

# Future Directions in Pathology Services

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Health  
Pathology

creating better health & justice systems  
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## Acknowledgement of Country

NSW Health Pathology acknowledges the people of the many traditional countries and language groups of New South Wales. It acknowledges the wisdom of Elders both past and present and pays respect to Aboriginal communities of today.

45 Watt Street, Level 5  
PO Box 846  
Newcastle NSW 2300  
T+61 2 4920 4000  
F+61 2 4920 4040

[NSWPATH-Info@health.nsw.gov.au](mailto:NSWPATH-Info@health.nsw.gov.au) [www.pathology.health.nsw.gov.au](http://www.pathology.health.nsw.gov.au)

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## Introduction

At NSW Health Pathology, we're driven by a clear purpose: to create better health and justice systems for the people of NSW.

Delivering on that purpose is an ongoing quest – one that forces us to continually examine what our customers and communities need from us, and then respond to meet those needs.

In our first five years, we have established ourselves as a critical statewide service. We've established our processes, our structure and our value-adds. We've also built a reputation as an organisation that gets things done.

Our history and achievements so far are something of which we can be proud. The expertise of our staff is undeniable, and the analysis and interpretation they provide is essential to quality patient care.

We're involved in research and innovation that improve diagnostics, support more personalised treatments and deliver better health outcomes.

We're breaking new ground in areas like genomics, biobanking, digital pathology, point of care testing, public health and more.

But we can't stop there. We operate in an increasingly competitive and demanding environment and need to ensure we have a strong, sustainable public pathology service fit for the future.

Ongoing advances in science and technology will drive changes at a faster rate than we've ever seen before, and this will affect the way we structure and deliver our services.

We need to find new ways to share our expertise so customers and patients can access what they need regardless of geography.

We need to strengthen the value we bring and provide better outcomes for customers and patients. We also need to carve out new opportunities that put us at the forefront of new tests, new technologies, new evidence and potentially, new markets.

The ultimate aim is to ensure our health and justice systems have the services they need – and that we're in the driver's seat in that process.

This document outlines the principles and priorities that will help us shape the future directions of our pathology services. It provides interim guidance while we develop our next strategic plan and our five-year clinical services plan for pathology.

We're also considering future directions of our forensic services and will look for ways to increase collaboration between our pathology and forensic teams in areas like genomics, public health, perinatal post-mortem services, and more.

While those important pieces of work are underway, our clinical operations and clinical service leaders will refer to this Future Directions paper to guide decision making and forward thinking.

## Our Corporate Compass

In considering future directions for our pathology services, we will be guided by the principles outlined in this document and those defined in our corporate compass.

Our compass captures the attributes we hold dear and those which guide our efforts to create a truly extraordinary service for the people of NSW:

- Our shared **purpose** to create better health and justice systems for the people of NSW
- Our promise to deliver excellence in diagnostics and analysis, lead research for the future, and make a positive difference in our communities
- Our **RITE values**, which guide how we interact with one another and our various stakeholders
- Our vision and **priorities** as outlined in our 2014–2018 Strategic Plan
- Our commitment to find new and innovative ways to enhance **the value we bring** to our customers, patients, families and communities



# The Case for Change

## Pathology services in the past

In NSW, public pathology services have traditionally developed locally in association with clinicians at health facilities, to support clinical service delivery at that location. Much of current pathology service provision is still anchored to the location of equipment and expertise. A hub and spoke service model for pathology test referral is in place; however, healthcare providers generally perceive off-site testing as a subpar solution that reflects adversely on the competency of local pathology teams. Fragmented logistics and incompatible Information Technology (IT) systems have hampered our ability to support effective off site service provision and therefore change this perception. As a result, there has been a growth in onsite laboratory size, equipment, personnel and the test menus provided.

The current arrangements are unsustainable and directly contribute to test duplication and replication of laboratory infrastructure. As a result, many laboratories are not operating at optimum capacity levels. This growth has also been at the expense of utilising our specialised clinical and scientific workforce for customer and clinician engagement.

## Current pathology services

In the last five years, NSW Health Pathology has established strong foundations for change. Robust organisational structures and processes for governance, strategic planning and accountability are now in place. NSW Health Pathology is delivering on business and strategic planning goals and has demonstrated the ability to build clinical capacity in pathology services. NSW Health Pathology is well placed to respond to future challenges.

Recognise our value to the NSW Health system and have listened to customers who want greater clinical engagement. Stakeholders are increasingly interested in the complete process of pathology testing, which is defined as from the time of specimen collection to the time the results are to hand for analysis and interpretation. To enhance our ability to invest in these areas we must consider disinvestment in areas that are not adding value or are duplicated elsewhere.

## Future industry-wide trends that will impact pathology services

Clinicians are treating patients with greater clinical complexity in shorter timeframes. NSW Health Pathology is committed to working with clinicians to support the delivery of appropriate models of care.

Innovation in genomic technologies has initiated more personalised medicine. 'Personalised' medicine requires assessment of the genotype and phenotype of the patient before they undergo specific and tailored treatment.

The development of 'Omics' within diagnostic services includes examination of DNA, RNA, proteins and metabolites. Genomics-transcriptomics-proteomics and metabolomics respectively are closely linked terms and cover the biology of conditions in health and disease. They can be used to investigate the progression of disease and the patient's response to therapy, nutrition, exercise and other interventions.

