



National Cervical Screening Programme

Operational Policy and Quality Standards

Section 5: Providing a Laboratory Service (interim)

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Overview and Objectives

Objectives

This section aims to provide health professionals with policies, guidelines and standards to enable them to provide an appropriate level of laboratory service. This ensures that all aspects of the screening pathway relevant to gynaecological cytology and/or histology are:

- meeting the NCSP standards
- able to be reviewed for the purpose of continually improving the service.

Compliance with policies and standards

It is a requirement of the Ministry of Health that all laboratories providing services to the NCSP will comply with the policies and standards set out in this section.

All policies and standards will be audited regularly.

Primary objective of gynaecological cytology

The primary objective of gynaecological cytology is to predict the nature of any pathological changes present in cervical squamous cells, and where possible also identify any glandular abnormalities.

The interpretation of gynaecological cytology samples involves the detection and interpretation of subtle changes in cell structure.

Limitations

It is acknowledged that there are limitations on diagnostic accuracy that result in recognised false negative and false positive rates, despite following “best practice”.

Primary objective of gynaecological histopathology

The primary objective of gynaecological histopathology is to ascertain the nature and extent of tissue abnormalities present in the submitted tissue.

Primary objective of high risk human papillomavirus testing

The primary objective of high risk human papillomavirus (HrHPV) testing is to provide ancillary testing to cytology to detect the presence of HrHPV subtypes which increase risk of developing high grade or worse lesions of the cervix.

Introduction to Laboratories

Reference to laboratory

The term 'laboratory' applies to each individual fixed laboratory site and includes all community laboratories and hospital laboratories carrying out gynaecological cytology and/or histology services.

All processing, evaluation and reporting of gynaecological cytology, histology and HrHPV testing must be performed on pathology laboratory premises. Screening is not permitted at any other venues; such as in the homes of screening staff.

Key functions

Laboratories have the following key functions:

- processing and reporting on gynaecological cytology and histology samples
- reporting results to smear takers and specialists
- forwarding results to the NCSP-Register
- forwarding relevant results to the Cancer Registry
- collaborating with the NCSP-Register Central Team
- providing advice to smear takers
- providing advice to specialists managing cervical disease.

In providing laboratory services to the NCSP, it is expected that laboratories will develop co-operative working relationships with other providers in the NCSP, in particular, smear takers, general practitioners, colposcopists, the NCSP-Register Central Team and their NCSP Regional Service.

Laboratories must provide to smear takers a consultative and advisory service, not simply a 'results only' service.

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Introduction to Laboratories, Continued

Laboratory staff

Staff making up a laboratory service includes:

- pathologists who are medical graduates with specialist qualifications in pathology
 - cytoscientists who are medical laboratory science or science graduates with specialised training in cytology (previously called cytotechnologists)
 - cytotechnicians who are laboratory trained in cytology and have gained the New Zealand Institute of Medical Laboratory Science’s Qualified Medical Laboratory Technician Certificate (previously called Qualified Technical Assistants (QTAs))
 - histoscientists who are medical laboratory science or science graduates with specialised training in histology
 - histotechnicians who are laboratory trained in histology and have gained the New Zealand Institute of Medical Laboratory Science’s Qualified Medical Laboratory Technician Certificate
 - scientists and technicians, where appropriate, take responsibility for the supervision of unregistered trainees or other staff members who are required to work under supervision
 - molecular biologists with expertise in HrHPV testing.
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Cytology samples

A cytology sample refers to both conventional cervical smears and liquid-based cytology (LBC) samples (e.g. Hologic ThinPrep® and BD SurePath™ specimens). Reference to a cytology slide includes both conventional smears and slides prepared from LBC samples.

Histology samples

A histology specimen includes punch biopsies, endocervical curettings, wedge biopsies, loop excisions (LEEP), large loop excisions (LLETZ), cone biopsies and hysterectomy specimens with a cervical component.

Cultural consideration

Appropriate consideration must be given to the various cultural contexts experienced in New Zealand. Particular attention must be shown to the cultural needs of Māori.

Kei motu te hono tangata.

Let the human link not be broken.

Staffing

Staffing Qualifications Policy

Purpose That the laboratory service is staffed by suitably qualified pathologists, scientists and technicians and professionally led by a suitably qualified pathologist.

Policy All pathologists, scientists and technicians reporting gynaecological cytology or histology and histoscientists and histotechnicians preparing histology specimens for the NCSP must have appropriate qualifications and be competent as defined under the Health Practitioners Competency Assurance Act 2003. All pathologists, cytoscientists and cytotechnicians reporting LBC specimens must first have completed an appropriate training course.

The requirements for each category of health professional are listed below.

Pathologists

Each pathologist working in gynaecological cytology or histology must:

- be a Fellow of the Royal College of Pathologists of Australasia, or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received sub-speciality training in general pathology, anatomical pathology or cytopathology
- must have a qualification to cover the sub-specialty in which the pathologist is working
- must 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
- pathologists who are not vocationally registered (have provisional or general registration) must work under supervision as required by the Medical Council of New Zealand.¹

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¹ Guidance for doctors working in supervised practice and their supervisors (May 2004) at www.mcnz.org.nz.

Staffing, Continued

Staffing Qualifications Policy, Continued

Policy, continued

Technical Staff

All cytoscientists and cytotechnicians reporting gynaecological cytology, and histoscientists and histotechnicians preparing histology specimens must have the following qualifications:

- a cytoscientist or histoscientist must be a registered health practitioner holding a current annual practising certificate issued by the New Zealand Medical Laboratory Science Board (NZMLSB) (Te Poari Mātai Oranga), with a scope of practise of Medical Laboratory Scientist with subspecialty training in cytology or histology, if practising within cytology or histology (respectively)
- a cytotechnician or histotechnician must be a registered health practitioner holding a current annual practising certificate issued by the NZMLSB, with a scope of practise of Medical Laboratory Technician with subspecialty training in cytology or histology, if practising within cytology or histology (respectively).

Staff reporting on HrHPV testing must be appropriately trained and qualified.

Details

The gynaecological cytopathology service must be professionally led by a named pathologist, who is currently reporting gynaecological cytology, and who is responsible for:

- delivering the agreed services in accordance with the NCSP Operational Policy and Quality Standards
- being available in the laboratory every working day or delegating this responsibility to another pathologist who is also currently reporting gynaecological cytology.

Responsibilities include:

- reporting results
 - managing a quality assurance programme
 - provision of in-service training
 - auditing of laboratory practice
 - liaising with clinical colleagues
 - liaising with the NCSP and NCSP-Register Central Team
 - monitoring of health and safety within the laboratory
 - facilitating a collaborative team-work environment amongst scientists, technicians and pathologists
 - managing the laboratory's gynaecological cytology service in partnership with the lead cytoscientist
 - ensuring the assimilation of new developments in the field and introducing these into the laboratory where they demonstrate an improvement in the service provided.
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Staffing, Continued

Staffing Qualifications Policy, Continued

Vocational Registration Programme for Cervical Cytology It is mandatory for all trainee cytotechnicians, and all Bachelor of Medical Laboratory Science graduates entering into cervical cytology for the first time, to undertake the Vocational Registration Programme in Cervical Cytology. This is to ensure minimum standards of competency are achieved before gaining an annual practising certificate.

See also

- Medical Council of New Zealand’s policy on registration at www.mcnz.org.nz/Registration/tabid/56/default.aspx
 - Code of Competencies and Standards for the Practice of Medical Laboratory Science at [_www.mlsboard.org.nz](http://www.mlsboard.org.nz)
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Standard 501: Qualifications for Pathologists

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

Target Every pathologist working in gynaecological cytology or histology must meet the following requirements:

- be a Fellow of the Royal College of Pathologists of Australasia or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received training in general pathology, anatomical pathology or cytopathology
- have a Fellowship covering the sub-specialty in which the pathologist is working
- if a pathologist is not vocationally registered (e.g. has provisional or general registration) they must work under supervision, as required by the Medical Council of New Zealand.

