bays. This must be carefully considered because collection trolleys don't stack like chairs or shopping trolleys.

- Restrooms should be available for patients, especially if they need to provide urine samples or if they are waiting for extended periods;
- A staff room, and personal lockers for storage;
- A space for administrative tasks, separate from the public areas. This could be included as part of the Pathology Administration.
- A dedicated space or storage for biohazardous waste, sharps disposal, and general trash, on top of the centralised waste storage;
- Easy access to emergency exits for safety considerations, and the layout should account for the easy flow of patients to avoid crowding or bottlenecks;
- Compliance with regulations for people with disabilities, including provision of ramps, wide doorways, and accessible restrooms;
- Parking and Transportation as important considerations to encourage patients to attend the collection centre;
- Consideration should be given to security relating to patient records, cash handling (if payments are made on-site), and any other sensitive materials;
- That the design must comply with NPAAC Requirements:
  - Collection premises must comply with all applicable laws and regulations;
  - The current approval certificate must be visibly displayed;
  - Patients and carers must not enter Laboratory testing areas to gain access to the collection rooms;
  - Easily cleanable surfaces must be available for clerical work, Specimen collection and Specimen handling;
  - Suitable, secure storage area for supplies must be available and accessible only to staff;
  - Floor coverings in the immediate collection and storage areas must have a non-porous surface;
  - There should be provision to accommodate carers as required;
  - Toilet doors should be lockable from the inside and unlockable from the outside in case of emergency. The doors should be removable or open outward for purposes of access;
  - Hours of operation should be displayed; and
  - Collection areas should have adequate space for furniture to enable patients to be seated or to be recumbent according to medical requirements as well as a work surface for the collection staff.

- **Specimen Reception** will be an essential part of the core laboratory.

Ventilation and Air Quality

As per "General Design Principles" in section 7.8.

Lighting

As per "General Design Principles" in section 7.8.

Temperature

As per "General Design Principles" in section 7.8.

Acoustic Control

Call centres can become noisy, making it difficult for staff to hear calls clearly. Consideration in design should be given to soundproofing, acoustic panels, or high partitions between workstations to mitigate noise. Noise-cancelling headsets can also be beneficial.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Collection Centres store the following:

- Collection Materials:
  - Vacutainer tubes (with various additives), needles, butterfly needles, tourniquets, syringes, needle disposal containers, blood collection chairs;
  - Sterile urine containers, sometimes containers with preservatives;
  - Sterile swab kits for throat swabs, nasal swabs, wound swabs, etc;
  - Stool Collection kits with or without preservatives;
  - Sputum containers, semen analysis containers, etc; and
  - Trolleys with consumables for hospital collections.
- Personal Protective Equipment (PPE):
  - Gloves, masks, gowns or aprons, face shields or goggles, hand sanitisers, and antiseptic hand wash.
- Initial Processing Equipment:
  - Centrifuges (for spinning down blood samples), tube racks, and sample mixers.
- Storage Equipment:
  - Storage cabinets for non-chilled/frozen samples awaiting pickup or transport; and
  - Trolley storage is required for those used for collections performed throughout the hospital.
- Transport Materials:
  - Sealable plastic bags and containers for samples, transport coolers with ice packs or gel packs, and transport paperwork or pouches.

- Waste Containers:
  - Sharps containers for used needles;
  - Biohazard bins for contaminated waste; and
  - General waste bins.
- Paperwork and Administrative Materials:
  - Patient forms, pathology request forms, stationery, pens, computer systems (for electronic record-keeping and tracking), printers, labels, and label printers.
- Cleaning and Disinfection Supplies:
  - Surface disinfectants, cleaning cloths or wipes, spill kits for biohazards.
- Informational Materials
  - Brochures or handouts about various tests, preparation instructions for certain tests (like fasting blood tests or 24-hour urine collections), privacy notices.
- Emergency Supplies:
  - Basic first aid kit, emergency contact numbers, and potentially an automated external defibrillator (AED) depending on regulations and centre size.
- Comfort Supplies:
  - Items like tissues, band-aids, cotton balls, and sometimes a small snack or juice (especially useful if a patient feels faint after a blood draw).
- Staff Refrigerator:
  - For food storage.
- IT Server Room/Storage:
  - Backup Power: Uninterruptible Power Source (UPS) and cooling systems. Server rooms generate heat, so they need cooling to maintain an optimal temperature;
  - Portable or Dedicated Air Conditioning Units to keep the room cool;
  - Fans or Ventilation Systems to assist in circulating air;
  - Racks or Cabinets: these structures hold the servers and other equipment, helping to keep the room organised;
  - Environmental Monitors to track temperature and humidity;
  - Security Systems: may include cameras or access logs for those entering the room;
  - Fire Suppression solutions;
  - Smoke Detectors to alert staff to potential fire hazards; and
  - Physical Security with restricted access.

Specimen reception is a pivotal section in any pathology laboratory. It serves as the primary interface between the laboratory and referrers, handling specimens that come in for testing. The processing of specimens requires mostly at workstation storage of stationery and waste.

The key storage area for specimen reception is for eskies and other specimen transport equipment that are waiting for retrieval by couriers. These could be empty and will be used by couriers in future transportation of specimens and packages ready for delivery to another laboratory for testing (that the laboratory doesn't currently perform).

Pre-Analytics also need to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

ACT Pathology is required to meet NPAAC requirements for the tracking and retention of laboratory records and diagnostic material. The relevant requirements for Pre-Analytics are outlined in section 7.8.2, with some additional requirements for specimen reception detailed below[33]:

- Laboratories must have policies and procedures in place regarding the tracking of specimens which are referred into or out of the laboratory, for the purposes of traceability;
- Laboratories that refer a specimen with prolonged retention requirements to a second laboratory must document the release and return of the specimen.
  - This requirement relates specifically to stained histological, cytological and bone marrow slides and/or blocks referred or requested for second opinion or additional testing;
  - Laboratories must not retain referred materials with prolonged retention requirements without the consent of the original/referring pathologist; and
  - Laboratories that receive a referral specimen with prolonged retention requirements must ensure its safe and prompt return to the original laboratory at the completion of review or additional testing. This does not apply to spare slides or recut slides upon which additional testing was performed, which should normally be retained in the laboratory performing the additional testing.
- Laboratories performing additional review or testing on any referral specimen must provide a copy of any report to the original laboratory to ensure continuity of the medical record.

Key Functional Relationships

Internal Relationships

Collection Services has a close clinical relationship with Specimen Reception. However, it does not need to be immediately proximal to the Specimen Reception or any other pathology function if patient-centred care considerations outweigh proximity (collection services must be close to outpatient public access/parking/ pickup/drop-off). There are other mechanisms such as pneumatic tubes that can reduce the need for close proximity.

Specimen Reception will be a part of the Pathology Core Laboratory services in the new facility along with (automated) Chemical Pathology, (automated) Haematology, and (automated) Immunology/Infectious Immunoassay, as one of its main future functions will be loading and unloading the tracking system.

External Relationships

Collection Services is the most outward facing department of ACT Pathology. It works with all CH departments, other CHS services, private health service providers, as well as pathology laboratories outside of CHS. Collection Services is strategically positioned to impact ACT Pathology's reputation and reflect 'customer needs'.

Specimen Reception is to be closely linked with courier services.

33. Australian Commission on Safety and Quality in Health Care, Requirements for the Retention of Laboratory Records and Diagnostic Material, Tier 3B Document, Ninth Edition 2022, available at https://www.safetyandquality.gov.au/sites/default/files/2022-04/retention_standard_ninth_edition_2022.pdf.

Management and Operational Support Services

Hours of Operation

Pre-Analytics services at the new Pathology facility will operate 24 hours a day, 7 days a week and 365 days a year, with reduced resourcing after-hours and weekends[34].

Collection services may also be offered outside of this building, if this is the case, hours of operation of this (other collection) service will be in line with the building and staff arrangements.

Service Integration and Collaboration

As noted above, Pre-Analytics is the 'front door' of the pathology service, and always available at the hospital site to receive specimens from CH, other hospitals and other collection sites across the ACT.

An important current and future function of the Pre-Analytics services is the capacity to further develop and maintain the market share for pathology services, which means:

- Maintaining its availability;
- Maintaining and improving its collaboration with community referrers and its responsiveness, including the timely collection of specimens; and
- The corresponding need for timely testing and reporting of results that is the responsibility of the Pathology Core Laboratory and each department.

  This also means having compatible ICT platforms for receipt of referrals and for reporting results in a timely manner: a core requirement of current and future Pathology services.

Major Equipment List

Current major equipment for Collection Services and Pre-Analytics services is detailed in the Appendix. This list is generated from a combination of ACT Pathology's equipment audit (in black), as well as other sources including NATA accreditation documents and department walk-through.

This list is generated from a combination of ACT Pathology's equipment audit (in black), and other sources including NATA accreditation documents and department walk-through.

Table A9-1 and Table A9-2 includes but is not exclusive to analysers and mixers, incubators and imaging systems, fridges and freezers, heat plates, centrifuges, and page writers.

Workforce Model

The workforce model[3536] determines the effectiveness of clinical capability of Pre-Analytics services. It is both the number of FTE as well as how staff are organised to meet demand in a timely manner that will be important to the viability of pathology as a business unit.

Current staffing levels provided in tables below, and total 99.1 FTE.

34. ACT Pathology, 02508 02501 86751 aid.
35. ACT Pathology, SR Staff List - January 2023
36. ACT Pathology, January 2023 Customer Service Staff List.

Table 7-5: Staffing by Workforce Category, Collection Services

Staff Category	Headcount	FTE
Customer Services Manager	1	1.0
Collections Manager	1	1.0
Collections Educator	1	1.0
Customer Liaison Officer	1	1.0
Receptionists	21	16.0
Phlebotomists	53	39.5
Pathology Courier	15	8.6
Total	93	68.1

Table 7-6: Staffing by Workforce Category, Specimen Reception

Staff Category	Headcount	FTE
Manager	1	1.0
Senior Technical Officers	5	5.0
Team Leaders	4	4.0
Technical Officers	28	21.0
Total	38	31.0

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

The Future State

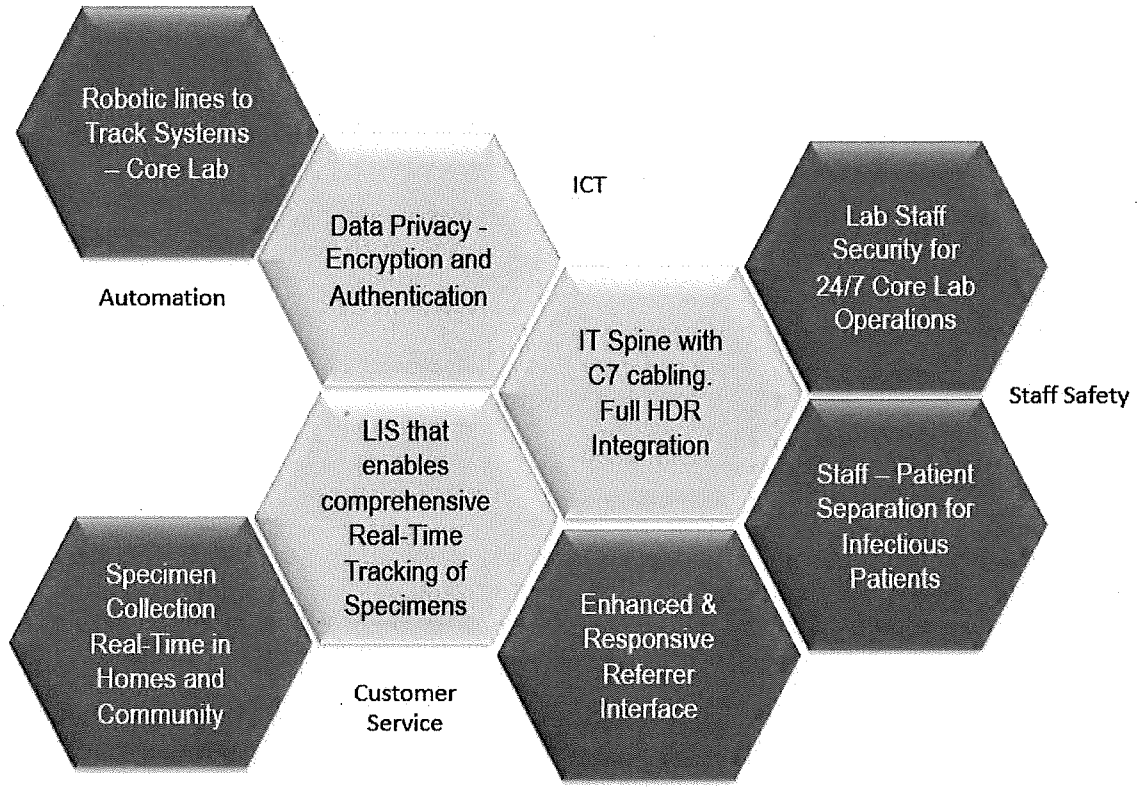
It is proposed that the current traditional Pre-Analytics model would be progressively developed to a fully digital service.

Ideally, there would be further automation of collection and reception of specimens, thereby increasing operational efficiencies and reducing risks associated with specimen identification and tracking.

The design of the Pre-Analytics area would effectively integrate Pre-Analytics with the Core Lab to maximise operational efficiencies.

Over time, this is expected to enable the enhanced automation, a robust ICT spine, enhanced customer service, and staff safety, as identified in Figure 7-8 below.

Figure 7-8: Future State for Pre-Analytics



7.9.2. Anatomical Pathology

Scope of Service

Test Volumes

Anatomical Pathology (AP) performs approximately 30,000 tests annually and is considered one of the most labour-intensive disciplines. The bulk of the testing is histology, which accounts for approximately 75% of the workload. The breakdown of testing, section and volume is provided Table 7-7 noting a slight decline year-on-year, which is most likely related to COVID.

Table 7-7: Anatomical Pathology Test Volumes – 2019-20 to 2021-22

Year	Histology	Cytology	Immuno-histochemistry	Perinatal Autopsies	Total
2019/2020	Not known	Not known	Not known	Not known	34,265
2020/2021	25,106	7567	Not known	95	33,157
2021/2022	22,507	7237	Not Known	77	30,221

Specialty Scope

AP is a specialty of pathology that involves the study of human organs and tissues and has a large role in cancer diagnoses. The tissues examined usually include biopsy material taken

from a patient in the operating theatre, on the ward, outpatients or during autopsy, and allows clinicians to give the most appropriate advice and treatment to patients[37]. A significant numbers of referrals also come from external specialists and GPs.

AP has roles in the following areas, noting the most significant volumes of work are for "tissues of living patients"[38]:

- Determining the cause of disease;
- The effect(s) these diseases have on the body and specific organs or tissues;
- The choice of treatment to be given;
- Prediction of prognosis; and
- Determining cause of death.

There are three sub-divisions within anatomical pathology; histology, cytology and mortuary services[39].

Histology

Histology focuses on microscopic structure of tissue obtained from biopsies or surgical procedures, processed (see below) and then examined by an anatomical pathologist under a microscope. There are several important components of histology that impact on the Service Model and the design of future AP space.

Immunohistochemistry (IHC) is a form of specialised staining employed on both histology and cytology samples. IHC uses antibodies to detect specific antigens in tissue samples and provides information about the location and intensity of antigen expression, giving a more detailed and specific analysis than traditional histology. This includes tumour markers (proteins) that are overexpressed in certain types of cancer (like HER2/neu in breast cancer), amongst many others.

Cytology

Cytology examines cells or cluster of cells under a microscope. Cytology includes examinations most often related to body fluids, cervical screening tests and fine needle aspirations. Cytology scientists attend many interventional radiology procedures to provide on-site rapid assessment of samples for diagnostic adequacy.

Mortuary services

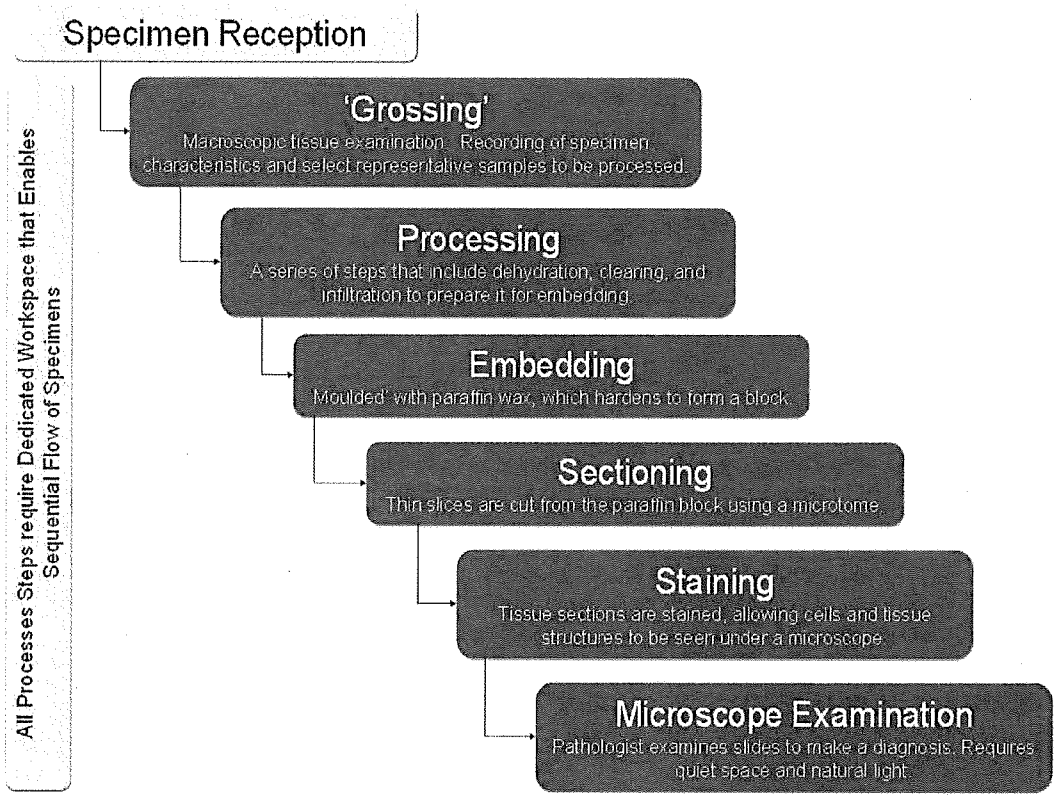
See section 8.

Specimen Pathway

Following receipt and registration of specimens (from Pre-Analytics), processes in AP follow a generally linear flow, but with recursive loops through parts of the process if additional work or stains are required. There are slightly different pathways for each of the units as indicated in the following schematic diagram.

37. NSW Health Pathology, Clinical Services Plan 2019 – 2025 Version 2:2021, https://pathology.health.nsw.gov.au/wp-content/uploads/2022/10/Clinical-Services-Plan.pdf
38. NSW Health Pathology, Clinical Services Plan 2019 – 2025 Version 2:2021, https://pathology.health.nsw.gov.au/wp-content/uploads/2022/10/Clinical-Services-Plan.pdf
39. Note Mortuary Services is detailed in section 8.

Figure 7-9: Unidirectional Specimen Flow for Histology



All findings/reports - including diagnosis and recommendations for treatment and/or management - are then documented, which is the principal means of communication with other clinicians involved in relation to overall patient care and management.

After analysis, specimens must be stored for a period of time (before disposal) based on CHS policies and statutory requirements. Disposal is similarly governed by policy and regulation/protocols, as biohazardous waste.

It is evident from the above description that AP requires space for receiving and managing/storing and processing a large variety of tissue types. Each of the stages of tissue examination requires dedicated space to ensure effective management and control of the tissue. Each process is sequential requiring the organisation of the histology unit to be established in a unidirectional and logical flow sequences.

Many of the process steps are currently manual but with an increasing propensity to automate most of these manual steps.

The pathologist may request additional sectioning and staining (including immunohistochemistry or in situ hybridisation) in order to make a diagnosis (looped workflow).

In some cases, specimens are sent fresh (rather than in formalin) for frozen section examination. Fresh tissues are also triaged and divided for examination by multiple other departments (for example, lymph nodes for Microbiology and Flow cytometry as well as Histology).

