National Cervical Screening Programme Policies and Standards

Section 5: Providing a Laboratory Service
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NCSP policies and standards

The National Cervical Screening Programme (NCSP) Policies and Standards document the agreed policies, guidelines and standards of practice for providers of NCSP services.

Their purpose is to support all those involved in the NCSP to achieve the programme's aims and objectives by ensuring a high standard and national consistency of service at each step of the screening pathway.

In this section

Section 5 of the NCSP Policies and Standards relates to the provision of gynaecological cytology and/or histology services, including high-risk human papillomavirus (hrHPV) testing for the NCSP.
Overview and objectives

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

All gynaecological cytology, histology, HPV testing (and other ancillary tests that may arise) undertaken as part of the cervical screening pathway should:
- meet the NCSP Policies and Standards and
- be subject to review in order to guarantee that the quality of the service is continually improving.

Compliance with policies and standards
The Ministry of Health (the Ministry) requires all laboratories that provide services to the NCSP to comply with the policies and standards set out in Section 5.

All Section 5 policies and standards will be audited regularly.

Primary objective of gynaecological cytopathology
The primary objective of gynaecological cytopathology (referred to as gynaecological cytology) is to predict the nature of any pathological changes present in cervical squamous cells, and where possible identify any glandular abnormalities.

The interpretation of gynaecological cytology samples involves detecting and interpreting subtle changes in cell structure.

Limitations
There are limitations on interpretive 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 (referred to as gynaecological histology) is to ascertain the nature and extent of tissue abnormalities present in submitted gynaecological tissue.
Primary objective of high-risk human papillomavirus testing

The primary objective of hrHPV testing is to provide ancillary testing to gynaecological cytology to detect the presence of hrHPV genotypes that increase the risk of developing high-grade or worse cervical lesions.
Introduction to laboratories

Reference to laboratory

The term ‘laboratory’ applies to each individual, fixed laboratory site and includes all community and hospital laboratories that carry out gynaecological cytology and/or histology services.

All processing, evaluating and reporting of gynaecological cytology, histology and hrHPV testing must be performed on pathology laboratory premises. Such work is not permitted at any other venue, such as in the homes of screening staff.

hrHPV testing is only permitted at a laboratory where gynaecological cytology is reported.

Key functions of laboratories

Laboratories:
- process and report on gynaecological cytology, histology and hrHPV samples
- consult with and provide advice and results to smear takers and specialists who are managing cervical disease
- forward results to the NCSP Register
- forward relevant results to the New Zealand Cancer Registry (NZCR)
- collaborate with the NCSP Register Central Team.

In providing laboratory services to the NCSP, it is expected that laboratories will develop cooperative working relationships with other providers in the NCSP, in particular, nurses, general practitioners, colposcopists, the NCSP Register Central Team and the NCSP regional services.

Laboratory staff

The staff working within a laboratory service include:
- pathologists, who are medical graduates with specialist qualifications in pathology
- cyto-scientists, who are medical laboratory science or science graduates with specialised training in cytology (previously called cytotechnologists)
- cyto-technicians, who are laboratory trained in cytology and have gained the New Zealand Institute of Medical Laboratory Science’s (NZIMLS’s) Qualified Medical Laboratory Technician (QMLT) certificate (cyto-technicians were previously called Qualified Technical Assistants (QTAs))
- histo-scientists, who are medical laboratory science or science graduates with specialised training in histology
- histo-technicians, who are laboratory trained in histology and have gained the NZIMLS’s QMLT certificate
scientists and technicians, who, as appropriate, take responsibility for supervising unregistered trainees or other staff members who are required to work under supervision
laboratory assistants (unregistered)
molecular pathology scientists and technicians with expertise in hrHPV testing.

Cytology samples
A cytology sample refers to a gynaecological liquid-based cytology (LBC) sample (for example, Hologic ThinPrep® and BD SurePath™ specimens). A cytology slide is a slide prepared from a LBC sample.

Note: For historical material, this will also include conventional cervical smears/slides.

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
Laboratory staff must respect and show appropriate consideration for the cultural values held by the variety of ethnicities residing in New Zealand, in particular, the cultural needs of Māori.

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

Staffing qualifications policy

Purpose
The aim is to ensure that each laboratory service is staffed by suitably qualified pathologists, scientists and technicians (for cytology, histology and hrHPV testing) and is led by a suitably qualified pathologist.

Policy
All pathologists, cyto-scientists and cyto-technicians reporting gynaecological cytology or histology, histo-scientists and histo-technicians preparing histology specimens and molecular pathology scientists and technicians preparing and reporting hrHPV tests for the NCSP must have appropriate qualifications and be competent as defined under the Health Practitioners Competency Assurance Act 2003 and any subsequent amendments.¹ All pathologists, cyto-scientists and cyto-technicians reporting LBC samples must first have completed an appropriate training course in accordance with manufacturers requirements for each LBC type screened and reported by the individual.

The requirements for each specific 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 (RCPA) or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received subspecialty training in general pathology, anatomical pathology or cytopathology
- have a qualification to cover the subspecialty in which they are working
- 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 (also refer to standard 501: Qualifications for pathologists – see below).

Pathologists who are not vocationally registered (have provisional or general registration) must work under supervision as required by the Medical Council of New Zealand.²

The lead supervising pathologist for cytology should have additional qualifications, for example, a diploma in cytopathology or fellowship of The International Academy of Cytology.

See also:


Scientific and technical staff

All cyto-scientists and cyto-technicians reporting gynaecological cytology or histology and histo-scientists and histo-technicians preparing histology specimens must have the following qualifications.

- A cyto-scientist or histo-scientist must be a registered health practitioner (medical laboratory scientist) holding a current annual practising certificate issued by the Medical Sciences Council of New Zealand (MSCNZ, formerly the Medical Laboratory Science Board), with a scope of practice of medical laboratory scientist with subspecialty training in cytology or histology, if practising within cytology or histology (respectively).

- A cyto-technician or histo-technician must be a registered health practitioner (medical laboratory technician) holding a current annual practising certificate issued by the MSCNZ, with a scope of practice of medical laboratory technician with subspecialty training in cytology or histology, if practising within cytology or histology (respectively).

Medical laboratory technicians who report cytology and hrHPV tests may release results as long as they are working under the direction of a medical laboratory scientist and are certified as competent to do so. Medical laboratory technicians who release results must be operating under a clear Standard Operating Procedure that specifies the circumstances when a result must be reviewed by a medical laboratory scientist or pathologist.

Medical laboratory scientists and medical laboratory technicians reporting on hrHPV testing must also be registered health practitioners with annual practising certificates and be appropriately trained, qualified and competent for the task.

A cyto-screener is a person who:

- screens, evaluates and reports cervical and vaginal cytology samples
- is a qualified and registered cyto-scientist or cyto-technician with a current annual practising certificate and
- demonstrates competency in the types of screening undertaken as defined in the NCSP Policies and Standards.

The term “cyto-screener” is used later in this document to refer collectively to cyto-scientists and cyto-technicians.

See also:

- Medical Sciences Council for registration of medical laboratory scientists and medical laboratory technicians at: www.mscouncil.org.nz

Details

Gynaecological cytology, histology and hrHPV testing services must be professionally led by a named pathologist, who is currently reporting in each of those sections and:

- delivers the agreed services in accordance with the NCSP Policies and Standards
- is available in the laboratory every working day or delegates this responsibility to another pathologist who is also currently reporting gynaecological cytology or histology.

Note: An appropriately qualified molecular pathology scientist must lead the reporting of hrHPV test results, with a pathologist’s oversight. Since not all laboratories performing hrHPV testing have a dedicated lead molecular pathology scientist, in such situations, the lead scientist
must have proven and substantial experience in hrHPV testing and reporting to lead this testing requirement.

