
RETENTION OF LABORATORY RECORDS / SPECIMENS

1. Purpose of the Document

This document represents the minimum standards for retention of laboratory records and diagnostic material at LabPLUS. All laboratory records and diagnostic material are kept secure, identifiable, and legible and stored in a readily retrievable form.

2. Scope

1. This policy applies to:

- All patient and business-related information collected, created, received, stored, accessed or retained in the course of LabPLUS business activity, which must be protected according to its level of sensitivity, criticality, or value, regardless of the media in which it is stored in.
- All locations where information is stored, accessed or retained, including offsite.

3. Responsibilities / Information

1. LabPLUS has a responsibility to comply with all legislation, standards, codes and guidelines relevant to the appropriate storage, management and retention of laboratory records and diagnostic material, patient or business-related.
2. It is the responsibility of **all** staff to ensure information is accurate, stored securely, protected from loss or damage, unauthorised access, alteration or corruption at all times.
3. Electronic records may be kept in place of hard copies where applicable.
4. Diagnostic records/reports belong in individual patient's clinical records.
5. All records containing patient information requiring disposal are to be placed in confidential rubbish.
6. Disposal of CD's and DVD's to be cut in half prior to disposal.
7. Minimum retention times are based on the following :
 - Disposal Authority Number: DA262 District Health Boards General Disposal Authority (**GDA**)
 - National Pathology Accreditation Advisory Council (**NPAAC**)- Requirements for the Retention of Laboratory Records and Diagnostic Material
 - Royal College of Pathologists (**RCP**) Retention and Storage of Pathological Records
 - Specimens and National Cervical Screening Programme (**NCSP**) Requirements for Retention

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- Hazardous Substances and New Organisms (HSNO)
- Ministry for Primary Industries (MPI)

4. General Minimum Retention Time

4.1 Table 1 – General Items Minimum Retention Times

Ref	GENERAL	Minimum Retention Time	Storage	Disposal Method
GDA 10.4	Assessments/ Audits of LabPlus Systems, Compliance, Environs etc	7 Years – final report 3 Years – raw data *	Quality Manager Medialab IANZ	Destroy
ADHB Research Policy	Clinical Trials <ul style="list-style-type: none"> • Documentation (Refer to LPADMCTUIN007 Clinical Trials Retention of Documents Letter) 	Variable depending on study 15 years from completion of the study	Prior to 2010: ACT database Current: stored on L drive	Destroy
RCP Appendix 1	Communication Records– Clinical e.g. communication of unexpected findings, urgent reports, delayed reports, images or photographs, clinical correspondence	Scanned into patient records 30 years	healthAlliance Server	Destroy
Local LabPlus Policy	Communication Records <ul style="list-style-type: none"> • Queries/ enquiries/ significant emails • Customer feedback forms • Customer survey forms 	3 years	Individual disciplines	Destroy
GDA 10.12 10.13 10.14 ADHB Policy	Complaints/ Quality Incident records and action taken <ul style="list-style-type: none"> • Minor incidents • Complaints and major incidents • Patient complaints 	7 Years 10 Years 10 years	Datix / RiskPro Individual disciplines ADHB Consumer Liaisons / Quality Manager	Destroy
NPAAC 1.6	Digital Images / Graphical Output Used in Diagnosis e.g. CD's/DVD's of radiology or x-rays	4 years	heathAlliance Server	Destroy

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Ref	GENERAL	Minimum Retention Time	Storage	Disposal Method
NPAAC 1.3	(Major) Equipment Records <ul style="list-style-type: none"> Refer QC /QA for minor equipment 	Life of equipment plus 4 years	Individual disciplines, or offsite	Destroy
GDA 13.4	Employee Attendance Records e.g. rosters, attendance registers, training/conference attendance, reports, time use recording	Employment + 7 years	Department Manager / Department Section Head	Destroy
GDA 10.1, 13.11 13.12	Employee Health, Safety and Welfare Accident and First Aid Minor Records (Employees) Incident, Accident, "Near Miss" and first aid records not involving fatalities and/or prosecution , for example accident, incident, near miss reports , first aid records . Administration Administration of OHS (Occupational, Health and Safety),employee welfare and support services such as safety administration, accident compensation claims / returns, vaccination and health checks, workplace support services(employee counselling), employee assistance programmes (EAP) Individual Employee Files Records outlining occupational health and safety issues in a separate employee file that contains information summarised or reported elsewhere. For examples, incident, accident, near miss reports, Employee health information	7 years after date of last action 7 years after date of last action 10 years after last date of employment	Prior to 2018:Kiosk Post 2018:Datix Individual disciplines Occupational Health Individual disciplines Occupational Health	Destroy
GDA 13.9	Employee Training/ Competency Records/ HR records	Employment + 7 Years	Individual disciplines HR	Destroy