Triaging of samples is a large component of AP, requiring a close collaboration between scientists and pathologists. Close proximity is therefore essential.

For Cytology. the processes are a truncated version of Histology.

Specific Design Elements for Anatomical Pathology

Space and Zoning

Operationally, AP and Diagnostic Genomics (DG) may be managed as a single department. The closer working relationship will provide an opportunity to better leverage new technologies (genomics and imaging in particular) and the evolving, closer professional relationships that are already emerging

AP site visits demonstrated that, new laboratories, even after a relatively short period of time (e.g. 5 years) outgrow the space. This is due to the high level of manual labour, especially in areas such as cut up grossing.

As workloads increase, space requirements also increase due to additional staff required. It is therefore critical to provide adequate expansion space for AP to ensure ACT Pathology can keep pace with future clinical requirements.

AP registrars with be located in a dedicated space to allow for their workstations/microscope, unlike registrars of other disciplines.

Other design considerations for AP include the following:

- *Modularised functions and adjacencies* of the following functions within AP that enable efficient work flow;
- *Reception and Specimen Accessing* Area: this is where specimens first arrive. The area should be designed to log, label, and sort specimens and route them to the appropriate next stage. It should have computer terminals for logging specimens and adequate storage for specimen containers;
- *Grossing Area*: this area is dedicated to the examination and dissection of large tissue samples. It should be equipped with adjustable-height tables, good lighting, and necessary tools. Ventilation is crucial due to the use of fixatives like formalin.

  Some labs utilise downdraft tables to evacuate fumes. It is recommended that ventilation specialists be consulted for the final solution design noting that formalin and xylene fumes are heavier than air and tend to be present in higher levels closer to the floor and benches. This zone may need to be close to the imaging device (Faxitron) if samples require X-rays before dissection, as well as cassette printers for voice recognition dictation;
- *Processing Area*: tissue samples are processed to remove water and infiltrate them with paraffin wax. Automated tissue processors are commonly used. Given the use of solvents like xylene, ventilation and chemical fume hoods are essential as well as other ventilation systems, note this area should not be part of an open plan lab as a result;
- *Embedding Area*: after processing, tissues are embedded in paraffin blocks. This zone requires embedding centres, which are heated workstations designed for this purpose. Typically, this is a manual area that design can underestimate growth requirements and not allocate enough space for addition of future workstations. Close proximity to the processing area can enhance workflow efficiency;
- *Sectioning Area*: paraffin-embedded tissues are sectioned using microtomes to create thin slices suitable for microscopy. This area requires adequate bench space for microtomes, storage for blocks awaiting sectioning, and a setup for floating out and

mounting sections onto slides. It should also be free from drafts and not located within main thoroughfare;

- *Staining Area*: once sectioned, tissues are stained to highlight different structures. Automated and manual staining stations are set up here. The area should be designed to manage the chemical reagents used for staining, with chemical storage and waste disposal considerations;
- *Slide Scanning* (Whole Slide Imaging): at this stage, before a pathologist examines the slide under a traditional microscope, the slide can be scanned to produce a high-resolution digital image[40]. This digital slide can be viewed on a computer monitor, allowing for zooming in or out, much like using a microscope. Digital annotations and measurements can be made directly on the digital image;
- *Microscopy*, diagnosis and reporting: pathologists (usually in individual office spaces) make a diagnosis using either the traditional microscope or the digital image, depending on their preference and the infrastructure available. Digital images allow for easy sharing and help to facilitate consultations with other experts or multidisciplinary team members. The design should prioritise ergonomic considerations, given the long hours pathologists may spend at the microscope. It should be quiet, with adjustable lighting to reduce eye strain; and.
- *Special Stains and Immunohistochemistry* Area: some specimens require special stains or IHC for accurate diagnosis. This zone should be equipped with the necessary equipment, reagents, and fume hoods.
- *Electron Microscopy (EM):* this specialised technology employs ultrathin sections of tissues embedded in hard resin and examined at a cellular or subcellular level. It is particularly relevant to the examination of renal biopsies. Electron Microscopy requires draft and vibration free areas for section cutting, and a stable platform free from vibration and electromagnetic fields. A separate sample processing area is required due to the nature of chemicals used.

Ventilation and Air Quality

The design will include following considerations for air quality and ventilation, including:

- Proper ventilation is required in histology laboratories to reduce the exposure to chemicals by ensuring those lingering in the air will leave the room without circulating back in;
- SafeWork Australia describes the risk management approaches with which organisations (including laboratories) must comply, such as:[41]
  - Formaldehyde has a workplace exposure standard of 1 ppm averaged over eight hours; and
  - Formaldehyde also has a secondary 15-minute (time weighted average) exposure standard of 2ppm; and
  - Risks to health and safety from exposures to hazardous chemicals must, so far as is reasonably practicable, be eliminated.
- In addition to solutions to manage ventilation, there will need to be systems to regularly monitor air quality which may be facilitated with an inbuilt design:

40. However noting that this is additive technology, which means everything else has to be done perfectly prior to this to get the best quality image.
41. NSW Government, 2017, Workplace exposure standards and air monitoring - WHS Regulation 2017, Formaldehyde - technical fact sheet, available at https://www.safework.nsw.gov.au/resource-library/hazardous-chemicals/formaldehyde-fact-sheets/formaldehyde-technical-fact-sheet#:~:text=Formaldehyde%20has%20a%20workplace%20exposure,average)%20exposure%20standard%20of%202ppm

- The design will need to balance the benefits of room separation/isolation versus workflow efficiencies of a more open planned space. Key factors will be the extent to which ventilation systems can operate effectively in more open spaces;
- Bench and floor scavenging is required in laboratory areas employing solvents and formaldehyde;
- No recirculation of air on the floor; and
- Provision of sufficient clean air return.

Lighting

- Gross examination:
  - These areas require good general illumination. A common recommendation is between 500 and 1000 lux, but this can vary based on the specific task;
  - More detailed tasks might require higher illuminance;
  - Microscopy areas, while primarily dependent on the microscope's internal illumination, should also have comfortable ambient lighting to reduce eye strain, typically around 500 lux. Overhead lighting should be designed to minimise shadows, which could obscure details of the specimen;
  - The CRI is a measure of a light source's ability to reveal the true colour of objects compared to a natural light source. A higher CRI (close to 100) is desirable in pathology labs since accurate colour differentiation is crucial, especially during gross examination;
  - It's also essential to minimise glare, which can cause eye strain, especially during prolonged observations. *Matte finishes on benches and walls* can help, as can the strategic placement of light fixtures.
- Pathologist offices
  - Adjustable lighting can be beneficial, allowing pathologists to increase or decrease light intensity based on the task or personal preference. Dimmable lights or task-specific lighting solutions can offer this flexibility which will be important in office spaces as well as where microscopes are used for group sessions;
  - When using microscopes, it's crucial to have a consistent and high-quality light source. LED-based illumination systems on microscopes offer consistent, bright light with good colour rendition;
  - Soft ambient lighting in areas where pathologists read slides or write reports can help reduce eye strain and fatigue; and
  - Employment of the 20:20:20 rule can also assist in avoiding eye strain (look 20 feet away for 20 seconds every 20 minutes).

Temperature

As per "General Design Principles" in section 7.8.

Acoustic Control

The following noise related considerations should be addressed when designing an AP laboratory:

- Equipment Noise – equipment like microtomes, centrifuges, automated staining machines, and tissue processors can generate significant noise. It's essential to position such equipment in areas where they cause minimal disruption and, if possible, enclose or insulate them to minimise noise;
- Ventilation and HVAC Systems - these systems are vital for safety and comfort but can be noisy. Quieter HVAC units, sound traps, or silencers, and ductwork can be considered;
- Acoustic Zoning – different areas of the lab will have different noise levels and requirements. For instance, microscopy rooms should be quieter than areas where equipment runs frequently. Proper zoning can help segregate these areas;
- Acoustic Materials – implement sound-absorbing materials in the lab's design. This includes acoustic ceiling tiles, wall panels, and flooring that dampens noise;
- Workstations and Layout – the arrangement of workstations can influence noise propagation. Open lab designs might be collaborative, but they can also spread noise more easily. Considerations should be made to strike a balance between open spaces and compartmentalised areas;
- Doors and Partitions – acoustically rated doors and partitions can help reduce noise transmission between different sections of the lab. This is especially crucial for rooms where precision work or delicate procedures are conducted;
- Flooring Materials – rubber or certain vinyl tiles can dampen the sound compared to hard tiles or concrete;
- The way specimens, slides, and tools are stored and handled can produce noise. Soft-close drawers, padded storage racks, and careful handling procedures can minimise these incidental noises; and
- Buffer Spaces – utility rooms, storage areas, or corridors could be designed in to act as buffer spaces, absorbing and preventing noise from traveling between different areas of the lab.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Storage requirements for an Anatomical Pathology department include:

- **Reagent Storage**: some can be kept at room temperature and some needs to be refrigerated (2-8 degrees Celsius) within the Centralised Walk-in Cold Room and Freezer Room;
- **Specimen Storage**: specimens will be kept in the Centralised Walk-in Cold Room and Freezer Room, or simply a well-ventilated space next to the AP lab for formalin-fixed specimens. Note disposal tissues are to be stored in the freezer room, and cytology specimens are to be stored in a refrigerated storage for two weeks.

- **Slide storage**: refer to appendix A5 for blocks and slides storage considerations;
- **Paraffin block storage**: refer to appendix A5 for blocks and slides storage considerations;
- **Chemicals Storage** (solvents and flammables);
- **Equipment Storage**: some laboratory equipment (such as analysers) may be stored away when not in use within the Centralised Equipment Store;
- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage**: Waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both immediate waste management needs and broader floor-wide requirements are adequately addressed.

Anatomical Pathology also need to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

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 for Anatomical Pathology accords with section 7.8.2 unless otherwise specified below[42].

Table 7-8: Minimum Retention Times for Anatomical Pathology

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-6-1	Copy of original report, or ability to reprint the information content of an original report	10 years or 7 years from the age of majority for minors (whichever is the greater)
3-6-2	Slides: ▪ Sections of fixed tissue preserved in mounting medium ▪ Sections of fixed tissue assessed by FISH ▪ Sections of unstained, fixed tissue not in permanent mounting medium (unstained spares) ▪ Sections of unfixed tissue not in permanent mounting medium (including immunofluorescence slides)	10 years (where the diagnosis is made on the slide); otherwise 4 years if the diagnosis is made on a digitised image 6 months 1 month See Table 3-2, row 3-2-7
3-6-3	Digital images used for diagnostic analysis	10 years (where diagnosis is made solely on the image); otherwise see Table 3-2, row 3-2-6

42. Australian Commission on Safety and Quality in Health Care, Requirements for the Retention of Laboratory Records and Diagnostic Material, Tier 3B Document, Ninth Edition 2022, available at https://www.safetyandquality.gov.au/sites/default/files/2022-04/retention_standard_ninth_edition_2022.pdf.

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-6-4	Blocks: Tissue embedded in paraffin wax or any other permanent embedding medium, including for ultrastructural study	10 years[43]
3-6-5	Specimens for intra-operative frozen section diagnosis: ▪ The original sections used for diagnosis, preserved on slides in permanent mounting medium. ▪ Residual tissue from which the frozen sections were prepared, embedded in paraffin blocks. ▪ All other blocks of paraffin embedded tissue from the same specimen/s from which tissue has been selected for frozen section examination .	10 years[28]
3-6-6	▪ Frozen tissue blocks, including specimens for immunofluorescence studies	1 month at −70°C or lower
3-6-7	▪ Containers with no residual tissue ▪ Unblocked wet tissue from specimens removed at surgery	1 month from date of issue of report 1 month from date of issue of report

Table 7-9: Minimum Retention Times for Cytology

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-7-1	Copy of original report, or ability to reprint the information content of an original report	10 years or 7 years from the age of majority for minors (whichever is the greater)
3-7-2	Exfoliative non-gynaecological cytology and fine needle aspiration (FNA) slides and cell blocks	10 years[44]
3-7-3	Gynaecological (cervical) cytology slides	10 years
3-7-4	Residual specimens of sputum, urine and other body fluids following preparation of cytology slides	See Table 3-2, row 3-2-7
3-7-5	Specimens received in liquid-based fixative	1 month[45]
3-7-6	Digital images used for diagnostic analysis e.g. semi-automated Thin Prep screening images	6 years

Key Functional Relationships

Internal Relationships

Within the department, Histology, Immunohistochemistry/Special Stains, EM and Cytology should be located together, as a single coherent unit. This is the primary functional relationship for AP.

As the next most important relationship, AP should be located proximal to (or contiguous with) Diagnostic Genomics. Anatomical Pathology and Diagnostic Genomics will be managed as a single department in the future. The closer working relationship will provide an opportunity to better leverage new technologies (genomics and imaging in particular) and the evolving, closer professional relationships that are already emerging.

43. Where the report or specimen relates to a paediatric patient, the retention period for anatomical pathology and cytology specimens should be the greater of 10 years or 7 years from the age of maturity..
44. Where the report or specimen relates to a pediatric patient, the retention period for anatomical pathology and cytology specimens should be the greater of 10 years or 7 years from the age of maturity.
45. Unless otherwise stated in the Requirements for laboratories reporting tests for the National Cervical Screening Program.

Anatomical Pathology site visits demonstrated that, new laboratories, even after a relatively short period of time e.g., 5 years, outgrow the space. This is due to the high level of manual labour, especially in areas such as cut up grossing. As workload increases, space requirements also increase due to additional staff and workplace. It is therefore critical to over spec the Anatomical Pathology laboratory to ensure ACT Pathology can keep pace with future clinical requirements. AP registrars with be located in a dedicated space to allow for their workstations/microscope, unlike registrars of other disciplines.

There is no requirement for Mortuary Services or the Pathology Museum to be collocated with the other AP units, but there will be a strong association between these services.

External Relationships

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

- Anatomical 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.

Management and Operational Support Services

Current Location

AP is currently located on Levels 1, 3 and 5, Building 10, CH as indicated:

- Histology (Level 3);
- Immunohistochemistry (Level 5);
- Cytology (Level 3); and
- Mortuary services (Level 1).

Additionally, archived 'slides and blocks' are stored in the basement primarily due to the weight of the blocks and also due to storage constraints on level 3 where a smaller store area is kept. The laboratory is required to retain slides and blocks generated as part of the diagnostic process for as many as 28 years.

The locations indicate the that the nature of the department is too fragmented and operates inefficiently from over-crowded spaces. The FB proposes a consolidation of AP, an increase in area, and with strong connection with DG.

Hours of Operation

Usually, AP operates five days a week Monday to Friday, with laboratory staff present from 5.30am to 8.00pm. Additional rostered shifts occur during extended hours, weekends and Public Holidays i.e., Easter and Christmas-New Year break.

AP supplements the usual operating times with a 24/7 out-of-hours on-call service for emergency/urgent tissue analysis, which includes:

- A pathologist on-call, out-of-hours;

- Scientists on-call to assist pathologist with any Frozen Section and Renal Biopsy which occur after-hours, as well as attending to the laboratory if processor and/or other instrumentation issues arise.

Major Equipment List

Current major equipment for AP is detailed in Appendix Table A9-3. The department is regularly adding new tests or changing technology, current range includes but is not exclusive to tissue Processors, Roche VENTANA HE 600 system, Roche BenchMark Special Stains system, Spectra Stainer, Embedding Centres, Hologic T/P processor, Elitech Aerospray PAP Stainer, Pixarray Imager, Leica Microtomes (Histology), fridges/freezers, centrifuges/cytofuge, ovens, cassette writer, microscopes, balances, safety and biohazard cabinet, and water baths.

See Table A10-1 for future equipment list for all departments.

Workforce Model

The workforce model reflects the clinical capability level of AP, with staffing levels provided in Table 7-10 below. The staffing complement includes clinical director, anatomical pathologists, registrars, chief scientist, administration support, laboratory/pathology scientists and technical officers.

Table 7-10: Staffing by Workforce Category, Anatomical Pathology[46]

Category	Section/Unit	Head Count	FTE
Director	All	1	1
Deputy Director	All	1	1
Pathologists	All	13	11.1[47]
Registrar	All	7	6.4[48]
Chief Scientist	All	1	1
Scientific Supervisor	AP	1	1
Scientific Supervisor	Cytology	1	1
Senior Scientist	Histology	2	2
Senior Scientist	IHC	1	1
Senior Scientist	Cytology	1	1
Base Grade Scientist	Histology and IHC	13	11.4
Cytoscreener	Cytology	6	5.8
Technical Officer	Histology and IHC	4	4
Administration Support	All	4	4

46. ACT Pathology, March 2022, ASSESSMENT INFORMATION DOCUMENT SUPPLEMENT – NCSP.
47. There are 11.1 FTE pathologists plus an ANU-funded pathologist for running the undergraduate pathology course, this ANU funded position is not part of the FTE count for this table.
48. There is a 0.2 FTE honorary registrar, not part of the FTE count for this table.

Category	Section/Unit	Head Count	FTE
	Current Total	56	51.7

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

A Future State

The future for AP is relatively clear. It incorporates a service model that has very significant investment in automation, particularly WSI, and embracing of the omics revolution as proposed in section 7.5. The future state has a significant elimination of manual processes.

Whole Slide Imaging and Artificial Intelligence

It is certain that AI and machine learning will assist AP with the automated evaluation of *digital slides*, improving accuracy, and reducing the time taken for manual diagnosis. This will reduce the workloads for Anatomical Pathologists.

The evolution to AI will be incremental. In the first instance, AI will be used as a clinical decision support tool. Nevertheless, even making the strategic decision to use slide imaging as a decision support tool for AP, it will require significant investment in the technology.

The technology currently exists and will continue to improve over time. *Whole Slide Imaging and Digital Pathology* technology can create digital slides that can be viewed on a computer, eliminating the need to manually handle glass slides. The digital images are easily shared and stored but will require additional digital storage capacity

Digital technologies in pathology are rapidly moving beyond imaging to guiding diagnosis. Some manufacturers are developing technology, dyes and analytic platforms to meet future demand and improve patient outcomes using nanotechnology. These new technologies are mostly replacing the staining technology and the scanner for new types of digital immunohistochemistry.

Integrated Automation and Tracking Solutions

While many steps of the pathology workflow are already automated, there is potential for even more automation using advanced robotics.

There are current automated processes for AP that are not yet operating at ACT Pathology. This is where 'leap frogging' investment is a key consideration. Indicatively:

- For histology and IHC workflow, individual components and workstations could become more automated, which highlights the need to design for open spaces as well as structural design of flooring to handle additional machinery and its weight;
- *Processing*: Automated tissue processors are a crucial part of the workflow in many labs including ACT Pathology. Future advancements in processing could involve more efficient or rapid methods, or using alternative chemicals that are safer or more environmentally friendly but will mostly be replacing equipment with similar sized equipment;
- *Embedding*: Automation of the embedding process is already available for simple specimen transfers and with advancements in robotics and machine learning, there will be more automated embedding systems in the future;

- *Sectioning*: Sectioning is currently primarily a manual task, as it requires a high degree of precision and skill. Automated microtomes are available with automatic, semi-automatic, and manual options available to meet a variety of circumstances and it's possible that with advancements in robotics and machine vision, more automated sectioning could become possible. Despite this advancement, however, scientists will still be just as needed and wanted as they will need to manage this process, with the automation part acting predominantly as a way to reduce manual labour and hence prevent repetitive strain injury (RSI); and
- *Staining*: Automated stainers are already widely used in histopathology labs. Advancements will be the replacement of current technology with new technology that offers more and/or better features.

Omics and individual therapies

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. *Perhaps more relevant, Diagnostic Genomic, and the 'omics revolution' for personalised diagnoses and treatments will become core business for ACT Pathology.*

7.9.3. Chemical Pathology

Chemical Pathology is the largest of the pathology departments by volume of testing. Examinations are broadly applicable to detect substances in blood and body fluids, measures cancer markers, hormones, poisons, and therapeutic and illicit drugs.

Scope and Capacity of Services

Chemical Pathology operates as a Level 6 laboratory[49].

