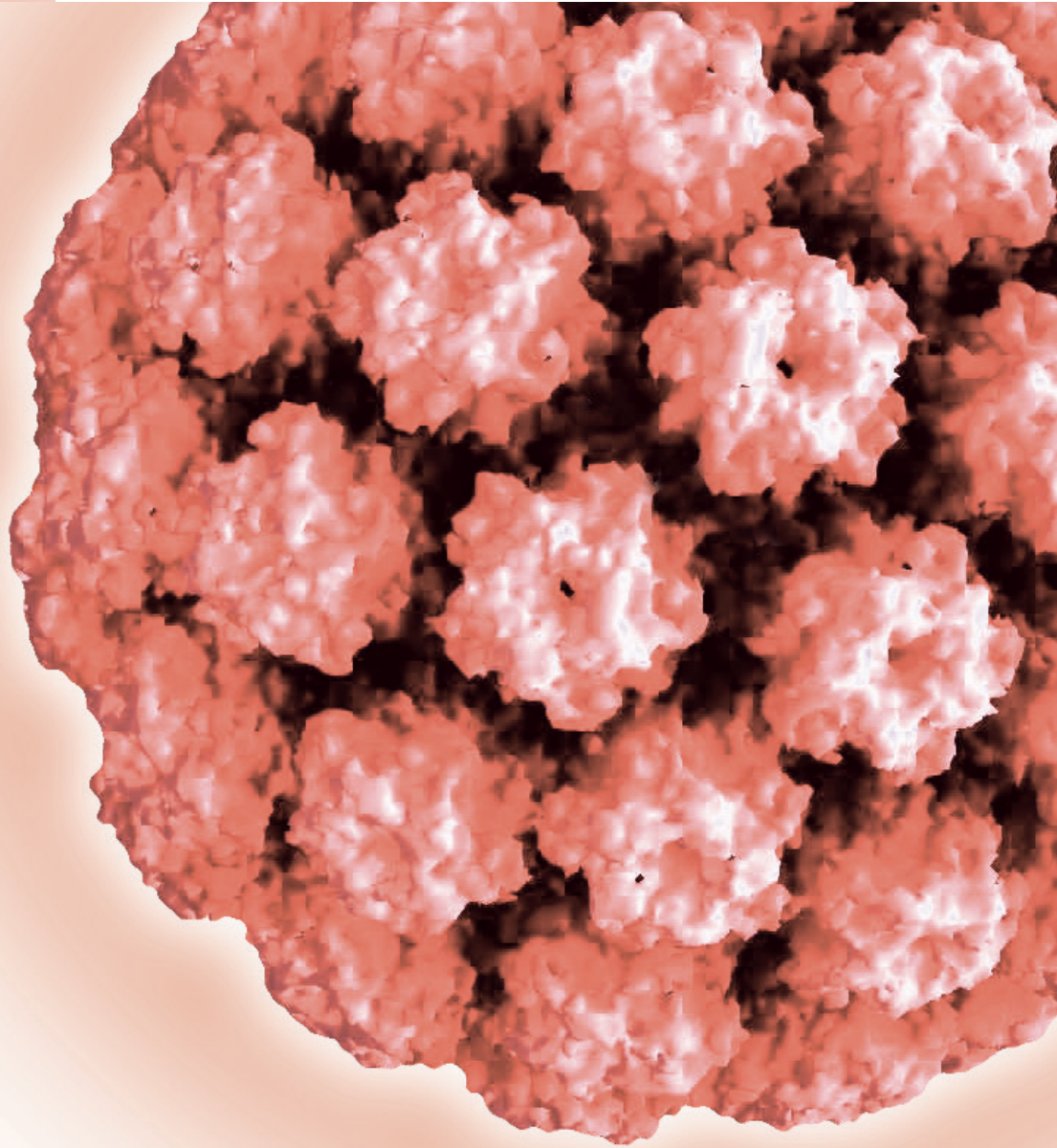


High-Risk HPV Test

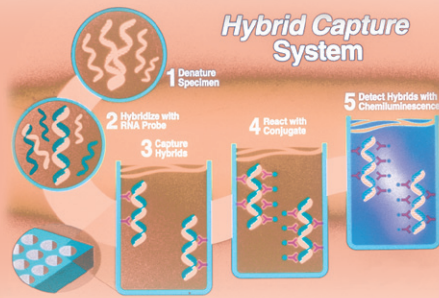
Hybrid Capture DNA Assay



GYNAEPATH
SPECIALIST GYNAECOLOGICAL PATHOLOGISTS



**DOUGLASS
HANLY MOIR**
PATHOLOGY



High-Risk HPV Test

Earlier disease detection - Improved patient management

As part of our comprehensive Cervical Cytology Service, Douglass Hanly Moir Pathology offers DNA testing for high-risk strains of human papillomavirus (HPV).

