National Screening Unit

Te Whatu Ora
Health New Zealand

NCSP Policies and Standards
Section 5: Providing a Laboratory Service

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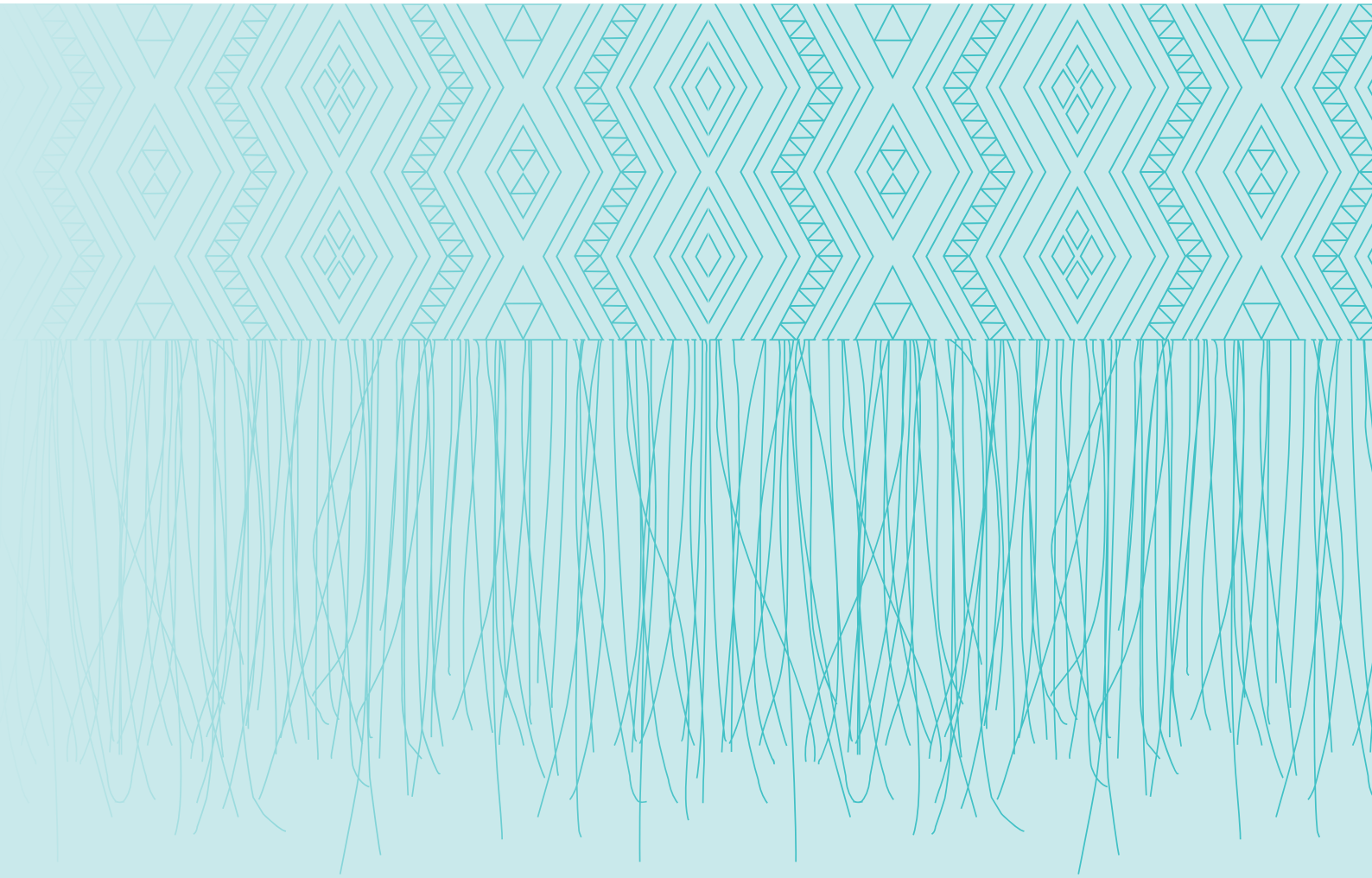
National Cervical Screening Programme, 2023



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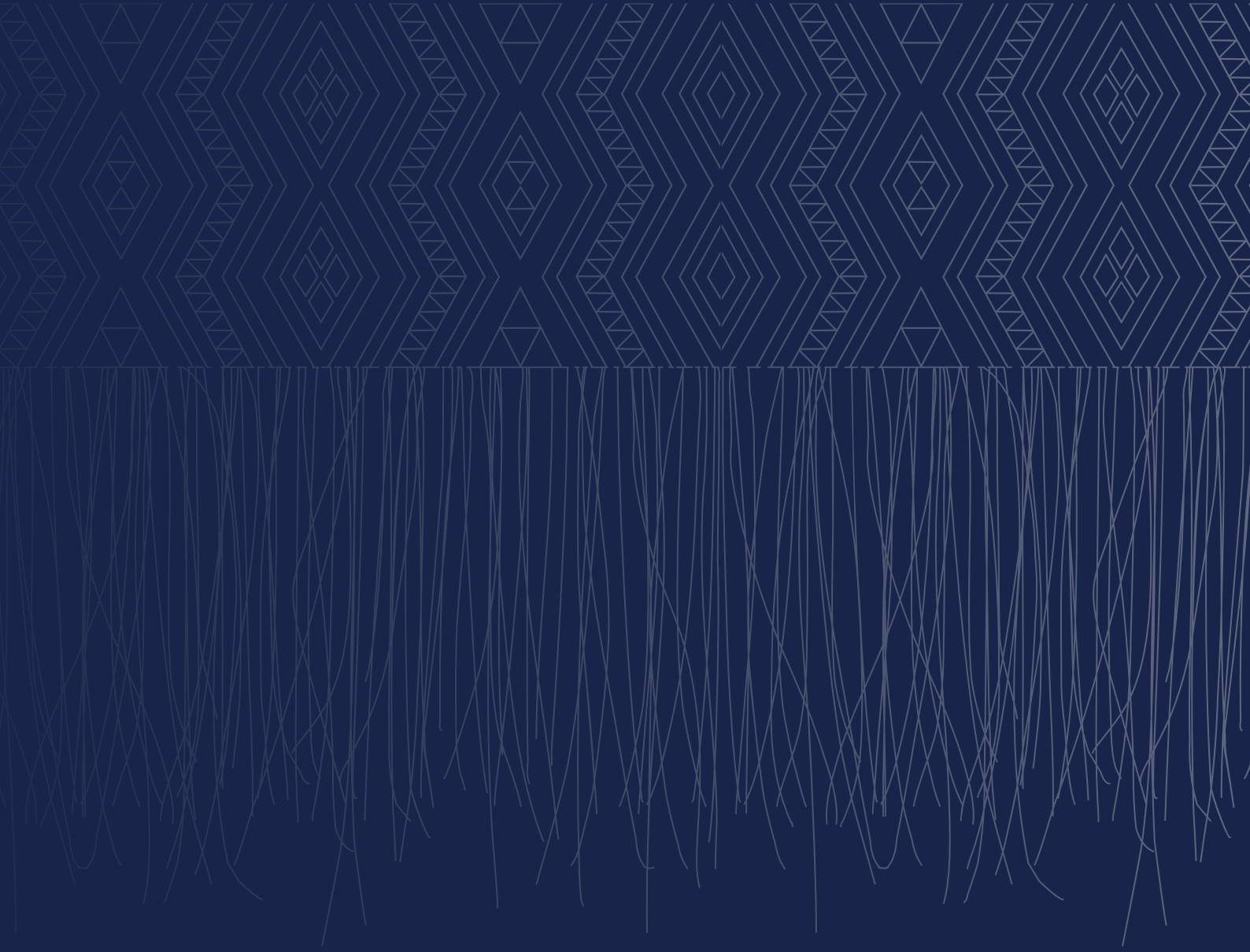

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Laboratory standards index

NO	STANDARD	DESCRIPTION
501 Page 18	**Handling, retaining, returning and disposing of human tissue, cells or any other samples containing human genetic material**	Laboratories must have written protocols for handling, retaining, returning and disposing of human tissue, cells or any other samples containing human genetic material. These protocols need to incorporate cultural considerations and comply with current New Zealand legislation. Laboratories must consult their local Health District and iwi, who may provide policy and advice for cultural requirements regarding handling samples.
502 Page 19	**Sending Māori samples offshore**	Laboratories must have written protocols that define processes to be followed when anatomic pathology material such as pathology slides containing Māori genetic material is sent outside of Aotearoa New Zealand. These protocols must comply with the *NCSP Policy for Sending tissues, cells or pathology samples of Māori people outside of Aotearoa/New Zealand*, available from the NCSP on request.
503 Page 20	**Qualifications for pathologists**	All pathologists reporting cervical/vaginal cytology and/or histology must be qualified.
504 Page 21	**Qualifications for scientific and technical staff**	All molecular scientists and technicians performing hrHPV testing, cytoscientists and cytotechnicians reporting cervical/vaginal cytology, and histoscientists and histotechnicians preparing histology specimens must be qualified.
505 Page 23	**The Lead NCSP Services Pathologist**	A named and suitably qualified pathologist, known as the Lead NCSP Services Pathologist, must lead the hrHPV testing services, cervical/vaginal cytology and histology. That person must be an active practitioner in cervical/vaginal cytology and/or histology and/or microbiology/virology (as specified by standard 502). They will also be the key laboratory pathologist in at least one of these disciplines.
506 Page 24	**The Lead HPV Testing Scientist, Cytoscientist and Histoscientist**	Laboratories providing reporting of hrHPV testing, cervical/vaginal cytology and/or histology services to the NCSP must employ and name the following lead scientists to professionally lead and manage the scientific and technical aspects, if these services are provided to the NCSP: • a Lead HPV Testing Scientist who is a medical laboratory scientist with a post-graduate degree in molecular science and a minimum of five years' full-time (or equivalent) post-qualification experience in molecular science including a minimum of two years of experience in diagnostic molecular testing • a Lead Cytoscientist with a minimum of five years' full-time (or equivalent) cervical/vaginal cytology experience • a Lead Histoscientist with a minimum of five years' full-time (or equivalent) experience.

NO	STANDARD	DESCRIPTION
507 Page 25	**Continuing professional development**	All pathologists, cytoscientists and cytotechnicians, histoscientists and hrHPV testing staff must meet CPD requirements. The laboratory must keep a record of the CPD requirements that each staff member has met.
508 Page 26	**Returning to work**	All staff returning to work following an extended absence must demonstrate competence in the tasks they undertake, with a documented retraining and supervision programme in place to re-establish their competency to practise and to update them on changes in laboratory processes.
509 Page 27	**Minimum volume of cervical /vaginal cytology cases per laboratory per annum**	Each fixed laboratory site must process, interpret and report a minimum of 15,000 liquid based cytology (LBC) samples for cervical or vaginal cytology per annum.
510 Page 27	**Minimum staffing for cervical/vaginal cytology**	Each fixed laboratory site must employ a minimum of four cytoscreeners and three cytopathologists who regularly report cervical cytology, in order to cover periods of sickness, annual and other leave and to ensure continuity of service through periods of resignation and recruitment.
511 Page 27	**Minimum number of cervical/vaginal cytology cases per pathologist per annum**	Each pathologist reporting cervical/vaginal cytology must report a minimum of 750 cervical/vaginal LBC samples per annum.
512 Page 28	**Maximum daily workloads for cytoscreeners**	The maximum workload for any cytoscreener performing manual or FOV screening (LBC samples) is 70 fully screened slides (or an equivalent workload) on any single working day. The maximum times any cytoscreener may spend screening cytology slides is 7 hours 30 minutes (7.5 hours) in any single day, and 45 hours over any consecutive seven-day period.
513 Page 29	**Minimum annual workloads for cytoscreeners**	Cytoscientists and cytotechnicians must conduct FOV reviews with first full screens if required (automation-assisted screening) or first full screens (manual screening), on a minimum of 2,500 gynaecological LBC samples per annum.
514 Page 32	**LBC samples, samples for HPV testing only and laboratory request form labelling policy**	Pre-analytical procedures (all steps of sample registration and processing) must conform to the requirements of ISO 15189:2022 Medical laboratories – Requirements for quality and competence.
515 Page 34	**Leaking and low fluid volume LBC vials and HPV collection tubes**	**1. Leaking vials** Laboratories must document the receipt of leaking LBC sample vials caused by inadequate sealing. Any leaking vial should be disposed of and not processed for HPV testing. A report should be issued recording the leakage and reporting the hrHPV result as *Unsuitable for analysis because of LBC vial or swab-collection tube leakage*. Where there is a sufficient volume of fluid remaining in an LBC vial (for example, if fluid was seeping around the lid and most of the fluid was retained) then cytology should be performed and reported, even if not requested. This is to allow the repeat sample for HPV to be performed using a vaginal swab sample, avoiding the need for a repeat LBC sample. The cytology result will already be available, if the repeat HPV result is HPV Detected.

NO	STANDARD	DESCRIPTION
515 Page 34	**Leaking and low fluid volume LBC vials and HPV collection tubes** Continued	A request for the sample to be recollected must be sent to the sample taker. • Leaking vials are disposed of because of the risk of HPV contamination • Because of the clinical significance of a "Not Detected" hrHPV test result, it is not acceptable to dilute samples if the volume of fluid available for hrHPV testing is not sufficient for testing **2. Low fluid volume vials** LBC vials that are not leaking but are received with a low volume of fluid (due to spillage either before or immediately after the sample has been added to the vial) must be disposed of and not processed because of the risks of sample contamination or compromise. A report should be issued recording the low volume and reporting the hrHPV result as *Unsuitable for analysis because of LBC vial or HPV-collection tube leakage*. A request for the sample to be recollected must be sent to the sample taker.
516 Page 34	**Reviewing case documentation to identify samples requiring cytology**	The request form and NCSP Register history for every LBC sample accepted for processing must be reviewed by a suitably competent and registered cytoscientist or cytotechnician who reports cervical cytology (or a cytology assistant approved by the Lead Cytoscientist who has been trained and is competent to perform this role), to determine the test requirements.
517 Page 36	**Ensuring all samples are appropriately tested or not tested for hrHPV**	Laboratories must conduct hrHPV testing on all samples as defined in the NSU's *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023* (www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand).
518 Page 37	**hrHPV test technology requirements**	For HPV DNA-based technologies, the hrHPV test technology used for clinician-collected samples must: • be endorsed for hrHPV testing by either the United States Food and Drug Administration or the Conformité Européenne • meet the equivalency criteria of Meijer et al 2009[1] • detect the 14 oncogenic HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 and separately identify HPV 16 and 18 • be validated for the specimen collection medium of the LBC system (ThinPrep® or SurePath™) that will be used for cytology reporting (when required) on the same sample • contain at least one control to monitor both: – inhibition and/or assay failure – cellularity to detect inadequate or empty cervical samples. HPV test technology used for HPV testing of swab-collected samples must: • be a PCR-based test that detects HPV DNA • be endorsed for hrHPV testing of swab-collected samples by either the United States Food and Drug Administration (FDA) or the Conformité Européenne (CE), OR have been validated at the reporting laboratory for use with swab-collected samples using the NCSP-approved validation process for HPV testing on swab-collected samples • meet all the above criteria for HPV DNA technologies for clinician-taken samples.

NO	STANDARD	DESCRIPTION
518 Page 37	**hrHPV test technology requirements** Continued	For biomarkers other than HPV DNA, the hrHPV test technology used for clinician-collected and self-collected swab samples must: • meet all the above requirements for HPV DNA-based technologies including the requirements for swab-collected samples where relevant • have at least five years of longitudinal data published in peer-reviewed literature, demonstrating non-inferior sensitivity and specificity performance for detecting and excluding CIN2+ compared with the DNA-based Hybrid Capture-2 test.
519 Page 41	**Storage and disposal of hrHPV test samples**	All samples must be stored according to the manufacturer's instructions. If possible, extracted nucleic acids should be kept until all testing and reporting on the original sample is completed, to allow retesting if required. This may not be possible with some high through-put automated testing systems, in which case, residual fluid from the original vial would need to be used if retesting were required. The residual sample in LBC vials must be retained until cytology and hrHPV testing have been reported, and for a minimum of one month after the sample was received. HPV collection tubes must be retained for a minimum of two weeks after the sample was received.
520 Page 43	**Validating an automated screening device**	All laboratories introducing an automated screening device for the first time must comply with and document the following requirements allowing review by audit bodies. The automated device must be operated and calibrated according to the manufacturer's instructions, and any non-compliance must be corrected. Laboratories must undertake and record daily calibrations, as recommended by the manufacturer. The first 1,000 cases processed by a laboratory introducing an imager platform must be fully primary and secondary screened following FOV review. Both laboratory and individual reporting rates for low- and high-grade abnormalities must be recorded for this process.
521 Page 44	**Validating cytoscreener competency for FOV review screening**	All cytoscreeners performing FOV reviews using an automated imager must have: • reviewed a wide range of abnormal cases • demonstrated competency during a documented individual validation process • been designated as competent to perform FOV reviews by the Lead Cytoscientist.
522 Page 45	**Manual screening**	All cases which are fully screened manually without the assistance of an automated screening device must have a first full screen followed by a second full screen by a different cytoscreener before reporting or referral to a pathologist.
523 Page 48	**Location-guided FOV screening**	The minimum number of location-guided FOVs specified by the imaging device manufacturer must be fully reviewed by the cytoscreener, and they must examine the complete cellular content for each FOV.