Test Panel Volumes

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

Table 7-11: 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

Specialty Scope

Chemical Pathology comprises four distinct sub-sections:

[49] 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

- Routine Chemistry;
- Endocrinology;
- Special Chemistry; and
- Point of Care Testing (POCT).

Routine Chemistry (in Core Lab)

Routine chemistry focuses on the analysis of bodily fluids such as blood, urine, and cerebrospinal fluid. It involves the measurement of various chemical components and biomarkers present in these fluids to evaluate the normal functioning of organs, diagnose and monitor diseases, assess and monitor treatment efficacy, and detect abnormalities or imbalances within the body. The tests for routine chemistry are typically automated. Chemical pathology tests are expected to be part of the routine 'Core laboratory' processes.

Common tests include:

- Blood glucose tests to diagnose and monitor diabetes;
- Lipid profiles to assess cardiovascular health and disease risk;
- Liver and kidney function tests to detect conditions such as hepatitis, cirrhosis, and renal failure;
- Electrolyte panel to assess the body's fluid balance, acid-base balance, and overall electrolyte status.

These functions would be undertaken in laboratories, including levels 3 to 6 clinical capability.

Endocrinology (in Core Lab)

Endocrinology focuses the study of endocrine disorders, including:

- Hormone assays;
- Metabolic markers;
- Bone markers;
- Steroid hormone analysis; and
- Pituitary hormone assessment.

Endocrinology involves the integration of laboratory test results with other clinical findings to help diagnose and manage endocrine-related conditions. Endocrinologists, along with chemical pathologists, registrars and laboratory scientists, collaborate to interpret these results accurately and provide optimal patient care. Endocrine pathology would be typically undertaken in Level 3 to 6 laboratories.

Special Chemistry

Special Chemistry focuses on advanced and specialised laboratory testing for the diagnosis and management of complex or rare diseases. It involves the analysis of specific analytes, biomarkers, or metabolic pathways that may not be included in routine chemistry panels. Special chemistry would only be undertaken in a Level 6 laboratory.

Point of Care testing

POCT is the performance of specific laboratory tests outside the traditional laboratory setting using portable or handheld devices, which typically include but are not limited to:

- Glucose monitoring;
- Coagulation monitoring;
- Electrolyte analysis;
- Cardiac markers;
- Haemoglobin analysis; and
- Lipid profiling.

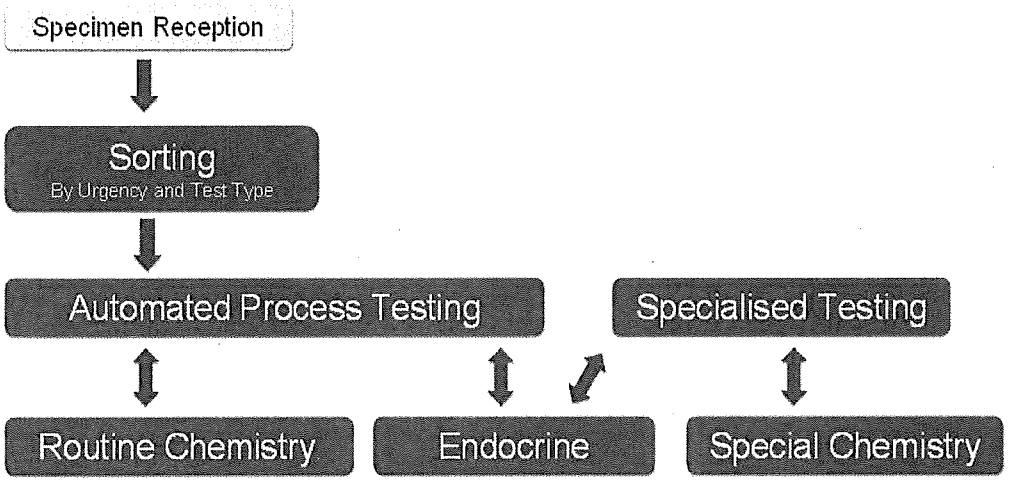
POCT enables immediate, real time test results, convenience, and the ability to make prompt clinical decisions at the patient's bedside, clinic or even patient's home. However, these devices also come with limitations in terms of accuracy, precision, and the range of tests they can perform compared to central laboratory analysers.

Specimen Pathway

The specimen pathway for Chemical Pathology is described below.

Specimens are received in specimen reception as for all specialty areas. The sample then typically follows the steps in Figure 7-10.

Figure 7-10: Specimen Pathway for Chemical Pathology



The pathway is multi-directional following the automated testing step where sample also have specialised tests or second sample tests or are transferred to another department for further testing.

All findings/reports - including diagnosis and recommendations for treatment and/or management - are then documented, which is the principal means of communication with other clinicians involved in relation to overall patient care and management.

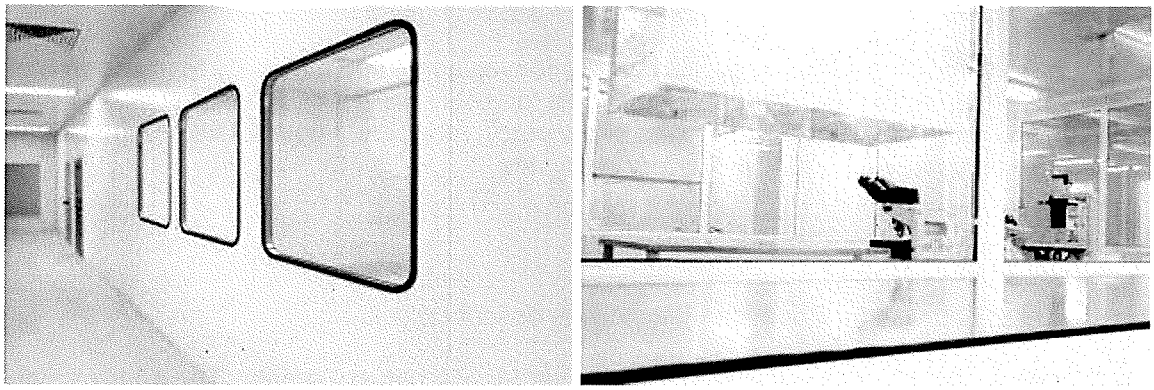
After analysis, specimens may be stored for a period of time (before disposal) based on CHS policies and statutory requirements. Disposal is similarly governed by policy and regulation/protocols, as biohazardous waste.

Specific Design Elements for Chemical Pathology

Space and Zoning

The chemical pathology section is part of the Core laboratory and while most of the chemical pathology section will be better suited in an open plan environment, mass spectrometry may be located separately inside a controlled environment. Ideally the design would ensure that staff are visible to supervisors and remain connected to the rest of the team (see Figure 7-11).

Figure 7-11: Some Design Examples for Mass Spectrometry



Ventilation and Air Quality

The design will include the following considerations for air quality and ventilation:

- The non-automated section of chemical pathology segment includes mass spectrometers. Mass spectrometers are sensitive instruments that require specific air quality and environmental conditions to function optimally. These are typically housed in enclosed rooms;
- Temperature Stability: the laboratory room temperature should be stable, typically the same as the other parts of the chemical pathology/core section i.e. between 20-25°C. The temperature stability ensures consistent performance and calibration of the instrument. It's essential to monitor and maintain temperature within specified limits as prescribed by the mass spectrometer's manufacturer;
- Humidity Control: humidity should be controlled, with levels typically kept below 60% relative humidity. Excess moisture can influence ionisation processes, potentially affect the equipment's internal components, and lead to corrosion over time;
- Vibration and Mechanical Stability: mass spectrometers, especially those with high-resolution capabilities, can be sensitive to vibrations. The laboratory should be isolated from sources of vibration or equipped with vibration-damping tables or platforms. Sources of nearby vibration could include the robotic track system;
- Clean, Dust-Free Environment: dust and other particulate matter can interfere with the instrument's operation. It's beneficial to have air filtering systems in place to ensure the lab remains as dust-free as possible but may also be kept in a separate room;
- Gas Supply: many mass spectrometers, especially those coupled with chromatography systems, require high-purity gases (e.g., helium, nitrogen, argon). It's essential to ensure a consistent and uncontaminated gas supply. Gas cylinders should be stored safely, and appropriate gas purifiers should be in place;
- Ventilation and Fume Hoods: some sample preparation steps might involve volatile or hazardous chemicals. Proper ventilation and fume hoods should be available to ensure the safety of laboratory personnel and to prevent contamination of the laboratory atmosphere;

- Electrical Supply: stable and clean power is essential. Power fluctuations or interruptions can affect mass spectrometer performance or even cause damage. UPS or backup power systems might be necessary, especially for critical applications;
- Magnetic Fields: for mass spectrometers that operate based on magnetic principles (e.g., magnetic sector instruments), it's crucial to keep the instrument away from any external magnetic fields or sources of electromagnetic interference i.e. robotic tracks; and
- Airborne Contaminants: laboratories should be kept free from volatile organic compounds (VOCs) or other potential sources of chemical interference, as these can influence the mass spectrometer's readings.

Lighting

As per "General Design Principles" in section 7.8.

Temperature

- For the macro environment, this should be 20-25°C like the rest of the laboratory. The department should have a controlled room temperature to ensure optimal operation of automated analysers. The temperature should be maintained within a specific range recommended by the manufacturers of the instruments; and
- In a micro setting, refrigerated environments need to be 2-8°C and freezer temperatures need to be -20°C which can be accommodated by the Walk-in Cold Room and Freezer.

Acoustic Control

Automated robotic track systems in chemical pathology laboratories, and analysers, can produce noise. The level of noise depends on the specific system, its components, and the operational state.

Factors contributing to noise can include:

- Movement of the Robot Arms;
- Conveyor Systems;
- Centrifuges and Decappers; and
- Alerts and Alarms.

Careful design of the laboratory can make a difference. Keeping the Total Laboratory Automation (TLA) system centralised and away from workstations or areas where staff spend prolonged periods can help. Other considerations can include:

- Acoustic Barriers or other acoustic dampening solutions; and
- The use of vibration-dampening floor materials can reduce noise transmission, especially if the system is on an upper floor.

The laboratory can also help to reduce noise by ensuring that the system is well-maintained.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Chemical Pathology, Haematology and Immunopathology departments operate as part of a broader core laboratory and in an open plan design. The types of storage required need to include:

- **Reagent Storage**: some can be kept at room temperature and some needs to be refrigerated (2-8 degrees Celsius) within the Centralised Walk-in Cold Room and Freezer Room;
- **Specimen Storage**: specimens will be kept in the Centralised Walk-in Cold Room and Freezer Room;
- **Consumable Storage:** there is also a need for free standing fridge/freezers for the storage of regular use consumables;
- **Equipment Storage**: some laboratory equipment (such as analysers) may be stored away when not in use within the Centralised Equipment Store;
- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage**: Waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both immediate waste management needs and broader floor-wide requirements are adequately addressed.

The non-automated spectrometry section within the department may necessitate the use of gas cylinders. This demands particular design measures to safely secure these cylinders and safeguard the surrounding area.

Chemical Pathology also need to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

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 for Chemical Pathology accords with Table 7-4 unless otherwise specified below in Table 7-12[50].

50. Australian Commission on Safety and Quality in Health Care, Requirements for the Retention of Laboratory Records and Diagnostic Material, Tier 3B Document, Ninth Edition 2022, available at https://www.safetyandquality.gov.au/sites/default/files/2022-04/retention_standard_ninth_edition_2022.pdf.

Table 7-12: Minimum Retention Times for Chemical Pathology

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-10-1	Serum, plasma, other body fluid and tissue specimens	As per Table 3 2, row 3-2-7

Key Functional Relationships

Internal Relationships

Chemical Pathology has a close clinical relationship with Specimen Reception (mainly due to volumes), Haematology and Immunopathology & Infectious Immunoassay (due to the move to automating as much of the analysis process as possible). This will include a direct pneumatic tube.

Specimen Reception, Automated Chemistry and Automated Haematology/transfusion will be joined by Automated Immunopathology & Infectious Immunoassay to form the **Core Laboratory**, as illustrated in Figure 7-3. Aspects of Microbiology and Molecular Pathology are increasingly becoming more automated and could also form part of the core laboratory in the future – These areas must be collocated in an open plan configuration as per the L2D functional designs

While the Chemical Pathology department manages both automated and manual testing, it is necessary that the automated processes are contiguous, and integral to the Core Lab.

External Relationships

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

- Chemical 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.

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

Management and Operational Support Services

Hours of Operation

Routine Chemistry and Endocrinology operates 24/7 every day of the year. The remainder of Chemical Pathology (that is, Specialised Endocrinology, Special Chemistry and POCT) routinely operate between 8.30am – 5.00pm Monday – Friday[51].

51. ACT Pathology, Chemical Pathology.

Major Equipment List

Current major equipment for Chemical Pathology is detailed in Appendix Table A9-4. The department is regularly adding new tests or changing technology. The current equipment includes:

- Routine Chemistry and Endocrinology: Abbott Pre-analytical track system, Abbott Alinity c/i modules, Roche E411, Diasorin Liason XL; Advanced osmometer Osmo 1, Wescor Chlorocheck.
- Special Chemistry: Shimadzu HPLC, Thermofisher Evolution 201 spectrophotometer, Thermofisher FTIR spectrophotometer, Shimadzu LC-MS;
- Point of Care Testing: Alere Affinion HbA1c analyser, Werfen Gem 5000 blood gas analyser, Abbott iSTAT; and
- General: centrifuges, balances, Labguard temperature probes, timers, pipettes, waterbath, temperature-controlled incubator, purified water system, biological safety cabinets, fume cabinet, fridges and freezers.

See Table A10-1 for future equipment list for all departments.

Workforce Model

The workforce model[52] reflects the clinical capability level of Chemical Pathology, with staffing levels provided in Table 7-13 below. The staffing complement includes clinical director, chemical pathologists, registrars, chief scientist, laboratory/pathology scientists and technical officers.

Table 7-13: Current Staffing by Workforce Category, Chemical Pathology

Category	Section/Unit	Head Count	FTE
Director	All	1	1
Pathologist	All	1	0.5
Registrar	All	1	1
Chief Scientist	All	1	1
Senior Scientists	Routine Chemistry	2	2
Base Grade Scientists	Routine Chemistry	15	12.68
Technical Officers	Routine Chemistry	2	2
Senior Scientist	Endocrinology	1	1
Base Grade Scientist	Endocrinology/	1	1
Senior Scientist	Special Chemistry	1	1
Base Grade Scientist	Special Chemistry/ Routine/Chemistry	1	1
Senior Scientist	POCT	1	1
Base Grade Scientist	POCT	1	1
	Current Total	29	26.18

52. ACT Pathology, Chemical Pathology.

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

Future State

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

7.9.4. Diagnostic Genomics

Diagnostic Genomics is a rapidly evolving area of pathology that has the potential to have significant impacts on the future development of medicine. DG is likely going to change the way we understand and manage cancer and disease-causing constitutional variants through diagnosis, screening, and monitoring. This will revolutionise disease diagnosis, tailored curative treatments, and clinical management based on each individual patient's genetic information.

At ACT Pathology, the DG laboratory initially operated as a cytogenetics lab, providing karyotype and Fluorescence In Situ Hybridization (FISH) services to various medical specialties, at which time only a small number of DNA extractions were performed manually. By 2000, the lab moved to its current location, initially equipped with very basic infrastructure and equipment, but experienced significant expansion and diversification over the 15 years from 2008 to 2023. During this period:

- The FISH service expanded to include analysis of paraffin embedded tumour samples from Anatomical Pathology;
- The number of DNA extraction requests increased from a handful to hundreds per year;
- The lab started performing multiple PCR-based assays, with specific PCR machines;
- Traditional karyotyping transitioned into molecular-based karyotyping using Single Nucleotide Polymorphism (SNP)s array technology, necessitating additional analytical software and scientists; and
- New technology, such as NGS has come to the fore, and is being developed for 2024/2025.

Demand has rapidly increased. The scale of operation, and the breadth of testing, has not been able to keep pace with the demand.

Scope of Service

Test Volumes

DG performs ~2,000 tests annually and is considered one of the smallest specialties. The noted decline in activity is principally due to COVID and higher levels of 'Refer Outs' (>2500, many of which will be performed in-house in the future with the development of NGS.

Table 7-14: Diagnostic Genomics Test Volumes – 2020-21 to 2022-23 (Projected)

Year	Diagnostic Genomics
2019/2020	2,131
2020/2021	4,597 (2,452 + 2,145) send outs
2021/2022	4,581 (1,978 + 2,603) send outs

Specialty Scope

Technology advances have merged molecular genetics and cytogenetic laboratories over time, into the area of genomics. As a discipline, there are three broad categories of genomic testing:

- **Cancer genomics**. This includes familial cancer predisposition testing; tumour profiling (e.g. solid tumours, haematological tumours), predictive selection of therapeutic cancer drugs, and monitoring of disease progression; and
- **Constitutional Genomics.** This includes inherited conditions (e.g. cystic fibrosis, haemochromatosis, population specific conditions), congenital disease diagnosis, pre-conception and post-conception screening, and post-natal genomic diagnostics (e.g. products of conception, fetal demise including post-mortem cases, newborn, and paediatric).

From the above potential scope of DG, ACT Pathology focuses predominantly on[53]:

- **Cancer diagnostic genomics** for haematological disorders and solid tumours utilising conventional karyotyping, FISH, single gene assays, and NGS; and
- **The investigation of fetal death** utilising SNP microarray, fertility investigations and rapid diagnosis of neonates utilising conventional karyotyping, and FISH.

Specimen Pathway

Typical genomic tests performed include[54]:

- Conventional Karyotyping (haematological and constitutional);
- FISH, including the analysis of formalin fixed paraffin embedded (FFPE) tissue, solid tumor (haematological and constitutional);
- Cryopreservation of cells;
- SNP Microarray (products of conception);
- DNA extraction and storage;
- Single Gene PCR Molecular Assays; and
- NGS (2024).

DG at ACT Pathology is currently modest, however, as a burgeoning specialty, there are active plans and considerable scope to invest in technologies and workforce to significantly develop this specialist field by 2025 and into the future. The area proposed for DG offers a considerable expansion.

Specimens are received in specimen reception as for all specialty areas.

The pathway requires close proximity to molecular pathology. To comply with regulatory requirements, the department also needs to include a separate clean room for PCR preparation noting separate isolated spaces are required to reduce risk of contamination of specimens.

Specific Design Elements for Diagnostic Genomics

The department **currently** comprises of:

53. ACT Pathology, Diagnostic Genomics.
54. ACT Pathology, Diagnostic Genomics.

- Office space which provides a quiet area for analysis;
- Main laboratory for cell culturing and harvest, banding, sample and reagent preparation; including PCR preparation and PCR amplification;
- Dark room for FISH analysis and automated slide scanning;
- DNA extraction; and
- PCR reagent preparation room for molecular assays.

Future Required Design Elements

Into the future, as DG will be managing testing of samples from AP, haematology, immunopathology and Pre-analytics, close working relationships will need to be established with all these departments to establish sample workflows and to better leverage new technologies.

As mentioned above, there will be **significant expansions** within Diagnostic Genomics in the near future, taking advantage of new technologies such as NGS-based tests on different sample types (including cell free DNA/RNA i.e. liquid biopsies), hence an expansion in the floor plate to accommodate this is critical.

DG utilises similar technologies and laboratory equipment as Molecular Pathology. Instead of duplicating laboratory space, DG and Molecular Pathology would benefit from being adjacent to each other to allow for the sharing of laboratory facilities (including equipment) and optimisation of space. The areas proposed to be shared would be DNA/RNA Amplification/Sequencing laboratories and could also include PCR setup rooms.

It would be challenging to design DG to be completely open plan given the requirements for isolated rooms to reduce contamination risk in accordance with regulatory guidelines. This includes but is not exclusive to PCR Amplicon and Reagent Preparation (which require positive pressured rooms), sample preparation (NGS/PCR), DNA/RNA amplification, DNA/RNA extraction (where a dedicated lab area is preferred), tissue processing (which comes with its associated fumes), and a dark room for fluorescence-based assays. There is also a requirement for some quiet space for quiet tasks such as software-based desktop analysis.

The immediate future state of the laboratory would be to ensure the PCR requirements meet all regulatory requirements, such as a separate clean room for PCR preparation to reduce risk of contamination.