Responsibilities of the lead pathologist and lead scientists (cytology, histology and hrHPV testing) include:

- reporting results
- managing a quality assurance programme
- providing in-service training
- auditing laboratory practice
- liaising with clinical colleagues
- liaising with the NCSP, NCSP Register Central Team and the NCSP regional services
- monitoring health and safety within the laboratory
- facilitating a collaborative environment among the staff
- managing the laboratory’s gynaecological cytology, histology and hrHPV testing services in partnership with the lead scientist for each respective discipline
- ensuring the assimilation of new developments in the field and introducing these new developments into the laboratory where such developments demonstrate an improvement in the service provided.

Vocational Registration Programme in Cervical Cytology

All trainee cyto-technicians and all Bachelor of Medical Laboratory Science graduates entering into cervical cytology for the first time must undertake the Vocational Registration Programme in Cervical Cytology (VRPCC). This is to ensure that such trainees and graduates achieve the minimum standards of competency before gaining an annual practising certificate.

See also:


Standard 501: Qualifications for pathologists

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

Target

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 subspeciality training in general pathology, anatomical pathology or cytopathology
- have a qualification to cover the subspecialty in which they are working
- 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 (for example, has provisional or general registration), they must work under supervision, as required by the Medical Council of New Zealand.

The lead supervising pathologist for cytology should have additional qualifications, for example, a diploma in cytopathology or fellowship of The International Academy of Cytology.
Measurement
The following method of measurement will be used:
- provider audits.

**Standard 502: Senior scientist requirements for laboratories conducting gynaecological cytology screening, histology processing and hrHPV testing**

Laboratories conducting gynaecological cytology screening must employ at least one senior registered cyto-scientist who has a minimum of five years full-time (or equivalent) cytology experience and who is a named lead senior cyto-scientist.

Laboratories conducting histology and molecular testing for hrHPV must employ at least one senior histo-scientist and senior molecular pathology scientist (see the note under Details on page 7) respectively with a minimum of two years full-time (or equivalent) experience. Each discipline must also be led by a named senior scientist.

**Target**

Each laboratory that reports gynaecological cytology must have at least one lead senior cyto-scientist who has a minimum of five years full-time (or equivalent) cytology experience.

Each laboratory processing histology and reporting hrHPV tests must have at least one lead senior histo-scientist and molecular pathology scientist (see the note under Details on page 7) who have a minimum of two years full-time (or equivalent) experience in the respective discipline.

Measurement
The following method of measurement will be used:
- provider audits.

**Standard 508: Qualifications for screening staff reporting gynaecological cytology**

All screening staff reporting gynaecological cytology must be qualified cyto-scientists or cyto-technicians.

For the purpose of screening, a senior cyto-scientist or senior cyto-technician is defined as a health professional with three years full-time (or equivalent) (FTE) work experience post-cytology qualification.

**Target**

All screening staff reporting gynaecological cytology must be qualified cyto-scientists or cyto-technicians.

**Measurement**

The following method of measurement will be used:
- provider audits.
Continuing education policy

**Purpose**
The aim is 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 reporting and processing gynaecological cytology, histology and hrHPV testing.

At the minimum, pathologists, cyto-scientists and cyto-technicians must:
- have documented evidence of their attendance at an internal and/or external teaching programme in cytology for neoplasms and associated diseases of the uterus, cervix and vagina
- have access to current editions of major standard texts, colour atlases and current issues of journals relevant to gynaecological cytology and histology in hard-copy form within the laboratory or as electronic versions via the internet or in e-book form
- allow all medical, scientific and technical staff to attend relevant local and international professional meetings regularly.

Staff processing and reporting hrHPV tests must participate in relevant educational activities determined by their respective laboratory discipline.

Scientists and technicians processing gynaecological histology must participate in relevant educational activities determined by their respective laboratory discipline.

All continuing education undertaken by any staff must be recorded within the laboratory and must be relevant to achieving the continuing medical education (CME) / continuing professional development (CPD) requirements of the appropriate health professional bodies.

**Details**
- All pathologists reporting gynaecological cytology must demonstrate external and in-house educational activity (this does not include routine daily practice) directly related to cervical pathology, which combined equates to 20 hours per annum averaged over three years.
- All pathologists reporting gynaecological histology should attend a specific gynaecological pathology education event at least once every three years.
- All cyto-scientists and cyto-technicians reporting gynaecological cytology must take part in external training in gynaecological cytology every three years. External training 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 percent as a practical component.
- All cyto-scientists and cyto-technicians must 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 FTE to enable staff to meet continuing professional development requirements. Such training may also include individual external quality assurance (EQA) programmes, quality assurance programmes (QAPs) and slide review activities.
• The laboratory must maintain a record of individual staff member’s participation in continuing education. These records must be available for any audit body to inspect.
• All pathologists, cyto-scientists and cyto-technicians must participate in external QAPs.
• All pathologists must regularly attend cytology/histology correlation meetings. Cyto-scientists and cyto-technicians should also attend when possible.
• Scientists and technicians processing and reporting hrHPV tests must participate in relevant internal and external education activities and external quality assurance programmes.
• Scientists and technicians processing gynaecological histology must participate in relevant internal and external education activities and external QAPs.

Returning to work
All staff returning to work following an extended absence must demonstrate competency in the tasks they undertake. If the absence is 12 months or longer, the lead pathologist or lead scientist should specify a retraining programme for the returning staff member to take part in. If the absence is less than 12 months, the lead pathologist or lead scientist should determine a suitable course of action to ensure the returning staff member’s appropriate re-introduction to their role. In all instances, the activities and outcomes must be documented and sign-off on the returning staff member’s competency should be recorded.

Standard 503: Continuing professional development requirements for cyto-scientists, cyto-technicians, pathologists and hrHPV testing staff
As a minimum, the continuing professional development requirements must be met by all pathologists, cyto-scientists, cyto-technicians and hrHPV testing staff and the laboratory must keep a record of the professional development requirements that have been met.

Target
• All pathologists, cyto-scientists, cyto-technicians and those reporting hrHPV results must meet the minimum continuing professional development requirements. This includes histo-scientists and histo-technicians who are processing gynaecological histology.
• All laboratories must maintain appropriate training records.

Measurement
The following method of measurement will be used:
• provider audits.
Volumes and workloads

Minimum volumes per laboratory

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

**Policy**
Each laboratory must report a minimum number of gynaecological LBC samples per annum.

**Details**
The designation of a volume of 15,000 gynaecological LBC samples per annum requires there to be at least two cyto-screeners working at any one fixed laboratory, and such a number of cases would generate about 1000 LBC samples per annum for a pathologist’s opinion.

**Standard 504: Volume of gynaecological cytology cases per laboratory per annum**
Each fixed laboratory site will process a minimum of 15,000 gynaecological LBC samples per annum. A single case may include multiple cytology samples per woman at any single patient episode.

**Target**
All fixed laboratory sites must process at least 15,000 gynaecological LBC samples per annum. A single case may include multiple cytology samples per woman at any single patient episode.

**Measurement**
The following methods of measurement will be used:
- monitoring reports
- NCSP Register data
- provider audits.
Minimum volumes for pathologists policy

Purpose
This policy aims to ensure that:

- a pathologist is available at all times
- pathologists maintain and improve their skills by being continually involved in reporting a wide range of abnormalities in gynaecological cytology, using gynaecological LBC samples.

Policy
Each pathologist that reports gynaecological cytology must report a minimum of 500 gynaecological LBC samples per annum.

Each fixed laboratory needs to have at least two pathologists who are competent in gynaecological cytology to cover for periods of sickness and annual and other leave.

Details
Each pathologist must report a minimum of 500 gynaecological LBC samples per annum.

Standard 505: Number of cases to be reported per pathologist per annum
Each pathologist will report at least 500 gynaecological LBC samples per annum. A single case may include multiple cytology samples per woman at any single patient episode.