NO	STANDARD	DESCRIPTION
524 Page 49	**Second full screen requirements**	A second full screen must be performed for all who: 1. have abnormal (G2 or G3) cervical/vaginal cytology identified by first full manual screening (where an automated device is not used) or by FOV review with full screen 2. have had a previous low-grade (ASC-US or LSIL) abnormality and have not been returned to five-yearly HPV screening after the low-grade result OR have not had a "Not Detected" hrHPV result since the low-grade cytology result 3. have had a previous high-grade cytologic or histologic abnormality and who: i. have not had the high-grade squamous abnormality treated ii. have been treated but have not successfully completed a Test of Cure since treatment and are having any one of the first three cytology samples after treatment iii. had a glandular abnormality in the previous five years 4. are overdue for a cervical screening test by more than five years 5. have unsatisfactory cervical/vaginal cytology 6. have suspicious clinical conditions, abnormal bleeding or observed cervical abnormalities, or are immune deficient.
525 Page 50	**Competency requirements for cytoscreeners performing second full screens**	A cytoscientist or cytotechnician may carry out second full screens of cervical/vaginal cytology if they have more than one year of full-time (or equivalent FTE) experience as a cervical/vaginal cytoscreener after completing the VRPCC AND are designated as competent for rescreening by the Lead Cytoscientist. Lead Cytoscientists may use their discretion with experienced staff who have not completed the VRPCC.
526 Page 50	**Timing of second full screens**	All second full screens must take place before the results are confirmed and sent to the sample taker and the NCSP Register.
527 Page 50	**Changing LBC technology policy**	If a cytoscreener or cytopathologist changes the type of LBC they manually screen and report (for example, a staff member who is BD SurePath™ trained changes to Hologic ThinPrep® screening) and they are not already certified for the alternative LBC type, they must undertake full retraining. This requirement also applies to cytoscreeners and cytopathologists who arrive from overseas to work in Aotearoa New Zealand and are (only) trained and experienced in an LBC type not currently used in Aotearoa New Zealand. Full retraining means: • complying with the training requirements of the LBC manufacturer • complying with any NCSP requirements for transitioning from one LBC type to another type • completing any additional competency requirements of the individual laboratory. If a cytoscreener changes to a different automated screening device system (for example, a staff member who is using the BD FocalPoint/GS™ system changes to the Hologic ThinPrep® Imager) and they are not already certified for the alternative automated system, they must undertake full retraining. Full means: • complying with the training requirements of the LBC manufacturer • complying with any NCSP requirements for transitioning from one LBC type to another type • completing any additional competency requirements of the individual laboratory.

NO	STANDARD	DESCRIPTION
528 Page 51	**Confirming and reporting abnormal results**	All results confirmed abnormal (G2 or G3) after second full screening must be sent to a cytopathologist for reporting.
529 Page 53	**Handling and preparing histology specimens**	All gynaecologic histology specimens must be handled, described and prepared for examination and reporting in accordance with the following professional protocols: • ISO 15189 (see International Accreditation New Zealand, IANZ, at: https://www.ianz.govt.nz/programmes/medical-laboratory and Specific Criteria Medical Testing, Requirements for Minimising Errors in Medical Histology Laboratories at: https://assets.website-files.com/5e447d8550a99c8326ee5ae6/5f07845d722b662ee6a0a5ce_AS%20LAB%20C7.2%20Supplementary%20Criteria%20-%20Minimising%20Histology%20Errors.pd • RCPA's *Anatomical Pathology: Macroscopic Cut-up Manual*, available from the RCPA website at: www.rcpa.edu.au/Manuals/Macroscopic-Cut-Up-Manual • RCPA's *Structured Reporting Protocol for Excisions and Colposcopic Biopsies Performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia* (1st edition 2017), available from the RCPA website at: www.rcpa.edu.au/getattachment/9ed056b7-6bcc-4885-a243-925053302e3b/Protocol-Cervical-pre-neoplasia.aspx • RCPA's *Cervical Cancer Structured Reporting Protocol* (1st Edition 2013), available from the RCPA website at: www.rcpa.edu.au/getattachment/2dfcc534-547d-455a-837b-79bfeb2b60e7/Protocol-Cervical-cancer.aspx
530 Page 55	**Examining and reporting histology slides**	A histopathologist must examine and report all histology slides.
531 Page 57	**Histopathologist access to cervical cytology results**	The histopathologist must have the complete current NCSP Register screening event history available at the time of reporting any histopathology specimen containing cervical or vaginal tissue, and must correlate the most recent cytology result (eg, the referral to colposcopy sample) with the histology specimen/s result/s when making their report.
532 Page 58	**Ensuring all HPV tests, cytology and histology samples received are reported to sample takers/ requestors and specialists**	Laboratories must have protocols and procedures in place to ensure they report all hrHPV test samples, cervical/vaginal cytology and histology samples analysed to the appropriate sample takers/ requestors and specialists.
533 Page 58	**Reporting HPV tests and cytology results**	1. **Reporting hrHPV (only) tests** Results must be reported in an approved format as either *hrHPV Detected, hrHPV Not detected, Invalid,* or *Unsuitable for analysis because of LBC vial* or *swab-collection tube leakage.* Where hrHPV is detected, the report must stipulate whether this is HPV 16 and/or HPV 18 and/or HPV "Other" i.e. one or more non-16/18 type(s). 2. **Reporting hrHPV and cytology tests (same sample)** Where a hrHPV test and cytology test are performed on the same sample, both test results must be reported to the sample taker at the same time in one report.

NO	STANDARD	DESCRIPTION
534 Page 59	**Reporting hrHPV tests and cervical/vaginal cytology results to sample takers/ requestors**	Where hrHPV testing only is performed on a sample, the laboratory must report: • 100 % of hrHPV test results to sample requestors within three working days of receipt of the sample. Where hrHPV and cytology tests are performed on the same sample, the laboratory must report: • 90% of the completed report containing both the hrHPV test result and the cervical/vaginal cytology result to the sample taker within seven working days of receipt of the specimen • 100% of the completed report containing both the hrHPV test result and the cervical/vaginal cytology result to the sample taker within 10 working days of receipt of the specimen. Where a cytology test only is performed on the sample (i.e. without an accompanying hrHPV test), the laboratory must report: • 100% of the completed report containing the cervical/vaginal cytology result to the sample taker within 10 working days of receipt of the specimen.
535 Page 60	**Reporting histology results**	Laboratories must report: • 90% of final histology results to referring specialists within 10 working days of receiving the specimen • 98% of final histology results to referring specialists within 15 working days of receiving the specimen.
536 Page 60	**Sending all cervical/ vaginal cytology results to the NCSP Register**	Laboratories must have processes in place to ensure that all reported hrHPV test results, cervical/vaginal cytology and histology results for samples taken in Aotearoa New Zealand are sent to the NCSP Register in the correct format.
537 Page 61	**Sending hrHPV-only results to the NCSP Register**	Where an HPV test is the only NCSP test performed on a sample, the laboratory must electronically send: • 100% of hrHPV test results to the NCSP Register in the approved format within three working days of receipt of the sample. Partial genotyping results identifying the presence of hrHPV 16, hrHPV 18 or hrHPV "Other" (i.e. non16/18) must be included.
538 Page 61	**Sending hrHPV with cytology results or cytology-only results to the NCSP Register**	Laboratories must electronically send to the NCSP Register 100% of all reports, both cytology only and cytology with an hrHPV test result, in the approved format and Bethesda coding within 10 working days of receiving the sample.
539 Page 62	**Sending histology results to the NCSP Register**	Laboratories must electronically send to the NCSP Register 90% of histology results in the approved format with NCSP SNOMED CT coding within 10 working days of receiving the sample. They must electronically send to the NCSP Register 98% of histology results in the approved format with NCSP SNOMED CT coding within 15 working days of receiving the specimen.
540 Page 63	**Sending results to the New Zealand Cancer Registry**	Laboratories must send all cytology results analysed and reported as definite or suspicious of invasive cancer and all histology results with a diagnosis of CIN2, CIN3, AIS/SMILE or invasive cancer to the NZCR (Te Whatu Ora Health New Zealand).

NO	STANDARD	DESCRIPTION
541 Page 67	**Reporting changes to cytology or histology results**	All amended cytology or histology results must be notified within five working days from the date of the slide review to: • the sample taker • anyone else who was issued with the original result report • the colposcopist managing the case, if appropriate • the NCSP Register • the NZCR, if appropriate (including cases where a cytology result previously reported to the NZCR is downgraded to less than suspicious or definite invasive cancer, or a previous histology result is downgraded to less than CIN2 or AIS/SMILE).
542 Page 69	**Minimum cytoscreener sensitivities for detecting abnormalities and identifying high-grade cases policy**	Individual cytoscientists and cytotechnicians must demonstrate competency to perform primary screening by achieving a sensitivity for detecting at least 95% of high-grade abnormalities and 90% of total abnormalities.
543 Page 70	**Monitoring cytopathologist performance**	The Lead Cytopathologist must review all individual cytopathologist reporting profiles every six months, with individual results and the overall reporting profile for the laboratory's pathologists provided to each person monitored.
544 Page 72	**Reviewing Atypical Squamous Cells cannot exclude HSIL (ASC-H) cases**	Laboratories must review all cytology cases reported as ASC-H six months after reporting, to consider histology outcomes. If the case outcome is not clear at six months, the case must be similarly reviewed at 12 months.
545 Page 73	**Reviewing previous cytology slides after a subsequent high-grade histology diagnosis**	The laboratory must review and document the review outcomes of: i. all cytology cases reported before 12 September 2023, where there was a cytology result of negative, benign/reactive or unsatisfactory, reported in the 42 months before a high-grade or invasive diagnosis on histology ii. all cytology cases reported on or after 12 September 2023 where there was a cytology result of normal, benign/reactive, unsatisfactory or low-grade (ASC-US/LSIL), in the nine months prior to a high-grade or invasive histology diagnosis.
546 Page 74	**All laboratories reporting cervical/vaginal cytology, histology and HPV testing participate in laboratory-based EQAPs**	All laboratories reporting cervical/vaginal cytology, histology and HPV testing must participate in laboratory-based EQAPs relevant to the discipline/s practised to ensure competency in hrHPV testing, for example, through the RCPA, the World Health Organization (WHO) reference laboratory or another appropriate body. All laboratories reporting cervical histopathology must participate in a laboratory-based EQAP in gynaecological histopathology, such as the RCPA's gynaecological histology QAP.
547 Page 74	**All staff reporting cervical/vaginal cytology participate in the RCPA's individual EQAP**	All staff who report cervical/vaginal cytology (cytopathologists and cytoscreeners) must participate in the NCSP-approved Individual EQAP run by the RCPA QAP.

NCSP Policies and Standards

The National Cervical Screening Programme (NCSP) Policies and Standards set out the agreed policies and standards of practice for NCSP service providers.

Their purpose is to support all those who are involved in the NCSP to achieve its aims and objectives by ensuring high standards and nationally consistent service at each step of the screening pathway, and allowing new developments to be incorporated if they have been shown to improve services.

In this section

Section 5 of the NCSP Policies and Standards relates to the provision of oncogenic human papillomavirus (also known as high-risk or hrHPV) testing, cervical/vaginal cytology and histology services for the NCSP.

Overview and objectives

Objectives

Section 5 of the NCSP Policies and Standards provides health professionals with policies and standards that support them in supplying appropriate laboratory services.

Te Whatu Ora Health New Zealand requires that all laboratories providing high-risk human papillomavirus (hrHPV) testing, cervical/vaginal cytology and histology services as part of the cervical screening and management pathway comply with all NCSP Policies and Standards in Section 5.

The hrHPV testing, cervical/vaginal cytology and histology services are reviewed regularly to ensure continual improvement in the quality of services. Laboratories providing hrHPV testing and cytology reporting services are audited annually by the NCSP to ensure compliance with NCSP Section 5 Policies and Standards.

All New Zealand laboratories are accredited by International Accreditation New Zealand (IANZ) to ensure compliance with ISO 15189.

Laboratory performance is measured by NCSP audits, laboratory internal quality assurance processes, external quality assurance programmes, contract monitoring reports and NCSP monitoring reports. These reports include the laboratory diagnostic reporting indicators itemised at the end of Section 5.

Section 5 Policies and Standards are reviewed regularly by the NCSP.

OBJECTIVE	DESCRIPTION
Objective of oncogenic (high-risk) HPV testing	The objective of hrHPV testing is to detect the presence of any of a defined group of oncogenic (high-risk) HPV types. These HPV types are selected because their presence indicates an increased risk of the presence or subsequent development of high-grade cervical lesions.
Objective of gynaecological cytopathology	The objective of cervical/vaginal cytopathology (referred to as cervical/vaginal cytology) is to predict the nature of pathological changes present in cervical or vaginal squamous cells and, if possible, to identify glandular abnormalities. The interpretation of cervical/vaginal cytology samples involves detecting and interpreting subtle changes in cell structure.
Objective of gynaecological histopathology	The objective of gynaecological histopathology (referred to as gynaecological histology) is to ascertain the nature and extent of tissue abnormalities in submitted gynaecological tissue, providing a definitive diagnosis to inform treatment and management.

Even with best practice there are limitations in interpretive accuracy that may result in recognised false-negative and false-positive results in both cytology and histology. On rare occasions, a participant with a high-grade lesion may have a negative (not detected) hrHPV test result.

Introduction to laboratories

Reference to laboratory

The term 'laboratory' applies to each individual, fixed laboratory site that carries out hrHPV testing, cervical/vaginal cytology and/or histology services as an NCSP service provider.

All processing, evaluating and reporting of hrHPV tests, cervical/vaginal cytology and histology* must be performed on pathology laboratory premises. This work is not permitted at any other venue.

Once a laboratory accepts a swab-collected cervical/vaginal sample or a liquid based cytology (LBC) sample, all preparation, processing and reporting of hrHPV testing and cytology for each individual sample must be performed at that same laboratory premises, unless a specific agreement is reached with the NCSP to cover exceptional short-term circumstances that make it difficult to comply with this requirement.

Key functions of laboratories

Laboratories:

- ensure correct labelling of samples and request forms to ensure that the participant is correctly and unequivocally identified
- process and report samples for hrHPV testing, cervical/vaginal cytology and histology
- consult with and provide advice and results to sample takers/requestors and specialists who are managing cervical disease
- forward results to the NCSP Register and collaborate with NCSP Register staff
- forward relevant results to the New Zealand Cancer Registry (NZCR).

In providing laboratory services to the NCSP, laboratories need to develop cooperative working relationships with the wider NCSP workforce. This includes the National Screening Unit (NSU), NCSP regional coordination services, NCSP National Coordination Centre Cervical Screening Register Team, sample takers/requestors and general practitioners who take cervical screening test samples, sample taker/requestor training providers, colposcopy services and screening support services.

* The NCSP has approved a variation to the requirement to report histopathology on laboratory premises, to allow histopathologists to report cervical histopathology on other premises (such as at home) during the COVID-19 pandemic. The variation applies to cervical histology but not to cervical cytology, and will be reviewed in 2023.

Laboratory staff

Staff working in a laboratory service include:

- pathologists, that is, medical graduates with specialist qualifications in pathology
- medical laboratory scientists with:
  - specialist qualifications or training and competencies in molecular science
  - specialist qualifications in cytology (cytoscientists)
  - specialist qualifications in histology (histoscientists)
- medical laboratory technicians with:
  - expertise in hrHPV testing
  - specialised training in cytology (cytotechnicians)
  - specialised training in histology (histotechnicians)
- laboratory assistants (unregistered).

The term 'cytoscreener' refers to any qualified and registered cytoscientist or cytotechnician with a current annual practising certificate who screens, interprets and reports cervical and vaginal cytology samples.

Cytopreparation staff process LBC samples to prepare slides for cytology screening and reporting, and may be involved in initial sample preparation before hrHPV testing. These staff:

- must have had specific training and demonstrated appropriate competence to perform the tasks required
- may be laboratory assistants, medical laboratory technicians or medical laboratory scientists.

See also:

- Medical Sciences Council of New Zealand for registration of medical laboratory scientists and medical laboratory technicians, at: www.mscouncil.org.nz
- Medical Council of New Zealand for registration of pathologists at: www.mcnz.org.nz

Samples for hrHPV testing and cytology

Laboratories perform hrHPV tests and cytology tests using LBC, such as Hologic ThinPrep® or BD SurePath™ samples, or using a vaginal swab sample (HPV testing only). Both HPV and cytology testing can be performed using an LBC sample whereas only HPV testing can be performed on a vaginal swab sample. The term cytology samples also includes historical conventional cervical smears/slides.

Vaginal swab samples may be collected by the screening participant (self-testing) or can be collected using a swab with assistance from a health practitioner.

Specimens for histology

A histology specimen refers to any whole tissue specimen removed from the cervix or vagina. This includes punch biopsies, endocervical curettings, wedge biopsies, large loop excisions of the transformation zone (LLETZ biopsies, sometimes called LEEP biopsies), cone biopsies and hysterectomy specimens with a cervical component.

Cultural and equity considerations

Cultural & Equity Policy

PURPOSE

Ensure that laboratory practices align with the cultural values and beliefs of all New Zealanders.

Laboratory staff must consider the values and beliefs held by the various groups of people residing in Aotearoa New Zealand and ensure they handle all samples and specimens with respect and without prejudice based on ethnicity, gender or age. Respectful and timely communication must occur with those who want their material returned.

Staff must recognise the cultural significance of human tissue for Māori, particularly with regard to the importance of the cervix as part of 'te whare tangata', the sacred 'house of humanity'.

Māori have a holistic concept of health. It spans the dimensions of physical, mental, spiritual and extended family, and incorporates the importance of land, language and culture. Māori see these dimensions as being interrelated and unable to be viewed separately. Wellbeing is maintained through a balance of all dimensions.

Within the context of cervical cancer, the entire reproductive system of women is considered a taonga (treasure, something of great worth). This view is upheld by the whakataukī (proverb):

He wāhine, he whenua, kua ngaro he tangata (Without women or land, people will be lost).

In te reo, the womb is often referred to as 'te whare tangata' (the house of humanity) since this is where human life is created and grows until it is born.

The multiple meanings of whānau (family and birth), whenua (placenta and land) and hapū (subtribe and pregnancy) all reinforce this importance.

The cervix is a key element of te whare tangata as it is the gatekeeper to all that te whare tangata encompasses. It is a pathway to whakapapa (genealogy) and te ao mārama (world of light, the physical world). It is thus essential that the NCSP Policies and Standards define and maintain practices that respect te whare tangata in a culturally appropriate manner.

Laboratories must give special consideration and follow tikanga protocols when handling any tissue, cells or samples containing Māori genetic material.

For Māori, human tissue is a taonga (treasure) and DNA from any genetic origin that connects to whakapapa is also considered a taonga. Iwi recognise the value of DNA for its cultural and spiritual significance. By extension, photographs and scanned images of samples are a representation of tissue so are also regarded as taonga.

Māori body tissue (including pathology slides) obtained as part of the NCSP needs to be treated in ways that respects the views of those from whom the samples have been obtained. This is particularly important if any materials containing Māori genetic material are sent offshore, and when samples and specimens containing Māori genetic material are disposed of after processing and reporting.

501 Standard 501: Handling, retaining, returning and disposing of human tissue, cells or any other samples containing human genetic material

Laboratories must have written protocols for handling, retaining, returning and disposing of human tissue, cells or any other samples containing human genetic material. These protocols need to incorporate cultural considerations and comply with current New Zealand legislation. Laboratories must consult their local Health District and iwi, who may provide policy and advice for cultural requirements regarding handling samples.

