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National Cervical Screening Programme Policies and Standards

Section 5: Providing a Laboratory Service 2021

National Screening Unit

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Laboratory standards index

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501 Page 15	Qualifications for pathologists	All pathologists reporting gynaecological cytology and/or histology must be qualified.
502 Page 18	The lead HPV testing scientist, cytoscientist and histoscientist	Laboratories providing reporting of hrHPV testing, gynaecological 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: • a lead HPV testing scientist who is a medical laboratory scientist with qualifications or training and competencies in molecular science, previous experience with molecular HPV testing and a minimum of five years of full-time (or equivalent) experience in HPV testing • a lead cytoscientist with a minimum of five years full-time (or equivalent) gynaecological cytology experience • a lead histoscientist with a minimum of five years full-time (or equivalent) experience.
503 Page 19	Continuing professional development	All pathologists, cytoscientists and cytotechnicians, histoscientists and hrHPV testing staff must meet continuing professional development (CPD) requirements. The laboratory must keep a record of the CPD requirements that each staff member has met.
504 Page 21	Minimum volume of gynaecological 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.
505 Page 21	Minimum number of gynaecological cytology cases per pathologist per annum	Each pathologist reporting gynaecological cytology must report a minimum of 500 gynaecological LBC samples per annum.
506 Page 22	Maximum daily workloads for cytoscreeners	The maximum workload for any cytoscreener performing manual or fields of view (FOV) screening (LBC samples) is 70 fully screened slides (or an equivalent workload) on any single working day. The maximum time 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.
507 Page 23	Minimum annual workloads for cytoscreeners	Cytoscientists and cytotechnicians in a manual screening environment must primary screen a minimum of 3,000 cervical or vaginal LBC samples per annum. For cytoscientists and cytotechnicians who have completed the VRPCC and have at least five years full-time (or full-time equivalent) post-VRPCC screening experience, and cytoscientists and

No	Standard	Description
		cytotechnicians who have not completed the VRPCC and have six years full-time or full-time equivalent post-qualification screening experience, this minimum may include up to 1,200 full secondary rescreen cases.
508 Page 16	Qualifications for scientific and technical staff	All molecular scientists and technicians performing hrHPV testing, cytoscientists and cytotechnicians reporting gynaecological cytology, and histoscientists and histotechnicians preparing histology specimens must be qualified.
530 Page 37	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.
509 Page 39	Rapid rescreening outcomes	At least 98 percent of 'Negative for intraepithelial lesion or malignancy' slides must be confirmed after rapid rescreening. Laboratories must record outcomes of rapid rescreening for all cases.
510 Page 43	Full rescreening	Full rescreening must be performed for all women who have: • abnormal (G2 or G3) gynaecological cytology • had a previous low-grade (ASC-US or LSIL) abnormality and have not been returned to usual (three yearly) screening after the low-grade abnormality • had a previous high-grade abnormality and who: – had a high-grade squamous abnormality without treatment and without subsequent successful completion of a test of cure – had a glandular abnormality in the previous five years • suspicious clinical conditions, abnormal bleeding or observed cervical abnormalities, or are immune deficient. • unsatisfactory gynaecological cytology • a discrepancy between their primary screening result and their rapid rescreening result.
511 Page 45	Confirming and reporting abnormal results	All results confirmed abnormal (G2 or G3) after full rescreening must be sent to a cytopathologist for reporting.
512 Page 43	Rescreening timing	All secondary rescreening will take place before the results are confirmed and sent to the sample taker and the NCSP Register.

No	Standard	Description
513 Page 54	Reporting hrHPV tests and cytology results to sample takers	For cytology tests only (ie, without an accompanying hrHPV test), the laboratory must report: • 90 percent of final gynaecological cytology results to sample takers within 7 working days of receiving a specimen • 98 percent of final gynaecological cytology results to sample takers within 15 working days of receiving a specimen. For hrHPV and cytology tests on the same sample, the laboratory must provide: • 98 percent of completed reports containing both results to the sample taker within 15 working days of receiving the specimen.
514 Page 51	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 result) with the histology specimen/s result/s at the time of making their report.
515 Page 49	Examining and reporting histology slides	A histopathologist must examine and report all histology slides.
516 Page 54	Reporting histology results	Laboratories must report: • 90 percent of final histology results to referring specialists within 10 working days of receiving the specimen • 98 percent of final histology results to referring specialists within 15 working days of receiving the specimen.
517 Page 13	Cultural sensitivity and appropriateness	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 district health board (DHB) and iwi, who may provide policy and advice for cultural requirements regarding handling samples. Laboratories must give special consideration and follow protocols when handling any tissue, cells or samples containing Māori genetic material.
518 Page 56	Sending hrHPV with cytology results or cytology-only results to the NCSP Register	Laboratories must forward to the NCSP Register 98 percent of all reports, both cytology only and cytology with an hrHPV test result, in the approved format and Bethesda coding within 16 working days of receiving the sample.
519 Page 56	Sending histology results to the NCSP Register	Laboratories must electronically forward to the NCSP Register 90 percent of histology results in the approved format with NCSP SNOMED coding within 15 working days of receiving the sample. They must electronically forward to the NCSP Register 98 percent of histology results in the approved format with NCSP SNOMED coding within 20 working days of receiving the specimen.