Each laboratory must have at least two pathologists who are competent in gynaecological cytology to cover for periods of sickness and annual and other leave.

Target
- Every pathologist must report at least 500 gynaecological LBC samples per annum. A single case may include multiple cytology samples per woman at any single patient episode.
- Each laboratory must have at least two pathologists who are competent in gynaecological cytology to cover for periods of sickness and annual and other leave.

Measurement
The following method of measurement will be used:
- provider audits
- contract monitoring reports
Staffing and workloads for cyto-scientists and cyto-technicians policy

**Purpose**

This policy aims to ensure that any single fixed laboratory has sufficient cyto-scientists and cyto-technicians on staff to handle the volume of gynaecological LBC samples reported and requires all staff to screen a sufficient number of cases to maintain and improve their skills.

**Policy**

A cyto-scientist or cyto-technician’s workload must be appropriate to their level of skill and considerate of their other tasks. The standard defines a maximum screening workload as an upper limit to prevent work overload and also defines a lower limit to ensure staff maintain their competency and skills.

Competency (both for reporting and educational purposes) for any aspect of screening is defined as a sensitivity of at least 95 percent for high grade and 90 percent for total abnormalities.

**Note:** High grade is defined as HS1+HS2+SC+AIS+AC1-5, while total abnormalities is defined as the total of all abnormalities excluding ASL.

For the purposes of the NCSP Policies and Standards: Section 5: Providing a Laboratory Service, sensitivity should be regularly measured at a period of no less than three months, and this should be combined with a measure of annual rolling sensitivity data. For internal monitoring of competency (for example, to include ASL and ASH), laboratories may undertake additional measures and timeframes, and monitoring may be extended to correlate with histology.

Protocols, outcomes and any remedial actions must be documented.

**Details**

A full-time cyto-screener’s workload must not exceed an equivalent of screening 70 primary gynaecological LBC samples in a six- to eight-hour working day. Full re-screens and other full reviews of slides (for example, 42-month, look-back slides) are counted as being equivalent to primary screening for this purpose.

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

**Standard 506: Maximum workload for screeners**

The maximum workload for any cyto-screener involved in manual primary screening (or equivalent full screens) of LBC samples is 70 cases on any one working day.

The maximum workload for any cyto-screener involved in location-guided field of view (FOV) review of LBC samples is 140 cases on any one working day.

- **FOV : LBC = 2 : 1.**

It is recommended that up to three rapid re-screens = one full primary screen = one full re-screen.
Note: A full review of historical conventional cytology slides is counted as being equivalent to one LBC sample full re-screen.

**Target**

Each cyto-screener involved in primary screening, FOV review or full re-screening must screen no more than (or proportionally):

- 70 LBC samples per working day
- 140 FOV reviews of LBC samples per working day.

**Measurement**

The following method of measurement will be used:

- provider audits.

**Standard 507: Minimum number of cases per annum per cyto-scientist/cyto-technician**

Cyto-scientists and cyto-technicians must primary screen a minimum of 3000 gynaecological LBC samples per annum. In the case of senior cyto-scientists and senior cyto-technicians (refer to standard 508: Qualifications for screening staff reporting gynaecological cytology on page 9), this may include a maximum of 1200 full re-screen cases.

Cyto-scientists and cyto-technicians must complete a minimum of 3000 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, cyto-scientists and cyto-technicians must complete a minimum of 1000 manual full-screen and 3000 FOV cases per annum.

Note: This does not apply to staff who are primary screening in a laboratory that has not fully converted to automation.

**Exemptions**

Lead senior cyto-scientists must primary screen and/or full review a minimum of 1000 LBC samples per annum. If their workload includes location-guided review, they must also complete a minimum of 1000 FOV review cases per annum.

‘Other’ senior cyto-scientists who have significant managerial, teaching, quality management, research or other non-cervical screening duties may also be granted exemption. Such exemptions must be approved by the lead pathologist 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 3000 gynaecological LBC samples or FOV reviews per annum.

Note: If any staff member changes the LBC type they screen and report (for example, a staff member who is BD SurePath™ trained and changes to Hologic ThinPrep® screening) and are not certified for the alternative LBC type, they must undertake a full conversion process, that is, the training requirements of the manufacturer and of this standard plus any additional requirements of the individual laboratory to determine competency.
Furthermore, if any staff member changes the automated screening device system (for example, a staff member who is using BD FocalPoint/GSTM system and changes to Hologic ThinPrep® Imager) and that staff member is not certified for the alternative automated system, they must undertake a full conversion process, that is, the training requirements of the manufacturer and of this policy and standard plus any additional requirements of the individual laboratory to determine competency.

**Target**

- All cyto-scientists and cyto-technicians must screen a minimum of gynaecological LBC samples per annum as indicated in standard 507: Minimum number of cases per annum per cyto-scientist/cyto-technician above.

- The lead senior cyto-scientist and ‘other’ senior cyto-scientists who have significant managerial and/or training responsibilities must screen a minimum of gynaecological LBC samples per annum as indicated in standard 507: Minimum number of cases per annum per cyto-scientist/cyto-technician above.

**Measurement**

The following method of measurement will be used:

- provider audits
- contract monitoring reports.
Cytology

Handling and identifying cytology slides policy

Purpose

Slides must be labelled unambiguously and tracked.

Policy

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

- Gynaecological cytology samples must be clearly identified and permanently marked to ensure accurate matching with the referral form. Laboratories must have a protocol in place that details the action to be taken if they receive any mislabelled or unlabelled slides or incomplete forms.

- Laboratories must have a tracking system with a minimum of two full unique identifiers 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 leaking LBC vial at the laboratory, and the record must identify if interpretation of the sample is compromised by the leakage.

There must be appropriate sample identification with documented quality control protocols. There must be appropriate checks of steps taken during the pre-analytical process that may be susceptible to mislabelling and cross-contamination/transfer. The checks must be recorded and maintained. The systems must allow for identification of which staff processed the specimen at each critical point.

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 must be informed.

- If an excessive amount of the sample has been lost, the sample is deemed unsatisfactory and the smear taker must be notified (refer to manufacturer’s instructions).

- If 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 cyto-scientist or cyto-technician should check the vial for blood and/or mucous and request a remake of the sample with an appropriate procedure for re-staining according to manufacturer’s instructions. Any repeat processing must be recorded.
Laboratories must document and also indicate to the smear taker for technical or educative reasons, 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.
- If abnormal cells are identified, the sample is reportable with a note to the smear taker indicating an error with the sampling device.

See also:
- Manufacturer’s instructions

**Cytology LBC slide preparation policy**

<table>
<thead>
<tr>
<th>Purpose</th>
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<tr>
<td>The aim is 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.</td>
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<th>Policy</th>
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<tr>
<td>Slide preparation and staining must be of optimal quality.</td>
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<th>LBC policy</th>
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<tr>
<td>LBC samples can be processed at a separate International Accreditation New Zealand (IANZ) accredited laboratory site from the laboratory site that they are read at.</td>
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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.

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<th>Slide staining</th>
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<tr>
<td>LBC slide staining must be performed as follows.</td>
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<td>- Cervical LBC slides must be stained using the Papanicolaou staining method or when staining for automation assisted screening as required by the manufacturer.</td>
</tr>
<tr>
<td>- 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.</td>
</tr>
<tr>
<td>- The cover slip must cover an area larger than the LBC cell preparation.</td>
</tr>
<tr>
<td>- Mounting media must not be allowed to contaminate the surface of the cover slip in such a way as to compromise visibility.</td>
</tr>
</tbody>
</table>

See also:
- Manufacturer’s instructions.
Primary screening policy (non-automated screening)

Purpose
The aim is to ensure that cytology slides are interpreted competently.

