
Chapter 5 – Providing a Laboratory Service

In this Chapter

Introduction The topics in this chapter relate to the provision of cytology and/or histology services for the NCSP and also to the performance of any cervical cytology and/or histology test whether or not associated with the NCSP. Laboratories not providing cervical cytology and/or histology services need not comply with the policy and standards.

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Laboratory Cytology and Histology Services

Laboratory services for women

Laboratory services are a significant component of the NCSP. Whilst women are not directly involved, they are directly affected by the provision of laboratory services. The NCSP requires that high quality laboratory services are available to women.

Results that indicate a serious or repeated minor abnormality may exist mean that some women will have to continue a journey to colposcopy.

Maori women and women from some other cultural groups, feel a strong connection to biological samples, provided to laboratories for analysis. This needs to be recognised as these represent a woman connected to whakapapa and future generations.

Kei motu te hono tangata.

Let the human link not be broken.

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Laboratory Cytology and Histology Services, Continued

Key laboratory functions

Laboratories have several key functions:

- processing and reporting on gynaecological cytology and histology samples
- reporting results to smear takers and specialists
- forwarding results to the NCSP
- forwarding invasive or in-situ cancer results to the Cancer Registry
- collaboration with the NCSP Regional Service
- providing advice to smear takers.

Laboratories should provide to smear takers a consultative and advisory service, not simply a ‘results only’ service.

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

Primary objective of gynaecological cytology

The primary objective of the gynaecological cytology phase is to predict with maximum accuracy the nature and extent of any pathological changes present in squamous cervical cells.

The reading / screening of cytological cervical smear tests involves the interpretation of subtle variations in the shape, size and structure of cervical cells.

Primary objective of gynaecological histopathology

The primary objective of the gynaecological histo-pathology phase is to ascertain the nature and extent of tissue abnormalities present in the submitted tissue.

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Laboratory Cytology and Histology Services, Continued

Compliance with policies and standards

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

Failsafe mechanisms

Laboratories must have in place failsafe mechanisms in the form of protocols and procedures to ensure:

- all cytology slides received by the laboratory are reported on to the smear taker and the NCSP
 - all histology samples received by the laboratory are reported on to the specialist and the NCSP
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Reference to 'laboratory'

Where reference is made in this publication to 'laboratory' this applies to each individual fixed laboratory site and includes both community laboratories and hospital laboratories conducting gynaecological cytology and/or histology services.

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

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Staffing, Qualifications and Continuing Education

Pathologist qualifications All pathologists reporting gynaecological cytology or histology for the NCSP will have appropriate qualifications.

Standard 501 **A pathologist working in gynaecological cytology or histology shall be a Fellow of the Royal College of Pathologists of Australasia or shall hold an equivalent qualification, which is recognised by the Medical Council of New Zealand. Training should be in general pathology or anatomical pathology. The Fellowship must cover the sub-specialty in which the pathologist is working.**

Responsibilities of the pathologist The cervical cytopathology service should be professionally led by a named cytopathologist who is responsible for delivering the agreed services in accordance with the policy and standards. He/she must liaise with the regional NCSP co-ordinator and other personnel and be available in the laboratory every working day or have delegated responsibility to another pathologist. Responsibilities include:

- Reporting results
 - Implementation of a quality assurance programme
 - Provision of in-service training
 - Audit of laboratory practice
 - Liaison with clinical colleagues
 - Monitoring of health and safety within the laboratory
 - Facilitating a collaborative team-work environment amongst cytotechnical staff and pathologists
 - Ensuring the assimilation of new developments in the field and introducing these into the laboratory where they demonstrate an improvement in the service provided.
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Staffing, Qualifications and Continuing Education, Continued

Qualifications of cytotechnologists and cytotechnicians

Cytotechnologists and cytotechnicians require specific and thorough training as well as ongoing education and evaluation of their work. The following are appropriate qualifications for staff working in smear processing, screening, and reporting:

- Cytotechnologists must hold a minimum qualification of Bachelor's degree in medical laboratory science (BMLSc) or equivalent (as decided by the MLTB) and be registered with the Medical Laboratory Technologists Board (MLTB)
 - Cytotechnicians must hold a minimum qualification of Qualified Technical Assistant (QTA) as recognised by the NZ Institute of Medical Laboratory Science (NZIMLS) or an equivalent qualification.
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Standard 502

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

Continuing education

Continuing education is required for all staff including pathologists. At a minimum this must include:

- A documented internal and/or external teaching programme on cytology and histology for cervical and vaginal cancer
 - Availability within the laboratory of the current editions of major standard texts and colour atlases relevant to gynaecological cytology and histology
 - Availability within the laboratory of current issues of principal journals relevant to gynaecological cytology and histology
 - Provision for all medical, scientific and technical staff to maintain and improve their skills in gynaecological cytology and histology as appropriate, by regular attendance at relevant local and international professional meetings.
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Standard 503

At least the minimum continuing education requirements are to be met by cytotechnical staff and pathologists and this is to be recorded within the laboratory.