Given the proximity to the Molecular Pathology department, consideration could be given to creating a central DNA/RNA Amplification/Sequencing room that meets the space requirements for both, but retains the same flow noting that this would be separate to the dedicated PC3 facilities.

Ideally, a PCR laboratory should have three rooms, each designed for specific tasks:

- The first room should be positive pressured and used exclusively for pre-PCR Amplicon and Reagent Preparation activities;
- The second room should be used for sample preparation, where air pressure is slightly positive to prevent aerosols from flowing in; and
- The third room should be a dedicated area for nucleic acid amplification and product analysis. Air pressure should be slightly negative to ensure that amplicon aerosols don't leave the room.

In the case that a three-room PCR laboratory is not feasible, the alternative is to set up 2 areas in the same room: pre-PCR Amplicon and Reagent Prep, and Sample Prep, but ensure they are as far from one another as possible.

The laboratory design must ensure **unidirectional workflow**, such that no materials or reagents used in the amplification and analysis areas can ever be taken into the pre-PCR space without a thorough decontamination. This means that dedicated equipment for each area is required, e.g., two different sets of pipettes.

This unidirectional workflow also applies to laboratory staff, where personal protective equipment must be changed when going back to the pre-PCR area, as it may have been contaminated by amplicon aerosols.

Another precautionary measure for the PCR laboratory, in addition to spatial separation, is **temporal separation**. For example, consideration can be given to set up all PCR reactions in the morning and perform the amplification and analysis steps in the afternoon. This may limit flexibility but will prevent contamination issues, and hence the risk of having to repeat experiments.

The key design feature around space is the adjacency to Molecular and Anatomical Pathology departments so that equipment and facilities can be shared.

Sample Flow

There should be a unidirectional flow to the sample processing commencing with tissue processing steps like histology. The design should consider whether an adjacency to the histology section can result in shared spaces. This should support appropriate workflows for specimen loading/tracking of shared samples between laboratories in the DHR and their storage.

Ventilation and Air Quality

The design will need to consider replicating the Anatomical Pathology (solvent extraction) ventilation requirements for areas where tissues are processed in a similar manner to histology tissues.

Lighting

DG General: refer to the design requirements in Anatomical Pathology and Molecular Pathology. Lighting in the analysis offices need careful consideration to reduce glare on screens.

In addition, a dark room is required for FISH wet lab processing. This wet lab dark room is different from the analysis room.

FISH is a molecular cytogenetic technique used to detect and locate specific DNA sequences on chromosomes. FISH uses fluorescent probes that bind to only those parts of a chromosome with which they show a high degree of sequence complementarity. The visualisation and interpretation of FISH results require specialised equipment and lighting conditions:

- Darkened Room: fluorescent signals can be faint, so FISH analysis is typically done in a darkened room to maximise the contrast between the fluorescent signals and the background. This also prevents fluorescence from fading (UV sensitive);

- Ultraviolet (UV) Light Source: UV light source is essential for exciting the fluorescent dyes. However, it's important to note that prolonged exposure to UV light can damage the fluorophore and reduce the fluorescence intensity. Therefore, the room should be able to be darkened and protected from UV light. Modern fluorescence microscopes often use high-intensity mercury or xenon lamps as light sources, though LED sources are becoming more common due to their longer lifespan and consistent output; and
- Probes can fade if exposed to light, hence the preference of sample preparation in a dark room. Current designs have FISH testing being conducted in separate rooms from the rest of the department(s) or open planned laboratory sections.

Temperature

The DG department should have a controlled room temperature to ensure optimal operation of automated analysers. The temperature should be maintained within a specific range recommended by the manufacturers of the instruments. Typically, the room temperature range for DG laboratories are maintained at room temperature. Samples and reagents are typically stored at 4-8C, -18C to -22C, and -80C. Access to cold and freezer storage is critical.

Acoustic Control

As per "General Design Principles" in section 7.8.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

DG requires various types of storage for different purposes noting it shares processing similarities with closely linked departments – Microbiology and Molecular Pathology.

The types of storage for DG department includes:

- **Specimen Storage**: specimens will be kept in the Centralised Walk-in Cold Room and Freezer Room, and frozen tissue bank;
- **DNA samples and Next-Generation sequencing libraries (future);** these require -20C and -80C freezers;
- **Cell lines or tissues and cytogenetics (LN2);**
- **Equipment Storage**: some laboratory equipment may be stored away when not in use within the Centralised Equipment Store;
- **Chemical storage**: diagnostic genomics assays utilise alcohols, acids, and phenols. Space for flammable cabinets, acid storage, and solvents is required with easy/close access to reduce WHS risks for the transportation of wichesters;

- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage:** waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both immediate waste management needs and broader floor-wide requirements are adequately addressed.

  Specific waste storage for DG includes:

  - Biological Waste: DG laboratories work with biological materials that may be potentially infectious or biohazardous, including:
    - Specimens: biological samples collected for testing or research that are no longer required; and
    - Contaminated Materials: items contaminated with potentially infectious materials, such as gloves, pipettes, Petri dishes, and disposable labware.

    Biohazard waste will need to be autoclaved (sterilised using high-pressure steam) before disposal. There will need to be an autoclave accessible to these departments as well as a separate system built into the PC3 facility.
  - Chemical Waste: DG laboratories utilise various chemicals for experiments, staining techniques, or disinfection. Chemical waste includes:
    - Hazardous and/or dangerous substances: acids, alcohols, solvents require safe and separated/isolated storage (such as flame store cabinets);
    - Reagents: expired or unused reagents, solutions, or media;
    - Stains: used staining solutions or dyes that are no longer required; and
    - Chemicals: discarded chemicals, such as disinfectants, fixatives, or solvents.
  - Sharps: needles, syringes, or other sharp objects used in the laboratory for specimen collection or other procedures;
  - General Laboratory Waste: DG laboratories also generate general laboratory waste, including:
    - Packaging: packaging materials, such as cardboard boxes, plastic wrap, or Styrofoam used for delivery or storage of laboratory supplies;
    - Recycling;
    - Non-Contaminated Waste: non-hazardous waste that does not fall under biological or chemical waste categories, including paper towels, disposable gloves, or non-infectious plastic items; and
    - Glassware: broken or discarded glassware, including test tubes, slides, or glass pipettes.
  - Liquid Waste: DG laboratories may produce liquid waste, such as liquid cultures and media and buffer solutions.

DG also needs to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1

Specimen Retention

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 for DG accords with section 7.8.2 unless otherwise specified below in Table 7-15[55].

Table 7-15: Minimum Retention Times for DG

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-2-1	Copy of original report, or ability to reprint the information content of an original report ▪ Constitutional genetic testing ▪ Somatic genetic testing	 100 years (effectively indefinite) 10 years[56]
3-2-2	Cytogenetics: ▪ Analysis records/karyotypes/digital images including FISH images. ▪ Stained microscope slides in permanent mounting medium ▪ Fixed chromosome cell suspension or FISH slides ▪ Original specimens and containers	4 years 4 years 6 months 1 month from date of issue of report
3-2-3	Cytogenetics/biochemical genetics/molecular genetics: Tissue cultures/cell culture lines ▪ Rare clinically significant variants ▪ Common clinically significant variants or clinically non-significant	 For indefinite cryopreservation As per Table 7-4, row 3-2-7
3-2-4	Biochemical genetics: Specimens of plasma, serum and urine ▪ Original container ▪ Analytic aliquot	 7 days 3 months after date of issue of report
3-2-5	Neonatal screening (dried blood spot): ▪ Specimen (Guthrie) cards ▪ Records	 2 years See row 3-2-1 above
3-2-6	Molecular genetics: ▪ Nucleic acid extracts for somatic or constitutive testing ▪ Nucleic acid extracts or frozen plasma for NIPT	 3 months[57] 12 months
3-2-7	Bioinformatic genetic data ▪ Read data (e.g. FASTQ) or aligned reads (e.g. BAM) ▪ Variant call files ▪ Microarray analysis files	 4 years from date of issue of report 10 years 4 years

55. Australian Commission on Safety and Quality in Health Care, Requirements for the Retention of Laboratory Records and Diagnostic Material, Tier 3B Document, Ninth Edition 2022, available at https://www.safetyandquality.gov.au/sites/default/files/2022-04/retention_standard_ninth_edition_2022.pdf.
56. Where the report relates to a paediatric patient, the retention period should be the greater of 10 years or 7 years from the age of maturity.
57. From date of issue of the report for an individual, or from completion of a family study where the proband's sample is required as a control, or from completion of testing; whichever of the three periods is the longest.

Key Functional Relationships

Internal Relationships

The functional relationships for Diagnostic Genomics are described in section 7.7 and illustrated in Figure 7-6.

External Relationships

Diagnostic genomics needs to be co-located with molecular pathology for shared facilities (DNA/RNA Amplification/Sequencing room). Location also needs to consider sample flow from AP, Haematology, and Pre-analytics. The location of shared fridge and freezer storage, including tissue banking, need to be within reasonable proximity as well.

Diagnostic Genomics receives a significant and important volume of samples from external referrers (private in vitro fertilization [IVF] clinics, GP's, private obstetrician and gynaecologist [OBGYN] clinics), and blood collections from outpatient collection centres. The key requirement for DG is similar to all other areas of pathology. The ICT connectivity and the IT platforms need to be robust in order that:

- Genomic pathologists are able to communicate with other medical practitioners, with sufficient bandwidth to display high fidelity images;
- Regular and constructive relationships with all referrers, including timely provision of results; and
- Analytical software is securely housed, backed-up, and located on virtual servers with ample space and speed to allow timely genomic analysis by multiple users. Karyotype, FISH, SNP array and NGS are software based, using large data files and high-resolution images hence breakdowns in processing speed and file back-up poses clinical risk.

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

Management and Operational Support Services

Current Location

The department is currently co-located on level 4 with Microbiology and Molecular Pathology.

Hours of Operation

DG operates largely within business hours, 8.30am – 5.30pm Monday to Friday, with a Saturday roster in place to harvest bone marrow cultures and prepare peripheral blood cultures[58].

On-call service is provided for emergency analysis between 9.00am – 5.00pm Saturdays and Sundays as well as public holidays, covered by experienced laboratory scientists at HP3 level or above.

58. ACT Pathology, Diagnostic Genomics.

Major Equipment List

Current major equipment for DG is detailed in Appendix Table A9-5. Key equipment includes but is not exclusive to PCR analysers, Extractors, Freezers, Refrigerators, Thermocyclers, Robotics, Biological Safety Cabinets (BSC II), Fume hoods, Incubators, Ovens, Humidity Cabinets, Water baths and Microscopes.

See Table A10-1 for future equipment list for all departments.

Workforce Model

The workforce model[59] reflects the clinical volumes and capability level of DG, with staffing levels provided in Table 7-16 below. The staffing complement includes clinical director, chief scientist, senior scientists, HP2 scientists and technical officers.

The workload is currently divided into two streams – *constitutional and oncology genomics*, each stream supervised by a senior scientist, under a single leadership model.

The senior scientists get rotated regularly to ensure they gain experience in each other's area. A similar process applies to the scientific and technical staff, with movement between tests to multi-skill all team members for redundancy planning, and to prepare for times of staff shortage:

- All HP2 staff will gain experience in all aspects of DG laboratory bench work and analysis; and
- Technical officers will gain experience in most aspects of DG lab bench work and ancillary tasks, but do not perform analysis with the exception of FV/FII Genexpert tests.

Table 7-16: Staffing by Workforce Category, Diagnostic Genomics

Category	Section/Unit	Head Count
Clinical Director	1	1
Supervising Pathologists/Clinical Supervisors	1	8 (part-time components, multiple individuals)
Supervising Scientist (HP4)	1	1
Senior Scientist (HP3)	2	2
Base Grade Scientist (HP2)	5	6
Technical Officer (TO1)	1	1
Total	11	19

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

A Future State

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.

59. ACT Pathology, Diagnostic Genomics.

A future state is possible with the design of the DG area of pathology likely to significantly expand, and develop, over time. (see accompanying Schedule of Accommodation):

- **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.

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 advances in omics technologies (possibly in partnership with others).

The current space allocations have been increased to accommodate for these new equipment additions and strategic direction to meet the patient demands and requirements for testing in the jurisdiction.

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

7.9.5. 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.

Scope of Service

Test Volumes

The Haematology department's highest volume of work is for 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 7-17: Haematology Test Volumes – 2019-20 to 2021-22

Year	Blood Transfusion	Haematology (incl. coagulation & immunophenotying)	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

Specialty Scope

In this context of CHS, the Haematology department[60] is 24/7 has a number of subspecialities 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.

60. ACT Pathology, Haematology Transfusion BMT.

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.

- **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.

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).

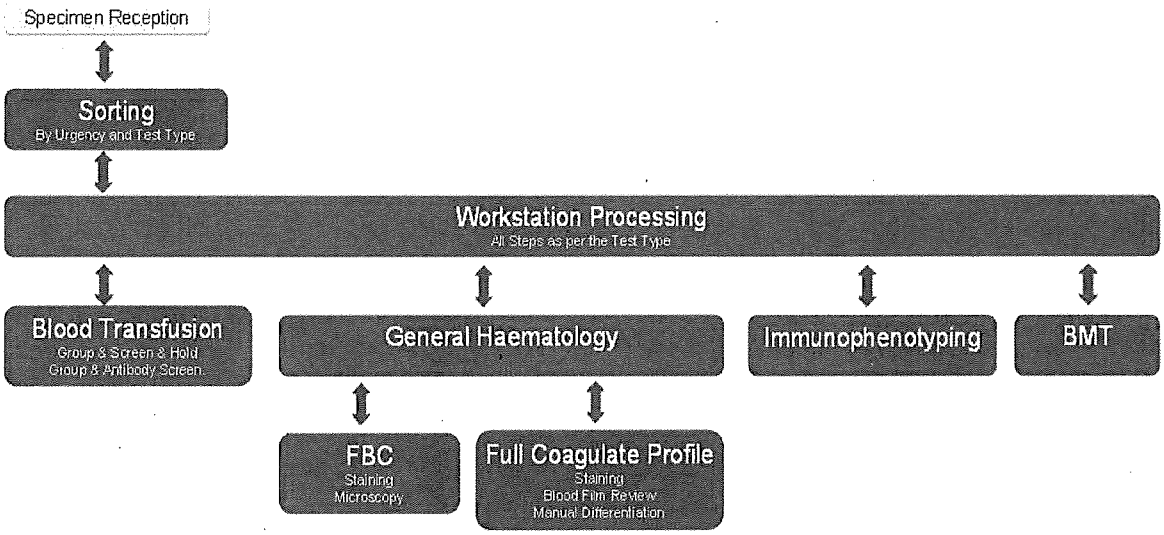
BMT laboratory receives BMT/cell therapy products (delivered by nurses) which require strict inspection and label verification procedures.

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.

Figure 7-12: Specimen Pathway for Haematology



The **blood bank** section is located 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.

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

Specific Design Elements for Haematology

The following elements should be considered in relation to the design of Haematology department in the relocated Pathology facility:

Space and Zoning

Located within the Core laboratory, the haematology section is envisioned predominantly in an open-plan setting. However, considering the specialised requirements, BMT subsection should be positioned within a controlled environment.

It is important for the design to promote visibility, ensuring that staff members are easily overseen by supervisors, fostering a sense of connectivity within the team. For a harmonious visual appeal, the enclosed design allocated for the BMT should echo the layout of Chemical Pathology's mass spectrometry area, achieving a symmetrical aesthetic.

Within transfusion services, there is currently a blood irradiator which uses a radioactive source. This requires a separate room with security measures built in. Decision has not yet been made as to whether ACT Pathology will continue to irradiate blood on site, therefore a blood irradiator should be incorporated for now and reviewed at a future stage.

Ventilation and Air Quality

For the BMT laboratory space where cell processing occurs, it's essential to maintain a controlled environment to prevent contamination of the transplant product. Below are specific ventilation and air quality requirements for a BMT lab that are in addition to the Core Laboratory:

- **Positive Air Pressure**: BMT units often maintain positive air pressure relative to the corridor or adjacent spaces. This ensures that when doors are opened, air flows out of the room rather than in, preventing the ingress of potential contaminants;
- **Temperature and Humidity Control**: maintaining a controlled environment is critical. BMT units and laboratories should have HVAC systems capable of regulating both temperature and humidity. Specific settings can vary and will depend on specifications of the equipment in the area;
- **Regular Monitoring and Maintenance**: The ventilation system should be regularly checked and maintained to ensure its efficiency. This includes routine checks of the filters, airflow rates, and pressure differentials;
- **LN2** is used in BMT laboratories for the cryopreservation of stem cells and other biological samples. When LN2 evaporates, it turns into nitrogen gas, which is inert and non-toxic, however, nitrogen gas can displace oxygen in a confined space. If the oxygen concentration drops below safe levels (typically below 19.5% at sea level), it can lead to asphyxiation. This is a significant hazard when using large quantities of LN2, especially in poorly ventilated areas.

  Additionally, if LN2 is stored in a sealed container, the evaporation of nitrogen can lead to an increase in pressure. This can potentially lead to the container bursting or exploding. It's essential to use only containers designed for LN2 storage and to ensure they have pressure-relief mechanisms.

  The extreme cold associated with LN2 can lead to condensation and ice formation, which can make surfaces slippery and pose a risk of falls. The floor design should consider this:
  - Ensure adequate ventilation in areas where Ln2 is used or stored. This is to prevent the build-up of nitrogen gas and subsequent oxygen displacement;
  - Install oxygen monitors (and cameras for monitoring) in areas with significant LN2 usage. These monitors can provide an alert if oxygen levels drop below safe thresholds; and
  - Carefully plan where LN2 containers will be stored in, how they can be well-ventilated, and how they are guaranteed to remain upright.

Lighting

For blood film reviews:

- Blood films should be adequately illuminated to provide sufficient brightness for clear visualisation of cells and structures. Insufficient lighting can lead to difficulty in identifying subtle abnormalities or distinguishing cell types. It is important to ensure that the brightness of the lighting is appropriate for comfortable and accurate examination;
- Reflections on the glass slide or coverslip can hinder visibility and make it difficult to interpret blood film findings. Anti-glare coatings on the microscope lenses and proper positioning of the light source can help minimise reflections and improve clarity;
- A cool light source, such as a daylight-balanced LED or fluorescent light, is preferred when reading blood films. Cool light sources provide a balanced colour temperature that closely

mimics natural daylight, which helps ensure accurate colour perception and differentiation of cellular components;

- Colour Rendering Index (CRI) measures how accurately a light source represents colours compared to natural light. A higher CRI (ideally above 90) is desirable to ensure accurate identification and interpretation of colour changes in stained specimens or indicators;
- While the microscope's illumination is crucial, the ambient lighting in the room also plays a role in the comfort and efficiency of the morphologist;
- The room's ambient light should not produce glare on the microscope or the slides;
- Indirect ambient lighting is preferred, as it reduces reflections and shadows that might interfere with slide examination;
- Room lighting should be adjustable. Different staining techniques and specific cellular features may require different lighting levels to enhance visibility and contrast. Also, some morphologists prefer dimmer ambient light to contrast with the bright microscope field, while others may want brighter room light to reduce eye strain when transitioning between looking through the microscope and reading labels or entering data. This may present a challenge in zoning lighting within an open plan environment.

  Adjustable light sources, such as adjustable desk lamps or microscope illuminators, can be used to optimise the illumination according to the specific requirements;
- The lighting should be adjusted to optimise contrast, allowing for better visualisation of cellular details. Adjusting the angle or direction of the light source can help enhance contrast by creating shadows and highlighting specific features of interest; and
- Consideration should be given to the comfort of the examiner's eyes during prolonged periods of reading blood films. Lighting should be gentle on the eyes, providing adequate but not overly bright illumination.

Temperature

As per "General Design Principles" in section 7.8.