Method of measurement The following methods of measurement are used:

- provider compliance audits.

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Staffing, Continued

Staffing Qualifications Policy, Continued

Standard 502: Senior Cytoscientist Requirements for Laboratories Conducting Gynaecological Cytology Screening

Standard Laboratories conducting gynaecological cytology screening must employ at least one senior registered cytoscientist who has a minimum of five years full time (or equivalent) cytology experience.

Target That each laboratory reporting gynaecological cytology has at least one senior cytoscientist with a minimum of five years full time (or equivalent) cytology experience.

Measurement The following methods of measurement are used:

- provider compliance audits.

Standard 508: Qualifications for Screening Staff Reporting Gynaecological Cytology

Standard All screening staff reporting gynaecological cytology must be qualified cytoscientists or cytotechnicians.

Target That 100% of screening staff reporting gynaecological cytology are qualified cytoscientists or cytotechnicians.

Measurement The following methods of measurement are used:

- provider compliance audits.

Continued on next page

Staffing, Continued

Continuing Education Policy

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

Policy Continuing education is mandatory for all staff reporting gynaecological cytology and/or histology.

The following minimum continuing education requirements must be met by pathologists, cytoscientists and cytotechnicians:

- documented attendance at an internal and/or external teaching programme in cytology for neoplasms and associated diseases of the uterus, cervix and vagina
- current editions of major standard texts, colour atlases, and current issues of journals relevant to gynaecological cytology and histology must be available within the laboratory or accessible via the internet
- provision for all medical, scientific and technical staff to attend relevant local and international professional meetings regularly.

Continuing education undertaken must be recorded within the laboratory.

Details

Please note the following details:

- all pathologists, cytoscientists and cytotechnicians reporting gynaecological cytology must take part in an external refresher course in cervical cytology every three years. An external refresher course is defined as a total of three days over three years (one three day course or three days spread over three years) with at least 50% practical microscopy component, and
 - participate in in-house continuing education in gynaecological cytology and/or histology. This must be structured to provide each staff member the equivalent of four days annually per FTE to enable staff to meet continuing professional development requirements
 - the laboratory must maintain a record of individual staff member's participation in continuing education. These records must be available for inspection by any audit body
 - all pathologists, cytoscientists and cytotechnicians must participate in external quality assurance programmes and regularly attend conferences
 - all pathologists must regularly attend cytology/histology correlation meetings.
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Staffing, Continued

Continuing Education Policy, Continued

Standard 503: Continuing Professional Development Requirements for Cytoscientist and Cytotechnician Staff and Pathologists

Standard **At least the minimum continuing professional development requirements must be met by all pathologists, cytoscientists and cytotechnicians and this is to be recorded within the laboratory.**

Target

- That all pathologists, cytoscientists and cytotechnicians meet the minimum continuing professional development requirements.
- All laboratories maintain appropriate training records.

Measurement The following methods of measurement are used:

- provider compliance audits.

Volumes and Workloads

Minimum Volumes per Laboratory Policy

Purpose Specifying minimum volumes at each laboratory site is designed to maintain and improve overall standards and skills in cytology screening and interpretation. Minimum numbers are specified for cytology reporting only, not for histology reporting.

Policy Each laboratory must report a minimum number of gynaecological cytology cases per annum.

Details The designation of a volume of 15,000 gynaecological cytology cases per annum requires that there will be at least two cytology screeners and would generate about 1,000 gynaecological cytology cases per annum for a pathologist's opinion.

Standard 504: Volume of Gynaecological Cytology Cases per Laboratory per Annum

Standard Each fixed laboratory site will process a minimum of 15,000 gynaecological cytology cases per year. A single case may include multiple cytology samples per woman at any single patient episode.

Target All fixed laboratory sites process at least 15,000 gynaecological cytology cases per year. A single case may include multiple cytology samples per woman.

Measurement The following methods of measurement are used:

- monitoring reports
- NCSP-Register data
- provider compliance audits.

Continued on next page

Volumes and Workloads, Continued

Minimum Volumes for Pathologists Policy

Purpose	<p>This policy is to ensure that:</p> <ul style="list-style-type: none"> • a pathologist is available at all times • pathologists maintain and improve their skill level by being continually involved in reporting a wide range of abnormalities in gynaecological cytology.
Policy	<p>Each pathologist reporting gynaecological cytology must report a minimum of 500 gynaecological cytology cases per year.</p> <p>Each laboratory needs to have at least two pathologists competent in gynaecological cytology to cover for periods of sickness and annual leave.</p>
Details	<p>Each pathologist must report a minimum of 500 gynaecological cytology cases per year. If a pathologist is reporting both LBC and conventional smears then the pathologist's minimum workload must include a minimum of 100 LBC cases and a minimum of 100 conventional smear cases per year.</p>

Standard 505: Number of Cases to be Reported Per Pathologist Per Annum

Standard	<p>Each pathologist will report at least 500 gynaecological cytology cases per year. A single case may include multiple cytology samples per woman.</p> <p>If the majority of a pathologist's workload (but not all) is comprised of conventional smears then the pathologist's total number of gynaecological cytology cases per annum must include a minimum of 100 LBC cases.</p> <p>If the majority of a pathologist's workload (but not all) is comprised of LBC specimens then the pathologist's total number of gynaecological cytology cases per annum must include a minimum of 100 conventional smear cases.</p> <p>Each laboratory must have at least two pathologists competent in gynaecological cytology to cover for periods of sickness and annual leave.</p>
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Target

- That every pathologist reports at least 500 gynaecological cytology cases per year. A single case may include multiple cytology samples per woman.
- That every pathologist whose workload comprises a mix of conventional and LBC samples has at least 100 cases of each annually
- That each laboratory has at least two pathologists competent in gynaecological cytology to cover for periods of sickness and annual leave.

Measurement

The following methods of measurement are used:

- provider compliance audits.

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Volumes and Workloads, Continued

Staffing and Workloads for Cytoscientists and Cytotechnicians Policy

Purpose To ensure that there are sufficient cytoscientists and cytotechnicians to handle the volume of gynaecological cytology cases reported by the laboratory, while retaining a requirement for all staff to screen a sufficient number of cases to maintain and improve their skills.

Policy A cytoscientist or cytotechnician's workload must be appropriate to their level of skill and considerate of their other tasks in addition to screening. The maximum screening workload defines an upper limit to prevent work overload, while minimum numbers of cytology cases screened annually defines a lower limit to ensure competency and maintenance of skill.

Competency for any aspect of screening is defined as a sensitivity of at least 95% for high grade and 90% for all abnormalities.

Details The workload must not exceed an equivalent of 60 primary conventional smear screenings or 70 primary LBC sample screenings of gynaecological cytology cases in a 6 - 8 hour working day for a full time screener. Full re-screens and 42 month reviews of slides are counted as equivalent to primary screening for this purpose.

Note: These limits are not recommended optimal or average workloads and are not to be used as performance targets for screeners.

Standard 506: Maximum Workload for Screeners

Standard The maximum workload for any screener involved in manual primary screening of conventional samples is 60 cases on any one working day.

The maximum workload for any screener involved in manual primary screening of LBC samples is 70 cases on any one working day.

The maximum workload for any screener involved in location guided FOV review of LBC samples is 140 cases on any one working day.

Where screeners undertake a case mix within a working day, the maximum workload is proportional to the mix i.e.

FOV : LBC : conventional = 14 : 7 : 6

It is recommended that up to 3 rapid re-screens = 1 full primary screen = 1 full re-screen for either conventional or LBC samples.