No	Standard	Description
520 Page 57	Sending results to the New Zealand Cancer Registry (NZCR)	Laboratories must forward all cytology results analysed and reported as definite or suspicious of invasive cancer and all histology results with a diagnosis of CIN 2, CIN 3, AIS/SMILE or invasive cancer to the NZCR (Ministry of Health).
521 Page 68	Correlating histology and cytology slides	Laboratories must correlate all histology results with any cytology slides taken in the previous six months. If there is a discrepancy and slides are reviewed, laboratories must document the review outcome and evidence of notification of amended results to colposcopists, sample takers and the NCSP Register and NZCR (when required) for audit purposes.
522 Page 70	Reviewing previous negative cytology slides after a subsequent high-grade histology diagnosis	Laboratories must review and document the review outcome of all cytology slides reported as negative, benign/reactive or unsatisfactory in the 42 months before a high-grade or invasive diagnosis on histology.
523 Page 17	The lead NCSP services pathologist	A named and suitably qualified pathologist, known as the lead NCSP services pathologist, must lead the hrHPV testing services, gynaecological cytology and histology. That person must be a current active practitioner in gynaecological cytology and/or histology and/or microbiology/virology (as specified by standard 501) and the key laboratory pathologist in at least one of these disciplines.
524 Page 20	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.
525 Page 26	LBC sample and laboratory request form labelling policy	Pre-analytical procedures (all steps of sample registration and processing) must conform to the requirements of ISO15189: Specific Criteria Medical Testing. LBC 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).
526 Page 30	Ensuring all samples are appropriately tested or not tested for hrHPV	Laboratories must conduct hrHPV testing on all samples as defined in *Clinical Practice Guidelines for Cervical Screening in New Zealand 2020*, published by the National Screening Unit and available from their website at: **www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand).**
527 Page 31	hrHPV test technology requirements	For HPV DNA-based technologies, the hrHPV test technology used for clinician-collected samples must:

No	Standard	Description
		• 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. For biomarkers other than HPV DNA, the hrHPV test technology used for clinician-collected samples must: • meet all the above requirements for HPV DNA-based technologies • 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.
528 Page 35	Storage and disposal of hrHPV test samples	All samples must be stored according to the manufacturer's instructions.
529 Page 41	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.
530 Page 31	Validating an automated screening device	All laboratories introducing an automated screening device for the first time must comply with and document the following: • The automated device must be operated and calibrated as per the manufacturer's instructions and any non-compliance must be rectified. The validation process must be documented and made available for review. • Laboratories must undertake and record daily calibrations, as recommended by the manufacturer. • Appropriately trained staff who are competent to undertake such tasks must prepare and process slides for automated screening devices.

[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, pp 516–20.

No	Standard	Description
		• Slides that are processed and rejected either due to calibration or other reasons must be either reprocessed before repeat automated screening or manually screened. • All screening staff must undertake training and assessment that includes a wide range of abnormal cases, and they must demonstrate competency during a validation process, as defined under the NCSP NPQS section 5. 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.
531 Page 48	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: • ISO15189 (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) • The Royal College of Pathologists of Australasia (RCPA) *Anatomical Pathology Macroscopic Cut-up Manual* (available from the RCPA website at: **www.rcpa.edu.au/Manuals/Macroscopic-Cut-Up-Manual**) • RCPA, *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/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer/Cancer-Protocols/Gynaecological/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**
532 Page 53	Ensuring all HPV tests, cytology and histology samples received are reported to sample takers and specialists	Laboratories must have protocols and procedures in place to ensure they report all hrHPV test samples, gynaecological cytology samples and histology specimens they analyse to the appropriate sample takers and specialists.
533 Page 53	Reporting HPV testing and cytology results	When an 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
	(same LBC sample) in one report	
534 Page 62	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 • all other people who were 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 CIN 2 or AIS/SMILE).
535 Page 66	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 percent of high-grade abnormalities and 90 percent of total abnormalities.
536 Page 67	All laboratories reporting gynaecological cytology, histology and HPV testing participate in laboratory-based EQAPs	All laboratories reporting gynaecological cytology, histology and HPV testing must participate in laboratory-based external quality assurance programmes (EQAPs) relevant to the discipline/s practised to ensure competency through the RCPA, the World Health Organization (WHO) reference laboratory or another appropriate body.
537 Page 68	All staff reporting gynaecological cytology participate in the RCPA's individual EQAP	All staff who report gynaecological cytology (cytopathologists and cytoscreeners) must participate in the NCSP-approved Individual EQAP run by the RCPA QAP.
538 Page 66	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.

NCSP policies and standards

NCSP policies and standards

The National Cervical Screening Programme (NCSP) Policies and Standards sets 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, gynaecological 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.

The Ministry of Health (the Ministry) requires that all laboratories providing high-risk human papillomavirus (hrHPV) testing, gynaecological 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, gynaecological 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 ISO15189.

Laboratory performance is measured by NCSP audits, laboratory internal quality assurance processes, contract monitoring reports and NCSP monitoring reports.

Section 5 policies and standards are reviewed regularly by the NCSP.

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 gynaecological cytopathology (referred to as gynaecological 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 gynaecological 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 woman 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, gynaecological cytology and/or histology services as an NCSP service provider.

- All processing, evaluating and reporting of hrHPV tests, gynaecological cytology and histology must be performed on pathology laboratory premises. This work is not permitted at any other venue.
- Once a laboratory accepts 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's 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:

- process and report samples for hrHPV testing, gynaecological cytology and histology
- consult with and provide advice and results to sample takers 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 and general practitioners who take cervical screening test samples, sample taker training providers, colposcopy services and screening support services.

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® and BD SurePath™ samples. A cytology slide is prepared from an LBC sample. Cytology samples also include historical conventional cervical smears/slides.

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

Laboratory staff must consider the values and beliefs held by the various groups of people residing in 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.

Standard 517: Cultural sensitivity and appropriateness

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 DHB and iwi, who may provide policy and advice for cultural requirements regarding handling samples. Laboratories must give special consideration and follow tikanga protocols when handling any tissue, cells or samples containing Māori genetic material.

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 DHB 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/substance, 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.

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, gynaecological cytology and histology services are staffed by suitably qualified pathologists, scientists and technicians.

Policy

All laboratory staff preparing, interpreting and/or reporting hrHPV tests, gynaecological 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.