The following trends in pathology services will also influence future pathology services:

- Changes in Information Technology and Communications capabilities have influenced consumer expectations and demand for locally based pathology testing with fast and direct delivery of results
- The increasing clinical complexity of patient cases places greater demand on the pathology workforce to engage in teaching, training and research activities
- Development and distribution of smaller, lower cost infrastructure for rapid testing and equipment with increased capacity will transform processing of high volume tests and support faster clinical decision-making
- Increased availability of Point of Care Technology will support urgent pathology testing at sites with no, or low, access to on-site laboratory services
- Increased information capabilities in data and information processing, storage and retrieval will boost capacity to detect and reduce unwanted variations in pathology test reporting
- Increased capabilities in information technology; in particular, improved software interfaces between information systems will improve access to results of pathology testing
- Innovations such as digital pathology will increase statewide access to subspecialty expertise
- Personalised medicine will require more intensive investigation using genomics, proteomics and metabolomics methodologies. These methodologies include the genetic code, manufactured proteins and the metabolites of human biology.

Market pressures within the pathology industry must also be considered. The pathology market is highly competitive. As a result, there has been increasing consolidation of private pathology providers. Private providers will continue to seek additional market share and standardise pathology service offerings to boost efficiencies of scale and maximise returns.

Public pathology provides services to predominantly in-hospital patients, often with complex, clinical needs. Over a long period of development, public pathology has built considerable consolidated intellectual, physical and logistic capital for NSW. This service is available to provide unbiased intelligence for NSW and the Commonwealth on diagnostics testing initiatives and futures.

## Future pathology services in NSW

The current service delivery model for pathology is unsustainable. Incremental changes to existing hub and spoke systems will not address underlying issues. However, adopting what is our understanding of the private sector pathology model-highly consolidated and offsite operation in relation to hospital facilities-would equally be unsuitable for public sector needs. Neither approach will provide the pathology service that the NSW Health system needs now and into the future.

Through the implementation of the NSW Government Commissioning and Contestability Policy, publicly funded services are charged with the task of ensuring that services provided represent the best value for public resources. NSW Health Pathology will take the lead in the commissioning and contestability process for pathology services.

NSW Health Pathology will:

- Deliver value in pathology services through improved effectiveness, efficiency and an improved customer and patient experience
- Ensure management of risk (for patient safety and clinical quality) in pathology services
- Leverage innovation and new technology
- Build capacity in ICT, workforce and logistics to support future pathology services
- Challenge internal and external providers through competition.

As part of the Commissioning and Contestability process, NSW Health Pathology will lead the evaluation and transformation process of current public pathology services as the provider and future commissioner of an integrated, statewide pathology service for NSW. In the next five years, we will:

- Streamline pathology service models to maximise efficiency and effectiveness whilst ensuring enhanced local engagement with Local Health District services
- Expand access to centres of excellence in specialty pathology services to improve patient outcomes
- Realign infrastructure, equipment and workforce in accordance with a new structure of pathology services.

NSW Health Pathology will build an integrated statewide pathology service. The role and scope of testing will be reviewed and streamlined within pathology laboratories. Laboratories will also be interconnected with other pathology support services, such as specimen collection centres, to provide a single statewide network of pathology services and expert advice to support quality outcomes.

Laboratories and pathology support services located in rural and remote areas will be scaled to utilise innovations in light infrastructure such as Point of Care Technology (PoCT).

NSW Health Pathology will invest in improved information technology, improved communication links and revised logistics arrangements to underpin the proposed network.

NSW Health Pathology will also leverage digital pathology technology to increase access to pathology expertise across NSW.



# Service Planning in NSW Health Pathology

NSW Health Pathology Clinical Streams will lead the way in transforming our organisation by making recommendations around service development and configuration, staffing profiles, rationalising pathology testing and other initiatives required to provide a more effective and efficient public pathology service.

A key document to inform this transformation is the Clinical Services Plan. The Clinical Services Plan will align future clinical pathology service provision to strategic directions in the NSW Health Pathology Strategic Plan and provide recommendations for future service development. The Clinical Services Plan will be developed with extensive consultation and is expected to be available in 2018.

The Clinical Services Plan is part of the NSW Health Pathology Planning and Accountability Framework. This framework has been developed to demonstrate the relationships between the NSW Ministry of Health, NSW Health Pathology strategic directions and the day-to-day work in the organisation. The framework on the following page shows how planning cascades down through NSW Health Pathology and how our colleagues are held accountable for our performance.

