The new Cervical Screening Test and pathway – A risk-based approach

The new Cervical Screening Test every five years is more effective than, and just as safe as, a Pap test every two years.

The new Cervical Screening Test detects infection with human papillomavirus (HPV).

The Cervical Screening Test and pathway is a risk-based approach to the management of patients participating in the National Cervical Screening Program (NCSP).

Partial genotyping is used to classify the type of HPV into one of two groups: oncogenic HPV 16/18 or oncogenic HPV types not 16/18 as a pooled result.

If HPV is detected, the pathology laboratory will automatically conduct a reflex liquid-based cytology (LBC) test on the same sample, to determine if any cervical cell abnormalities are present.

Patients are managed according to their risk of developing cervical abnormalities, which is determined by their HPV test result and reflex LBC result, if indicated. If both tests are performed, the pathology report will include the combined result as a risk category and the recommended clinical management. If any glandular abnormalities are detected on a screening test follow up in accordance with the 2016 Guidelines.

There are three risk categories: low risk, intermediate risk and higher risk.

Return to screen in five years (Low risk result)

A low risk result means oncogenic HPV was not detected. HPV is required for the development of most cases of cervical cancer. Patients at low risk of developing cervical cancer can safely return for a Cervical Screening Test in five years.

We cannot assure patients that they are at ‘no risk’ because they may subsequently acquire an HPV infection or have a latent infection that becomes active and may develop into cervical cancer over time usually 10–15 years.

Patients with a low risk result will be invited to screen again in five years.

Repeat the HPV test in 12 months (Intermediate risk result)

An intermediate risk result means an HPV infection (not 16/18) was detected. A reflex LBC conducted on the same sample showed that the patient has negative, possible low-grade squamous intraepithelial lesion (LSIL), or LSIL abnormal cervical cells.

An intermediate risk result is not associated with high-grade cell changes that require treatment.

Patients with an intermediate risk result will be invited by the NCSP to return for a repeat HPV test in 12 months. This is to check if the body has cleared the HPV infection.
12 months – Repeat test

The patient should have a repeat HPV test, and will receive one of two possible results:

- HPV not detected: The immune system has cleared the HPV infection. The patient can now safely return to five-yearly screening.

- HPV detected (any type): This result means that there is a persistent HPV infection (any type). Since HPV is detected, reflex LBC will be performed and the patient should be referred for colposcopic assessment (regardless of LBC result). Further investigation with colposcopy will assist in the identification of abnormal cells that require treatment, to prevent the progression to cervical cancer.

Refer to specialist (Higher risk result)

A higher risk result means the patient has received one of two possible results:

- HPV detected (not 16/18): A reflex LBC will be conducted on the same sample. If possible high-grade squamous intraepithelial lesion (HSIL) or HSIL abnormal cervical cells are detected the patient should be recommended a colposcopic assessment because they are at a higher risk of cervical cancer. A colposcopy will determine if a biopsy is needed and this will determine if treatment is required.

- HPV detected (16/18): HPV types 16 and 18 are associated with approximately 70% of cervical cancers. These HPV types are also more likely to progress to cervical cancer than other oncogenic HPV types. Regardless of the reflex LBC test result, the patient should be recommended to have a colposcopic assessment because they are at a higher risk of cervical cancer. The LBC will inform the colposcopic assessment.

Symptomatic patients

Patients who have signs or symptoms suggestive of cervical cancer are tested and managed on a different clinical pathway from those who are asymptomatic.

The following signs or symptoms can be suggestive of cervical cancer:

- unusual or abnormal vaginal bleeding (post-coital, inter-menstrual or post-menopausal)
- pain during intercourse, or
- unusual vaginal discharge.

Patients at any age who have signs or symptoms suggestive of cervical cancer should have a co-test (HPV and LBC). Consider referral for the appropriate investigations to exclude genital tract malignancy.


Testing during pregnancy

If a patient is due for screening, this can be done safely at any time provided that the correct equipment is used. A cytobrush or combi-brush should not be inserted into the cervical canal because of the risk of bleeding. The sample collection device will vary depending on the type provided by the pathology laboratory.

Test of Cure: Management after treatment

It is recommended that patients who have received treatment for a high-grade abnormality should complete Test of Cure surveillance to confirm their treatment has been successful.

Test of Cure surveillance is a co-test (HPV and LBC test) performed 12 months after treatment, and annually thereafter, until the patient receives a negative co-test on two consecutive occasions. They should then return to five-yearly screening.

For information on the renewed National Cervical Screening Program, self-collected vaginal sample, MBS items and the NCSR, see the Quick Reference Guide – Self-Collected Vaginal Sample for HPV Test
### Requesting cervical and vaginal pathology tests

Clinical information on pathology request forms assists pathology laboratories in performing the right tests, matching the right clinical recommendations and selecting the right MBS item/s.