Bone Marrow Transplant

The BMT area must comply with Requirements For Procedures Related To The Collection, Processing, Storage And Issue Of Human Haemopoietic Progenitor Cells (Sixth Edition 2021)[61]. The main, but not all of the key requirements are:

- Haematopoietic Progenitor Cell products are stored using various procedures and temperatures depending on the required duration of storage;
- There must be physically separate areas designated for the storage of products during quarantine, before issue and for non-conforming products;
- Oxygen monitors must be installed in all areas where LN2 storage tanks are located;
- Video cameras with central monitoring are also recommended so that staff in the BMT can be observed in case they are overcome by any increase in nitrogen in the air and lose consciousness;

61. 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.

- Products stored in a liquid state must be maintained within specified temperature range to maintain viability and function, to inhibit infectious agents and for a period of time not to exceed that specified in the standard operating procedures;
- Materials that may adversely affect products must not be stored in the same refrigerators or freezers as the cellular products;
- Refrigerators and freezers for product storage must have a system to monitor the temperature continuously and record the temperature at least every four hours;
- There must be a mechanism to ensure that levels of LN2 in LN2 freezers are maintained constantly to ensure that products remain within the specified temperature range; and
- Storage devices for products or reagents for product processing must have alarm systems that are active continuously.

Acoustic Control

Automated robotic track systems in chemical pathology laboratories, and analysers, can produce noise. The level of noise depends on the specific system, its components, and the operational state. Factors contributing to noise can include:

- Movement of the Robot Arms;
- Conveyor Systems;
- Centrifuges and Decappers; and
- Alerts and Alarms.

Careful design of the laboratory can make a difference. Keeping the TLA system centralised and away from workstations or areas where staff spend prolonged periods can help. Other considerations can include:

- Acoustic Barriers or other acoustic dampening solutions; and
- The use of vibration-dampening floor materials can reduce noise transmission, especially if the system is on an upper floor.

The laboratory can also help to reduce noise by ensuring that the system is well-maintained.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Haematology, Chemical Pathology and Immunopathology departments operate as part of a broader core laboratory and in an open plan design. The types of storage required need to include:

- **Reagent Storage**: some can be kept at room temperature and some needs to be refrigerated (2-8 degrees Celsius) within the Centralised Walk-in Cold Room and Freezer Room;
- **Specimen Storage**: specimens will be kept in the Centralised Walk-in Cold Room and Freezer Room;
- **Equipment Storage**: some laboratory equipment (such as analysers) may be stored away when not in use within the Centralised Equipment Store;
- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage**: Waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both immediate waste management needs and broader floor-wide requirements are adequately addressed.

In addition to general storage requirements for the core laboratory (above), Haematology department also requires various other types of storage for different purposes. These include:

- **Blood Transfusion Services – Blood Bank Storage** needs to be proximal to haematology laboratory space and requires precise temperature control (and alarmed) to ensure the viability and safety of blood components, including:
  - Whole blood and red blood cell (RBC) units are typically stored at temperatures between 1°C and 6°C (and alarmed), which helps maintain structural integrity and extend their shelf life; and
  - Plasma and platelet units, on the other hand, are frozen and stored at temperatures below -18°C or -30°C, respectively, to prevent degradation and maintain their therapeutic properties.
- **BMT.** The BMT Laboratory, also referred to as a cell therapy processing facility, is a specialised medical facility that manages, receives, tests, processes, stores and issues hematopoietic stem cells for transplantation. Proper storage in such departments is critical given the sensitive nature of the transplant material and the vulnerability of patients undergoing transplantation. Here are the specialised storage requirements for a BMT department:
  - Hematopoietic Stem Cell (HSC) storage requires:
    - Fresh product storage: monitored refrigerated storage meeting requirements of transfusion medicine/blood refrigerators at 2-8°C with 24/7 monitoring and alarms;
    - Cryopreservation: stem cells for transplantation are often cryopreserved using controlled-rate freezing methods to ensure cell viability. These cells are stored in LN2 freezers at very low temperatures (often -196°C);
    - Cryogenic processing and storage facility: special LN2 storage vessels store cryopreserved cells indefinitely in the vapour-phase of LN2. Nitrogen storage tanks access a supply of LN2 (at a specific pressure) at all times to enable automatic filling. Nitrogen storage tanks are equipped with alarms to monitor temperature and LN2 levels; and

  - Refrigerated storage: chemotherapy drugs, growth factors and cytokines used to stimulate stem cell growth, often require refrigeration.
- Waste Storage requires:
  - Biohazardous Waste; and
  - Chemical Waste.
- Reagents for the BMT laboratory require cold storage and they could be stored with other reagents requiring cold storage in the shared Walk-in Cold Room and Freezer Room.

Haematology also needs to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

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 for Haematology accords with section 7.8.2 unless otherwise specified below in Table 7-18 and Table 7-19[62].

Table 7-18: Minimum Retention Times for Haematology

	RECORD/MATERIAL	MINIMUM PERIOD OF RETENTION
3-16-1	Blood Films[EN8] ▪ Clinically Significant ▪ Not Clinically Significant	 ▪ 1 Year ▪ 1 Month
3-16-2	Plasma for Special Haemostasis testing	1 month @ -20C or lower
3-16-3	Blood Specimens, Other than 3-16-1 and 3-16-2	As per Table 3-2, row 3-2-7 for purposes of identification and traceability, noting that repeat testing may not be technically reliable after 2 days
3-16-4	Bone Marrow slides and reports	▪ 10 years for adults ▪ 7 years from the age of majority for minors
3-16-5	Flow Cytometry ▪ Reports ▪ Graphical Output used in diagnosis	 ▪ 10 years for adults, 7 years from the age of majority for minors ▪ As per Table 3-2, row 3-2-6

Table 7-19: Minimum Retention Times for Immunohaematology (Blood Transfusions)

	RECORD/MATERIAL	MINIMUM PERIOD OF RETENTION
3-17-1	Lab records of blood products received and issues[EN9]	20 years
3-17-2	Lab records of all immunohaematology testing[EN9]	20 years

Key Functional Relationships and Adjacencies

Internal Relationships

62. Australian Commission on Safety and Quality in Health Care, Requirements for the Retention of Laboratory Records and Diagnostic Material, Tier 3B Document, Ninth Edition 2022, available at https://www.safetyandquality.gov.au/sites/default/files/2022-04/retention_standard_ninth_edition_2022.pdf.

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**, as illustrated in Figure 7-3.

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)[63].

Management and Operational Support Services

Current Location

Haematology is currently located on Level 2, Building 10.

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).

63. 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.

Responsiveness

Turnaround times of reports and access to haematologists for secondary consultations is critically important for the business of pathology, and a sustainability client base.

Major Equipment List

Current major equipment for Haematology is detailed in Appendix Table A9-6. Key equipment used in Haematology laboratory includes but is not exclusive to blood bank refrigerators, freezers (includes freezers for fresh frozen plasma and platelets), incubators for platelets, plasma thawers, aggregometers, ROTEM Sigma (Viscoelasticity haemostasis testing analyser), refrigerators, microscopes, eSR analysers, stainers, cytometer, flow cytometers, biological safety cabinets, LN2 storage tanks, controlled rate freezers, centrifuges, coagulation analysers and haematology analysers.

See Table A10-1 for future equipment list for all departments.

Workforce Model

The workforce model reflects the clinical capability level of Haematology, with staffing levels provided in Table 7-20 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 7-20: 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
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.

A Future State

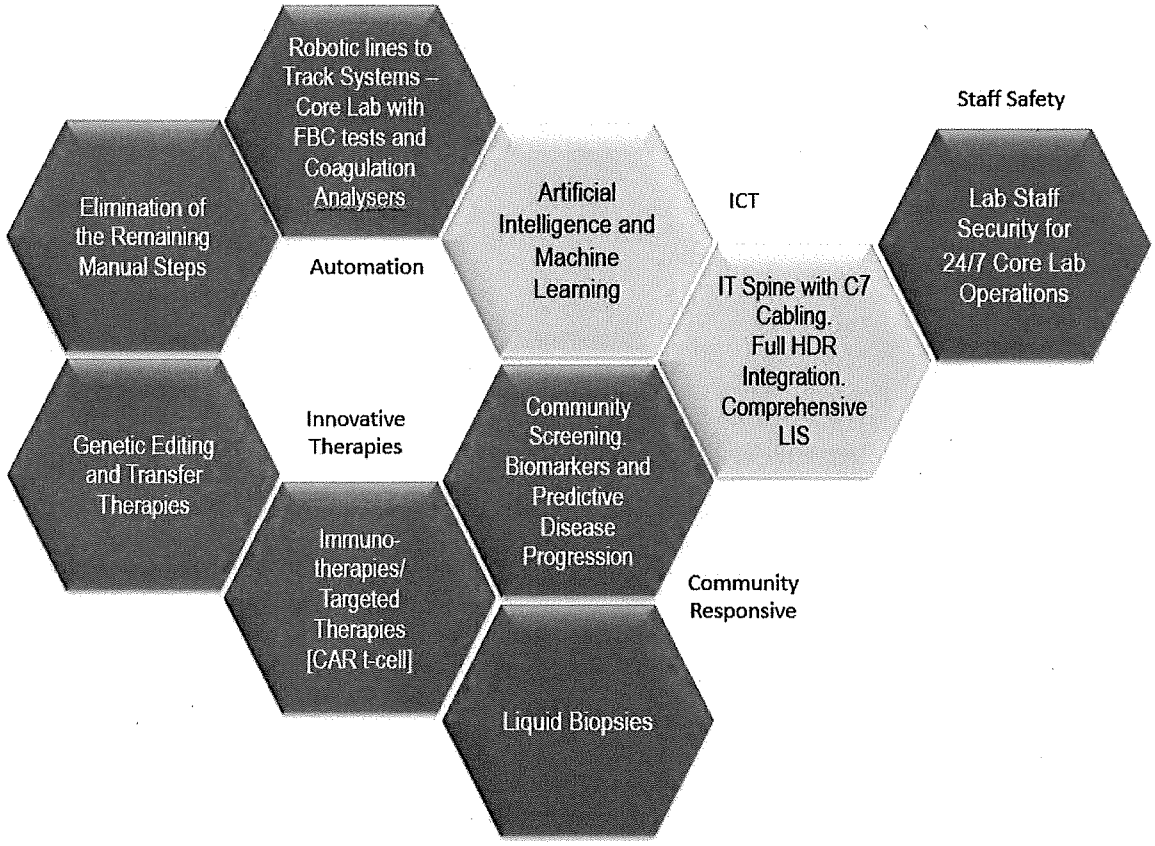
Haematology is a pathology discipline that continues to evolve.

Figure 7-13 below *identifies the expected developments for haematology. As with other specialties, all of the developments are inter-related. Many are inter-dependent. The principal drivers are developments that:*

- Continue to automate manual processes;
- Fully integrate with the Core Lab;
- A robust ICT spine and AI capability;
- Develop innovative therapies. At the forefront of these new therapies would be CAR T-cell therapies, genetic editing and transfer therapies more generally;
- Response to specific community needs that pathology can lead, such as community screening predictive disease progression and liquid biopsies; and
- Staff Safety.

The future for the interface between haematology and genomics and molecular pathology will continue to evolve as it develops capability to extend its functional capability to better align with capacity of interstate laboratories.

Figure 7-13: Future State for Haematology



7.9.6. Immunopathology and Infectious Immunoassay

Immunopathology 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.

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 7-21: 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

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).

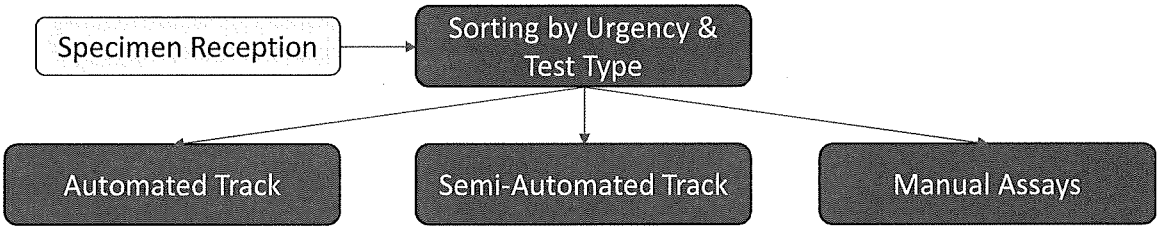
Infectious Immunoassay

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.

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 7-14.

Figure 7-14: Specimen Pathway for Immunopathology and Infectious Immunoassay



Specific Design Elements for Immunopathology and Infectious Immunoassay

The following elements should be considered in relation to the design of Immunopathology & Infectious Immunoassay department in the relocated Pathology facility.

Space and Zoning

In the new design, the following orientations should be adopted:

- The automated elements of Immunopathology and Infectious Immunoassay will be fully incorporated into the Core Lab, with staff having expertise in both Immunopathology and Infectious Immunoassay reporting the testing;
- Many Immunopathology and Infectious Immunoassay tests are semi-automated or manual and cannot be performed within a 'true core' laboratory. These tests would be performed in specialised laboratory areas adjacent to the core laboratory; and
- Immunopathology and Infectious Immunoassay can be designed to act independently as there are no inter-departmental dependencies. However, it would be beneficial to be adjacent to flow cytometry and the core laboratory.

Ventilation and Air Quality

The design will include the following considerations for air quality and ventilation:

- Temperature Stability: the laboratory room temperature should be stable, typically the same as the other parts of the core laboratory section i.e. between 20-25°C. The temperature stability ensures consistent performance and calibration of the instrument. It's essential to monitor and maintain temperature within specified limits as prescribed by the mass spectrometer's manufacturer;

- Humidity Control: humidity should be controlled, with levels typically kept below 60% relative humidity. Excess moisture can influence ionisation processes, potentially affect the equipment's internal components, and lead to corrosion over time;
- Clean, Dust-Free Environment: dust and other particulate matter can interfere with the instrument's operation. It's beneficial to have air filtering systems in place to ensure the lab remains as dust-free as possible but may also be kept in a separate room;
- Gas Supply: It's essential to ensure a consistent and uncontaminated gas supply. Gas cylinders should be stored safely, and appropriate gas purifiers should be in place;
- Ventilation and Fume Hoods: some sample preparation steps might involve volatile or hazardous chemicals. Proper ventilation and fume hoods should be available to ensure the safety of laboratory personnel and to prevent contamination of the laboratory atmosphere;
- Electrical Supply: stable and clean power is essential. UPS or backup power systems might be necessary, especially for critical applications; and
- Airborne Contaminants: laboratories should be kept free from volatile organic compounds (VOCs) or other potential sources of chemical interference.

Lighting

As per "General Design Principles" in section 7.8.

Temperature

- For the macro environment, this should be 20-25°C like the rest of the laboratory. The department should have a controlled room temperature to ensure optimal operation of automated analysers. The temperature should be maintained within a specific range recommended by the manufacturers of the instruments; and
- In a micro setting, refrigerated environments need to be 2-8°C and freezer temperatures need to be -20°C which can be accommodated by the Walk-in Cold Room and Freezer.

Acoustic Control

Automated robotic track systems in immunopathology laboratories, and analysers, can produce noise. The level of noise depends on the specific system, its components, and the operational state. Factors contributing to noise can include:

- Movement of the Robot Arms;
- Conveyor Systems;
- Centrifuges and Decappers; and
- Alerts and Alarms.

Careful design of the laboratory can make a difference. Keeping the TLA system centralised and away from workstations or areas where staff spend prolonged periods can help. Other considerations can include:

- Acoustic Barriers or other acoustic dampening solutions; and
- The use of vibration-dampening floor materials can reduce noise transmission, especially if the system is on an upper floor.

The laboratory can also help to reduce noise by ensuring that the system is well-maintained.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Immunopathology and Infectious Immunoassay, Chemical Pathology and Haematology departments operate as part of a broader core laboratory and in an open plan design. The types of storage required need to include:

- **Reagent Storage**: some can be kept at room temperature and some needs to be refrigerated (2-8 degrees Celsius) in a Centralised Walk-in Cold Room and Freezer Room;
- **Specimen Storage**: specimens will be kept in the Centralised Walk-in Cold Room and Freezer Room;
- **Equipment Storage**: some laboratory equipment (such as analysers) may be stored away when not in use within the Centralised Equipment Store;
- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage**: Waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both immediate waste management needs and broader floor-wide requirements are adequately addressed.

Immunopathology and Infectious Immunoassay also needs to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

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 for Immunopathology[64] accords with section 7.8.2 Table 7-4 unless otherwise specified below in Table 7-22 and Table 7-23[65].

64. Note the relevant section for Infectious Immunoassay has been placed in the Microbiology section.
65. Australian Commission on Safety and Quality in Health Care, Requirements for the Retention of Laboratory Records and Diagnostic Material, Tier 3B Document, Ninth Edition 2022, available at https://www.safetyandquality.gov.au/sites/default/files/2022-04/retention_standard_ninth_edition_2022.pdf.

Table 7-22: Minimum Retention Times for Immunopathology

	RECORD/MATERIAL	MINIMUM PERIOD OF RETENTION
3-20-1	Serum, plasma, other body fluid and tissue specimens	As per Table 3-2, row 3-2-7
3-20-2	Frozen tissue blocks, including specimens for immunofluorescence studies	1 month at −70°C or lower
3-20-3	Immunofluorescence slides	As per Table 3-2, row 3-2-7
3-20-4	Digital images used for diagnostic analysis	As per Table 3-2, row 3-2-6

Table 7-23: Minimum Retention Times for Immunohaematology (blood transfusion)

	RECORD/MATERIAL	MINIMUM PERIOD OF RETENTION
3-21-1	Laboratory records of blood products received and issued[66]	20 years
3-21-2	Laboratory records of all Immunohaematology testing[52]	20 years

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,** as illustrated in Figure 7-3.

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.

66. Should be done in accordance with the *Requirements for transfusion laboratory practice.*

Management and Operational Support Services

Current Locations

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

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 requests[67].

Major Equipment List

Current major equipment for Immunopathology and Infectious Immunoassay is detailed in Appendix Table A9-7.

Key equipment used in Immunopathology laboratory includes but is not exclusive to Electrophoresis Systems, Chemilumunescence Analyser, EIA Plate Analyser, EIA Platforms, Microscopes, Freezers (-20), Refrigerators, Deionised Water System, Biological safety cabinets (BSC II), and Immunoassay analysers.

Workforce Model

The workforce model reflects the clinical capability level of Immunopathology & Infectious Immunoassay, with staffing levels provided in Table 7-24 below. The staffing complement includes clinical director, Immunopathologists, registrar, chief scientist, senior scientists, scientists and technical officers.

Table 7-24: Staffing by Workforce Category, Immunopathology & Infectious Immunoassay [68]

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.

67. ACT Pathology, 02508 02501 86750 aid.
68. Microbiology/Infectious Immunoassay clinical Director and Pathologist are represented in the Microbiology workforce category.

A Future State

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. Immunopathology will be contiguous with the Core Lab, and:

- **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.

7.9.7. 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.

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 7-25: Microbiology Test Panel Volumes – 2019-20 to 2021-22

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

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.