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Ref	GENERAL	Minimum Retention Time	Storage	Disposal Method
GDA 11.1	Financial Approvals and Accounting Records e.g. approval of capital and/or operational expenditure	10 years after date of last action	Operations Manager Administration Individual Disciplines	Destroy
GDA 8.1, 8.2	Historical Records e.g. Post Mortem books, Mortuary books	Prior to 1920 Prior to 1946 FP-hold indefinitely	Off site On site in FP	Transfer to Archives NZ Offer to Archives NZ
GDA 14.6	I.S Systems – Installation, testing and ongoing maintenance e.g. test scripts, fixes, customisations, network operations and monitoring, database management etc.	Retain for active life of system	LIS Office Project Management Lead	Destroy
GDA 14.1	I.S. System eg records of DCF/TCP changes and testing	2 years after completion of implementation	Individual disciplines LIS office	Destroy
MPI HSNO Stds	MPI and HSNO Requirements <ul style="list-style-type: none"> • Biosecurity Clearance Certificates BACC • Containment/ Transitional facility approval • Permits to import • Containment controls, release approvals, records after release, export and destruction of organism • Biosecurity Manual 	7 Years	Operations Coordinator Operations Coordinator Operations Coordinator Individual disciplines Operations Coordinator	Destroy
GDA 2.8 NPAAC 1.4	Manuals/ Methods/ Procedures/ Guidelines/Test Kit Inserts	While current + 4 years superseded	Medialab Pre IQMS in individual disciplines	Destroy
GDA 9.15	Meeting Minutes e.g. minutes, agendas, section/employee team meetings including occupational health and safety committee	3 Years	Individual disciplines	Destroy

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Ref	GENERAL	Minimum Retention Time	Storage	Disposal Method
GDA 18.4	Procurement documents e.g. Freight consignments and delivery dockets, Stock records and inventories, tender documentations, sales brochures and information, order/purchase documentation, service contracts and requisition orders, financial authority forms, equipment supply forms.	7 years after date of last action	Individual disciplines healthAlliance	Destroy
GDA 2.7, 6.3 NPAAC 1.2 Local LabPlus Policy	QC/QA records <ul style="list-style-type: none"> Includes internal QC EQA Minor equipment etc 	4 Years Temperature Charts: 5 years Spatial Checks: 6 years	Individual disciplines	Destroy
GDA 2.7 NPAAC 1.8	Reports (Diagnosis)/ Results (Final) <ul style="list-style-type: none"> Copy of original report, or ability to reprint the information content of an original report Hard copy reports returned from referral labs 	Adults: 10 Years from date created Minors: 7 years from age of maturity Scanned into Delphic or image viewer. Hard copy held 1 month post scanning.	Delphic & LIS	Destroy
GDA 2.6 NPAAC 1.5	Request Forms <ul style="list-style-type: none"> Scanned forms archived onto discs Hard copies of scanned forms Hard copies of non-scanned forms 	4 years from date of request 1 month 4 years from date of request NB. request form storage times may be subject to special requirements	heathAlliance Server 30 years with instruction to review before destruction	Destroy
NPAAC 1.7	Specimens NB. Unless specified otherwise under individual disciplines	7 days from receipt or until 2 days after report issued (whichever is longer)	Retain under appropriate storage conditions	Destroy
GDA 10.24	Standards and Regulations eg ISO15189, CLSI documents, IANZ Specific Criteria	While current plus 7 years superseded	Individual Disciplines, Quality Manager or Offsite once superseded	Destroy

