

ACT Pathology is required to meet National Pathology Accreditation Advisory Committee's Requirements for the retention of laboratory records and diagnostic material. The relevant retention period is also outlined in the Functional Design Brief.

4.6.9. Environmental and Safety Considerations

There are important environmental components for the Service Model that incorporate:

- Future required design elements;
- Sample flow;
- Ventilation and air quality;
- Lighting (particularly for blood film reading),
- Temperature controls;
- Noise abatement;
- Floor loading; and
- Sustainable practices.

These considerations form part of the Functional Design Brief.

4.6.10. Diagnostic Genomics Future Challenges, Trends and Innovations

As previously noted, the specialty of genomics is both exciting and challenging with the potential it offers health practice. There is more scope to invest in genomics than in any other specialty.

The big picture challenges and trends that will make a significant impact on DG are similar to the broader pathology sector:

- **NGS** is a parallel or deep (DNA) sequencing technology which has revolutionised genomic research over the recent years. Current lab space limitation is a constraint to the procurement of a NGS, which would be highly relevant and substantially beneficial to the work of DG. In many cases is now the frontline test for diagnosis and treatment of various cancers and this will only expand further. Plans to implement this technology by 2024/2025 are underway with significant future growth anticipated.
- **Integrating multiple omics technologies**, similar to the way that multidisciplinary teams approach works in healthcare, the multi-omics approach (including technologies such as genomics, transcriptomics, epigenomics, proteomics, and metabolomics) will provide a much more holistic view of disease mechanisms, which not only works to enhance the accuracy of diagnosis, but also enables personalised treatment strategies based on individual patient profiles. The drive towards individually targeted therapies is expected to continue to increase the level of testing, workforce expertise and need for individualised reports, particularly in cancer treatments. *It is likely that in the not-so-distant future, the 'omics revolution' for personalised diagnoses and treatments could become core business for ACT Pathology.*
 - ▶ Increased integration of genomics into routine clinical practice – essential for timely diagnosis of cancer, for prognostication and to identify targeted treatments;
 - ▶ Pharmacogenomics;
 - ▶ Screening for disease: including minimal residual disease in cancer patients, and carrier screening in parents/families; and
 - ▶ Tissue banking to allow for retesting of samples.

- **Automation of Manual Steps.** Common to all specialties, there will be opportunities to automate more manual steps with automated machines and AI assisted software.
- **AI and machine learning** are being much more widely used in pathology as algorithms and pattern recognition can help humans perform much faster, much more accurately with much less effort. Together, they will play a significant role in analysing and interpreting large-scale genomic data, and identification of disease patterns moving forward. AI-assisted technology is already utilised in DG for slide scanning and image analysis; this will increase in the future.

Some key operational challenges include:

- Senior workforce capability is problematic across Australia and is certainly the case at ACT Pathology. Recruitment and outplacement at another institution interest are strategies that have been successful in other Research Institutes;
- Specimens that are sent to other laboratories requires an investment of time on behalf of the clinical staff of DG. 'Refer-Outs' may benefit from administrative support that would improve the efficiency of the department;
- The introduction of DHR and a new LIS has brought changes to sample processing, requiring the lab to have additional workstations;
- The increasing complexity of genomic testing led to the inclusion of new processes such as RNA stabilisation, cell separation, and RNA & DNA extraction. These will require additional space, reagents, and specialised storage (i.e., a minus 80-degree freezer or liquid nitrogen storage); and
- Current lab space is not fit for purpose, nor does it meet all of the NATA requirements (proper clean and dirty separation); which may compromise the way DG can support the treatment of its patients, especially those with metastasised cancer or life-threatening rare diseases.

4.6.11. Diagnostic Genomics Strategic Developments

The future for DG is expected to incorporate a service model that has very significant investment in automation and multiple omics technologies, this includes a variety of new equipment that ACT Pathology does not currently have. The automation will be predominately focused on NGS (genetic sequencing), reagent testing, DNA extraction, quality testing, and Fresh Frozen Plasma (FFP) extraction; and advances in omics technologies (possibly in partnership with others).

It is also clear that the current space allocations will need to be increased to allocate for these new equipment additions.

*One strategic option is to commence DG (and Molecular Pathology) in the new building with a **substantial investment in automation equipment**, which would place ACT Pathology at the fore of DG and Molecular Pathology across jurisdictions. The scale of the investment would be determined as part of a future capital investment funding and business case. The default position is to progressively enhance technology capability in automation and 'omics' as the investment funds would ordinarily become available.*

4.7. HAEMATOLOGY

Haematology is concerned with blood and its components. Haematology tests enable the diagnosis, treatment, and prevention of blood disorders and disorders of blood producing tissues/organs. Haematology testing is one of the most widely used forms of pathology.

4.7.1. Scope of Service

Test Volumes

The Haematology department's highest volume of work is for Full Blood Count (FBC) testing with over 290,000 tests annually. The comparison of two sections and the total testing is provided below. The decline in number of tests is most likely due to COVID.

Table 4-9: Haematology Test Volumes – 2019-20 to 2021-22

Year	Blood Transfusion	Haematology (incl. coagulation & immunophenotyping)	Total
2019/2020	53,448	523,564	577,012
2020/2021	56,472	537,756	594,228
2021/2022	56,021	531,487	587,508

Area

The current NDA for Haematology is ~333 sqm.

Specialty Scope

In this context of CHS, the Haematology department³³ is 24/7 has a number of subspecialties including:

- General Haematology;
- Morphology;
- Coagulation;
- Immunophenotyping; and
- Transfusion Bone Marrow Transplant (BMT).

In addition, there is critical connectivity required by haematology department with units across the CH, mainly with the Haematology Ward (Building 3 in the oncology building) and Apheresis Unit (Building 19 with blood donations). It is expected that the Haematology Ward and Apheresis Unit will remain in their current locations.

For Haematology services in the new pathology facility:

■ Haematology laboratory services

This encompasses all forms of blood cell analysis (such as blood cell morphology and physiology, haematological malignancies, coagulation disorders, bone marrow disorders, overseeing blood transfusions, and haemoglobinopathies (inherited blood disorders).

Routine tests include patient sample testing, storage and management of FBC, blood films, routine and special coagulation; flow cytometry, haemoglobinopathy testing, and haematological genetic testing.

Given ACT Pathology is a regional transfusion centre, catering to a potentially large number of trauma-related transfusion cases, is an important function of the transfusion service.

33. ACT Pathology, Haematology Transfusion BMT.

■ Bone Marrow Transplant

BMT is a highly specialised service. It is an integrated team that collect, process, store and issue Human Haemopoietic Progenitor Cells, ready for use. The service is clinically integrated with the Canberra Regional Cancer Service and affiliated with the BMT+CT Network in NSW.

The BMT Unit is involved with approx. 50 stem cell collections and 35 transplants per year. CH haematologists determine the suitability of each patient for transplant.

The ACT Pathology Haematology department has a purpose-built cryogenic storage facility adjacent Building 10, fitted with reticulated LN2 supply and oxygen monitoring. The facility houses three LN2 storage tanks dedicated to haematopoietic progenitor cell storage, a -80 freezer and a controlled rate freezer. Transport vessels are also stored in this facility (two permanent, others when products are shipped in or out). LN2 bulk supply is located outside of the building for convenient refilling by external contractors and for safety.

4.7.2. Specimen Pathway

Specimens are received by the laboratory from the specimen reception area, similar to all other pathology specialties. Specimens arrive at reception via pneumatic tube, CH staff, couriers Australian Red Cross Blood Service (ARCBS), and external transport (such as taxis). Urgent testing is commonly delivered by hospital staff, and couriers if external to CH.

Blood products are delivered by the ARCBS for crossmatch and received by blood transfusion services (closely proximate to the hospital/specimen reception access point), which requires careful verifying and documenting that the products match what has been requested to ensure accuracy and traceability (by barcoding).

BMT laboratory receives BMT/cell therapy products (delivered by nurses) which require strict inspection and label verification procedures.

The process steps for haematology are not necessarily sequential or require unidirectional flow.

The key process is the **automation of specimen analysis**, integrated with the Core Lab, followed by reporting of results. If there are queries in relation to the results, a second sample is assessed and/or the sample is manually assessed.

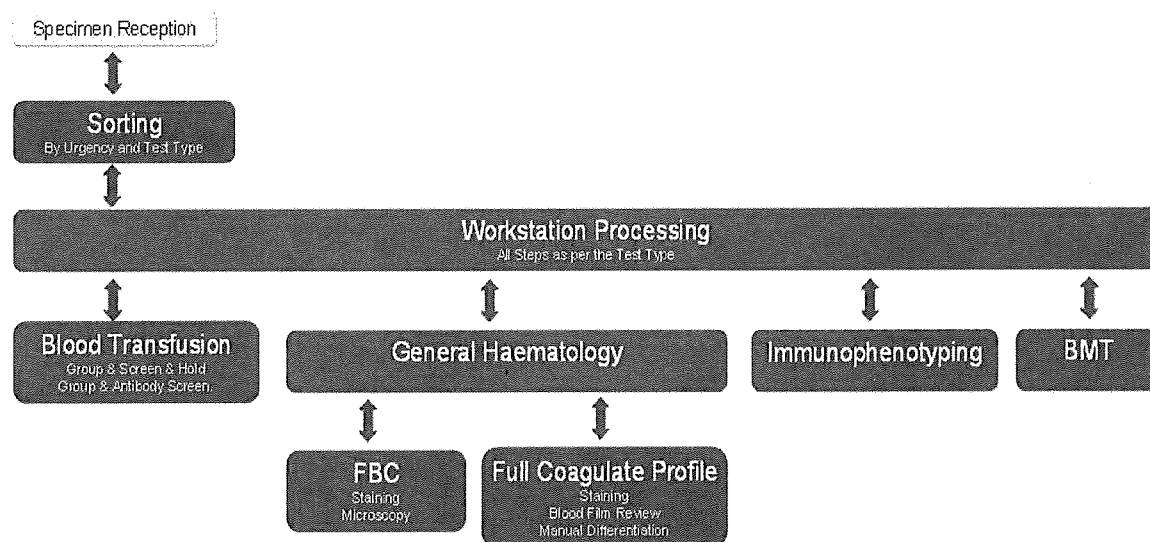
In relation to **transfusion services**, various tests are performed on the blood products to ensure compatibility with the intended recipient prior to any patient transfusion. These tests include ABO and Rh typing, antibody screening, and crossmatching. Blood products are then released for transfusion by the blood transfusion services. For **BMT**, all processing is performed in a biological safety cabinet.

The **blood bank** section is in close proximity to the hospital/specimen reception access point to allow for easy collection of blood products. Immunophenotyping (flow cytometry) and BMT are located behind the more automated sections.

The specimen flow in the new facility will need to accommodate:

- Blood transfusion services with blood bank refrigerators close to the hospital/specimen reception access point;
- Automated haematology and coagulation testing; and
- BMT and immunophenotyping behind automated areas.

Figure 4-6: Specimen Pathway for Haematology



Storage and specimen retention are also part of the pathway, detailed below.

The specimen pathway impacts service models and related issues of ongoing storage, teaching and operational efficiencies, all of which form part of the design of the new Haematology department.

4.7.3. Hours of Operation

Haematology laboratory services is a 24/7 service with a more limited range of services offered after-hours (6pm to 7:30am Monday to Friday, all day Saturdays Sundays and public holidays).

4.7.4. Workforce Model

The workforce model reflects the clinical capability level of Haematology, with staffing levels provided in Table 4-10 below. The staffing complement includes clinical director, specialist haematologists, registrars, laboratory manager, chief scientist, senior scientists, scientists, and technical officers. Like the Department of Microbiology, the Pathologists have a clinical role as well and are fractional appointments to the laboratory.

Table 4-10: Staffing by Workforce Category, Haematology

Position	Headcount	FTE
Clinical Director	1	0.4
Pathologists	7	1.7
Registrars	3	3
Laboratory Manager	1	1
Chief Scientist	1	1
Senior Scientists (HP4)	2	2
Senior Scientists (HP3)	7	6.8

Position	Headcount	FTE
Base Grade Scientists	20	18.3
Technical Officers	4	3.6
Total	46	37.8

Staffing numbers are at a point in time and will not reflect future FTE or workforce mix needs.

4.7.5. Key Functional relationships and adjacencies

Internal Relationships

Haematology has a close clinical relationship with Specimen Reception and courier services (in relation to Blood Bank),

Due to the 24/7 nature of timely service delivery and the integral part that haematology has for the Core Lab, automated Haematology processes will be contiguous with automated Chemical Pathology, automated Immunopathology & Infectious Immunoassay specimen reception to form the new **Core Laboratory**.

There are also some functional links to Diagnostic Genomics with molecular haematology processes focusing on the molecular and genetic aspects of haematological disorders and involves the analysis of specific genes, chromosomal abnormalities, or molecular markers associated with various blood disorders (including leukemias, lymphomas, and inherited blood disorders). While important in the overall diagnostic reporting, the three related processes do **not** require adjacency in the design, however it would be ideal.

The proximity of the Blood Bank to automated Pre-Analytics (hence Pathology Core Laboratory) will be an important relationship in the design.

Implied in the functional adjacencies and central to the increase in convergence technology, pathologists, registrars, and scientists will have greater synergy working alongside each other in the laboratory (which acts as a “watchdog” system for the blood results). Close proximity needs to be developed as much as possible within the new facility.

External Relationships

The key requirement for Haematology is similar to all other areas of pathology. The ICT connectivity and the IT platforms need to be robust in order that:

- Haematologists are able to communicate with other medical practitioners, with sufficient bandwidth to display high fidelity images; and
- Regular and constructive relationships with all referrers, including timely provision of results.

Haematology also has critical relationships with accreditation and regulatory bodies. In addition to the NATA requirements, BMT must comply with *Requirements For Procedures Related To The Collection, Processing, Storage And Issue Of Human Haemopoietic Progenitor Cells* (Sixth Edition 2021)³⁴.

34. National Pathology Accreditation Advisory Council. (2021). Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Sixth Edition 2021). Retrieved from https://www.safetyandquality.gov.au/sites/default/files/2022-08/tier_4_requirements_for_procedures_related_to_the_collection_processing_storage_and_issue_of_human_haemopoietic_progenitor_cells_sixth_edition_2021.pdf.

4.7.6. Current Location

Haematology is currently located on Level 2.

4.7.7. Storage and Specimen Retention

Haematology storage is an issue. The Haematology department requires various types of storage for different purposes. These include proximal blood bank storage at precise temperature controls (and alarmed), cryopreservation, controlled freezing capability for BMT, and various types of reagent store, specimen store, equipment store and waste store.

The department shares processing similarities with closely linked departments – Chemical Pathology and Immunopathology & Infectious Immunoassay.

It is important to note that Haematology, Chemical Pathology and Immunopathology & Infectious Immunoassay departments will operate as part of a broader core laboratory in the new pathology facility, details on the core laboratory and its storage/waste requirements are further outlined in the Functional Design Brief.

ACT Pathology is required to meet National Pathology Accreditation Advisory Committee's Requirements for the retention of laboratory records and diagnostic material. The relevant retention period is also outlined in the Functional Design Brief.