Details

All responses to requests from individual/s regarding the handling, retaining, returning and disposing of human cell and/or tissue samples must follow local Health District tikanga protocols.

All laboratory staff handling human tissue or cell samples must demonstrate a clear understanding of the principles and application of tikanga protocols in relation to handling, retaining, returning and disposing of human tissue, cells and any other samples containing human genetic material.

Laboratories must make every effort to ensure that when they receive a request for the return of human tissue/substances this is done promptly, providing it is safe to do so. Staff will inform the recipient of any necessary safety precautions regarding the handling and disposal of the returned material.

Laboratories must keep a record of all requests for the return of human tissue/substances, the outcome of each and the time taken to return the material. All these records must be made available to audit bodies.

If a laboratory cannot meet a request, the reason/s for declining the return must be clearly stated and understood by all involved. If the individual/s who made the request do not agree with the decision, an appropriate person designated by the laboratory will meet with them to attempt to reach agreement. The discussion and outcome must be documented.

Audit bodies must be able to review laboratory protocols for human tissue management, records of cases of tissue/substances requests and details of cases where such requests were declined.

502 Standard 502: Sending Māori samples offshore

Laboratories must have written protocols that define processes to be followed when anatomic pathology material such as pathology slides containing Māori genetic material is sent outside of Aotearoa New Zealand. These protocols must comply with the *NCSP Policy for sending tissues, cells or pathology samples of Māori people outside of Aotearoa/New Zealand.*

Details

When sending Māori genetic material offshore:

- Where material is sent for a second opinion:
  - personal identifiers on slides and documentation are required when material is sent offshore for a second opinion because of the clinical risk of incorrect identification of samples, if personal identifiers were removed
  - consent to send material offshore must be obtained and documented in the clinical file before slides or samples are sent offshore for a second opinion, because personal identifiers need to be retained
  - laboratories must notify the recipient if the slide/sample contains Māori genetic material, and send a printed instruction sheet with the case material, identifying the specific requirements of Māori in relation to the material sent, to be signed and returned to the sender. This must include a guarantee of confidentiality, where personal identifiers are included.
- Where samples are sent for educational or quality assurance purposes, the laboratory must ensure that the recipient provides a written statement before the material is sent, agreeing to adhere to NCSP requirements. Personal identifiers must be removed from slides, samples or documentation sent for Quality Assurance or educational purposes.
- For all samples, laboratories must have a tracking process in place to ensure that all material is signed out and signed back in at the laboratory when returned. If the material is not returned within a reasonable time frame, this must be actively investigated by the laboratory. Records of these activities for NCSP samples must be available for audit purposes.

See also:

- Medical Council of New Zealand resources, such as cultural safety information, available at: www.mcnz.org.nz/our-standards/current-standards/cultural-safety/
- Medical Sciences Council of New Zealand resources, such as the Statement of Cultural Competence (2007), available at: www.mscouncil.org.nz/assets_mlsb/Uploads/Cultural-Competence-Statement.pdf
- MauriOra Health Education Research, trainers in Māori health, for courses in cultural competence and similar topics, see: www.mauriora.co.nz
- Human Tissues Act 2008 (see: www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html)

Kei motu te hono tangata.
Let the human link not be broken.

Staffing

Staffing qualifications policy

PURPOSE

To ensure that hrHPV testing, cervical/vaginal cytology and histology services are staffed by suitably qualified pathologists, scientists and technicians.

Policy

All laboratory staff preparing, interpreting and/or reporting hrHPV tests, cervical/vaginal cytology and/or histology for the NCSP must be appropriately qualified and competent as defined under the Health Practitioners Competence Assurance Act 2003 and any subsequent amendments.

503 Standard 503: Qualifications for pathologists

All pathologists reporting cervical/vaginal cytology and/or histology must be qualified.

Every pathologist working in cervical/vaginal cytology or histology must:

- be a fellow of the RCPA or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received specialty training in general pathology, histopathology and/or cytopathology as appropriate for the specialty practised
- hold a current annual practising certificate issued by the Medical Council of New Zealand, with a scope of practice of anatomical pathology or general pathology.

If a pathologist is not vocationally registered (eg, has provisional or general registration), they must work under supervision, as required by the Medical Council of New Zealand.

A cytopathologist who is reporting cervical/vaginal cytology must have completed an appropriate training course in accordance with the manufacturer's requirements for the LBC type used.

Every pathologist supervising hrHPV testing must:

- be a fellow of the RCPA or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received specialty training in microbiology, molecular pathology, or anatomic pathology. Anatomic pathologists supervising HPV testing must demonstrate specialist level expertise and experience in HPV testing and HPV testing technologies, and be approved by the NCSP to perform this role
- have received appropriate training to provide competent clinical advice, routine surveillance and supervision of quality assurance aspects of HPV testing services
- hold a current annual practising certificate issued by the Medical Council of New Zealand.

See also:

- Health Practitioners Competence Assurance Act details on the Ministry of Health's webpage, at: www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act
- Medical Council of New Zealand's policy on registration, available at: www.mcnz.org.nz/get-registered/registration-policy/registration-in-new-zealand-policy/

504 Standard 504: Qualifications for scientific and technical staff

All molecular scientists and technicians performing hrHPV testing, cytoscientists and cytotechnicians reporting cervical/vaginal cytology, and histoscientists and histotechnicians preparing histology specimens must be qualified.

All scientists performing or reporting hrHPV testing, cytoscientists and histoscientists must be registered medical laboratory scientists holding a current annual practising certificate issued by the Medical Sciences Council of New Zealand, with a scope of practice of medical laboratory scientist with relevant specialty training in molecular biology/microbiology, cytology or histology, if performing/reporting hrHPV testing, or practising in cytology or histology respectively.

All technicians performing or reporting hrHPV testing, cytotechnicians and histotechnicians must be registered medical laboratory technicians holding a current annual practising certificate issued by the Medical Sciences Council of New Zealand, with a scope of practice of medical laboratory technician with specialty training in, for example, molecular biology/microbiology, cytology or histology if performing or reporting hrHPV testing, or practising within cytology or histology respectively.

All Bachelor of Medical Laboratory Science graduates entering cervical cytology for the first time must undertake the Vocational Registration Programme in Cervical Cytology (VRPCC). This is to ensure that graduates achieve minimum standards of competency before gaining authority to sign out cervical cytology samples.

All cytoscientists and cytotechnicians preparing and reporting cytology must have completed an appropriate training course in accordance with the manufacturer's requirements for the LBC type used. Additional training is also required before using automated screening devices.

Training and qualification of new cytotechnicians ceased in Aotearoa New Zealand in 2014.

Medical laboratory technicians who process, interpret and/or report cytology and who perform and/or report hrHPV tests may release results as long as they are working under the supervision of a medical laboratory scientist and are certified as competent to perform the tasks they undertake. Medical laboratory technicians who release results must be operating under a clear standard operating procedure that specifies the circumstances under which a result must be reviewed by a medical laboratory scientist or pathologist.

See also:

- Medical Sciences Council of New Zealand for registration of medical laboratory scientists and medical laboratory technicians, at: www.mscouncil.org.nz
- Medical Sciences Council of *New Zealand's Code of Competencies and Standards for the Practice of Medical Laboratory Science*, available at: www.mscouncil.org.nz/assets_mlsb/Uploads/Documents/Code-of-Competencies-and-Standards.pdf
- NCSP Policies and Standards: Standard 529: Validating cytoscreener competency for FOV review screening

Management and leadership policy

PURPOSE

To ensure that senior leadership is available to appropriately manage laboratory services.

Policy

NCSP services at each laboratory site must be led by a named and suitably qualified pathologist, referred to as the Lead NCSP Services Pathologist. A Lead Pathologist must be identified for each discipline of cervical cytology, histology and HPV testing, where these services are provided to the NCSP. Each laboratory service must also have a named Lead Scientist responsible for providing hrHPV testing, cytology and/or histology, if the laboratory is an NCSP service provider in these disciplines.

The individuals occupying these positions of responsibility must be named and a document outlining the clinical leadership structure must be made available to audit bodies. Pathologists may occupy one or more of these roles in some laboratories.

505 Standard 505: The Lead NCSP Services Pathologist

A named and suitably qualified pathologist, known as the Lead NCSP Services Pathologist, must lead the hrHPV testing services, cervical/vaginal cytology and histology. That person must be an active practitioner in cervical/vaginal cytology and/or histology and/or microbiology/virology (as specified by standard 502).

They will also be the key laboratory pathologist in at least one of these disciplines. They must:

- deliver the agreed services in accordance with the NCSP Policies and Standards
- be responsible for leading, coordinating and supervising all NCSP services provided by the laboratory
- ensure that all staff delivering NCSP services are appropriately trained and meet ongoing professional competency requirements
- document and coordinate the clinical leadership structure within the laboratory for NCSP reporting services, outlining the relationships between themselves and other key pathologist/s in each discipline that they do not cover themselves, and with the lead scientists (detailed below) relevant to the NCSP services provided
- ensure that there is adequate liaison between experts in anatomical pathology and HPV testing, if the laboratory reports these different types of samples
- be available in the laboratory every working day or delegate this responsibility to another pathologist who is also an active practitioner in cervical/vaginal cytology/histology and/or HPV testing and who is available in the laboratory when the Lead NCSP Services Pathologist is absent.

506 Standard 506: The Lead HPV Testing Scientist, Cytoscientist and Histoscientist

Laboratories providing reporting of hrHPV testing, cervical/vaginal cytology and/or histology services to the NCSP must employ and name the following lead scientists to professionally lead and manage the scientific and technical aspects, if these services are provided to the NCSP:

- a Lead HPV Testing Scientist who is a medical laboratory scientist with a post-graduate degree in molecular science and a minimum of five years' full-time (or equivalent) post-qualification experience in molecular science including a minimum of two years of experience in diagnostic molecular testing
- a Lead Cytoscientist with a minimum of five years' full-time (or equivalent) cervical/vaginal cytology experience
- a Lead Histoscientist with a minimum of five years' full-time (or equivalent) experience.

The Lead NCSP Services Pathologist and lead scientists (hrHPV testing, cervical/vaginal cytology and histology) are collectively responsible for:

- reporting results
- managing a quality assurance programme
- providing in-service training
- auditing laboratory practices
- liaising with clinical colleagues
- liaising with the NCSP, NCSP Register managers and NCSP regional services
- monitoring health and safety within the laboratory
- facilitating a collaborative environment among the staff
- keeping up to date with new developments and implementing them if they demonstrate an improvement in service.

Continuing education policy

PURPOSE

To ensure that all laboratory staff are involved in continuing education so that they continue to maintain and improve their skills.

Policy

Continuing education is mandatory for all staff who are processing, interpreting and reporting hrHPV tests, cervical/vaginal cytology samples and histology specimens.

All departments reporting cervical/vaginal cytology must:

- provide easy access to current editions of major standard texts, colour atlases and current issues of journals relevant to cervical/vaginal cytology and histology, in hard-copy or electronic form
- support medical, scientific and technical staff to attend local and international professional meetings as part of their continuing professional development (CPD) requirements.

507 Standard 507: Continuing professional development

All pathologists, cytoscientists and cytotechnicians, histoscientists and hrHPV testing staff must meet CPD requirements. The laboratory must keep a record of the CPD requirements that each staff member has met.

1. HPV testing

All molecular scientists and technicians performing hrHPV testing must participate in relevant internal and external education activities and external quality assurance programmes. All pathologists supervising or working in hrHPV testing services must:

- demonstrate external and in-house educational activity (excluding routine daily practices) directly related to HPV testing, totalling an average of 20 hours per annum over three years
- attend a relevant HPV-related education event at least once every two years.

The NCSP will accept relevant educational activities acceptable under the RCPA CPD programme.

2. Cytology

All cytoscientists and cytotechnicians reporting cervical/vaginal cytology must meet the following requirements.

- Take part in external training in cervical/vaginal cytology totalling three days over three consecutive years (Time attending training by external trainers who provide workshops and talks in laboratories may be counted towards meeting this requirement.)

- Participate in in-house continuing education in cervical/vaginal cytology. This training must be structured to provide each staff member with the equivalent of three days annually per full-time equivalent, to enable staff to meet CPD requirements. It may include participation in EQAPs – individual and laboratory-based – and slide review activities.
- Participate in external laboratory and individual quality assurance programmes.
- Participate regularly in cytology/histology correlation reviews.

All cytopathologists reporting cervical/vaginal cytology must:

- demonstrate external and in-house educational activity (excluding routine daily practice) directly related to cervical pathology, totalling an average of 20 hours per annum over three years
- participate in individual and laboratory-based EQAPs
- participate in cytology/histology correlation reviews regularly.

The NCSP will accept relevant educational activities accepted by the RCPA CPD programme.

3. Histology

All histoscientists and histotechnicians processing gynaecological histology must participate in relevant internal and external education activities and EQAPs.

All histopathologists reporting gynaecological histology must attend a specific gynaecological pathology education event at least once every three years.

Documentation

The laboratory must maintain a record of all activities undertaken by all individual staff in relation to the CPD requirements of their health professional bodies. The records must be available for audit bodies to review.

508 Standard 508: Returning to work

All staff returning to work following an absence of greater than six months must demonstrate competence in the tasks they undertake, with a documented retraining and supervision programme in place to re-establish their competency to practise and to update them on changes in laboratory processes.

If the absence was 6 to 12 months, the Lead NCSP Services Pathologist or relevant lead scientist must determine a suitable course of action and/or supervision to support the returning staff members reintroduction to their role.

If the absence was longer than 12 months, the Lead NCSP Services Pathologist or relevant lead scientist must design an individualised retraining and supervision programme for the returning staff member to complete.

The activities and outcomes must be documented, along with a record of sign-off on the returning staff member's competence.

Volumes and workloads

Minimum volumes and staffing requirements per laboratory policy

Minimum volumes and staffing are specified for cytology reporting but not for histology or hrHPV test reporting.

PURPOSE

To maintain and improve standards and skills by ensuring that laboratories reporting cervical/vaginal cytology process, interpret and report a minimum number of cases and employ sufficient staff to maintain a high-quality service.

509 Standard 509: Minimum volume of cervical/vaginal cytology cases per laboratory per annum

Each fixed laboratory site must process, interpret and report a minimum of 15,000 LBC samples for cervical or vaginal cytology per annum.

510 Standard 510: Minimum staffing requirement for cervical/vaginal cytology

Each fixed laboratory site must employ a minimum of four cytoscreeners and three cytopathologists who regularly report cervical cytology, in order to cover periods of sickness, annual and other leave and to ensure continuity of service through periods of resignation and recruitment.

Minimum volumes of cervical/vaginal cytology per pathologist policy

511 Standard 511: Minimum number of cervical/vaginal cytology cases per pathologist per annum

Each pathologist reporting cervical/vaginal cytology must report a minimum of 750 cervical/vaginal LBC samples per annum.

Details

This requirement is the minimum permitted workload to maintain competency and applies regardless of the number of hours worked or level of seniority. The minimum volume of 750 cases per annum must not be regarded as optimal or best practice.

If a cytopathologist does not reach this standard, the Lead NCSP Services Pathologist must determine a suitable course of action and/or supervision to ensure their continuing competency, in line with Standard 508: Returning to work.

Cytopathologists who change LBC type must comply with Standard 527: Changing LBC technology policy (cytoscreeners and cytopathologists). This standard also applies to cytopathologists who commence reporting in Aotearoa New Zealand for the first time, and have qualifications and experience only using an LBC type not in current use in Aotearoa New Zealand.

Workloads for cytoscreeners policy

PURPOSE

To ensure that each fixed laboratory site employs sufficient cytoscientists and cytotechnicians to process, interpret and report the gynaecological LBC samples registered at the laboratory, and that each cytoscientist and cytotechnician screens a sufficient number of cases to maintain their competence and improve their skills.

Policy

A cytoscientist/cytotechnician's workload must be appropriate to their level of skill and considerate of their other tasks. The standards define a maximum screening workload to prevent work overload, and a minimum screening workload to ensure that staff maintain their competency and skills.

These limits are not to be used as performance targets for screeners.

512 Standard 512: Maximum daily workloads for cytoscreeners

The maximum workload for any cytoscreener performing manual or FOV screening (LBC samples) is 70 fully screened slides (or an equivalent workload) on any single working day.

The maximum times any cytoscreener may spend screening cytology slides is 7 hours 30 minutes (7.5 hours) in any single day, and 45 hours over any consecutive seven-day period.

Details

In calculating workloads:

- two FOV reviews are counted as equivalent to one full screen
- one FOV review followed by a full manual screen on the same slide are to be counted separately i.e. 1.5 workload units
- second full screens and other full screen reviews of slides (eg, previous negative slide reviews because of high-grade histology) are counted as equivalent to one primary full screen.

For staff who screen for less than seven hours and 30 minutes in any one working day, the maximum must be reduced on a pro-rata basis.

Cytoscreeners:

- may screen cytology slides (FOV review, full manual screens or cytology case reviews) for a maximum of 7 hours 30 minutes (7.5 hours) in any single day
- are not permitted to perform FOV reviews, full manual screens or cytology case reviews for more than 45 hours over any consecutive seven-day period.

There must be three spaced breaks totalling at least one hour within any full-time day, with an appropriate pro-rata allocation of breaks for part-day employees.

These time limits apply specifically to time spent screening. They are permitted maximums used to limit the potential for screening fatigue during periods of high workload and are not to be used as optimal or performance targets for cytoscreeners.

513 Standard 513: Minimum annual workloads for cytoscreeners

Cytoscientists and cytotechnicians must conduct FOV reviews with first full screens if required (automation-assisted screening) or first full screens (manual screening), on a minimum of 2,500 gynaecological LBC samples per annum.

Details

For calculating annual workloads, one sample means

- FOV review plus one full manual screen if required (of the same slide as the FOV review), or
- one first full manual screen where FOV review has not been performed.

This is a requirement to maintain competency and applies regardless of the number of FTE's worked or the level of seniority in the department.

Pre-analytical requirements

Providing advice to cervical screening sample requestors policy

PURPOSE

To support ongoing quality improvement in cervical sample taking and increased knowledge about cervical screening among sample requestors.

Policy

The laboratory must provide advice to cervical sample requestors on ways to improve the quality of sample taking.

