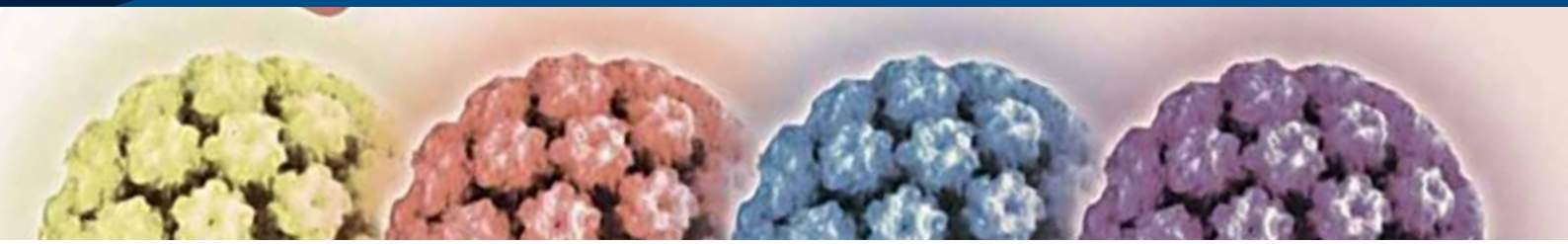
MELBOURNE PATHOLOGY
Quality is in our DNA

High-Risk HPV Test - Changes to the Collection Method and Reporting

June 2013



- Melbourne Pathology is introducing a new testing method for HPV
- The new testing allows the individual detection of HPV16 and HPV18
- Samples for HPV testing should be collected using a cervical cytology sampler (not a swab) vigorously rinsed into a ThinPrep® vial

Earlier disease detection – Improved patient management

Human Papilloma Virus (HPV) infection has been shown to be the major factor in the development of cervical cancer and its precursor lesions. There are many different genotypes of HPV, however, only some have been implicated in the development of high-grade cervical lesions. HPV 16 and 18 are associated with about 70% of cervical cancers and are 2 of the types targeted by the HPV vaccine.

As part of our comprehensive cervical screening service, Melbourne Pathology provides PCR testing for the 14 HPV genotypes associated with the highest risk of developing cervical disease. The specific and sensitive detection of these "high-risk genotypes" alerts the clinician to the increased risk of cervical disease enabling early management strategies.

Melbourne Pathology uses the Roche cobas® 4800 HPV assay, which detects the "high-risk" genotypes 16 and 18 individually, and also 12 other "high-risk" genotypes, as a group.

HPV and cervical disease

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

What is the basis of the assay?

The Roche cobas® 4800 HPV assay is a Polymerase Chain Reaction (PCR) assay. It detects 14 high-risk HPV genotypes and produces a result consisting of 3 components.

HPV 16:	detected or not detected
HPV 18:	detected or not detected
Other High-Risk HPV*:	detected or not detected

(*Indicates the presence/or absence of one or more of other high-risk HPV genotypes 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.)

Advantages of the Roche cobas® 4800 HPV assay:

- It has been clinically validated in more than 46,000 women and referenced against histologically confirmed HSIL.
- The assay includes an internal control (beta-globin) for sample adequacy. Therefore a negative result which is due to sample inadequacy can be readily identified, and will be noted in the report.
- The same ThinPrep® liquid based sample can be used for cervical cytology, Chlamydia and Gonorrhoea testing, if specifically requested.
- Automation of sample preparation and analysis allows for more frequent test runs in the laboratory, improved turnaround time and accuracy of results.