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Staffing, Qualifications and Continuing Education, Continued

Frequency of updates

All cytotechnical staff and pathologists should take part in a formal update course in cervical cytology every three years.

In-house continuing education should be structured to provide each staff member the equivalent of four days annually per FTE.

Records must be maintained

The laboratory must maintain a record of individual staff members' participation in continuing education. These records must be available for inspection by any Audit Body.

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Accreditation

Accreditation requirements

All laboratories contracted by the Ministry of Health for the purposes of providing services for the NCSP must be accredited by International Accreditation New Zealand (IANZ) for the provision of cytology services.

Informing the Ministry of Health

Laboratories must inform the Ministry of Health of the results of the IANZ assessment (both the annual surveillance process and the four yearly reassessment) and any change to their accreditation status.

IANZ will also inform the Ministry of Health at the time of informing the laboratory if there is any change in accreditation status.

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Internal Quality Control

Internal quality control Internal quality control for a laboratory is an essential component of quality assurance for the NCSP. Internal quality control systems must provide means of identifying potential sources of error in the laboratory's operation, implement controls to detect and minimise errors, particularly the incidence of false negative and false positive results. The internal quality system must also include processes to implement improvements to operational processes, especially when the need for remedial action has been identified.

Internal quality mechanisms Laboratories must have policies and practices that ensure the quality of gynaecological cytology and histology assessment. Policies must define staff responsibilities and laboratory procedures. Laboratories must ensure that:

- Staff appointed are appropriately qualified and experienced
 - High quality and accurate systems are in place for reporting, including mechanisms for ensuring data integrity throughout all key steps in the preparing, reading and reporting process
 - NCSP approved Bethesda coding system for cytology¹ and the SNOMED system for histology results² are used for reporting
 - Control processes are in place to ensure that the reporting requirements of the Cancer Registry Act 1993 and the Health (National Cervical Screening Programme) Amendment Act 2004 are met
 - Satisfactory internal systems for quality control and quality improvement are in place, including monitoring of data entry
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¹ See Appendix 7

² See Appendix 8

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Internal Quality Control, Continued

Internal quality control activities	<p>Each lab must have documented internal quality control activities, which include:</p> <ul style="list-style-type: none">• Ensuring that the re-screening of smears occurs prior to the result being reported and forwarded to the smear taker and NCSP Regional Service• A system for evaluating individual performance for all cytotechnical staff and pathologists working in the laboratory• A system for monitoring the sensitivity of primary screening for each primary screener and the laboratory as a whole, utilising rapid review• A system of follow-up for correlating the results of cervical cytology with respective cervical histopathology• A review of previous 42 months negative cervical cytology smears from patients with current high grade/invasive cytology/histology• Ensuring that any change in a result, due to a full case review, which has any clinical or follow-up management implications, will have the updated result forwarded to the NCSP at the same time that it is notified to the woman's smear taker.
Formal arrangements for multidisciplinary case reviews	<p>Pathologists must ensure that formal arrangements are in place for multi-disciplinary case reviews with colleagues as part of case management, and quality control of reading and reporting on gynaecological cytology and histology.</p> <p>This could include cytotechnical staff, other pathologists, gynaecologists, smear takers, and oncologists as appropriate.</p> <p>NCSP co-ordination issues may also be addressed in this multidisciplinary forum.</p>

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External Quality Assurance

Participation in an external quality assurance programme

The objectives of external quality assessment schemes are to promote uniformly high standards of reporting opinions given by each laboratory. A centrally organised method of testing the accuracy of cytological screening and reporting is yet to be devised in New Zealand or elsewhere. Pilot studies on the value of slide exchanges show educational value, and that they assist in standardisation of interpretation and reporting.