## Planning for Clinical Services

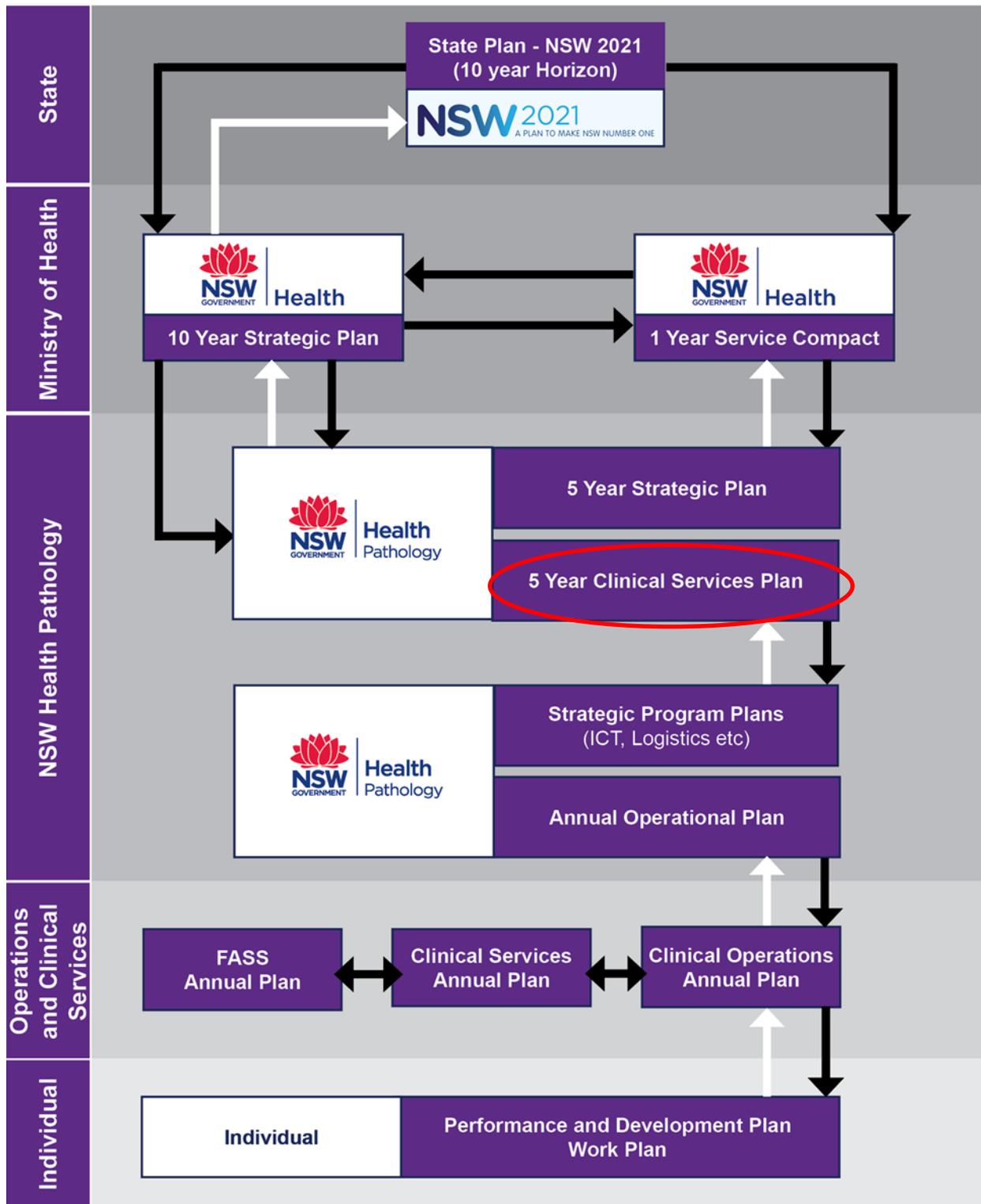
The NSW Health Pathology Clinical Services Plan will be available in 2018 and will include service planning for the Forensic and Analytical Science Service (FASS).

In the interim, the 'Future Directions in Pathology Services' document, provides a number of broad statements that describe the aims of clinical service delivery for pathology. In conjunction with the NSW Health Pathology Planning Principles, these 'Future Directions' will provide context to service planning decisions that need to be made for our organisation until a comprehensive Clinical Services Plan is developed. The following broad statements will also be used as overarching, high level guiding principles for service delivery by FASS.

Information for these statements was obtained by conducting a series of consultations with Clinical Stream Leads. As part of this process, Clinical Stream Leads predicted key changes to Clinical Stream services for the next five years.

These broad statements are for use by NSW Health Pathology staff, Local Health Districts, the Ministry of Health and Health Infrastructure so they can be informed about the general direction of clinical service development in NSW Health Pathology.

# NSW Health Pathology Planning and Accountability Framework



## NSW Health Pathology Planning Principles

The Planning Principles are used when NSW Health Pathology is making decisions about the suitability of a proposed change in pathology services. These principles are used to provide context to these decisions and ensure that planned service changes are consistent with increasing the value of our services.

Use of these Planning Principles in decision-making ensures our services are provided as part of a single statewide organisation and that delivery of high quality diagnostic services is maintained.

Proposed service changes must meet the following principles:

- Consider the best interests of the whole of the State in making decisions
- Focus on the needs of patients
- Deliver safe, accessible and culturally appropriate services
- Deliver the best outcome in clinical quality, efficiency and effectiveness
- Achieve sustainable, contestable and value for money services
- Be feasible, affordable and optimise use of resources.

Proposed service changes must consider the following desirable principles:

- Respond to key stakeholder priorities to enhance service delivery
- Support the right workforce and workforce models
- Utilise the right technology and innovative technology where appropriate
- Strengthen IT infrastructure and systems
- Promote innovation in service delivery
- Contribute to the quality use of pathology
- Deliver services that are agile and flexible
- Enhance the value proposition of NSW Health Pathology as delivered to patients, clinicians and NSW Health.

Where proposals for service development are unable to meet any of the desired planning principles, the reasons why should be clarified and documented.

# Future Directions in Pathology Services

The following future directions apply to pathology service provision in NSW Health Pathology:

## 1. Streamline workflows to increase operating efficiency

- **Develop a core laboratory service to improve capacity to meet future demand**

Recent advances in automation now allow integration of pre-analytic and post-analytic handling of specimens and analytic processing for high volume tests for a number of pathology areas, such as Chemical Pathology, Haematology, Coagulation, Microbiology, Serology, Endocrinology and Immunology. These tests will form the future test profile of 'core laboratory' testing. In addition, a number of manual and semi-automated tests in many laboratory areas will also be automated.

- **Increase capacity of pre-existing cross-specialty technology platforms**

Advances in technology have provided equipment and techniques that can be used for pathology testing across traditional pathology disciplines. As a result, there are a number of highly specialised technology platforms (such as flow cytometry and chromatography-mass spectrometry and sequencing) with unused capacity. NSW Health Pathology Clinical Streams will engage in cross stream negotiations to optimise utilisation of these technologies.

