

AUCKLAND CERVICAL CYTOLOGY SERVICES

DML's Cytology Team based at Ellerslie is well recognised for providing quick access for Auckland clinicians and smeatakers seeking important clinical advice. DML's large, established cytology laboratory has reported on cervical cytology for more than 60 years. Our service is provided by a team of 15 cytology scientists and six cytopathologists, all highly trained, with most having more than ten years service at DML.

We perform ancillary testing for women having cervical smears, including *Chlamydia* testing for specialist referrals and when required, HrHPV testing.

DML & LabPLUS - A Partnership for Auckland



In July 2010 with the start of the new National Screening Unit contract, DML and LabPLUS committed to a partnership arrangement to ensure Auckland women and their health practitioners received a safe, quality, Auckland based cervical screening and gynaecological cytology service.

The Cytology section at LabPLUS provides a quality service processing both gynaecological and non-gynaecological specimens. These specimens have a high degree of complexity with samples from the outpatient gynaecology clinics at Auckland, Middlemore, North Shore and Northland Hospitals, as well as from specialist referrers.

Pathologists and scientists employed in the cytology section at LabPLUS have a high level of expertise and experience in processing and reading complex and abnormal smears, more than any other laboratory in New Zealand.

LabPLUS and DML chose ThinPrep® liquid based cytology for their cervical cytology screening contracts with the National Screening Unit. This decision has established a close working relationship between the two laboratories.

ThinPrep® is used at the hospital outpatient gynaecology clinics in Auckland and Northland, by all specialist gynaecologists and by more than 92% of general practices in the greater Auckland region.

DML sends a limited number of ThinPrep® samples to LabPLUS for processing and screening to support LabPLUS's accreditation for cervical cytology. The National Screening Unit supports and endorses this arrangement which ensures the continuation of local hospital cytology expertise.

As is standard practice, LabPLUS and DML participate in

the RCPA Quality Assurance Programme ensuring a high level of external quality assurance. Both laboratories are IANZ accredited against NZS/ISO 15189: 2007.

Both DML and LabPLUS are committed to maintaining the safety, quality and educational standards required by the New Zealand Screening programme (NCSP).

Fundamental to this is the training of Anatomical Pathology registrars who rotate through Cytology at LabPLUS and DML as a requirement of their fellowship training. These registrars are our future Anatomical Pathologists.

The proud history of training in Cytology at LabPLUS has its roots from the National Women's Hospital training programme for scientist and pathologists.

It is essential for the future of cytology in New Zealand that a credible training structure for pathologists and scientists is in place and the working partnership between DML and LabPLUS ensures this can continue.

Our partnership enables pathologists and scientists from both laboratories to participate in training and teaching sessions. These joint sessions ensure commonality of practice, allow for discussion of challenging or rare cases and are an opportunity to resolve any quality issues. This collegiality ensures consistency of service, especially with the requirement to hold Multi-Disciplinary Meetings (MDMs) with local clinicians. These meetings are essential to optimise patient care.

In summary, the working relationship between LabPLUS and DML provides Auckland with a patient oriented service for cervical cytology. The combined expertise of both organisations enhances and adds value to a vital health service for the women of Auckland and their health practitioners.

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This partnership philosophy between a community laboratory and a DHB laboratory is a unique approach to the regional sharing of training and experience.

DML & LabPLUS Meet NCSP Operational Policy & Quality Standards

All laboratories performing cervical cytology hold a contract with the National Screening Unit and must meet the NCSP Operational Policy and Quality Standards (OPQS). DML and LabPLUS are the only laboratories in the Auckland region to hold a contract. We meet all the requirements under the standards.

Laboratories must be able to correlate cytology and histology data and microscopically review all cases where there is discordance between the cytology and histology results with clinical management implications.

The NCSP OPQS state:

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

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

Correlation of Histology and Cytology at DML & LabPLUS:

NCSP OPQS - Standard 521: All histology results must be correlated with any cytology slides, with management implications taken in the previous six months and the results recorded for audit and statistical purposes.

All ThinPrep® cytology and cervical biopsies received by DML and LabPLUS are tested in Auckland. Therefore the laboratories have ready access to both cytology and histology results and also slides for correlation purposes. DML archives cervical cytology slides for 20 years, over and above the NCSP requirement of 14 years.

Reviewing Cases with a High Grade Diagnosis:

NCSP OPQS - Standard 522: All cases (100%) with a high grade/invasive diagnosis on histology must have a review of any prior cytology slides reported as negative, benign/reactive, or unsatisfactory in the previous 42 months.

DML receives all cervical biopsies from the Auckland community, therefore enabling ThinPrep® cytology slides reported as 'negative', 'benign/reactive', or 'unsatisfactory' in the previous 42 months to be quickly retrieved for review.

Management of Discordant Results:

NCSP OPQS: If a lesion correlating with the cytology cannot be confirmed on the histology specimen the cytology slide must be reviewed. If following review of the cytology a high grade lesion is confirmed this must be communicated to the colposcopist.