Target That each screener involved in primary screening, FOV review or full re-screening screens no more than (or proportionally):

- 60 conventional smear samples per working day
- 70 LBC samples per working day
- 140 FOV review of LBC samples per working day.

Measurement The following methods of measurement are used:

- provider compliance audits.

Staffing and Workloads for Cytoscientists and Cytotechnicians Policy, Continued

Standard 507: Minimum Number of Cases per Annum per Cytoscientist/Cytotechnician Standard

Standard Cytoscientists and cytotechnicians must primary screen a minimum of 3,000 gynaecological cytology cases per annum. In the case of senior cytoscientists and senior cytotechnicians this may include a maximum of 1,200 full re-screen cases.

For a mixed workload, if the majority of the cytoscientist's or cytotechnician's workload is comprised of conventional smears, the total number of gynaecological cytology cases per annum must include a minimum of 1000 LBC cases per annum.

For a mixed workload, if the majority of the cytoscientists or cytotechnicians' workload is comprised of LBC samples, then the total number of gynaecological cytology cases per annum must include a minimum of 1000 conventional smear cases per annum.

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

Exemptions:

Senior cytoscientists who are the head of the department must primary screen or full review a minimum of 1000 cases per annum (at least 500 conventional smear cases and 500 LBC samples per annum if they have a mixed workload). If their workload includes location guided review they must also complete a minimum of 1000 FOV review cases per annum.

Other senior cytoscientists who have significant managerial, teaching, quality management, research or other non cervical screening duties must primary screen or full review a minimum of 1000 cases per annum (at least 500 conventional smear cases and 500 LBC cases per annum if they have a mixed workload). If their workload includes location guided review they must complete a minimum of 1000 FOV review cases per annum. This must be approved by the lead cytopathologist based on the individual's roles, responsibilities and requirements in the laboratory.

The NCSF must be notified of any staff exempt from the minimum of 3,000 gynaecological cases or FOV reviews per annum.

- Target**
- That all cytoscientists and cytotechnicians screen a minimum of gynaecological cytology cases per annum as indicated in the standard above.
 - That the Head of Department and 'other' senior cytoscientists with significant managerial and/or training responsibilities screen a minimum of gynaecological cytology cases per annum as indicated in the standard above.

Measurement The following methods of measurement are used:

- provider compliance audits.

Cytology

Handling and Identifying Cytology Slides Policy

Purpose That slides are labelled unambiguously and tracked.

Policy Gynaecological cytology samples must be clearly identified and permanently marked to ensure accurate matching with the referral form.

The laboratory must have a protocol detailing the action to be taken if any mislabelled or unlabelled slides or forms are received by the laboratory.

Laboratories must have a tracking system with a unique identifier on the sample and the referral form following confirmation that details are correct and complete on both sample and form.

A record must be kept of any slide broken prior to arrival at the laboratory or in the laboratory, and the report must identify if the interpretation is compromised by the breakage.

- LBC policy** Laboratories must document leaking sample vials that have been caused by inadequate sealing and attempt to salvage the sample. If:
- the cellular yield is unsatisfactory and only normal cells are identified, the slide must be reported as unsatisfactory and the smear taker informed
 - an excessive amount of sample has been lost, the sample is unsatisfactory and the smear taker must be notified (refer to manufacturer’s instructions)
 - abnormal cells are identified the sample is reportable with a note to the smear taker indicating that part of the sample was lost
 - laboratories must follow specified protocol for reporting and handling unsatisfactory samples (refer to Bethesda 2001 (New Zealand Modified)).

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

Laboratories must document and also indicate to the smear 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. If:

- the cellular yield is unsatisfactory and only normal cells are identified, the slide must be reported as unsatisfactory
- abnormal cells are identified, the sample is reportable with a note to the smear taker indicating an error with the sampling device.

Laboratories must follow specified protocol for reporting and handling unsatisfactory samples (refer to Bethesda 2001 (New Zealand Modified)).

See also

- Manufacturer’s instructions
- Appendix 6 - Bethesda 2001 (New Zealand Modified).

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Cytology, Continued

Cytology Slide Preparation Policy

Purpose	To ensure that optimal samples are prepared and preserved, as accurate interpretation of cytology slides depends on accurate slide identification, good quality staining and slide preparation.
Policy	Slide preparation and staining must be of optimal quality.
LBC Policy	<p>LBC specimens can be processed at a separate IANZ accredited laboratory site from which they are read.</p> <p>The methods for processing ThinPrep® and SurePath™ specimens are not interchangeable. Slide preparation must conform to the manufacturer's instructions or a clinically validated protocol accredited by IANZ.</p>
Staining of slides	<p>Staining of slides must be performed in accordance with the following:</p> <ul style="list-style-type: none"> • cervical cytology slides must be stained using the Papanicolaou staining method • 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 be at least 22 mm by 50 mm and cover as much of the material on the slide as possible • mounting media must not be allowed to contaminate the surface of the cover-slip in such a way as to compromise visibility.
See also	<ul style="list-style-type: none"> • Manufacturer's instructions.

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Cytology, Continued

Primary Screening Policy

Purpose To ensure that cytology slides are interpreted competently.

Policy Primary screening of cytology slides must be carried out by appropriately skilled screeners.

- All staff performing primary screening must demonstrate their ability to detect abnormalities using this method prior to any of their cases being re-screened by rapid review.

All cytology screening and re-screening (rapid re-screening and full re-screening) must be completed prior to a result being reported to the:

- smear taker and
- NCSP-Register.

These processes must be completed in accordance with the expected timeframes set out in this section.

Details

Please note the following:

- the cyto-screener must attempt to 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
 - pathologists are excluded from primary screening
 - any slides screened by a Bachelor of Medical Laboratory Science graduate holding an interim practising certificate or a trainee Medical Laboratory Technician in medical cytology must be fully primary screened by a qualified and registered cytoscientist or cytotechnician, with full secondary re-screening or rapid re-screening until they receive their annual practising certificate.
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Cytology, Continued

Rapid Re-screening Policy

Purpose	To rapid re-screen slides called “Negative for intraepithelial lesion or malignancy” at primary screening, prior to the report being issued.
Policy	Laboratories must conduct rapid re-screening of all slides called “Negative for intraepithelial lesion or malignancy” with the exclusion of those negative slides requiring a full re-screen. The outcomes of all rapid re-screens must be recorded.
Details	<p>This is a process whereby a screener, who is not the same person as the primary screener, performs a rapid (minimum 60 second) re-screen of the slide.</p> <p>The following guidelines apply:</p> <ul style="list-style-type: none"> • rapid re-screening must be carried out by cytoscientists or cytotechnicians designated by the laboratory charge cytoscientist/pathologist • all staff performing rapid review must demonstrate their ability to detect abnormalities using this method prior to conducting rapid review • rapid review ability is determined by the charge cytoscientist • where possible all screeners should be involved but must not review their own work • the primary screener must identify if the case requires rapid or full re-screen for accurate analysis of rapid re-screen outcomes • rapid re-screening of LBC slides comprises full coverage (minimum 60 seconds) horizontally or vertically across the slide.

Standard 509: Rapid Re-screening Results and Recording Outcomes

Standard	<p>95-98% of “Negative for intraepithelial lesion or malignancy” slides are confirmed as such after rapid re-screening.</p> <p>Outcomes of rapid re-screening must be recorded for all cases.</p>
Target	<ul style="list-style-type: none"> • That 95-98% of “Negative for intraepithelial lesion or malignancy” slides are confirmed as such after rapid re-screening. • That 100% of outcomes are recorded.
Measurement	<p>The following methods of measurement are used:</p> <ul style="list-style-type: none"> • provider compliance audits.