- **Increase use of robotics and automation in test processing**

NSW Health Pathology will investigate where advances in robotics and automation can improve the delivery of diagnostic services through eliminating manual processing steps and reducing technical variation in testing. This technology is also likely to have applications that can be used by more than one Clinical Stream.

## 2. Create statewide standards to enhance our agility

Until recently, laboratory processes and interpretation of results for many pathology tests have been developed in isolation from similar testing in other laboratories. NSW Health Pathology will facilitate a process for statewide standardisation of test names, test processes, test intervals and harmonisation of test equipment. This will reduce duplication and enhance transferability of pathology services across the State. NSW Health Pathology will also standardise clinical quality standards and systems on a statewide basis.

## 3. Embrace new technology and innovation to ensure we are leading the way

The implementation of new technologies is well underway within Clinical Operations in NSW Health Pathology. Use of digital imaging technology will ensure statewide access to experts in the sub specialties within Microbiology, Anatomical Pathology and Haematology. Pathologists will be able to rapidly provide advice and consultation to clinicians at health facilities in NSW.

Increasing use of molecular techniques coupled with the use of mass spectrometry for proteomic and metabolomic biomarkers in routine diagnostic testing will leverage pathology expertise in healthcare. In particular, the highest impact will be in support for personalised, preventative care and treatment protocols in oncology services and chronic disease.

#### **4. Leverage our expertise and skills across the State**

NSW Health Pathology's workforce has significant knowledge and expertise in pathology. We will use technological innovations to maximum advantage to facilitate statewide access to recognised experts across our Clinical Stream sub-specialities.

#### **5. Lead the way in research in pathology to inform better outcomes for patients**

Research and innovation is a core business area of NSW Health Pathology and a culture of research and innovation will be embedded within governance and organisational activities. As a result, NSW Health Pathology will be positioned at the forefront of new test development and emerging technologies by actively supporting translation of research outcomes into clinical practice.

NSW Health Pathology will also actively support innovation and research in health systems by building strong research collaborations with universities, medical research institutes, hospitals, industry and other health services.

## Pre and Post Analytical Services

Pre and post analytical services covers the areas of specimen collection, transport, registration, processing and delivery to the laboratory, as well as activities relating to the delivery of results and communicating with clinicians who refer tests to the laboratory.

The Pre and Post Analytical Clinical Stream provides advice and direction for pathology sample collection, sample storage and transport, sample registration, initial processing and, when required, forwarding of samples to other laboratories for further testing and receipting of results.

A primary obligation of pathology service function is to ensure specimen security and integrity. Pre and Post Analytical Services play a critical role in maintaining specimen integrity, managing correct patient identification (ID), the delivery of results and any follow-up communication with patients and clinicians.

The following table provides examples of service development activities that are consistent with the agreed Future Directions in Pathology Services. These activities are undertaken in collaboration (as appropriate) with other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Pre and Post Analytical Services will be pursued:

Future Directions (the next five years)	Examples
<p>1. Streamline workflows to increase operating efficiency</p>	<ul style="list-style-type: none"> <li>◦ Work closely with core laboratory services to review and improve sample workflow for high volume tests</li> <li>◦ Increase integration of pre-analytical and analytical equipment and processes</li> <li>◦ Investigate and implement integrated barcode technology for specimen transfers across the State</li> <li>◦ Investigate greater use of automation via electronic ordering, sample delivery and process management (both on and off site)</li> </ul>

Future Directions (the next five years)	Examples
<p>2. Create statewide standards to enhance our agility</p>	<ul style="list-style-type: none"> <li>◦ Develop standard operating procedures for key processes in pre-analytical services across the State</li> <li>◦ Facilitate and coordinate the development of a statewide test directory</li> <li>◦ Participate in statewide tender processes to standardise equipment and consumables</li> </ul>
<p>3. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Support the expansion of electronic ordering of pathology tests</li> <li>◦ Support positive patient identification initiatives</li> <li>◦ Expand links with Non Acute, Ambulatory Care, Community Health and external customers (such as GP's and community based specialists)</li> <li>◦ Investigate existing and future technology to improve patient services</li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Develop the role of pre and post analytical staff in providing customer services to key stakeholders, such as clinicians, Local Health District staff, private providers and the general public</li> <li>◦ Review pathology staff member roles and training practices in pre-analytical processes across the State</li> <li>◦ Develop capacity in business support</li> </ul>
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Develop pre-analytic standardised operating procedures to support pre-analytical processing for research projects and clinical trials</li> </ul>

## Haematology Services

Haematology is a clinical specialty concerned with the cause, diagnosis and treatment of diseases of the blood and blood producing organs. Haematologists provide clinical advice and treatment directly to patients and clinicians in other specialties.

Haematologists are also involved in laboratory testing related to diagnosis and ongoing monitoring of treatments. High volume haematology and coagulation testing form part of the 'core' laboratory test menu.