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Ref	GENERAL	Minimum Retention Time	Storage	Disposal Method
GDA 2.7 NPAAC 1.2, 1.5	Worksheets, Workbooks, Records of analysis, Calculations, Observations, Instrument Printouts, Test Validity, Equipment Calibration Records, Lot documentation, QA/QC and test result validity, etc	4 Years in retrievable form NB. Hard copies not required if identical info available electronically Exception Where data has been changed on result sheets from interfaced analysers, individual record needs to be retained (LabPlus Policy)	Individual disciplines	Destroy
GDA 20.10, 20.11	<p>Property and Asset Management</p> <p>Security/ Buildings and Facilities (Minor) Low level / minor routine management and administration of security (both physical and electronic) of buildings and facilities. Monitoring of visitors (e.g. visitors' log, contractors' log)</p> <p>Routine Management Provision of building services (e.g. cleaning, heating, refrigeration, power, gardening, lifts, pumping, lighting, pest control, furnishings, air-conditioning), provision of accommodation (e.g. layout planning, space allocation, parking, plant/equipment), telecommunications (e.g. systems installation and maintenance systems, telephone extension allocation), occupational health and safety, rent /rates and valuations, directional signage, accommodation moves, building warrant of fitness, fire protection, building certification, energy conservation, booking rooms and venues, building registration, naming, numbering, notification of plant, electrical, reticulation shutdowns, building management systems, provision of storage for</p>	<p>2 years after date of last action</p> <p>7 years after date of last action</p>	LabPlus Administration	Destroy

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Ref	GENERAL	Minimum Retention Time	Storage	Disposal Method
	equipment, records, routine maintenance of waste management			

5. Department Specific Minimum Retention Time

Please refer to the **GENERAL** section for retention of all specimens/ records unless otherwise specified below

5.1 Table 2 - Anatomical Pathology

Ref	ANATOMICAL PATHOLOGY Histology	Minimum Retention Time	Storage
RCP 136	Slides <ul style="list-style-type: none"> Sections preserved in mounting medium incl. stained sections from frozen sections Sections, fixed tissue not preserved in mounting medium Direct Immunofluorescence (DIF) 	30 years 1 month 1 month post reporting	On site (1Year minimum) then off site
RCP 100	Tissue Blocks embedded in wax/ resin or other permanent embedding medium	30 years	On site (1Year minimum) then off site
RCP 98 NPAAC 2.5	Specimens for intra-operative frozen section diagnosis: <ul style="list-style-type: none"> Original section used for diagnosis preserved on slides in permanent 	30 years	On site (1Year minimum) then off site

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Ref	ANATOMICAL PATHOLOGY Histology	Minimum Retention Time	Storage
	mounting medium. <ul style="list-style-type: none"> Residual tissue from which the frozen sections were prepared, embed 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. 		
NPAAC 2.6	Frozen tissue blocks including specimens for immunofluorescence studies	1 month at -70°C or lower	In the Laboratory
NPAAC 1.7 LOCAL LABPLUS POLICY	Direct immunofluorescence (slides) Direct immunofluorescence (frozen tissue blocks): <ul style="list-style-type: none"> Skin/Renal Muscle 	7 days from receipt or until 2 days after report issued (whichever is longer) 3 years maximum Indefinitely	In the Laboratory
NPAAC 2.7	Containers with no residual tissue Unblocked wet tissue from specimens removed at surgery	1 month after report issued	In the laboratory
RCP 120	Electron microscopy blocks Electron microscopy grids for	30 years 10 years	On site (1Year minimum) then off site

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Ref	ANATOMICAL PATHOLOGY Histology	Minimum Retention Time	Storage
LOCAL POLICY	Electron microscopy Tol Blue	3 years	In the laboratory
NPAAC 2.3	Digital images used for diagnostic analysis	4 years	In the laboratory
Ref	CYTOLOGY	Minimum Retention Time	Storage
NPAAC 4.1	Copy of the 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)	In the laboratory
NCSP	Report duplicates/records/block keys/ diagrams/ request forms and copies of any representative images prepared	10 Years	3 Years minimum onsite then off site
NCSP NPAAC 4.2	Exfoliative cytology and FNA's including slides and cell blocks	10 Years	3 Years minimum onsite then off site
NCSP NPAAC 4.3	Gynaecological (cervical) cytology slides	10 Years	3 Years minimum onsite then off site
NPAAC 4.4	Specimens of sputum, urine, other body fluids	7 days from receipt or until 2 days after report issued (whatever is longer)	In the laboratory
NPAAC 4.5	Specimens received in liquid based fixative	1 month	In the laboratory
NPAAC 4.6	Digital images used for diagnostic analysis e.g. semi-automated pap screening images.	6 years	In the laboratory