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Cytology, Continued

Automated Screening Device Policy

Purpose To ensure that cytology LBC slides are accurately processed and screened using an automated screening device when installed and validated

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

Details Please note the following (for validation of laboratory/imager):

- The automated devices must be operated and calibrated as per manufacturer's instructions and any non compliance rectified. The validation process must be documented and made available for review.
- Daily calibrations as recommended by the manufacturer must be undertaken and recorded.
- All staff must undertake training and assessment that includes a wide range of abnormal cases to demonstrate competency during a validation process.
- The first 1000 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 grade and high grade change must be recorded for this process.
- The preparation and processing of slides for automated screening devices must be undertaken by appropriately trained staff who are competent to undertake these tasks.
- Slides that are processed and are rejected either due to calibration or other reasons must be either reprocessed prior to repeat automated screening or manually screened.

Definitions

Field of view (FOV): Microscopic field of view at x10 objective magnification presented to the cytologist by location guided technology.

FOV review: The microscopic review of FOV by a cytologist. At least the minimum number of FOV as defined by the manufacturer must be reviewed for each case and the complete cellular content for each field of view must be examined.

FOV with additional full screen: Full manual screen after completion of FOV review.

Location Guided Screening Policy

Purpose To review and screen slides using location guided screening that have been satisfactorily scanned using an automated screening device prior to the report being issued.

Policy Laboratories must conduct location guided field of view (FOV) review of all slides that have been satisfactorily scanned using an automated device. Those cases requiring full screen (see Standard 510) must receive a minimum of FOV review with at least one full screen performed by a different person. All staff performing FOV review must demonstrate their ability to detect abnormalities using this method prior to conducting FOV review. The result of all negative FOV reviews with additional full screen must be recorded.

Details This is a process whereby a reviewer performs a location guided review of the slide. This is by microscopic review of the minimum number of location guided fields of view (FOV) as specified by the manufacturer's instructions.

The following guidelines apply (for validation of individuals):

- FOV review must be carried out by cytoscientists or cytotechnicians designated as competent by the laboratory charge cytoscientist/pathologist.
- Prior to achieving FOV competency sign off by the charge scientist/pathologist, the following must be completed and documented:
 - a manufacturer's training course in FOV review
 - a test set consisting of a minimum of 250 cases with the first half weighted to more abnormal cases
 - a minimum of 1500 FOV cases fully re-screened as per full rescreening policy (additional to training and test set cases for validation):
 - achieving a sensitivity of at least 95% for high grade and 90% for all abnormalities
 - maintaining detailed records for each screener, including sensitivities
 - where a screener fails to achieve the required sensitivities, further aliquots of 1000 FOV cases with full re-screening is required until the specified sensitivities are achieved.
- The FOV reviewer shall identify if the case is limited to FOV review only or requires full screening.
- For each case that has an additional full screen, laboratories must correlate and record the reasons and outcome of all cases with non-correlation between the FOV result and final result.

Full Re-screening Policy

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

Policy Full re-screening must be performed for all:

- abnormal (G2 or G3) gynaecological cytology
- gynaecological cytology from women with an abnormal screening history prior to returning to usual (3 yearly) screening after the abnormal diagnosis
- gynaecological cytology from women with past history of high grade (or worse) abnormalities. The exception is where the results of two consecutive HPV/cytology tests are negative as per HPV testing guidelines (return to routine screening)
- gynaecological cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities, or immunosuppression
- gynaecological cytology taken at STI clinics
- gynaecological cytology taken at colposcopy
- gynaecological cytology taken at oncology clinics
- unsatisfactory gynaecological cytology
- gynaecological cytology where there has been shown to be a discrepancy between the primary screening result and the rapid re-screening result.

Cases scanned using automated screening devices where abnormal cell changes are identified by location guided FOV must have a minimum of two manual full screens. This may be either:

- FOV continued as a full screen followed by an additional full re-screen by a different person or
 - FOV followed by two additional full screens by two different people.
-

Details

Only the following staff, as designated by the charge cytoscience, may carry out full re-screening of gynaecological cytology:

- a cytoscience who has completed the Vocational Registration Programme in Cervical Cytology (VRPCC) with more than three years full time experience post qualification
- a cytoscience with more than four years full time experience post qualification
- a cytotechnician who has completed the VRPCC with more than three years full time experience post qualification
- a cytotechnician with more than four years full time experience post qualification.

In an automated screening environment only the following staff, as designated competent by the charge cytoscience, may carry out additional full screen of gynaecological cytology:

- a cytoscience or cytotechnician already undertaking full manual re-screening
- a trainee cytoscience or cytotechnician who completes the VRPCC must demonstrate competency by actively participating in full re-screening over a period of at least one year full time equivalent working experience (post VRPCC) on first full screens of imager generated slides.
 - This may include full screening of high-risk negative and abnormal cases generated after FOV review and any cases requiring full re-screen after manual primary screening.
 - Any abnormal or high-risk negative cases must be further full screened by experienced staff according to Standard 510.
 - Any low-risk negative cases following sign out at FOV may be fully screened to assist in developing competency but any non-correlating cases must be further reviewed by an experienced staff member.
- qualified cytotechnicians and cytoscientists who have not already achieved competency to fully re-screen must complete their time for competency as above but pro-rata as follows:
 - completed the VRPCC – complete the equivalent of one year full time equivalent experience post qualification
 - without the VRPCC – complete the equivalent of two years full time equivalent experience post qualification.

Note:

- A pathologist must report all abnormal (G2 or G3) gynaecological cytology.

Continued on next page

Cytology, Continued

Full Re-Screening Policy, Continued

Standard 510: Full Re-screening

Standard	<p>Full re-screening must be performed for gynaecological cytology in all of the following categories:</p> <ul style="list-style-type: none"> • abnormal (G2 or G3) gynaecological cytology • gynaecological cytology from women with an abnormal screening history prior to returning to usual (3 yearly) screening after the abnormal diagnosis • gynaecological cytology for women with past history of high grade (or worse). The exception is where the results of two consecutive HPV/cytology tests are negative as per HPV testing guidelines (return to routine screening) • gynaecological cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities, or immunosuppression • gynaecological cytology taken at STI clinics • gynaecological cytology taken at colposcopy • gynaecological cytology taken at oncology clinics • unsatisfactory (U) gynaecological cytology • gynaecological cytology where there has been shown to be a discrepancy between the primary screening result and the rapid re-screening result. • Cases scanned using automated screening devices where abnormal cell changes are identified by location guided FOV must have a minimum of two full manual screens.
Target	That all of the categories above receive full re-screening.
Measurement	<p>The following methods of measurement are used:</p> <ul style="list-style-type: none"> • provider compliance audits.

Standard 511: Confirmation and Reporting for Abnormal Results

Standard	All results confirmed abnormal (G2 or G3) after full re-screening will be sent to the cytopathologist for confirmation and reporting.
Target	That 100% of results confirmed abnormal (G2 or G3) after full re-screening are sent to the cytopathologist for confirmation and reporting.
Measurement	<p>The following methods of measurement are used:</p> <ul style="list-style-type: none"> • provider compliance audits.

Continued on next page

Cytology, Continued

Full Re-Screening Policy, Continued

Standard 512: Re-screening Timing

Standard All re-screening (rapid and full) will take place prior to the result being confirmed and sent to the smear taker and the NCSP-Register.

Target That all re-screening (rapid and full) takes place prior to the result being confirmed and sent to the smear taker and the NCSP-Register.

Measurement The following methods of measurement are used:

- provider compliance audits.

Cytology, Continued

Ensuring Optimal Recommendations Policy

Purpose To ensure the optimal recommendation for recall or referral is made from each cytology sample.

Policy For the optimal recommendation for recall and/or referral made for each cytology sample, laboratories must ensure that a woman's screening event history is available at each stage of the screening process and in their analysis.

Recommendations for recall or referral must be based on the cytological findings of the present slide and the woman's complete gynaecological history in accordance with the NCSP Guidelines.