Details

Pathologists and senior scientists must be readily available to advise sample requestors about:

- the suitability of hrHPV testing and cervical/vaginal cytology samples
- storage, transportation and expiry dates for LBC collection vials
- systems and processes for sample collection, transportation and storage to prevent cross-contamination of vials with HPV
- correct labelling of samples and specimens and the accompanying request form, and the importance of including relevant clinical details on laboratory request forms.
- the terminology used in cervical/vaginal cytology reports
- the terminology used in hrHPV test reports
- the clinical significance of the laboratory results
- the significance of invalid hrHPV tests and unsatisfactory cytology samples
- further procedures or investigations that may be helpful
- updates and changes to the NCSP in Aotearoa New Zealand.

Sample collection policy

PURPOSE

To ensure all samples for cervical screening tests are collected in a standardised way.

Samples for HPV testing may be collected by:

- a sample taker using a plastic cervix broom and/or cytobrush into an LBC vial
- a sample taker using an approved sampling device which is validated for use as a sampling device for HPV testing when used in conjunction with the HPV testing platform that will be used to analyse the sample
- the individual being sampled (self-testing) using an approved sampling device validated for use as a sampling device for HPV testing when used in conjunction with the HPV testing platform that will be used to analyse the sample.

All samples for cervical or vaginal cytology must be collected by a sample taker into an LBC vial. Swab-collected samples are not suitable for cytology.

Sampling, collection, transportation, volume and storage of all samples for cytology and hrHPV testing must be in accordance with either the manufacturer's recommendations or an alternative suitably validated process.

Transporting samples to the processing laboratory policy

PURPOSE

To ensure that all samples are transported safely to the laboratory where processing will occur, without sample loss or cross-contamination with HPV.

Policy

All samples are transported to the laboratory by a safe, standardised process to ensure that sample loss or cross-contamination with HPV does not occur.

The Lead HPV Testing Scientist has specific responsibility for ensuring that processes are in place to prevent cross-contamination of samples during collection, transportation, specimen registration and cytopreparation.

Details

The laboratory must have written protocols that specify packaging and all transportation arrangements from the point of collection to the room where the sample is to be processed. These protocols must be available for NCSP audit.

All separate laboratory collection centres must be notified of the laboratory's packaging and transport policies.

All staff who handle LBC vials and HPV collection tubes, including all collection centre staff who handle samples, must be actively educated about the potential for cross-contamination and must be fully aware of the laboratory's packaging and transport policies. The notification and ongoing education of collection centre staff must be documented and made available for NCSP audit.

All staff must wear gloves when handling LBC vials or HPV collection tubes.

LBC vials and HPV collection tubes must not be opened in specimen reception.

If an LBC vial or an HPV collection tube is noted to be leaking or seeping fluid around the lid, then:

- the specimen must be isolated, and the Lead HPV Testing Scientist notified before any further packaging or transportation occurs
- any person who has handled the sample must remove their gloves immediately, wash or sanitise their hands and put on new gloves before handling any further samples
- if the leaking vial is in a clam shell for transportation, the entire clam shell must be isolated, the Lead HPV Testing Scientist must be informed, and all samples in the clam shell must be externally decontaminated before processing
- the sample taker must be informed of the leakage/seepage in the laboratory report so that the provider is prompted to take steps to prevent further occurrences.

Handling and identifying samples for HPV testing and cytology policy

PURPOSE

LBC vials, samples collected for HPV testing only and laboratory request forms must be labelled accurately and tracked within the laboratory.

514 Standard 514: LBC samples, samples for HPV testing only and laboratory request form labelling policy

Pre-analytical procedures (all steps of sample registration and processing) must conform to the requirements of ISO 15189 2022: Medical laboratories – Requirements for quality and competence.

All samples must be clearly and unambiguously identified with permanent marking to ensure accurate matching with the laboratory request form. Laboratories must have a tracking system with a minimum of two full unique identifiers on the sample (full name and either NHI number or date of birth).

The minimum information required on the sample is:

- the particpant's family name and given name(s)
- NHI number and/or date of birth (preferably both)
- the sample date
- the collection site.

Laboratories must document and inform the sample taker if a ThinPrep® sample has the sampling device head in the vial or a SurePath™ sample does not have the sampling device head in the vial.

The **laboratory request form** information must include the following details.

Demographic information

- NHI number
- Family name and given name(s), plus any other names known by, if available
- Date of birth
- Gender
- Contact details/location – a valid New Zealand residential address, including post code, and postal address, if different
- Ethnicity (self-identified by the participant).

Test information

- Date of sample collection
- Collection method and sample type i.e.
  - SurePath™ LBC or ThinPrep® LBC
  - Clinician-collected swab (for HPV testing only) or self-collected swab (for HPV testing only)
- Collection site (cervix or vagina)
- The test(s) requested.

Clinical information
Gynaecological history, which must include:

- last menstrual period
- use of an intrauterine contraceptive device (IUCD) or Depo Provera
- if the patient is post-partum and/or breastfeeding
- if the patient has had a hysterectomy (total/subtotal), is post-menopausal or on hormone replacement treatment
- if the patient has a history of post-coital, intermenstrual or postmenopausal bleeding, pelvic pain or a persistent or abnormal discharge
- any other relevant clinical information that may influence either the result or the laboratory recommendations for recall or referral, such as symptoms of cervical disease, an abnormal appearance of the cervix, or if the participant is immune-deficient
- any history of abnormal hrHPV tests or cervical cytology/histology results reported outside Aotearoa New Zealand that are not already recorded on the NCSP Register. Any laboratory that has received this information must forward it to the National Coordination Centre Cervical Screening Register Team with documented evidence of the result, if provided by the sample requestor.

Sample taker/requestor information

- Health facility name, address and identifier (ID) number
- Name and registration (ID) number of the person requesting the test/s and receiving the result/s.

Other information

- Contact details for anyone who needs a copy of the result/s
- Notification if urgent processing is requested. A name and contact phone number where the result is to be delivered should be given. The reason for urgent processing and a date that the result is required by is also recommended.

Laboratories must have a protocol in place that details the action to be taken if they receive any mislabelled, incompletely labelled or unlabelled samples or request forms.

If a sample requestor notifies the laboratory of a change in patient details after the report has been issued, the laboratory must notify the NCSP Register staff of the change to maintain the accuracy of information held on the NCSP Register.

See also:

- NCSP Policies and Standards Section 3: Cervical Screening Services.
- IANZ. 2020. *IANZ Specific Criteria for Accreditation: Medical Testing AS LAB C7*, 4th edition. Auckland: International Accreditation New Zealand (IANZ).

515 Standard 515: Leaking and low fluid volume LBC vials and HPV collection tubes

1. **Leaking vials**
   Laboratories must document the receipt of leaking LBC sample vials caused by inadequate sealing. Any leaking vial must be disposed of and not processed for HPV testing. A report must be issued recording the leakage and reporting the hrHPV result as *Unsuitable for analysis because of LBC vial or swab-collection tube leakage*.

   Where there is a sufficient volume of fluid remaining in an LBC vial (for example, if fluid was seeping around the lid and most of the fluid was retained) then cytology should be performed and reported, even if not requested. This is to allow the repeat sample for HPV to be performed using a vaginal swab sample, avoiding the need for a repeat LBC sample. The cytology result will already be available, if the repeat HPV result is HPV Detected.

   A request for the sample to be recollected must be sent to the sample taker.

   - Leaking vials are disposed of because of the risk of HPV contamination.
   - Because of the clinical significance of a "Not Detected" hrHPV test result, it is not acceptable to dilute samples if the volume of fluid available for hrHPV testing is not sufficient for testing.

2. **Low fluid volume vials**
   LBC vials that are not leaking but are received with a low volume of fluid (due to spillage either before or immediately after the sample has been added to the vial) must be disposed of and not processed because of the risks of sample contamination or compromise. A report must be issued recording the low volume and reporting the hrHPV result as *Unsuitable for analysis because of LBC vial* or *swab-collection tube leakage*. A request for the sample to be recollected must be sent to the sample taker.

516 Standard 516: Reviewing case documentation to identify samples requiring cytology

The request form and NCSP Register history for every LBC sample accepted for processing must be reviewed in order to accurately identify the testing requirements.

Details

The request form and NCSP Register history for every LBC sample accepted for processing must be reviewed by a suitably competent and registered cytoscientist or cytotechnician who reports cervical cytology (or a cytology assistant approved by the Lead Cytoscientist who has been trained and is competent to perform this role), to determine the test requirements.

- Where hrHPV testing is performed, identifying whether cytology is also required must occur prior to the hrHPV test result being released as both results must be released in one report.

- Cytology reporting will be required for some cases where the hrHPV test result is Not detected, e.g. Test of Cure samples, participants with a previous glandular abnormality, symptomatic participants and in some specific clinical circumstances such as immunodeficiency.
- Symptoms requiring co-testing include suspicious abnormal bleeding including postmenopausal bleeding, an abnormal-appearing cervix and pelvic pain. Further details are available in the *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023*.
- Situations where cytology will be reported without hrHPV testing are:
  1. a sample for cytology following a previous recent hrHPV:Detected result on a swab-collected sample
  2. a repeat LBC sample taken after a previous sample where HPV testing was reported but the cytology was unsatisfactory
  3. a sample taken at colposcopy for cytology where HPV testing is not required eg. referred to colposcopy with a recently reported HPV 16/18 positive swab-collected sample, with no cytology result prior to colposcopy.

The following information must be reviewed for every individual sample.

- The **laboratory request form** for evidence of
  - symptoms such as abnormal vaginal bleeding
  - a clinical history of an abnormal-appearing cervix
  - specific clinical circumstances such as immune deficiency
  - a request for cytology only from a specialist colposcopist or gynaecologist.
- The **NCSP history** for evidence of:
  - previous high-grade squamous histology or cytology requiring a Test of Cure
  - previous high-grade glandular histology or cytology requiring specific follow-up, e.g. a previous glandular abnormality requiring co-testing follow-up or atypical glandular cells requiring referral to gynaecology services.

Accessing the NCSP screening history

Laboratories will access the patient's screening history directly from the NCSP Register using online screening histories. If electronic access is not available, laboratories can ask the Register Central Team at the NCSP National Coordination Centre for a participant's screening event history. They must provide the participant's:

- surname
- first name
- preferred name
- date of birth
- NHI number.

The history will be supplied within four working hours of the request.

Oncogenic (high-risk) HPV testing

'Oncogenic' refers to the 14 HPV types that are recognised as being associated with a higher risk of cervical cancer. Oncogenic HPV is also called high-risk HPV or hrHPV.

Validation of sampling devices for collecting vaginal samples for HPV testing only policy

PURPOSE

To ensure that all samples collected for HPV testing only are taken with a validated sampling device.

Policy

Samples that are swab-collected for HPV testing only, including samples collected by a clinician for HPV testing only that are not taken using a speculum, must be taken using a sampling device that has been validated for use as an HPV test sampling device when used in conjunction with the specific HPV test technology that will be used to test for hrHPV.

Sampling devices used to collect vaginal swab samples for HPV tests must be validated for this purpose using the specific HPV test technology that will be used for processing the sample and reporting the HPV test. Validation can be achieved by:

- international validation by either the United States Food and Drug Administration (FDA) or the Conformité Européenne (CE-marking) for processing and reporting hrHPV tests using swab-collected samples taken using the specific sampling device and HPV test technology that will be used at that laboratory in Aotearoa New Zealand
- conducting a local laboratory validation trial comparing the HPV test results of self-collected swab samples with clinician-collected LBC samples, according to the approved NCSP protocol (available from the NCSP programme manager on request).

Performing hrHPV testing policy

PURPOSE

To ensure that LBC samples are appropriately tested for hrHPV.

Policy

Laboratories must perform hrHPV testing on all samples as defined in the NSU's *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023*. Each individual fixed laboratory site carrying out hrHPV testing must select and use one type of HPV test technology for all hrHPV testing for NCSP purposes.

517 517: Ensuring all samples are appropriately tested or not tested for hrHPV

Laboratories must conduct hrHPV testing on all samples as defined in the NSU's *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023* (www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand).

hrHPV testing will be required on most samples. Specific situations where cytology (LBC samples) will be performed without hrHPV testing are listed under Standard 516: Reviewing case documentation to identify samples requiring cytology.

- If a participant's NCSP Register history indicates eligibility for the first or second co-test for a Test of Cure as follow-up after previous high-grade squamous results and the sample taker has ordered HPV testing only on an LBC sample, the laboratory must add a cytology test to commence or complete the Test of Cure, except:
  - where the participant is already at colposcopy (eg, having been re-referred because of an abnormal first co-test TOC result), the colposcopist is responsible for determining the types of further tests ordered
- Where cytology is added by the laboratory, a comment must be added to the report to explain the reason for this to the sample taker
- If a participant's NCSP Register history indicates eligibility for a Test of Cure as follow-up after previous high-grade squamous results and a swab-collected sample has been taken for HPV testing only, the laboratory must add a comment to the report requesting the sample taker to invite the participant to return for a cytology LBC sample to commence or complete the Test of Cure.

Oncogenic (high-risk) HPV test technology policy

PURPOSE

To ensure that LBC samples are accurately processed and tested for hrHPV using a validated test procedure.

Policy

Laboratories must carry out hrHPV testing of LBC samples using approved and validated processes in accordance with the manufacturer's instructions to ensure accurate results.

Laboratories must comply with section 5.5 of the Specific Criteria for Accreditation: Medical Testing IANZ 4th Edition 2020.

518 Standard 518: hrHPV test technology requirements

For HPV DNA-based technologies, the hrHPV test technology used for clinician-collected samples must:

- be endorsed for hrHPV testing by either the United States Food and Drug Administration or the Conformité Européenne
- meet the equivalency criteria of Meijer et al 2009[1]
- detect the 14 oncogenic HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 and separately identify HPV 16 and 18
- be validated for the specimen collection medium of the LBC system (ThinPrep® or SurePath™) that will be used for cytology reporting (when required) on the same sample

- contain at least one control to monitor both:
  - inhibition and/or assay failure
  - cellularity to detect inadequate or empty cervical samples.

HPV test technology used for HPV testing of swab-collected samples must:

- be a PCR-based test that detects HPV DNA
- meet all the above criteria for HPV DNA-based technologies for clinician-taken LBC samples
- be endorsed for hrHPV testing of swab-collected samples by any of the following:
  - the United States Food and Drug Administration (FDA)
  - the Conformité Européenne (CE marking)
  - the NCSP-approved process for validating HPV testing using self-collected vaginal swab samples in New Zealand laboratories. This involves comparing the HPV test sensitivities of 313 self-collected vaginal swab samples with paired clinician-collected LBC samples taken concurrently at colposcopy. The full protocol is available from the NCSP programme manager on request.

A laboratory that is already validated to perform swab-collected samples using one type of HPV test technology can validate a different type of HPV test technology by in-house paired testing of 50 self-collected samples, comparing the HPV test sensitivity of the new technology with the established validated HPV test technology. Further details are available at: NPAAC. *Requirements for Medical Testing of Microbial Nucleic Acids*. Australian Government Department of Health. www1.health.gov.au/internet/main/publishing.nsf/Content/E688964F88F4FD20CA257BF0001B739D/$File/V0.25%20NAD%20Human%20Genetics.pdf

For biomarkers other than HPV DNA, the hrHPV test technology used for clinician-collected LBC samples must:

- meet all the above requirements for HPV DNA-based technologies including the requirements for swab-collected samples, where relevant
- have at least five years of longitudinal data published in peer-reviewed literature, demonstrating non-inferior sensitivity and specificity performance for detecting and excluding CIN2+ compared with the DNA-based Hybrid Capture-2 test.

See also:

- Meijer CJLM, Castle PE, Hesselink AT, et al. 2009. Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. *Int J Cancer*;124: 516–20.
- Arbyn M, Snijders PJF, Meijer CJLM, et al. 2015. Which high-risk HPV assays fulfil criteria for use in primary cervical cancer screening? *Clin Microbiol Infect*, 21(9), 817–26. DOI:10.1016/j.cmi.2015.04.015.
- NPAAC. 2019. Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019). Canberra: Australian Government Department of Health. URL: www1.health.gov.au/internet/main/publishing.nsf/Content/npaac-cervical-screening (accessed 21 July 2020)
- www.gov.uk/government/publications/cervical-screening-laboratory-testing-for-human-papillomavirus/nhs-cervical-screening-programme-laboratory-quality-control-and-assurance-for-human-papillomavirus-testing

Operational verification for implementing new hrHPV test technology policy

The laboratory must assess panels of 100 or more samples (at least 40% of hrHPV positive samples including 10% of HPV 16 plus HPV Other cases, and 5% of HPV 18 plus HPV Other cases) with a clinically validated reference assay. The testing must achieve at least 87% concordance between observed and expected results.

As suppliers of large volumes of quality assurance samples are not readily available to create external sample verification panels for hrHPV testing, in-house verification is acceptable.

Residual routinely analysed anonymised samples, together with residual material used or received for quality control purposes can be assessed for in-house verification purposes.

Documentation of operational verification

Documentation of operational verification processes must include:

- the rationale for introducing the test/change in use
- details of the test and how it meets the equivalency criteria of Meijer et al 2009[1]
- details of sample selection and annotation
- full details of test method verification
- performance characteristics, including measurement of uncertainty, analytical specificity and analytical sensitivity
- interpretation of the results
- conclusions as to whether the test is suitable for the proposed application.

Verification reports must also include:

- the person/s who reviewed and authorised the verification
- the implementation of the testing process
- any required actions arising from the verification process.

Verification reports must be made available for NCSP audit.

See also:

- Section 5.5.1.3 Validation of examination procedures in IANZ's Specific Criteria for Accreditation: Medical Testing IANZ 4th Edition (2020)
- NHS Cervical Screening Programme: laboratory quality control and assurance for human papillomavirus testing. Updated 25 January 2017
- NPAAC. 2019. *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program* (Second Edition 2019). Canberra: Australian Government Department of Health. URL: www1.health.gov.au/internet/main/publishing.nsf/Content/npaac-cervical-screening (accessed 21 July 2020).

Using residual LBC fluid for other tests

Use of residual LBC fluid for tests other than hrHPV testing and cytology reporting (such as testing for chlamydia) must only occur after the hrHPV test/LBC report has been issued.

1 Meijer CJLM, Castle PE, Hesselink AT, et al. 2009. Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. *Int J Cancer* ;124: 516–20.

Invalid hrHPV tests policy

Because of the clinical significance of a 'Not detected' hrHPV test result, it is critical that laboratories identify unsuitable specimens and specimens where testing may be inhibited by the presence of lubricant, blood or inflammatory exudate to avoid such specimens being incorrectly reported as 'hrHPV Not detected'.

Following an invalid hrHPV test result, another sample may be collected at any time if hrHPV testing only is required, but must be collected between six weeks and three months of the initial test if cytology is (or may be) required on the recollected sample.