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5.1 Table 3-Forensic Pathology

Ref	FORENSIC PATHOLOGY	Minimum Retention Time	Storage
NPAAC 2.8 NPAAC 2.4, 2.8	Autopsy (Hospital and Non-Coronial): <ul style="list-style-type: none"> • Registers, Report duplicates, Records of tissue and organ disposal or return to Family • Blocks and Slides • Wet Tissue samples & unblocked tissue, Organs retained at post-mortem with consent 	10 years 10 years 3 months from date of issue of report unless limitation is imposed, such as the need to reunite retained specimens with the body before a funeral has been stipulated by the next-of-kin.	Forensic Pathology – minimum of 3 years on site, then off site Anatomical Pathology and offsite Forensic Pathology
Coroners Act 2006, 54(2)	Forensic and medico legal Registers, Report duplicate, Records of tissue and organ disposal or return to Family	Indefinitely.	Forensic Pathology – minimum of 3 years on site, then off site
Coroners Act 2006, 54(2)	Tissue Slides, Blocks	Indefinitely until written instruction received from Coronial Service for Disposal or Return to Family. Indefinitely unless written instruction received from Coronial Service for Return to Family.	Forensic Pathology Anatomical Pathology and off site

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5.2 Table 4 -Haematology

Ref	HAEMATOLOGY	Minimum Retention Time	Storage
NPAAC 7.1	Blood Films	Clinically Significant: 1 year Not Significant: 1 month	1 month on site then off site
NPAAC 7.2	Plasma samples for special haemostasis	1 months at -20 degrees C or lower	In the laboratory
NPAAC 7.3	Blood samples other than NPACC 7.1-7.2 <ul style="list-style-type: none"> • including manual ESR tubes 	7 days from receipt or until 2 days after report issued (whatever is longer) For purpose of id and traceability, noting repeat testing technically unreliable after 2 days	In the laboratory
RCP134	Bone marrow (and CSF) slides	30 years	At least 5 years on site then off site
RCP136	Cell Marker slide preparations	30 years	18 months on site then off site
NPAAC 11.3	Flow cytometry on non-haematological samples e.g. tissue, cerebrospinal fluid) - graphical outputs used in diagnosis, such as gated dot plots and histograms of other specimens	4 years	Discuss haem
RCP47	Flow Cytometry Analyses and Archived Files	30 years	3 months onsite then offsite
RCP72	Lab Testing Records on Transplant Products	30 years	2 years on site then offsite

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5.3 Table 5 – Immunology/ Virology

Ref	IMMUNOLOGY VIROLOGY	Minimum Retention Times	Storage
Local LabPlus Policy	Rubella/ Syphilis etc (Refer to LPVIMADMIN011 Virology/Immunology Infectious Serology Sample Storage Variation)	Cobas Serology Tests- : 7 days, <ul style="list-style-type: none"> • Includes Hep A,B,C /HIV /Rubella / Toxoplasma / Syphilis (serology)/needle stick source and recipient sera ID Serology : 2 months	In the laboratory
Local LabPlus Policy	Serum/plasma for infectious disease Antenatal Sera Syphilis (Reactive) Source and recipient sera from body fluid exposure (needle-stick), where this has been notified to the laboratory	2 months 2 months 2 months	In the laboratory
NPAAC 1.7	Viral specimens/ cultures	7 days from receipt or until 2 days after report issued (whatever is longer)	In the laboratory
NPAAC 9.2	Frozen tissue blocks , including specimens for immunofluorescence studies	1 month at -70°C or lower	
NPAAC 9.3	Immunofluorescence slides	7 days from receipt or until 2 days after report issued (whatever is longer)	In the laboratory
NPAAC 9.4	Digital images used for diagnostic analysis	4 years	In the laboratory
NPAAC 10.3	Molecular infectious disease DNA/ RNA extracts	4 months	In the laboratory