Laboratory staff must seek information from the NCSP-Register (electronically if available) if the laboratory does not have the screening event history of a woman who is enrolled on the NCSP-Register, or if staff are unsure if they have the full history.

Details Laboratories who request the screening history electronically will receive this directly from the NCSP-Register. If the laboratory does not have electronic access to the woman's history or if the laboratory requests this in hard copy, the NCSP-Register Central Team will send the woman's screening event history to laboratories by fax within four working hours of a request, provided the following information is forwarded from the laboratory:

- surname
 - first name
 - any other name known by
 - date of birth
 - NHI number.
-

Reporting changes to results If as a result of a review or later re-screen, there is a change to a woman's result this revised result must be forwarded with updated recommendations, interpretation and information on the smear adequacy to the smear taker and the NCSP-Register.

See also

- Guidelines for Cervical Screening in New Zealand

Histology

Preparing, Examining and Reporting Histology Specimens Policy

Purpose To ensure that histology slides are prepared, examined and reported correctly. Gynaecological histology specimens are examined for the purpose of detecting the presence, degree and extent of tissue abnormality, which may include confirmation of a diagnosis of cancer.

Policy The histopathologist should be advised whether a biopsy is considered diagnostic or excisional. The histopathologist must be aware of a woman's screening event history at the time of reporting gynaecological histology specimens.

Note:

- Refer to page 5.29 for the policy (Ensuring Optimal Recommendations) on obtaining the woman's screening history.
-

Types of biopsies

The types of biopsies covered include:

- cervical punch biopsies
 - endocervical curettings
 - wedge biopsies
 - loop excisions (LEEP)
 - large loop excisions (LLETZ)
 - cone biopsies (laser or cold knife)
 - hysterectomy specimens with a cervical component.
-

Continued on next page

Histology, Continued

Preparing, Examining and Reporting Histology Specimens, Continued

Handling of specimens

All specimens are to be received in 10% buffered formalin (or an appropriate alternative fixative).

Cervical punch biopsies are prepared as follows and must have:

- optimal orientation
- the number and diameter of biopsies recorded
- all tissue processed and sectioned
- an initial six levels of the tissue examined, with further levels if required, to identify all pathology.

Loops (LEEP, LLETZ) are prepared as follows and must have:

- the loop orientated on its edge
- the number of pieces recorded
- all tissue submitted for processing and sectioning
- the tissue sliced at 2-3 mm intervals
- an initial three levels of the tissue examined, with additional levels if indicated by clinical information or findings on the initial three levels.

Cone biopsies are prepared as follows:

- record the anterior/posterior diameter, height of specimen, location of the cervical canal (central or marginal) and note any macroscopic lesions and the position of orientation markers (sutures)
- if the specimen is received intact and closed, parallel sectioning is recommended at 2-3mm slices. If the specimen is received open, parallel or radially section at 2-3mm slices to achieve a good profile of the transformation zone. All tissue must be submitted for processing and sectioning
- an initial three levels should be examined, with additional levels if indicated by clinical information or findings on the initial three levels.

Additional investigations (e.g. immunohistochemistry) for difficult to grade lesions should be performed as required.

Continued on next page

Histology, Continued

Preparing, Examining and Reporting Histology Specimens, Continued

Reporting of specimens

Information in reports should include:

- for a punch biopsy:
 - site of biopsy (ectocervix and transformation zone, endocervix)
 - types of normal epithelium present (both glandular and squamous)
 - histological type and grade of lesion.

- for a LEEP, LLETZ and cone:
 - histological type and grade of lesion
 - uni/multifocal
 - tissue margins
 - types of normal epithelium present (both glandular and squamous)
 - invasion if present (reported using FIGO guidelines (2006)):
 - uni/multifocal
 - depth
 - horizontal and length of lesion
 - lymphovascular invasion
 - stromal reaction.

Management of discordant results

If a lesion correlating with the cytology cannot be confirmed on the histology specimen the cytology slide must be reviewed. If following review of cytology a high grade lesion is confirmed this must be communicated to the colposcopist (see NHSCSP guidelines: Histopathology Reporting in Cervical Screening (1999)).

See also

- The International Federation of Gynaecology and Obstetrics (FIGO) guidelines: Staging Classifications and Clinical Practice Guidelines for Gynaecologic Cancers (2nd Ed.) (2006) available from www.figo.org/files/figo-corp/Clinical%20practice%20guidelines.pdf
- Histopathology Reporting in Cervical Screening (1999) available from www.cancerscreening.nhs.uk/cervical/publications/nhscsp10.pdf

Continued on next page

Histology, Continued

Preparing, Examining and Reporting Histology Specimens, Continued

Standard 514: Histopathologist Access to Cervical Cytology Results

Standard **The histopathologist must have the screening event history available at the time of reporting the gynaecological biopsy.**

Target All histopathologists have the screening event history available at the time of reporting the gynaecological biopsy.

Measurement The following methods of measurement are used:

- provider compliance audits.

Standard 515: Examining and Reporting Histology Slides

Standard **All histology slides must be examined and reported by a histopathologist.**

Target That all histology slides are examined and reported by a histopathologist.

Measurement The following methods of measurement are used:

- provider compliance audits.

Communicating Results

Reporting to Smear Takers and Specialists Policy

Purpose That 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 cytology results directly to smear takers using approved NCSP Bethesda terminology, and for reporting all histology samples to the referring specialist.

Laboratories must have in place protocols and procedures to ensure that all:

- cytology samples received by the laboratory are reported to the smear taker and the NCSP-Register for all women residing in New Zealand at the time the sample was taken
- histology samples received by the laboratory are reported to the specialist and the NCSP-Register for all women residing in New Zealand at the time the sample was taken
- HrHPV test samples received by the laboratory are reported to the smear taker and the NCSP-Register for all women residing in New Zealand at the time the sample was taken.

Conjunct cytology and HrHPV tests should be reported to the smear taker at the same time.

Details It is recognised that for some histology cases, additional time is needed to allow collaborative discussion and referral before issuing a result. The specialist should be informed if it takes more than 10 working days for a histology result to be reported.

Histology diagnoses must be coded using the SNOMED coding system as denoted by the NCSP (including topography(T), morphology(M) and procedure(P) codes).

Changes to reporting methods All changes that could impact on laboratory reporting methods, including changes to Bethesda or SNOMED codes, must be co-ordinated through the Ministry of Health National Screening Unit. These will be made following engagement and discussion with laboratories and other affected parties.

See also

- Appendix 6 - Bethesda 2001 (New Zealand Modified)
- Appendix 7 - SNOMED codes
- NCSP National Targets and Indicators

Continued on next page

Communicating Results, Continued

Reporting to Smear Takers and Specialists Policy, Continued

Standard 513: Reporting Gynaecological Cytology and HrHPV Test Results

Standard **Laboratories are required to report 90% of final gynaecological cytology results to smear takers within seven working days of receiving the specimen.**

Laboratories are required to report 100% of final gynaecological cytology results and HrHPV test results to smear takers within 15 working days of receiving the specimen.

Results for cytology and conjunct HrHPV tests should be reported together to the smear taker.

Target That laboratories report:

- 90% of the final gynaecological cytology results to smear takers within seven working days of receiving the specimen
- 100% of the final gynaecological cytology results and HrHPV test results to smear takers within 15 working days of receiving the specimen.

Measurement The following methods of measurement are used:

- monitoring reports
- NCSP-Register data
- provider compliance audits.

Standard 516: Reporting Histology Results

Standard **Laboratories are required to report 90% of final histology results to referring colposcopists within five working days of receiving the specimen.**

Laboratories are required to report 99% of final histology results to referring colposcopists within 15 working days of receiving the specimen.