In accordance with accreditation requirements, laboratories providing cervical screening services for the NCSP must participate to a satisfactory standard in an external quality assurance programme specific to cervical cytology. One such programme is the Royal College of Pathologists of Australasia Quality Assurance programme.

The external quality assurance programme should include assessment against outcome measures, which are quantitative performance standards as agreed between the NCSP and the quality assurance programme from time to time. External quality assurance reports, outcome measures and action sheets must be retained and made available to Audit Bodies.

Monitoring and Audit of the NCSP

The National Indicators and Targets for monitoring the NCSP have been agreed and are monitored by an independent monitoring group. The National Indicators are annexed as appendix 5.

There are a number of laboratory specific indicators with targets which are monitored on a quarterly basis by the independent monitoring group. Laboratories will receive quarterly monitoring reports and any issues arising from the reports will be followed up by the National Screening Unit. Laboratories will also be expected to use the reports as part of their own quality control processes.

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Cytology Services – Volumes and Workloads

Laboratory volumes Specifying minimum screening volumes at each laboratory site is designed to maintain and improve overall standards and skills in cytology screening.

The designation of a volume of 15,000 gynaecological cytology cases requires that there will be at least two cytology screeners and would generate about 1000 gynaecological cytology cases per annum for a pathologist's opinion.

Standard 504 **Each fixed laboratory site will process a minimum of 15,000 gynaecological cytology cases (a single case may include multiple smears per woman) per annum.**

Minimum volumes for pathologists Every laboratory should have at least two pathologists competent in cytopathology to cover for periods of sickness and annual leave so the minimum each pathologist would see per annum would be 500 gynaecological cytology cases (plus review of all previous smears for high grade lesions).

Standard 505 **Each pathologist will report at least 500 abnormal gynaecological cytology cases (ASCUS / AGUS+; a single case may include multiple smears per woman) per year.**

Optimal involvement for cytopathologists To maintain skills for optimal involvement in the reporting, pathologists should be continually involved in reading and reporting on a wide range of gynaecological cytology including targeted full review.

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Cytology Services – Volumes and Workloads, Continued

Sufficient cytotechnical staff To function effectively a laboratory must have sufficient cytotechnical staff to handle, under general supervision, the volume and diversity of tests performed. Non-screening activities, such as cytopreparation, computer and administrative work can affect time available for screening. Screening workload ratios should be based on the time spent in actual screening.

Cytotechnical staff's workload Cytotechnical staff's total workload should be determined by the relative proportions of different types of slides (nature, type of preparation, routine, follow-up of previous abnormality and non-gynaecological specimens).

Their workload should not exceed (an equivalent of) primary screening of 60 cervical-vaginal smears per 6-8 hour working day for a full time screener and must not exceed 10 slides per hour.

These limits are not a recommended optimal or average workload and are not to be employed as performance targets for screeners.

Standard 506 **The maximum workload for any screener involved in primary screening is 60³ slides on any one working day and must not exceed 10 slides per hour. Screeners must not exceed this standard regardless of the number of sites at which they are employed.**

Standard 507 **Cytotechnical staff must primary screen a minimum of 3000 gynaecological cytology cases (a single case may include multiple smears per woman) per annum. In the case of senior cytotechnical staff this may include a maximum of 1200 full re-screens.**

³ This limit is not a recommended daily screening workload. It is specified to ensure that this volume is not exceeded.

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Cytology Slide Preparation

Slide preparation Interpretation of cytological material depends on the quality of preparation and staining. An optimal sample, properly prepared and preserved is essential.

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

Staining of smears Staining of smears should be performed in accordance with the following:

- Cervical smears should be stained using the Papanicolaou staining method
- There should be laboratory protocols detailing the method and optimal desirable staining results, including the frequency of replacing or filtering reagents.

Chromatin detail should be clearly and sharply defined and cytoplasmic staining should be transparent to permit examination of the nuclei of underlying cells.

Mounting and cover-slipping Mounting and cover-slipping of slides should be done in accordance with the following:

- Stained slides should be adequately cleared before mounting, the cover-slip should cover all the material on the slide and mounting media should not be allowed to contaminate the surface of the cover-slip in such a way as to compromise visibility
- The coverslip should be of a size sufficient to cover as much of the material on the slide as is possible
- A record should be kept of any slide broken prior to arrival at the laboratory or in the laboratory. The report must identify if the interpretation is compromised by the breakage.