Standard 501: Qualifications for pathologists

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

Every pathologist working in gynaecological 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 subspecialty training in general pathology, histopathology and/or cytopathology as appropriate for the subspecialty 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 gynaecological 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 RCPA or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received subspecialty training in microbiology, molecular pathology, anatomic pathology or general pathology
- have received appropriate training to provide competent clinical advice and 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/**

Standard 508: Qualifications for scientific and technical staff

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

- All scientists performing or reporting hrHPV testing, cytoscientists and histoscientists must be a registered medical laboratory scientist and hold 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 subspecialty training in, for example, molecular biology/microbiology, cytology or histology if performing/reporting hrHPV testing, or practising in cytology or histology.
- All technicians performing or reporting hrHPV testing, cytotechnicians and histotechnicians must be a registered medical laboratory technician and hold a current annual practising certificate issued by the Medical Sciences Council of New Zealand, with a scope of practice of medical laboratory technician with subspecialty training in, for example, molecular biology/microbiology, cytology or histology if performing or reporting hrHPV testing, or practising within cytology or histology.
- 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 the 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 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. Each laboratory service must also have a named lead scientist responsible for providing hrHPV testing, cytology and/or histology, if the laboratory is an NSCP 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.

Standard 523: The lead NCSP services pathologist

A named and suitably qualified pathologist, known as the lead NCSP services pathologist, must lead the hrHPV testing services, gynaecological cytology and histology. That person must be an active practitioner in gynaecological cytology and/or histology and/or microbiology/virology (as specified by standard 501). 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 NPQS
- 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 gynaecological cytology/histology and/or HPV testing and who is available in the laboratory when the lead NCSP services pathologist is absent.

Standard 502: The lead HPV testing scientist, cytoscientist and histoscientist

Laboratories providing reporting of hrHPV testing, gynaecological 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 qualifications or training and competencies in molecular science, previous experience with molecular HPV testing and a minimum of five years full-time (or equivalent) experience in HPV testing
- a lead cytoscientist with a minimum of five years full-time (or equivalent) gynaecological 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, gynaecological 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, gynaecological cytology samples and histology specimens.

All departments reporting gynaecological cytology must:

- provide easy access to current editions of major standard texts, colour atlases and current issues of journals relevant to gynaecological 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.

Standard 503: 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 gynaecological cytology must meet the following requirements.

- Take part in external training in gynaecological 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 gynaecological 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 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 gynaecological 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 acceptable under 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.

Standard 524: 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.

- If the absence was 12 months or longer, the lead NCSP services pathologist or relevant lead scientist must design an individualised retraining and supervision programme for the returning staff member to complete.
- 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 member's reintroduction to their role.
- 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 gynaecological cytology process, interpret and report a minimum number of cases and employ sufficient staff to maintain a high-quality service.

Standard 504: Minimum volume of gynaecological 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.

Minimum volumes of gynaecological cytology per pathologist policy

Standard 505: Minimum number of gynaecological cytology cases per pathologist per annum

Each pathologist reporting gynaecological cytology must report a minimum of 500 gynaecological 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 500 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 524: Returning to work.

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.

Standard 506: 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
- three rapid rescreens are counted as equivalent to one 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
- secondary full rescreens 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.

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.

Standard 507: Minimum annual workloads for cytoscreeners

Cytoscientists and cytotechnicians in a manual screening environment must primary screen a minimum of 3,000 cervical or vaginal LBC samples per annum. For cytoscientists and cytotechnicians who have completed the VRPCC and have at least five years full-time (or full-time equivalent) post-VRPCC screening experience, and cytoscientists and cytotechnicians who have not completed the VRPCC and have at least six years full-time (or full-time equivalent) post-qualification screening experience, this minimum may include up to 1,200 full secondary rescreen cases.

Cytoscientists and cytotechnicians must complete a minimum of 3,000 FOV review cases per annum to maintain competency for location-guided FOV work.

In an automated environment for a mixed workload of manual full screens and FOV screening, cytoscientists and cytotechnicians must complete a minimum of 1,000 manual full screens and 3,000 FOV cases per annum.

Exemptions

Lead cytoscientists must primary screen and/or fully review a minimum of 1,000 LBC samples per annum. If their workload includes location-guided review, they must also complete a minimum of 1,000 FOV review cases per annum.

Other senior cytoscientists who have significant managerial, teaching, quality management, research or other non-cervical screening duties may also be granted the same exemption. Such exemptions must be approved by the lead cytopathologist based on the individual's roles, responsibilities and requirements in the laboratory.

The NCSP must be notified of any staff who are exempt from completing the minimum of 3,000 gynaecological LBC samples or FOV reviews per annum.

Pre-analytical requirements

Providing advice to cervical screening sample takers policy

Purpose

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

Policy

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

Details

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

- the suitability of hrHPV testing and gynaecological 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
- the terminology used in gynaecological 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 New Zealand
- sample labelling requirements and the importance of including relevant clinical details on laboratory request forms.

Sample collection policy

Purpose

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

All samples for cervical or vaginal cytology and hrHPV testing must be collected into an LBC vial. Sampling, collection, transportation, volume and storage of LBC 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 LBC samples are transported safely to the laboratory where processing will occur, without sample loss or cross-contamination with HPV.

Policy

All LBC 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, including all collection centre staff who handle LBC 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.
- LBC vials must not be opened in specimen reception.

- If an LBC vial 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 put on new gloves immediately
  - if the leaking vial is in a clam shell for transportation, the entire clam shell must be isolated, the lead molecular 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 so that they can take steps to prevent further occurrences.

Handling and identifying samples for hrHPV testing and cytology policy

Purpose

LBC vials and laboratory request forms must be labelled accurately and tracked within the laboratory.

Standard 525: LBC sample and laboratory request form labelling policy

Pre-analytical procedures (all steps of sample registration and processing) must conform to the requirements of ISO15189: Specific Criteria Medical Testing.

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

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

If a sample taker 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.