Target That laboratories report:

- 90% of final histology results to referring colposcopists within five working days of receiving the specimen
- 99% of final histology results to referring colposcopists within 15 working days of receiving the specimen.

Measurement The following methods of measurement are used:

- monitoring reports
- NCSP-Register data
- provider compliance audits.

Communicating Results, Continued

Providing Advice to Smear Takers Policy

Purpose To promote the laboratory’s role in providing advice to smear takers, with the aim of improving the quality of smear taking.

Policy The laboratory must provide advice to smear takers on ways to improve the quality of smear taking.

Details Pathologists and senior cytoscientists must be readily available to advise smear takers regarding:

- the suitability/adequacy of gynaecological cytology samples and HrHPV test samples
- terminology of gynaecological cytology reports
- terminology of HrHPV test reports
- the clinical significance of the laboratory results
- further procedures or investigations that may be helpful
- updates and changes.

Multi-disciplinary case reviews Pathologists must ensure that, as part of case management and quality control, formal arrangements are in place for multi-disciplinary case reviews with colleagues.

The multi-disciplinary team could include:

- cytotechnical/scientific staff
 - pathologists
 - gynaecologists, colposcopy nurses, smear takers, and oncologists as appropriate.
-

Continued on next page

Communicating Results, Continued

Forwarding Results to the NCSP-Register Policy

Purpose To ensure that the NCSP-Register receives all gynaecological cytology, histology and HrHPV test results.

Policy Laboratories must have processes in place for ensuring that all gynaecological cytology, histology and HrHPV test results are forwarded in the correct format to the NCSP-Register.

Details Results must be forwarded in the agreed codes and electronic format. HrHPV tests are reported as detected, not detected, or invalid.

Results must be sent in the approved NCSP versions of Bethesda Coding Standard for cytology and SNOMED codes for histology.

Results sent through HL7 messaging must be accompanied by the matching laboratory referral form.

All electronic data must be accompanied by the matching laboratory referral forms containing the following information:

- full name
- date of birth
- address
- stated ethnicity (if available)
- NHI number
- previous screening event history (if not already recorded on the NCSP-Register)
- the identity of the smear taker or specialist according to their correct smear taker/specialist and health centre code.

HL7 messaging and electronic data must be formatted in accordance with the 'NCSP- Register Implementation Guide' (cytology, histology and HrHPV file format) distributed to the laboratories by the National Screening Unit.

Notes:

- If the NCSP-Register rejects the result provided by the laboratory, the laboratory must review the result and amend where necessary. The laboratory must then resend the result to the NCSP-Register.
 - It is the smear taker's responsibility to gain the consent of a woman who has previously opted off/withdrawn from the NCSP to have her previous screening event history sent to the NCSP-Register.
-

Continued on next page

Communicating Results, Continued

Forwarding Results to the NCSP-Register, Continued

Histology results to be forwarded All gynaecological histology results for women must be forwarded to the NCSP-Register. This includes:

- all cervical and vaginal gynaecological histology biopsies
- all cervical and vaginal polyps
- the histology of the cervical component of all hysterectomies.

See also

- Appendix 6 - Bethesda 2001 (New Zealand Modified)
- Appendix 7 - SNOMED codes for histology
- NCSP-Register Implementation Guide (cytology and histology file format)

Standard 518: Sending Cytology Results to the NCSP-Register

Standard All cytology results and HrHPV test results must be forwarded to the NCSP-Register, in the approved format and Bethesda coding, within 16 working days of receipt of specimen.

Target That 100% of the cytology results and HrHPV test results are forwarded to the NCSP-Register, in the approved format and Bethesda coding, within 16 working days of receipt of specimen.

Measurement The following methods of measurement are used:

- monitoring reports
- NCSP-Register data
- provider compliance audits.

Continued on next page

Communicating Results, Continued

Forwarding Results to the NCSP-Register, Continued

Standard 519: Sending Histology Results to the NCSP-Register

Standard **90% of the histology results must be forwarded electronically to the NCSP-Register, in approved format and NCSP SNOMED coding, within 10 working days of receipt of specimen.**

99% of the histology results must be forwarded electronically to the NCSP-Register, in approved format and NCSP SNOMED coding, within 20 working days of receipt of specimen.

Histology results must include all appropriate topography(T), morphology(M) and procedure(P) SNOMED codes.

Target

- That 90% of the histology results are forwarded electronically to the NCSP-Register, in approved format and NCSP SNOMED coding, within 10 working days of receipt of specimen.
- That 99% of the histology results are forwarded electronically to the NCSP-Register, in approved format and NCSP SNOMED coding, within 20 working days of receipt of specimen.

Measurement The following methods of measurement are used:

- monitoring reports
- NCSP-Register data
- provider compliance audits.

Continued on next page

Communicating Results, Continued

Cancer Registry Act (1993) Requirements

Purpose To support the compilation of a statistical record of the incidence of cancer in its various forms, and for the enhanced direction of programmes for research and cancer prevention.

Policy The Cancer Registry Act (1993) and the Cancer Registry Regulations (1994) require that all tests which indicate the presence of cancer be reported to the Cancer Registry.

Details All cytology and histology results with a diagnosis of invasive or in situ cancers must be forwarded to the National Cancer Registry. These results include:

- cytology:
 - abnormal squamous cells consistent with a high grade squamous intraepithelial lesion (HSIL) with features consistent with CIN2 or CIN3 (HS1)
 - abnormal squamous cells showing changes consistent with a high grade squamous intraepithelial lesion (HSIL) with features suspicious for invasion (HS2)
 - abnormal squamous cells showing changes consistent with squamous cell carcinoma (SC)
 - abnormal endocervical cells consistent with adenocarcinoma in situ (AIS)
 - abnormal glandular cells consistent with adenocarcinoma (AC1-4)
 - abnormal cells consistent with a malignant adenocarcinoma (AC5)
- histology:
 - CIN3
 - CIN2/CIN3
 - AIS
 - invasive lesions.

See also

- The Cancer Registry Act (1993) is available at: www.nzhis.govt.nz/moh.nsf/pagesns/219?Open
- The Cancer Registry Regulations (1994) are available at: www.nzhis.govt.nz/moh.nsf/pagesns/220?Open

Continued on next page

Communicating Results, Continued

Cancer Registry Act (1993) Requirements, Continued

Standard 520: Sending Results to the National Cancer Registry

Standard All cytology and histology results with a diagnosis of invasive or in situ cancers must be forwarded to the National Cancer Registry (at the New Zealand Health Information Service) by the laboratory that has analysed the sample.

Target That all cytology and histology results with a diagnosis of invasive or in situ cancers are forwarded to the National Cancer Registry (at the New Zealand Health Information Service) by the laboratory that has analysed the sample.

Measurement The following methods of measurement are used:

- provider compliance audits.

Quality Assurance

Accreditation Policy

Purpose	To ensure that all laboratories providing services for the NCSP are accredited.
Policy	All laboratories providing services for the NCSP must be accredited by International Accreditation New Zealand (IANZ) for provision of gynaecological cytology and/or histology services.
Details	<p>Laboratories must inform the Ministry of Health of the results of the IANZ assessment (both the annual surveillance process and the four yearly reassessment) and any change to their accreditation status.</p> <p>IANZ must also inform the Ministry of Health at the time of informing the laboratory if there is any change in accreditation status.</p> <p>A laboratory considering introducing new tests or technologies into the cervical screening pathway must first:</p> <ul style="list-style-type: none"> • notify the NCSP that the test or technology is under consideration • ensure that the test or technology has been appropriately validated. This includes approval of all sites partaking in multi-site processing (hub and spoke arrangements) • ensure that the test or technology has been notified to IANZ in accordance with requirements of their contract • communicate to smear takers any transition to new tests or technologies well in advance of implementation, to allow ample time for smear takers to clarify the implications of any changes.