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Cytology Reading

Cytology screening and re-screening

All cytology screening and re-screening (rapid review and full re-screening) must be completed prior to a result being reported to the smear taker and the NCSP. These processes must be completed in a timely manner, in accordance with the expected timeframes set out in this chapter.

Primary screening

Primary screening of cytological slides must be carried out by appropriately skilled screeners. Screening staff reporting gynaecological cytology must all be cytotechnologists or cytotechnicians.

The microscopic examination of one cervical smear slide takes around 4-10 minutes since the average smear contains over 500,000 cells.

The cyto-screener should attempt to evaluate all the cellular material on the slide by systematically scanning the slide from one edge to the other, overlapping each field of view so that no area of cellular material is missed.

Standard 508

All primary screening staff reporting gynaecological cytology must be qualified cytotechnologists or cytotechnicians.

Slides read by less experienced staff

Any slides read by less experienced staff during training and prior to gaining qualification must be fully re-screened and reported by a cytotechnologist.

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Cytology Reading, Continued

Rapid re-screening

Following primary screening laboratories must conduct rapid re-screening of all negative and benign reactive smears.

This is a process whereby a screener, who was not the same person who was the primary screener, performs a rapid (minimum 60 second) re-screen of the slide.

Rapid re-screening must be carried out by skilled cytotechnologists or skilled cytotechnicians designated by the laboratory charge cytotechnologist / pathologist.

All staff performing rapid review should demonstrate their ability to detect abnormalities using this method prior to conducting rapid review.

Where possible all screeners should be involved but must not review their own work.

It is unwise to have small numbers of staff review large numbers of slides.

The method of review, e.g. up and down or side to side, may be individual to the screener provided screeners review as much of the slide as possible, at normal magnification, within the timeframe.

Standard 509

85-95% of normal smears should be confirmed as normal after rapid re-screening and outcomes must be recorded.

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Cytology Reading, Continued

Full re-screening

A senior cytotechnologist or senior cytotechnician (with greater than 5 years full time experience since 1985 and designated by the cytopathologist) will fully re-screen cervical cytology in selected clinical categories, smears for those women with abnormal smear histories and cervical cytology which shows a discrepancy between primary screen and rapid review (detailed in standard below).

Standard 510

Full re-screening must be performed for cervical cytology in the following categories:

- **All abnormal (ASCUS/AGUS+) cervical cytology**
 - **All cervical cytology from women with an abnormal smear history who have had 2 or fewer normal smears since the abnormal diagnosis**
 - **All cervical cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities, immunosuppression, STD, and colposcopy patients**
 - **All unsatisfactory(A3) cervical cytology**
 - **All cervical cytology where there has been shown to be a discrepancy between the primary screening result and the rapid re-screening result.**
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Abnormal reporting

A pathologist must report all abnormal (ASCUS/AGUS+) cervical cytology and histology.

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Chapter 5 – Providing a Laboratory Service

Cytology Reading, Continued

Pathologist availability

The pathologist must be readily available to consult with and advise cytotechnical staff. In addition the pathologist must be readily available to advise the smear taker on:

- The suitability/adequacy of the requested procedure
- The suitability/adequacy of the submitted smear
- Reporting of the smear
- The clinical significance of the laboratory results
- Further procedures, which may be helpful.

Standard 511

All results confirmed abnormal (ASCUS/AGUS+) (following being fully re-screened) will be sent to the cytopathologist for confirmation and reporting.

Standard 512

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

Unsatisfactory smears

Laboratories should not attempt to make a cytological assessment on unsatisfactory smears but recommendations should request a repeat smear in accordance with Bethesda coding (within 1-3 months).

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Cytology Reporting to Smear Takers

Advice to smear takers

The laboratory has a role in providing advice to smear takers and clinicians on procedures for improving quality of smear-taking. This may be either by documented telephone discussion or a written information sheet.

For reporting to smear takers on smear adequacy please refer to Cytology Reading section in this chapter.

Reporting cytology to smear takers

Laboratories must directly report all cytology results to smear takers in the approved NCSP Bethesda descriptors. The Bethesda system includes a statement of specimen adequacy, general categorisation and a descriptive diagnosis of findings and recommendations for recall and referral.

Please refer to Appendix 5 for the Revised Bethesda Coding Standard 1998.

Standard 513

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

Laboratories are required to report 100% of final gynaecological cytology results to smear takers within 14 working days of receipt of the specimen.