<table>
<thead>
<tr>
<th>Patient presents as</th>
<th>Context*</th>
<th>Age</th>
<th>Sample type</th>
<th>Test type</th>
<th>What to write on the pathology request form</th>
</tr>
</thead>
</table>
| Asymptomatic        | NCSP routine five-yearly screening  
• Only 1 of this MBS item is claimable in a 57-month period | ≥ 24yrs & 9mths | Cervical | HPV test | Cervical Screening Test (CST) |
| Asymptomatic        | Screening in specific populations  
• Immune-deficient  
• Early sexual debut, prior to 14 years and not vaccinated prior to sexual debut (only one claimable between 20 to 24 years of age) | Any age | Cervical | HPV test |  
• HPV test, Immune-deficient  
• HPV test, Early debut HPV  
Follow-up test claimable after previous positive screening test (12-month repeat)  
Follow-up or post-treatment for clinical management  
• Following treatment of HSIL (also called “test of cure”)  
• Following treatment of AIS  
• DES exposed in utero | Co-test (HPV & LBC) |  
• “Co-test” or “HPV & LBC”, Test of Cure  
• “Co-test” or “HPV & LBC” Post-treatment  
• “Co-test” or “HPV & LBC”, DES  
“Co-test” or “HPV & LBC”, Symptomatic |
| Symptomatic         | For investigation of symptoms e.g. abnormal bleeding | ≥ 30yrs | Vaginal | HPV test | Self-collect HPV follow-up test |
|                     | Only claimable within 21 months following the detection of oncogenic HPV (any type) on a self-collected screening test | | Cervical | HPV test | LBC |
| Repeat test         | Following an unsatisfactory test  
• Only claimable when preceded by another cervical or vaginal MBS Item | Any age | Cervical | HPV test | HPV test, previous result unsatisfactory  
Vaginal | HPV test | HPV test, previous result unsatisfactory  
Cervical | LBC | LBC, previous result unsatisfactory |

Ensure you order the correct test for your patient. To avoid ordering a test that your patient is not eligible for and having your patient charged the cost of this test by the pathology laboratory, check the table at the back of the booklet Understanding the National Cervical Screening Program Management Pathway – a Guide for Healthcare Providers.

### National Cancer Screening Register

The National Cancer Screening Register (NCSR) supports the NCSP by sending eligible patients invitations to screen and reminders when due.

The NCSR supports you to manage your patients through the clinical management pathway. Find out your patients’ screening history by calling 1800 627 701.

Pathology laboratories can no longer act on Not for Register instructions on the pathology request form. If a patient chooses to ‘opt out’ of the National Cancer Screening Register then the patient themselves, or with their consent; their healthcare provider, or their personal representative can arrange this by calling 1800 627 701.

Opting a patient out of the Register for cervical screening will not opt this patient out of other screening programs (i.e. bowel screening), and they can rejoin the Register at any time.

Understanding the National Cervical Screening Program Management Pathway
A Guide for Healthcare Providers

**Figure 1: Cervical screening pathway for clinician-collected sample**

### Understanding intermediate risk

What does an intermediate risk result mean?

An intermediate risk result means an HPV not 16/18 was detected. A reflex LBC conducted on the same sample showed that the patient has negative, possible LSIL, or LSIL abnormal cervical cells.

An intermediate risk result is not associated with high-grade cell changes that require treatment.

Patients with an intermediate risk result will be invited by the NCSP to return for a repeat HPV test in 12 months. This is to check if their body has cleared the HPV infection.

What happens 12 months after an intermediate risk result?

The patient should have a repeat HPV test, and will receive one of two possible results:

- HPV not detected: The immune system has cleared the HPV infection. The patient can now safely return to five-yearly screening.
- HPV detected (any type): This result means that there is a persistent HPV infection (any type). Since HPV is detected, reflex LBC will be performed and the patient will be referred for colposcopic assessment (regardless of LBC result). Further investigation with colposcopy will assist in the identification of abnormal cells that require treatment, to prevent the progression to cervical cancer.

### Understanding higher risk

What does a higher risk result mean?

A higher risk result means the patient has received one of two possible results:

- HPV not 16/18 detected: If HPV not 16/18 is detected, a reflex LBC will be conducted on the same sample. If possible HSIL or HSIL abnormal cervical cells are detected the patient should be recommended a colposcopic assessment because they are at a higher risk of cervical cancer. A colposcopy will determine if a biopsy is needed and this will determine if treatment is required.
- HPV 16/18 detected: HPV types 16 and 18 are associated with approximately 70% of cervical cancers. These HPV types are also more likely to progress to cervical cancer than other oncogenic HPV types. Regardless of the reflex LBC test result, the patient should be recommended to have a colposcopic assessment because they are at a higher risk of cervical cancer. The LBC will inform the colposcopic assessment.

If a glandular abnormality is detected on a screening test, follow up in accordance with the 2016 Guidelines.

If you would like some tips and resources for communicating results to patients go to page 19 of this booklet.

For more information on further testing and treatment go to page 20 of this booklet.

Screening pathway for clinician-collected cervical sample

For clinician-collected cervical samples, refer to the screening pathway (Figure 1, opposite) and the results matrix (Table 1, see page 8) to see how the risk categories and management strategies are determined based on the combined HPV and LBC (if performed) results.

**Definitions:**
- CST = Cervical Screening Test
- HPV = Human papillomavirus
- LSIL = low-grade squamous intraepithelial lesion
- HSIL = high-grade squamous intraepithelial lesion
- LBC = liquid-based cytology

Diagram adapted from Cervical Screening Guidelines 2016.