Multi-disciplinary meetings are joint meetings of gynaecologists, a histo/cytopathologist and a senior medical laboratory scientist to discuss **best patient management** and care.

A patient list is generated by local gynaecologists, with most cases having a discordant cytology and histology result or colposcopic findings which are discordant with the cytology and/or histology result. A senior cytology scientist retrieves and reviews the cytology with a histo/cytopathologist who also reviews the cervical biopsy.

The findings are discussed in conjunction with colposcopic findings, age of the patient, previous history and management recommendations from multiple gynaecologists, to ensure best practice and patient management.

The MDMs offer a further opportunity for the continuing education of cytopathologists and cytology scientists alike.



High Risk Human Papilloma Virus (HrHPV) Testing

All ThinPrep® sample vials are stored on-site at DML and are retrieved for HrHPV testing if a smear shows evidence of any abnormalities that qualify for testing under the funded NCSP criteria.

If there are special circumstances where a referrer considers HrHPV testing is required outside the funded NCSP criteria, a request to the laboratory can be made either by telephone or by indication on the request form. There is a patient fee for non-funded HrHPV testing. Please contact the laboratory on 571 4000 to obtain the current price.



DML Move to Automated Screening of Cervical Cytology

In 1997 DML was the first laboratory in New Zealand to introduce liquid based cytology using the ThinPrep® system. Over the past 13 years we have built up substantial experience in the processing, screening and reporting of liquid based cytology. It was only in 2009 that liquid based cytology finally became standard practice in New Zealand.

In January 2011 DML launched automated primary screening of liquid based cytology using the ThinPrep® Imager system. DML will be the only laboratory in Auckland using this method. The move to automated screening meets the objectives of the NCSP and reflects a world wide trend to automated primary screening for cervical cancer.

Training of the DML cytology screeners at Ellerslie is well underway and meets the NCSP requirements for validation of individual screeners. Full implementation of automated screening will be completed by mid-April.

ThinPrep® Imager Study at DML

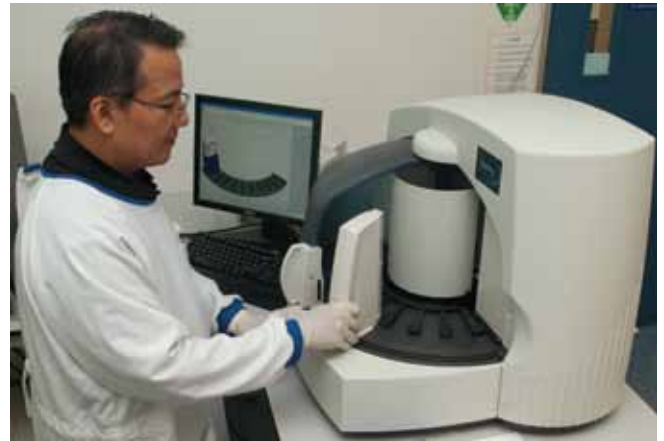
The launch of automated screening at DML follows on from a study at the laboratory in 2008 of the relative efficacies of manual screening and ThinPrep® Imager assisted screening. Although several large international studies already existed, the DML study was undertaken to determine the concordance rate in our regional setting, and to see if automated screening could be practiced under the stringent operational policy and quality standards of the NCSP. We felt confident that some variability of results in other studies may in part be related to the various experience of screeners.

Automation is a joint process between the ThinPrep® Imager and screener interpretation which remains a critical component of Imager assisted screening.

Our study results are soon to be submitted for publication in a peer reviewed journal.

Conclusions from the Imager Study

- **Imager assisted screening is as good as manual screening in the detection of abnormalities.**
- **There is an improved pick-up rate of high grade lesions with Imager assisted screening.**
- **There is a high concordance rate for the pick up of low grade abnormalities in the order of 95%.**
- **Imager assisted screening showed a 50% reduction in the reporting rate of 'Unsatisfactory' smears.**
- **Screeners can safely report 40% more samples per day.**
- **The screener is greatly aided by the highly standardized computer assisted detection of abnormality. However interpretation of that abnormality, whether it is a low grade or high grade lesion, is still dependent on the skill and expertise of the screening scientist.**



How does Automated Screening Work?

After initial processing of the ThinPrep® sample, the slide is stained with a highly specialized nuclear stain. Cellular nuclei stain with varying intensities depending on the amount of DNA present, ie. dysplastic nuclei will stain darker than normal nuclei, or those with benign changes. The stained slides are then scanned by the Imager which identifies and marks 22 fields of view (FOV).

It is a requirement that the cytology scientist must screen the entire area of each of the marked 22 FOV. A full re-screen of the slide is performed where an abnormality is identified in a FOV, or where the risk of an abnormality is known to be higher than that of the total screening population. A further full re-screen is performed for all abnormalities and the slide is then sent to a cytopathologist for reporting.