4.7.8. Environmental and Safety Considerations

There are important environmental components for the Service Model that incorporate:

- Space and zoning;
- Ventilation and air quality;
- Lighting (particularly for blood film reading),
- Temperature controls;
- Bone marrow transplant;
- Noise abatement;
- Floor loading; and
- Sustainable practices.

These considerations form part of the Functional Design Brief.

4.7.9. Haematology Future Challenges, Trends and Innovations

Haematology is a pathology discipline that continues to evolve. The main challenges and expected future trends are outlined below. Many of the therapeutic trends are inter-related. Current research at ACT Pathology includes flow cytology, molecular research and new technology evaluation.

- **Automation of manual steps:** The relatively few manual steps in haematology are likely to become automated. Much of the technology currently exists. The future automation is likely to replace most of the existing workstations in the future.
- **The Development of the Core Laboratory:** Urgent testing on existing haematology instruments is likely to shift to a Core Laboratory operating 24/7 and operated by multi-disciplinary pathology staff. Robotics will be extended to accommodate more of the high-volume testing of a Core Laboratory. It is likely that haematology testing (FBC etc) will be the first added to track systems followed closely by coagulation analysers.

- **Immunotherapies and targeted therapies.** ACT residents who are currently candidates for CAR T-cell therapies are having their samples sent interstate or overseas for production, this service/treatment could be made available in Canberra with targeted investment. CAR T-cell therapy and immune checkpoint inhibitors brings new treatment options for patients with haematological disorders (including malignancies).
- **New technologies leading to new workstations.** As new fields of haematology testing emerge, the service range for haematology can be extended if embraced by ACT Pathology. These areas include blood analysis as part of microbiome analysis. Any expansion of scope will increase the requirement for additional workstations. Overall, it is expected that there will be some reduction in workstations due to greater automation as well as increase the need for workstations as new services emerge.
- **Recycling and sustainability:** each department will have equipment and technology designed to help recycle.
- **Community screening.** There will be opportunities to support community screening programs and personalised wellness testing expanding the range of services from predominantly diagnostic (i.e., HbA1C testing on microsamples self-collected from the community and microbiome analysis).
- **Liquid biopsies** have emerged as a non-invasive cancer diagnostic tool, which may assist in the early detection, residual disease monitoring, and treatment response assessment for haematologic malignancies.
- **Artificial Intelligence.** AI and machine learning will help automate processes (analysing big data sets in haematology. Like other specialties, haematology will be in a position to utilise AI as a decision support tool and security checks that are not systematically built into current day-to-day processes. This will not reduce the staff, building footprint but instead give the adopting laboratory more capacity to increase the range of services offered.
- **Gene editing and gene transfer therapies** are potentially achievable for ACT Pathology, again with targeted investment.
- **Biomarkers and predictive models** help predict disease progression, treatment response, and patient outcomes. It is an important area of research in haematology and has the potential to make a massive difference to patient outcomes alongside other technologies such as the omics revolution.

Some key operational challenges include:

- Pathologists, registrars, and scientists have a lot of synergy working alongside each other in the laboratory (which acts as a “watchdog” system for the blood results). Close proximity needs to be developed as much as possible within the new facility.
- Given ACT Pathology is a regional transfusion centre, catering to a potentially large number of trauma-related transfusion cases, is an important function of the transfusion service.
- Turnaround times of reports and access to haematologists for secondary consultations may be important for the sustainability of the client base.
- Referrals to haematology at ACT Pathology have declined since the introduction of the new DHR. There appear to be operational impediments to maintaining current market share for haematology (and other high-volume specialties).

4.7.10. Haematology Strategic Developments

The future for the high volume and routine haematology testing will be a progressive elimination of the remaining manual processes.

The future for the interface between haematology and genomics and molecular pathology will continue to challenge ACT Pathology as it develops capability to extend beyond the current 'norms' at leading interstate laboratories.

There are several potential service model variations for the design and Service Model for haematology.

The first option is to collocate the Apheresis Unit with the new pathology building. At present, a relocation of blood donations is not being planned.

A second option, common to other pathology specialties, is to invest in the remaining automated processes at the new facility, particularly the automations to extend the Core Laboratory. The alternative is to continue with the current technologies of the existing MoC.

A third option relates to the access and storage of liquid nitrogen tanks. The current tanks and accommodated in a separately built facility abutting Building 10 at ground level. The option is to continue the siting of the liquid nitrogen tanks on the perimeter of the new facility, or the accommodated them within the building. This issue needs to be considered in the context of the proposed expanded cryogenic capacity and new Dewar system as well as the logistics and distances of the design of the new building.

4.8. IMMUNOPATHOLOGY AND INFECTIOUS IMMUNOASSAY

Immunopathology & Infectious Immunoassay is a particularly challenging area of pathology.

Testing and investigating for immune disorders from specimens are often only part of the solution to a definitive diagnosis and treatment pathway. There is a crucial liaison role between the complex testing of specimens and patient management advice of other physicians.

4.8.1. Scope of Service

Test Volumes

Immunopathology & Infectious Immunoassay's test panel volumes are combined with Chemical Pathology, performing more than 1 million tests annually. The year-by-year breakdown is as below.

Table 4-11: Chemical Pathology, Immunopathology & Infectious Immunoassay Test Panel Volumes – 2019-20 to 2021-22

Year	Total
2019/2020	1,661,806
2020/2021	1,756,151
2021/2022	1,748,351

Area

The current NDA for Immunopathology & Infectious Immunoassay is ~222 sqm.

Specialty Scope

At ACT Pathology, Immunopathology and Infectious Immunoassay embodies two Pathology disciplines – Immunopathology and Infectious Immunoassay.

A typical range of tests include:

Immunopathology

- Auto-immune serology: testing for organ specific and systemic autoimmune disease with indirect immunofluorescence and more specific antibody tests;
- Specialised immunochemistry: Immunopathology supervises all immunochemistry which includes determination of complement levels, immunoglobulin testing, serum and urine electrophoresis, serum and urine immunofixation, CSF IEF,
- Allergy testing;
- Immunogenetics: HLA B27 testing; and
- Flow cytometry for B and T cell enumeration, and characterisation of B cell subsets: performed in Haematology but interpreted and overseen by Immunology.

Also importantly, Immunopathology testing overlaps with other areas, such as:

- HIV testing (with Microbiology);
- Flow cytometry (with Haematology);
- Endocrine testing (with Chemical Pathology);
- Complex therapeutic monitoring (with therapeutic drug monitoring);
- Human Leukocyte Antigen (HLA) and other genetic testing (with Diagnostic Genomics / Molecular Pathology); and
- Some individual tests also cross disciplines (such as latent tuberculosis and H Pylori – a common digestive tract infection).

Infectious Immunoassay

An infectious immunoassay test detects the presence of infectious agents, such as bacteria, viruses, parasites, or fungi, in a patient's sample (e.g., blood, urine, or respiratory secretions). It involves the use (i.e., the presence or absence) of specific antibodies or antigens that can bind to target molecules associated with the infectious agent to indicate a current or past infection. With respect to the model of care, Infectious Immunoassay range of testing is not necessarily unidirectional and involves a high level of automation but with important manual testing and second sample testing.

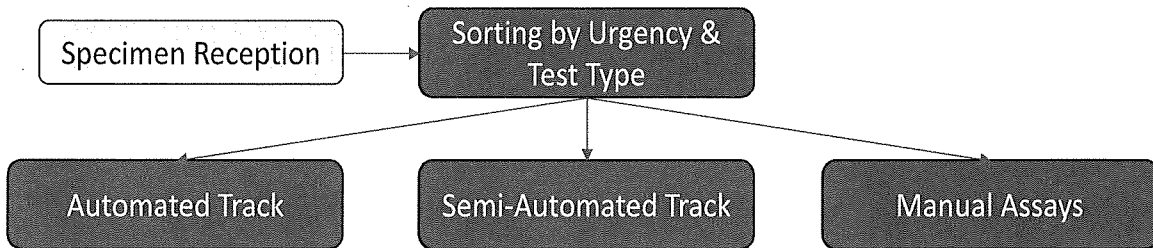
4.8.2. Current Locations

At present, Immunology and Immunoassay is split over two levels, (Level 2 and Level 6). This is not conducive the operational efficiency and carries quality risks.

4.8.3. Specimen Pathway

Specimens are retrieved from Specimen Reception (where they are registered) and transported by hand from Level 2 to Level 6, specific pathway is described in Figure 4-7.

Figure 4-7: Specimen Pathway for Immunopathology and Infectious Immunoassay



From the description of the scope and the specimen pathway, Immunopathology is a specialty that requires close proximity to almost all other specialties, especially the Core Laboratory. The extent that proximal location cannot be achieved introduces inefficiencies and poorer levels of communication and coordination.

4.8.4. Hours of Operation

Immunopathology and Infectious Immunoassay operates in extended business hours from 8.30am – 8.00pm Monday to Friday, with pathologist and scientist on-call out-of-hours for urgent requests³⁵.

4.8.5. Workforce Model

The workforce model reflects the clinical capability level of Immunopathology & Infectious Immunoassay, with staffing levels provided in Table 4-12 below. The staffing complement includes clinical director, Immunopathologists, registrar, chief scientist, senior scientists, scientists and technical officers.

Table 4-12: Staffing by Workforce Category, Immunopathology and Infectious Immunoassay³⁶

Staff Category	Headcount	FTE
Clinical Director	1	0.5
Pathologists	2	0.5
Registrar	1	1.0
Chief Scientist	1	1.0
Senior Scientists	3	3.0
Base Grade Scientists	10	9.1
Technical Officers	2	2.0
Total	20	17.1

Staffing numbers are at a point in time and will not reflect future FTE or workforce mix needs.

35. ACT Pathology, 02508 02501 86750 aid.

36. Microbiology/Infectious Immunoassay clinical Director and Pathologist are represented in the Microbiology workforce category.

4.8.6. Key Functional Relationships

Internal Relationships

Immunopathology and Infectious Immunoassay have a close relationship with other departments. The two specialties with highly integrated pathways include:

- Haematology (immunophenotyping); and
- Chemical Pathology (operational support for analysers on the track system).

Automated Immunopathology & Infectious Immunoassay will be joined by Specimen Reception, Automated chemical pathology and Automated Haematology to form the new **Core Laboratory**.

External Relationships

The key requirement for Immunopathology & Infectious Immunoassay is similar to all other areas of pathology. The ICT connectivity and the IT platforms need to be robust in order that:

- Immunopathologists and Clinical Microbiologists are able to communicate with other medical practitioners, with sufficient bandwidth to display high fidelity images; and
- Regular and constructive relationships with all referrers, including timely provision of results.

The future development of this specialty will require close and frequent communication with referrers to build the specialty and broaden the scope of services.

4.8.7. Storage and Specimen Retention

Immunopathology storage is an issue. The department requires various types of storage for different purposes noting it shares processing similarities with closely linked departments – Chemical Pathology and Haematology.

It is important to note that Immunopathology & Infectious Immunoassay, Haematology, and Chemical Pathology departments will operate as part of a broader core laboratory in the new pathology facility, details on the core laboratory and its storage/waste requirements are further outlined in the Functional Design Brief.

ACT Pathology is required to meet National Pathology Accreditation Advisory Committee's Requirements for the retention of laboratory records and diagnostic material. The relevant retention period is also outlined in the Functional Design Brief.

4.8.8. Environmental and Safety Considerations

There are important environmental components for the Service Model that incorporate:

- Space and zoning;
- Ventilation and air quality;
- Lighting (particularly for blood film reading),
- Temperature controls;
- Noise abatement;
- Floor loading; and
- Sustainable practices.

These considerations form part of the Functional Design Brief.

4.8.9. Immunopathology Future Challenges, Trends and Innovations

Immunopathology continues to evolve as a discipline. The main challenges and expected future trends are outlined below. Many of the therapeutic trends are inter-related.

Some key future trends include:

- **Automate manual processes, where possible.**
- **Immunotherapies and targeted therapies.**

Immunogenomics is an emerging field that integrates Immunopathology and genomics to understand the genetic basis of immune responses and immune-related diseases. Immunopathologists have the opportunity to identify novel biomarkers, therapeutic targets, and individualised treatment approaches, as has been the case with CAR T-cell therapy and immune checkpoint inhibitors.

- **Community screening.**

There will be opportunities to support community screening programs and personalised wellness testing expanding the range of services from predominantly diagnostic (i.e., COVID).

- **Artificial Intelligence.**

AI and machine learning will help automate processes (analysing big data sets in Immunopathology). Like other specialties, Immunopathology will be in a position to utilise AI as a decision support tool and security checks that are not systematically built into current day-to-day processes.

- **Collaborative research initiatives**

The complex nature of immune-related diseases necessitates interdisciplinary collaborations and the integration of diverse expertise. Future trends in immunopathology are likely to involve increased collaborations among immunologists, pathologists, geneticists, bioinformaticians, and clinicians from various specialties and various settings to facilitate the sharing of knowledge, resources, and data, leading to a deeper understanding of immune-mediated diseases and the development of more effective diagnostic and therapeutic approaches.

Some key operational challenges include:

- Operational constraints on space. Whilst the move to Level 6 has alleviate some of the space constraints it has been at the expense of collaboration and coordination, and inefficient use of equipment.
- Referrals to Immunopathology at ACT Pathology have declined since the introduction of the new DHR. There appear to be operational impediments to maintaining current market share for Immunopathology (and other high-volume specialties).

4.8.10. Immunopathology Strategic Developments

The future for the high volume and routine Immunopathology and Infectious Immunoassay testing will be a progressive elimination of the remaining manual processes, where possible.

The future is to invest in the remaining automated processes into the new facility, particularly the automations to extend the Core Laboratory. The alternative is to continue with the current technologies of the existing service model.

The future for the interface between Immunopathology and genomics and molecular pathology will continue to challenge ACT Pathology as it develops capability to extends beyond the current 'norms' at leading interstate laboratories.

4.9. MICROBIOLOGY

Microbiology is the identification of infectious agents (such as bacteria, viruses, fungi and parasites) that are responsible for causing infectious diseases. It also explores the susceptibility of organisms to antibiotics to help decide on treatment, across a spectrum of activities including infection control and public health (including most recently the response to COVID-19).

4.9.1. Scope of Services

Microbiology operates as a Level 6 clinical capability.

Test Volumes

Microbiology performs around 120,000 tests annually, with much of it manually processed.

Testing involves the following sample types: blood, urine, faeces, sputum, synovial fluids, cerebrospinal fluid, spore strips for environmental investigations and/or infection control, and aspirates of bacterial isolates, biopsy specimens, bronchoalveolar lavage, bronchoalveolar washings, cerebrospinal fluid, cervical swabs, dry swabs, ear swabs, eye swabs, faeces, fine needle aspirates (FNA), fluids; gastric aspirates; genital swabs; human breast milk, nasal swabs; nasopharyngeal swabs, operative specimens; oral sites, post-operative wounds, pus, respiratory specimens, skin, tissues and more.

Table 4-13: Microbiology Test Panel Volumes – 2019-20 to 2021-22

Year	Microbiology
2019/2020	127,840
2020/2021	124,093
2021/2022	121,327

Area

The current NDA for Microbiology (and molecular pathology) is ~674 sqm.