Continued on next page

Quality Assurance, Continued

Internal Quality Assurance Policy

Purpose Internal quality control for a laboratory is an essential component of quality assurance for the NCSP.

The purpose of internal quality control systems is to:

- identify potential sources of error in the laboratory's operation
 - implement controls to detect and minimise errors, particularly false negative and false positive results
 - implement improvements to operational processes, especially when the need for remedial action has been identified.
-

Policy Laboratories must have policies and practices that ensure the quality of gynaecological cytology, HrHPV testing and histology. Policies must define staff responsibilities and laboratory procedures.

Laboratories must ensure that:

- staff appointed are appropriately qualified and experienced
 - staff achieve and maintain competency in the tasks they perform
 - high quality and accurate systems are in place for reporting, including mechanisms for ensuring data integrity throughout all key steps in the preparing, reading and reporting process
 - NCSP approved Bethesda coding system for reporting cytology and the SNOMED system for classifying histology results are used
 - control processes are in place to ensure that the reporting requirements of the Health (National Cervical Screening Programme) Amendment Act 2004 and the Cancer Registry Act 1993 are met
 - satisfactory internal systems for quality control and quality improvement are in place, including monitoring of data entry.
-

Continued on next page

Quality Assurance, Continued

Internal Quality Assurance Policy, Continued

Details

Each laboratory must have documented internal quality control activities, which include:

- ensuring consistent sample registration, processing and staining
- ensuring that the re-screening of slides occurs prior to the result being reported and forwarded to the smear taker and NCSP-Register
- a system for evaluating individual performance for all cytoscientists, cytotechnical staff and pathologists working in the laboratory
- a system for monitoring the sensitivity of primary screening for each primary screener and the laboratory as a whole
- a system of follow-up for correlating the results of gynaecological cytology with respective gynaecological histopathology
- a review of the previous 42 months negative gynaecological cytology slides from patients with current high grade/invasive histology
- ensuring that any change in a result because of a full case review will have the updated result forwarded to the NCSP-Register at the same time that the woman's smear taker is notified.

See also

- Appendix 6 - Bethesda 2001 (New Zealand Modified)
- Appendix 7 - SNOMED codes for histology

Continued on next page

Quality Assurance, Continued

External Quality Assurance Policy

Purpose	The objectives of external quality assessment schemes are to promote uniformly high standards of diagnostic reporting including adjunct testing (eg HrHPV testing) at each laboratory.
Policy	In accordance with accreditation requirements, laboratories providing gynaecological cytology, HrHPV testing and/or histology services for the NCSP must participate to a satisfactory standard in an appropriate external quality assurance programme.
Details	<p>The external quality assurance programme must include:</p> <ul style="list-style-type: none"> • assessment against quantitative performance standards accepted by the NCSP, such as the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Program • external quality assurance reports, outcome measures and action sheets, which must be retained and made available to audit bodies • laboratories are expected to use external quality assurance reports as part of their own quality control processes • where there is an individual external quality assurance programme approved by the NCSP, this will be compulsory for individual participants • individual external quality assurance programmes must include an appropriate mix of conventional smears and LBC slides for the mix of workload of the staff member (e.g. staff reporting 60% of conventional slides should see a ratio of three conventional smears for every two LBC slides).
Monitoring details	The National Indicators for monitoring the NCSP have been agreed to and are reported against in the monitoring report. Details of the indicators are listed at the end of the section on page 5.54.

Reviewing Cases

Correlation of Cytology and Histology Policy

Purpose To ensure that laboratories correlate cytology and histology data and microscopically review all cases where there is discordance between the cytology and histology results with clinical management implications.

Policy In order to facilitate efficient histology/cytology correlation, it is best practice for:

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

Note:

- Where this does not occur, the results of previous cytology/histology reports, and slides if needed, must be available to the reporting cytology/histology laboratory.

Mandatory histology-cytology correlations All histology results must be correlated and documented with any cytology slides taken in the previous six months.

Histological slides and cytology slides must be reviewed by a senior cytoscientist and/or pathologist where the following discrepancies have occurred:

Cytology	Histology
HSIL/Invasive SCC	LSIL/Negative/Reactive
AIS/AG4/AG5 AC1-AC5	Negative/Reactive
Unsatisfactory/Negative	HSIL/Invasive SCC/Glandular Abnormalities/Invasive Adenocarcinoma <i>Required under retrospective review of smears taken up to 42 months prior to high grade or invasive diagnosis on histology policy.</i>

Note:

- AG4 is atypical endocervical cells favouring a neoplastic process
- AG5 is atypical glandular cells favouring a neoplastic process
- AC1 is abnormal glandular cells consistent with endocervical adenocarcinoma
- AC2 is abnormal glandular cells consistent with endometrial adenocarcinoma
- AC3 is abnormal glandular cells consistent with extrauterine adenocarcinoma
- AC4 is abnormal glandular cells consistent with adenocarcinoma
- AC5 is abnormal cells consistent with a malignant neoplasm

Reviewing Cases, Continued

Correlation of Cytology and Histology Policy, Continued

Recommended histology-cytology correlations Histology slides and cytology slides must be reviewed by a senior cytoscientist and/or pathologist, for continuing education purposes, where the following discrepancies have occurred:

Cytology	Histology
ASC-US/LSIL/AIS	HSIL or Invasive SCC
AGC/ASC-US/LSIL/HSIL	Glandular abnormalities or Invasive Adenocarcinoma
ASC-H/AG1/AG2/AG3	Negative/reactive

Note:

- AG1 is atypical endocervical cells present
- AG2 is atypical endometrial cells present
- AG3 is atypical glandular cells present

Correlation and monitoring reports

An NCSP-Register generated report correlates women’s results nationally and is produced for each individual reporting laboratory. For every histology result from any laboratory, the report lists the screening event history for the same woman reported by the laboratory within the previous five years.

Full case review policy

If there remains a lack of correlation (high grade/low grade or greater) which has any management or clinical implications for the woman, the case must be fully reviewed by a multidisciplinary team of experienced practitioners.

The review process must follow a standard format and be documented for the purpose of audit. The colposcopist must be informed if there remains a lack of correlation.

Continued on next page

Reviewing Cases, Continued

Correlation of Cytology and Histology Policy, Continued

Full case review details

The reviewing team should include:

- specialist colposcopists
- cytoscientists
- cytopathologists
- histopathologists.

If as a result of the review, there are any changes to the cervical screening report which have any clinical or follow-up management implications, the original reporting laboratory must communicate to the following within five working days:

- all laboratories involved in the reading of the slides
- the smear taker
- the NCSP-Register
- the Cancer Registry (if a previous cytology result reported to the Cancer Registry has since been downgraded to below invasive or in situ cancer).

Note:

- Failure to notify the NCSP-Register of a downgrading of the original report from a high grade status to a low grade or negative status in the absence of HPV testing, may lead to the woman having unnecessary annual screening instead of returning to three year screening.

See also

- Pages 39-40 of the NHSCSP guidelines: Histopathology Reporting in Cervical Screening (1999) available from:
www.cancerscreening.nhs.uk/cervical/publications/nhscsp10.pdf
-

Standard 521: Correlation of Histology and Cytology Slides

Standard All histology results must be correlated with any cytology slides with management implications taken in the previous six months and the results recorded for audit and statistical purposes.

Target All histology results are correlated with any cytology slides taken in the previous six months and recorded.

Measurement The following methods of measurement are used:

- provider compliance audits.