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. They must also have systems in place to ensure that staff handling LBC vials for hrHPV testing understand and carry out this requirement.

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 woman).

Test information

- Date of the test
- Type of sample (ie, SurePath™ or ThinPrep®)
- Collection site
- 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 woman is immune-deficient.
- Any history of abnormal hrHPV tests or cervical cytology/histology results reported outside 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 taker.

Sample taker information

- Health facility identifier (ID) number
- Sample taker's registration (ID) number
- Sample taker's name
- Name and address of clinic.

Other information

- Contact details of anyone who needs a copy of the result
- The reason for any request for urgent processing, with a contact number if the result needs to be given by phone.

See also

- NCSP policies and standards Section 3: Cervical Screening Services.
- IANZ. 2014. *IANZ Specific Criteria for Accreditation: Medical testing AS LAB C 7*, 2nd edition. Auckland: International Accreditation New Zealand (IANZ).

Leaking and low fluid volume LBC vials

Laboratories must document leaking sample vials that have been caused by inadequate sealing and attempt to salvage the sample.

For cytology

- If the cellular yield is unsatisfactory and only normal cells are identified, the slide must be reported as unsatisfactory and the sample taker must be informed.
- If an excessive amount of the sample has been lost, the sample is unsatisfactory and the sample taker must be notified (refer to manufacturer's instructions).
- If abnormal cells are identified, the sample is reportable with a note to the sample taker indicating that part of the sample was lost.
- Laboratories must follow specified protocols for reporting and handling unsatisfactory samples (refer to Bethesda 2001 (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 restaining according to the manufacturer's instructions. Any repeat processing must be documented.

For hrHPV testing

- Testing must not be performed on any leaking vial because of the risk of cross-contamination.
- If HPV testing has been requested by a sample taker and the vial is leaking, the HPV test must not be registered or reported.

- Samples for hrHPV testing that are not processed because of leakage must be documented in a report to the sample taker who requested the test, with a copy to anyone else who would have received the test report.

Accessing the NCSP screening history

Laboratories will access the patient's screening history directly from the NCSP Register using the online screening histories. If electronic access is not available, laboratories can ask the Register Central Team at the NCSP National Coordination Centre to send a woman's screening event history by fax (or other secure means). They must provide the woman's:

- surname
- first name
- any other name known by
- 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.

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 New Zealand 2020*. 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.

Standard 526: 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 New Zealand 2020* (available from the NSU website at: www.nsu.govt.nz/publications/guidelines-cervical-screening-new-zealand).

If a participant's NCSP Register history indicates eligibility for a test of cure as follow-up after previous high-grade results and this was not ordered by the sample taker, the laboratory must add a comment to the report encouraging the sample taker to consider ordering a test of cure. The comment must explain how the sample taker can arrange hrHPV testing for the test of cure, either using the current sample before the LBC vial disposal date or with the participant's next cervical cytology sample.

If a participant's NCSP Register history indicates eligibility for the second co-test of a test of cure and an HPV test was not ordered by the sample taker, the laboratory may perform HPV testing on the sample in addition to cytology, as consent for the HPV test should have been given when the first co-test was performed.

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 manufacturer's instructions to ensure accurate results. Laboratories must comply with section 5.5 of the Specific Criteria for Medical Testing (7) IANZ 2014.

Standard 527: 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.

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

- meet all the above requirements for HPV DNA-based technologies
- 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 percent hrHPV positive samples including 10 percent of HPV-16 plus HPV-Other cases, and 5 percent of HPV-18 plus HPV-Other cases) with a clinically validated reference assay. The testing must achieve at least 87 percent 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[2]
- details of sample selection and annotation
- full details of test method verification

[2] 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.

    - 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 5.5.1.2 Validation of examination procedures in IANZ's Specific Criteria Medical Testing
- 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.

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 must be collected between six weeks and three months of the initial test.

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

Quality assurance for oncogenic HPV testing

Laboratories must comply with the requirements of ISO15189:2012 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 ISO15189 and standard 5.6.2.3.

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 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

- ISO15189:2012 – Medical laboratories: Requirements for quality and competence
- IANZ's Specific Criteria Medical Testing (2014)
- NPAAC's Requirements for Medical Testing of Microbial Nucleic Acids.[3]

Standard 528: Storage and disposal of hrHPV test samples

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

- If possible, extracted DNA 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 the LBC vial must be retained until cytology and hrHPV testing have been reported, and for a minimum of one month after the sample was received.

[3] NPAAC. 2013. *Requirements for Medical Testing of Microbial Nucleic Acids.* Canberra: Australian Government Department of Health. URL: **www1.health.gov.au/internet/main/publishing.nsf/Content/E688964F88F4FD20CA257BF0001B739D/$File/V0.25%20NAD%20Human%20Genetics.pdf** (accessed 20 June 2020)

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 ISO15189 requirements.

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

Slide staining

LBC slide staining must be performed as follows.

- Gynaecological 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 2001 (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 restaining 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.

Standard 530: 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.

Standard 529: 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 250 cases, with the first half weighted with more abnormal cases
- a minimum of 1,500 FOV cases fully screened by a different cytoscreener in accordance with Standard 510: Full rescreening policy, (additional to the training and test set cases for validation), achieving:
  - a detection sensitivity of at least 95 percent of all high-grade abnormalities and 90 percent of the total abnormalities identified as high-grade or abnormal respectively
  - a specificity of at least 85 percent of all true negative cases identified as negative/reactive. If normal endometrial cells in women 40 years of age and over are present 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 250 FOV cases with full screening by a different cytoscreener are required 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

If manual screening is used without the use of automated screening devices, two appropriately qualified and competent cytoscreeners must screen cytology slides for each case, with one full screen and one rapid rescreen, *or* two full screens, in order to maximise the sensitivity of the screening process.

Manual screening requirement

All cases that are fully screened manually must have a full primary screen followed by either a rapid rescreen or a second full rescreen by a different cytoscreener before reporting or referral to a pathologist.

