

National CERVICAL SCREENING MANAGEMENT GUIDE

From 1st December 2017 the new National Cervical Screening Guidelines will take effect

A BRIEF OVERVIEW

Cancer Council Australia has recommended significant changes to the National Cervical Screening Program. The new 2016 Guidelines will replace the 2005 NHMRC Guidelines.

From December 2017, the Pap smear process will now be known as Cervical Screening. The cervical cells will be collected in the same way as previously collected for Pap smears, with the only difference being that the sample is to be placed in a ThinPrep® vial with liquid media rather than smeared onto glass slides. Testing the sample for oncogenic Human papillomavirus (HPV) will replace cytology as the primary screening process. Liquid-based cytology (LBC) will be performed on the sample by the laboratory if the HPV test is positive (i.e. reflex cytology) or in specific clinical circumstances (i.e. HPV and cytology co-test).

The cervical screening program will be available to women between the ages of 25 and 74 years. Women over the age of 25 will be invited by the National Cancer Screening Register to participate in the new National Cervical Screening Program. The recommended interval between cervical screening tests will change from 2 to 5 years.*

Women who have had the HPV vaccination must still participate in the screening program.

A detailed explanation of the program is available from Cancer Council Australia.



HPV TESTING

Human papillomavirus is a common virus. Most infections are harmless and resolve spontaneously in about a year. In some patients, persistent infection with one of the oncogenic genotypes of HPV can lead to cervical pre-cancer or cancer. Types 16 and 18 are more virulent than other HPV types, consistently causing around 75% of all cervical cancers.*

Testing for oncogenic HPV types has been shown to be as sensitive as cytology in identifying women at risk of developing cervical neoplasia. However, it is the strong negative predictive value of HPV testing that has the most clinical use.*

Dorevitch Pathology will use the latest HPV testing technology for the detection of the 14 HPV genotypes known to be associated with cervical cancer. The test specifically detects HPV 16 and 18 (which cause 75% of cervical cancers) while simultaneously detecting the 12 other oncogenic genotypes. There is an internal control which minimises the risk of false negative results for each patient.

Remember, a positive HPV result does not necessarily indicate that the woman has cervical neoplasia, but does indicate an increased risk.

ROUTINE 5-YEARLY CERVICAL SCREENING

For women aged 25 to 69

Depending on the result of the HPV, and any additional reflex cytology testing, women are assigned a clinical risk category – Low Risk, Intermediate Risk or Higher Risk. Each risk category follows a different clinical pathway:

Cervical Screening Pathways

Low Risk

The HPV test is negative

- The woman will be invited to rescreen in five years

Intermediate Risk

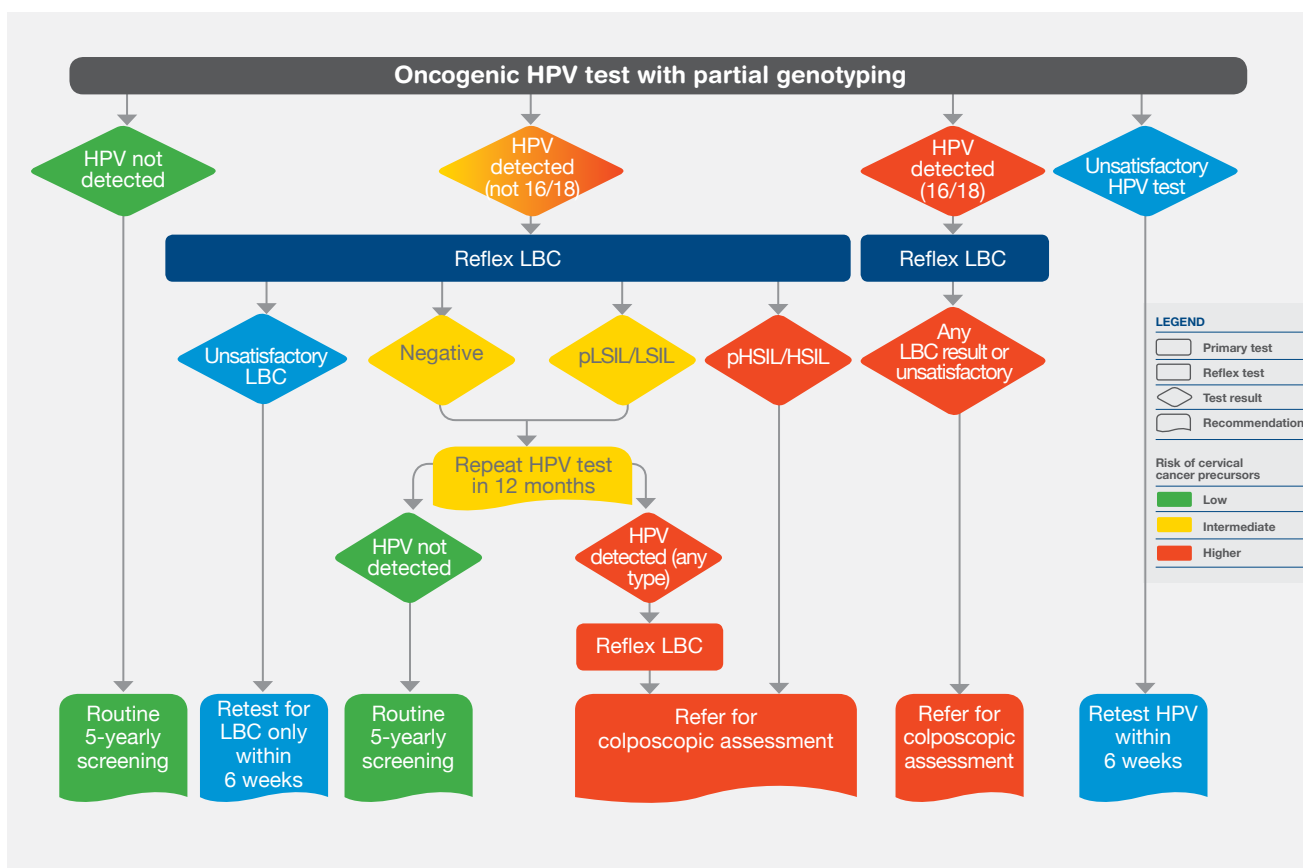
The HPV test is positive for one of the other oncogenic HPV types (i.e. NOT 16/18) and the reflex cytology performed by the lab is either negative or only shows low grade changes.