Speciality Scope

At ACT Pathology, services provided by the Department of Microbiology at a tertiary-level 6 lab, and includes:

- **General bacteriology** – isolation and identification of pathogens;

- **Virology** – limited testing for respiratory and gastrointestinal viruses, using immunochromatographic or molecular techniques. Viral cultures are no longer performed locally;
- **Mycology** – isolation and identification of pathogenic fungi, including dermatophytes;
- **Mycobacteriology** – isolation and identification of mycobacterium tuberculosis complex and mycobacterium avium/intracellular group;
- **Parasitology** – microscopy for enteric parasites and helminths (including hydatids);
- **Antimicrobial** susceptibility testing and reporting;
- **POCT e.g. Covid 19**; and
- Testing for organisms of **public health** significance in collaboration

Microbiology is an enabler of Antimicrobial Stewardship, including a registrar who has dual roles in both departments.

4.9.2. Specimen Pathway

Microbiology mainly receives tissue samples from the following places:

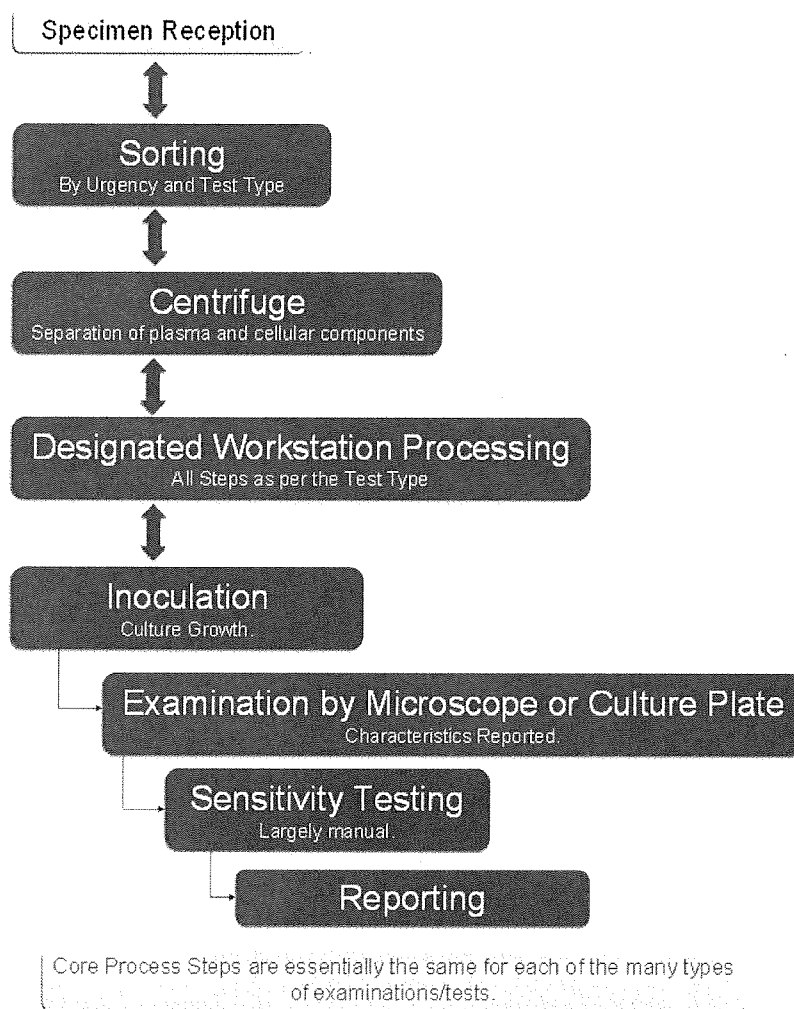
- Inpatient and outpatient services, TCH; and
- Other public and private hospitals in the ACT and parts of NSW.

The core steps are not unidirectional. The workflow is partly sequential and often requires movements to and from workstations.

Movement of specimens by staff between other areas of Pathology (e.g. shared specimens, should be transported by the safest route to other pathology units where there are shared specimens.

The specimen pathway impacts service models and related issues of ongoing storage, teaching and operational efficiencies that are able to be introduced.

Figure 4-8: Specimen Pathway for Microbiology



4.9.3. Hours of Operation

Microbiology operates 8.00am – 10.30pm Monday to Friday and 8.00am – 9.30pm Saturdays and Sundays, with pathologist and scientist on-call out-of-hours for urgent requests³⁷.

4.9.4. Workforce Model

The workforce model³⁸ reflects the clinical capability level of Microbiology, with staffing levels provided in Table 4-14 below. The staffing complement includes clinical director, specialist microbiologists, registrars, chief scientist, senior scientists, laboratory scientists, and technical officers. Some of the pathologists have a dual role, working with the laboratory as a staff specialist and a clinical role in the hospital as an Infectious Disease Clinician.

37. ACT Pathology, Microbiology.

38. ACT Pathology, 02508 02501 86766 tasl - Microbiology.

Table 4-14: Staffing by Workforce Category, Microbiology

Staff Category	Headcount	FTE
Clinical Director - Microbiology	1	0.6
Specialist Microbiologists	4	1.45
Registrar	2	1.5
Chief Scientist	1	1.0
Supervising Scientist	1	1.0
Senior Scientists	4	4.0
Base Grade Scientists	13	12.5
Quality Control Officer	1	1.0
Technical Officers	4	3.0
Total	31	26

Staffing numbers are at a point in time and will not reflect future FTE or workforce mix needs.

4.9.5. Current location

The Microbiology Department is currently location on Level 4 of the Pathology Services building, co-located with Molecular Pathology and Diagnostic Genomics.

4.9.6. Key Functional relationships and adjacencies

Internal Relationships

Microbiology and Molecular Pathology will combine as a single operational discipline due to the significant clinical overlap, shared specimens, movement of traditional microbiology to molecular based staff and ability to cross train staff.

Both Microbiology and Molecular pathology are moving to an increased level of robotics and their functional relationship is based around some key principles:

- Much microbiology testing will move to tracked robotics, which has an increased floor print e.g. Kiestra;
- Molecular Pathology has moved and will further embrace increased robotics e.g. Roche 6800;
- Molecular Pathology must be adjacent to Diagnostic Genomics to allow shared of laboratory space and equipment e.g. PCR Clean Preparation, Specimen Preparation, DNA Amplification. If not co-located with Diagnostic Genomics, then shared areas would need to be duplicated on the other floor, including, PCR set up, specimen preparation and DNA amplification;
- Molecular Pathology should also be adjacent to the core laboratory. More instrumentation is being enabled to connect to track systems, with Molecular Pathology robotics likely able to connect to a track system when the Pathology building is opened – this is already possible with Roche instrumentation;
- The spaces will be open plan wherever possible, with some exceptions including the PC3 facility; and
- Provision of sufficient space to allow fast scale up of services e.g. pandemic.

Microbiology also has a close clinical relationship with Infectious Diseases, Infection Prevention and Control, and Antimicrobial Stewardship

External Relationships

The key requirement for Microbiology is similar to all other areas of pathology. The ICT connectivity and the IT platforms need to be robust in order that:

- Specialist Microbiologists are able to communicate with other medical practitioners, with sufficient bandwidth to display high fidelity images; and
- Regular and constructive relationships with all referrers, including timely provision of results.

Specialist Microbiologists and senior laboratory scientists work collaboratively with Infectious Diseases, Antimicrobial Stewardship, Infection Prevention and Control and Occupational Medicine Unit to provide support services across Canberra Health Services and ACT Health related to infection prevention, diagnosis and management.

Many specialists are employed within two or more of these units and collocation should improve collaboration and information flow, resulting in improved integration and better patient care, including research and teaching.

The infection related services could include:

- Clinical Microbiology staff specialists;
- Infectious Diseases staff specialists, registrars and administrative staff;
- Infection Prevention and Control and Occupational Medicine Unit nursing, administrative staff and specialist (typically an Infectious Diseases physician);
- Antimicrobial Stewardship Team – pharmacist, epidemiologist, registrar, specialist (typically an Infectious Diseases physician); and
- If Pharmacy was also located within the same building, this would connect well with the Antimicrobial Stewardship team.

4.9.7. Storage and Specimen Retention

The department requires various types of storage for different purposes noting it shares processing similarities with closely linked departments – DG and Molecular Pathology departments. The design could create special efficiency by having shared storage.

Stock will need to be retrieved from storage locations strategically placed to optimise workflow. Waste is relocated to a dedicated waste removal space awaiting collection by the waste disposal service.

Details on storage and waste are further outlined in the Functional Design Brief.

ACT Pathology is required to meet National Pathology Accreditation Advisory Committee's Requirements for the retention of laboratory records and diagnostic material. The relevant retention period is also outlined in the Functional Design Brief.

4.9.8. Environmental and Safety Considerations

There are important environmental components for the Service Model that incorporate:

- Space and zoning;
- Safety and security;

- Office and workspaces;
- Ventilation and air quality;
- Lighting (particularly for blood film reading),
- Temperature controls;
- Noise abatement;
- Floor loading; and
- Sustainable practices.

These considerations form part of the Functional Design Brief.

4.9.9. Microbiology Future Challenges, Trends and Innovations

Microbiology discipline spans support for public health services to highly specialised targeted responses to patient conditions.

The future challenges and opportunities for microbiology at ACT Pathology include:

- Collaboratively work with other laboratories to address challenges of **antimicrobial resistance**.
- Like other areas, **Automation of manual steps**: The relatively few manual steps in Microbiology are likely to become automated. Much of the technology currently exists. Future automation would be able to manage increased demand, workforce shortages. In particular:
 - ▶ **Plate readers**: further to what was mentioned above, these instruments will carry out most of the Microbiology lab work in the future. They provide the flexibility for pathologists to analyse results from the comfort of their own homes, which is valuable given the requirement for ongoing afterhours work, and also meet the time sensitive requirement of generating rapid analysis and reports back to the patient's treating clinician in order to carry out timely, accurate and targeted treatment;
 - ▶ **NGS** has the potential to revolutionise Microbiology testing at ACT Pathology by offering ultra-high throughput, scalability and speed, enabling comprehensive and rapid analysis of microbial genomes for pathogen identification, genomic epidemiology, and antimicrobial resistance profiling, among other applications;
- **Development of a Core Laboratory**: Urgent testing on existing Microbiology instruments is likely to shift to a Core Laboratory operating 24/7 and operated by multi-disciplinary pathology staff. Robotics will be extended to accommodate more of the high-volume testing of a Core Laboratory. It is likely that Microbiology testing (FBC etc) will be the first added to track systems followed closely by coagulation analysers.
- **Mycology laboratory**. The longer-term future would envisage a distinct mycology laboratory.
- **Research**. There are potentially new fields for collaborative research for ACT Pathology, including Metagenomics, Microbiome, microbiological surveillance, and/or Bioinformatics;

Some key operational challenges include:

- Operational constraints on space, particularly impacting on inefficient workflow from workstation to track and storage.

- Referrals to Microbiology at ACT Pathology have declined since the introduction of the new DHR. There appears to be operational impediments to maintaining current market share for Microbiology (and other high-volume specialties).
- Equipment redundancy will improve operational efficiency (such as a dual access autoclave).
- ICT equipment and systems to enable storage of large sets of laboratory data (for research, analysis, data retention/compliance) and on-demand virtual case discussions.

4.9.10. Microbiology Strategic Developments

The future for the moderate volume and routine microbiology testing will be a progressive elimination of the substantial manual processes including reviewing the culture plates (plate readers) and NGS capability. AI is likely to have a significant impact on microbiology, either as an aid/tool or as the main diagnostic instrument.

This requires investment in the remaining automated processes into the new facility, particularly the automations to establish the Core Laboratory. The alternative is to continue with the current technologies of the existing service model.

The future for the interface between microbiology and molecular pathology will continue to challenge ACT Pathology as it develops capability to extends beyond the current 'norms' at leading interstate laboratories.

4.10. MOLECULAR PATHOLOGY (MICROBIOLOGY)

Molecular pathology (Microbiology) focuses on the study and diagnosis of disease at a molecular level. This means that there is significant crossover with other pathology Departments, especially Microbiology. The Molecular Pathology Department perform diagnostic assays based on molecular biology techniques. Most tests are based on the initial isolation of nucleic acid from a variety of diagnostic specimens including but not limited to blood, swabs, plasma, CSF and respiratory specimens/nasopharyngeal aspirates.

4.10.1. Scope of Service

Molecular Pathology operates at a Level 6³⁹ service.

Test Volumes

The Molecular Pathology was the most impacted department from the COVID-1 pandemic with workload increasing more than 20-fold at its peak.

Table 4-15: Molecular Pathology Test Volumes – 2020-21 to 2022-23 (Projected)

Year	Molecular Pathology (excl COVID PCR)	Molecular Pathology Total
2019/2020	39,980	71,801
2020/2021	40,304	241,405
2021/2022	34,491	614,282

³⁹ NSW Role Delineation of Clinical Services,(2021). The NSW Role Delineation of Clinical Service is used as the default clinical capability framework for NSW, Victoria and ACT, unless there is a specific jurisdictional capability framework

Area

The current NDA for Molecular Pathology (and Microbiology) is ~674 sqm.

Specialty Scope

On the basis that Molecular Pathology has service links to all pathology disciplines, the Molecular Pathology (Microbiology) ranges from high throughput, more automated assays (using larger equipment) to low throughput, often in-house traditional assays which require dedicated operational units as outlined below:

- The Nucleic Acid Extraction Laboratory;
- The PCR Set-up Laboratory (Clean Room); and
- The PCR Analysis Laboratory.

All three units are physically separated from each other to mitigate the risk of cross-contamination within the laboratory. The three units have differing levels of cleanliness and sterility. The PCR Set-up Laboratory is essentially the cleanest section with no sample derived nucleic acid followed by the Nucleic Acid Extraction Laboratory where sample nucleic acid extractions are carried out. Finally, the PCR Analysis Laboratory is considered the lowest level clean area where all PCR amplifications occur.