Specimen Pathway

Microbiology mainly receives tissue samples from the following places:

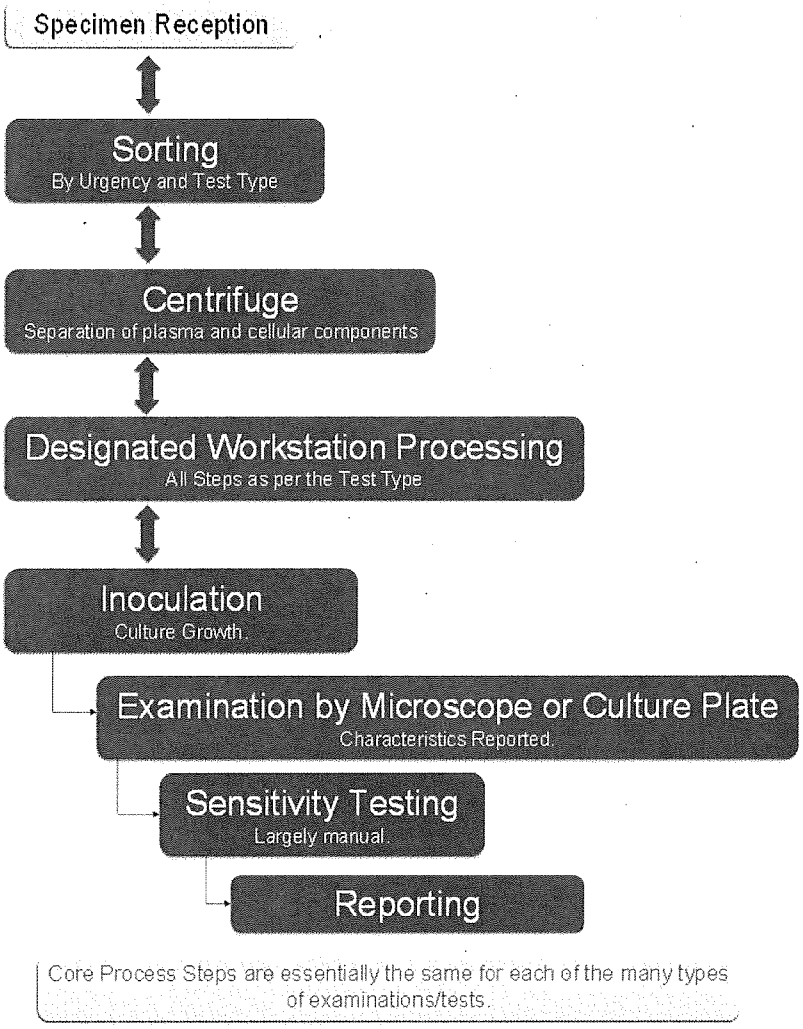
- Inpatient and outpatient services, TCH; and
- Other public and private hospitals in the ACT and parts of NSW.

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 7-15: Specimen Pathway for Microbiology



Specific Design Elements for Microbiology

Space and Zoning

To streamline workflow and staff training, the laboratory is divided into the:

- Specimen set up;
- **Processing Sections** that manage **microscopic examinations** from all specimen types;
- **Analytical Sections** perform **culture plate reading and interpretation**, and identification and susceptibility testing on all significant isolates, from all specimen types; and
- **Additional sections for specialist areas**. These include:
  - Mycology – processing of specimens requiring fungal examination; and

- Mycobacteriology/PC3 laboratory.

The microbiology department should be designed to be mostly open plan to allow flexibility for equipment and workflow reconfiguration with no specific flow to workstations but rather access to biological safety cabinets, Stock, incubators and anaerobic chambers where required.

The general laboratory space should meet the standards for a PC2 laboratory (AS/NZS 2243.3:2022)[69].

Office spaces for staff who are directly supervising the laboratory (i.e., Chief Scientist, Supervising Microbiologist and Registrars) should have direct access to the laboratory but preferably are not situated within the PC2 laboratory – for instance they may have windows and door (access controlled) into the laboratory but also are also accessible external to the laboratory via another entrance.

Entries, walkways, locations of hand washing/hand hygiene facilities and hooks for PPE within the PC2 laboratory should be considered to ensure compliance with PPE requirements and hygiene at the point of entry and exit to the laboratory.

Microbiology will require access to a PC3 facility that meets AS/NZS 2243.3:2022 standards, as well as the Commonwealth Government Security Sensitive Biological Agents legislative Standards[70]. The facility is used when working with high-risk or highly infectious agents that may pose significant health risks.

PC3 facilities are designed to provide a higher level of containment compared to PC2 facilities, offering additional safeguards to protect laboratory personnel, the surrounding environment, and public health. PC3 facilities are typically utilised in diagnostic laboratories where high-risk pathogens need to be identified and managed. This includes handling clinical specimens that may contain dangerous or contagious agents that require enhanced containment measures.

This PC3 facility should:

- Be larger than the current PC3 laboratory to also enable basic molecular testing including a benchtop extractor;
- Have a pass-through autoclave for waste management;
- Be able to safely manage Security Sensitive Biological Agent (SSBAs);
- Be within/adjacent to the PC2 Microbiology/Molecular laboratories with visibility within the PC3 from the PC2 areas for staff safety and security; and
- Have access to shower facilities – preferably in the vicinity/same floor as the PC3 laboratory.

There must be a separate area/room for mycology within the Microbiology Department to minimise the risk of laboratory fungal spores contaminating culture plates. The area requires a BSC, microscope, bench space, computer, temperature adjustable incubators.

Safety and Security

The department requires appropriate safety and security features to:

- Adhere to PC2/PC3/SSBA regulations;

69. Standards Australia, 25 November 2022, AS/NZS 2243.3:2022 Safety in Laboratories, Part 3: Microbiological Safety and Containment, available at https://store.standards.org.au/product/as-nzs-2243-3-2022.
70. https://www.health.gov.au/sites/default/files/documents/2022/06/ssba-standards.pdf

- Monitor access to the area;
- Restrict access to the area using electronic swipe cards; and
- Ensure the design allows for staff access via a single entry only so that gowns/hand washing facilities are easily accessible when going in and out.

Office and Workspaces

The department requires offices, write-up areas, analysis areas, which do not require PC2 conditions and should be outside of the PC2 area but adjacent/visible of the laboratory for operational reasons.

The required offices spaces include:

- An office for the Director;
- An office for the Chief Scientist for each laboratory;
- Supervising microbiologist and registrars work area – needs to be directly accessible and visible by laboratory staff of microbiology/molecular but preferably outside of PC2 – shared work area with at least 3 separate workspaces;
- Shared office spaces/hot desks for quality assurance activities – within the vicinity of the laboratories – one workspace for each laboratory (microbiology/molecular/infectious immunoassay);
- Future space for analysis/culture reading with introduction of automation for microbiology;
- Future space for genomic analysis for molecular pathology; and
- Non-Clinical Office Areas for pathologists.

Ventilation and Air Quality

The design will include the following considerations for air quality and ventilation:

- **Adequate Air Exchange**: the laboratory should have a sufficient air exchange rate to ensure proper ventilation and reduce the concentration of airborne contaminants. The specific air exchange rate may vary based on the size of the laboratory, the number of occupants, and the activities performed. Generally, a minimum of 6-12 air changes per ACH is recommended;
- **Engineering Controls**: the laboratory should be equipped with appropriate engineering controls to manage and control airborne contaminants. These controls may include the use of fume hoods, laminar flow cabinets, or biosafety cabinets (BSCs) to provide containment and prevent the release of hazardous substances;
- **HVAC Systems**: HVAC systems play a crucial role in maintaining air quality and temperature control in the laboratory. The HVAC system should be properly designed, installed, and maintained to ensure effective air distribution, filtration, and removal of contaminants. The system should be equipped with HEPA filters to remove airborne particles, including microorganisms;
- **Filtration**: HEPA filters should be used in the HVAC system and other ventilation devices to remove airborne particles, including potentially infectious microorganisms. The filters should be regularly inspected, cleaned, or replaced to maintain their effectiveness;
- **Directional Airflow**: the laboratory should have a well-designed airflow pattern that ensures directional airflow from clean to potentially contaminated areas. This helps prevent the spread of contaminants within the laboratory. Typically, airflow should be from

areas with lower risk (e.g., clean work areas) to areas with higher risk (e.g., sample processing areas);

- **Pressure Differentials**: maintaining appropriate pressure differentials between different areas of the laboratory is important. Negative pressure differentials should be maintained in areas where potentially hazardous materials are handled to prevent the release of airborne contaminants. Positive pressure differentials should be maintained in clean areas to prevent the entry of contaminants from adjacent spaces;
- **Normal airflow patterns** in the department must be designed to minimise cross-contamination between the three areas previously described; and
- **Odour Management:** Microbiology laboratories can sometimes have strong odours due to the presence of microbial cultures, chemical reagents, and organic matter. The design will include consideration of the following to deodorise the spaces:
  - Air purification systems;
  - Easy access to clean and disinfect equipment and workstations;
  - Proper waste management areas;
  - Odour absorption sand control systems; and
  - Consider how to isolate the odours from other parts of the laboratory.

Lighting

CRI: Microbiology laboratories often require accurate colour perception. The CRI is a measure of a light source's ability to render colours faithfully compared to natural light. Higher CRI values (close to 100) are preferred to ensure accurate identification of colour changes in stained specimens or growth media.

For Mycology, some fungi are sensitive to light, and their growth or sporulation can be influenced by exposure to light. Dimmable lighting or controlled light exposure might be necessary for specific procedures or for cultivating certain fungal species.

Some Matrix-Assisted Laser Desorption/ Ionisation (MALDI) matrices are light-sensitive. Ambient light can impact sample preparation, especially if the matrix begins to degrade or prematurely polymerise. This is more of a consideration for sample preparation areas than for the instrument itself.

Temperature

Matrix-Assisted Laser Desorption/ Ionisation – Time Of Flight (MALDI-TOF) instruments are typically recommended to be operated in a room where the temperature is stable. Sudden temperature fluctuations can influence the calibration and stability of the instrument. Manufacturers often suggest an optimal temperature range, commonly between 18°C and 24°C (64°F to 75°F).

High humidity and dust can adversely affect the instrument, particularly during sample preparation. The matrix used in MALDI-TOF can be hygroscopic, meaning it can absorb moisture from the air, which can interfere with crystal formation and subsequently impact the quality of the spectra. It's generally recommended to maintain a relative humidity below 60%, though specific recommendations can vary based on the manufacturer and model.

For Mycology, some fungi prefer moist conditions. However, excessive humidity can also promote the growth of unwanted organisms and can affect laboratory equipment. Humidity

levels should be controlled and monitored, especially if the lab is located in a region with high ambient humidity.

Acoustic Control

As per "General Design Principles" in section 7.8.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Microbiology requires various types of storage for different purposes noting it shares processing similarities with closely linked departments – Molecular Pathology and Diagnostic Genomics.

The types of storage for Microbiology department includes:

- **Reagent Storage**: some can be kept at room temperature and some needs to be refrigerated (2-8 degrees Celsius) within the Centralised Walk-in Cold Room and Freezer Room;
- **Specimen and Isolates Storage**: specimens will be kept in warm rooms as well as the Centralised Walk-in Cold Room and Freezer Room;
- **Culture media;**
- **Control strains;**
- **Antibiotics and antifungals for susceptibility testing;**
- **Incubators including anaerobic and CO2 incubators;**
- **Equipment Storage**: some laboratory equipment may be stored away when not in use within the Centralised Equipment Store.
- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage:** waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both

immediate waste management needs and broader floor-wide requirements are adequately addressed. Specific waste storage for Microbiology includes:

- Biological Waste

  Microbiology laboratories work with biological materials that may be potentially infectious or biohazardous, including:

  - Cultures: microbial cultures, such as bacteria, fungi, viruses, or parasites, that are no longer needed;
  - Specimens: biological samples collected for testing or research that are no longer required; and
  - Contaminated Materials: items contaminated with potentially infectious materials, such as gloves, pipettes, Petri dishes, and disposable labware.

  Biohazard waste will need to be autoclaved (sterilised using high-pressure steam) before disposal. There will need to be an autoclave accessible to these departments as well as a separate system built into the PC3 facility.

- Chemical Waste

  Microbiology laboratories utilise various chemicals for experiments, staining techniques, or disinfection. Chemical waste includes:

  - Reagents: expired or unused reagents, solutions, or media;
  - Stains: used staining solutions or dyes that are no longer required; and
  - Chemicals: discarded chemicals, such as disinfectants, fixatives, or solvents.

- Sharps: needles, syringes, or other sharp objects used in the laboratory for specimen collection or other procedures;

- General Laboratory Waste

  Microbiology laboratories also generate general laboratory waste, including:

  - Packaging: packaging materials, such as cardboard boxes, plastic wrap, or Styrofoam used for delivery or storage of laboratory supplies;
  - Non-Contaminated Waste: non-hazardous waste that does not fall under biological or chemical waste categories, including paper towels, disposable gloves, or non-infectious plastic items; and
  - Glassware: broken or discarded glassware, including test tubes, slides, or glass pipettes.

- Liquid Waste

  Microbiology laboratories may produce liquid waste, such as liquid cultures and media and buffer solutions.

Microbiology also needs to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

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 for Microbiology accords with section 7.8.2 unless otherwise specified below in Table 7-26.

Table 7-26: Minimum Retention Times for Microbiology

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-22-1	Slides	
	▪ Wet preparations	Nil (discard)
	▪ Immunofluorescence slides	7 days
	▪ Gram stains	2 weeks
	▪ Ziehl-Neelsen stains	6 weeks
	▪ Other stained slides	2 weeks
3-22-2	Isolates[71]	
	▪ Clinically significant[72]	5 days
	▪ Not clinically significant	Discard
3-22-3	Serum/plasma for infectious Immunoassay	
	▪ All sera unless specified below	4 months
	▪ Antenatal sera	12 months
	▪ Reactive syphilis sera	12 months
	▪ Source and recipient sera from body fluid exposure (needle-stick), where this has been notified to the laboratory	12 months
3-22-4	Urine specimen for microbiological examination	3 days from date of issue of report, under refrigeration
3-22-5	Molecular Pathology:	1 month from date of issue of report[73]
	▪ Nucleic acid for diagnostic microbiological examination – extract or original specimen	1 month from date of issue of report[74]
	▪ Nucleic acid for screening examination – extract or original specimen	

Key Functional Relationships and Adjacencies

Internal Relationships

Microbiology has a close clinical relationship with Molecular Pathology, infectious diseases, Infection Prevention and Control, and Antimicrobial Stewardship

In particular, Microbiology and molecular laboratories need to be adjacent to enable seamless flow of specimens, staff and intellect between the units. Microbiology/Molecular and Anatomical Pathology could be adjacent due to shared specimens and processes while Diagnostic Genomics and Molecular could be adjacent due to shared equipment and processes (histopathology processing).

Microbiology and Molecular Pathology are currently functioning as two separate departments but would benefit from being combined as a single operational department in the new Pathology Facility due to the significant clinical overlap, shared specimens, movement of traditional microbiology to molecular based staff and ability to cross train staff.

71. Unless addressed by the Security Sensitive Biological Agent (SSBA) legislation.
72. Clinically significant isolate is considered to be all blood culture and sterile isolates, plus any cultured isolate which is reported by the laboratory as a potential pathogen (in contrast to contaminants and commensal flora).
73. Except during the period of the COVID-19 pandemic where the retention period for both positive and negative COVID-19 test samples is reduced to one week after results are released. See also fact sheet on retention period for COVID-19 test samples on the Commission website.
74. Unless otherwise stated in the Requirements for laboratories reporting tests for the National Cervical Screening Program.

Both Microbiology and Molecular pathology are moving to an increased level of robotics, and the FRD (see Figure 7-4) is based around the following key principles:

- Much of Microbiology testing will move to tracked robotics, which will increase size of the required 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 DG to allow sharing of laboratory space and equipment e.g. PCR Clean Prep, Specimen Prep, and DNA Amplification;
- Molecular Pathology should also be adjacent to the Core Laboratory. More and more instrumentations are being enabled to connect to track systems over time, with Molecular Pathology robotics likely being able to connect to a track system when the new Pathology Facility opens – this is already possible with Roche instrumentation.

  It should be noted that only approximately 50% of the processing and analysis can be automated for Molecular Pathology, hence the department will always require is its own contained laboratory for in house/low volume assays.
- The spaces will be open plan wherever possible, exceptions of which include the mycology lab, the mass spectrometry, and the PC3 facility; and
- There will be sufficient space to allow a fast scale-up of services if needed, e.g. pandemic.

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.

Management and Operational Support Services

Current location

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

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 requests[75].

Major Equipment List

Current major equipment for Microbiology is detailed in Appendix Table A9-8. Key equipment used in Microbiology laboratory includes but is not exclusive to Autoclaves (pass through from PC3 and benchtop), Steam Steriliser, Reverse Osmosis Water Unit, Mycobacteria Analyser, Biological Safety Cabinets (BSC II), Carbon Dioxide Incubators, Freezers, Microscopes, Maldi Biotyper Analyser, Vitek 2 Analyser, Blood Culture Analysers, and Biofire Filmarray Torch system.

See Table A10-1 for future equipment list for all departments.

Workforce Model

The workforce model[76] reflects the clinical capability level of Microbiology, with staffing levels provided in Table 7-27 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.

Table 7-27: 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

75. ACT Pathology, Microbiology.
76. ACT Pathology, 02508 02501 86766 tasl - Microbiology.

Staff Category	Headcount	FTE
Total	31	26

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

A Future State

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. The development of plate reader capability and NGS are critical developments for the future of microbiology.

The proposed areas provide for growth and development of microbiology.

7.9.8. 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.

Scope of Service

Molecular Pathology operates as a Level 6[77] 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 7-28: 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

Specialty Scope

[77] 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

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.

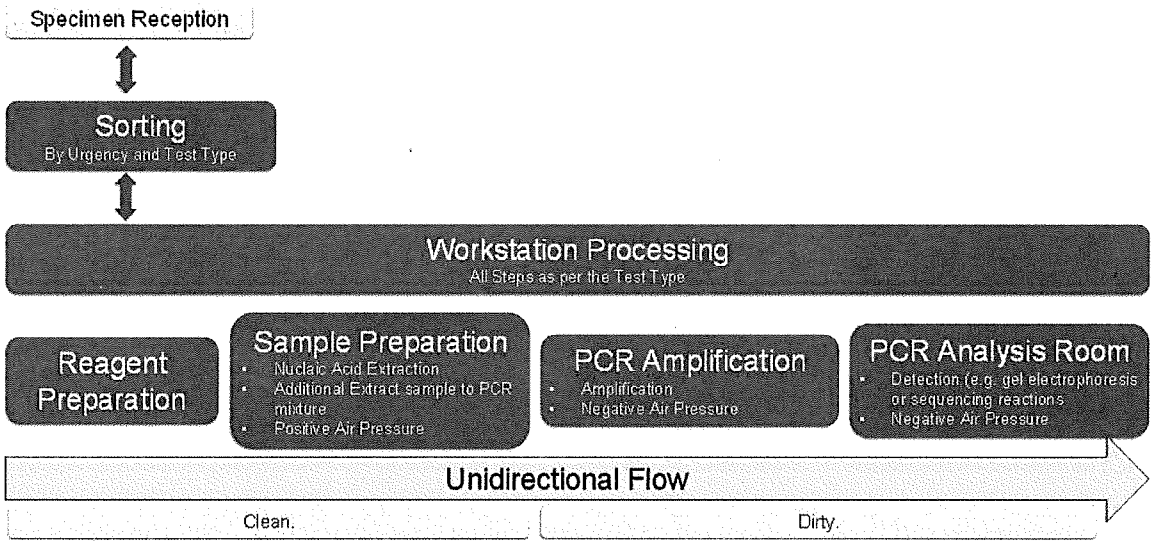
Molecular Pathology shares the following with Microbiology:

- 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.

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 7-16: Schematic Specimen Pathway for Molecular Pathology (manual tests only)



The process steps for Molecular Pathology are summarised in Figure 7-16. 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.

Specific Design Elements for Molecular Pathology

Space and Zoning

The department must meet NPAAC Requirements for Medical Testing of Microbial Nucleic Acids[78] for accreditation by the National Association of Testing Authorities Australia (NATA).

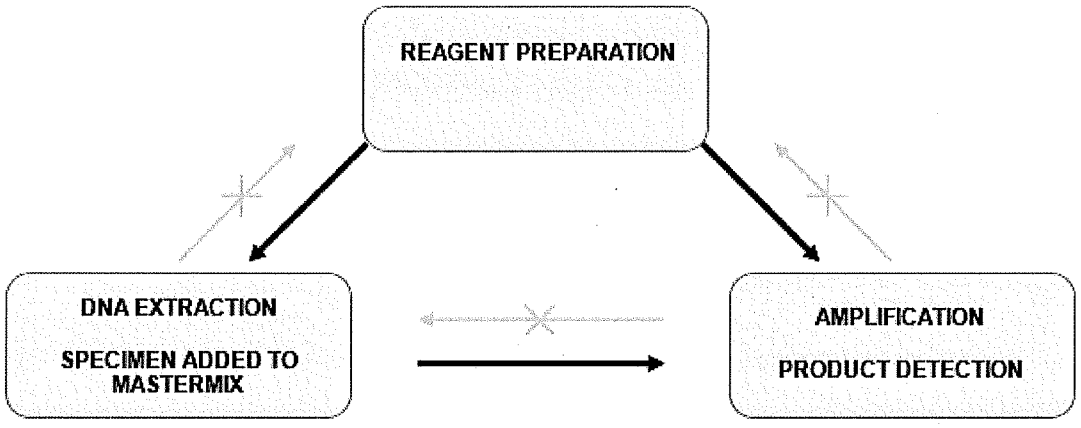
Minimum standards for a Nucleic Acid Test (NAT) assay using target amplification can be summarised as:

- Laboratories undertaking NAT assays should be configured to minimise the risk of contamination of specimens and reagents by other specimens in the laboratory or by amplified material;
- At least three contained areas must be provided in order to reduce the risk of cross-contamination and carry-over contamination. The normal airflow pattern between each of the areas and the layout of the laboratory must be designed to minimise the potential for aerosol cross-contamination. The three contained areas required are for:
  - The preparation of reagents;
  - The extraction of nucleic acids from specimen and for the addition of specimen DNA to tubes containing master mix before PCR amplification; and
  - Amplification and product detection.