If a patient has two consecutive invalid hrHPV test results, the sample requestor must be advised to discuss with a colposcopist, whether to refer the patient for a colposcopy.

Quality assurance for oncogenic HPV testing policy

Laboratories must comply with the requirements of ISO 15189:2022 Standards 5.6.2.2 and 5.6.2.3.

Internal quality assurance

Positive and negative controls must be run as follows.

- Controls provided by the test manufacturer must be run according to the manufacturer's instructions.
- Laboratories must perform, log and monitor internal quality control results (to monitor trend and drift controls) to meet ISO 15189.

External quality assurance

Laboratories providing HPV testing must participate and perform adequately in an accredited EQAP for molecular detection of HPV, such as the RCPA Quality Assurance Programme, the United Kingdom's National External Quality Assessment Scheme, or the Quality Control for Molecular Diagnostics programme.

Laboratories must assess and document any performance issues with EQAPs and record any corrective actions.

Managing HPV cross-contamination risk policy

Laboratories must have processes in place to regularly monitor for cross-contamination of samples in the sample preparation area, in cytology and in the hrHPV testing laboratory, that is, any place where an LBC vial or an HPV collection tube is opened. The outcomes of checks for cross-contamination must be documented.

Details

A blank LBC vial must be included in the regular processing of LBC vials for HPV testing once a week and tested for cross-contamination.

Environmental swabbing

Laboratories must reduce the risk of contamination by adhering to laboratory environment requirements, routinely cleaning and decontaminating surfaces and equipment, and maintaining a one-way flow between pre- and post-amplification areas.

To maintain the sterility of the environment, laboratories must carry out monthly environmental swabbing of the testing areas. If any sample is positive for HPV, laboratory decontamination must be carried out before processing any further samples.

Laboratories must document results of environmental swabbing and record any issues or actions.

See also:

- ISO 15189:2022 – Medical laboratories: Requirements for quality and competence
- Specific Criteria for Accreditation: Medical Testing IANZ 4th Edition (2020)
- NPAAC's Requirements for Medical Testing of Microbial Nucleic Acids.[2]

519 Standard 519: Storage and disposal of hrHPV test samples

All samples must be stored according to the manufacturer's instructions.

If possible, extracted nucleic acids should be kept until all testing and reporting on the original sample is completed, to allow retesting if required. This may not be possible with some high through-put automated testing systems, in which case, residual fluid from the original vial would need to be used if retesting were required.

The residual sample in LBC vials must be retained until cytology and hrHPV testing have been reported, and for a minimum of one month after the sample was received.

HPV collection tubes must be retained for a minimum of two weeks after the sample was received.

2 NPAAC. *Requirements for Medical Testing of Microbial Nucleic Acids*. Canberra: Australian Government Department of Health. www1.health.gov.au/internet/main/publishing.nsf/Content/E688964F88F4FD20CA257BF0001B739D/$File/V0.25%20NAD%20Human%20Genetics.pdf

Cytology

Cytology LBC slide preparation policy

PURPOSE

To ensure that optimal samples are prepared and preserved because accurate interpretation of cytology slides depends on high-quality staining and slide preparation.

Policy

Slide preparation and staining must be of optimal quality.

The methods for processing ThinPrep® and SurePath™ specimens are not interchangeable. Slide preparation must conform to the manufacturer's instructions and meet ISO 15189 requirements.

The LBC processing system must be one that ensures a secure chain of custody.

The preparation and processing of LBC slides must be undertaken by trained, competent staff.

Slide staining

LBC slide staining must be performed as follows.

- Cervical/vaginal cytology slides must be stained using the Papanicolaou staining method required by the manufacturer, using appropriate staining for automation-assisted screening, if this is used.
- There must be laboratory protocols detailing the method and optimal desirable staining results, including the frequency of replacing or filtering reagents and internal quality control procedures.
- The cover slip must cover an area larger than the LBC cell preparation.
- Mounting media must not be allowed to contaminate the surface of the cover slip and compromise visibility.

See also:

- Manufacturer's instructions.

Handling and reporting unsatisfactory LBC samples

If the sample is unsatisfactory for cytology reporting, laboratories must follow the protocol for reporting and handling unsatisfactory samples specified in Bethesda 2014 (NZ Modified).

If there is an adequate volume of fluid remaining in the vial, a cytoscientist or cytotechnician must check the vial for blood and/or mucus and request a remake of the sample with an appropriate procedure for re-staining according to the manufacturer's instructions. Any repeat processing must be recorded.

See also:

- Manufacturer's instructions
- *Bethesda 2001 (NZ Modified): Codes, descriptors and assessment of sample adequacy for cytology laboratories,* available from the NSU website at: www.nsu.govt.nz/health-professionals/1060.aspx

Automated screening device policy

PURPOSE

To ensure that, when an automated screening device is used, cytology LBC slides are accurately processed and screened and the device has been appropriately installed and validated.

Policy

Automated screening of LBC slides must be carried out using approved and validated automated screening devices used in accordance with the manufacturer's instructions.

Details

Appropriately trained staff who are competent to undertake such tasks must prepare and process slides for automated screening devices.

Slides that are processed and rejected (due to calibration or other reasons) must be either reprocessed before repeat automated screening or manually screened.

520 Standard 520: Validating an automated screening device

All laboratories introducing an automated screening device for the first time must comply with and document the following requirements allowing review by audit bodies.

The automated device must be operated and calibrated according to the manufacturer's instructions, and any non-compliance must be corrected.

Laboratories must undertake and record daily calibrations, as recommended by the manufacturer.

The first 1,000 cases processed by a laboratory introducing an imager platform must be fully primary and secondary screened following FOV review. Both laboratory and individual reporting rates for low- and high-grade abnormalities must be recorded for this process.

521 Standard 521: Validating cytoscreener competency for FOV review screening

All cytoscreeners performing FOV reviews using an automated imager must have:

- reviewed a wide range of abnormal cases
- demonstrated competency during a documented individual validation process
- been designated as competent to perform FOV reviews by the Lead Cytoscientist.

The validation of an individual's competency to perform FOV screening must include:

- a manufacturer's training course in FOV review
- a test set consisting of a minimum of 300 cases, weighted with abnormal cases to reflect an abnormality rate of 30-40%. (90 to 120 abnormal cases)
  - the case mix must include a minimum of;
    - 60 high-grade cases comprising at least 30 cases of HSIL, 5 cases of squamous cell carcinoma, 5 cases of AIS, 3 cases of endocervical adenocarcinoma, 3 cases of endometrial carcinoma and 4 cases of atypical glandular cells (any type).
    - 30 low-grade cases
    - 10 cases which include normal endometrial cells.

The individual's rate of detection of abnormality must achieve:

- a detection sensitivity of at least 95% of all high-grade abnormalities and 90% of the total abnormalities identified as high-grade or abnormal respectively
- a specificity of at least 85% of all true negative cases identified as negative/reactive. If normal endometrial cells are present in samples from participants who are 45 years of age and over but are not identified, this is classed as an error under this criterion, even if the case is correctly called negative/reactive.

If a cytoscreener does not achieve the required sensitivities and specificities, further collections of 300 FOV cases must be reviewed until the requirements are met.

Laboratories must maintain detailed records for each screener, including sensitivities achieved.

Primary manual screening policy

PURPOSE

To ensure that cytology slides are interpreted competently at primary manual screening.

Policy

Manual screening of cytology slides without the use of automated screening devices must be carried out by appropriately skilled and competent cytoscreeners with a minimum of two full screens by two different cytoscreeners for each slide in order to maximise the sensitivity of the screening process.

522 Standard 522: Manual screening

All cases which are fully screened manually without the assistance of an automated screening device must have a first full screen followed by a second full screen by a different cytoscreener before reporting or referral to a pathologist.

If either cytoscreener considers that the slide is abnormal then the case must be referred to a pathologist for reporting, with an option that under specific circumstances defined by the Lead Cytoscientist, the Lead Cytoscientist and one other designated experienced cytoscientist performing the second full screen on cases where the first full screen opinion was low-grade only (ASC-US or LSIL), may downgrade and report cases as normal. This option is approved to reduce the potential for over-reporting of low-grade cytology. Any case where any screener's opinion is high-grade must be referred to a cytopathologist for reporting.

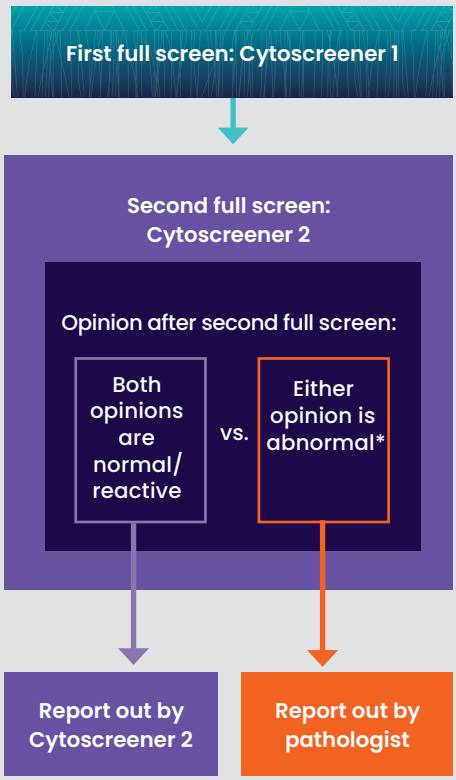
Details

For full manual screening the cytoscreener must evaluate all the cellular material on the slide by systematically scanning the slide from one edge to the other, overlapping each field of view so that no area of cellular material is missed.

Any slides screened by a Bachelor of Medical Laboratory Science graduate holding provisional registration with the Medical Sciences Council of New Zealand (e.g. first year of post-qualification employment) must be fully primary screened by a registered cytoscientist or cytotechnician with a full annual practising certificate, with full rescreening where required being performed by a different registered cytoscientist or cytotechnician with an annual practising certificate, until the graduate receives their full annual practising certificate.

Pathologists are excluded from performing the role of a cytoscreener for first or second full manual screens of cervical cytology slides for reporting purposes.

Figure 1: Primary manual screening workflow



* Lead Cytoscientists performing Cytoscreener 2 screens are permitted to approve downgrades of cytology called ASC-US or LSIL (low-grade only) by Cytoscreener 1 and report cases as normal without referral to a pathologist, if they wish to do so under specific circumstances in their laboratory. Where this provision is used, one other experienced cytoscientist in the department may be delegated to report normal cytology under the same circumstances, to provide cover. Any cytology called high-grade by any cytoscreener must be referred to a pathologist for reporting.

Primary location-guided screening policy

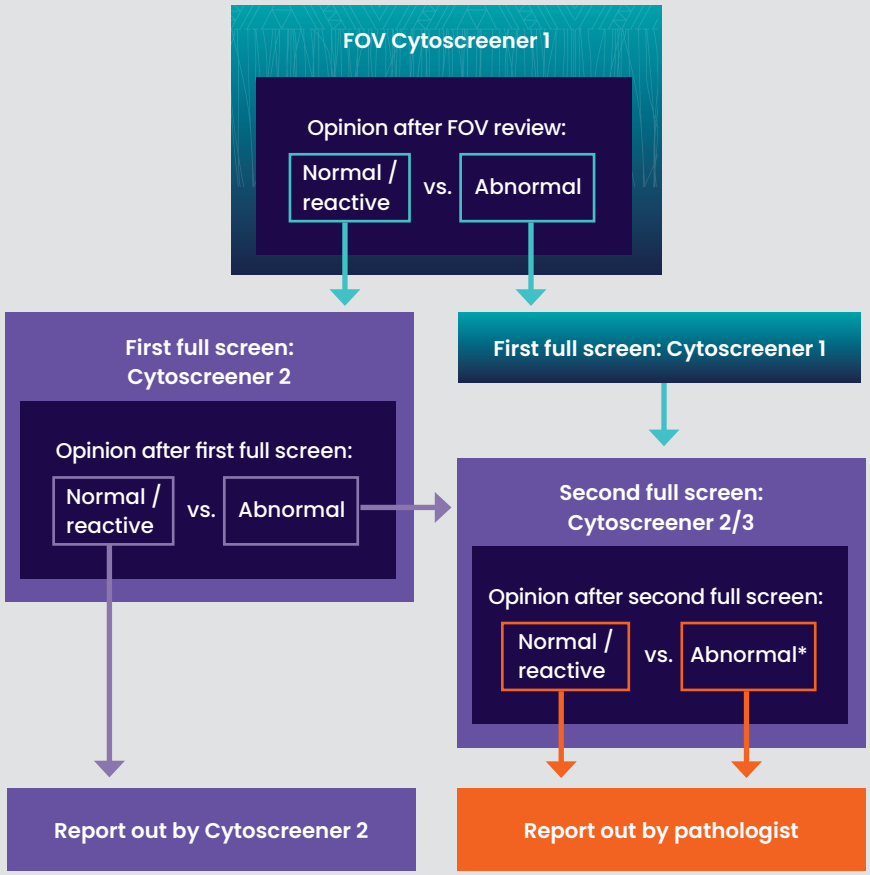
PURPOSE

To ensure that cytology slides reported using location-guided FOV screening are examined and interpreted competently.

Policy

Laboratories may conduct a location-guided FOV review of any slide that has been satisfactorily scanned using an automated screening device as part of an NCSP-approved screening process. Cytoscientists and cytotechnicians performing FOV review must have demonstrated their ability to detect abnormalities using this method and be designated as competent to do so by the Lead Cytoscientist.

Figure 2: Primary location-guided screening workflow



DEFINITIONS
FIELD OF VIEW (FOV) Microscopic FOV at x10 objective magnification selected and presented to the cytoscreener by location-guided technology
FOV REVIEW The microscopic review of all imager-selected FOVs by a cytoscreener
FOV REVIEW WITH FIRST FULL SCREEN First full manual screen after FOV review
SECOND FULL SCREEN A second full manual screen performed after the FOV review with first full screen is completed. A second full screen will usually be performed because an abnormality has been identified at the first full screen stage.

* Lead Cytoscientists performing Cytoscreener 2/3 full screens are permitted to approve downgrades of cytology called ASC-US or LSIL (low-grade only) by Cytoscreener 1/2 and report cases as normal without referral to a pathologist, if they wish to do so under specific circumstances in their laboratory. Where this provision is used, one other experienced cytoscientist in the department may be delegated to report normal cytology under the same circumstances, to provide cover. Any cytology called high-grade by any cytoscreener must be referred to a pathologist for reporting.

523 Standard 523: Location-guided FOV screening

The minimum number of location-guided FOVs specified by the imaging device manufacturer must be fully reviewed by the cytoscreener, and they must examine the complete cellular content for each FOV.

- If an **epithelial abnormality is identified in a FOV review** a full manual screen must be performed by the same cytoscreener who performed the FOV review. A second full manual screen must then be performed by a different cytoscreener who then sends it to a pathologist for reporting. Under specific circumstances defined by the Lead Cytoscientist, there is an option for the Lead Cytoscientist and one other designated experienced cytoscientist performing the second full screen on cases where the first full screen opinion was low-grade only (ASC-US or LSIL) to downgrade and report cases as normal. This option is approved to reduce the potential for over-reporting of low-grade cytology. Any case where any cytoscreener's opinion is high-grade (including the FOV option) must be referred to a cytopathologist for reporting.
- If **no epithelial abnormality is identified in a FOV review**, a full manual screen must still be performed. In this case, the full manual screen must be performed by a different cytoscreener from the person who performed the FOV review.

Laboratories must correlate and record the reasons and outcome of all cases with non-correlation between the FOV result and final result.

Pathologists are excluded from the role of a cytoscreener for performing FOV reviews, or first or second full screens of cervical cytology slides as part of the reporting process in an automated environment.

Second full screens policy

PURPOSE

To ensure that second full screens of cytology samples are performed for all cases where an abnormality has been identified by the first full screen (without automation) or FOV review with first full screen.

Policy

Cases requiring a second full screen (Standard 524: Second full screen requirements) must receive an FOV review with one manual screen performed by

the same cytoscreener, and a second full screen by a different cytoscreener.

A minimum of two full manual screens by two different cytoscreeners must be performed before pathologist reporting for all cases where an abnormality is identified by FOV review or at first manual screening.

524 Standard 524: Second full screen requirements

A second full screen must be performed for all who:

1. have abnormal (G2 or G3) cervical/vaginal cytology identified by first full manual screening (where an automated device is not used) or by FOV review with full screen
2. have had a previous low-grade (ASC-US or LSIL) abnormality and have not been returned to five-yearly HPV screening after the low-grade result OR have not had a "Not Detected" hrHPV result since the low-grade cytology result
3. have had a previous high-grade cytologic or histologic abnormality and who:
    i. have not had the high-grade squamous abnormality treated
    ii. have been treated but have not successfully completed a Test of Cure since treatment and are having any one of the first three cytology samples after treatment
    iii. had a glandular abnormality in the previous five years
4. are overdue for a cervical screening test by more than five years
5. have unsatisfactory cervical/vaginal cytology
6. have suspicious clinical conditions, abnormal bleeding or observed cervical abnormalities, or are immune deficient.

Details

Samples reported using automated screening devices that require a second full screen must receive a minimum of FOV review with one full manual screen performed by the same cytoscreener as performed the FOV review, and a second full screen performed by a different cytoscreener from the person who conducted the FOV review.

If a fully automated laboratory has to temporarily revert to manual screening (for example, due to equipment failure), then all screened samples must have a second full screen in accordance with all sections of the NCSP Policies and Standards relating to manual screening (includes staffing, reporting and procedural requirements for manual screening).

525 Standard 525: Competency requirements for cytoscreeners performing second full screens

A cytoscientist or cytotechnician may carry out second full screens of cervical/vaginal cytology if they have more than one year of full-time (or equivalent FTE) experience as a cervical/vaginal cytoscreener after completing the VRPCC AND are designated as competent for rescreening by the Lead Cytoscientist. Lead Cytoscientists may use their discretion with experienced staff who have not completed the VRPCC.

Completion of these requirements must be documented for all staff performing second full screening and this information must be made available for audit.

526 Standard 526: Timing of second full screens

All second full screens must take place before the results are confirmed and sent to the sample taker and the NCSP Register.

Changing LBC technology policy

PURPOSE

To ensure that, if a laboratory changes the LBC technology used for cytology reporting, all staff are appropriately trained to report using the new LBC type (including the use of a new automated screening device, if appropriate).