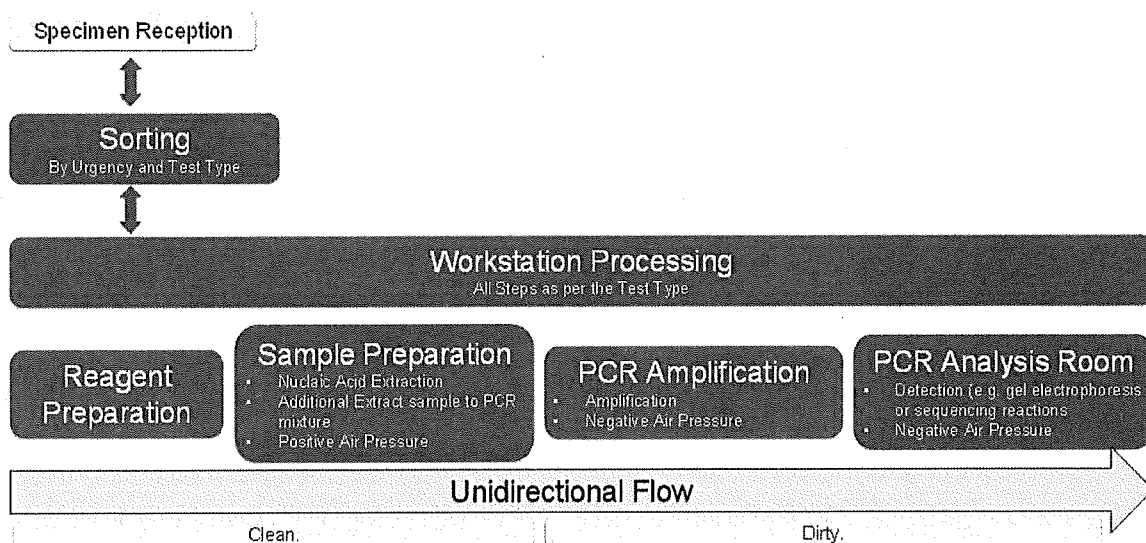
Molecular Pathology shares the following with Microbiology:

- The wash up room (shared with Microbiology) containing autoclaves and water filtration system; and
- The media room (shared with Microbiology) containing the centrifuge and the balance.

4.10.2. Specimen Pathways

Specimens are received by the laboratory from the specimen reception area, similar to all other pathology specialties. Specimens arrive at reception via pneumatic tube, CH staff, couriers, and external transport (such as taxis). Urgent testing is commonly delivered by hospital staff, and couriers if external to CH.

Figure 4-9: Schematic Specimen Pathway for Molecular Pathology (manual tests only)



The process steps for Molecular Pathology are summarised in Figure 4-9. There are seven core steps:

- Sorting specimens by test(s) required and the urgency of the test;
- There is a split pathway:
 - ▶ Specimens are sent to Molecular pathology if specimens are not shared by other laboratories; and
 - ▶ HIV Viral Load, Hepatitis C (HCV), PCR, HBV viral load and CMV viral load requests are sent to These specimens are generally sent directly to the Separations Laboratory where serum/plasma is fractionated and stored at 4°C pending collection by Molecular Pathology staff.

Movement of specimens by staff between other areas of Pathology (e.g. shared specimens, should be transported by the safest route to other pathology units where there are shared specimens.

- Allocation to staff/workstation based on the test required;
(Most tests performed in Molecular Pathology are batched. Some tests are performed more urgently and on request [such as Monkeypox, Meningococcal or Measles PCR]).
- Reagent Preparation
- Sample Preparation;
- PCR Amplification;
- PCR Analysis; and
- Reporting.

4.10.3. Hours of Operation

Molecular Pathology Operates Monday- Friday 0730-1800, with a weekend winter service. Urgent testing moving to the Core Laboratory expanding from GeneXpert platforms to also include technology with broader menus (i.e. BioFire FilmArray for Meningococcal infections).

4.10.4. Workforce Model

The workforce model⁴⁰ reflects the clinical capability level of Molecular Pathology, with staffing levels provided in Table 4-16 below. The staffing complement includes clinical director, pathologists, registrar, chief scientist, and laboratory/pathology scientists.

Table 4-16: Staff and Workforce Category for Molecular Pathology

The Clinical Director, Pathologists, and Registrar for Molecular Pathology are the same as for Microbiology.

Position	Headcount	FTE
Director	1	0.6
Pathologists	5	1.6
Registrar (also Microbiology)	1	1
Chief Scientist	1	1

40. ACT Pathology, 02508 02501 86766 tasl - Molecular Pathology.

Position	Headcount	FTE
Senior Scientist	2	2
Base Grade Scientist	4	4
Technical Officer	1	1
Total	15	11.2

Staffing numbers are at a point in time and will not reflect future FTE or workforce mix needs.

4.10.5. Current location

The department is currently co-located on level 4 with Microbiology and Diagnostic Genomics.

4.10.6. Key Functional relationships and adjacencies

Internal Relationships

Microbiology and Molecular Pathology will combine as a single operational discipline due to the significant clinical overlap, shared specimens, movement of traditional microbiology to molecular based staff and ability to cross train staff.

Both Microbiology and Molecular pathology are moving to an increased level of robotics and their functional relationship is based around some key principles:

- Much microbiology testing will move to tracked robotics, which has an increased floor print e.g. Kiestra;
- Molecular Pathology has moved and will further embrace increased robotics e.g. Roche 6800;
- Molecular Pathology must be adjacent to Diagnostic Genomics to allow shared of laboratory space and equipment e.g. PCR Clean Preparation, Specimen Preparation, DNA Amplification. If not co-located with Diagnostic Genomics, then shared areas would need to be duplicated on the other floor, including, PCR set up, specimen preparation and DNA amplification;
- Molecular Pathology should also be adjacent to the core laboratory. More instrumentation is being enabled to connect to track systems, with Molecular Pathology robotics likely able to connect to a track system when the Pathology building is opened – this is already possible with Roche instrumentation;
- The spaces will be open plan wherever possible, with some exceptions including the PC3 facility; and
- Provision of sufficient space to allow fast scale up of services e.g. pandemic.

Molecular Pathology also has a close clinical relationship with Diagnostic Genomics.

External Relationships

The key requirement for Molecular Pathology is similar to all other areas of pathology. The ICT connectivity and the IT platforms need to be robust in order that:

- Molecular Pathologists are able to communicate with other medical practitioners, with sufficient bandwidth to display high fidelity images; and
- Regular and constructive relationships with all referrers, including timely provision of results.

4.10.7. Storage and Specimen Retention

Molecular Pathology storage has been problematic for some time. The department requires various types of storage for different purposes noting it shares processing similarities with closely linked departments – DG and Microbiology departments. The design could create special efficiency by having shared storage.

Stock will need to be retrieved from storage locations strategically placed to optimise workflow. Waste is relocated to a dedicated waste removal space awaiting collection by the waste disposal service.

Details on storage and waste are further outlined in the Functional Design Brief.

ACT Pathology is required to meet National Pathology Accreditation Advisory Committee's Requirements for the retention of laboratory records and diagnostic material. The relevant retention period is also outlined in the Functional Design Brief.

4.10.8. Environmental and Safety Considerations

There are important environmental components for the Service Model that incorporate:

- Space and zoning;
- Ventilation and air quality;
- Lighting (particularly for blood film reading),
- Temperature controls;
- Noise abatement;
- Floor loading; and
- Sustainable practices.

These considerations form part of the Functional Design Brief.

4.10.9. Molecular Pathology Future Challenges, Trends and Innovations

Molecular Pathology discipline intersects with the most other pathology disciplines. This intersection means that Molecular pathology will benefit from advances across the pathology spectrum.

The future opportunities for Molecular Pathology at ACT Pathology include:

- **Continued automation** of existing manual processes.
- **Personalised Medicine and NGS** is a parallel or deep (DNA) sequencing technology which has revolutionised genomic research over the recent years. Using this technology, an entire human genome can be sequenced within a single day in comparison to its predecessor which required over a decade⁴¹. NGS will become a part of routine clinical practice in the future, as it helps to detect rare genetic variants and enables a deeper understanding of complex diseases.

Molecular Pathology and DG is rapidly advancing in technology and the laboratory hasn't been able to keep up with this, NGS is an immediate next step in the future direction, especially to support CH oncologists who are actively seeking this technology.

41. Behjati, S. and Tarpey, P.S. (2013) What is next generation sequencing?, ADC Education & Practice Edition. Available at: <https://ep.bmj.com/content/98/6/236> (Accessed: 09 June 2023).

Current lab space limitations is a constraint to the procurement of a NGS, which would be highly relevant and substantially beneficial to the work of Molecular Pathology and DG. In many cases is now the frontline test for diagnosis and treatment of various cancers and this will only expand further.

- **Integrating multiple omics technologies**, similar to the way that multidisciplinary teams approach works in healthcare, the multi-omics approach (including technologies such as genomics, transcriptomics, epigenomics, proteomics, and metabolomics) will provide a much more holistic view of disease mechanisms, which not only works to enhance the accuracy of diagnosis, but also enables personalised treatment strategies based on individual patient profiles. The drive towards individually targeted therapies is expected to continue to increase the level of testing, workforce expertise and need for individualised reports, particularly in cancer treatments. *It is likely that in the not-so-distant future, the 'omics revolution' for personalised diagnoses and treatments could become core business for ACT Pathology.*
- **Automation of Manual Steps.** Common to all specialties, there will be opportunities to better integrate all of the manual steps with track systems.
- **AI and machine learning** are being much more widely used in pathology as algorithms and pattern recognition can help humans perform much faster, much more accurately with much less effort. Together, they will play a significant role in analysing and interpreting large-scale genomic data, and identification of disease patterns moving forward.
- **Liquid biopsies** involve the analysis of various biomarkers, including circulating tumour cells (CTCs), circulating tumour DNA (ctDNA), and exosomes, from a simple blood sample. This approach offers a non-invasive and real-time method for monitoring disease progression, treatment response, and minimal residual disease detection. Future advancements in liquid biopsy technologies may lead to improved sensitivity and specificity, making it a routine tool in cancer management.
- **AI and machine learning** algorithms will continue to advance in molecular pathology, aiding in the interpretation of complex molecular data. These technologies can assist in identifying patterns, predicting disease outcomes, and improving diagnostic accuracy. AI-based tools may also help pathologists automate routine tasks, such as image analysis, thereby enhancing efficiency and reducing human error.
- **Theranostics** combines diagnostics and therapeutics into a single integrated approach. Molecular pathology will likely play a significant role in the development of theranostic strategies, allowing simultaneous identification of disease biomarkers and targeted therapy delivery. This approach holds promise for personalised treatment, optimising drug efficacy, and minimising side effects.
- **Single-cell analysis techniques** will become increasingly important in molecular pathology. They provide the ability to analyse individual cells at a molecular level, enabling the characterisation of cellular heterogeneity within tissues, identification of rare cell types, and tracking of cellular dynamics during disease progression. Advancements in single-cell technologies will provide valuable insights into disease mechanisms and potential therapeutic targets.
- **Digital pathology involves the digitisation of histopathology slides**, enabling remote access, storage, and analysis of tissue samples. This technology has the potential to enhance collaboration, improve diagnostic accuracy, and facilitate the integration of molecular data with traditional pathology.

4.10.10. Molecular Pathology Strategic Developments

The future for Molecular pathology is similar to that of DG. The future is likely to embrace a service model that has very significant investment in automation and multiple omics technologies, this includes a variety of new equipment that the laboratory does not currently have. The automation will be predominately focused on NGS (genetic sequencing), reagent testing, DNA extraction, quality testing, and single cell analysis techniques; and advances in omics technologies (possibly in partnership with others).

It is also clear that the current space allocations will need to be increased to allocate for these new equipment additions.

One strategic option is to commence Molecular Pathology (and DG) in the new building with a **substantial investment in automation equipment**, which would place ACT Pathology at the fore of Molecular pathology and DG across jurisdictions. The scale of the investment would be determined as part of a future capital investment funding and business case.

The default position is to progressively enhance technology capability in automation and 'omics' as the investment funds would ordinarily become available.

4.11. CLINICAL AND NON-CLINICAL SUPPORT SERVICES

This section identifies the range of inter-dependencies that ACT Pathology has with other clinical and non-clinical services.

Some of these services potentially impact on the service model for pathology. However, most relate to the Functional Design Brief in the next stage of the planning process for the capital redevelopment.

4.11.1. Clinical Support Services

Pathology itself is principally a clinical support service to almost all other medical specialties delivering patient care at TCH, private hospitals and community referrers.

There is minimal clinical interdependency with:

- Medical Imaging; or
- Pharmacy, except for microbial stewardship and community testing.

Quality and Infection Control is the exception. There is considerable inter-dependency between pathology and quality and infection control; a core consideration in all pathology departments.

Quality Department

The Quality Department supports the systems and structures that enable assurance of the the quality and consistency of testing and reporting. The role of quality is to:

- Ensure **standard operating procedures (SOPs)** for all laboratory processes;
- Establishing and maintaining a comprehensive **quality management system**;
- Designing and implementing **quality control measures**;
- Implementing and overseeing **quality assurance programs**;

- **Compliance and accreditation** including ISO 15189-2012 (AS ISO 15189-2013), NATA ISO 15189, NPAAC requirements and guidelines, and all other relevant NATA and Australian standards including statutory regulations and good laboratory practice standards;
- Leading **quality improvement initiatives**;
- Providing **training and education programs** for laboratory personnel to ensure they are knowledgeable about quality standards, procedures, and best practices.; and
- **Liaising with external organisations, regulatory bodies, and accreditation agencies** to stay updated on industry standards, guidelines, and best practices, including the participation in external proficiency testing programs and collaborate with other laboratories for benchmarking and knowledge sharing.

Teaching

Teaching and training is a core and integrated element of the provision of pathology services. The teaching and training occurs at both post-graduate and undergraduate level.

ACT Pathology is funded by the ANU to undertake pathology teaching for Medical undergraduates and postgraduate degrees through the School of Medicine and Psychology. Training of registrars in disciplines other than pathology is also required to assist them in passing the pathology components of their exams.

ACT Pathology prides itself on attracting pathology registrars in significant numbers.

It is expected that teaching and training will continue to be integral to the service model for pathology. This translates to dedicated teaching and research spaces, and spaces within the clinical specialties for pathology related activities.

Gross Pathology Teaching

This is commonly called the Museum, which houses gross pathology specimens. The Museum is not critical to day-to-day functions, however, it is important that there is easy access for staff to maintain/repair precious specimens when needed, that public access is restricted to learning and teaching purposes only, and that the department is located adjacent to a teaching space to allow for tutorials and conferences involving pathology case materials and wet specimens.

The current NDA for Pathology Museum and its associated support services is ~162 sqm.

Research

Research at CH is detailed in the *Clinical Support Services Service Model*, and the research projects and functions undertaken by ACT Pathology are core to its operations. It is anticipated that the core research functions for pathology will migrate with the pathology services into the new facility.

There are discrete research activities undertaken by ANU that are not integral to ACT Pathology and are not expected to be included in the scope of the new Pathology facility. These research activities may be well suited to be accommodated in a dedicated research facility on campus.

Prototyping

ACT Pathology does not currently have a prototype laboratory.

It is part of the proposed expansion of function as articulated in the L2D high level FDB.

A prototyping laboratory is a concept that is being increasingly adopted by modern pathology services. It provides a dedicated area to prototype new equipment or showcase and trial a supplier's technology. Trialling robotics before the expense of acquiring the equipment can be invaluable. It can also be helpful to conduct early trials and testing/commissioning of new technology to speed up the compliance period. It may also provide a capacity to be used in a future expansion or core activities. For further details refer to section 4.1.2.

DNA Extraction and Amplification

ACT Pathology has a limited capability for DNA extraction as part of the DG functions. This is an area that has been highlighted for major expansion in the future. The proposed increase in area if included in the expanded space for DG. This can be a shared function with any future (PC2) pandemic readiness area.

Cryogenic Processing and Storage Facility

ACT Pathology has a LN2 tank (Cryogenic store) adjacent to and connected into Building 10 currently. This supports the small DG service.