- The woman will be invited to have another HPV test in 12 months
- If the repeat HPV test in 12 months is negative then the woman can return to routine 5 yearly screening
- If the repeat HPV test in 12 months is positive (regardless of type) then referral to colposcopy is advised

High Risk

- If the test is positive for HPV 16/18 then referral for colposcopy is advised (regardless of the result of the reflex cytology)
- If the test is positive for other oncogenic HPV types (i.e. NOT 16/18) and the reflex cytology performed by the lab shows possible or definite high grade changes then referral for colposcopy is advised

Flowchart 6.1. Cervical screening pathway for primary oncogenic HPV testing



Source: National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Cancer Council Australia, Sydney (2016)

For women aged 70-74

- If the routine screening HPV test is negative, then the patient is discharged from the screening program and no further screening is required.
- Any positive oncogenic HPV result (regardless of type) should be referred for colposcopy in this age group.
- Women aged 75 years or older who have never had a cervical screening test, or not had one in previous five years may request a test and be screened.

Test of cure for women with treated high-grade intraepithelial lesion (HSIL)

- HPV testing and cytology co-testing should be performed at 12 and 24 months post treatment.
- Once a woman has tested negative by both tests on two consecutive occasions, she is regarded as passing the Test of Cure and can safely return to the normal five-yearly screening interval.
- Any positive test for HPV 16/18 or a cytology result of possible HSIL or HSIL should be referred back to colposcopy.

Follow-up of women treated for Endocervical Adenocarcinoma in-situ (AIS)

- The follow-up of women treated for AIS is annual HPV and cytology co-test indefinitely.
- Any abnormal result will require referral back to colposcopy.
- Currently, the clinical evidence does not support a Test of Cure for endocervical lesions as there is for squamous lesions.
- It is important to inform the pathology laboratory if a woman has a history of AIS so that the appropriate cytology co-test is performed and the appropriate clinical recommendation can be made.

Screening after hysterectomy

- If the hysterectomy was for benign reasons (e.g. fibroids) and there was no history of cervical abnormality, then no follow-up is required.
- If the hysterectomy was for benign reasons (e.g. fibroids) and the cervical screening history is not available, then two consecutive negative HPV tests, 12 months apart, are advised before no further testing is required.
- Any woman with a hysterectomy and a history of HSIL is advised to pass the Test of Cure (as described previously). The Test of Cure can be done either prior to or after the hysterectomy. Once the Test of Cure is passed, then no further follow-up is required.
- Any woman with a hysterectomy and a history of Endocervical AIS should have annual HPV and cytology co-testing indefinitely as described in the previous section.

- Women who have undergone a subtotal hysterectomy (the cervix is not removed) should be invited for 5-yearly HPV testing in accordance with the recommendation for the general population.