A schematic representation of areas required to minimise cross-contamination is presented below in Figure 7-17. These separate areas may be separate rooms or contained areas such as within an instrument. The latter is an important consideration as instrument capabilities are progressing rapidly towards there being no required room separations.

78. National Pathology Accreditation Advisory Council, 2013, Requirements for Medical Testing of Microbial Nucleic Acids (Second Edition 2013).

Figure 7-17: A Minimum of Three Contained Areas Are Required for a NAT Assay



Instruments capable of producing aerosols such as vortex mixers, PCR machines and centrifuges should be placed at as great a distance from preparation areas as possible. If material from the first-round PCR is to be subjected to further amplification, such as in a nested PCR, these materials must be handled in a fourth separate area.

Reagents must be limited to the appropriate areas. Amplified nucleic acid specimens must not be taken into the reagent preparation area. Specimens and amplicons must be stored separately from reagents. The movement of specimens must be unidirectional, that is, from pre-amplification to post-amplification areas. Only sealed PCR amplification tubes and tube racks are to be carried between the pre-amplification area and the post- amplification area.

The Molecular Pathology department will have access to the PC3 facility (shared with Microbiology), which is used when working with high-risk or highly infectious agents that may pose significant health risks. PC3 facilities are designed to provide a higher level of containment compared to PC2 facilities, offering additional safeguards to protect laboratory personnel, the surrounding environment, and public health. PC3 facilities are typically utilised in diagnostic laboratories where high-risk pathogens need to be identified and managed. This includes handling clinical specimens that may contain dangerous or contagious agents that require enhanced containment measures.

The Molecular Pathology department typically requires various spaces and zoning to support its operations and ensure efficient workflow, including:

- Sample Reception and Processing Area: this area is dedicated to receiving and handling patient samples received via Specimen Reception. It includes spaces for sample accessioning, labelling, and initial processing (such as centrifugation, aliquoting, and storage). Adequate bench space and storage facilities for samples and reagents are necessary;

- Nucleic Acid Extraction Area: this zone is designed for nucleic acid extraction from patient samples. It should be equipped with dedicated workstations, safety cabinets, and equipment specifically designed for the extraction process, such as automated extraction systems, centrifuges, and refrigerated storage for extracted nucleic acids;

- PCR and Amplification Area: this area is dedicated to the amplification and preparation of nucleic acids for further analysis. It includes bench space, thermal cyclers, PCR workstations, and appropriate safety cabinets or hoods to prevent contamination;

- Sequencing and Analysis Area: this zone is equipped with equipment and resources for DNA sequencing and data analysis. It includes DNA sequencers, computer workstations for data analysis, and software for interpreting sequencing results;

- Quality Control and Validation Area: this space is dedicated to quality control measures, ensuring the accuracy and reliability of laboratory results. It may include equipment for running positive and negative controls, validating assays, and monitoring assay performance;

- Reporting and Documentation Area: this zone is designated for the analysis and interpretation of molecular pathology results, as well as generating reports. It includes computer workstations, software for data analysis, reporting tools, and a secure area for maintaining patient records and confidentiality;

- Equipment and Instrumentation Area: this area is allocated for specialised equipment and instrumentation required for Molecular Pathology testing, such as DNA analysers, real-time PCR machines, sequencers, and other molecular analysis platforms. Sufficient space, power supply, and proper ventilation are necessary to accommodate these instruments; and

- Ancillary Spaces: additional ancillary spaces may include storage areas for reagents, supplies, and consumables, as well as dedicated spaces for equipment maintenance and calibration. These areas help maintain efficient operations and ensure the availability of necessary resources.

Ventilation and Air Quality

The design will include consideration of the following to deodorise the spaces.

Adequate Air Exchange: the laboratory should have a sufficient air exchange rate to ensure proper ventilation and reduce the concentration of airborne contaminants. The specific air exchange rate may vary based on the size of the laboratory, the number of occupants, and the activities performed. Generally, a minimum of 6-12 air changes per hour (ACH) is recommended.

Engineering Controls: the laboratory should be equipped with appropriate engineering controls to manage and control airborne contaminants. These controls may include the use of fume hoods, laminar flow cabinets, or biosafety cabinets (BSCs) to provide containment and prevent the release of hazardous substances.

Filtration: HEPA filters should be used in the HVAC system and other ventilation devices to remove airborne particles, including potentially infectious microorganisms. The filters should be regularly inspected, cleaned, or replaced to maintain their effectiveness.

Directional Airflow: the laboratory should have a well-designed airflow pattern that ensures directional airflow from clean to potentially contaminated areas. This helps prevent the spread of contaminants within the laboratory. Typically, airflow should be from areas with lower risk (e.g., clean work areas) to higher risk areas (e.g., sample processing areas).

Pressure Differentials: maintaining appropriate pressure differentials between different areas of the laboratory is important. Negative pressure differentials should be maintained in areas where potentially hazardous materials are handled to prevent the release of airborne contaminants. Positive pressure differentials should be maintained in clean areas to prevent the entry of contaminants from adjacent spaces.

Monitoring and Alarm Systems: air quality monitoring systems can be installed to continuously monitor parameters such as temperature, humidity, and air particulate levels. Alarm systems can be implemented to alert personnel in case of deviations or unsafe conditions.

Matrix-Assisted Laser Desorption/Ionisation – Time Of Flight (MALDI-TOF): the operation of MALDI-TOF mass spectrometers, like many precision instruments, can be influenced by environmental conditions. Dust and contaminants can influence sample preparation and instrument performance. It's essential to maintain a clean environment, particularly during the sample preparation phase. This is why the technology is often situated in an enclosed space (refer to Chemical Pathology – Mass spectrometry section for further details).

Lighting

CRI measures how accurately a light source represents colours compared to natural light. A higher CRI (ideally above 90) is desirable to ensure accurate identification and interpretation of colour changes in stained specimens or indicators.

Temperature

As per "General Design Principles" in section 7.8.

Acoustic Control

As per "General Design Principles" in section 7.8.

Floor Loading

As per "General Design Principles" in section 7.8.

Sustainability

As per "General Design Principles" in section 7.8.

Storage and Specimen Retention

Storage

Molecular Pathology requires various types of storage for different purposes noting it shares processing similarities with closely linked departments – Microbiology and Diagnostic Genomics.

The types of storage for Molecular Pathology department includes:

- **Reagent and PCR products Storage**: some can be kept at room temperature and some needs to be refrigerated (2-8 degrees Celsius) within the Centralised Walk-in Cold Room and Freezer Room;
- **Specimen and Isolates Storage**: Molecular Pathology specimens include purified nucleic acids, they will be kept in the Centralised Walk-in Cold Room and Freezer Room;

- **Equipment Storage**: some laboratory equipment may be stored away when not in use within the Centralised Equipment Store.
- **Record Storage**: some space for record storage will need to be allocated as some physical records (such as patient records, quality control records, and maintenance logs) may still need to be kept on site despite ACT Pathology moving towards complete electronic record-keeping using DHR; and
- **Waste Storage:** waste storage will be organised at two distinct levels in a multi-floor structure. At the workstation level, individual waste containment solutions will be tailored to the immediate needs of each specific workstation, ensuring efficient and safe waste disposal during daily operations. On the floor level, centralised waste storage areas will be designated to consolidate waste from various workstations, facilitating easier collection, segregation, and eventual disposal. This dual-level approach ensures both immediate waste management needs and broader floor-wide requirements are adequately addressed. Specific waste storage for Molecular Pathology includes:
  - Biological Waste: Molecular Pathology laboratories work with biological materials that may be potentially infectious or biohazardous, including:
    - Cultures: microbial cultures, such as bacteria, fungi, viruses, or parasites, that are no longer needed;
    - Specimens: biological samples collected for testing or research that are no longer required; and
    - Contaminated Materials: items contaminated with potentially infectious materials, such as gloves, pipettes, Petri dishes, and disposable labware.

    Biohazard waste will need to be autoclaved (sterilised using high-pressure steam) before disposal. There will need to be an autoclave accessible to these departments as well as a separate system built into the PC3 facility.
  - Chemical Waste: Molecular Pathology laboratories utilise various chemicals for experiments, staining techniques, or disinfection. Chemical waste includes:
    - Reagents: expired or unused reagents, solutions, or media;
    - Stains: used staining solutions or dyes that are no longer required; and
    - Chemicals: discarded chemicals, such as disinfectants, fixatives, or solvents.
  - Sharps: needles, syringes, or other sharp objects used in the laboratory for specimen collection or other procedures;
  - General Laboratory Waste: Molecular Pathology laboratories also generate general laboratory waste, including:
    - Packaging: packaging materials, such as cardboard boxes, plastic wrap, or Styrofoam used for delivery or storage of laboratory supplies;
    - Non-Contaminated Waste: non-hazardous waste that does not fall under biological or chemical waste categories, including paper towels, disposable gloves, or non-infectious plastic items; and
    - Glassware: broken or discarded glassware, including test tubes, slides, or glass pipettes.
  - Liquid Waste: Molecular Pathology laboratories may produce liquid waste, such as liquid cultures and media and buffer solutions.

Molecular Pathology also needs to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

Specimen Retention

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 for Molecular Pathology accords with section 7.8.2 unless otherwise specified below in Table 7-29.

Table 7-29: Minimum Retention Times for Molecular Pathology

	RECORD/MATERIAL	MINIMUM RETENTION TIME
3-2-3	Cytogenetics/biochemical genetics/molecular genetics: Tissue cultures/cell culture lines ▪ Rare clinically significant variants ▪ Common clinically significant variants or clinically non-significant	 For indefinite cryopreservation As per Table 7-4, row 3-2-7
3-2-6	Molecular genetics: ▪ Nucleic acid extracts for somatic or constitutive testing ▪ Nucleic acid extracts or frozen plasma for NIPT	 3 months[79] 12 months

Key Functional Relationships and Adjacencies

Internal Relationships

Molecular Pathology has a close clinical relationship with Microbiology and operationally can share laboratory space with DG. Molecular and Microbiology laboratories need to be adjacent if possible to enable seamless flow of specimens, staff and intellect between the two departments.

In terms of other adjacencies, Microbiology and Molecular should be adjacent as much as possible due to shared specimens and processes, while DG and Molecular Pathology should be adjacent due to shared equipment for WGS.

Molecular Pathology and Microbiology are currently functioning as two separate departments, within the same clinical discipline, but would benefit from being combined as a single operational department in the new Pathology Facility due to the significant clinical overlap, shared specimens, movement of traditional microbiology to molecular based staff and ability to cross train staff.

Both Molecular pathology and Microbiology are moving to an increased level of robotics, and the FRD (see Figure 7-4) is based around the following key principles:

- Much of Microbiology testing will move to tracked robotics, which will increase size of the required 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 DG to allow sharing of laboratory space and equipment e.g. PCR Clean Prep, Specimen Prep, and DNA Amplification;

79. From date of issue of the report for an individual, or from completion of a family study where the proband's sample is required as a control, or from completion of testing; whichever of the three periods is the longest.

- Molecular Pathology should also be adjacent to the Core Laboratory. More and more instrumentations are being enabled to connect to track systems over time, with Molecular Pathology robotics likely being able to connect to a track system when the new Pathology Facility opens – this is already possible with Roche instrumentation;
- The spaces will be open plan wherever possible, exceptions of which include the PC3 facility; and
- There will be sufficient space to allow a fast scale-up of services if needed, e.g. pandemic.

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.

Management and Operational Support Services

Current location

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

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 (ie BioFire FilmArray for Meningococcal infections).

Major Equipment List

Current major equipment for Molecular Pathology is detailed in Appendix Table A9-9 Key equipment used in Molecular Pathology laboratory includes but is not exclusive to PCR analysers, Extractors, Freezers, Thermocyclers, Robotics, Biological Safety Cabinets (BSC II) and fume hoods.

See Table A10-1 for future equipment list for all departments.

Workforce Model

The workforce model[80] reflects the clinical capability level of Molecular Pathology, with staffing levels provided in Table 7-30 below. The staffing complement includes clinical director, pathologists, registrar, chief scientist, and laboratory/pathology scientists.

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

Table 7-30: 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
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.

A Future State

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 WGS and metagenomics, DNA extraction, quality testing, and advances in omics technologies (possibly in partnership with others). Microbial Genomics and Metagenomics as established technologies for public health purposes but over the next 5 -10 years will transition more into routine clinical diagnostics.

Provision has been made for enhanced area allocation to enable the expected growth.

7.10. 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.

7.10.1. 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:

- Easy access is provided at all times for staff to maintain/repair precious specimens when needed;
- If appropriately located, public access needs to be carefully controlled so that it is for education/learning purposes only, mainly to medical undergraduates and other junior medical staff; and
- The Museum should be adjacent to a teaching space allowing for tutorials and clinicopathologic conferences involving pathology case materials and wet specimens.

Research

Research at CH is detailed in section 12, 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 and 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.

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.

7.10.2. 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.

8. 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.

8.1. SCOPE OF SERVICE

The mortuary service will include:

- **The acceptance and safe repository** of bodies during and after business hours[81] 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 Organisations[82], including the management of relevant/necessary paperwork;

- **Perinatal post-mortem service** (PPMS)[83]: 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 Coordinator[84] 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.

8.2. PATHWAYS

Coronial Matters

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

Non-Coronial Deaths

81. ACT Pathology, Anatomical Pathology Introduction.
82. ACT Pathology, Anatomical Pathology Introduction.
83. NSW Health Pathology, Clinical Services Plan 2019 – 2025.Version 2:2021.
84. This is a Midwife on ward function.

Mortuary pathways[85] 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 8-1);
- 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 8-1: Infectious Diseases a Deceased Person is Suspected or Known to have been Exposed to, List A vs List B[86]

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	

8.3. SPECIFIC DESIGN ELEMENTS FOR THE MORTUARY

Space and Zoning

The design of a forensic mortuary is, to a significant extent, determined by the workflow of forensic examinations and the related activities that take place within the facility. The design can help guide the process from the arrival of a body to the completion of a forensic examination and the subsequent tasks, including:

- **Arrival and Reception**
  - The body arrives, often accompanied by personal effects;

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

- A discreet unloading zone should be close to the body reception area, ideally via a garage with sufficient clearance for a range of vehicles;
- There will need to be a workstation for cataloguing and storing personal effects; and
- There should be sufficient space to unload the body and move the body to weighing stations. This is typically an open atrium like space.

- **Body Storage:** the body is transferred to a refrigerated holding area or cooler. Consider the need for specialised storage, e.g., for decomposed bodies.
- **Case Review:** before the autopsy, the forensic pathologist reviews the case details, including any available medical records, police reports, and preliminary investigations. Office space or a designated area for such reviews is essential.
- **Autopsy:** the body is moved to an autopsy suite(s). All required instruments, protective equipment, and facilities (e.g., sinks, tables) should be readily available.

Other Mortuary design considerations include:

- Unlike the laboratory environments, many of the spaces will require separation/access restriction;
- The design should be flexible to accommodate evolving technologies and practices. Ensuring efficient flow, minimising unnecessary movements, and segregating 'clean' and 'dirty' zones will contribute to a functional and efficient facility;
- Good lighting, efficient ventilation, and easy-to-clean surfaces. Samples for histology, toxicology, microbiology, etc., are collected during the autopsy. These samples are then processed or sent to the relevant laboratory spaces;
- Body Preparation for Release: after the autopsy, the body is prepared for release, either for burial or cremation. A dedicated area for body preparation, restoration, and cleaning is necessary;
- Reporting: forensic pathologists need space to compile their findings, write reports, and consult with colleagues. Office spaces or dedicated report-writing areas, equipped with necessary IT infrastructure, are essential. However it is noted that most Anatomical Pathologists would chose to do this in their routine offices.
- Viewing space is ideally located adjacent to the autopsy suite(s);
- Provision for offices, meeting rooms, storage areas, as well as other administrative spaces; and
- Given the sensitive nature of the work, there should be security measures throughout the facility, including controlled access points, CCTV, and secure zones.

While primarily focused on indoor activities, a mortuary design may also benefit from well-designed outdoor spaces. These spaces can cater to both functional requirements and the socio-cultural needs of those visiting or working at the facility. Some important outdoor spaces for mortuaries may include:

- Arrival and Departure Zone: a private and respectful space where bodies can be brought in or taken out. This area should be shielded from public view and have easy access to the main mortuary area;
- Visitor Parking: adequate parking for grieving families, officials, or other visitors should be available and clearly demarcated;
- Private Family Waiting or Gathering Area: an outdoor garden or seating area where families can gather before or after viewing their deceased loved ones. This space should offer privacy, serenity, and a natural setting;

- Smoking or Ritual Area: some cultures and individuals might have specific rituals, including smoking rituals, to honour the deceased. A dedicated outdoor space for this, which adheres to local smoking regulations, is important and away from solvents and other flammables;
- Reflection or Memorial Garden: a peaceful garden area where families can reflect and remember their loved ones. This can also be a therapeutic space for staff;
- Service or Utility Area: an area designated for services like waste management, laundry pickups, or other utility needs. This space should be separated from the main visitor areas to maintain privacy and cleanliness;
- Staff Break Area: working in a mortuary can be emotionally taxing. Providing an outdoor break space for staff where they can relax and detach for a short time is crucial for well-being management;
- Secure Delivery and Storage: a dedicated area for the safe and secure delivery of supplies, equipment, and chemicals, separated from main visitor and body arrival zones;
- Barrier Plantings: planting shrubs or trees strategically to provide privacy, reduce noise, and shield sensitive areas from public view; and
- Water Features: the sound of flowing water can be soothing for many. Inclusion of a fountain or a small pond can enhance the tranquillity of outdoor spaces.

Ventilation and Air Quality

Below are some considerations for ventilation and air quality in the mortuary space.

- Negative Pressure: autopsy rooms and certain storage areas should maintain negative pressure relative to adjoining spaces. This ensures that odours, contaminants, or potential airborne pathogens from the autopsy area do not spread to other parts of the facility;
- Air Changes per Hour (ACH): ACH is a measure used in ventilation planning and design to describe how many times the entire volume of air within a specific space or room is replaced by fresh or filtered air in one hour. If a room has an ACH of 6, it means the entire volume of air in that room is replaced six times in an hour. Autopsy suites should have a high number of air changes per hour to remove contaminants effectively. Typically, this might range from 6-12 ACH, but the exact number might vary based on local guidelines or the size and design of the facility;
- Exhaust Systems: should be designed to direct air away from intake vents, building air systems, and pedestrian areas. This ensures that contaminated air doesn't re-enter the building or affect nearby area;
- Air Filtration: HEPA filters should be employed to capture fine particulates and potential pathogens, ensuring clean air circulation;
- Odour Control: given the nature of work in a mortuary, effective odour control is essential. This not only makes the environment more pleasant but is crucial when there are family members or other visitors in adjacent spaces like viewing rooms. Activated charcoal or other specialised filters can help in managing odours;
- Special Considerations for Hazardous Materials: in cases where chemicals or hazardous materials (e.g., formalin) are used, there should be effective fume hoods or localised exhaust systems. This ensures that fumes are captured and removed directly at the source (refer to anatomical pathology section for more details);
- Emergency Ventilation: in the event of a significant chemical spill or release of hazardous fumes, emergency exhaust systems should be in place to quickly remove contaminant;.