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

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

All cytology screening and re-screening (rapid re-screening and full re-screening) must be completed before a result is reported to the smear taker and the NCSP Register.

These processes must be completed in accordance with the expected timeframes set out in standards 513: Reporting gynaecological cytology and hrHPV test results and 518: Sending cytology results to the NCSP Register.

Details
Note:
- The cyto-screener 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.
- 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 cyto-scientist or cyto-technician (with an annual practising certificate), with full secondary re-screening or rapid re-screening until the graduate or trainee technician receives their annual practising certificate.

Rapid re-screening policy

Purpose
The aim is to rapidly re-screen slides categorised as ‘Negative for intraepithelial lesion or malignancy’ at primary manual screening, before the report is issued.

Policy
Laboratories that manual screen only or have not fully converted to automated screening must conduct rapid re-screening of all manually primary screened slides categorised as ‘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.
All cases registered by a laboratory for automated screening require full screening for any manual screening component – rapid review does not apply. Standard 509: Rapid re-screening results and recording outcomes (see below) only applies to cases processed in a laboratory that does not have automated screening or is the workload component registered for manual screening in a laboratory that is in the process of but has not completed conversion to full automation.

There are no additional quality control measures for cases signed out as negative with FOV only, but discrepancies between FOV followed by full screen must be monitored and recorded for each individual screener.

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

Details
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.

The following guidelines apply:
- Rapid re-screening must be carried out by cyto-scientists or cyto-technicians designated by the laboratory’s lead cyto-scientist/pathologist.
- All staff performing rapid re-screening must demonstrate their ability to detect abnormalities using this method before conducting rapid re-screening.
- Rapid re-screening ability is determined by the lead cyto-scientist.
- Where possible, all cyto-screeners should be involved but must not review their own work.
- The primary cyto-screener must identify if the case requires rapid or full re-screen.
- 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
At least 98 percent but less than 100 percent of ‘Negative for intraepithelial lesion or malignancy’ slides are confirmed as such after rapid re-screening.

Outcomes of rapid re-screening must be recorded for all cases.

Note: Refer to Rapid re-screening policy above for details on applying rapid review.

Target
- At least 98 percent but less than 100 percent of ‘Negative for intraepithelial lesion or malignancy’ slides must be confirmed as such after rapid re-screening.
- All outcomes must be recorded.
Measurement
The following method of measurement will be used:

- provider audits.

Automated screening device policy

Purpose
The aim is to ensure that cytology LBC slides are accurately processed and screened using an automated screening device once such a device has been 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 the manufacturer’s instructions.

Details
For validation of laboratory/imager, the following guidelines apply:

- The automated devices 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.
- 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 and they must 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 such tasks.
- Slides that are processed and rejected either due to calibration or other reasons must be either reprocessed before repeat automated screening or manually screened.

Definitions
- **Field of view (FOV):** Microscopic FOV 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**
The aim is to review and screen slides using location-guided screening, where such slides have been satisfactorily scanned using an automated screening device, before the report is issued.

**Policy**
Laboratories must conduct location-guided FOV review of all slides that have been satisfactorily scanned using an automated device. Those cases requiring full screen (see standard 510: Full re-screening below) must receive a minimum of FOV review with at least one full screen performed by a different staff member. All staff performing FOV reviews must demonstrate their ability to detect abnormalities using this method before conducting a 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 FOV as specified by the manufacturer’s instructions.

For validation of individuals, the following guidelines apply.

- FOV review must be carried out by cyto-scientists or cyto-technicians designated as competent by the laboratory’s lead cyto-scientist/pathologist.

- Before the lead scientist/pathologist signs off FOV competency, 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 re-screening policy (additional to training and test set cases for validation):
    - achieving a sensitivity of at least 95 percent for high-grade and 90 percent for all abnormalities (see the clarification of sensitivity under the staffing workloads for cyto-scientists and cyto-technicians policy on page 14)
    - maintaining detailed records for each screener, including sensitivities
    - where a cyto-screener fails to achieve the required sensitivities, further collections of 1000 FOV cases with full re-screening are 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.

Note: If any staff member changes from one automation system to another and is not certified for the alternative system, that staff member must fulfil all the requirements listed above for the new automation system.
Full re-screening policy

Purpose
The aim is 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 (not high grade) who have not been hrHPV tested before returning to usual (three-yearly) screening after the abnormal diagnosis. Women being followed up with annual smears for a previous high grade require annual smears with a minimum of rapid review (manual screening) or FOV (automated screening) or for squamous only lesions until they have completed appropriate hrHPV testing returning them to usual three-yearly screening
- gynaecological cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities or immunosuppression (optional at the discretion of the laboratory)
- 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.

Note: Samples scanned using automated screening devices that require full screen must receive a minimum of FOV review as per the location-guided screening policy (see page 22) with at least one full screen performed by a different staff member.

Samples scanned using automated screening devices where abnormal cell changes are identified by location-guided FOV must have 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 (for example, due to equipment failure), then all primary screened samples must be re-screened in accordance with all sections of the NCSP Policies and Standards relating to manual screening (includes staffing, reporting and procedural requirements for manual screening).

Details
Only the following staff, as designated by the lead cyto-scientist at the laboratory, may carry out full re-screening of gynaecological cytology in a manual screening laboratory:

- a cyto-scientist or cyto-technician who has completed the VRPCC and who has more than three years full-time experience post qualification
- a cyto-scientist or cyto-technician with more than four years full-time experience post qualification.
In an automated screening environment only the following staff, as designated competent by the lead cyto-scientist at the laboratory, may carry out additional full screen of gynaecological cytology:

- a cyto-scientist or cyto-technician already undertaking full manual re-screening
- a trainee cyto-scientist or cyto-technician who completes the VRPCC must demonstrate competency by actively participating in full re-screening over a period of at least one year FTE 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: Full re-screening (see below)
  - 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 cyto-scientists and cyto-technicians who have not already achieved competency to fully re-screen must complete their time for competency as detailed above but pro-rata as follows:
  - completing the VRPCC (complete the equivalent of one year FTE work experience post qualification)
  - without the VRPCC (complete the equivalent of two years FTE work experience post qualification).

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

**Standard 510: Full re-screening**

Full re-screening must be performed for gynaecological cytology in all of the following categories:

- abnormal (G2 or G3) gynaecological cytology
- gynaecological cytology from women with abnormal screening histories (not high grade) who have not been hrHPV tested before returning to usual (three-yearly) screening after the abnormal diagnosis. Women being followed up with annual smears for a previous high grade require annual smears with a minimum of rapid review (manual screening) or FOV (automated screening) or for squamous only lesions until they have completed appropriate hrHPV testing returning them to usual three-yearly screening.
- gynaecological cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities or immunosuppression (optional at the discretion of the laboratory)
- 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.

Samples scanned using automated screening devices where abnormal cell changes are identified by location-guided FOV must have a minimum of one full manual screen performed by a different staff member.
Target
All of the categories listed above must receive full re-screening.

Measurement
The following method of measurement will be used:
- provider audits.

**Standard 511: Confirmation and reporting for abnormal results**
All results confirmed abnormal (G2 or G3) after full re-screening will be sent to the pathologist for confirmation and reporting.

Target
All results confirmed abnormal (G2 or G3) after full re-screening must be sent to the pathologist for confirmation and reporting.

Measurement
The following method of measurement will be used:
- provider audits.

**Standard 512: Re-screening timing**
All re-screening (rapid and full) will take place before the results are confirmed and sent to the smear taker and the NCSP Register.

Target
All re-screening (rapid and full) must occur before the results are confirmed and sent to the smear taker and the NCSP Register.

Note: The exception to this is cases that only require FOV review in an automated laboratory.