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Haematology services will be pursued:

Future Directions (the next five years)	Examples
<p>1. Streamline workflows to increase operating efficiency</p>	<ul style="list-style-type: none"> <li>◦ Work closely with pre-analytical services and other clinical disciplines to integrate workflow for core laboratory testing</li> <li>◦ Continue to support the migration of manual tests into the core laboratory test menu</li> <li>◦ Support technology for specimen tracking and storage across the State</li> <li>◦ Establish an integrated flow cytometry service</li> <li>◦ Work with Point of Care Technology coordinators and local clinicians to expand the use of Point of Care Technology and scalability of testing in rural, regional and metropolitan locations where clinically appropriate</li> <li>◦ Support the integration of haematology and coagulation analysers into core laboratory automation systems</li> </ul>

Future Directions (the next five years)	Examples
<p>2. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Promote equity of access to expertise across the State; particularly in rural and remote areas</li> <li>◦ Develop statewide linkages to pathology expertise, particularly in rural and remote areas using digital imaging technology</li> <li>◦ Develop molecular services to support diagnostic haematology</li> </ul>
<p>3. Create statewide standards to enhance our agility</p>	<ul style="list-style-type: none"> <li>◦ Develop statewide standardised evidence-based, high risk result alert thresholds for haematology testing</li> <li>◦ Ensure reference intervals for tests are the same across the State</li> <li>◦ Standardise operating procedures for laboratories across the State</li> <li>◦ Facilitate harmonisation of test analysers across the State</li> <li>◦ Consolidate complex testing in Haemostasis</li> <li>◦ Support the development of a statewide test directory</li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Develop guidelines to identify and access sub-specialty pathologist expertise across the State</li> <li>◦ Document and consolidate expertise in morphology</li> <li>◦ Define the roles of medical scientists and pathologists in Haematology and Genomics</li> <li>◦ Clarify the responsibilities of clinical and dual-qualified haematologists</li> <li>◦ Support the establishment of clinical scientist roles</li> </ul>

Future Directions (the next five years)	Examples
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Encourage staff to participate in clinical and laboratory based research projects</li> <li>◦ Establish a framework for collaborative research between Haematology and other clinical and laboratory specialties</li> <li>◦ Develop services to support research projects and clinical trials</li> </ul>

## Transfusion Services

Transfusion services manage patient sample collection, storage and management of fresh blood and fresh blood components at the pre-transfusion stage. Transfusion services also provide antenatal and post-natal immune-haematology testing. Consultation and support for Transfusion Services is provided in a broad spectrum of medical and surgical settings; particularly in acute and critical care settings.

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Transfusion services will be pursued:

Future Directions (the next five years)	Examples
<p>1. Streamline workflows to increase operating efficiency</p>	<ul style="list-style-type: none"> <li>◦ Optimise the placement of remote-release blood and blood product fridges in Operating Theatres and Emergency Departments</li> <li>◦ Support technology for positive patient identification and specimen tracking across the State</li> <li>◦ Work with Point of Care Technology Coordinators and local clinicians to expand the use of Point of Care Technology and near patient testing technology where clinically appropriate</li> </ul>
<p>2. Create statewide standards to enhance our agility</p>	<ul style="list-style-type: none"> <li>◦ Standardise equipment and laboratory operating procedures across NSW laboratories</li> <li>◦ Support the adoption of a statewide blood management system</li> <li>◦ Support the development of a statewide test directory</li> <li>◦ Develop statewide standardised evidence based high risk result alert thresholds for transfusion testing</li> </ul>

Future Directions (the next five years)	Examples
<p>3. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Proactively engage with industry to participate in the development of new concepts and technology</li> <li>◦ Explore potential synergies and links between services provided by Transfusion and Pharmacy services</li> <li>◦ Identify and develop opportunities to up-skill and add value to current services, such as providing advice to Local Health Districts regarding mass transfusion protocols and expert advice to private healthcare providers</li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Develop strategies to increase support offered to Local Health District Transfusion Committees</li> <li>◦ Provide greater access to teaching and training for rural and regional transfusion staff</li> <li>◦ Optimise the placement of remote release blood and blood product storage at health sites without an on-site transfusion service where clinically appropriate</li> <li>◦ Support the establishment of clinical scientist roles</li> </ul>
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Develop services to support research projects and clinical trials</li> <li>◦ Establish a framework for collaborative research between Transfusion and other clinical and laboratory specialties</li> </ul>

## Immunology Services

Immunology is both a laboratory and clinical-based specialty concerned with the diagnosis and monitoring of diseases of the immune system, including immunodeficiency, autoimmunity, lymphoid malignancy and allergy.

Immunology services also diagnose and monitor other medical conditions that depend on identifying abnormalities of a patient's immune function or on the results of tests based on immunological methodology, including disease-specific Human leukocyte antigen (HLA) typing.

Immunologists play a critical role in the supervision and clinical governance of laboratory testing and provide a diagnostic service, interpretation and advice to clinicians. Immunologists may also be qualified in the allergy sub-speciality.

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Immunology services will be pursued:

Future Directions (the next five years)	Examples
1. Streamline workflows to increase operating efficiency	<ul style="list-style-type: none"> <li>◦ Identify further tests that can be performed in a core laboratory arrangement</li> </ul>
2. Create statewide standards to enhance our agility	<ul style="list-style-type: none"> <li>◦ Standardise equipment used for immunology testing</li> <li>◦ Standardise reference intervals for pathology tests across similar technology</li> <li>◦ Consider options for consolidation of specialised testing</li> <li>◦ Identify time critical tests that need to be performed at all laboratories with immunology services</li> <li>◦ Support the development of a statewide test directory by contributing to the production of a test handbook</li> <li>◦ Establish an integrated flow cytometry service</li> <li>◦ Develop statewide standardised evidence-based, high risk result alert thresholds for Immunology tests</li> </ul>