An expanded cryogenic service is proposed for the new pathology service, with expanded functionality that is likely to require expanded storage of ultra-low temperature samples

Cryogenic storage must adhere to best safety principles and should be collocated that incorporates the correct provisions for oxygen depletion detection, alarms and ventilation systems. Ideally, cryo-storage is on a well-ventilated external wall. There is likely to be a requirement for vapour phase and full immersion dewars.

Cryo-speed truck access is a requirement as well as the exclusion zone during filling process.

Digital Pathology

The service could be located off-site or on-site. It would nevertheless require a 'digital backbone' with sufficient bandwidth (Cat 6 or 7 level capability) to support real-time digital pathology operations, as well as off-site and remote work by Pathologists. For further details refer to section 4.1.3.

4.11.2. Non-Clinical Support Services

Pathology Administration

Pathology Administration manages the business unit that is ACT Pathology. This includes:

- Operations oversight and management;
- Quality;
- Human resources management;
- Financial management,
- Data management and reporting;
- Strategic planning;
- Clinical and non-clinical liaison with the rest of CH services;
- Communications and public relations; and

- Engagement in research and education activities.

Enabler Services

There are an important range of non-clinical services that will be described in the Functional Design Brief, including:

- Logistics: This includes the collection, transport and storing of specimens, particularly couriers, and other supply chain requirements for supplies
- ICT: This is an increasingly critical enabler for pathology services. This includes ICT standardisation, high bandwidth the communicate with clinical personnel, remote monitoring of POCT, enhanced automated testing and reporting processes, meta-data analytics, and many other areas.
- Bio-Medical engineering;
- Maintenance and equipment repair (at CH and by manufacturers);
- Ventilation and air quality, Lighting, Temperature controls and Noise abatement;
- Store replenishment;
- Waste disposal; and
- Access and Safety, amongst others

5. Mortuary Services

Mortuary services will be incorporated in the new Pathology facility building.

This may need to be revisited depending on the location of Pathology relative to core clinical areas on the campus, the travel distances, and having to use shared public pathways for transporting deceased persons.

5.1. SCOPE OF SERVICE

The mortuary service will include:

- **The acceptance and safe repository** of bodies during and after business hours⁴² for persons who have died at CH, as well as potentially other deceased persons depending on the capacity for storing at the Forensic Medical Centre;

Non-autopsy services including Body Release: CH's services involve the release of bodies to appropriate Funeral Homes/Transport Companies/Religious Organisations⁴³, including the management of relevant/necessary paperwork;

- **Perinatal post-mortem service (PPMS)**⁴⁴: autopsy procedures conducted on deceased perinatal bodies where deaths occurred during pregnancy, or during and (just) after birth, at CH.

Perinatal anatomical pathology is highly specialised, with the quality and clinical utility of reports requiring a higher degree of expertise/experience of the pathologist, scientist and technical staff. The majority of postmortem examinations provided by ACT Pathology are perinatal postmortems.

The PPMS Care Coordinator⁴⁵ also supports families during a difficult and sensitive time by providing family-focused care and consultation with relevant health care teams to identify the cause of death, providing answers to the families.

Full adult autopsies are no longer performed at CH and are performed at the Forensic Medical Centre (Botany Rd Phillip), although we are renewing our scope of accreditation to include limited autopsies for post-mortem biopsy and organ retrieval for consented research.

Area

The current NDA for Mortuary and Autopsy is ~294 sqm.

5.2. PATHWAYS

Coronial Matters

ACT Pathology provides a temporary storage location for the coroner if they cannot arrange direct transfer at the time of passing.

42. ACT Pathology, Anatomical Pathology Introduction.

43. ACT Pathology, Anatomical Pathology Introduction.

44. NSW Health Pathology, Clinical Services Plan 2019 – 2025 Version 2:2021.

45. This is a Midwife on ward function.

Non-Coronial Deaths

Mortuary pathways⁴⁶ begin with the **Verification** and then **Notification** of Death. The mortuary service either undertakes or supports other CH staff in all subsequent processes, including:

- **Documentation** mainly associated with death certificates;
- **Care of the Deceased** is another important step in the process, focusing on maintaining the dignity of the deceased patient and supporting the family; and
- **Release of the deceased person** and transfer to a Funeral Home.

There may also be services provided by the mortuary service including documentation/certificates, and particular processes for:

- Perinatal deaths;
- Infectious diseases (as noted in Table 5-1);
- Death of a patient in the Perioperative Unit;
- Radioactive or Cytotoxic substances;
- Bariatric and tall stature patients in inpatient settings;
- Deceased person who's next of kin are unable to claim them or there is no next of kin.

Table 5-1: Infectious Diseases a Deceased Person is Suspected or Known to have been Exposed to, List A vs List B⁴⁷

List A Does not require hermetically sealed bag	List B Does require hermetically sealed bag
Acquired Immunodeficiency Syndrome (AIDS)	Anthrax
Acute Viral Hepatitis (Unclassified)	Diphtheria
Hepatitis A, B, C, D	Creutzfeldt-Jakob Disease (CJD)
Human Immunodeficiency Virus Infection (HIV)	Plague
Meningococcal Disease	Small Pox
Rabies	Yellow Fever
Active tuberculosis	(Any) Viral Haemorrhagic Fever including: Lassa, Marburg, Ebola, and Congo Crimean Fevers
COVID-19	

5.3. HOURS OF OPERATION

Mortuary's normal opening hours are Monday to Friday: 8:00-4:00pm. On weekends, the department is open for releases, body wash and viewing only, which is organised by the out of hours shift coordinator and performed by hospital (non-pathology) staff.

5.4. WORKFORCE MODEL

The workforce model reflects the clinical capability level of mortuary services, with staffing levels provided in Table 5-2 below. The staffing complement includes a mortuary team leader, a mortuary assistant, as well as some shared staffing arrangements with AP. Note, this shared arrangement is not explicitly detailed in Table 5-2.

46. ACT Health Canberra Health Services, 22 Sept 2021, Canberra Health Services Procedure - Providing Care after Death.

47. ACT Health Canberra Health Services, 22 Sept 2021, Canberra Health Services Procedure - Providing Care after Death.

Table 5-2: Staffing by Workforce Category - Mortuary

Staff Category	Headcount	FTE
Mortuary Team Leader	1	1.0
Mortuary Assistant	1	1.0
Current Total	2	2

Staffing numbers are at a point in time and will not reflect future FTE or workforce mix needs.

5.5. CURRENT LOCATION

The department is currently collocated on level 1, with Pathology Administration, Collection Services and Pathology Museum.

5.6. KEY FUNCTIONAL RELATIONSHIPS

Internal Relationships

Mortuary services often shares staff with AP, however, there are no functional relationships that require mortuary to be proximal to any other pathology department.

External Relationships

Mortuary services work closely with clinical staff within inpatient services and emergency departments. They coordinate or support the transfer of deceased individuals from hospital units to the mortuary and ensure proper documentation.

There will typically have a working relationship with local funeral homes or funeral directors and will involve interactions with authorities such as coroners, and ACT Health to comply with regulations regarding body transportation, handling, and burial/cremation procedures.

5.7. MORTUARY KEY CHALLENGES/FUTURE SERVICE TRENDS

The future for mortuary services will need to consider the following service trends:

- **Discrete body transition:** Deceased persons are frequently being transferred from department to mortuary via hospital corridors/grounds that are shared with the public. It will be important for future transfers not to be undertaken through public spaces. Only underground tunnels and staff only areas should be used.
Opportunities should also be sought as part of the facilities developments to:
 - ▶ Automate body transits; and
 - ▶ Maintain integrity and prevent contamination.
- **Cultural sensitivity and inclusivity:** Along with all other parts of CHS, mortuary services place a strong emphasis on cultural sensitivity and inclusivity, ensuring that practices and services accommodate diverse cultural and religious traditions;
- **Technology integration:** The Mortuary services should leverage advances in technology to better coordinate and transit deceased patients and ensure efficient administration of regulations; and
- **Sustainable practices:** with growing environmental consciousness, there might be a shift towards more eco-friendly practices in mortuary services. This could include options for natural or biodegradable materials.

- **Scale.** The proposed capacity for the new mortuary service as indicated in the L2D FB is for 75 deceased persons.

Whilst there are expected to be some changes to the technology platforms and streamlined operations in the mortuary, the basic Service Model will not change substantially. It is expected that there might be reduced space required for mortuary services (unless there is a major ACT policy change to undertake more autopsies at CH).

A1. ACT Health Policies, Strategies and Plans

The following policies, strategies and plans are relevant to the ongoing enhancement and accessibility of pathology and other clinical services as they are developed in the new Pathology facility.

ACT Government policies, strategies and plans

- Accessible, Accountable, Sustainable: A Framework for the ACT Public Health System 2020-2030
- Healthy Canberra: ACT Preventative Health Plan 2020-2025
- ACT Health Digital Health Strategy 2019 –2029
- ACT Wellbeing Framework
- ACT Drug Strategy Action Plan 2018 –2021
- ACT Carers Strategy
- ACT Aboriginal and Torres Strait Islander Agreement 2019-2028
- ACT Climate Change Strategies 2019-2025
- ACT Women's Plan 2016-2026
- Capital of Equality Plan 2019-2020
- ACT Mental Health Strategic Plan –under development
- Other Policies, Strategies and Plans

Ongoing Territory-wide planning

- ACT Child and Adolescent Clinical Services Plan
- ACT Mental Health Services Plan
- Joint planning framework with Southern New South Wales Local Health District Planning Team
- Models of care and facility planning for Canberra Hospital Expansion Project
- Models of care and facility planning for Centenary Hospital for Women and Children expansion
- Other Specific Services Plans

Canberra Health Services planning

- Canberra Health Services' Strategic Plan, 2020 –2023
- Canberra Health Services' Clinical Services Plan 2021-2031
- Canberra Health Services: COVID-19 Recovery Roadmap 2020
- Canberra Hospital Master Plan
- Implementation and enabling plans.

A2. Pathology Clinical Capability Framework

Pathology role descriptions below are for all six levels of pathology. ACT Pathology is a Level 6 pathology service.⁴⁸

LEVEL	SERVICE SCOPE	SERVICE REQUIREMENTS	WORKFORCE
NPS	No planned service.		
1	Blood and diagnostic specimen collecting services available.	Supported by a timely courier service to a National Association of Testing Authorities / Royal College of Pathologists of Australasia (NATA/RCPA) accredited laboratory for testing. Collection policies and procedures established by the accredited laboratory. Referral pathways to relevant Aboriginal programs and services. Compliance with the quality and safety requirements as determined by NATA and the National Pathology Accreditation Advisory Council (NPAAC)	Workforce requirements in accordance with standards and guidelines specified by the NPAAC; accredited for compliance by NATA.
2	As for Level 1. In addition, a range of urgent tests available. Tests may be performed by appropriately trained health workers using approved Point of Care Testing devices (see NSW Health PD2018_028 Managed Point of Care Testing (PoCT) Service.)	As for Level 1. In addition, comply with NSW Health PD2018_042 Blood Management.	As for Level 1.
3	As for Level 2. In addition, an accredited Category B (Branch) ¹ laboratory providing core pathology services, either on-site or through networked arrangements. Range of tests available varies according to clinical need. Will usually include basic haematology (e.g. full blood count, cross matching, blood grouping and basic coagulation), biochemistry (e.g. liver and renal function tests, electrolytes) and microbiology (e.g. urine microscopy, Gram staining)	As for Level 2. In addition, under the overall control of, with specialist scientific and clinical supervision from, an accredited laboratory. 24-hour on call access to Category G laboratory	As for Level 1.
4	As for Level 3. In addition, part of a service network providing some specialist diagnostic tests (e.g. fine needle aspiration, frozen section, bone marrow biopsy) and/or an expanded range of tests.	As for Level 3. In addition, provide an extended hours service to meet agreed clinical needs.	As for Level 1.
5	As for Level 4. In addition, accredited as Category B or G ² laboratory. Provide access to comprehensive range of pathology services, either on-site or through networked arrangements. Provide support for clinical trial and research activities. May act as 'hub' laboratory, providing diagnostic and clinical services for other hospitals or laboratories in the region or pathology network.	As for Level 4. In addition, provide 24 hour access to comprehensive range of pathology services	As for Level 1.
6	As for Level 5. In addition, accredited as Category G laboratory. Provide	As for Level 5	As for Level 1.

48. <https://www.health.nsw.gov.au/services/Publications/role-delineation-of-clinical-services.PDF>.

LEVEL	SERVICE SCOPE	SERVICE REQUIREMENTS	WORKFORCE
	comprehensive range of core clinical, laboratory and business support services as part of the clinical management team. Perform testing of a complex technical nature in a range of fields to support clinical services. May initiate and lead clinical trial and research activities. May operate reference laboratories and provide public health services for the State		

1. Category B (Branch): This category is used for a laboratory that is either: an integral part of a Category G laboratory apart from its geographic location, or a part of a regional pathology service. A Category B laboratory shall have a documented agreement with a Category G laboratory to ensure that the range of pathology tests provided and the standard of work in the laboratory is under the direction and control of a designated supervising pathologist or senior scientist of an accredited Category G laboratory⁴⁹.

2. Category G (General): These categories are used for both large and small multidiscipline or general laboratories providing comprehensive services. It is also used for limited or single discipline laboratories⁵⁰. Introduction of PoCT and specialised testing has resulted in new categories of laboratories for these sites. For further information please contact NSW Health Pathology.

49. NPAAC (2018) Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories. Fifth edition. Commonwealth of Australia, Canberra

50. NPAAC (2018) Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories. Fifth edition. Commonwealth of Australia, Canberra

A3. Functional Relationship Diagrams – by L2D Architects

Below functional relationship diagrams are designed by L2D Architects for the purpose of the Functional Design Brief.