There is now overwhelming scientific evidence that HPV infection is a major factor in the development of cervical cancer and its precursor lesions. There are however, many different types of HPV and only some of these have been shown to be associated with the development of high grade cervical lesions.

The HPV assay tests for thirteen subtypes shown to be most strongly associated with cervical disease.

HPV and Cervical Disease

- > Extensive scientific studies over the last few years have established a strong association between cervical disease and HPV infection.
- > HPV infection is a sexually transmitted disease that is very common.
- > Some overseas studies have shown that it may be present, at some stage, in many sexually active women. Estimates of a prevalence of up to 65% in women under 30 have been made.
- > Not all women who have HPV infection develop cervical disease.
- > HPV is an essential factor in the development of cervical cancer; however, other factors must also be present for cervical cancer to occur.
- > Most Low- and High-Grade Squamous Intraepithelial Lesions are associated with HPV infection.
- > Low-Grade Squamous Intraepithelial Lesions (LSIL) are associated with productive viral infections and most (but not all) will resolve spontaneously.
- > High-Grade Squamous Intraepithelial Lesions (HSIL) are associated with viral infections where the viral particles are integrated into the host DNA. Many of these will also spontaneously resolve but there are no tests currently available which indicate which of these lesions are likely to regress, and which are likely to persist and enlarge.

What is the basis of the test?

The test uses a "cocktail" format to detect 13 high-risk HPV types.

The types tested are: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68.

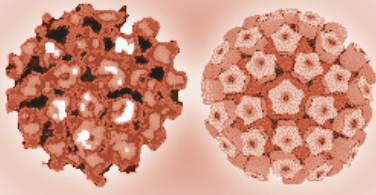
- > The target DNA in the specimen hybridises with the HPV-RNA probe "cocktail".
- > The resulting DNA-RNA hybrids are captured onto the surface of a microplate.
- > After various reactions, their presence is demonstrated by the emission of light.
- > The intensity of the light emission denotes the presence or absence of DNA in the original specimen.

The result is reported as Negative or Positive for high-risk HPV.

When is it indicated?

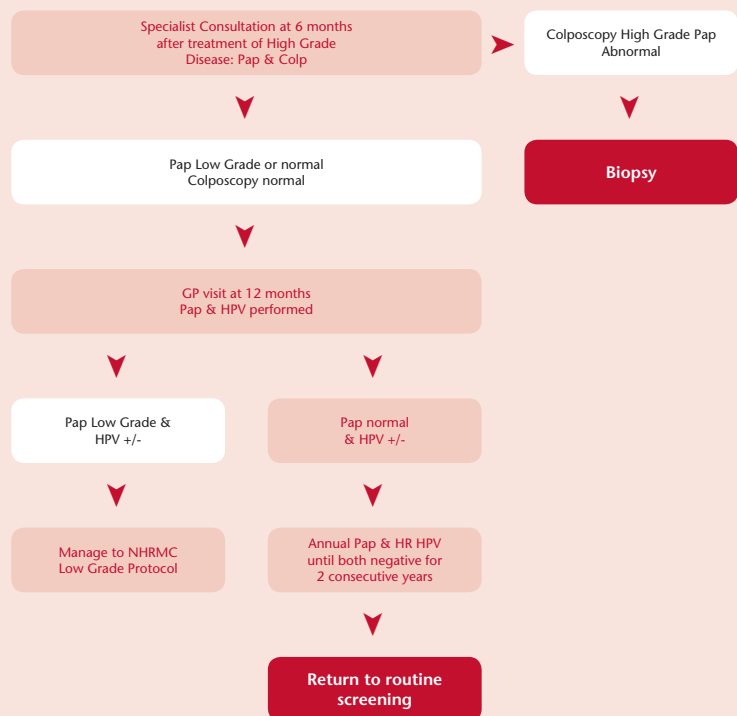
Follow-up after treatment of High-Grade Squamous Intraepithelial Lesions (HSIL)