Future Directions (the next five years)	Examples
<p>3. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Investigate the impact of transferring immunology testing to a genomics platform; in particular, testing for rare immunological diseases</li> <li>◦ Develop a service delivery model to meet increasing demand from non-traditional sources<sup>1</sup></li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Facilitate access to consultation with subspecialty experts across the State</li> <li>◦ Promote the consultative role that Immunology provides to other medical specialties, i.e. 'Right test for the right question in the right environment'</li> <li>◦ Promote the clinical utility of Immunology to clinicians in acute care outside the traditional Immunological specialties</li> <li>◦ Review staff member training practices and requirements across the State</li> <li>◦ Define and acknowledge the roles of pathologists, medical scientists, technologists and technicians within the Immunology laboratory</li> <li>◦ Define the role and responsibilities of dual qualified Pathologists in Immunology</li> <li>◦ Support the establishment of clinical scientist roles</li> </ul>
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Promote use of systematic methods and establish the clinical utility of tests when conducting research and experimentation in Immunology</li> <li>◦ Establish a framework for collaborative research between Immunology and other clinical and laboratory specialties</li> </ul>

<sup>1</sup> Examples of expanding areas of non-traditional request sources are Renal Medicine, General Practice, Mental Health and Dietetics

## Chemical Pathology Services

Chemical Pathology services are involved with the vast majority of disease diagnosis, treatment and ongoing management. Chemical Pathology testing includes detection of levels and changes in substances that are an indicator of the presence, cause or severity of a disease and the progress of disease treatment. The majority of Chemical Pathology tests are part of the 'core laboratory' test arrangement. Some specialist areas in Chemical Pathology are inherited metabolic diseases, trace and toxic elements and environmental monitoring, therapeutic drug monitoring, drugs of abuse, and nutrition.<sup>2</sup>

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Chemical Pathology will be pursued:

Future Directions (the next five years)	Examples
1. Streamline workflows to increase operating efficiency	<ul style="list-style-type: none"> <li>◦ Increase integration of core testing for all disciplines within the core laboratory setting</li> <li>◦ Consolidate mass spectrometry testing and review the range of tests performed</li> <li>◦ Investigate further increases in capacity for mass spectrometry instrumentation (in particular, automation and software for analysing large amounts of data)</li> <li>◦ Work with Point of Care Technology Coordinators and local clinicians to expand the use of Point of Care Technology where clinically appropriate</li> <li>◦ Support the migration of manual tests into core laboratory automation systems or mass spectrometry solutions that have front-end automation to increase test accuracy and speed of processing</li> </ul>

<sup>2</sup> Model Scope of Clinical Practice. At: <http://www.schn.health.nsw.gov.au/professionals/professional-resources/nsw-state-scope-of-clinical-practice-unit>. Accessed: 11 September 2017.

Future Directions (the next five years)	Examples
<p>2. Create statewide standards to enhance our agility</p>	<ul style="list-style-type: none"> <li>◦ Standardise equipment, reference intervals and operating procedures in Chemical Pathology services</li> <li>◦ Categorise testing into areas of essential, desirable and unnecessary duplication of services</li> <li>◦ Establish an approach to denote location of specialised testing, platforms and experts across the State</li> <li>◦ Support the development of a statewide test directory</li> <li>◦ Develop statewide standardised evidence-based, high risk results alert thresholds for Chemical Pathology tests</li> </ul>
<p>3. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Develop molecular diagnostic tests including genomic, proteomic and metabolomics biomarker panels for routine diagnostic use to provide personalised preventative care and treatment regimes</li> <li>◦ Support the development of scalable solutions across models of service delivery</li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Identify and promote designated statewide specialists in test analysis, test processes and test reporting within Chemical Pathology Services</li> <li>◦ Support the establishment of clinical scientist roles</li> </ul>
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Establish a framework for collaborative research between Chemical Pathology and other clinical and laboratory specialties</li> </ul>

## Microbiology Services

Microbiology services are concerned with the diagnosis, treatment and surveillance of infectious diseases. Services focus on specimen collection and analysis, reporting and interpretation of results. Microbiologists also advise, educate and provide consultant advice to clinicians regarding aspects of the pathogenesis, epidemiology, diagnosis, prevention and management of infection including recommending antimicrobial therapy. Research and teaching are also important parts of the role.<sup>3</sup>

In addition to providing a diagnostic service with interpretation and advice to clinicians, Microbiologists also contribute to infection prevention and control within health facilities, including antimicrobial stewardship programs.

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Microbiology Services will be pursued:

Future Directions (the next five years)	Examples
1. Streamline workflows to increase operating efficiency	<ul style="list-style-type: none"> <li>◦ Identify tests that can be performed in a core laboratory and work with other Clinical Streams when transitioning selected tests</li> <li>◦ Support technology for specimen tracking and storage across the State</li> <li>◦ Optimise use of mass spectrometry techniques in Microbiology testing</li> <li>◦ Work with Point of Care Technology Coordinators and local clinicians to expand the use of Point of Care Technology and near patient testing technology where clinically appropriate</li> <li>◦ Develop a statewide strategy for the use of robotics and digital imaging for automating agar-based testing</li> </ul>

<sup>3</sup> Model Scope of Clinical Practice. At: <http://www.schn.health.nsw.gov.au/professionals/professional-resources/nsw-state-scope-of-clinical-practice-unit>. Accessed: 11 September 2017.