Immune-deficient women

- Women with Human immunodeficiency virus (HIV) or a solid organ transplant should have 3-yearly HPV Screening tests.
- Immune-deficient women with any positive oncogenic HPV result (regardless of type) should be referred for colposcopy.
- It is important to inform the pathology laboratory if a patient is immune-deficient so that the appropriate clinical recommendation can be made.

Screening in diethylstilbestrol (DES) exposed women

- Women exposed to DES in utero should be offered an annual HPV and cytology co-test indefinitely.
- Any abnormal result will require referral back to colposcopy.
- Self-collection is not recommended.
- It is important to inform the pathology laboratory if a woman has a history of DES exposure so that the appropriate cytology co-test is performed and the appropriate clinical recommendation can be made.

Investigation of abnormal vaginal bleeding

- Women with abnormal vaginal bleeding should be offered an HPV and cytology co-test.
- Regardless of the test results, referral to gynaecological assessment for investigation of the bleeding should be considered.
- It is important to inform the pathology laboratory if a woman has clinical symptoms so that the appropriate cytology co-test is performed and the appropriate clinical recommendation can be made.

For women under 25 years old

- Routine cervical screening is NOT recommended for asymptomatic women under the age of 25 years.
- For women who experience first sexual activity at a young age (<14 years) and had not received the HPV vaccine before becoming sexually active, a single HPV test between age 20 and 24 can be considered on an individual basis.

SPECIMEN COLLECTION FOR CERVICAL SCREENING

The collection of cervical cells is completed the same way a usual Pap Smear was collected, with the only difference being that the cervical cells are now placed in a ThinPrep® vial, rather than on a slide.

1. Obtain an adequate sample from the cervix

- Use luke warm water to lubricate and warm the speculum. A water soluble gel lubricant can be sparingly applied to the posterior blade if necessary. Do not use carbomer-based lubricants.
- Insert the speculum.
- Insert the central bristles of the Cervical Sampler deep enough into the endocervical canal to ensure the shorter bristles contact the exocervix, then push gently and rotate the broom in a full clockwise direction **4 - 5 times**.

Please note:

An endocervical brush should not be used in pregnant women.

2. Place the Cervical Sampler into the ThinPrep® vial ASAP

- Ensure the ThinPrep® vial is within the use by date. It can be stored at room temperature.
- Push the Cervical Sampler into the bottom of the vial **10 times**, ensuring to push hard enough to force the bristles apart.
- Swirl the Cervical Sampler before removing it from the vial.
- Discard the Cervical Sampler.

Please note: Do not make any glass slides.

3. Secure the cap on the vial

Tighten the cap enough that the torque line on the cap is in line with the torque line on the vial.

4. Record the patient details & complete the request form

- Record the patient's full name and date of birth on the vial.
- Complete the patient's details on the request form providing as much information as possible.

Pertinent clinical details are essential for reliable cervical screening. Please ensure to request **HPV for cervical screening** and state the **REASON** for test, e.g. screening or symptomatic.

Other important information should be noted on the request form under clinical notes.

Doctor please consider:

- Patients who are symptomatic (e.g. history of abnormal vaginal bleeding) require both an HPV and a concurrent liquidbased cytology (LBC).
- Patients who have previously been diagnosed with endocervical adenocarcinoma in-situ (AIS), also require a concurrent LBC annually.
- Patients who are immune deficient are advised to repeat testing in 3 years not 5 years.

5. Package the sample and request form for transport

Place both the vial and request form into a specimen bag for transport to the laboratory in the usual manner.

SELF-COLLECTION

- Self-collection with a dry flocked swab is available for patients who have never been screened (>30 years old) or are under-screened (>30 years old and >2 years overdue for cervical screening).
- The accuracy of self-collected samples is limited compared to practitioner-collected samples and therefore self-collection is not advised as an alternative for women who would otherwise participate in the screening program.
- If the HPV result is positive, the woman may be referred for colposcopy or may have to return for a second sample (this time practitioner-collected) so that a LBC sample can be taken.
- For more information on self-collect see the Self-Collect - HPV Specimen Collection for the Cervical Screening Program available at (insert brand website).

TURNAROUND TIME

Results will be released to the requesting Doctor in approximately 2-3 days after the sample is received by the laboratory.

COST

Cervical screening requests that follow the national prescribed laboratory process will be bulk billed subject to Medicare guidelines and criteria.

If Medicare guidelines and criteria are not met, an out-of-pocket fee may apply. If the patient wants additional cervical cytology smears that do not fit the MBS criteria, these tests will not be rebated by Medicare.

FURTHER INFORMATION

Dr Leonard Wu

BMed PhD FRCPA

Acting Pathologist in Charge

Faye Kapoulitsas

Manager Cytopathology

(03) 9244 0313

REFERENCE:

* National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Cancer Council Australia, Sydney (2016)