Measurement
The following method of measurement will be used:
- provider audits.
Ensuring optimal recommendations policy

**Purpose**

The aim is to ensure that the optimal recommendation for recall or referral is made for each cytology sample.

**Policy**

For the optimal recommendation for recall and/or referral to be made for each cytology sample, laboratories must ensure that a woman’s full and current 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 *Guidelines for Cervical Screening in New Zealand* (Ministry of Health 2008).

Laboratory staff must obtain the full and current screening history from the NCSP Register for all women in the gynaecological screening programme.

**Details**

Laboratories will access the screening history electronically directly from the NCSP Register using the online screening histories (OLSH) web function. If electronic access is not available due to a technical failure, laboratories can ask the NCSP Register Central Team to send a woman’s screening event history by fax (or other secure means) within four working hours of making the request provided the laboratory supplies the NCSP Register Central Team with the woman’s:

- 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, the 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:
Histology

Preparing, examining and reporting histology specimens policy

**Purpose**
The aim is 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 malignancy.

**Policy**
The histopathologist should be advised whether a biopsy is considered diagnostic or excisional. The histopathologist must be aware of a woman’s full and current NCSP Register screening event history at the time of reporting gynaecological histology specimen.

Note: See Ensuring optimal recommendations policy above for more details on obtaining a 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.

**Handling specimens**
Pre-analytical procedures must conform with requirements of ISO15189.

There must be appropriate, documented quality control checks at steps in the pre-analytical process that may be susceptible to mislabelling and cross-contamination/transfer. The checks must be recorded and maintained and can help identify staff processing at critical points.

All specimens are to be received in 10 percent neutral buffered formalin (or an appropriate alternative fixative).
Cervical punch biopsies are to be prepared as described under Cone biopsies preparation below and must have:

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

Loop excisions (LEEP, LLETZ) are to be prepared as described under Cone biopsies preparation below and must have:

- optimal orientation
- 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 further levels examined if indicated by clinical information or findings on the initial three levels.

**Cone biopsies preparation**

Cone biopsies are to be prepared as follows:

- Record the anterior/posterior diameter, height of specimen and 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 2–3 mm slices. If the specimen is received open, parallel or radially section the specimen at 2–3 mm 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 examined if indicated by clinical information or findings on the initial three levels.

Additional investigations (for example, immunohistochemistry) for difficult-to-grade lesions should be performed as required.

**Reporting on 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
  - identification of any inadequacies and reason(s) why
- for a LEEP, LLETZ and cone:
  - histological type and grade of lesion
  - uni-/multi-focal (if evident)
  - tissue margins (if evident)
  - types of normal epithelium present (both glandular and squamous)
– invasion if present (reported using International Federation of Gynecology and Obstetrics (FIGO) guidelines (2006)):
  o uni-/multi-focal (if evident)
  o depth
  o horizontal and vertical length of lesion
  o lymphovascular invasion
  o stromal reaction.

Managing 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 Histopathology Reporting in Cervical Screening: An integrated approach. Second edition (NHS Cancer Screening Programme (NHSCSP), Publication No. 10, September 2012)). Also see standards 521: Correlation of histology and cytology slides and 522: Reviewing cases with a high-grade diagnosis below.

See also:

Standard 514: Histopathologist access to cervical cytology results
The histopathologist must have the full and current NCSP Register screening event history available at the time of reporting the gynaecological biopsy.

Target
All histopathologists must have the full screening event histories available at the time of reporting gynaecological biopsies.

Measurement
The following method of measurement will be used:
- provider audits.
**Standard 515: Examining and reporting histology slides**

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

**Target**

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

**Measurement**

The following method of measurement will be used:

- provider audits.
Communicating results

Reporting to smear takers and specialists policy

Purpose
The aim is to have cytology, histology and hrHPV test samples 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 all histology samples to the referring specialist using the approved NCSP SNOMED coding.

Laboratories must have protocols and procedures in place 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 samples were 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 samples were 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 samples were taken.

Conjunct cytology and hrHPV tests must be reported to the smear taker at the same time.

Details
Cytology, histology and hrHPV results that exceed the prescribed reporting turnaround time targets should be reported as soon as possible to minimise delays in recall, referral and management.

It is recognised that some histology cases need additional time to allow collaborative discussion and referral before issuing a result. The specialist should be informed if it takes more than 15 working days for a histology result to be reported (and noted as a laboratory record).

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

Changes to reporting methods
All changes that could impact on laboratory reporting methods, including changes to Bethesda or SNOMED codes, must be coordinated through the Ministry (specifically the NCSP). These will be made following engagement and discussion with laboratories and other affected parties.
See also:

**Standard 513: Reporting gynaecological cytology and hrHPV test results**

Laboratories are required to report 90 percent of final gynaecological cytology results to smear takers within seven working days of receiving a specimen.

Laboratories are required to report 98 percent of final gynaecological cytology results and hrHPV test results to smear takers within 15 working days of receiving a specimen.

Results for cytology and conjunct hrHPV tests must be reported together to the smear taker.

**Target**

Laboratories must report:
- 90 percent of the final gynaecological cytology results to smear takers within seven working days of receiving the specimen
- 98 percent 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 will be used:
- monitoring reports
- NCSP Register data
- provider audits.

**Standard 516: Reporting histology results**

Laboratories are required to report 90 percent of final histology results to referring colposcopists within 10 working days of receiving a specimen.

Laboratories are required to report 98 percent of final histology results to referring colposcopists within 15 working days of receiving a specimen.

**Target**

Laboratories must report:
- 90 percent of final histology results to referring colposcopists within 10 working days of receiving the specimen
- 98 percent of final histology results to referring colposcopists within 15 working days of receiving the specimen.
Measurement
The following methods of measurement will be used:
- monitoring reports
- NCSP Register data
- provider audits.

Providing advice to smear takers policy

Purpose
The aim is to promote the laboratory’s role in providing advice to smear takers and improve 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 cyto-scientists must be readily available to advise smear takers regarding:
- the suitability/adequacy of gynaecological cytology samples and hrHPV test samples
- the terminology used in gynaecological cytology reports
- the terminology used in hrHPV test reports
- the clinical significance of the laboratory results
- further procedures or investigations that may be helpful
- updates and changes.

Multidisciplinary meetings
Pathologists must participate in multidisciplinary meetings (MDMs) as part of case management and quality control, and formal arrangements are in place for MDMs with colleagues.

The multidisciplinary team could include:
- cyto-technical/cyto-scientific staff
- pathologists
- gynaecologists, colposcopy nurses, smear takers and oncologists as appropriate.

The laboratory that issues the original report should, where possible, have their reporting pathologist representative attend the MDM to discuss review outcomes directly with the colposcopy team.

Where a pathologist, who is not the original reporting pathologist, presents at an MDM, the results of previous cytology/histology reports, and slides if requested for correlation, must be made available by the laboratory (holding the reports and slides) in a timely manner to the pathologist presenting at the MDM. In addition, pathologists should consider:
• that the original reporting laboratory provides its own slide review outcome to the pathologist attending the MDM
• that there will be times where there is not a consensus between the two reviewing pathologists and further review may be needed
• the appropriateness of reviewing of LBC technology they are not routinely reporting in their laboratory (i.e. a pathologist who routinely reports ThinPrep presenting SurePath review at MDM and vice versa)
• amending reports that reflect the final outcome so that accurate recall is provided to smear takers and the NCSP register for future management and follow up.

Outcomes of MDMs must be recorded and linked to the original result.


Forwarding results to the NCSP Register policy

Purpose
The aim is 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.

All electronic data must contain:
• 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 National Cervical Screening Programme-Register Implementation Guide (NSU Implementation Guide)
This guide, which specifies the cytology, histology and hrHPV file format, is distributed to laboratories by the National Screening Unit (NSU) and is available on request.

Note:
- 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.