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.
- All staff performing primary screening must demonstrate their ability to detect abnormalities at full manual primary screening before any of their cases can be reported after rapid review.
- The primary cytoscreener must identify if the case requires rapid review or full rescreening.
- All cytology screening and rescreening (rapid and full) must be completed before a result is reported to the sample taker and the NCSP Register.
- Pathologists cannot carry out first or second full manual screens of cervical cytology slides for reporting purposes.

Any slides screened by a Bachelor of Medical Laboratory Science graduate holding provisional registration with the Medical Sciences Council of New Zealand (eg, first year of post-qualification employment) must then be fully primary screened by a registered cytoscientist or cytotechnician with a full annual practising certificate, followed by rapid rescreening or full rescreening as required, by a different registered cytoscientist or cytotechnician with an annual practising certificate. This process continues until the graduate receives their full annual practising certificate.

Rapid rescreening after primary manual screening policy

Purpose

To rapidly rescreen slides categorised as 'Negative for intraepithelial lesion or malignancy' at primary manual screening, as a second check for abnormal cells before a negative report is issued.

Policy

Laboratories that manual screen only or have not fully converted to automated screening must conduct rapid rescreening of all manually primary screened slides categorised as 'Negative for intraepithelial lesion or malignancy', except for negative slides requiring a full rescreen under Standard 510: Full rescreening. The outcomes of all rapid rescreens must be recorded.

Details

- Rapid rescreening is when a second cytoscreener performs a rapid (minimum 60 second) rescreen of the slide.
- Rapid rescreening must be carried out by cytoscientists or cytotechnicians designated by the laboratory's lead cytoscientist or lead pathologist.
- All staff performing rapid rescreening must have demonstrated their ability to detect abnormalities using this method.
- All rapid rescreening must take place before the results are confirmed and sent to the sample taker and the NCSP Register.

Standard 509: Rapid rescreening outcomes

At least 98 percent of 'Negative for intraepithelial lesion or malignancy' slides must be confirmed after rapid rescreening. Laboratories must record outcomes of rapid rescreening for all cases.

Primary location-guided screening policy

Purpose

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

Policy

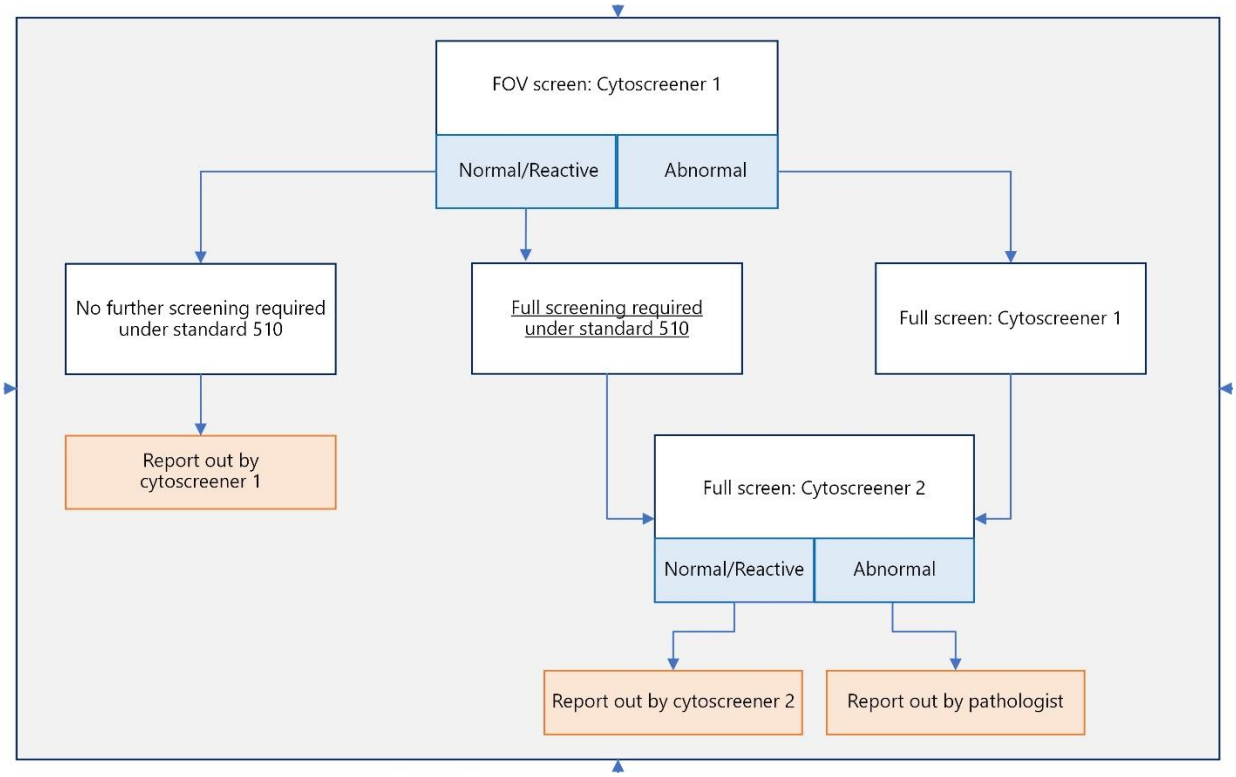
Laboratories may conduct a location-guided FOV review of any slide that has been satisfactorily scanned using an automated screening device as part of an NCSP-approved screening process. Cytoscientists and cytotechnicians performing FOV review must have demonstrated their ability to detect abnormalities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

Definitions

- Field of view (FOV) – Microscopic FOV at x10 objective magnification selected and presented to the cytologist 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
- Secondary rescreen – A second full manual screen performed after the FOV review when a first full manual screen has also been completed. Most second full rescreens will be performed because an abnormality has been identified at the first full screen stage.