- Regular Monitoring and Maintenance: air quality should be routinely monitored to ensure safety standards are maintained. This might include checking for chemical concentrations, particulate levels, or microbial contaminants. Regular maintenance of the ventilation system ensures it operates efficiently and safely; and

Lighting

The needs of a mortuary might change over time. Designing a lighting system that allows for adaptability and adjustments can be beneficial:

- Task Lighting:
  - Examination and Autopsy Areas: these require bright, shadow-free lighting to ensure accurate visual assessment during examinations. Adjustable or movable lighting fixtures can be beneficial;
  - Workstations: areas where paperwork, documentation, or computer-based tasks are done will require focused task lighting that minimises glare on screens and documents;
  - Ambient Lighting: for non-examination areas like corridors, waiting areas, or offices, the lighting should create a calm and peaceful ambiance. Soft, indirect lighting can be appropriate;
- CRI: A high CRI is crucial in autopsy or examination areas. It ensures that the true color of tissues and samples is accurately represented. Typically, a CRI of 90 or above is recommended;
- Dimmable Lights: having the option to dim lights can be valuable, especially in areas where different tasks or ceremonies might take place;
- Natural Light: while mortuaries traditionally might not prioritise natural light due to their nature and function, introducing natural light can improve the well-being of staff and provide a more pleasant environment. However, considerations for privacy and the potential effects of sunlight on decomposing bodies or samples must be addressed;
- Mood Lighting for Viewing Rooms: If the mortuary has rooms where families come to view or spend time with the deceased, soft and comforting lighting is essential. This can help create a more serene and peaceful environment for grieving families.
- Safety and Navigation: areas like corridors, entrances, and exits should be adequately lit for safety. Emergency exit paths should have backup lighting in case of power failures;
- UV or Specialised Lighting - In some instances, special lighting might be needed for particular examinations or tasks. For example, UV lights can help highlight certain bodily fluids or tissue changes; and
- Energy Efficiency - Given the potential for long hours of operation, using energy-efficient lighting options like LED can lead to significant energy and cost savings over time; and
- Consider the ease of replacing or maintaining lighting fixtures, especially in areas that need to be kept sterile or clean.

Temperature and Humidity Control

Apart from air quality, controlling temperature and humidity is essential. Cool temperatures are necessary in storage areas to prevent decomposition. In autopsy areas, a comfortable temperature ensures staff comfort. Humidity control is crucial for preserving evidence and preventing mould growth.

Flooring

Non-slip floor covering for floors that may get wet is critical.

Acoustic Control

The following are some of the noise considerations when designing the space:

- Conversations, especially those involving grieving families or sensitive topics, should be private. Walls, doors, and partitions should be soundproofed to ensure conversations remain confidential;
- Examination and autopsy rooms should also have a degree of acoustic privacy to prevent potentially distressing sounds (i.e. power tools) from being heard in adjacent spaces;
- External Noise Intrusion: proper insulation and soundproofing materials can reduce noise intrusion from adjacent roads;
- Equipment Noise: certain equipment used in a mortuary, such as saws, refrigeration units, or ventilation systems, can generate noise. These should be sound-insulated or located in areas where noise will have the least impact;
- Flooring Materials: soft, sound-absorbing flooring materials can reduce noise from foot traffic and moving equipment like trolleys;
- Reverberation Control: large, hard surfaces can cause sounds to reverberate and amplify. Using acoustic panels or ceiling tiles can help in reducing reverberation;
- Dedicated Quiet Areas: spaces for reflection, counselling, or private conversations should be especially quiet. Ensure these areas are distant from noisy equipment or operations and well-insulated;
- Designing buffer zones, such as storage areas or corridors, between noisy spaces and quiet spaces can help reduce noise transmission;
- Doors and Windows: using acoustically rated doors (especially for examination rooms and consultation areas) as well as double-glazed windows can also help in reducing external noise intrusion;
- Ventilation and HVAC Noise: the design of the ventilation system should minimise noise. Using silencers, sound traps, or specifying low-noise HVAC units can be beneficial;
- Notification Systems - Instead of loud bells or alarms, consider using light-based signals or vibration alerts. If audio alerts are necessary, ensure they are gentle and not jarring; and
- External Spaces: if the mortuary has outdoor spaces, consider the potential noise sources affecting them. The design should ensure that the environment respects both the deceased and the living.

Floor Loading

The following is a list of items with considerable impact on the load design:

- Static Loads:
  - Storage Racks and Cabinets: these can get quite heavy, especially when fully loaded with bodies or specimens. The weight of stainless-steel cabinetry, refrigerated units, and their contents can add up;
  - Autopsy Tables and Equipment which includes permanent fixtures like autopsy tables, large sinks, and specialised equipment; and
  - Personnel.
- Dynamic Loads:
  - Body Transfer Systems: Motorized lifts, hoists, or conveyance systems used for moving bodies will add to the dynamic loads on the floor.
  - Mobile Equipment: this includes items like portable X-ray machines, carts, or other mobile tools that might be moved in and out of autopsy rooms or storage areas; and
  - Trolleys and Carts: these are used frequently in mortuaries to move bodies and samples. Consider their weight when loaded to capacity.
- Impact Loads:
  - While not directly related to loading, ensure that the floor is waterproof and has adequate drainage, especially in autopsy areas. A sloped floor towards drains can be beneficial; and
  - Some equipment, like large refrigeration units or mechanical body transfer systems, might produce vibrations. This isn't strictly related to static or dynamic load but can affect the integrity and lifespan of the flooring system.

8.4. STORAGE AND SPECIMEN RETENTION

Mortuary services require specific storage facilities and equipment to handle and preserve deceased bodies with dignity and in accordance with public health standards. Here are the primary storage requirements for mortuary services:

- Body Refrigeration Units;
- Stainless steel trays are used for holding bodies, and the racking system allows for efficient use of space in refrigeration units;
- Bariatric Storage;
- Temporary Freezer Units;
- Space for Autopsy Tables;
- Body Hoists and Lifts;
- PPE Storage;
- Histology and Sample Storage: after autopsies, tissue samples might be taken for further histological examination. These samples need to be stored in formalin-filled containers or other preservative solutions and might require refrigeration or freezing;
- Chemical storage cabinets for storing disinfectants, formalin, and other chemicals used in the autopsy process;
- Instrument Storage: for autopsy tools like scalpels, saws, forceps, and other instruments.
- Documentation and records storage systems for organising and storing records related to each case, including autopsy reports, photographs, and other relevant documents;

- Waste Storage and Disposal: bins and containers for biohazardous waste, sharps containers for needles and blades, and general waste bins;
- Facilities or storage for larger waste items, such as body parts or organs that are not returned to the body, until they can be appropriately disposed of;
- Secure Storage for personal items that come with the deceased. These items are catalogued and stored until they can be returned to the family or next of kin;
- Emergency equipment storage for equipment like defibrillators, first aid kits, and other emergency tools in case of any incidents; and

Given the sensitive nature of their work, mortuaries must maintain strict standards of cleanliness, respect for the deceased, and adherence to legal and ethical guidelines. Mortuary services also need to be consistent with the broader pathology specimen storage principles as outlined in section 7.8.1.

8.5. KEY FUNCTIONAL RELATIONSHIPS

Internal Relationships

Mortuary services' internal functional relationship is denoted in Figure 7-2. The department 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.

8.6. MANAGEMENT AND OPERATIONAL SUPPORT SERVICES

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.

8.7. MAJOR EQUIPMENT LIST

Current major equipment for the Mortuary is detailed in Appendix Table A9-10. Key equipment used in Mortuary includes but is not exclusive to Balances, Freezers, Refrigerators, Fume Cabinets, Safety Cabinets, Thermometers, Safety Showers, Examination Tables, Cameras, Body Trolleys, TVs, Bone Saws, Metal Shelvings, Lifters, Lounge, Chairs, Beds, and Flammable Liquid Cabinets.

8.8. WORKFORCE MODEL

The workforce model reflects the clinical capability level of mortuary services, with staffing levels provided in Table 8-2 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 8-2.

Table 8-2: 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.

8.9. 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 given the reduced role and volumes for adult autopsies.

9. Pharmacy

9.1. DESCRIPTION OF SERVICE

The Pharmacy Service is a core clinical support function that supports the provision and quality (safe and effective) use of medicines throughout the health service.

The Pharmacy service at CHS operates at a Level 6 clinical capability. It is critically important that Pharmacy continues to operate at the highest clinical capability level as many other clinical services depend on Pharmacy being able to consistently function at Level 6[87].

A Level 6 service means the provision of a comprehensive range of pharmacy functions that includes but not restricted to:

- Clinical pharmacy advice and support to all health service providers at CH in matters relating to quality use of medications in patient care;
- 24-hour on-call arrangements;
- Medication distribution to inpatient, outpatient, and discharged patients;
- Medication distribution to CHS health care locations in the community;
- Sterile manufacturing of cytotoxic medications for inpatients and approved outpatients, and clinical reviews of cytotoxic medicines;
- Pharmacological support for clinical trials;
- Sterile and non-sterile compounding, including infusions, ophthalmological preparations, and total parenteral nutrition;
- Provision of specialised pharmacy services for renal dialysis, drug and alcohol, oncology, and cystic fibrosis;
- Support of contemporary practice with pharmacy as part of a Multi-Disciplinary Team (MDT), particularly for clinical areas with complex or poly-pharmacy patients;
- Medication information distribution and promoting medication safety in the health service; and
- Quality and risk management programs in line with current NSQHS Standards as appropriate.

9.2. SPECIFIC DESIGN PRINCIPLES

The overarching planning principles for the Pharmacy unit are derived from the AusHFG for Pharmacy Units, HPU 560.

The overarching design principle for Pharmacy in the Phase 2 redevelopment is to automate and replace functions with robots to the greatest extent possible. Robots can organise medicines and prepare prescriptions, monitor medicine expiration dates, perform stock control and automate orders.

Further specific design principles relevant to pharmacy include:

- A reception/waiting area and an interview area for patient counselling;

87. NSW Ministry of Health, NSW Health Guide to the Role Delineation of Clinical Services, Fourth Edition, October 2019, available: https://www.health.nsw.gov.au/services/Publications/role-delineation-of-clinical-services.PDF.

- An after-hours drug store which may be located close to clinical areas, or on the periphery of the pharmacy with internal and external access;
- An automated packing and dispensing system (*PillPick*);
- Pneumatic tube infrastructure and system for medications;
- Provision for bulk store, distribution, and support;
- Pharmacy Administration areas;
- Two contained aseptic production units;
- Provision of pharmacy dedicated space for clinical trials;
- Medication Inventory - In addition to the stock control and the reliance on an imprest system to deliver timely medicines for all clinical purposes, the on-site storing of medications is expected to change, with reduced space due to an efficient imprest system, and increased space needs due to the ever-increasing range and type of pharmaceutical products that need to be available. Therefore, it is expected that overall inventory space will not reduce;
- Storage requirements - Pharmaceutical products have different storage requirements including some that are refrigerated (at different temperatures). Others will also require temperature monitoring, even if not refrigerated;
- Regulatory storage requirements - There are regulatory requirements for the secure storage of restricted (scheduled) medications that are applicable within the pharmacy, at satellite pharmacies and in patient areas; and
- Distribution - The distribution systems are likely to change significantly in the future. There are low tech systems such as pneumatic tubes and Automated Dispensing Cabinets (ADCs) as well as robotics and Artificial Intelligence (AI).

9.3. OPERATIONAL MANAGEMENT

9.3.1. Hours of operation

Pharmacy services currently operate from 8.30am-4.30pm Monday to Friday with extended hours (emergency service) from 4:30pm-7.00pm, and on Saturdays and Sundays from 9.00am-4:30pm. There is:

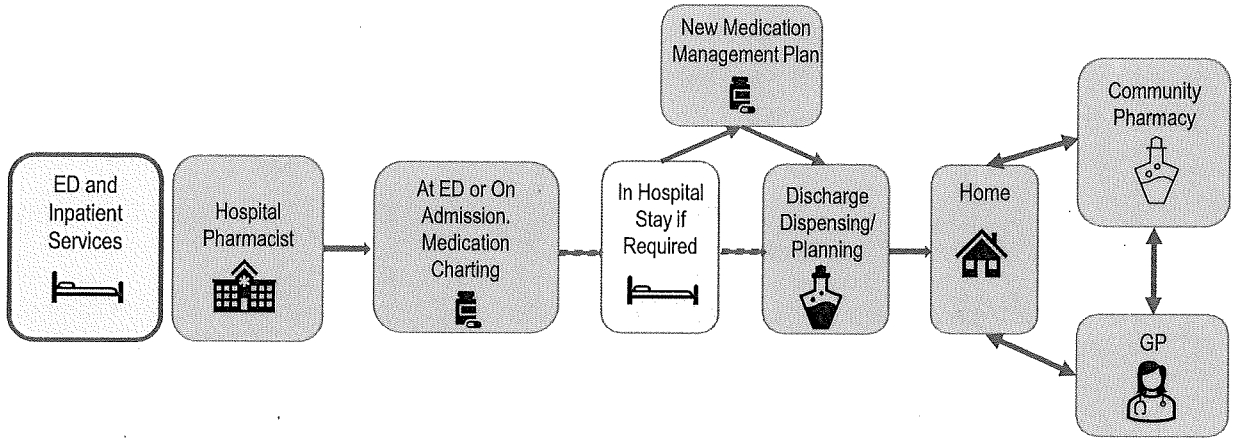
- A remote clinical pharmacy service (5pm to 1am weekdays and 2pm to 10pm Saturdays);
- A limited pharmacy service for surgery that commences at 7am;
- An emergency on-call pharmacy service for all other times; and
- A plan to move towards a 24-hours, 7 days service model in the future.

9.3.2. Patient journey

The respective patient pathways for inpatients and outpatients at CH in relation to the pharmacy service is shown in Figure 9-1 and Figure 9-2 and described below.

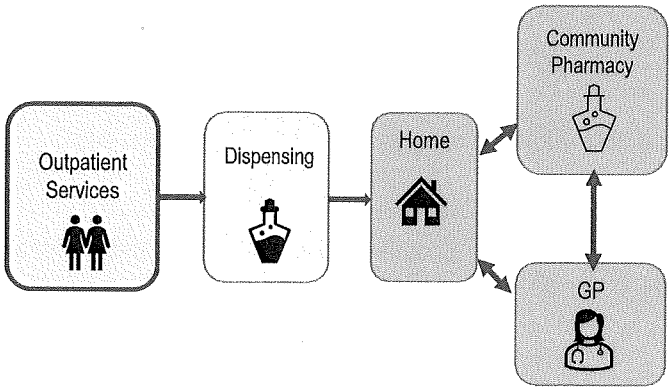
For inpatients, a hospital pharmacist will visit the patient while they are admitted. The patient's current medications will be discussed, and any changes to medications after treatment, if known. Discharge pharmacy services include dispensing of medication (with a default supply equivalent to the quantity outlined under the Pharmaceutical Benefits Scheme) and arranging services with the patient's local community pharmacy.

Figure 9-1: ED and Inpatient Pathway in Relation to Pharmacy Service



For outpatients, some medications may be dispensed by the hospital at the time of the specialist outpatient service. Most often these are medications that are usually only available at hospital pharmacies. Otherwise, scripts are dispensed at the patient's community pharmacy of choice.

Figure 9-2: Outpatient Pathway in Relation to Pharmacy Service



9.3.3. Family and carer support

The pharmacists may involve families / carers when counselling patients, according to the patients' wishes.

9.3.4. Staff support

Pharmacy staff will require a beverage bay, and/or a staff room with kitchenette facilities within the department. Staff will also require access to end of trip facilities.

9.4. FUNCTIONAL CONTENT

There are currently five pharmacies across CHS:

- Main Pharmacy and dispensary, Building 1 Level 2 (street level);

- (Specialist) Oncology Pharmacy, Building 19, Level 3, Canberra Region Cancer Centre. Whilst this pharmacy is not accessible to patients, pharmacists visit clinics to provide services to oncology patients alongside their treating physicians/specialists;
- Justice Health Pharmacy, Building 3, Level 2;
- North Canberra Hospital; and
- University of Canberra Hospital (UCH) Pharmacy.

The main pharmacy in B1 is the in-scope Pharmacy service for this FDB as it represents the criterion of 'like-for-like' relocation.

CHS has a clear preference for a consolidation of the main pharmacy with the on-campus pharmacy satellites. This would increase space requirements that are not like-for-like. Whilst this can be a consideration, the satellite consolidation is not a contemporary direction for tertiary pharmacies. It would appear that there is likely to be greater net benefits from maintaining high volume satellite services (such as oncology) in preference to consolidation. These are obviously important issues that need further consideration in the refinement process in future planning stages.

9.5. FUNCTIONAL ADJACENCIES

Pharmacy has functional relationships with **all clinical services at CH and other campuses**. There are some clinical relationships that are stronger and more prominent than others, which may have influence over the following:

- ADCs; and/or
- Regularly assigned pharmacists to patient planning meetings and clinical areas; and
- IPU rounds for newly admitted patients.

Notwithstanding the critical and close clinical support provided by pharmacy, the central pharmacy does not need to be proximal to other clinical services.

External relationships include:

- Healthcare providers (e.g., GPs, specialists, and allied health practitioners): providing medication management such as drug selection, tailored patient (medication) service, advice about drug interactions, dosage requirements/adjustments, and alternative therapies;
- Regulatory Agencies (such as Pharmacy Board of Australia, TGA and AHPRA) to ensure ongoing compliance;
- Health Authorities in relation to regulatory regimes and antimicrobial stewardship (AMS);
- Research Institutions and Universities;
- Medicines procurement and distribution services;
- Quality and risk management programs in line with NSQHS Standards current as appropriate;
- Aboriginal programs and services including relevant referral pathways; and
- Community pharmacies.

9.6. WORKFORCE

Staff and skills mix for the main Pharmacy Service would ensure consideration of the range of general and specialised pharmacy skills, experience, and core competencies to manage the range of pharmacy services expected of a Level 6 service. In addition, a future workforce would be able to support more teaching and research positions, particularly in new clinical practices, individual therapies, and safer use of medicines.

10. Mental Health Short Stay Unit

10.1. DESCRIPTION OF SERVICE

The Mental Health Short Stay Unit (MHSSU) is a standalone mental health inpatient unit designed to facilitate short admissions of up to 48 hours. All clients must be assessed in a face-to-face assessment by a Psychiatry Registrar for an admission to MHSSU. Admissions from other sources are also considered, pending assessment of suitability by MHHSU consultants.

The MHSSU provides:

- Psychosocial assessment, short term stabilisation, brief therapeutic intervention, and organisation of follow up care for primary mental health issues, provided by the multidisciplinary team (medical, nursing, allied health clinicians);
- Medical assessment and support for concurrent physical health issues;
- Assessment and treatment for concurrent AOD issues;
- Other supports as required, e.g., Aboriginal Liaison Officers, peer workers; and
- Close liaison with community health providers (e.g., Community MH Teams, General Practitioner (GPs), family and carers, as well as NGO supports.

Clients are deemed ineligible for MHSSU admission if they are:

- Likely to require a mental health admission extending beyond 48 hours;
- Under the age of 18 years;
- Not assessed as medically stable by a member of the ED medical staff;
- Exhibiting aggressive behaviours;
- Exhibiting signs of delirium, overt confusion, or decreased level of consciousness;
- Have a primary diagnosis of dementia, developmental disability, or traumatic brain injury (unless they are experiencing a significant psychiatric disorder);
- Frail elderly; or
- Intoxicated from alcohol or other drugs; or
- Experiencing a primary diagnosis of drug or alcohol related conditions without significant mental health co-morbidities.

Clients who are referred from the ED (or other sources) and accepted as eligible and appropriate for care are formally admitted to the unit for observation and management.

The MHSSU is an approved and gazetted facility and can accommodate clients under specific legislative arrangements, including under the Mental Health Act 2015 (Section 80) and the Crimes Act 1900 (Section 309).

10.2. SPECIFIC DESIGN REQUIREMENTS

Refer to Section 3 for the design principles of the patient environment.

The MHSSU will comprise separate rooms with ensuites. There will also be an open lounge area with kitchen or kitchenette. There should be no ligature points in the unit.