Table A3-1: Pathology Departmental Overview – All Departments

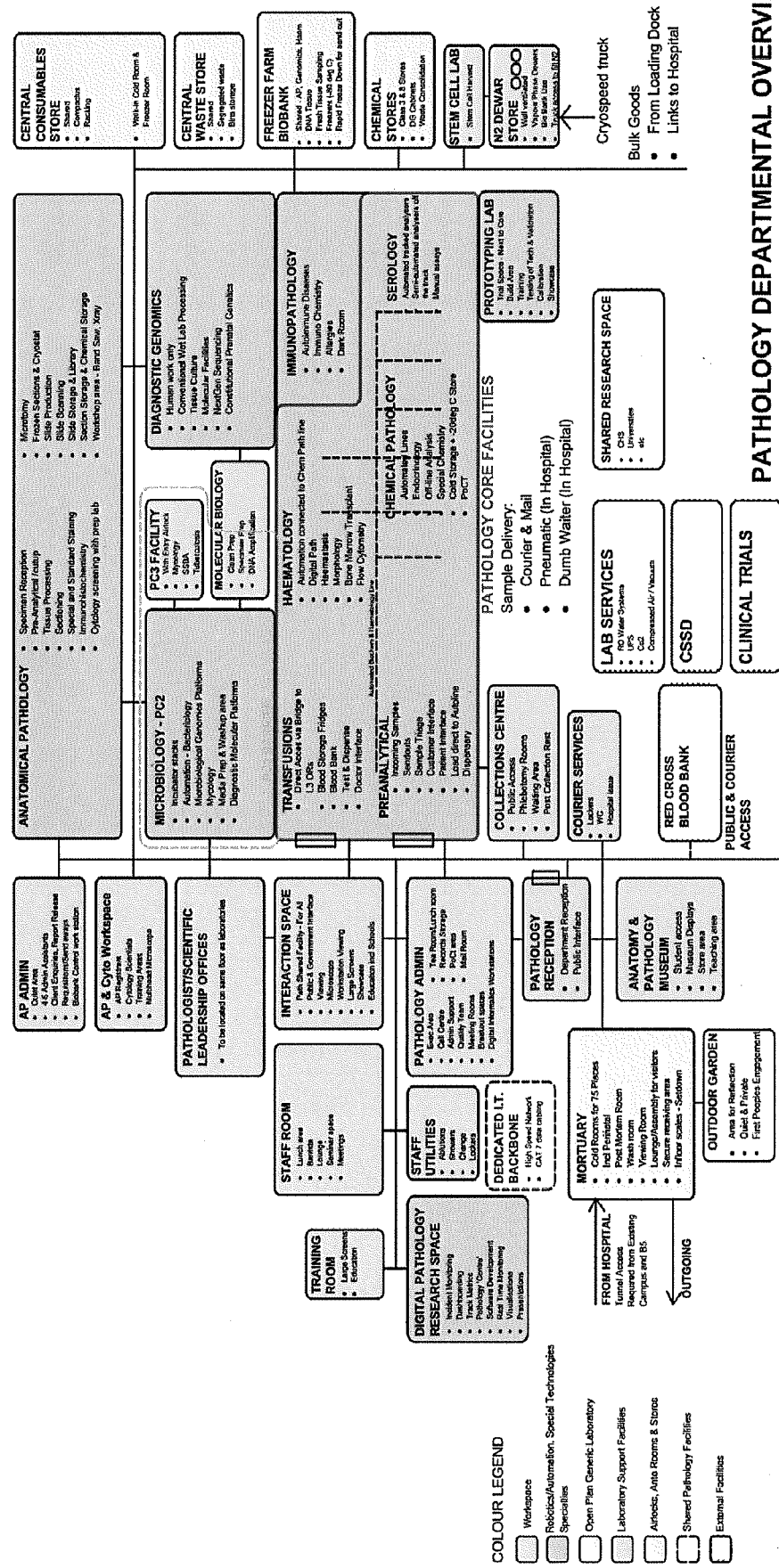
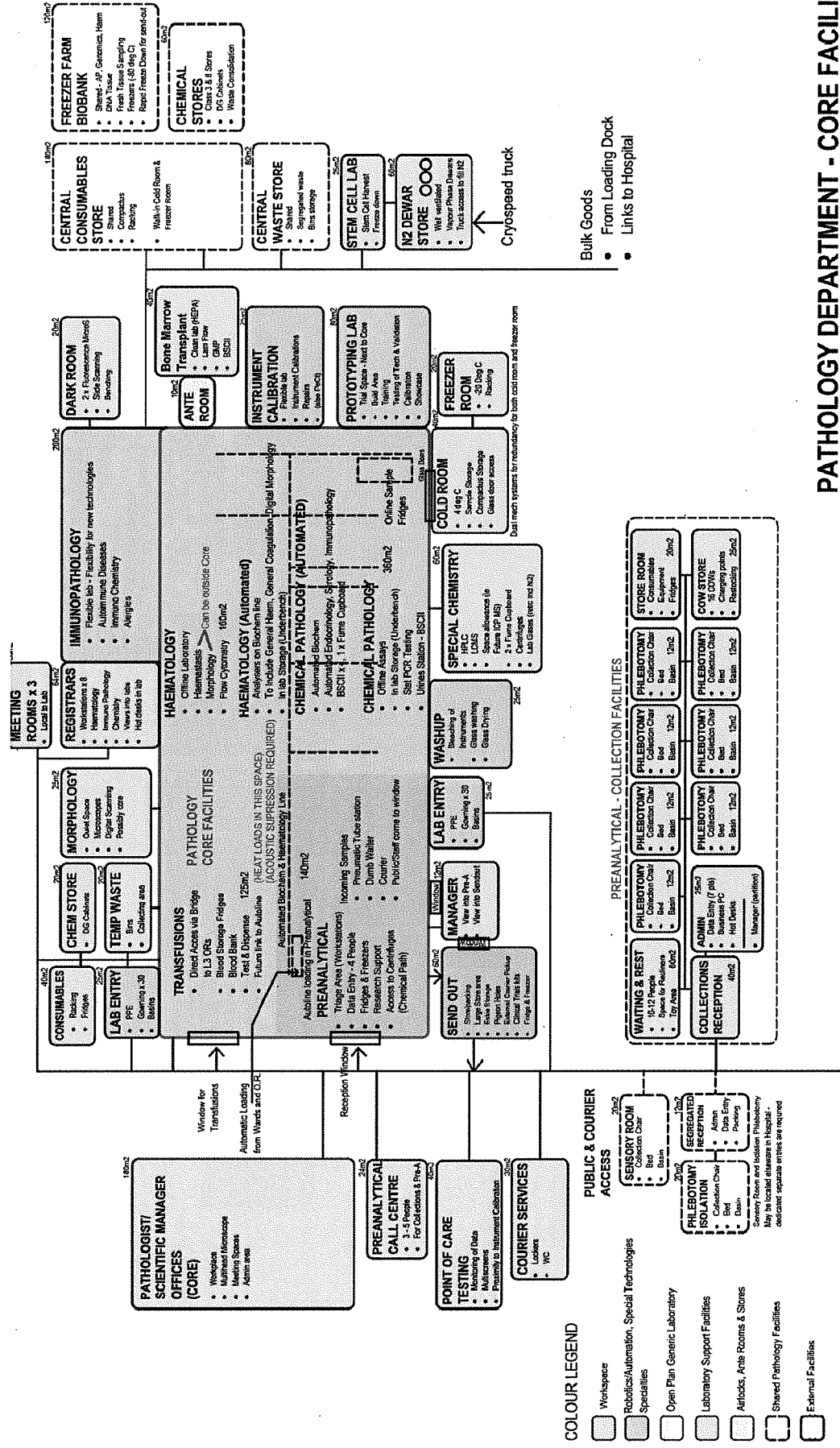
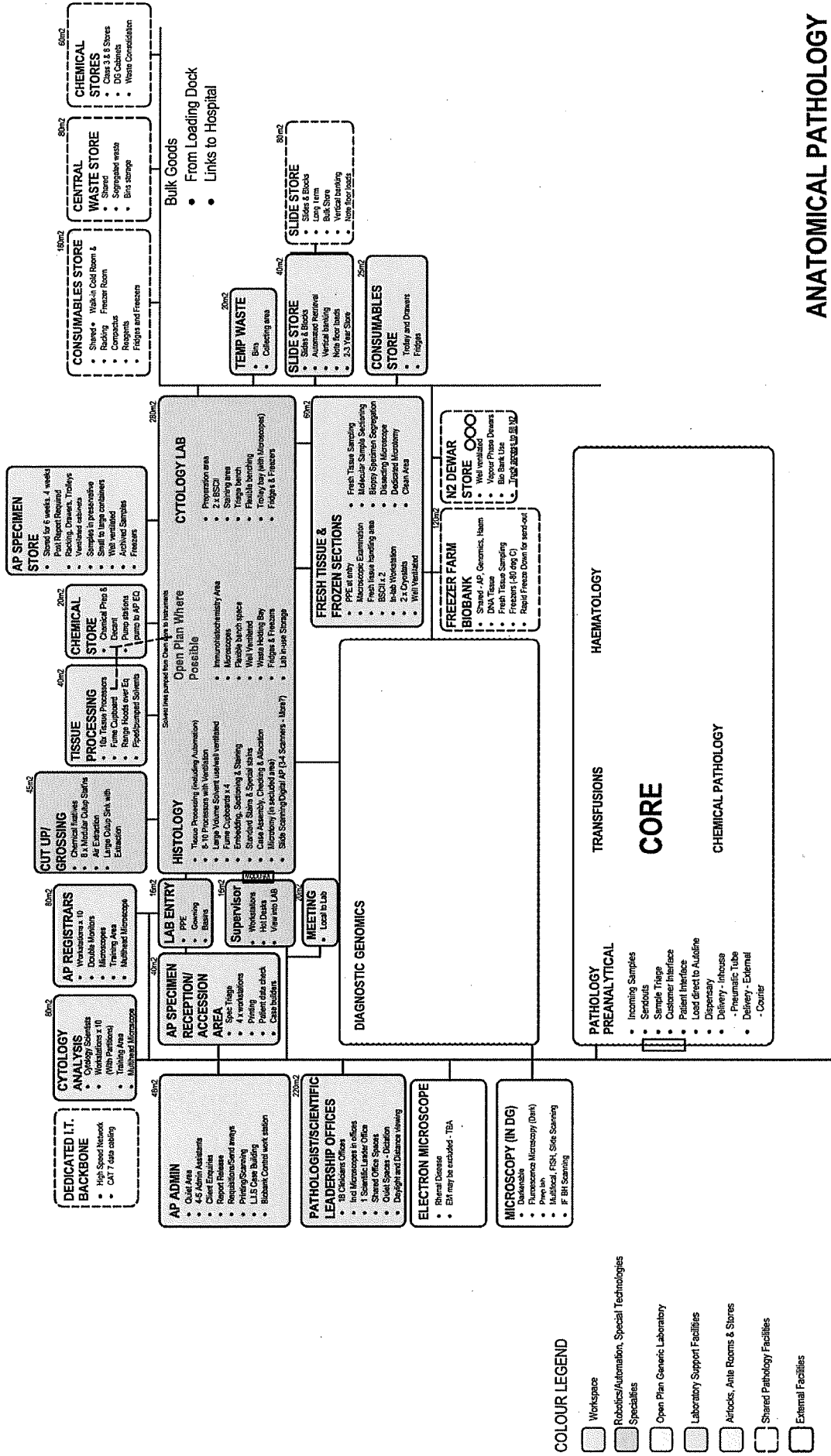


Table A3-2: Pathology Department – Core Facilities and Immunopathology



**PATHOLOGY DEPARTMENT - CORE FACILITIES
AND IMMUNOPATHOLOGY**

Table A3-3: Anatomical Pathology



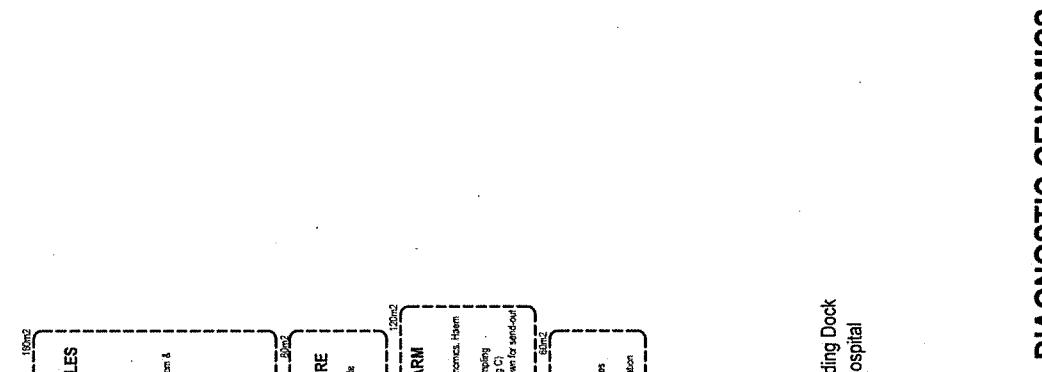
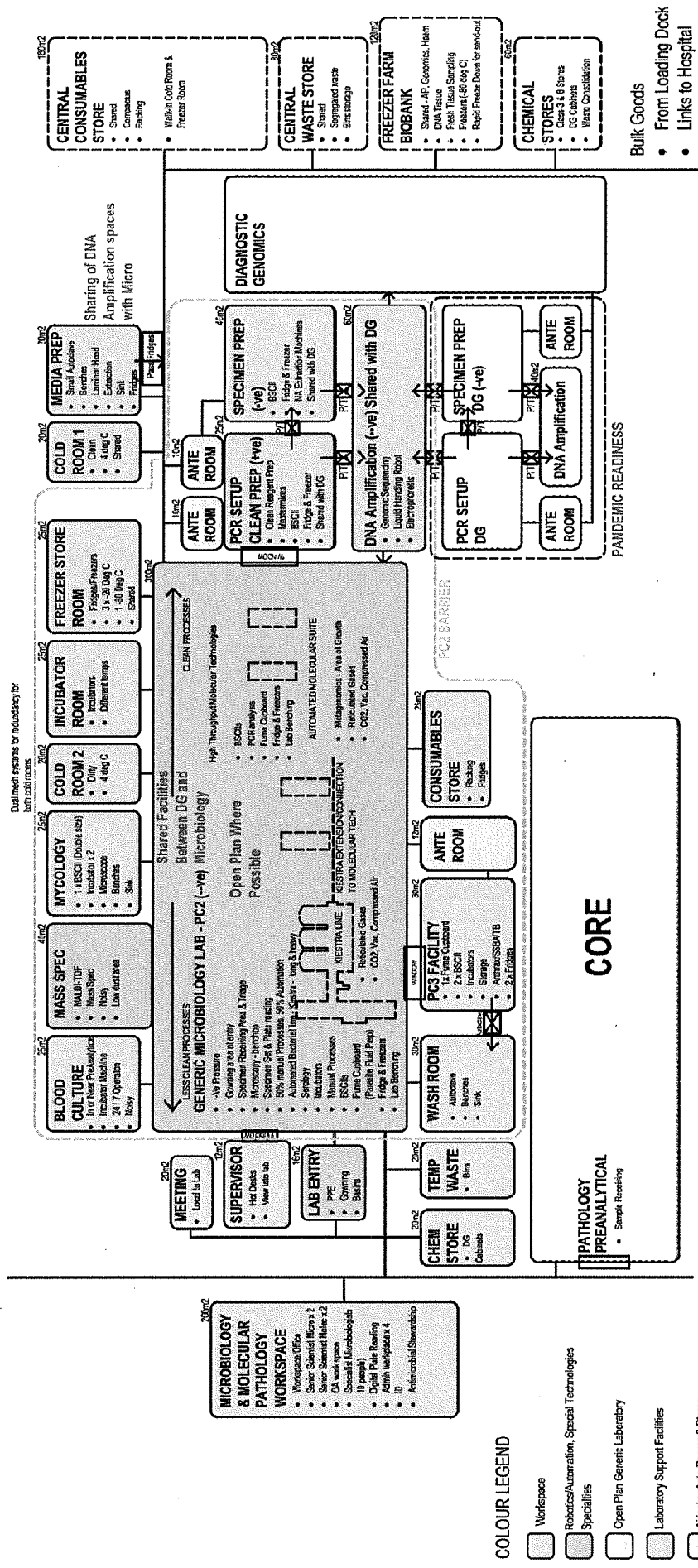
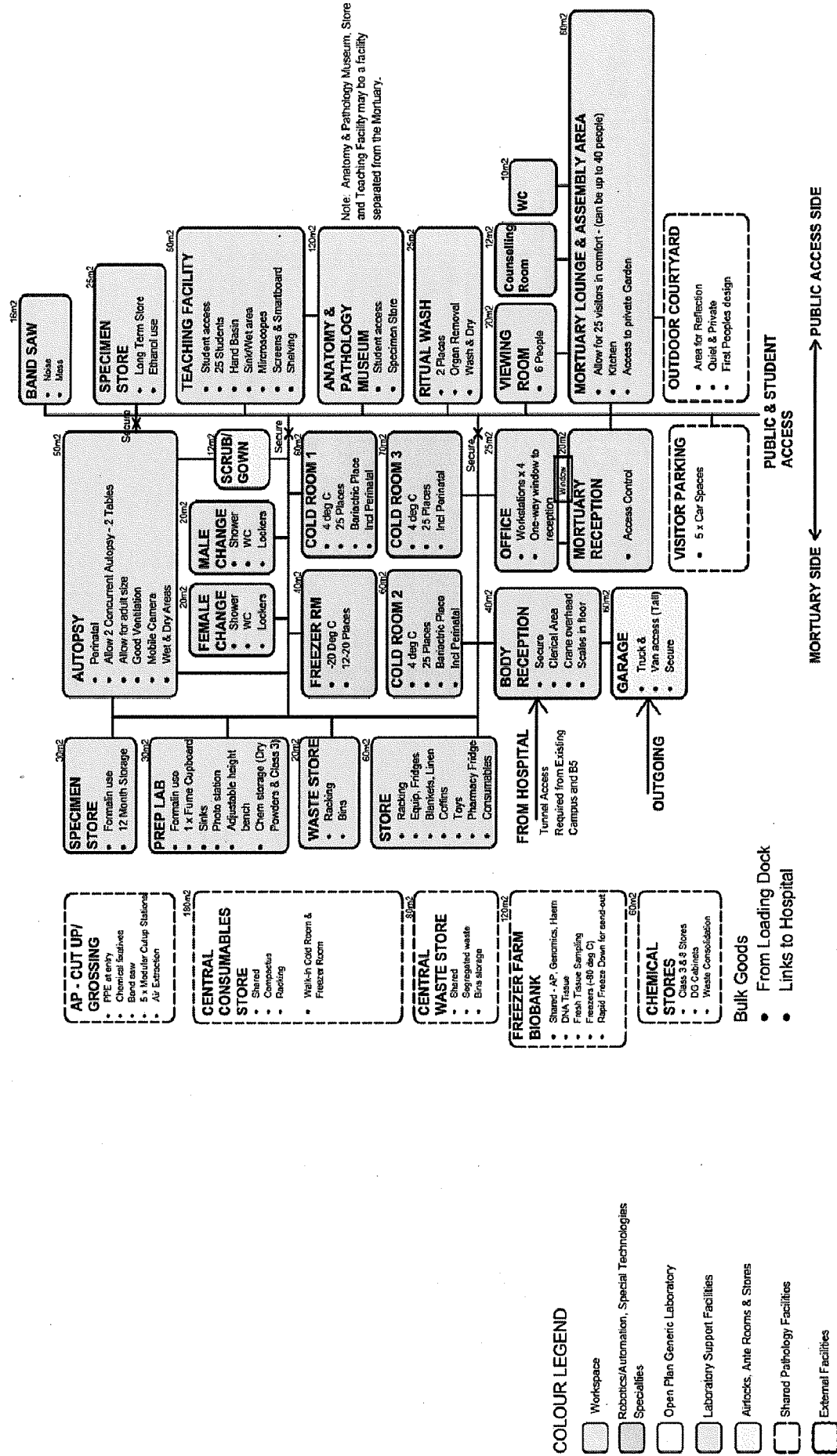