527 Standard 527: Changing LBC technology policy

If a cytoscreener or cytopathologist changes the type of LBC they manually screen and report (for example, a staff member who is BD SurePath™ trained changes to Hologic ThinPrep® screening) and they are not already certified for the alternative LBC type, they must undertake full retraining. This requirement also applies to cytoscreeners and cytopathologists who arrive from overseas to work in Aotearoa New Zealand and are (only) trained and experienced in an LBC type not currently used in Aotearoa New Zealand.

Full retraining means:

- complying with the training requirements of the LBC manufacturer
- complying with any NCSP requirements for transitioning from one LBC type to another type
- completing any additional competency requirements of the individual laboratory.

If a cytoscreener changes to a different automated screening device system (for example, a staff member who is using the BD FocalPoint/GS™ system changes to the Hologic ThinPrep® Imager) and they are not already certified for the alternative automated system, they must undertake full retraining. Full retraining means:

- complying with the training requirements of the LBC manufacturer
- complying with any NCSP requirements for transitioning from one LBC type to another type
- completing any additional competency requirements of the individual laboratory.

The Lead Services Pathologist must ensure that the retraining undertaken is documented and that the individual concerned is signed off as competent to screen and/or report using the new LBC system.

Cytopathologist reporting policy

PURPOSE

To ensure that a specialist cytopathologist reports all cases with an identified epithelial abnormality.

528 Standard 528: Confirming and reporting abnormal results

All results identified as abnormal (G2 or G3) either at first or second full screening must be sent to a cytopathologist for reporting.

Details

All cases reported by a pathologist must have been fully screened by at least two cytoscreeners.

All cases with possible or definite invasion reported on a cervical cytology sample must be communicated verbally to the sample taker or referring practitioner facility when the written report is issued, except when there is a concurrent histologic biopsy confirming the invasion. The laboratory must keep a record of the conversation in the case records.

Ensuring correct recommendations in cytology reports policy

PURPOSE

To ensure that all cytology reports include the correct recommendation for follow-up or referral as specified in the NCSP *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023* to encourage optimal and consistent management of participants across Aotearoa New Zealand.

Policy

Laboratories must have processes in place to ensure that recommendations for follow-up or referral in cytology reports are consistent with the NCSP *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023*.

Details

Laboratories must ensure that a participant's complete current screening event history from the NCSP Register is readily available and considered by all laboratory staff involved at each stage of the cytology screening and reporting process.

Recommendations for recall or referral must be based on the clinical details, the hrHPV test result if applicable, and the cytological findings of the current sample if cytology has been performed, as well as the participant's complete NCSP screening event history in accordance with the *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023* www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand).

If a result is rejected by the NCSP Register because it is incorrectly formatted or contains invalid data or an incorrect recommendation, the laboratory must send an amended result or respond to the NCSP Register within 10 working days of the date of notification. All amended cytology or histology results must also be notified to:

- the sample taker
- all other recipients issued with the original result report
- the colposcopist managing the case, if appropriate
- the NZCR, if appropriate (this includes cases where a cytology result previously reported to the NZCR has been downgraded to less than invasive or in situ cancer).

See also:

- NCSP Policies and Standards Section 5 Standard 541: Reporting changes to cytology or histology results.
- NCSP *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023* available at www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand

Histology

All cervical and vaginal tissue specimens submitted to a pathology laboratory for histological examination are covered by the NCSP Policies and Standards.

The types of biopsies covered include:

- cervical punch biopsies
- endocervical curettings
- wedge biopsies
- large loop excisions of the transformation zone (LLETZ) (also called LEEP)
- cone biopsies (laser or cold knife)
- hysterectomy specimens with a cervical component
- vaginal biopsies and resection specimens.

Subtotal hysterectomy specimens

Histology results from subtotal hysterectomy specimens when no cervical tissue has been excised do not need to be forwarded to the NCSP Register. If part of the cervix is excised as part of a subtotal hysterectomy, then the result must be forwarded to the NCSP Register.

Preparing histology specimens policy

PURPOSE

To ensure that histology slides are correctly prepared for histopathological examination.

Handling specimens

Pre-analytical procedures must comply with the requirements of ISO 15189.

Laboratories must have appropriate and regular documented quality control checks at all steps in the pre-analytical process to mitigate risks of mislabelling and cross-contamination/transfer. Laboratories must keep records of the checks, identifying the staff who process the samples at critical points.

529 Standard 529: Handling and preparing histology specimens

All gynaecologic histology specimens must be handled, described and prepared for examination and reporting in accordance with the following professional protocols.

- ISO 15189 (see International Accreditation New Zealand, IANZ, at: https://www.ianz.govt.nz/programmes/medical-laboratory and Specific Criteria for Accreditation Medical Testing, IANZ 4th Edition 2020).
- Requirements for Minimising Errors in Medical Histology Laboratories at: https://assets.websitefiles.com/5e447d8550a99c8326ee5ae6/5f07845d722b662ee6a0a5ce_AS%20LAB%20C7.2%20Supplementary%20Criteria%20-%20Minimising%20Histology%20Errors.pd
- RCPA's *Anatomical Pathology: Macroscopic Cut-up Manual*, available from the RCPA website at: www.rcpa.edu.au/Manuals/Macroscopic-Cut-Up-Manual

- RCPA's *Structured Reporting Protocol for Excisions and Colposcopic Biopsies Performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia* (1st edition 2017), available from the RCPA website at: www.rcpa.edu.au/getattachment/9ed056b7-6bcc-4885-a243-925053302e3b/Protocol-Cervical-pre-neoplasia.aspx
- RCPA's *Cervical Cancer Structured Reporting Protocol* (1st Edition 2013), available from the RCPA website at: www.rcpa.edu.au/getattachment/2dfcc534-547d-455a-837b-79bfeb2b60e7/Protocol-Cervical-cancer.aspx

Laboratories must also meet the following NCSP Policies and Standards requirements.

Cervical punch biopsies

An initial six levels of the tissue must be examined, with consideration to keeping extra levels for immunoperoxidase staining, if required.

Further levels must be examined to identify all pathology (if additional tissue is still present in the block/s) if there is a discrepancy between initial levels and recent (eg, referral to colposcopy) cytology and the cytology report is of a higher grade than the initial histology levels reveal.

Loop excisions (LLETZ) and cone biopsies

LLETZ and cone biopsies should have three levels examined on all tissue blocks, with further levels if indicated by clinical information or findings on the three initial levels.

Pathologists may use their discretion regarding the number of initial and subsequent levels, depending on clinical circumstances and findings in the initial sections examined.

Hysterectomy specimens with previous CIN1/2/3/AIS

The cervix must be amputated and handled in accordance with cone biopsy protocols with all cervical tissue processed for histologic examination, when:

- the hysterectomy is done wholly or in part to treat the cervical abnormality (eg, a participant with adenocarcinoma in situ (AIS) who decides to proceed to hysterectomy, a participant with a high-grade squamous intraepithelial lesion (HSIL) and another gynaecological issue such as large fibroids and menorrhagia who decides to proceed to hysterectomy to deal with both issues)
- an identified high-grade abnormality has not been treated or resolved (eg, previous HSIL without successful completion of a Test of Cure)
- an identified low-grade abnormality has not resolved (the participant had not returned to regular interval screening before hysterectomy) and there is a concurrent hrHPV Detected test result (any subtype) or their hrHPV status is unknown.

The hysterectomy specimen can be handled according to usual hysterectomy protocols if:

- a previous high-grade abnormality was resolved before hysterectomy (eg, previous HSIL treated with subsequent successful completion of Test of Cure)
- the person had a previous low-grade squamous intraepithelial lesion (LSIL/CIN1) and was returned to usual interval screening after follow-up, or had a concurrent hrHPV Not detected test result with their LSIL/CIN1 cytology.

Reporting gynaecological histology specimens policy

530 Standard 530: Examining and reporting histology slides

A histopathologist must examine and report all histology slides.

All specimens must be reported in concordance with the RCPA's *Structured Reporting Protocol for Excisions and Colposcopic Biopsies Performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia* (1st edition 2017)[3] or the RCPA *Cervical Cancer Structured Reporting Protocol* (1st Edition 2013)[4]. Pathologists must be familiar with the reporting requirements of these protocols.

Reporting adequacy in relation to the transformation zone

Please note the following comments in the RCPA's *Structured Reporting Protocol for Excisions and Colposcopic Biopsies Performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia*.

- Sampling of the squamocolumnar junction in a small diagnostic biopsy is not required for adequacy as the clinician is targeting the colposcopic abnormality
- Documentation of the tissues present facilitates clinicopathologic correlation
- A specific statement on adequacy by the pathologist is not required as adequacy requires clinical correlation.

Reporting margins for LLETZ and cone biopsy excision specimens containing HSIL and/or AIS

If HSIL or AIS is identified in an excision specimen, the RCPA's *Structured Reporting Protocol for Excisions and Colposcopic Biopsies Performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia* S3.10 applies as follows.

The status of all surgical excision margins must be recorded (ectocervical, endocervical and radial/deep stromal). For each margin, the status of HSIL and/or AIS (including SMILE) must be recorded.

- In occasional cases where tumour involvement of the margin cannot be determined for various reasons (processing artefact, thermal artefact, multiple pieces or poor tissue orientation), it must be specified as 'indeterminate' and the reason explained.

3 See: www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer/Cancer-Protocols/Gynaecological/Protocol-Cervical-pre-neoplasia.aspx

4 See: www.rcpa.edu.au/getattachment/2dfcc534-547d-455a-837b-79bfeb2b60e7/Protocol-Cervical-cancer.aspx

Additional guidelines are given at G3.09 in the RCPA's *Structured Reporting Protocol for Excisions and Colposcopic Biopsies Performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia* for reporting and measuring margins. The following have been accepted by the NCSP to apply in New Zealand.

- For HSIL, measuring distances to surgical margins is not required
- For AIS and/or SMILE, distances to excision margins (ectocervical, endocervical and radial/deep stromal) that are less than 5 mm must be recorded as "closely excised (<5mm)". An exact measurement is not required.
- If the surface epithelium is stripped, assessment of the adequacy of excision should be to the end of the intact surface epithelium.

Reporting invasive cervical cancers

All reports suggestive of or definitely diagnosing invasive cervical cancer must state in the report whether the cancer is HPV-related, HPV-independent or HPV-unknown.

- If possible, and particularly when the invasive cancer is completely excised, the histology report must include International Federation of Gynaecology and Obstetrics (FIGO) staging.

Reporting using LAST and CIN terminology

All cervical and vaginal histology specimens where dysplasia or malignancy is reported must be reported using LAST terminology, with the CIN terminology given in brackets, for example, HSIL (CIN3).

Both terminologies must be used to reduce the possibility of clinicians misinterpreting the report.

Immunohistochemistry

Additional investigations (such as immunohistochemistry for difficult-to-grade lesions) should be performed as professionally appropriate.

See also:

- Darragh TM, Colgan TJ, Cox JT, et al. 2012. The lower anogenital squamous terminology standardization project for HPV-associated lesions: Background and consensus recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology. *Arch Pathol Lab Med* Vol 136, October, 1266–97. URL: www.archivesofpathology.org/doi/full/10.5858/arpa.LGT200570 (accessed 22 June 2020).

Correlating histopathology, cytology and hrHPV results when reporting histology policy

531 Standard 531: Histopathologist access to cervical cytology results

The histopathologist must have the complete current NCSP Register screening event history available at the time of reporting any histopathology specimen containing cervical or vaginal tissue, and must correlate the most recent cytology result (eg, the referral to colposcopy sample) with the histology specimen/s result/s when making their report.

Details

If the most recent cytology result reported was possible or definite high grade and the histology specimen/s being reported is/are less than high grade, then the following apply.

1. If the most recent cytology sample was reported at the same laboratory as the histology being reported, it is best practice for the cytology slide to be reviewed at the time of histology reporting.
   - If the cytology sample is confirmed as possible or definite high grade, the cytology review can be communicated to the colposcopist in the histology report and the case referred for consideration for multidisciplinary meeting (MDM) review.
   - If the cytology sample is not confirmed as possible or definite high grade, an amended cytology report can be issued and MDM review may not be required.
2. If the most recent cytology sample was not reported at the laboratory where the histology is being reported or if the most recent cytology sample has not been reviewed when the histology is reported, then it is recommended that the histology report states that the most recent cytology sample has not been reviewed and the case be referred for consideration for MDM review.

See also:

- Bhatla N, Berek JS, Fredes MC, et al. 2019 Revised FIGO staging for carcinoma of the cervix uteri. FIGO Committee report. *Int J Gynecol Obstet* 2019; 145: 129–135. DOI: 10.1002/ijgo.1274
- Hirschowitz L, Albus AD, Brown LJR, et al. 2012. *Histopathology Reporting in Cervical Screening: An integrated approach* (2nd edition) NHS Cancer Screening Programme (NHSCSP), Publication No. 10, September 2012. URL: www.cancerscreening.nhs.uk/cervical/publications/cc-04.html (accessed 22 June 2020).

Communicating results

Reporting to sample takers/requestors and specialists policy

PURPOSE

To ensure that cervical/vaginal cytology, histology and hrHPV test samples are reported in the correct format to the right recipients in a timely manner.

Policy

Laboratories are responsible for reporting all hrHPV test results using NCSP-approved reporting terminology and cytology results using NCSP-approved Bethesda 2014 (NZ Modified) terminology to sample takers/requestors, and all histology samples to the referring specialist using the NCSP-approved SNOMED coding, in a timely manner.

532 Standard 532: Ensuring all HPV tests, cytology and histology samples received are reported to sample takers/requestors and specialists

Laboratories must have protocols and procedures in place to ensure they report all hrHPV test samples, cervical/vaginal cytology and histology samples analysed to the appropriate sample takers/requestors and specialists.

533 Standard 533: Reporting HPV tests and cytology results

1. Reporting hrHPV (only) tests

Results must be reported in an approved format as either *hrHPV Detected, hrHPV Not Detected, Invalid,* or *Unsuitable for analysis because of LBC vial or swab-collection tube leakage*.

Where hrHPV is detected, the report must stipulate whether this is HPV 16 and/or HPV 18 and/or HPV "Other" i.e. one or more non-16/18 type(s). Additional genotyping information, such as extended genotyping results, may be included in the report at the laboratory's discretion.

Molecular scientists must only sign out/validate reports if:

- the result is *hrHPV Not Detected* AND the sample is a regular screening sample (i.e. not taken because of a recommendation for early repeat testing at the last event on the NCSP Register) for repeat testing in five years AND there is no concurrent cytology being reported
- the HPV test has been performed on a swab-collected sample AND the result is HPV Detected (any type) AND there are no previous HPV:Detected, abnormal cytology or abnormal histology results on the NCSP Register
- they have received training to ensure that the correct recommendation is given in the report before signing out

- the hrHPV result is *Invalid* or *Unsuitable for analysis because of LBC vial or swab-collection tube leakage* and the recommendation is for a repeat sample for HPV testing.

All reports must be released by a cytoscientist/cytotechnician or a cytopathologist if any of the following apply.

- The result is *hrHPV Detected* including self-test swab samples where there is a previous HPV detected, abnormal cytology or abnormal histology result on the NCSP Register.
- The sample has been taken at an "earlier than five years" interval because of a recommendation for early repeat testing (for example a Test of Cure sample or follow-up after a previous HPV detected result).
- The recommendation for the current test is NOT for hrHPV testing in five years.

2. Reporting hrHPV and cytology tests (same sample)

HPV results must be reported in an approved format as either *hrHPV Detected, hrHPV Not Detected, Invalid,* or *Unsuitable for analysis because of LBC vial or swab-collection tube leakage*.

Where hrHPV is detected, the report must stipulate whether this is HPV 16 and/or HPV 18 and/or HPV "Other" i.e. one or more non-16/18 type(s). Additional genotyping information, such as extended genotyping results, may be included in the report at the laboratory's discretion.

Where hrHPV and cytology tests are performed on the same sample, both test results must be reported to the sample taker at the same time in one report.

Timeframes for reporting to sample takers/requestors and specialists

534 Standard 534: Reporting hrHPV tests and cervical/vaginal cytology results to sample takers/requestors

Where hrHPV testing only is performed on a sample, the laboratory must report:

- 100% of hrHPV test results to sample requestors within three working days of receipt of the sample.

Where hrHPV and cytology tests are performed on the same sample, the laboratory must report:

- 90% of the completed report containing both the hrHPV test result and the cervical/vaginal cytology result to the sample taker within seven working days of receipt of the specimen
- 100% of the completed report containing both the hrHPV test result and the cervical/vaginal cytology result to the sample taker within 10 working days of receipt of the sample.

Where a cytology test only is performed on the sample (i.e. without an accompanying hrHPV test), the laboratory must report:

- 100% of the completed report containing the cervical/vaginal cytology result to the sample taker within 10 working days of receipt of the sample.

535 Standard 535: Reporting histology results

Laboratories must report:

- 90% of final histology results to referring specialists within 10 working days of receiving the specimen
- 98% of final histology results to referring specialists within 15 working days of receiving the specimen.

Details

Histology diagnoses must be coded using the SNOMED CT codes approved by the NCSP and include topography, morphology and procedure codes.

Introducing changes to reporting terminology and methods

All potential changes to laboratory reporting, including changes to Bethesda or SNOMED CT codes, must be coordinated through the NCSP. Changes can only be made following engagement and discussion with the NCSP, other laboratories and any other affected parties.

See also:

- NCSP. 2014. *Bethesda 2001 (NZ Modified): Codes, descriptors and assessment of sample adequacy for cytology laboratories.* Wellington: National Cervical Screening Programme (NZ), Ministry of Health. URL: www.nsu.govt.nz/system/files/resources/bethesda_august_2014.pdf (accessed 22 June 2020)
- NCSP. 2013. *SNOMED Coding for Histology*. Wellington: National Cervical Screening Programme (NZ), Ministry of Health. URL: www.nsu.govt.nz/system/files/resources/snomed-coding-for-histology-updated-jan-2013.pdf (accessed 22 June 2020).

Policy for sending results to the NCSP Register

PURPOSE

To ensure that the NCSP Register receives all hrHPV, cervical/vaginal cytology and histology test results.

Policy

All cervical or vaginal hrHPV tests, cytology samples and histology specimens taken in Aotearoa New Zealand must be recorded on the NCSP Register, unless the participant withdraws from the NCSP.

536 Standard 536: Sending all cervical/vaginal cytology results to the NCSP Register

Laboratories must have processes in place to ensure that all reported hrHPV test results, cervical/vaginal cytology and histology results for samples taken in Aotearoa New Zealand are sent to the NCSP Register in the correct format.