The adoption of automated screening is a significant departure from traditional screening methods and is a move towards a higher level of objectivity for the screening process. Screening is now a "partnership" between computerized science and a skilled specially trained scientist.

This "partnership" has proven successful in studies comparing the efficacies of manual and automated screening, the majority of these using the ThinPrep® Imager. These studies have demonstrated a higher pick-up rate for abnormalities, higher pick-up rate of high grade lesions and fewer smears interpreted as 'Unsatisfactory'.

The ThinPrep® vial contains a preservation solution which serves as a transport and antibacterial medium. It is designed to ensure the preservation of the cells in solution, prior to processing, for up to 3 weeks at room temperature.

DML has an unbroken record of prompt turnaround time for the reporting of smears and the current turnaround time will remain the same.

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The result turnaround time is on average 3 days for smears and 5 days for smears with an accompanying HrHPV result.



The Clinical Relevance of an 'Unsatisfactory' Result

Lower 'Unsatisfactory' Rates Do Not Equal a Better Screening Process

- Some cervical smears, regardless of the testing method will for a variety of reasons be reported as 'Unsatisfactory'.
- The NCSP National Indicator for 'Unsatisfactory' rates for LBC is no less than 1% and no greater than 5%. DML's 'Unsatisfactory' rate is 2.9%, and will be lower with automated screening.

Reasons For an 'Unsatisfactory' Result Outcome

While an 'Unsatisfactory' result is a valid outcome for a cervical smear test, it can present a challenge for both the practitioner and the patient.

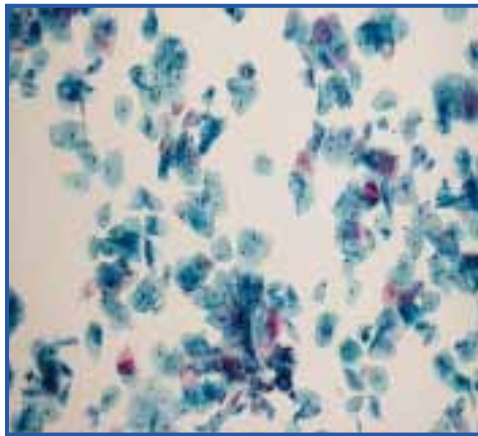
An 'Unsatisfactory' result provides critical information and may be caused by a variety of factors – including, but not limited to:

- patient biology
- personal lubricants
- the use of lubricant on the speculum
- collection technique
- test processing and interpretation

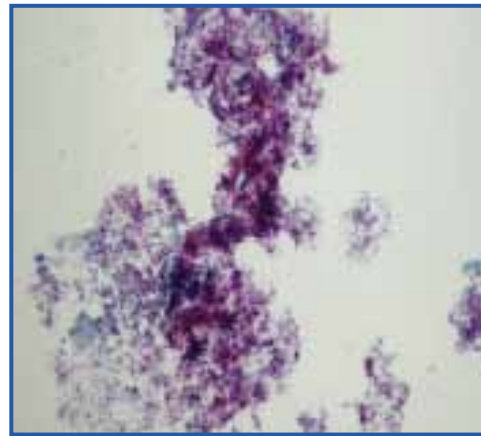
When a cervical smear is determined to be 'Unsatisfactory', the sample is put through an additional process in our Cytology department. This process may eliminate excess blood, breakdown excess mucus or detach cells from lubricant. In many cases this re-processing will provide a satisfactory result.

However, when a sample remains 'Unsatisfactory', the smear undergoes two full re-screens because the risk of abnormality with an 'Unsatisfactory' is known to be higher than that of the total screening population.

Comparison of Satisfactory and 'Unsatisfactory' Smears



Satisfactory with abundant squames



'Unsatisfactory' with abundant lubricant and few squames

It is Important to Note the Clinical Implications of an 'Unsatisfactory' Result:

- An increased risk of underlying disease has been linked to an unsatisfactory result.
- 26% of unsatisfactory specimens come from women with ASCUS or LSIL.
- A woman with an 'Unsatisfactory' result has an up to 4 times greater risk of having CIN II/III.

In light of these associations, a recall at 3 months instead of 3 years is appropriate to safeguard a woman from an undetected abnormality.

TIPS TO REDUCE 'UNSATISFACTORY' SMEAR RESULTS

A recent review of 'Unsatisfactory' results at DML indicates that up to 8% of post-menopausal women are reported with an 'Unsatisfactory' smear result. Factors that may contribute to an 'Unsatisfactory' smear result in a post-menopausal woman are:

- The use of lubricants which increase the risk of contaminating or obscuring the epithelial cells. We recommend the use of warm water to warm and lubricate the speculum. If lubricant is necessary, a small amount can be applied only to the shaft of the speculum.
- Atrophy – due to atrophy, the cervical squamous epithelium is thin and it is more difficult to obtain cells from the surface. A course of topical estrogen before smear taking is recommended.