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5.4 Table 6 - Microbiology

Ref	MICROBIOLOGY	Minimum Retention Times	Storage
NPAAC 10.1	Slides	Wet preps discard IMF slides 7 days Gram stains 2 weeks ZN stains 6 weeks Other stains 2 weeks	In the laboratory
NPAAC 10.2	Isolates: (i) Clinically significant§§§ (ii) Not clinically significant	5 days Discard	In the laboratory
NPAAC 10.3	Serum/plasma for infectious disease	All sera 4 months	In the laboratory
NPAAC 10.4	Urine Specimens for Microbiological examination	6 days	Under refrigeration
NPAAC 10.5	i) Nucleic acid for diagnostic microbiological examination – extract or original specimen (ii) Nucleic acid for screening examination – extract or original specimen	1 month from date of issue of report 1 month from date of issue of report****	
Local Policy RCPATH	Human heart valves for transplant: Valves Documentation	Indefinitely until used 30 years	In the laboratory In the laboratory and off-site

§§§ Clinically significant isolate is considered to be all blood culture and sterile site isolates, plus any cultured isolate which is reported by the laboratory as a potential pathogen (in contrast to contaminants and commensal flora).

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5.5 Table 7 - Genetics

Ref	GENETICS	Minimum Retention Times	Storage
NPAAC 6.1	<p>Copy of original report, or ability to reprint the information content of an original report</p> <p>(i)Constitutional genetic testing</p> <p>(ii)Somatic genetic testing</p> <ul style="list-style-type: none"> • Cytogenetics • Molecular Genetics • Molecular Haematology • Biochemical Genetics • New Born Screening 	<p>100 years (effectively indefinite)</p> <p>10 years***</p>	In the laboratory and off site
NPAAC 6.2	<p>Cytogenetics:</p> <p>(i)Analysis records/karyotypes/digital images including FISH images</p> <p>(ii)Stained microscope slides in permanent mounting medium</p> <p>(iii)Fixed chromosome cell suspension or FISH slides</p> <p>(iv)Original specimens and containers</p>	<p>4 years</p> <p>4 years</p> <p>6 months</p> <p>1 month from date of issue of report</p>	In the laboratory and off site
NPAAC 6.3	<p>Cytogenetics/biochemical genetics/molecular genetics:</p> <p>Tissue cultures/cell culture lines</p> <p>(i)Rare clinically significant variants</p> <p>(ii)Common clinically significant variants or clinically non-significant</p>	<p>For indefinite cryopreservation</p> <p>7 days from receipt or until 2 days after report issued (whichever is longer)</p>	In the laboratory
NPAAC 6.4	<p>Biochemical genetics:</p> <p>Specimens of plasma, serum and urine</p> <p>(i)Original container</p> <p>(ii)Analytic aliquot</p>	<p>7 days</p> <p>3 months after the date of issue of report</p>	In the laboratory

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Ref	GENETICS	Minimum Retention Times	Storage
NPAAC 6.6	Molecular genetics: (i)Nucleic acid extracts for somatic or constitutive testing (ii) Nucleic acid extracts or frozen plasma for NIPT	3 months 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 12 months	In the laboratory
NMSP Policy 13.2	Neonatal screening (dried blood spot): (i)Specimen (Guthrie) cards (ii)Records	Indefinite Indefinite	18 months on site then off site
Local LabPlus Policy	Maternal Serum Screen Specimens	12 months	In the laboratory
NPAAC 6.7	Bioinformatics genetic data: (i)Read data (e.g. FASTQ) or aligned reads(e.g. BAM) (ii)Variant call files (iii)Microarray analysis files	4 years from date of issue of report 10 years 4 years	In the laboratory and off site

*** 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 majority

5.6 Table 8- Point of Care

Ref	POINT OF CARE	Minimum Retention Time	Storage
Local Policy	POCT Samples	Analyse then discard	N/A

**** Unless otherwise stated in the *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)*

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6. References:

- DHB General Disposal Authority 2007 (Archives Act)
- NPAAC Requirements for the Retention of Records and Diagnostic Material, Seventh Edition, (2018)
- AS/NZS4308:2008 Procedures for Collection, Detection and Quantitation of Drugs of Abuse in Urine
- HSNO Acts (Hazardous Substances and New organisms 1996) (Low risk GM 1998)
- Facilities for Microorganisms and Cell Cultures:2007a, MAFBNZ and ERMA Standard
- National Cervical Screening Program Policies and Standards Section 5 (2015)
- New Zealand Human Tissues Act 2008
- Coroners Act 2006
- The Royal College of Pathologists (IBMS) – The Retention and storage of Pathological Records and Specimens, 5th Edition, (2015)
- New Born Metabolic Screening Programme Policy Framework (June 2011)