**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:
- SNOMED coding for histology at: www.nsu.govt.nz/health-professionals/1060.aspx
- *NSU Implementation Guide* (cytology and histology file format) (see above).

**Standard 518: Sending cytology results to the NCSP Register**

Ninety-eight percent of all cytology results and hrHPV test results must be forwarded to the NCSP Register, in the approved Bethesda coding and format, within 16 working days of receipt of a specimen.

**Target**

Staff must forward 98 percent of the cytology results and hrHPV test results to the NCSP Register, in the approved Bethesda coding and format, within 16 working days of receipt of a specimen.

**Measurement**

The following methods of measurement will be used:
- monitoring reports
- NCSP Register data
- provider audits.

**Standard 519: Sending histology results to the NCSP Register**

Ninety percent of the histology results must be forwarded electronically to the NCSP Register, in approved format and NCSP SNOMED coding, within 15 working days of receipt of a specimen.
National Cervical Screening Programme Policies and Standards

Section 5: Providing a Laboratory Service

Ninety-eight percent 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 a specimen.

Histology results must include all appropriate topography, morphology and procedure SNOMED codes.

Target

- Staff must electronically forward 90 percent of the histology results to the NCSP Register, in the approved format and with NCSP SNOMED coding, within 15 working days of receipt of the specimen.

- Staff must electronically forward 98 percent of the histology results to the NCSP Register, in the approved format and with NCSP SNOMED coding, within 20 working days of receipt of the specimen.

Measurement

The following methods of measurement will be used:

- monitoring reports
- NCSP Register data
- provider audits.

Cancer Registry Act 1993 requirements

Purpose

The aim is 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 to be reported to the NZCR.

Details

All cytology and histology results with a diagnosis of invasive or in situ cancers must be forwarded to the NZCR. 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 adenocarcinoma (AC5)
  - abnormal cells consistent with a high grade squamous intraepithelial lesion (HSIL) with features suspicious for invasion (HS2)

- histology:
  - CIN3
  - CIN2/CIN3 when reported together
  - endocervical AIS
- invasive lesions
- other malignancies.

See also:

**Standard 520: Sending results to the New Zealand Cancer Registry**

The laboratory that has analysed the sample must forward all cytology with an interpretation of cancer (or suspicious of) and histology results with a diagnosis of invasive or in situ cancers to the NZCR (at the Ministry of Health).

**Target**

The laboratory that has analysed the sample must forward all cytology **with an interpretation of cancer** and histology results with a diagnosis of invasive or in situ cancers to the NZCR (at the Ministry of Health).

**Measurement**

The following method of measurement will be used:
- provider audits.

See also:
Quality assurance

Accreditation policy

**Purpose**
The aim is 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 the provision of gynaecological cytology, adjunct molecular testing and/or histology services.

**Details**
Laboratories must inform the Ministry of the results of the IANZ assessment (both the annual surveillance process and the periodic full peer reassessment) and any change to their accreditation status.

IANZ (or other New Zealand accreditation agencies) must also inform the Ministry at the same time as they inform the laboratory if there is any change in 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 (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 the 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.

Internal quality assurance policy

**Purpose**
A laboratory’s internal quality control system is an essential component of quality assurance for the NCSP.

An internal quality control system will:
- identify potential sources of error in a laboratory’s operations
- 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 in place that ensure the quality of gynaecological cytology, hrHPV testing and histology (and any adjunct molecular testing). 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 preparation, reading and reporting process
- the 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 and validation of data entry and timely calibration checks for all instrumentation used.

**Details**

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

- ensuring consistent sample registration, processing and staining
- ensuring that the re-screening of slides occurs before the results are reported and forwarded to the smear taker and NCSP Register
- evaluating individual performance for all cyto-scientists, cyto-technical staff and pathologists working in the laboratory
- monitoring the sensitivity of primary screening for each primary cyto-screener and the laboratory as a whole
- following up in order to correlate the results of gynaecological cytology with respective gynaecological histology
- reviewing the previous 42 months of 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 be forwarded to the NCSP Register at the same time as the woman’s smear taker is notified.

See also:

- SNOMED coding for histology at: www.nsu.govt.nz/health-professionals/1060.aspx
External quality assurance policy

Purpose

The objectives of external QAPs 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, including adjunct testing for the NCSP, must participate to a satisfactory standard in an appropriate external QAP.

Details

The QAP must include:

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

Laboratories are expected to use external quality assurance reports as part of their own quality control processes, and it is compulsory for all staff to participate in an individual external QAP approved by the NCSP.

Note: In recent years, the World Health Organization (WHO) has set up an HPV reference laboratory to assist with assessing the quality of HPV testing. For further information about the WHO HPV Laboratory Network, see: www.who.int/biologicals/areas/vaccines/hpv_labnet/en/

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 under NCSP indicators and targets below.
Reviewing cases

Correlation of cytology and histology policy

Purpose
The aim is to ensure that laboratories correlate cytology, histology and hrHPV test data and microscopically review all cases where there is discordance between the cytology and histology results with clinical management implications. Slides reviewed with outcomes should be utilised as an educational tool and quality improvement activity for all staff.

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

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

Note: Where this does not occur, the results of previous cytology/histology reports, and slides if requested for correlation, must be made available in a timely manner to the requesting 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 cyto-scientist and/or pathologist where the following discrepancies have occurred:

<table>
<thead>
<tr>
<th>Cytology</th>
<th>Histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSIL/invasive SCC</td>
<td>LSIL/negative/reactive</td>
</tr>
<tr>
<td>AIS/AG4/AG5 AC1-AC5</td>
<td>Negative/reactive</td>
</tr>
<tr>
<td>Unsatisfactory/negative</td>
<td>HSIL/invasive SCC/glandular abnormalities/invasive adenocarcinoma Required under retrospective review of smears taken up to 42 months before high-grade or invasive diagnosis on histology policy</td>
</tr>
</tbody>
</table>

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.
Recommended histology–cytology correlations

Histology slides and cytology slides may be reviewed by a senior cyto-scientist and/or pathologist, for continuing education purposes, where the following discrepancies have occurred:

<table>
<thead>
<tr>
<th>Cytology</th>
<th>Histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC-US/LSIL/AIS</td>
<td>HSIL or invasive SCC</td>
</tr>
<tr>
<td>AGC/ASC-US/LSIL/HSIL</td>
<td>Glandular abnormalities or invasive adenocarcinoma</td>
</tr>
<tr>
<td>ASC-H/AG1/AG2/AG3</td>
<td>Negative/reactive</td>
</tr>
</tbody>
</table>

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

Where a lack of correlation (high grade/low grade or greater) 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 of any remaining lack of correlation.

Also see Managing discordant results (page 29) and Multidisciplinary meetings, under the Providing advice to smear takers policy (page 33).

Full case review details

The reviewing team should include:
- specialist colposcopists
- cyto-scientists
- cytopathologists
- histopathologists.

If, as a result of the review, changes must be made to the cervical screening report that 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 NZCR (if a previous cytology result reported to the NZCR 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-yearly screening.

See also:
• The International Federation of Gynecology and Obstetrics (FIGO) guidelines *Staging Classifications and Clinical Practice Guidelines for Gynaecological Cancers*, available at: www.ginecologia.unipd.it/Assistenza-Documenti/Unita%27%20operative/Ginecologia%20Oncologica/staging_booklet.pdf

**Standard 521: Correlation of histology and cytology slides**

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

**Target**

All histology results must be correlated with any cytology slides that have management implications and were taken in the previous six months, and the results must be recorded.

**Measurement**

The following method of measurement will be used:
• provider audits.

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

**Purpose**

The aim is to ensure that:
• pathologists, cyto-scientists and cyto-technicians 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 before 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
• the review process and outcomes are used for educative purposes for all staff involved in screening and reporting.
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.