Future Directions (the next five years)	Examples
<p>2. Create statewide standards to enhance our agility</p>	<ul style="list-style-type: none"> <li>◦ Standardise equipment, reference intervals and sensitivity methodology across the State</li> <li>◦ Review the production and procurement of media</li> <li>◦ Support the development of a statewide test directory</li> <li>◦ Develop statewide harmonised evidence-based, high risk result alert thresholds for Microbiology testing</li> </ul>
<p>3. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Develop molecular and metabolomics biomarker tests for routine diagnostic use in microbiology</li> <li>◦ Develop remote access linkages to expertise using automation and digital imaging</li> <li>◦ Consolidate complex microbiology testing across the State</li> <li>◦ Complete the transition for the National Cervical Screening Program from the Pap smear test to Human Papillomavirus testing</li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Identify and promote designated statewide specialists in test analysis, test processes and test reporting within Microbiology services</li> <li>◦ Support the establishment of clinical scientist roles</li> <li>◦ Clarify the responsibilities of laboratory microbiologists and infectious disease physicians</li> </ul>
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Encourage staff in microbiology to undertake research projects</li> <li>◦ Develop services to support research projects and clinical trials</li> <li>◦ Establish a framework for collaborative research between microbiology and other clinical and laboratory specialties</li> </ul>

## Anatomical Pathology Services

Anatomical Pathology services provide diagnosis, exclusion and monitoring of disease by general examination of body tissues. Tissue samples may be obtained in the form of specimens, cells body fluids and secretions from all parts of the body. Anatomical Pathology services include the specialties of Surgical Pathology and Cytology.<sup>4</sup>

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

During the next five years, the following broad service directions in Anatomical Pathology Services will be pursued:

Future Directions (the next five years)	Examples
1. Streamline workflows to increase operating efficiency	<ul style="list-style-type: none"> <li>◦ Support technology for specimen tracking and storage within the laboratory and across the State</li> <li>◦ Consolidate Immunohistochemistry (IHC), In Situ Hybridisation (ISH) and enzyme chemistry testing</li> <li>◦ Develop statewide standardised evidence based high risk result alerts for Anatomical Pathology findings</li> </ul>
2. Create statewide standards to enhance our agility	<ul style="list-style-type: none"> <li>◦ Standardise equipment and operating procedures</li> <li>◦ Support the development of a statewide test directory</li> <li>◦ Develop a statewide strategy for the implementation of digital imaging</li> </ul>
3. Embrace new technologies and innovation to ensure we are leading the way	<ul style="list-style-type: none"> <li>◦ Develop molecular diagnostic tests for routine use in anatomical pathology</li> <li>◦ Investigate applications of mass spectrometry in Anatomical Pathology such as using imaging mass spectrometry to produce a metabolomics profile</li> <li>◦ Develop a standard structured reporting format which supports embedded images</li> </ul>

<sup>4</sup> Model Scope of Clinical Practice. At: <http://www.schn.health.nsw.gov.au/professionals/professional-resources/nsw-state-scope-of-clinical-practice-unit>. Accessed: 11 September 2017.

Future Directions (the next five years)	Examples
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Develop a system to identify and access sub-specialty pathologist expertise across the State</li> <li>◦ Define roles and establish staff member development programs in key areas, such as cut-up procedures</li> <li>◦ Develop and embed systems for staffing allocations that are based on the volume and complexity of case workload</li> <li>◦ Support the establishment of clinical scientist roles</li> </ul>
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Promote collaborations in research between Anatomical Pathology and other clinical and laboratory specialties</li> </ul>

## Genomics Services

Medical Genomics is the application of genomics technology to the care and management of patients within the hospital and community environments.<sup>5</sup>

Innovations in genomics technology have led to new capabilities in personalised medicine, based on accurate diagnosis and focused therapies. As previously mentioned, personalised medicine involves assessing the genotype and phenotype (e.g. proteome and metabolome) of the patient before they undergo any treatment. *Proteomics* and *Metabolomics* are emerging pathology disciplines that are distinct from current pathology disciplines such as Genomics. *Proteomics* generally refers to the analysis of proteins. *Metabolomics* refers to the study of small (molecular weight) molecules called 'metabolites' within a biological matrix, such as body tissues, blood, urine and other body fluids. Metabolic and proteomic biomarkers are currently studied using mass spectrometry based technologies; most recently in the context of testing within the Chemical Pathology discipline.

It is envisaged that the future of pathology testing lies in multi-parameter test panels<sup>6</sup> that combine proteomic, metabolic and genetic profiles; hence the emerging terms of proteogenomics and metabologenomics. These scientific developments will shape the future of pathology testing and call for a more integrated approach between various pathology disciplines.

NSW Health Pathology is a leading contributor to national and international innovation in the area of genomics and personalised medicine, and will be positioning itself as a provider of high quality, clinically relevant genomic diagnostic services to health providers and their patients.

A statewide NSW Health Pathology Genomics service has been established in line with the NSW Health Pathology Genomics Strategic Plan (2016-2018). This service is operating through three broad areas of service provision; Rare Diseases, Cancer and Infectious Disease/ Public Health Genomics services.

When establishing genomics as a statewide service it was also envisaged that such a model would not be limited by the currently available technologies, but would serve as a template for future technology-driven service delivery systems such as proteomics and metabolomics.<sup>7</sup>

Similar initiatives have commenced in Chemical Pathology services by proposing a statewide integrated clinical mass spectrometry service that, beyond its traditional clinical service role, links pathology services to clinical and academic research as well as to the in vitro diagnostics (IVD) industry.

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<sup>5</sup> NSW Health Pathology (2016) Planning for the Future. NSW Health Pathology Genomics Strategic Plan 2016-2018.

<sup>6</sup> A Test panel is a collection of diagnostic tests that have proved to be the most sensitive, specific and cost-effective combination to evaluate a particular condition.

<sup>7</sup> NSW Health Pathology (2016) Planning for the Future. NSW Health Pathology Genomics Strategic Plan 2016-2018

The following table provides examples of service development activities that are consistent with the five Future Directions in Pathology Services. These activities are undertaken in collaboration with (as appropriate) other clinical services to ensure that NSW Health Pathology provides an integrated, seamless pathology service.