Change to a result

If as a result of a review or later re-screen, there is a change to a woman's result which has clinical or management implications, this revised result must be forwarded to the smear taker with updated recommendations and information on the smear adequacy and to the NCSP.

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Histology Specimen Preparation and Reading

Cervical histology specimens

Cervical histology specimens are examined for the purpose of detecting the presence and degree of tissue abnormality or confirming a diagnosis of cancer.

Diagnostic biopsies

The pathologist should be advised whether a biopsy is considered diagnostic or excisional.

The cytology result(s), and ideally the index smear(s), must be available to the histopathologist at the time of or following the reporting the biopsy specimens.

Standard 514

The histopathologist must have the cervical cytology result available at the time of reporting the cervical biopsy.

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Histology Specimen Preparation and Reading, Continued

Preparation and reading histology	Preparing and reading histology should be performed in accordance with the the RCPA Broadsheet No 35 “Current Issues in Cervical Biopsy Pathology” McKenzie, P. July 1994.
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Standard 515	All histology slides must be examined and reported by a histopathologist.
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Reporting to colposcopists	The timeliness and accuracy of reporting results to colposcopists are important quality measures. In some instances more time needs to be taken, to enable collaborative discussion making to occur.
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If it is likely to take more than 10 days for the result to be reported the colposcopist should be informed.

Standard 516	Laboratories are required to report 90% of final histology results to referring colposcopists within five working days of receipt of the specimen.
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Laboratories are required to report 100% of final histology results to referring colposcopists within a reasonable time period of receipt of the specimen.

Requirement to use the SNOMED code	Laboratories are required to code histology diagnosis using the SNOMED coding system.
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Please refer to Appendix 10 for the approved NCSP SNOMED Coding for Histology codes (1998).

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General Requirements for Cytology and Histology

Introduction Policy and standards in this section apply to both cytology and histology laboratory services (unless otherwise specified).

Unambiguous identification The slides submitted for gynaecological cytology or histological examination must be permanently marked in such a way as to ensure an unambiguous identification with the referral form.

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

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

Standard 517 Requests regarding culturally appropriate methods of handling and disposal of human tissue will be treated sensitively and in accordance with local protocols⁴.

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⁴ Local organisational protocol accepted by iwi.

Chapter 5 – Providing a Laboratory Service

General Requirements for Cytology and Histology, Continued

Ensuring optimal recommendations

To ensure the optimal recommendation for recall and / or referral is made for each smear test, laboratories must ensure that a woman's smear history is included in their analysis.

Recommendations for recall or referral must be based on the cytological findings of the present slide and the woman's complete gynaecological history in accordance with the NCSP guidelines.⁵

If the laboratory does not have the smear history of a woman who is enrolled in the NCSP-Register, or is unsure if it has the full history, this must be sought from the NCSP-Register.

The NCSP-Register will send smear history and histology reports to laboratories within four working hours of its initial request, provided appropriate identifying information is forwarded from the laboratory (surname, first name, any other name known by, date of birth, NHI). A turnaround time of four hours cannot be guaranteed if all these details are not supplied in full.

Reporting of samples

A report must be issued for all cytology and histology samples received by the laboratory.

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⁵ Refer Chapter 1 and Cervical Screening: Guidelines for the Management of Women with Abnormal Cervical Smears. National Cervical Screening Programme (NZ) 1999.

Chapter 5 – Providing a Laboratory Service

General Requirements for Cytology and Histology, Continued

**Forwarding
results to the
NCSP**

Laboratories must have in place control processes for ensuring that all cervical smear and histology results are forwarded to the NCSP.

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

Electronic data must be accompanied by the matching laboratory referral forms containing the information necessary to enrol the woman or update information (full name, date of birth, NHI, address, previous smear history and stated ethnicity) and identifying the smear taker or specialist according to their correct smear taker / specialist and health centre code.

Electronic data must be formatted in accordance with “The NCSP Cytology and Histology pack” distributed to the laboratories by the NCSP.

Standard 518

All cytology results must be forwarded to the NCSP in the approved Bethesda coding within 16 working days of receipt of specimen.

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Chapter 5 – Providing a Laboratory Service

General Requirements for Cytology and Histology, Continued

Histology results to be forwarded

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

- All cervical histology
 - biopsies whether diagnostic or treatment
 - cervical polyps
 - cervical component of hysterectomies with a diagnosis on the cervical component
 - All vaginal histology
 - biopsies
 - vaginal polyps.
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Standard 519

90% of the histology must be forwarded electronically to the NCSP in approved NCSP SNOMED coding within 10 working days of receipt of specimen.