Note: This information provides an indication of the laboratory’s false negative rate with respect to detecting high-grade lesions.

Details

Any abnormality identified as high grade on review of a previously reported negative or unsatisfactory cytology slide must be fully reviewed by a senior cyto-scientist or senior cyto-technician (qualified for full review). If there is a lack of consensus on an agreed false negative, the case must be reviewed by a pathologist.

Confirmed high-grade abnormalities must be documented by the laboratory. Cumulative data must be forwarded to the NSU to help ensure the accuracy of submitted negative cytology reports.

See also:


Standard 522: Reviewing cases with a high-grade diagnosis

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

Target

All cases with a high-grade diagnosis on histology must have a review of all cytology slides that have been reported as negative, benign/reactive or unsatisfactory in the previous 42 months.

Measurement

The following method of measurement will be used:

- provider audits
- contract monitoring reports.
Retaining slides, tissue and documentation

Retaining slides, tissue and associated documentation policy

**Purpose**

All gynaecological cytology and histology slides, tissue 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, tissue, request forms and reports, including electronic copies, in accordance with the NCSP laboratory services contract, IANZ requirements and relevant legislation (for example the Public Records Act 2005, and the Health (Retention of Health Information) Regulations 1996).

Māori women and women from other cultural groups may feel a strong connection to biological samples provided to laboratories for analysis. Such cultural values need to be recognised in any actions taken.

**Details**

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

Timeframes for the retention of stained slides, tissue and associated documentation is set out in the table below.

<table>
<thead>
<tr>
<th>Type of record</th>
<th>Minimum retention period.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records of eligible people</td>
<td>A record of all eligible people to whom you provide services should be held for a minimum period of 20 years from the date of sample. This record should include all substantial personal interviews with eligible people which impact on their health or disability,</td>
</tr>
<tr>
<td>Records in respect of laboratory test results and test reports</td>
<td>A record of the laboratory test results and test reports should be retained for a minimum period of 20 years from the date of sample.</td>
</tr>
<tr>
<td>Records in respect of cytology slides, histology slides and histology blocks</td>
<td>Gynaecological cytology slides should be retained for a minimum of 10 years from the date of the final test report. This is a minimum retention period, and 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 should be retained for a minimum of 20 years from the date of the final test report.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Records in respect of laboratory referrer test request forms.</td>
<td>A copy of each request form, or a complete electronic image of each request form, for which a payment is claimed should be retained for a minimum of 15 years from the date of sample.</td>
</tr>
<tr>
<td>LBC samples</td>
<td>The vial must be retained in the laboratory as per the manufacturer’s specifications for a minimum of one month or longer until reported.</td>
</tr>
<tr>
<td>Other associated records and reports, for example, policy data</td>
<td>Must be retained in accordance with Archives New Zealand’s recordkeeping guidelines and any other relevant national legislative requirements.</td>
</tr>
</tbody>
</table>

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

**Laboratories who cease to provide gynaecological cytology and/or histology**

If a laboratory ceases to undertake gynaecological cytology, hrHPV testing 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 a laboratory’s closure.

Other information can be found at:

- National Pathology Accreditation Advisory Council (NPAAC) Guidelines (see: www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-RetLabRecDI.htm (Please note, where 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)
- New Zealand Medical Council guidelines
• the NSU retention and disposal schedule (see: www.archway.archives.govt.nz/ViewEntity.do?code=DA539).

**Standard 517: Cultural sensitivity and appropriateness**

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

**Target**

All requests regarding culturally appropriate methods of handling and disposing of human tissue must be treated sensitively and in accordance with local protocols.

Laboratories must have written protocols for handling and disposing of human tissue incorporating cultural considerations.

**Measurement**

The following method of measurement will be used:

• provider audits.

See also

• NZ Medical Council resources
  – www.mcnz.org.nz/support-for-doctors/resources/

• Medical Sciences Council resources
  – www.mauriora.co.nz/

Laboratories should also consider their local DHB and iwi who may provide policy and advice for cultural competency and considerations.
High-risk human papillomavirus testing

hrHPV testing policy

**Purpose**
The aim is to ensure that cytology LBC samples are accurately processed and tested for hrHPV using a validated test procedure.

**Policy**
hrHPV testing of LBC samples must be carried out using approved and validated processes and in accordance with manufacturer instructions.

Laboratories must conduct adjunct hrHPV testing to cytology as defined in the *Guidelines for Cervical Screening in New Zealand* (Ministry of Health 2008), incorporating guidelines for hrHPV testing.

**Details**

**Note:**
- The test procedure must be endorsed by an internationally recognised accreditation agency, such as the United States Food and Drug Administration (FDA), or be Conformité Européenne (CE) marked and/or internally clinically validated to meet at least the performance of internationally validated tests.\(^3\)
- The sensitivity of the test for the detection of CIN2 or worse in women 30 years of age or older must be at least 90 percent.
- Processes must be in place to regularly monitor for risk of cross-contamination both in the cytology preparation area and hrHPV testing laboratory. The outcomes must be documented.
- Appropriate controls must be included, and the outcomes must be documented and stored.
- The hrHPV test must test for a minimum of the 14 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, transportation, volume and storage of LBC samples for hrHPV testing must be in accordance with the manufacturers’ recommendations or with a suitably validated process.
- All staff performing hrHPV testing must demonstrate competency in performing the test procedure and issuing results.

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\(^3\) For an example of the validation procedure, with reference to Clinical Laboratory Improvement Amendments (CLIA), see: Seabrook JM, Hubbard RA. 2003. Achieving quality reproducible results and maintaining compliance in molecular diagnostic testing of human papillomavirus. *Archives of Pathology and Laboratory Medicine* 127: 978–83.
• Results must be reported to the NCSP Register in an approved format as either 'hrHPV detected', 'not detected' or 'invalid test'.

• Cytology with adjunctive hrHPV testing must be reported together, and the cytology must be reported in consideration of the hrHPV test result. hrHPV test results must not be issued independently when adjunct to a cytology request.

• Turnaround times are defined under standards 513: Reporting gynaecological cytology and hrHPV test results and 518: Sending cytology results to the NCSP Register (see above).

**Quality assurance and HPV testing**

As there are several hrHPV tests either already commercially available or in the process of becoming available, laboratories must participate in external QAPs to ensure competency in hrHPV testing, for example, through the RCPA, the WHO reference laboratory or another appropriate body (also refer to External Quality Assurance Policy page 40).

See also: WHO HPV Laboratory Network at:
www.who.int/biologicals/areas/vaccines/hpv_labnet/en/
NCSP indicators and targets

Monitoring details

The indicators for monitoring the NCSP are reported in the monitoring reports. They are listed below and are reviewed periodically.

Note:

- There are a number of laboratory-specific indicators with targets that 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 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: Case mix (ratio of community versus hospital cases) is a consideration when calculating and monitoring the laboratory total abnormality rate.

Indicator L2

Not in use.

Unsatisfactory samples by laboratory

Indicator L3

Number of LBC sample reports by a 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/SQCC on histology

Indicator L4
Target for PPV for HSIL/SQCC = 65–85 percent.

Accuracy of negative cytology reports

Indicator L5
Also refer to standard 522: Reviewing cases with a high-grade diagnosis (page 44).