The current NSW Health Pathology Genomics Strategic Plan (2016-2018) will be reviewed in the latter half of 2018 and a new strategic plan will be developed. In the interim, the following broad service directions in Genomics Services will be pursued:

<b>Future Directions (until end of 2018)</b>	<b>Examples</b>
1. Streamline workflows to increase operating efficiency	<ul style="list-style-type: none"> <li>◦ Reduce unnecessary duplication in medical genomics testing</li> <li>◦ Implement a statewide service model and streamline decision-making processes across genomics services</li> <li>◦ Develop consolidated and coordinated genomic service specialties based upon current strengths and expertise</li> </ul>
2. Create statewide standards to enhance our agility	<ul style="list-style-type: none"> <li>◦ Standardise quality assurance and clinical governance activities consistent with the NSW Health Pathology Clinical Governance Framework</li> <li>◦ Standardise the monitoring and reporting of genomic testing across NSW Health Pathology</li> <li>◦ Implement consistent funding guidelines and a statewide financial structure for Genomics services</li> <li>◦ Support the development of a statewide test directory</li> </ul>

Future Directions (until end of 2018)	Examples
<p>3. Embrace new technologies and innovation to ensure we are leading the way</p>	<ul style="list-style-type: none"> <li>◦ Develop and prioritise plans for the application and integration of genomic technologies for NSW Health Pathology Clinical Stream testing</li> <li>◦ Develop and deliver enhanced pathology services that are highly integrated with the patient care process</li> <li>◦ Implement a cloud based data analysis and data storage solution consistent with the NSW Health Pathology Information Communication and Technology Strategy</li> <li>◦ Develop a research and innovation plan for Genomics Services that is consistent with the NSW Health Pathology Research and Innovation Framework</li> </ul>
<p>4. Leverage our expertise and skills across the State</p>	<ul style="list-style-type: none"> <li>◦ Deliver equitable access to appropriate and effective diagnostic genomics services, with a particular focus on rural and regional areas and areas of disadvantage<sup>8</sup></li> <li>◦ Develop new models of care for the diagnostic/ clinical interface and the handover of information that are appropriate for complex genomic/ proteogenomic/ metabologenomic testing</li> <li>◦ Support the establishment of clinical scientist roles</li> <li>◦ Develop training opportunities for staff in NSW Health Pathology Genetics services</li> </ul>

<sup>8</sup> Australian Bureau of Statistics (2011) Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2011 (cat. no. 2033.0.55.001).

Future Directions (until end of 2018)	Examples
<p>5. Lead the way in research in pathology to create better outcomes for patients</p>	<ul style="list-style-type: none"> <li>◦ Develop comprehensive partnerships with major referral clinics, key research institutes, State and Federal governments and relevant national and international genomics initiatives</li> <li>◦ Develop a NATA-accredited service stream targeting research undertaken by universities, medical research institutes and private organisations (including research infrastructure such as the NSW Health Statewide Biobank)</li> <li>◦ Develop a clinical trials strategy consistent with the NSW Health Pathology Research and Innovation Framework</li> </ul>

# Consultation

The following NSW Health Pathology colleagues were consulted in the development of this document:

## NSW Health Pathology Executive

- Ms Vanessa Janissen, Executive Director, Strategy and Reform; A/Director Forensic and Analytical Services
- Mr Darren Croese, A/Executive Director, Strategy and Reform
- Dr Stephen Braye, Executive Director, Clinical Services
- Associate Professor Robert Lindeman, Executive Director, Clinical Operations
- Professor Roger Wilson, Executive Director Clinical Governance and Quality
- Dr Gary (Gus) Koerbin, Executive Director, Scientific and Technical
- Ms Carina Bates, Executive Director, Strategic Communications
- Dr Michael Whiley, Director, Medical Services

## NSW Health Pathology Directors, Operations

- Ms Heather Sharman, Director, Operations; Southern Local Health Districts
- Associate Professor Susan McLennan, Director, Operations; Eastern Local Health Districts
- Mr Neil Catlett, Director, Operations; Rural and Regional Local Health Districts
- Mr Keiran Wicks, Director, Operations; Western Local Health Districts
- Mr Robert Bettinelli, Operations Manager, Hunter (Northern Local Health Districts) (on behalf of Mr Darren Croese, Director, Operations; Northern Local Health Districts)

## NSW Health Pathology Clinical Stream and Statewide Service Leads

- Associate Professor Paul McKenzie (Chair), Anatomical Pathology Clinical Stream
- Dr Raymond Chan (Chair), Microbiology Clinical Stream
- Dr Margaret Janu (Chair), Chemical Pathology Clinical Stream
- Dr Elizabeth Tegg (Chair), Haematology Clinical Stream
- Dr Theo de Malmanche (Chair), Immunology Clinical Stream
- Ms Judy Kempton-Webb (Chair), Pre and Post Analytical Clinical Stream
- Associate Professor Mark Dean (Chair), Transfusion Clinical Stream
- Mr Andrew Sargeant, Director, Point of Care Testing
- Dr Cliff Meldrum, Director, Genomics
- Ms Jane Carpenter, Project Manager, Statewide Biobanking Services

## NSW Health Pathology Staff members

- Ms Nerrida Barton, Director, Planning
- Mr Scott Jansson, Co-ordinator, Clinical Streams
- Professor Rita Horvath, Clinical Director, Chemical Pathology, NSW Health Pathology (Prince of Wales Hospital)



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