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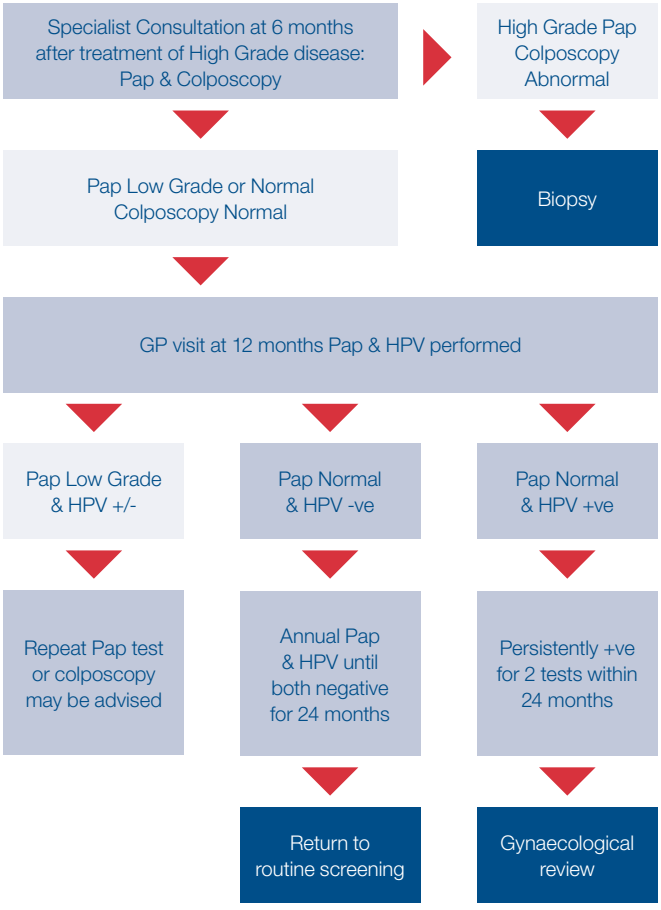
When is it indicated?

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

- The NHMRC "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 woman has tested negative by both cytology and HPV testing on two consecutive occasions, one year apart, she can return to routine HPV screening, rather than needing annual Pap tests for the rest of her life.
- HPV tests performed for the above clinical indication attract a Medicare rebate. To ensure correct billing, it is important to note this history on the request form.
- Screening for HPV in the absence of a previous cervical High Grade abnormality does not attract a Medicare rebate.
- HPV tests are currently not recommended for "test-of-cure" follow-up of in situ glandular disease (adenocarcinoma-in-situ, AIS).

High-Risk "Test-of-Cure" after treatment of HSIL (CIN2, CIN3)



Collection

How is the sample for the Roche cobas 4800® HPV assay collected?

Samples for HPV testing should be collected using a cervical cytology sampler (not a swab) vigorously rinsed into a ThinPrep® vial.

The HPV test can be collected at the same time as a cervical cytology sample or as a separate follow-up specimen.

Collection equipment

ThinPrep® vial and Cervex broom

Co-collection of the conventional Pap test with cytological assessment of the ThinPrep® sample

The conventional Pap test is made and fixed. The sampling device is then rinsed vigorously into the ThinPrep® vial. The liquid-based cytology and the HPV test are both performed on this vial.

Co-collection with the conventional Pap test without cytological assessment of the ThinPrep® sample

The conventional Pap test is made and fixed. The sampling device is then rinsed vigorously into a ThinPrep® vial for HPV testing. Please clearly indicate that the ThinPrep® vial is for HPV testing ONLY.

As a separate stand-alone specimen

The specimen is collected with a cervical cytology sampler which is rinsed vigorously into a ThinPrep® vial for HPV testing. Please clearly indicate that the ThinPrep® vial is for HPV testing ONLY.

There is currently no validated testing method for detection of HPV in males.

Chlamydia and Gonorrhoea testing can also be performed from a sample collected into a ThinPrep® vial as described above. The ThinPrep® vials are stored in the laboratory for four weeks. If indicated, HPV and/or Chlamydia/Gonorrhoea testing can be requested at any time during this period. The tests will not be affected by the delay.

To order ThinPrep® vials, please contact our Stores Department on 9287 7824.