Continued on next page

Reviewing Cases, Continued

Retrospective Review of Cytology Slides Taken Prior to a High Grade or Invasive Diagnosis on Histology Policy

Purpose	<p>To ensure that:</p> <ul style="list-style-type: none"> • cytopathologists, cytoscientists and cytotechnicians regularly review cases in which a high grade abnormality may have been missed (false negative cases) • appropriate records are kept of reviews of cases reported as negative, benign/reactive or unsatisfactory in the 42 months prior to a high grade or invasive diagnosis on histology • laboratories have an indication of their false negative reporting with respect to detection of high grade lesions.
Policy	<p>The laboratory must document the results of the review of all cases reported as negative, benign/reactive or unsatisfactory in the 42 months prior to a high grade or invasive diagnosis on histology.</p> <p>Note:</p> <ul style="list-style-type: none"> • This information provides an indication of the laboratory's false negative rate with respect to the detection of high grade lesions.
Details	<p>Any abnormality identified as high grade on review of a prior reported negative or unsatisfactory cytology slide must be reviewed by a senior cytoscientist or senior cytotechnician (qualified for full review). If there is a lack of consensus on an agreed false negative the case must be reviewed by a pathologist.</p> <p>Confirmed high grade abnormalities must be documented by the laboratory. Cumulative data must be forwarded to the NSU as part of the accuracy of negative cytology reports submission.</p>
See also	<ul style="list-style-type: none"> • Guidelines for Cervical Screening in New Zealand • the NHSCSP guidelines: Histopathology Reporting in Cervical Screening (1999) available from www.cancerscreening.nhs.uk/cervical/publications/nhscsp10.pdf • NCSP National Targets and Indicators

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Reviewing Cases, Continued

Retrospective Review of Cytology Slides Taken Prior to a High Grade or Invasive Diagnosis on Histology Policy, Continued

Standard 522: Reviewing Cases with a High Grade Diagnosis

Standard All cases with a high grade/invasive diagnosis on histology must have a review of any prior cytology slides reported as negative, benign/reactive, or unsatisfactory in the previous 42 months.

Target That 100% of cases with a high grade diagnosis on histology have a review of all prior cytology slides reported as negative, benign/reactive or unsatisfactory in the previous 42 months.

Measurement The following method of measurement is used:

- provider compliance audits.

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Retaining Slides

Retaining Slides and Associated Documentation Policy

Purpose All gynaecological cytology and histology slides and associated documentation must be kept to allow both adequate review of previous slides and cytology/histology correlation where necessary.

Policy Laboratories must retain slides, request forms and reports, including electronic copies, in accordance with the current IANZ guidelines.

Māori women and women from other cultural groups may feel a strong connection to biological samples provided to laboratories for analysis. This needs to be recognised.

Details Stained slides and associated documentation must be retained in a secure repository in compliance with current best practice and relevant legislation.

Laboratories must keep slides and tissue in accordance with current guidelines recognised by IANZ. These include:

- National Pathology Accreditation Advisory Council 2007 guidelines
- New Zealand Medical Council guidelines
- Public Records Act 2005
- Health (Retention of Health Information) Regulations 1996.

Request forms and reports must be kept for the same period of time as the slides to which they pertain.

For LBC samples the vial must be retained in the laboratory as per manufacturer’s specifications for a minimum of one month.

Laboratories who cease to provide gynaecological cytology and/or histology If a laboratory ceases to undertake gynaecological cytology and/or histology reading, it must ensure specimens and records are available on request or are forwarded to the new contracted provider.

The NSU must be notified immediately of any likelihood of closure of a laboratory.

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Retaining Slides, Continued

Retaining Slides and Associated Documentation Policy, Continued

Standard 517: Cultural Sensitivity and Appropriateness

Standard **Requests regarding culturally appropriate methods of handling and disposal of human tissue will be treated sensitively and in accordance with local protocols.**

Target That all requests regarding culturally appropriate methods of handling and disposal of human tissue are treated sensitively and in accordance with local protocols.

Measurement The following methods of measurement are used:

- provider compliance audits

See also • Local organisational protocol accepted by iwi

High risk human papillomavirus testing

HrHPV testing Policy

Purpose	To ensure that cytology LBC samples are accurately processed and tested for high risk human papillomavirus (HrHPV) using a validated test procedure.
Policy	HrHPV testing of LBC samples must be carried out using approved and validated processes and used in accordance with manufacturer instructions. Laboratories must conduct adjunct HrHPV testing to cytology as defined in the Guidelines for Cervical Screening in New Zealand incorporating guidelines for HrHPV testing.
Details	<p>Please note the following:</p> <ul style="list-style-type: none"> • the test procedure must be endorsed by an internationally recognised accreditation agency such as FDA or be CE marked and/or • internally clinically validated to meet at least the performance of internationally validated tests² • sensitivity of the test for the detection of CIN2 or worse in women 30 years or over must be at least 90% • appropriate controls must be included and the outcomes documented and stored • the HrHPV test must test for a minimum of 13 most common HrHPV subtypes • LBC samples only are recommended for HrHPV testing. The HrHPV test procedure must be validated (internationally or in-house) for each LBC product being tested • sampling, collection, transport, volume, and storage of LBC samples for HrHPV testing must be in accordance with manufacturers' recommendations or with a suitably validated process • all staff performing HrHPV testing must demonstrate competency in performing the test procedure and issuing results • results must be reported to the NCSP-Register in approved format as either <i>HrHPV detected</i>, <i>not detected</i> or <i>invalid test</i> • cytology with adjunctive HrHPV testing should be reported together or the cytology reported in consideration of the HrHPV test result • turnaround times are defined under standards 513 and 518 • swabs are not recommended for NCSP funded HrHPV testing where LBC is available. If a laboratory does not provide LBC for HrHPV testing, advice to smear takers as to the type of HrHPV swab to be used must be provided.

² Example of validation procedure:

Seabrook JM and Hubbard RA. Achieving Quality Reproducible Results and Maintaining Compliance in Molecular Diagnostic Testing of Human Papillomavirus. *Arch Pathol Lab Med.* 2003;127:978–983 (reference to Clinical Laboratory Improvement Amendments (CLIA)).

Quality assurance and HPV testing:

As there are several HrHPV tests either already commercially available or in the process of becoming available, laboratories are expected to participate in external quality assurance to ensure competency in HrHPV testing e.g. through the RCPA, WHO reference laboratory or other appropriate body.

National Indicators and Targets

Monitoring details The National Indicators for monitoring the NCSP are reported against in the monitoring reports. These are listed below and are reviewed periodically.

Please note that:

- there are a number of laboratory specific indicators with targets which will be monitored on a six monthly basis by the NCSP Advisory Group
- laboratories will receive six monthly monitoring reports and any issues arising from the reports will be followed up by the NSU
- laboratories are expected to use the reports as part of their own quality control processes.

Laboratory sample reporting

Indicator: L1

Number of sample reports by a laboratory in the following categories:

- Negative for intraepithelial lesion or malignancy (TBS G1) = Not more than 96% reported as negative
- HSIL (TBS HS1) = not less than 0.6% reported as HSIL
- Total abnormalities (TBS G2 and G3) = Not more than 10% reported as total abnormalities

Cytology turn around time

Indicator L2 (also see Standard 513)

That laboratories report to the smear taker:

- Not less than 90% of samples within 7 working days
- Not less than 100% of samples within 15 days
- Unsatisfactory samples by laboratory

Indicator L3

- Number of sample reports by a laboratory reported as unsatisfactory (TBS UA-UG)
- Conventional sample: Not less than 1% and not more than 8%
- LBC sample: Not less than 1% and not more than 5%

Accuracy of cytology reports predicting HSIL/SQCC on histology

Indicator L4

- Target for PPV for HSIL/SQCC = 65-85%

Accuracy of negative cytology reports

Indicator L5 (also see Standard 522)

- For women with a histological diagnosis of CIN2, CIN3, invasive SQCC, AIS or invasive endocervical adenocarcinoma, the proportion of slides originally reported within the preceding 42 months as negative which on review are consistent with ASC-H, HS1, HS2, AGC or AIS = not more than 20% (combined).