Details

Samples taken offshore for HPV testing, cervical cytology or histology (eg, in Antarctica or in the Pacific Islands) and reported in Aotearoa New Zealand laboratories must not be sent to the NCSP Register.

All electronic data must contain:

- full family name and given name
- date of birth
- contact address
- ethnicity (if available)
- NHI number
- the sample taker/requestor or specialist's (ID) registration

number and the health facility identifier (ID) number
- name and address of the clinic.

HL7 messaging and electronic data must be formatted in accordance with the NCSP Register implementation guide. This guide specifies the hrHPV, cytology and histology file format and can be requested from the NCSP.

- Where hrHPV is detected, the electronic data must stipulate whether this is HPV 16 and/or HPV 18 and/or HPV "Other" i.e. one or more non-16/18 type(s).
- Additional specific genotyping or extended genotyping data may also be sent to the NCSP Register.

Screening event history is not contained in HL7 messaging.

Any results or documented evidence of results that are not already recorded on the NCSP Register must be forwarded to the NCSP Register Central Team at the National Coordination Centre.

This includes references to results of tests performed offshore that have been provided to the laboratory on the cervical screening request form, where the test result is not already on the NCSP Register.

See also:

- Ministry of Health. 2015. *HISO 10008.2:2015 Pathology and Radiology Messaging Standard*. Wellington: Ministry of Health. URL: www.health.govt.nz/publication/hiso-1000822015-pathology-and-radiology-messaging-standard
- National Coordination Centre contact details available at https://www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/ncsp-register

537 Standard 537: Sending hrHPV-only results to the NCSP Register

Where a hrHPV test is the only NCSP test performed on a sample, the laboratory must electronically send:

- 100% of hrHPV test results to the NCSP Register in the approved format within three working days of receipt of the sample. Partial genotyping results identifying the presence of hrHPV 16, hrHPV 18 or hrHPV "Other" (i.e. non 16/18) must be included.

538 Standard 538: Sending hrHPV with cytology results or cytology-only results to the NCSP Register

Laboratories must electronically send to the NCSP Register 100% of all reports, both cytology only and cytology with an hrHPV test result, in the approved format and Bethesda coding within 10 working days of receiving the sample.

539 Standard 539: Sending histology results to the NCSP Register

Laboratories must electronically send to the NCSP Register 90% of histology results in the approved format with NCSP SNOMED CT coding within 10 working days of receiving the specimen.

Laboratories must electronically send to the NCSP Register 98% of histology results in the approved format with NCSP SNOMED CT coding within 15 working days of receiving the specimen.

See also:

- NCSP 2014 *Bethesda 2001 (NZ Modified): Codes, descriptors and assessment of sample adequacy for cytology laboratories*. Wellington: National Cervical Screening Programme (NZ), Ministry of Health. URL: www.nsu.govt.nz/system/files/resources/bethesda_august_2014.pdf (accessed 22 June 2020)
- NCSP. 2013. *SNOMED Coding for Histology*. Wellington: National Cervical Screening Programme (NZ), Ministry of Health. URL: www.nsu.govt.nz/system/files/resources/snomed-coding-for-histology-updated-jan-2013.pdf (accessed 22 June 2020)

New Zealand Cancer Registry requirements

PURPOSE

To support the compilation of a statistical record of the incidence of cancer in its various forms and to enhance the direction of programmes related to cancer research and prevention.

Policy

The Cancer Registry Act 1993 and the Cancer Registry Regulations 1994 require all tests that indicate the presence of cancer, except squamous cell carcinoma and basal cell carcinoma of non-genital skin, to be reported to the NZCR.

540 Standard 540: Sending results to the New Zealand Cancer Registry

Laboratories must send all cytology results analysed and reported as definite or suspicious of invasive cancer and all histology results with a diagnosis of CIN2, CIN3, AIS/SMILE or invasive cancer to the NZCR (Te Whatu Ora Health New Zealand).

For cervical/vaginal samples and specimens, these results include:

- cytology:
  - abnormal squamous cells showing changes consistent with squamous cell carcinoma (SC)
  - abnormal glandular cells consistent with adenocarcinoma (AC1–4)
  - abnormal cells consistent with a malignant neoplasm NOS (AC5)
  - abnormal cells consistent with a high-grade squamous intraepithelial lesion (HSIL) with features suspicious for invasion (HS2)
- histology:
  - CIN2
  - CIN3
  - endocervical AIS/SMILE
  - invasive primary cervical or vaginal malignancies
  - other malignancies involving the cervix or vagina.

Under Cancer Registry Regulations 1994, reports must be sent to the NZCR no later than 21 days after the end of the calendar month in which the tests were carried out.

See also:

- Cancer Registry Act 1993, available from the New Zealand Legislation website at: www.legislation.govt.nz/act/public/1993/0102/latest/DLM318888.html
- Cancer Registry Regulations 1994, available from the New Zealand Legislation website at: www.legislation.govt.nz/regulation/public/1994/0089/latest/DLM190120.html
- NZCR, available from Te Whatu Ora website at: www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections/new-zealand-cancer-registry-nzcr

Reviewing histology and cytology cases

Multidisciplinary meetings case review policy

PURPOSE

To ensure that, for all cases where a discrepancy in the cytology and histology results has clinical management implications, there is a full case review at a multidisciplinary meeting (MDM).

Policy

All cases with discrepancies between cytology and histology results that could have implications for clinical management must be fully reviewed by a multidisciplinary team of experienced practitioners at an MDM.

Details

Discrepancies should be reviewed at an MDM if possible.

Under extenuating circumstances, if case review is required for clinical management before the next available MDM, slide review/s by an appropriate pathologist/s can be arranged on a case-by-case basis.

All laboratories reporting cervical/vaginal cytology must provide one or more pathologists to participate interactively in MDMs as part of case management and quality control. Formal arrangements must be in place for regular MDMs to occur with clinical colleagues.

MDM participants may include:

- cytoscientists and cytotechnicians
- histopathologists and cytopathologists
- colposcopy nurses
- colposcopists and gynaecologists
- gynaecologic oncologists.

See also:

- Ministry of Health. 2012. *Guidance for Implementing High-Quality Multidisciplinary Meetings: Achieving best practice cancer care.* Wellington: Ministry of Health. URL: www.health.govt.nz/publication/guidance-implementing-high-quality-multidisciplinary-meetings (accessed 22 June 2020).

4 NCSP. 2020. *Clinical Practice Guidelines for Cervical Screening in New Zealand 2020.* Wellington: National Screening Unit, Ministry of Health. URL: https://www.nsu.govt.nz/system/files/resources/final_ncsp-guidelines-for-cervical-screening-new-zealand-5_june_2020.pdf (accessed 21 June 2020).

Pathologists presenting cases at multidisciplinary meetings policy

PURPOSE

To ensure that pathologists participate in regular discussions with clinicians about options for the treatment and care of individual participants.

Policy

A pathologist representative from each laboratory that issued original reports of cervical cytology and/or histology samples for any case to be discussed at an MDM must attend the MDM either in person, by videoconference or by telephone to present their findings and participate in the case discussion directly with the colposcopy team.

Details

If a pathologist from the original reporting laboratory is not available and a pathologist from a different laboratory is presenting the case/s at an MDM, or any time that slides from a different laboratory are being presented, then:

- the laboratory holding the reports and slides of previous cytology/histology reports requested for MDM case review must make those reports and slides available to the pathologist presenting at the MDM in a timely manner
- pathologists must only formally review cytology slides for MDM purposes in the same LBC type that they normally report. If the slide for review is of a different LBC type, the presenting pathologist must arrange for a formal review to be done by a pathologist who does report using the same LBC type.

Changing a cytology or histology result at MDM review

If a cytology or histology result is changed as a result of an MDM review in any way that has implications for patient management, an amended report must be issued.

If the reviewing pathologist is from the laboratory which issued the original report, the laboratory must ensure that the reviewing pathologist issues an amended report that communicates the revised result to the colposcopist, the sample taker, the NCSP Register and the NZCR (if appropriate), and anyone else who was issued with the original report in accordance with the NCSP Policies and Standards Section 5: Reporting changes to cytology or histology results (Standard 541). By amending the report, the reviewing pathologist takes responsibility for the sample/specimen.

If the slide/s were originally reported at a different laboratory from that of the review/presenting pathologist, the review/presenting pathologist must inform the original reporting laboratory of the revised diagnosis opinion in writing. The laboratories involved must negotiate and follow a clear process for ensuring that an amended report is issued to the colposcopist, the sample taker, the NCSP Register and the NZCR (if appropriate), and anyone else who was issued with the original report in accordance with the NCSP Policies and Standards Section 5: Reporting changes to cytology or histology results (Standard 541).

Documenting MDM outcomes and subsequent responsibilities policy

PURPOSE

To ensure that the lines of responsibility for documenting and following up cases discussed at MDM meetings are clearly defined so that the management of individual participants is not compromised.

Policy

All cases discussed at MDM meetings must be fully documented, including the outcome of the review, future management plans and the names of those responsible for further actions for each case.

Details

The clinical chair of the MDM is responsible for ensuring that, for each case discussed, the recommendations from the meeting are clearly communicated to an identified colposcopist responsible for further management and that this is documented.

The participant's colposcopist is responsible for communicating the MDM recommendations to them and for ensuring appropriate ongoing care.

Presenting pathologists are responsible for ensuring that all slide reviews and amended/supplementary reports relevant to the cases presented are issued within five working days following the meeting.

Laboratories must record outcomes of MDM reviews of pathology material and link them to the original result in the laboratory electronic records to provide a clear record of the time of the review, the reviewing pathologist, the outcome of the review and any further actions taken. This is to provide accurate patient records as well as a clear audit trail.

Meeting documentation must include a list of everyone present at the meeting and be circulated to all those who attended the meeting.

Issuing amended cytology and/or histology reports policy

PURPOSE

To ensure that accurate cytology and histology results are provided to sample takers, clinicians and the NCSP Register so that appropriate patient follow-up and management occurs. It is also important to maintain the integrity of the data held by the NCSP Register and the NZCR for monitoring and evaluation purposes.

Policy

If changes are made to a cytology or histology report as a result of a slide review, the reviewing pathologist must either issue a written amended report or ensure that an amended report is issued by the laboratory that issued the original report (if this is a different laboratory). The review outcome must be communicated to all people who were issued with the original report or who are involved in clinical management and to all relevant registers.

541 Standard 541: Reporting changes to cytology or histology results

All amended cytology or histology results must be notified within five working days from the date of the slide review to:

- the sample taker
- anyone else who was issued with the original result report
- the colposcopist managing the case, if appropriate
- the NCSP Register
- the NZCR, if appropriate (including cases where a cytology result previously reported to the NZCR is downgraded to less than suspicious or definite invasive cancer, or a previous histology result is downgraded to less than CIN2 or AIS/SMILE).

Details

The amended report must clearly state what has changed from the original report.

If the original report was issued by a cytoscreener, a pathologist at the same laboratory may take responsibility for the review and issue the amended report. This is mandatory when a cytoscreener's report is amended to an abnormal result.

If the original reporting pathologist is not available for a reason beyond the laboratory's control (eg, illness, extended leave, departure), the Lead NCSP Services Pathologist must arrange for the original report to be amended by another pathologist in the department.

See also:

- Hirschowitz L, Albus AD, Brown LJR, et al. 2012. *Histopathology Reporting in Cervical Screening: An integrated approach* (2nd edition) NHS Cancer Screening Programme (NHSCSP), Publication No. 10, September 2012. URL: www.cancerscreening.nhs.uk/cervical/publications/cc-04.html (accessed 22 June 2020)
- *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023*, available from the NSU website at: www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand

Quality assurance

Accreditation policy

PURPOSE

To ensure that all laboratories providing services to the NCSP are accredited.

Policy

All laboratories providing services to the NCSP must be accredited by IANZ for providing hrHPV testing, cervical/vaginal cytology and/or histology services.

Details

Laboratories must inform the NCSP of the results of all IANZ assessments (annual surveillance and periodic full peer assessments) and any change to their accreditation status.

A laboratory that is considering introducing new tests or technologies into the cervical screening pathway must first:

- notify the NCSP that the test or technology is under consideration
- ensure that the test or technology has been appropriately validated (where applicable) according to:
  - the manufacturer's requirements
  - NCSP requirements
- ensure that the test or technology has been notified to IANZ and approved (where applicable) in accordance with the requirements of their contract
- communicate details of any transition to new tests or technologies to sample takers/requestors well in advance of implementation, to allow ample time for sample takers and requestors to clarify the implications of any changes.

Internal quality assurance policy

PURPOSE

To ensure that every laboratory reporting to the NCSP has a high-quality internal quality assurance system as an essential component of quality assurance.

Policy

Laboratories must have policies and practices in place that ensure that high-quality hrHPV testing, cervical/vaginal cytology and histology are performed. Policies must define staff responsibilities and laboratory procedures.

Details

Each laboratory must have documented internal quality assurance activities that comply with ISO 15189: Specific Criteria for Accreditation: Medical Testing IANZ 4th Edition 2020. Specific systems must be in place for:

- evaluating the individual performance of cytoscientists, cytotechnicians and cytopathologists reporting cervical/vaginal cytology by:
  - monitoring the sensitivity and specificity of screening for each cytoscreener and the combined screener performance for the laboratory against the final cytology report
  - monitoring the percentage in each diagnostic category issued by individual cytopathologists, against the reporting profile issued by the laboratory's pathologists as a group

- investigating discrepancies between cytology and histology results by:
  - reviewing all cytology cases reported as Atypical Squamous Cells cannot exclude HSIL (ASC-H) at 6 and/or 12 months post-reporting to consider the histologic outcome of the case in relation to the ASC-H report
  - conducting retrospective reviews of cases with a high-grade outcome on histology.

Evaluating individual performance policy

PURPOSE

Monitoring of individuals is needed to ensure consistent reporting between individual cytoscreeners and individual cytopathologists in each laboratory.

Policy

Each individual who screens and/or reports cervical cytology must have their reporting profile monitored on a regular basis and compared with their peers in the same laboratory.

Details

1. Cytoscreeners

The rate of detection of abnormality by cytoscreeners must be monitored. Each cytoscreener must undergo regular monitoring to ensure their competency to detect abnormalities when screening slides.

542 Standard 542: Minimum cytoscreener sensitivities for detecting abnormalities and identifying high-grade cases policy

Individual cytoscientists and cytotechnicians must demonstrate competency to perform primary screening by achieving a sensitivity for detecting at least 95% of high-grade abnormalities and 90% of total abnormalities.

When determining screener sensitivities, 'high-grade' is defined as a definite high-grade result, that is, HS1+HS2+SC+AIS+AC1-5 (excluding ASC-H and AG1-5), while total abnormalities is defined as the total of all abnormal reports excluding ASC-US.

Individual cytoscreener sensitivity data must be measured regularly, at a frequency of three months or more, and combined to provide annual rolling sensitivity data. The results must be reviewed at least six-monthly by the Lead Cytoscientist, with individual results and the overall laboratory performance provided to each individual monitored.

If any cytoscreener does not meet laboratory sensitivity performance parameters, the Lead Cytoscientist must:

- meet with them to discuss this and document any corrective actions and further educational activities
- notify the Lead Cytopathologist.

Laboratories may undertake additional monitoring measures of competency (eg, to include ASC-US, AG1-5 and ASC-H). Timeframes and monitoring may also be extended to include correlations of cytology with histology.

2. Cytopathologists

Monitoring the performance of individual cytopathologists relative to the performance of other pathologists at the same laboratory provides assurance about consistency of reporting. This is particularly important for new graduates or new staff. Lead Cytopathologists are responsible for reviewing the monitoring data for their laboratory pathologists.

543 Standard 543: Monitoring cytopathologist performance

The Lead Cytopathologist must review all individual cytopathologist reporting profiles every six months, with individual results and the overall reporting profile for the laboratory's pathologists provided to each person monitored.

If the Lead Cytopathologist has any concerns about individual cytopathologist performance they must meet to discuss this, and document outcomes and remedial actions.

The results of cytoscreener monitoring and evidence that a review process is in place for cytopathologist monitoring must be made available for audit bodies.

See also:

- NCSP. 2014. *Bethesda 2001 (NZ Modified): Codes, descriptors and assessment of sample adequacy for cytology laboratories*. Wellington: National Cervical Screening Programme (NZ), Ministry of Health. URL: www.nsu.govt.nz/system/files/resources/bethesda_august_2014.pdf (accessed 22 June 2020)
- NCSP. 2013. *SNOMED Coding for Histology*. Wellington: National Cervical Screening Programme (NZ), Ministry of Health. URL: www.nsu.govt.nz/system/files/resources/snomed-coding-for-histology-updated-jan-2013.pdf
- ISO 15189:2022 – Medical laboratories: Requirements for quality and competence.

Investigating discrepancies between cytology and histology results

PURPOSE

Investigating discrepant results between cytology reports and histology results optimises clinical management by reviewing previously issued reports to maximise diagnostic accuracy.

Policy

Discrepancies between cytology and histology results are investigated by ASC-H outcome reviews and by retrospective reviews of cases with a high-grade outcome on histology.

The National Coordination Centre (NCSP Register team) supplies a monthly cytology/histology correlation report to each individual laboratory, identifying cases where histology has been reported (at any New Zealand laboratory) with cytology reported previously or concurrently at that individual laboratory. This report allows laboratories to identify cases that need to be reviewed for quality assurance purposes.

Atypical Squamous Cells cannot exclude HSIL (ASC-H) reviews

Laboratories must have systems in place to record and correlate all cytology cases reported as Atypical Squamous Cells cannot exclude HSIL (ASC-H) with the histology outcome.

Details

- All cytology cases reported as ASC-H must be reviewed regardless of the histology outcome.
- All cytoscreeners and cytopathologists must take part in at least some of the reviews, to ensure feedback to all who report cervical cytology.
- Cases can be identified for review six months after the ASC-H report, to capture at least one colposcopy investigation. Those cases where a definite histology outcome has not been determined at six months, should be considered again at 12 months to see if a final outcome is known.
- If any result is amended by the review, the reviewing pathologist must issue a written amended report and ensure it is communicated to the colposcopist, the sample taker and the NCSP Register or NZCR in accordance with Standard 541: Reporting changes to cytology or histology results.
- All cytoscreeners and cytopathologists who screened or reported the slide/s when originally reported must be informed of the amended result and have the slides made available to them for their review.
- Reviewing histology slides is not a requirement but may be performed on a case-by-case basis. If requested from another laboratory for correlation review, the previous histology reports and slides must be made available in a timely manner to the requesting cytology laboratory.