100% of the histology results must be forwarded electronically to the NCSP in approved NCSP SNOMED coding within a reasonable time period of receipt of specimen.

Changes to reporting methods

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

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Chapter 5 – Providing a Laboratory Service

General Requirements for Cytology and Histology, Continued

Cancer Registry Act (1993) requirements

The Cancer Registry Act (1993) and The Cancer Registry Regulations (1994) requires that all tests, which indicate the presence of cancer, be reported to the Cancer Registry to make better provision for the compilation of a statistical record of the incidence of cancer in its various forms and to provide a basis for the better direction of programmes for research and for cancer prevention.

Standard 520

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

Cyto-histo correlations

It is best practice for histology samples to be sent to the same laboratory as reported the cervical cytology. It is also best practice for excisional histology specimens to be sent to the same laboratory that reported the punch biopsy histology.

Where this is not possible, the results of previous histology reports, and slides if needed, must be available to the reporting cytology laboratory.

The previous cytology results, and slides if needed, must be available to the reporting histology laboratory.

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General Requirements for Cytology and Histology, Continued

Cyto -histo correlations

All histology results must be correlated and documented with any cytology smears taken in the previous six months.

Histologic slides and cytology smears must be reviewed by a cytotechnologist and/or pathologist, where the following discrepancies have occurred:

Cytology

Unsatisfactory
ASCUS/LSIL
AIS
HSIL
HSIL
AIS
Unsatisfactory
AGUS
ASCUS/LSIL/HSIL

Histology

HSIL or Invasive SCC⁶
HSIL or Invasive SCC
HSIL or Invasive SCC
LSIL
Negative/reactive
Negative/reactive
AIS or Invasive Adenocarcinoma
AIS or Invasive Adenocarcinoma
AIS or Invasive Adenocarcinoma

Standard 521

All histology results must be correlated with any cytology smears taken in the previous six months and recorded.

Full case review

If there remains a lack of correlation (high grade / low grade or greater) which has any management or clinical implications for the woman the case should be fully reviewed by a multidisciplinary team of experienced practitioners. This team should include specialist colposcopists, cytotechnologists, cytopathologists and histopathologists.

Any changes to the cervical screening report as a result of the review which has any clinical or follow-up management implications should be communicated by the reviewing laboratory to all laboratories involved in the reading of the slides, the smear taker, and the NCSP within 5 working days.

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⁶ Note: Benign/reactive smears prior to a histologic diagnosis of a high grade or invasive lesion are reviewed under Standard 522.

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General Requirements for Cytology and Histology, Continued

42 month prior negative smear review following a high grade diagnosis The laboratory should document the results of the review of all smears reported as negative or benign/reactive in the 42 months prior to a high grade or invasive diagnosis on histology. This information can be used by a laboratory to provide an indication of the laboratory's false negative rate with respect to the detection of high grade lesions.

Standard 522 **All cases with a high grade diagnosis on either histology or cytology must have a review of any prior smears reported as negative or benign/reactive in the previous 42 months.**

Correlation reports A NCSP-Register generated report correlates women's results nationally and is produced for each individual reporting laboratory. The report lists, for each laboratory that has reported on a cytology smear, histology results for the same woman that have been reported by other laboratories within the previous five years. Laboratories will also receive HSIL correlation information from the regular monitoring reports.

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Chapter 5 – Providing a Laboratory Service

General Requirements for Cytology and Histology, Continued

Retaining smears and associated documentation

Laboratories must retain smears and associated documentation (to allow both adequate review of previous smears and histo/cyto correlation where necessary) in accordance with the following:

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

Stained smears and associated documentation must be retained in a secure compository in compliance with current best practice and relevant legislation.

Current IANZ guidelines recommend that laboratories must keep exfoliative cytology slides (normal and abnormal) for a minimum of 14 years and histology slides for minimum of 20 years (in accordance with National Pathology Accreditation Advisory Council 1998 Guidelines).

Associated documentation should be kept for the same period of time as the slides to which it pertains.

In the event that a laboratory is sold, all cytology and histology specimens and all records and documentation must be handed over to the new laboratory.

In the event that a laboratory ceases to undertake gynaecological cytology and histology reading it must ensure specimens and records are available on request.

The National Screening Unit must be notified immediately of any likelihood of closure of a laboratory.