Cases requiring a full screen (see standard 510: Full rescreening) must receive a minimum of FOV review with at least one full screen performed by a different staff member.

Laboratories can elect to perform additional full-slide reviews if desired, for example, requiring the cytoscreener who performs the FOV review to fully manual screen slides under standard 510 before full rescreening by a second cytoscreener.



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.

The cytoscreener performing FOV review must determine if the case is suitable for reporting after FOV review only or if full screening is required.

If **no epithelial abnormality is identified at FOV review** and there is no requirement for full rescreening under standard 510: Full rescreening, the cytoscreener who performed the FOV review may report the case without further screening or quality control review.

For each case with additional full screening, laboratories must correlate and record the outcome if there is a discrepancy between the FOV result and the final result.

Any **epithelial abnormality identified at FOV review** must be followed by a minimum of one manual full screen performed by a different staff member.

If a fully automated laboratory has to temporarily revert to manual screening (eg, due to equipment failure), then all primary screened samples must be rescreened in accordance with all sections of the NCSP policies and standards relating to manual screening (including staffing, reporting and procedural requirements).

Pathologists are not permitted to carry out FOV reviews, or first or second full rescreens of cervical cytology slides, as part of the reporting process in an automated environment.

Full rescreening policy

Purpose

To ensure that full rescreening for gynaecological cytology is performed for cases with an abnormality identified at primary screening or at location-guided FOV review, or if the risk of abnormality is known to be higher than that of the total screening population.

Policy

Full manual rescreening must be performed for gynaecological cytology samples from women in clinical circumstances associated with evidence of an increased risk of cervical/vaginal preneoplastic or neoplastic disorders.

Standard 510: Full rescreening

Full rescreening must be performed for all women who have:

- abnormal (G2 or G3) gynaecological cytology
- had a previous low-grade (ASC-US or LSIL) abnormality and have not been returned to usual (three yearly) screening after the low-grade abnormality
- had a previous high-grade abnormality* and who:

– had a high-grade squamous abnormality without treatment and without subsequent successful completion of a test of cure

– had a glandular abnormality in the previous five years

- suspicious clinical conditions, abnormal bleeding or observed cervical abnormalities, or are immune deficient.
- unsatisfactory gynaecological cytology
- a discrepancy between their primary screening result and their rapid rescreening result.

* It is best practice to also perform full rescreening for women who have had a high-grade squamous lesion treated by excision (eg, LLETZ or cone biopsy), but without subsequent successful completion of a test of cure, who are having any one of the first three cytology samples after treatment. This is not mandatory in the current LBC cytology-based screening programme.

Details

In a **non-automated manual screening environment**, only the following staff designated by the lead cytoscientist may carry out full rescreening of gynaecological cytology:

- cytoscientist or cytotechnician who has completed the VRPCC and has at least one year full-time equivalent experience post-qualification
- cytoscientist or cytotechnician who has not completed the VRPCC and who has at least two years full-time equivalent experience post-qualification.

For a cytoscientist or cytotechnician who is new to New Zealand and starting work in cytology, the lead cytoscientist and lead cytopathologist must first assess their individual experience and competency to carry out full rescreening.

In an **automated screening environment** only the following staff who are designated as competent by the lead cytoscientist at the laboratory, may carry out manual rescreening of gynaecological cytology:

- cytoscientist or cytotechnician already undertaking full manual rescreening
- cytoscientist or cytotechnician who has completed the VRPCC and has demonstrated competency by actively participating in full manual screening over a period of at least one year full-time equivalent working experience (post-VRPCC) on first full screens of imager-generated slides.

A qualified cytoscientist or cytotechnician who has not achieved competency to fully rescreen slides must complete either:

- the VRPCC and the equivalent of one year full-time equivalent work experience with full manual screening on first full screens of imager-generated slides post-VRPCC qualification, or
- the equivalent of two years full-time equivalent work experience with full manual screening on first full screens of imager-generated slides post-qualification.

Standard 512: Rescreening timing

All secondary rescreening must take place before the results are confirmed and sent to the sample taker and the NCSP Register.

Changing LBC technology policy

If a cytoscreener 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 other LBC type, they must undertake full training. This means:

- complying with the training requirements of the LBC manufacturer
- complying with the NCSP policies and standards
- 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 other automated system, they must undertake full training. This means:

- complying with the training requirements of the LBC manufacturer
- complying with the NCSP policies and standards
- completing any additional competency requirements of the individual laboratory.

The lead services pathologist must ensure that the training is documented and that the individual concerned is signed off as competent to screen and/or report using the new technique.

Cytopathologist reporting policy

Purpose

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

Standard 511: Confirming and reporting abnormal results

All results confirmed abnormal (G2 or G3) after full rescreening 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 New Zealand 2020* to encourage optimal and consistent management of women across 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 New Zealand 2020*.

Details

- Laboratories must ensure that a woman'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 woman's complete NCSP screening event history in accordance with the *Clinical Practice Guidelines for Cervical Screening in New Zealand 2020*
- 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 people who were 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 534: Reporting changes to cytology or histology results.
- NCSP *Clinical Practice Guidelines for Cervical Screening in New Zealand 2020* 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 ISO15189.

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.

Standard 531: 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:

- ISO15189 (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**

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 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 woman with adenocarcinoma in situ (AIS) who decides to proceed to hysterectomy, a woman 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 woman had not returned to regular interval screening before hysterectomy) and there is a concurrent hrHPV Detected test result (any subtype) or her 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

Standard 515: 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).[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.

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

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 should be specified as 'indeterminate' and the reason explained.

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 requirements apply in New Zealand.

- For AIS and/or SMILE, distances to excision margins (ectocervical, endocervical and radial/deep stromal) that are less than 5 mm must be measured and documented in the report.
  - If the surface epithelium is stripped, the measurement should be to the end of the intact surface epithelium.
- For HSIL, measuring distances to surgical margins is not required.