- > The NH & MRC "Guidelines for the Management of Asymptomatic Women with Screen-Detected Abnormalities" recommends high-risk HPV testing as a "test-of-cure" for women who have been treated for HSIL. Once a patient has tested negative by both cytology and HPV testing on two consecutive occasions one year apart, she can return to routine screening, rather than needing annual smears for the rest of her life.
- > HPV tests performed for this clinical indication attract a Medicare rebate.



High-Risk HPV Test

High-Risk HPV DNA for “Test-of-Cure” after treatment of HSIL (CIN 2, CIN 3)



Other Indications

- > HPV testing may also be of benefit in other clinical circumstances. Please note, however, that when HPV testing is used outside the “test-of-cure” protocol described above, it does not currently attract a Medicare rebate and will therefore be privately billed.
- > Overseas, HPV testing is commonly used for investigation of equivocal cervical cytology results.
- > HPV testing may be of benefit, for example, in women who have had cytology showing possible LSIL, possible HSIL, or glandular lesions of uncertain significance.
- > HPV testing may be of particular significance in older women. In this group the prevalence of HPV is lower than in younger women and is likely to represent persistent disease, which is known to increase risk of significant cervical neoplasia.
- > A negative HPV test and a normal colposcopy give a negative predictive value of 99%.
- > HPV testing in women less than 30 years of age has very limited value.

High-Risk HPV Test

How is it collected?

The HPV test can be collected as a separate follow-up specimen, or at the same time as a Pap smear.

> As a separate stand-alone specimen

The HPV test is collected with the Digene Cervical Sampler kit, or can be collected into a ThinPrep vial.

> Co-collection of the conventional Pap smear and the HPV test

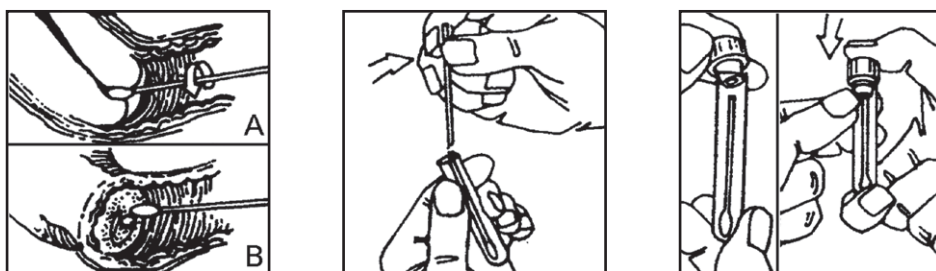
The conventional Pap smear is performed first.

The HPV test is then collected using the Digene kit.

> Co-collection of the conventional Pap smear and the ThinPrep test

The conventional Pap smear is performed and the instrument is then rinsed in the ThinPrep vial. The HPV test can be performed from the sediment remaining in the vial after the ThinPrep test has been completed. There is no need to take a separate HPV sample.

The ThinPrep vials are kept in the laboratory for four weeks. If indicated, HPV testing can be requested during that time. The HPV test will not be affected by the delay.



The suggested technique for taking a sample for the high-risk HPV test using the specially designed kits. HPV testing can also be performed on specimens collected for the ThinPrep Pap test. To obtain HPV or ThinPrep kits please phone the Stores Department on 98 555 210 or 1800 222 365 (ext. 5210).

HPV Testing - A valuable adjunct to Pap smear screening

The use of HPV testing allows effective triage of low-grade and equivocal lesions by identifying women who are at higher risk of developing cervical cancer and so:

- > Allows earlier treatment of significant lesions.
- > Helps avoid unnecessary colposcopies.
- > May be used as a test-of-cure following treatment of HSIL.
- > Provides reassurance for doctors and patients.

If you require more information about high-risk HPV testing, please contact
Dr Annabelle Farnsworth on (02) 98 555 180, or Dr Ian Chambers on (02) 98 555 330