Table A3-5: Microbiology / Molecular Pathology



MICROBIOLOGY / MOLECULAR PATHOLOGY

Table A3-6: Mortuary

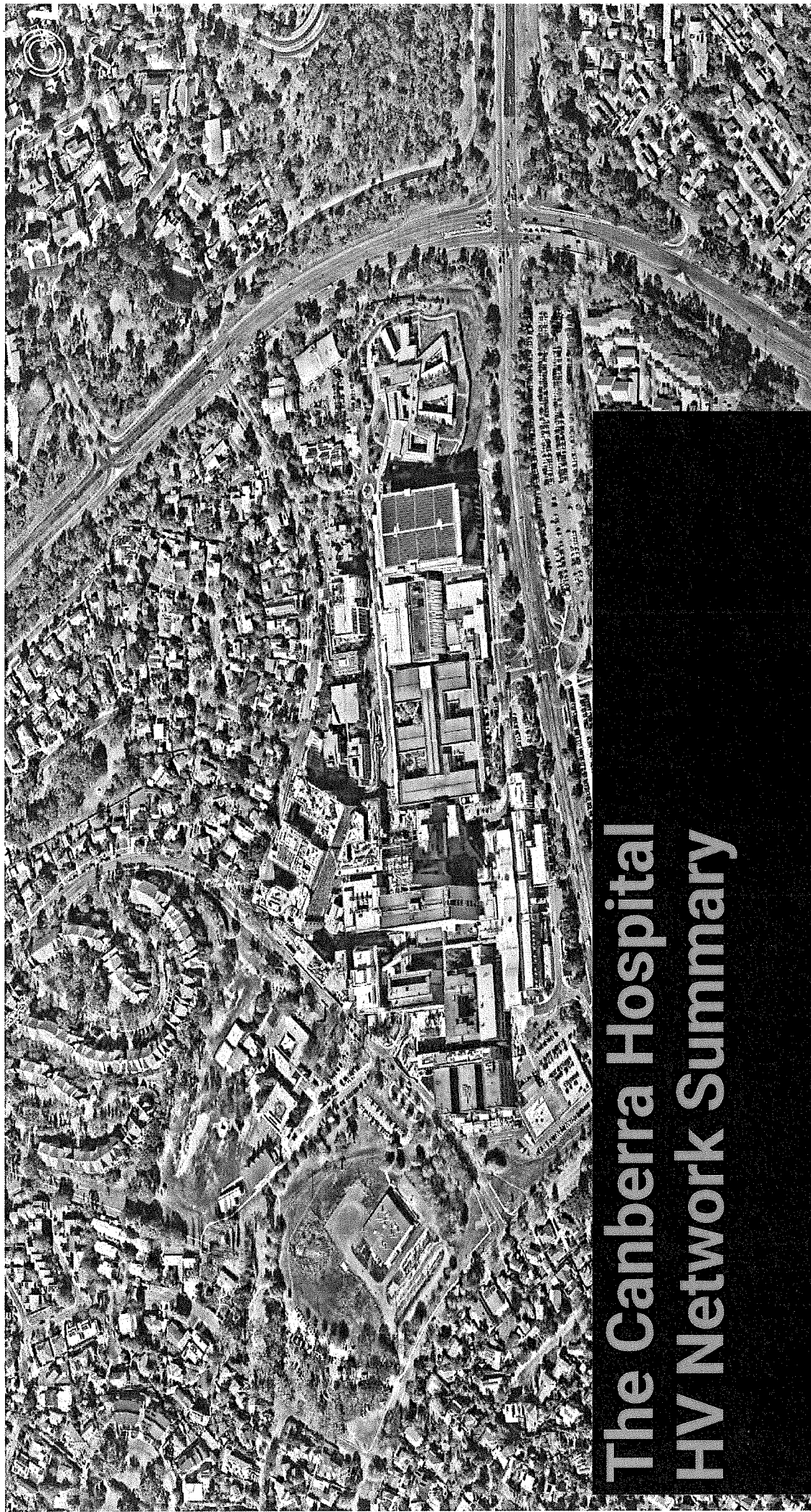


A4. Prohibited Actions for Suspected Coronial Deaths

CHS staff must NOT carry out any of the following without first confirming with the ACT Police Coroner's Team Representative⁵¹:

- Leave all tubes, drains, cannula, airway devices and dressings are to remain in situ on the deceased person. Permission for the removal of any device or equipment should be sought from ACT Policing and must be noted in the patient's clinical record and on the Deceased Person Checklist (including the asset number of equipment, if labelled) and staff should consider describing the site of the device or equipment with a sketch/diagram;
- Not place anything in or on the deceased person, including surgical packs, dressings, and drains;
- Not take foot and/or handprints without ACT Policing permission in the case of a death of a child/neonate;
- Not wash the deceased person's body. If the body is going to be viewed by relatives before leaving the perioperative unit to go to the Mortuary, ask for instruction from ACT Policing prior to removing any blood or fluid from the body;
- If ACT Policing give permission for the deceased person to be viewed by relatives or have rights administered by a Minister of Religion and have given permission for the deceased person to be moved, the deceased person may be moved out of the theatre and into a nearby room such as the perioperative tutorial room. The deceased person is to be covered with a clean sheet;
- Gastric aspirate and vomitus from the deceased person are to be placed in a yellow top specimen container, labelled with a patient ID label, and sent with the deceased person to the Mortuary;
- Ensure the deceased person's identification is checked as correct and identification tags are attached to the deceased person's ankle and wrist. After the patient identification process has been completed and the police are instructed by the coroner's office, the deceased person may be removed from the theatre complex. Do not remove the body until instructed to do so by the Police. When transferring the deceased person, a wards person is to be contacted to assist with placing the deceased person into a body bag and transferring them to the Mortuary; and
- If requested to give a statement to ACT Policing, please refer to document "Staff Options - interaction with ACT Policing following a coronial death".

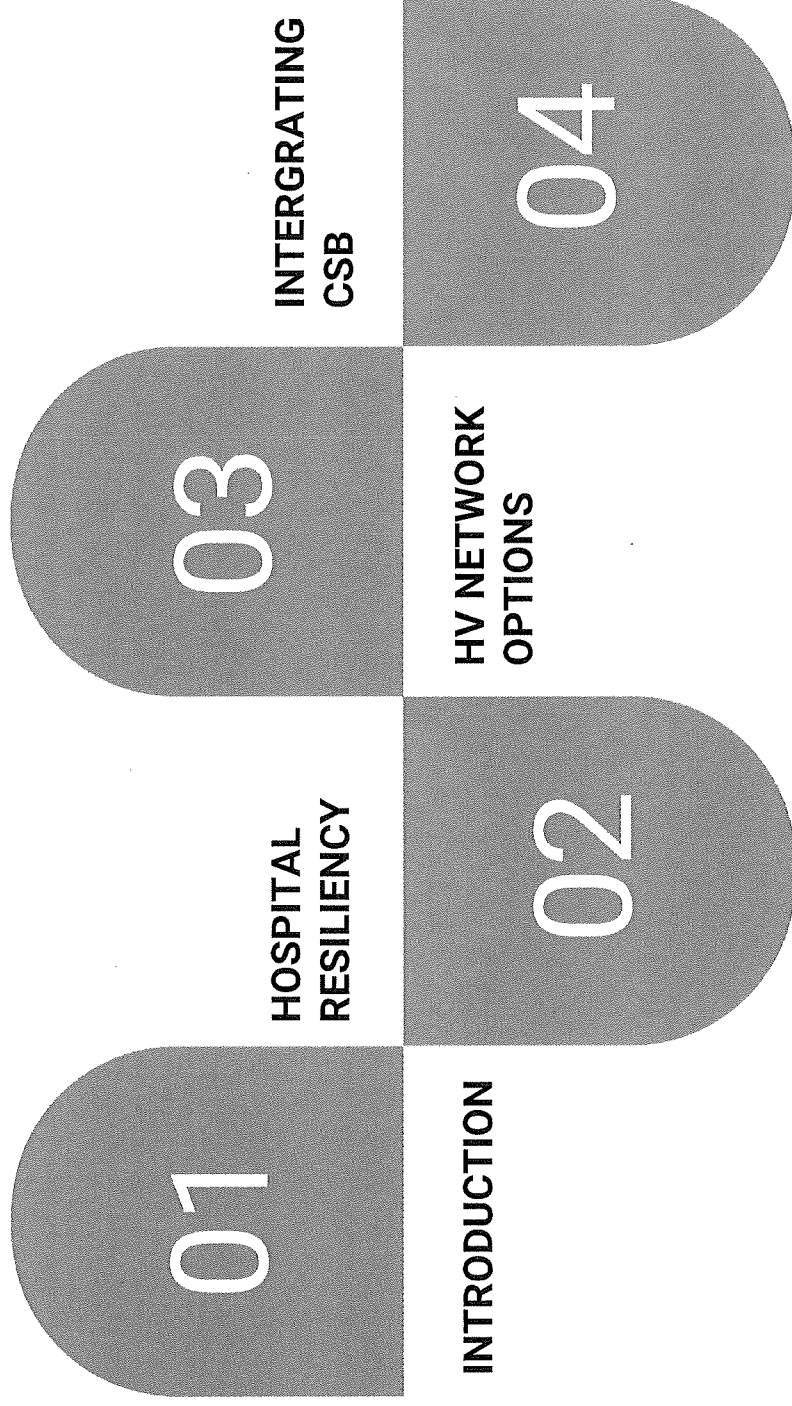
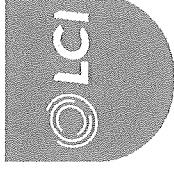
51. ACT Health Canberra Health Services, 22 Sept 2021, Canberra Health Services Procedure - Providing Care after Death.



The Canberra Hospital HV Network Summary

20 December 2023

Agenda



Resiliency

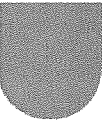
Keep the Hospital Running



Minimisation, Limiting the extent of failures



Redundancy, Installing Extra Equipment to step-in



Diversity, Separating Equipment, Providing Alternate Pathways



Availability, Minimising maintenance downtime.



Expansion, Catering for a growing hospital.



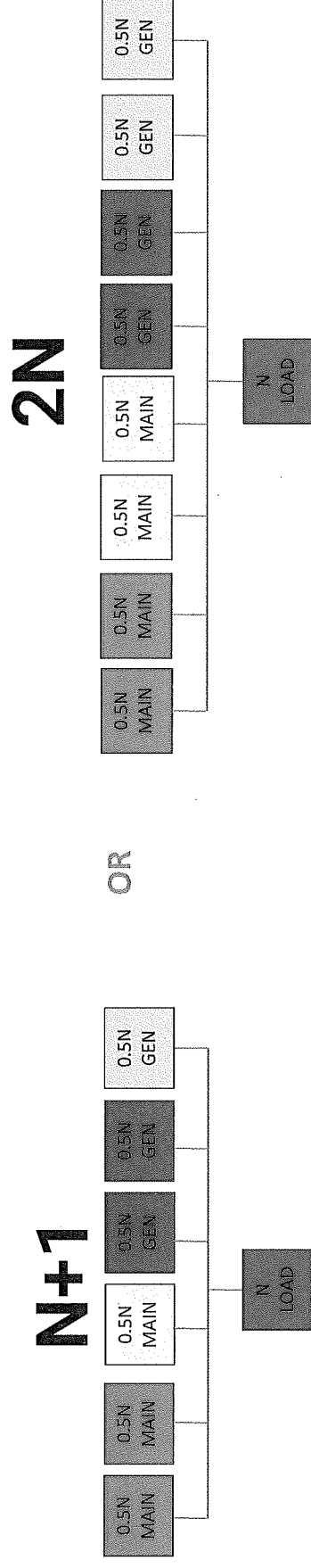
Hospital Design and Resilience.