Reporting FIGO staging for invasive cervical cancers

If possible, and particularly when the invasive cancer is completely excised, the histology report must include International Federation of Obstetricians and Gynecologists (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 (CIN 3).
- 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

Standard 514: 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 and specialists policy

Purpose

To ensure that gynaecological 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 2001 (NZ Modified) terminology to sample takers, and all histology samples to the referring specialist using the NCSP-approved SNOMED coding, in a timely manner.

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

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

Standard 533: Reporting HPV testing and cytology results (same LBC sample) in one report

When an 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.

Timeframes for reporting to sample takers and specialists

Standard 513: Reporting hrHPV tests and cytology results to sample takers

For cytology tests only (ie, without accompanying hrHPV tests), the laboratory must report:

- 90 percent of final gynaecological cytology results to sample takers within 7 working days of receiving a specimen
- 98 percent of final gynaecological cytology results to sample takers within 15 working days of receiving a specimen.

For hrHPV and cytology tests on the same sample, the laboratory must provide:

- 98 percent of completed reports containing both results to the sample taker within 15 working days of receiving the specimen.

Standard 516: Reporting histology results

Laboratories must report:

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

Details

Histology diagnoses must be coded using the SNOMED 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 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, gynaecological cytology and histology test results.

Policy

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

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

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

All electronic data must contain:

- full family name and given name
- date of birth
- contact address
- ethnicity (if available)
- NHI number
- the sample taker 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.

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, and 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 (accessed 22 June 2020)**
- National Coordination Centre contact details available at **https://www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/ncsp-register**

Standard 518: Sending hrHPV with cytology results or cytology-only results to the NCSP Register

Laboratories must forward to the NCSP Register 98 percent of all reports, both cytology only and cytology with an hrHPV test result in the approved format and Bethesda coding within 16 working days of receiving the sample.

Standard 519: Sending histology results to the NCSP Register

Laboratories must electronically send to the NCSP Register 90 percent of histology results in the approved format with NCSP SNOMED coding within 15 working days of receiving the specimen.

Laboratories must electronically send to the NCSP Register 98 percent of histology results in the approved format with NCSP SNOMED coding within 20 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.

Standard 520: 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 (Ministry of Health).

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:
  - CIN 2
  - CIN 3
  - CIN 2/CIN 3 when reported together
  - 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 the Ministry of Health 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.
- Guideline 19 in the NSU's *Clinical Practice Guidelines for Cervical Screening in New Zealand 2020*,[5] states that an MDM discussion should include (but is not limited to) cases of:

– HSIL (CIN 2) in women aged under 25 years
– high-grade or invasive cytology *and* normal or low-grade histology or colposcopy
– abnormal glandular cytology *and* no identified lesion at colposcopic assessment
– normal colposcopic assessment of women with possible high-grade disease on cytology.

All laboratories reporting gynaecological 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.

[5] 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).

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).

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 women.

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 a case/s at an MDM, or if relevant 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 NPQS Section 5: Issuing amended reports policy. By amending the report, the reviewing pathologist takes responsibility for the 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 NPQS Section 5: Issuing amended reports policy.

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 women 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 woman's colposcopist is responsible for communicating the MDM recommendations to her 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.

Standard 534: 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 CIN 2 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 New Zealand 2020*, 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, gynaecological cytology and/or histology services.

Details

Laboratories must inform the Ministry of Health 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
- ensure that the test or technology has been notified to IANZ in accordance with the requirements of their contract
- communicate details of any transition to new tests or technologies to sample takers well in advance of implementation, to allow ample time for sample takers 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, gynaecological 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 Medical Testing. Specific systems must be in place for:

- evaluating the individual performance of cytoscientists, cytotechnicians and cytopathologists reporting gynaecological 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
- following up cases in order to correlate the results of gynaecological cytology with concurrent or subsequent gynaecological histology
- reviewing the previous 42 months of gynaecological cytology slides reported as negative/benign/unsatisfactory when subsequent high-grade/invasive histology is identified or notified.

Evaluating individual performance policy

Purpose

Monitoring of individuals is needed to ensure consistent reporting between individual cytoscreeners and individual pathologists 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.

Standard 535: 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 percent of high-grade abnormalities and 90 percent 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.

Standard 358: Monitoring cytopathologist performance

The lead pathologist 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 protocols, outcomes and any 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** (accessed 22 June 2020)
- ISO15189:2012 – Medical laboratories: Requirements for quality and competence.

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, gynaecological 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.

Standard 536: All laboratories reporting gynaecological cytology, histology and HPV testing participate in laboratory-based EQAPs

All laboratories reporting gynaecological 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/**

Standard 537: All staff reporting gynaecological cytology participate in the RCPA's individual EQAP

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

Correlation of cytology and histology policy

Purpose

To ensure that laboratories correlate cytology and histology results and review all cases where a discrepancy in the cytology and histology results has clinical management implications.

Policy

If there is discrepancy between histology results and cytology reported within the previous six months, laboratories must review the cytology and histology slides to ensure optimal clinical management. Reviewing slides with known outcomes also provides valuable educational and quality improvement feedback for staff.

In correlating histology and cytology, it is best practice for:

- cervical histology specimens to be sent to the laboratory that reported the referral gynaecological cytology
- excisional cervical histology specimens to be sent to the laboratory that reported the preceding cervical punch biopsy histology.

Standard 521: Correlating histology and cytology slides

Laboratories must correlate all histology results with any cytology slides taken in the previous six months. If there is discrepancy and slides are reviewed, laboratories must document the review outcome and evidence of notification of amended results to colposcopists, sample takers, the NCSP Register and NZCR (when required) for audit purposes.

Histology and cytology slide reviews are mandatory or recommended when discrepancies have occurred, as shown in the table below.