544 Standard 544: Reviewing Atypical Squamous Cells cannot exclude HSIL (ASC-H) cases

Laboratories must review all cytology cases reported as ASC-H six months after reporting, to consider histology outcomes. If the case outcome is not clear at six months, the case must be similarly reviewed at 12 months.

- Cases already reviewed at MDM do not require further review.
- Documenting the outcome of the reviews should be arranged to best serve the requirements of the staff, as the reviews are done for educational and quality improvement reasons.
- If reports require amendment, this should occur under the requirements of Standard 541: Reporting changes to cytology or histology results in this document.
- For audit purposes, the laboratory must document the number of ASC-H cases reviewed. Monitoring of ASC-H PPV's will occur as part of laboratory diagnostic performance indicator monitoring.

Retrospective reviews of cytology slides taken before a high-grade or invasive diagnosis on histology policy

Note: The current 42-months timeframe for retrospective cytology reviews will be retained for the first 3.5 years after the introduction of HPV primary screening for cytology reported prior to 12 September 2023. For cytology reported after 12 September 2023, a nine-month retrospective review time frame will apply, to capture the referral to colposcopy cytology result.

PURPOSE

To ensure that:

- pathologists, cytoscientists and cytotechnicians regularly review and record review outcomes for cases in which a high-grade abnormality may have been missed
- the accuracy of the distinction between low-grade/normal cytology from high-grade cytology is regularly reviewed, because of the key triage role of cytology in determining referral to colposcopy for those who are HPV positive
- the review process and outcomes are used to help educate all staff involved in reporting cervical cytology.

Policy

Pathologists, cytoscientists and cytotechnicians must regularly review and document the review outcomes for cytology slides from cases where a high-grade or invasive abnormality was identified at colposcopy, and where (within appropriate timeframes) there was normal, benign/reactive or unsatisfactory cytology reported prior to 12 September 2023 OR where there was normal, benign/reactive/unsatisfactory or low-grade (ASC-US/LSIL) cytology reported on or after 12 September 2023.

545 Standard 545: Reviewing previous cytology slides after a subsequent high-grade histology diagnosis

The laboratory must review and document the review outcomes of:

i. all cytology cases reported before 12 September 2023, where there was a cytology result of negative, benign/reactive or unsatisfactory, reported in the 42 months before a high-grade or invasive diagnosis on histology

ii. all cytology cases reported on or after 12 September 2023 where there was a cytology result of normal, benign/reactive, unsatisfactory or low-grade (ASC-US/LSIL), in the nine months prior to a high-grade or invasive histology diagnosis.

The results of the reviews are to be recorded in two separate groups according to whether the last positive HPV test prior to the high-grade histology was HPV Other or HPV 16/18.

Previous cytology slide reviews for this standard must be undertaken by a cytoscreener approved by the Lead Cytoscientist, with a second cytoscreener review if the first review is discrepant with the original report. If there remains a lack of consensus between the original cytology report and the review opinion, a pathologist must review the case to finalise the review outcome.

The laboratory must document any confirmed slides reviewed as upgraded to definite or possible high-grade abnormalities. The laboratories must forward cumulative data to the NCSP every six months, no later than three months after the end of the six-month period.

See also:

- *Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023*, available from the NSU website at: www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/cervical-screening-guidelines
- Hirschowitz L, Albus AD, Brown LJR, et al. 2012. *Histopathology Reporting in Cervical Screening: An integrated approach* (2nd edition) NHS Cancer Screening Programme (NHSCSP), Publication No. 10, September 2012. URL: www.cancerscreening.nhs.uk/cervical/publications/cc-04.html (accessed 22 June 2020)
- NCSP monitoring reports, available from the NSU website at: www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/independent-monitoring-reports

External quality assurance policy

PURPOSE

To promote uniformly high standards of diagnostic reporting of hrHPV testing, cytology and histology at each laboratory.

Policy

In accordance with accreditation requirements, laboratories providing hrHPV testing, cervical/vaginal cytology and/or histology services, must participate to a satisfactory standard in appropriate EQAPs.

The EQAP must include:

- assessment against quantitative performance standards accepted by the NCSP, such as the RCPA-QAPs
- external quality assurance reports, outcome measures and action sheets, which must be retained and made available to any audit bodies.

Laboratories must use external quality assurance reports as part of their own quality control processes.

546 Standard 546: All laboratories reporting cervical/vaginal cytology, histology and HPV testing participate in laboratory-based EQAPs

All laboratories reporting cervical/vaginal cytology, histology and HPV testing must participate in laboratory-based EQAPs relevant to the discipline/s practised to ensure competency in hrHPV testing, for example, through the RCPA, the World Health Organization (WHO) reference laboratory or another appropriate body.

All laboratories reporting cervical histopathology must participate in a laboratory-based EQAP in gynaecological histopathology, such as the RCPA's gynaecological histology QAP.

See also:

- WHO HPV Laboratory Network, available from the WHO website at: www.who.int/biologicals/areas/vaccines/hpv_labnet/en/

547 Standard 547: All staff reporting cervical/vaginal cytology participate in the RCPA's individual EQAP

All staff who report cervical/vaginal cytology (cytopathologists and cytoscreeners) must participate in the NCSP-approved Individual EQAP run by the RCPA QAP.

Completed action sheets for all staff who received a letter from the RCPA QAP based on their performance in an IEQAP survey must be made available to NCSP auditors at on-site laboratory audits.

Retaining slides, tissue and documentation

Retaining slides, tissue and associated documentation policy

PURPOSE

All cervical/vaginal cytology and histology slides, paraffin-embedded tissue blocks, records, results and all other documentation relating to hrHPV testing, cytology and/or histology samples must be kept, enabling future case and slide reviews where necessary.

Policy

Laboratories must retain slides, tissue, request forms and reports, including electronic copies, in accordance with the NCSP laboratory services contract, IANZ requirements and relevant legislation (eg, the Public Records Act 2005 and the Health (Retention of Health Information) Regulations 1996).

Laboratories must comply with their written protocols for handling, retaining, returning and disposing of human tissue, cells or any other samples containing human genetic material, in accordance with NCSP Section 5 Standard 501: Cultural sensitivity and appropriateness.

Participants from some cultural groups feel a strong connection to biological samples that have been provided to laboratories for analysis. Such cultural values need to be respected in any actions taken.

Details

Laboratories must hold stained slides, tissue and associated documentation in a secure repository in compliance with current best practice and relevant legislation.

Timeframes for holding slides, blocks, tissue and associated records and documentation are set out in the table below.

TYPE OF RECORD	MINIMUM RETENTION PERIOD
Laboratory referrer test request forms (or a complete electronic image) for which a payment is claimed	10 years from the date of the sample
Laboratory test results and test reports	10 years from the date of the sample
Cervical/vaginal cytology slides	10 years from the date of the final test report, but a longer retention period is encouraged
Histology slides and blocks of tissue embedded in paraffin wax or any other permanent embedding medium relating to NCSP tests	10 years from the date of the final test report
Digital cytology images for FOVs used with automated screening devices	Six years
LBC vials	One month after the sample has been received or until the sample has been reported, if longer
HPV collection tubes	Two weeks after the sample was received
Other records and reports, for example, policy data	In accordance with Archives New Zealand's record-keeping guidelines and any other national legislative requirements

Laboratories must ensure that the records are properly archived and readily accessible, and have in place appropriate back-up and disaster recovery procedures to protect against loss of electronically stored information. Request forms and pathology reports may be in an electronic form.

LBC vials must be stored in a secure place within the laboratory premises before disposal in order to protect patient identity details and to ensure that retesting can occur if required within the retention timeframe.

Laboratories must also be aware of and comply with any longer retention period required under law or by any other appropriate body.

Laboratories that no longer provide cervical/vaginal cytology and/or histology

If a laboratory stops hrHPV testing, cervical/vaginal cytology and/or histology reporting, it must comply with the relevant contract provisions to ensure that all samples/specimens and records are available on request or are forwarded to the new contracted provider. The NSU must be notified of the name of the provider who is taking responsibility for the samples/specimens and records.

The NSU must be notified in a timely manner of any circumstances that arise that could result in a laboratory's closure.

See also:

- Health (Retention of Health Information) Regulations 1996, available from the New Zealand Legislation website at: http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html
- *National Pathology Accreditation Advisory Council (NPAAC) Best Practice Pathology Guidelines*, available from the Australian Government, Department of Health website at: www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-path-bestpractice (Please note, if the minimum retention timeframe in the table above and the NCSP contract is longer than that specified in the NPAAC Guidelines, the timeframe in the table above and the NCSP contract applies.)
- https://www.mcnz.org.nz/assets/standards/ca6c11b3cd/Maintenance-patient-records.pdf
- Public Records Act 2005, available from the New Zealand Legislation website at: www.legislation.govt.nz/act/public/2005/0040/latest/DLM345529.html

NCSP indicators and targets

Monitoring details

Laboratory performance is monitored regularly by the NCSP.

- Laboratories receive six-monthly Laboratory Indicator Reports from the NCSP and are expected to use the reports as part of their internal quality control processes.
- Data is supplied from laboratories to the NCSP in six-monthly contract reports for NCSP review.
- Laboratory performance data is published in relation to indicators and targets in NCSP Annual Monitoring Reports, which cover the whole NCSP programme. These reports are reviewed by the NCSP Advisory and Action Group and published on the NCSP website.

Laboratory diagnostic reporting indicators

Laboratory diagnostic reporting indicators are specific measurable key parameters of the accuracy of laboratory diagnostic reporting. Where targets are required, most will be set after 12 months of implementation of HPV primary screening.

INDICATOR 1: HSIL, ASC-H AND TOTAL ABNORMALITIES	
NUMBER OF SAMPLES AND RATE	**Number of samples and the rate as a percentage of all satisfactory samples (Bethesda S1 and S2), reported by a laboratory in the following categories:** 1. **HSIL (TBS HS1+HS2)**. New target needed: above a certain rate 2. **ASC-H (TBS ASH)**. New indicator: target range needed 3. **Total abnormalities** (TBS G2 and G3). New target range needed
TARGETS	New targets set at 12 months after HPV primary screening implementation
REPORTED	Six monthly in Laboratory Indicator Reports and annually in NCSP Annual Monitoring Report
RATIONALE	Monitors the rate at which abnormalities are detected by cytology and investigates the possibility of under-reporting or over-reporting in specific categories of abnormality, by interlaboratory comparison.

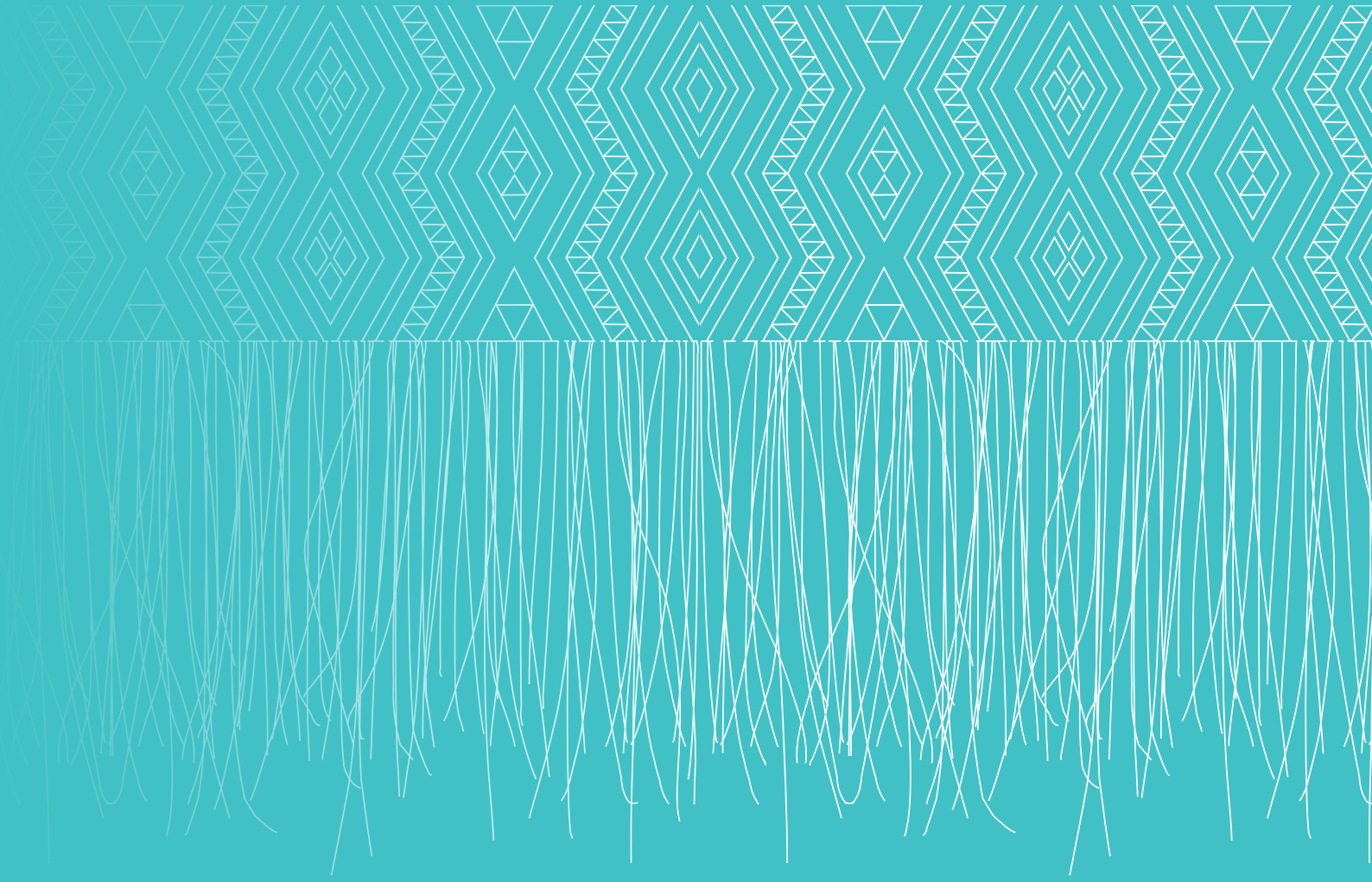
INDICATOR 2: UNSATISFACTORY CYTOLOGY SAMPLES	
NUMBER OF SAMPLES AND RATE	**Number and rate of unsatisfactory cytology samples reported**
TARGETS	Current target ranges used, based on LBC type
REPORTED	Annually in NCSP Annual Monitoring Reports
RATIONALE	Investigates the possibility of under-reporting or over-reporting of unsatisfactory cytology samples. Sample taker practice and laboratory reporting both contribute to this indicator. Laboratories are expected to work with sample takers to maintain the unsatisfactory reporting rate within acceptable limits

INDICATOR 3: INVALID HPV TEST RESULTS	
NUMBER OF SAMPLES AND RATE	1. **Number and rate of invalid HPV test results reported, by sample type: swab or LBC sample** 2. **Number and rate of unsuitable for analysis because of leaking LBC vial or HPV collection tube reports**
TARGETS	Targets set at 12 months after HPV primary screening implementation
REPORTED	Annually in NCSP Monitoring Reports
RATIONALE	The invalid/unsatisfactory HPV test reporting rate should be very low. The indicator checks that this occurs at each laboratory.

INDICATOR 4: PPVS FOR HSIL AND FOR ASC-H CYTOLOGY REPORTS	
NUMBER OF SAMPLES AND RATE	**1. The number and rate of HSIL cytology cases that are confirmed as having a high-grade lesion on histology within six months of the cytology report** **2. The number and rate of ASC-H cytology cases that are confirmed as having a high-grade lesion on histology within six months of the cytology report**
TARGETS	New targets set at 12 months after HPV primary screening implementation (as PPVs are dependent on disease prevalence)
REPORTED	Six monthly in Laboratory Indicator Reports and annually in NCSP Annual Monitoring Report
RATIONALE	A parameter of the accuracy of using HSIL and ASC-H report codes to predict high-grade histology.

INDICATOR 5: ACCURACY OF NORMAL AND LOW-GRADE CYTOLOGY REPORTING	
NUMBER OF SAMPLES AND RATE	**For cases with a histological diagnosis of HSIL, SCC, AIS or invasive endocervical adenocarcinoma, the number of cytology slides originally reported as unsatisfactory, negative, benign/reactive, ASC-US or LSIL concurrently or within the preceding nine months where on review, the original cytology report is upgraded to possible or definite high-grade, as a number and proportion of all slides reviewed.** **The results of the reviews are to be recorded in two separate groups according to whether the last positive HPV test prior to the high-grade histology was HPV Other or HPV 16/18**
TARGETS	Targets set at 12 months after HPV primary screening implementation
REPORTED	Six monthly in Laboratory Indicator Reports and annually in NCSP Annual Monitoring Report
RATIONALE	This indicator investigates the accuracy of cytology reporting prior to a high-grade diagnosis at colposcopy. It is particularly relevant for those who are HPV-Other positive, as cytology plays a key triage role. Those who are HPV 16/18 positive are included because reviewing all slides reported as less than high-grade where the outcome is a histologically confirmed high-grade lesion will assist in maintaining and developing diagnostic accuracy in cytology reporting.

INDICATOR 6: AMENDED CYTOLOGY REPORTS			
NUMBER OF SAMPLES AND RATE	**1. The number and rate of cytology reports where an amended interpretation has been issued after review in the monitoring period as a proportion of the number of slides reported by the laboratory**	NUMBER OF SAMPLES AND RATE	**2. The number and rate of amended reports as a proportion of all cases amended where:** **(a) the review diagnosis is confirmed on histology (subsequent to the date of the cytology review)** **(b) the original diagnosis is confirmed on histology (subsequent to the date of the cytology review)**
TARGETS	New targets set at 12 months after HPV primary screening implementation	TARGETS	No targets will be set for amended report accuracy outcomes
REPORTED	Six monthly in Laboratory Indicator Reports and Annually in NCSP Annual Monitoring Reports	REPORTED	The information will be provided as feedback to individual laboratories. The outcomes will not be included in NCSP monitoring reports
RATIONALE	The indicator investigates the possibility of high rates of amended reporting. Where the target is exceeded, further investigation to determine the level of upgrading, re-grading (to unsatisfactory) or down-grading will be undertaken.	RATIONALE	This information will be of direct benefit to those who review cytology cases for MDM discussion, as feedback about the quality of their case reviews. The information will be seen by the NCSP but is not of any concern to other laboratories so will not be included in any monitoring reports.



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