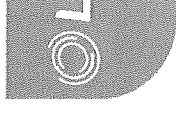
Tertiary healthcare facilities are typically provided with N+1 resilience on key electrical infrastructure as shown below

CHS Electrical Standard Inclusions,

- Each piece of equipment will be sized so that any single piece of equipment can fail/be removed and the system still function

N is the capacity required





Canberra Hospital Requirements

Per Building Requirements.

HV Supply

- Any 1 Supply is unavailable, the load can be switched, and the site can operate at 100%.
- Supplies to be installed in Fully Diverse Pathways,
- Each separate supply requires a separate fire rated substation.

Generator Supply

- Critical Areas, 100% supported by 2 Generator 'Streams' individually.
- High Importance Areas, 100% supported by 1 Generator 'Stream'.
- Generator Streams require separate fire rated compartments.
- Generator Streams require separate fuel storage.

Main Switchboards

- Must be 100% duplicated supply from 2 separate Main Switchboards.
- Must be in separate fire rated Main Switch rooms.
- Outgoing supplies must be installed in diverse pathways.

NOTE: This reads as a 2N solution, however Generators and HV Supplies have been installed as N+1 onsite, including CSB

Central Energy Plant



1x Facility, Separate Fire Compartments

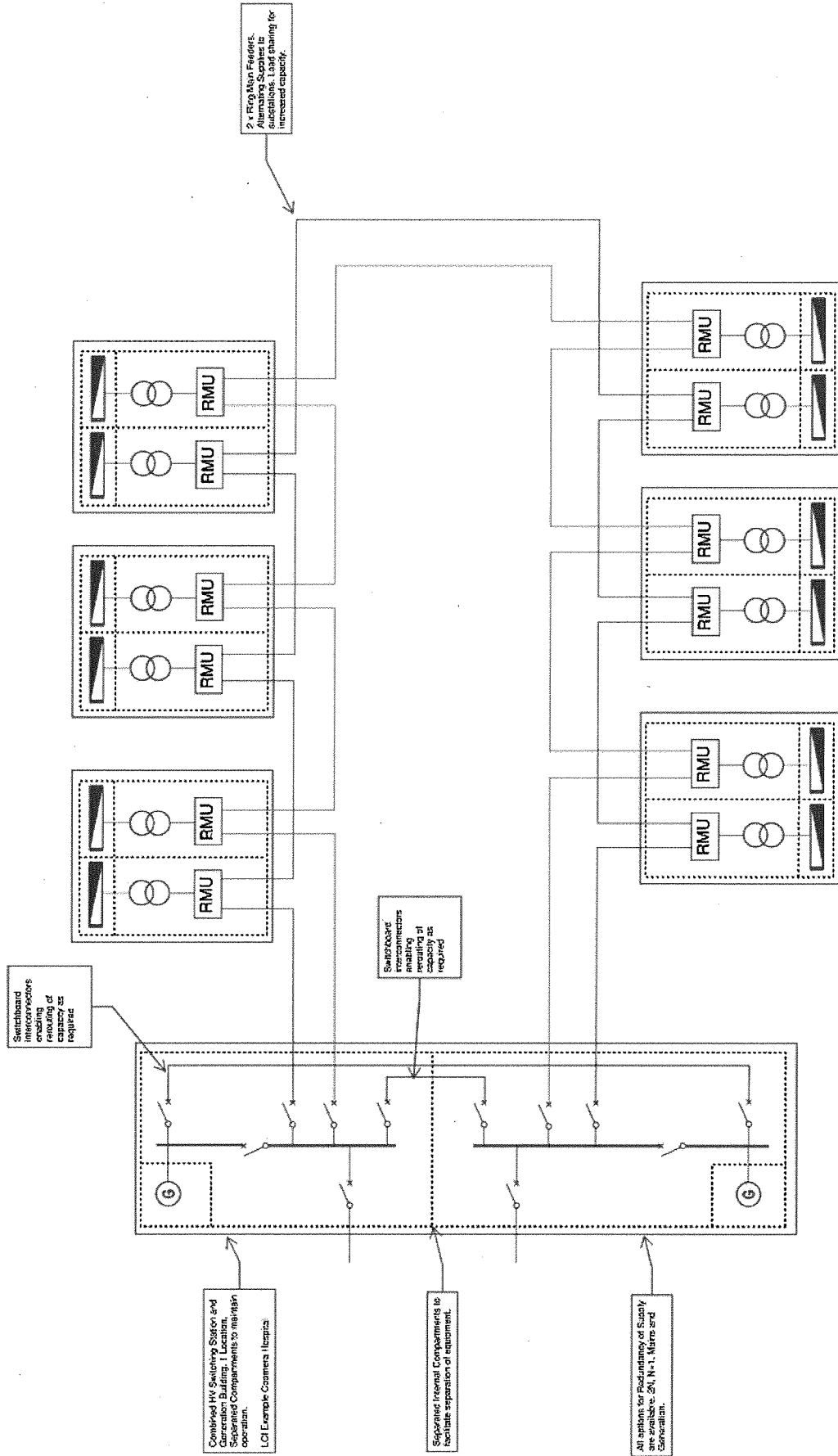
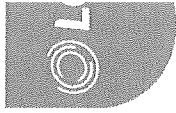
Flexibility of Redundancy

Diverse Location and Pathways

1 Facility, 1 Critical Service

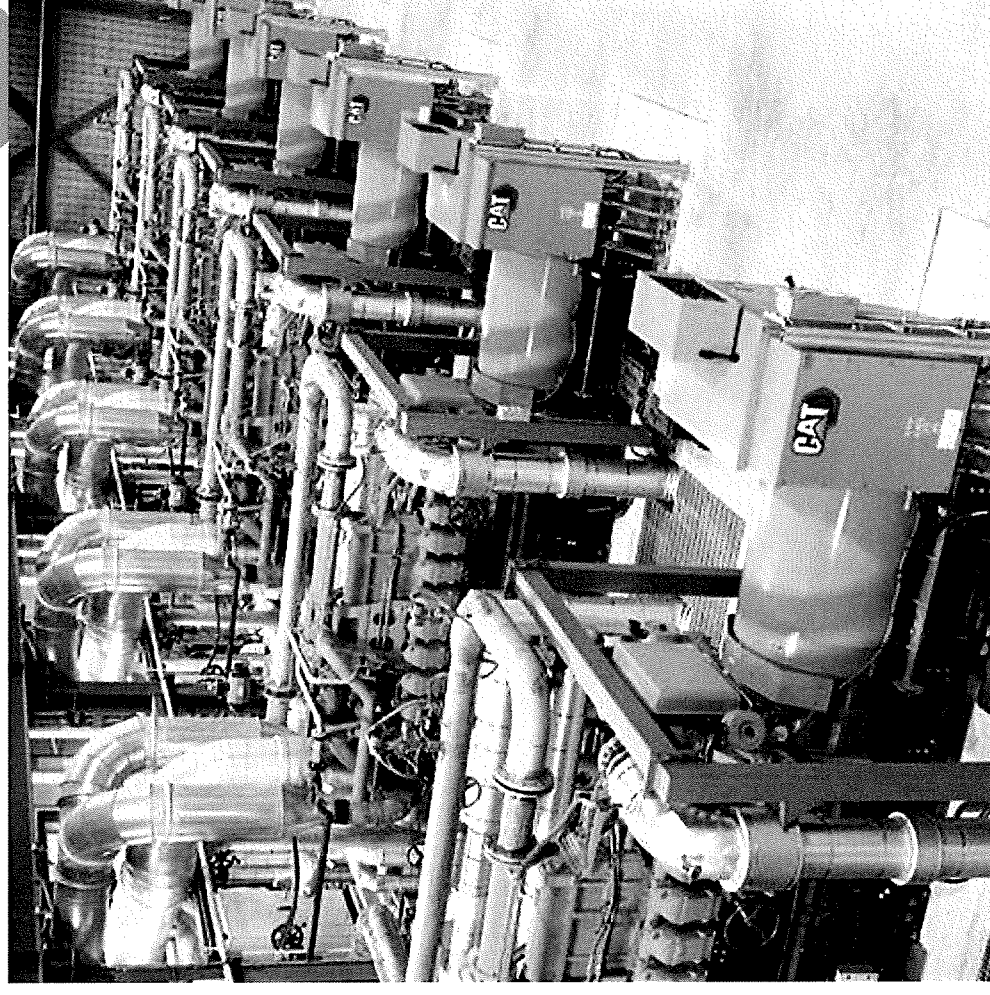
Benefits and flexibility in one location





Generator Hall

- HV Generator Plant, Distribute to multiple buildings on site
- Ease of Expandability, Stage Capacity as required.
- Consolidate Redundant plant in One Combined Facility.
- Test Generators Without Disconnection of Mains.
- Less Plant space within clinical buildings.
- Control Vibration and Sound away from Clinical Centre.
- Single Maintenance location. One Simple Design.



Estimated Staged Capacity

Example of how the capacity requirements can be met below.

Stage 1 – 4.5 MVA est. capacity (approx. 2026)

- 2 x 6 MVA HV Feeder (1 Redundant)
- 3 x 2.5 MVA Gensets (1 Redundant)

Stage 2 – 9 MVA est. capacity (approx. 2030)

- 4 x 6 MVA HV feeder (2 Redundant)
- 5 x 2.5 MVA Gensets (1 Redundant)

Stage 3 – 13 MVA est. capacity (approx. 2034)

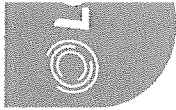
- 6 x 6 MVA HV feeder (3 Redundant)
- 7 x 2.5 MVA Gensets (1 Redundant)

Stage 4 – 15.5 MVA est. capacity (approx. 2038)

- 6 x 6 MVA HV feeder (3 Redundant)
- 8 x 2.5 MVA Gensets (1 Redundant)

Estimated Required Capacity, MVA

	EXISTING		NEW HV NETWORK		HV GEN CAPACITY	
	LOWER	UPPER	LOWER	UPPER	LOWER	UPPER
EXISTING	5.20	7.09	0.00	0.00	0.00	0.00
STAGE 1	3.72	5.11	3.49	4.21	3.11	3.46
STAGE 2	1.60	1.60	7.70	8.79	7.32	8.04
STAGE 3	0.00	0.00	11.33	13.06	10.96	12.31
STAGE 4	0.00	0.00	13.14	15.35	12.77	14.60



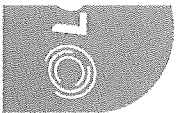
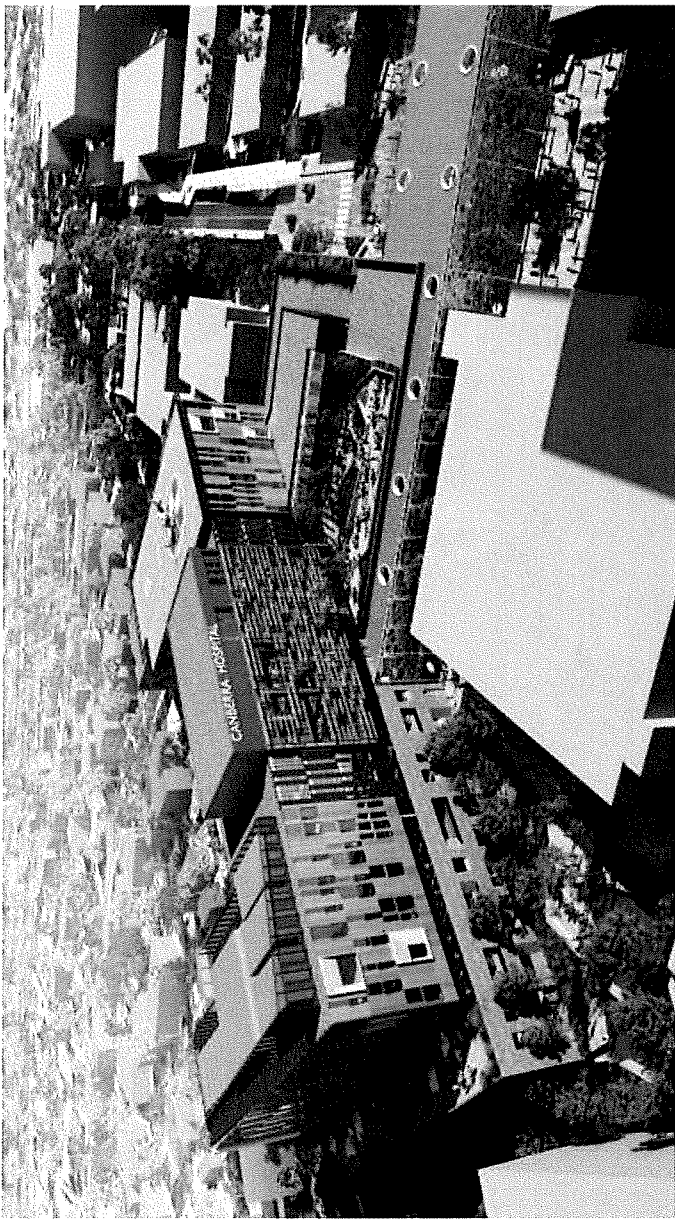
Integrating CSB Generation

Interlink new switching stations. Reuse new feeders.

If CSB is integrated into the new HV Private Network. Can the new Generators be re-used?
Yes,

8 MVA of LV Generation
4 x 2MVA Generators Sets in N+1 Configuration

What Modifications are required?



Integrating CSB Generation

1. Move to New Generator Plant.
 - Covert to HV Generator or Build Step-Up substation
 - Expensive, Complex, Significant Staging and works required.
 - Regain floor space within CSB for other uses.
 - Centralise all plant within dedicated locations
2. Modify to have both mains and generator paralleled for extended periods.
 - Export into the HV Network, building generator capacity for site.
 - Existing Generators become part of the Generator Pool for the Campus.
 - Generators likely have sufficient electronic controls to parallel mains and generator
 - Control gear and programming will need adjustment and modification.
 - Less expensive.
3. Do Nothing, CSB maintains separate LV generation to the rest of site.
 - CSB is disconnected from the rest of the Campus when Generation is in use.
 - Reduce required new capacity of new site.
 - Virtually no cost



Recommendation

Inclusions

2N HV Feeders, 1 Set from Woden Zone Sub and 1 from Alternate Zone Sub
N+1 HV Generation Plant
1 Facility 1 Location
Segregated Fire Compartments for Containment
Diverse Ring Main Pathways
CSB Building remains standalone

Advantages

- Reduced Impact of Footprint
- Flexible Redundancy options
- Equipment is Closer together, Reducing Complexity of Controls
- HV Interconnectors to provide diverse pathways
- Simplified Interface with Supply Authorities

Disadvantages

- Increased Risk if failures are not contained