Histology–cytology correlations

Cytology	Histology	Mandatory reviews	Recommended reviews
HSIL/invasive SCC	LSIL/negative/reactive	Yes	_
AIS/AG4/AG5 AC1-AC5	Negative/reactive	Yes	_
Unsatisfactory/negative	HSIL/invasive SCC/glandular abnormalities/invasive adenocarcinoma	Yes	_
ASC-US/LSIL/AIS	HSIL/invasive SCC	_	Yes
AGC/ASC-US/LSIL/HSIL	Glandular abnormalities/invasive adenocarcinoma	_	Yes
ASC-H/AG1/AG2/AG3	Negative/reactive	_	Yes

Slide review procedure when histology/cytology discrepancies are identified

A senior cytoscientist or pathologist must review all cytology and histology slides when discrepancies need a mandatory review.

- If the histology and cytology have been reported in the same laboratory, the lead cytopathologist is responsible for ensuring that all relevant slides are reviewed, the review outcome is documented and any amended results are communicated to the colposcopist, the sample taker and the NCSP Register or NZCR in accordance with the NPQS Section 5: Issuing amended reports policy.
- If the cytology and the histology are not reported in the same laboratory, the lead cytopathologist at the laboratory where the cytology is reported must ensure that all relevant slides are reviewed, the review outcome is documented, and any amended

results are communicated to the colposcopist, the sample taker and the NCSP Register or NZCR in accordance with the NPQS Section 5: Issuing amended results policy.

- Histology slides may be reviewed at the reporting laboratory, sent to the laboratory where the cytology was reported for the histology review or reviewed at MDM meetings.
- If requested for correlation review, the results of previous cytology/histology reports and slides must be made available in a timely manner to the requesting cytology/histology laboratory.

The outcome of all reviewed cases must be documented and assessed to determine if further action is required.

- Any cytology that remains HSIL/AIS or greater with histology that is less than high-grade after review must be communicated to the colposcopist if this has not already occurred.
- If any result is amended by the review, the original reporting pathologist (or cytoscreener/cytopathologist if a cytoscreener issued the original report) 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 the NPQS Section 5: Issuing amended results policy.

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

Purpose

To ensure that:

- pathologists, cytoscientists and cytotechnicians regularly review cases in which a high-grade abnormality may have been missed
- laboratories keep appropriate records of reviews of cytology cases reported as negative, benign/reactive or unsatisfactory in the 42 months before a high-grade or invasive diagnosis on histology
- laboratories have an indication of their false negative reporting with respect to detecting high-grade lesions
- the review process and outcomes are used to help educate all staff involved in reporting cervical cytology
- data is available for measuring the NCSP indicator 'Accuracy of negative cytology'.

Policy

The laboratory must document the results of the review of all cases reported as negative, benign/reactive or unsatisfactory in the 42 months before a high-grade or invasive diagnosis on histology.

Details

The NCSP National Coordination Centre cervical screening 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 at that individual laboratory. This report allows laboratories to identify cases that need to be reviewed for quality assurance purposes.

Standard 522: Reviewing previous negative cytology slides after a subsequent high-grade histology diagnosis

Laboratories must review and document the review outcome of all cytology slides reported as negative, benign/reactive or unsatisfactory in the 42 months before a high-grade or invasive diagnosis on histology.

Previous negative cytology slide reviews must be undertaken by a senior cytoscientist or senior cytotechnician approved by the lead cytoscientist. If there is a lack of consensus on the review outcome, a pathologist must review the case.

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 New Zealand 2020,* 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**

Retaining slides, tissue and documentation

Retaining slides, tissue and associated documentation policy

Purpose

All gynaecological 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 to enable 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 NPQS Section 5 Standard 517: Cultural sensitivity and appropriateness. Women 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
Gynaecological 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	6 years
LBC vials	1 month after the sample has been received or until the sample has been reported, if longer
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.

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 gynaecological cytology and/or histology

If a laboratory stops hrHPV testing, gynaecological cytology and/or histology reading, it must comply with the relevant contract provisions to ensure that all 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 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

Indicators for monitoring the NCSP are reported regularly in NCSP monitoring reports and are reviewed periodically. Indictors for monitoring laboratory performance are as follows.

- Laboratory-specific performance is reviewed in relation to indicators and targets on a six-monthly basis by the NCSP advisory group. Issues arising from the reports are followed up by the NCSP.
- Laboratories receive six-monthly monitoring reports and are expected to use the reports as part of their internal quality control processes.

Laboratory sample reporting

Indicator L1

Number of samples reported by laboratory in the following categories as a percentage of all satisfactory samples (Bethesda S1 and S2):

- Negative for intraepithelial lesion or malignancy (TBS G1) = Not more than 96 percent reported as negative
- HSIL (TBS HS1+HS2) = not less than 0.5 percent reported as HSIL
- Total abnormalities (TBS G2 and G3) = Not more than 10 percent reported as total abnormalities.

Note: The case mix (ratio of community versus hospital cases) is taken into consideration when monitoring the laboratory total abnormality rate.

Indicator L2

Not currently in use.

Unsatisfactory samples by laboratory

Indicator L3

The number of LBC samples by laboratory reported as unsatisfactory (TBS UA-UG) is not less than 0.1 percent and not more than 3.0 percent.

Accuracy of cytology reports predicting HSIL/SCC on histology

Indicator L4

Target for PPV for HSIL/SCC = 65–85 percent.

Accuracy of negative cytology reports

Indicator L5

For women with a histological diagnosis of CIN2, CIN3, invasive SCC, AIS or invasive endocervical adenocarcinoma, the proportion of cytology slides originally reported within the preceding 42 months as negative, benign/reactive or unsatisfactory that on review are consistent with:

- HS1, HS2, SC, AIS or AC1-5 = not more than 10 percent combined
- ASC-H, HS1, HS2, SC, AG4-5, AIS or AC1-5 = target of less than 15 percent, but not more than 20 percent combined.