For women with a histological diagnosis of CIN2, CIN3, invasive SQCC, AIS or invasive endocervical adenocarcinoma, the proportion of cytology slides originally reported within the preceding 42 months as negative, benign/reactive or unsatisfactory which 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 aim for less than 15 percent, but not more than 20 percent combined.
# Appendix 1: Laboratory standards index table

<table>
<thead>
<tr>
<th>Standard number</th>
<th>Standard</th>
<th>Description</th>
<th>Page reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>501</td>
<td>Qualifications for pathologists</td>
<td>All pathologists reporting gynaecological cytology and/or histology must be qualified.</td>
<td>8</td>
</tr>
<tr>
<td>502</td>
<td>Senior scientist requirements for laboratories conducting gynaecological cytology screening, histology processing and hrHPV testing</td>
<td>Laboratories conducting gynaecological cytology screening must employ at least one senior registered cyto-scientist who has a minimum of five years full-time (or equivalent) cytology experience and who is a named lead senior cyto-scientist. Laboratories conducting histology and molecular testing for hrHPV must employ at least one senior histo-scientist and senior molecular pathology scientist (see the note under Details on page 7) respectively with a minimum of two years full-time (or equivalent) experience. Each discipline must also be led by a named senior scientist.</td>
<td>9</td>
</tr>
<tr>
<td>503</td>
<td>Continuing professional development requirements for cyto-scientists, cyto-technicians, pathologists and hrHPV testing staff</td>
<td>As a minimum, the continuing professional development requirements must be met by all pathologists, cyto-scientists, cyto-technicians and hrHPV testing staff and the laboratory must keep a record of the professional development requirements that have been met.</td>
<td>11</td>
</tr>
<tr>
<td>504</td>
<td>Volume of gynaecological cytology cases per laboratory per annum</td>
<td>Each fixed laboratory site will process a minimum of 15,000 gynaecological LBC samples per annum. A single case may include multiple cytology samples per woman at any single patient episode.</td>
<td>12</td>
</tr>
<tr>
<td>505</td>
<td>Number of cases to be reported per pathologist per annum</td>
<td>Each pathologist will report at least 500 gynaecological LBC samples per annum. A single case may include multiple cytology samples per woman at any single patient episode. Each laboratory must have at least two pathologists who are competent in gynaecological cytology to cover for periods of sickness and annual and other leave.</td>
<td>13</td>
</tr>
<tr>
<td>506</td>
<td>Maximum workload for screeners</td>
<td>The maximum workload for any cyto-screener involved in manual primary screening (or equivalent full screens) of LBC samples is 70 cases on any one working day.</td>
<td>14</td>
</tr>
</tbody>
</table>
The maximum workload for any cyto-screener involved in location-guided field of view (FOV) review of LBC samples is 140 cases on any one working day.

- **FOV : LBC = 2 : 1.**

It is recommended that up to three rapid re-screens = one full primary screen = one full re-screen.

Note: A full review of historical conventional cytology slides is counted as being equivalent to one LBC sample full re-screen.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>507</td>
<td>Minimum number of cases per annum per cyto-scientist/cyto-technician</td>
<td>Cyto-scientists and cyto-technicians must primary screen a minimum of 3000 gynaecological LBC samples per annum. In the case of senior cyto-scientists and senior cyto-technicians (refer to standard 508: Qualifications for screening staff reporting gynaecological cytology on page 9), this may include a maximum of 1200 full re-screen cases. Cyto-scientists and cyto-technicians must complete a minimum of 3000 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, cyto-scientists and cyto-technicians must complete a minimum of 1000 manual full-screen and 3000 FOV cases per annum. Note: This does not apply to staff who are primary screening in a laboratory that has not fully converted to automation.</td>
</tr>
<tr>
<td>508</td>
<td>Qualifications for screening staff reporting gynaecological cytology</td>
<td>All screening staff reporting gynaecological cytology must be qualified cyto-scientists or cyto-technicians. For the purpose of screening, a senior cyto-scientist or senior cyto-technician is defined as a health professional with three years full-time (or equivalent) (FTE) work experience post-cytology qualification.</td>
</tr>
<tr>
<td>509</td>
<td>Rapid re-screening results and recording outcomes</td>
<td>At least 98 percent but less than 100 percent of ‘Negative for intraepithelial lesion or malignancy’ slides are confirmed as such after rapid re-screening. Outcomes of rapid re-screening must be recorded for all cases. Note: Refer to Rapid re-screening policy for details on applying rapid review.</td>
</tr>
</tbody>
</table>
| 510 | Full re-screening | Full re-screening must be performed for gynaecological cytology in all of the following categories:  
  - abnormal (G2 or G3) gynaecological cytology  
  - gynaecological cytology from women with abnormal screening histories (not high grade) who have not been hrHPV tested before returning to usual (three-yearly) screening after the abnormal diagnosis. Women being followed up with annual smears for a previous high grade require annual smears with a minimum of rapid review (manual screening) or FOV (automated screening) or for squamous only lesions until they have completed appropriate hrHPV testing returning them to usual three-yearly screening.  
  - gynaecological cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities or immunosuppression (optional at the discretion of the laboratory)  
  - 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.  
Samples scanned using automated screening devices where abnormal cell changes are identified by location-guided FOV must have a minimum of one full manual screen performed by a different staff member. | 24 |
| 511 | Confirmation and reporting for abnormal results | All results confirmed abnormal (G2 or G3) after full re-screening will be sent to the pathologist for confirmation and reporting. | 25 |
| 512 | Re-screening timing | All re-screening (rapid and full) will take place before the results are confirmed and sent to the smear taker and the NCSP Register. | 25 |
| 513 | Reporting gynaecological cytology and hrHPV test results | Laboratories are required to report 90 percent of final gynaecological cytology results to smear takers within seven working days of receiving a specimen.  
Laboratories are required to report 98 percent of final gynaecological cytology results and hrHPV test results to smear takers within 15 working days of receiving a specimen.  
Results for cytology and conjunct hrHPV tests must be reported together to the smear taker. | 32 |
<p>| 514 | Histopathologist access to cervical | The histopathologist must have the full and current NCSP Register screening event history | 29 |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>515</td>
<td>Examining and reporting histology slides</td>
<td>All histology slides must be examined and reported by a histopathologist.</td>
</tr>
<tr>
<td>516</td>
<td>Reporting histology results</td>
<td>Laboratories are required to report 90 percent of final histology results to referring colposcopists within 10 working days of receiving a specimen. Laboratories are required to report 98 percent of final histology results to referring colposcopists within 15 working days of receiving a specimen.</td>
</tr>
<tr>
<td>517</td>
<td>Cultural sensitivity and appropriateness</td>
<td>Requests regarding culturally appropriate methods of handling and disposal of human tissue will be treated sensitively and in accordance with local protocols.</td>
</tr>
<tr>
<td>518</td>
<td>Sending cytology results to the NCSP Register</td>
<td>Ninety-eight percent of all cytology results and hrHPV test results must be forwarded to the NCSP Register, in the approved Bethesda coding and format, within 16 working days of receipt of a specimen.</td>
</tr>
<tr>
<td>519</td>
<td>Sending histology results to the NCSP Register</td>
<td>Ninety percent of the histology results must be forwarded electronically to the NCSP Register, in approved format and NCSP SNOMED coding, within 15 working days of receipt of a specimen. Ninety-eight percent 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 a specimen. Histology results must include all appropriate topography, morphology and procedure SNOMED codes.</td>
</tr>
<tr>
<td>520</td>
<td>Sending results to the New Zealand Cancer Registry</td>
<td>The laboratory that has analysed the sample must forward all cytology with an interpretation of cancer (or suspicious of) and histology results with a diagnosis of invasive or in situ cancers to the NZCR (at the Ministry of Health).</td>
</tr>
<tr>
<td>521</td>
<td>Correlation of histology and cytology slides</td>
<td>All histology results must be correlated with any cytology slides that have management implications and were taken in the previous six months, and the results must be recorded for audit and statistical purposes.</td>
</tr>
<tr>
<td>522</td>
<td>Reviewing cases with a high-grade diagnosis</td>
<td>All cases with a high-grade/invasive diagnosis on histology must have a review of any cytology slides that have been reported as negative, benign/reactive or unsatisfactory in the previous 42 months.</td>
</tr>
</tbody>
</table>