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Document History:

Title:	Laboratory Records & Materials Retention Policy	Site(s):	Shared Health Diagnostic Services
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Section:	**Operations**	**Subsection:**	**General Laboratory**

Approved by: *(approval on file)*	Beth Luhowy	**Date:**	14-AUG-2023
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Details of Recent Revision

Toxicology retention table updated as per ANAB

1.0 Purpose

1.1 To provide a guideline for the minimum retention requirements for laboratory records and diagnostic materials.

2.0 Scope

2.1 This document provides retention guidelines for:

2.1.1 General Laboratory
2.1.2 Clinical Biochemistry
2.1.3 Hematology
2.1.4 Clinical Microbiology
2.1.5 Genomics
2.1.6 Immunology
2.1.7 Miscellaneous Records

2.2 This document ***does not*** provide specific retention guidelines for the following diagnostic areas (refer to discipline specific retention guidelines):

2.2.1 Diagnostic Imaging – refer to #130-10-01, *DI Record Retention Policy*
2.2.2 Transfusion Medicine – refer to #160-APP-07*, Appendix 8: Record Retention (MB Transfusion Manual)*
2.2.3 Pathology - #170-10-04, *Records & Materials Retention Policy – Pathology*

3.0 Policy

3.1 The time of retention of laboratory records and materials is defined by the nature of the examination or specific record and reflects best practice and/or statutory/regulatory authority.

3.2 In some instances, laboratories may elect to retain records and/or materials for a longer period of time than specified when such would be appropriate for patient care, education or quality improvement needs or to facilitate troubleshooting

3.3 Consideration shall be given for legal liability for certain types of procedures which may require retention of certain records or materials for longer periods of time than for other records or materials

3.4 Original reports are forwarded for inclusion on the health record. Copies of original reports (electronic or paper) are retained as outlined in this policy

3.5 Where there is discrepancy noted between retention guidelines for similar records/materials, the stricter retention timeline will be followed.

3.6 All diagnostic disciplines shall follow the general retention guidelines outlined in this policy, in addition to any discipline specific guidelines outlined in individual discipline policy. Where there is discrepancy in retention guidelines, the stricter timeline will be followed

3.7 Consideration must be given to the obligations as Health Custodians under the Personal Health Information Protection Act, 2004.

3.8 In the event that Shared Health ceases operations, arrangements shall be made to ensure that all records and materials are retained for the required retention periods outlined.

3.9 Laboratory records that are being converted onto another medium for storage and retention must be verified for accuracy, legibility and completeness before the original record is destroyed

3.10 For data directly transmitted from instruments to the laboratory computer system via an interface, it is not necessary to retain paper worksheets, printouts, etc., so long as the computer retains the data for at least two years

3.11 Manual computer entry of patient result data from worksheets, printouts, etc., requires retention of all worksheets, printouts, etc., for at least two years (digitized or photographic images are acceptable)

4.0 Definitions

4.1 Records Records include any information that produces evidence (i.e. requisitions, examination results and reports, instrument printouts, laboratory workbooks, worksheets, accession records, calibration records, quality control records, records of audits, complaints and action taken, external quality assessment records, instrument maintenance records, incident/accident reports, staff training and competency records, personnel records)

4.2 Documents Documents include any information that provides direction (i.e. instructions including policy statements, textbooks, biological reference intervals and their origins, procedures, specifications, calibration tables, charts, posters, notices, memoranda, plans, software, drawings, regulations and standards)

4.3 Specimen / Diagnostic Material One or more parts taken from a system, and submitted for examination/measurement, with the intention to provide information on the system

5.0 Storage Guidelines

5.1 Records

5.1.1 All records shall be legible and stored in such a way that they are readily retrievable and in a suitable environment to prevent loss, unauthorized access, damage or deterioration because of factors such as temperature, water or fire.

5.1.2 Records may be kept in electronic or paper format so long as the data will be available for the retention periods outlined in this policy.

5.1.3 Records converted to electronic format for storage must be verified for accuracy, legibility and completeness before the original records are destroyed

5.2 Specimens / Diagnostic Material

5.2.1 Specimens shall be stored in conditions that ensure:

5.2.1.1 Stability of sample properties to enable repetition of the examination after reporting of the result or for additional examinations

5.2.1.2 Integrity of material after retention times as specified by laboratory or statutory requirements

6.0 General Laboratory Retention Guidelines

Records / Materials	Period of Retention
Accession Records	2 years (CAP)
Requisitions (paper ***or*** electronic)	MANQAP sites - 3 months after specimen processed CAP sites – 2 years after specimen processed
Instrument/equipment maintenance and function check records (including temperature charts)	Life of equipment plus 2 years (MANQAP)
Critical results notification records (paper/electronic)	2 years (CPSA)
Package inserts	2 years after procedure taken out of service (CPSA)

Records / Materials	Period of Retention
Test Procedures; including dates of initial use and discontinuance	2 years (CAP) after the procedure has been discontinued Exception: Genomics policy/procedure retain for 23 years
Instrument printouts (ie. original patient test results) Note - only if no direct interface with the LIS; ie. if data is manually transcribed/entered into a computer or into the patient report	2 years (CAP)
Reportable infectious disease reports	7 years (OAML)
Shipping documents (i.e. Batcher Sheets)	3 months after specimen processed
Chain-of-custody collection, receipt, accessioning and handling records	2 years or longer as applicable (CAP)
Testing Records	
Instrument printouts (not interfaced with the laboratory computer system) and worksheets for data manually transcribed into a LIS or into the patient report. This includes worksheets for manual tests/kits where no instrumentation is involved	2 years (CAP)
Electronic records for data directly transmitted from instruments to the LIS via an interface	2 years (CAP)
Patient test results and reports, including original and corrected reports and referral laboratory reports Note: some subspecialty areas may have longer retention requirements; these will be noted in individual section areas	2 years (CAP)
Quality Control Records	
Quality control records Examples include: • Levey-Jennings • Cumulative summaries • QC corrective actions • Temperature Charts • Environmental monitoring	2 years (CAP)
Individualized Quality Control Plan (IQCP), including risk assessment and supporting date and approval of quality control plan	length of time the test is in use, plus 2 additional years (CAP)
Ongoing quality assessment data	2 years (CAP)
Quality Improvement Records	
Management Review Records	2 years (CAP)
LIS Programs: • Documentation of changes, modifications, additions and/or deletions in programs, test library & major computer functions • Software application validation records	2 years beyond service life of system (CAP)
Records of external inspections, self and peer assessments	2 years (CLIA, CAP)

Records / Materials	Period of Retention
Review of policies, processes and procedures	At least 2 years following discontinuance (CAP)
Record of destruction of records containing personal health information	2 years (CLIA, CAP)
Equipment calibration records, for example: • Thermometers • Balances • Pipettes	Life of instrument plus 2 years (CLIA, CAP)
Quality Management records	2 years (CAP)
Supplier Qualification Records (includes vendor and reference laboratories)	2 years (CAP)
Analyzer Correlation Results	Life of instrument plus 2 years (owned) *or* 2 years after lease expiry date (leased)
Records of Method Performance Specifications • Validation / verification records	Length of time the test is in use, plus 2 additional years (CAP)
Mislabeled specimens (specimens rejected as per specimen acceptance policy)	As per specific discipline requirements (see below)
Critical Incident documentation	Indefinitely
Non-conformance documentation ▪ Occurrences ▪ Critical Occurrences ▪ Near Misses ▪ Complaints	5 years
Proficiency Testing materials	Until final participant results are received (OAML)
Proficiency Testing Records Note: includes all information regarding the PT event: ▪ Test records ▪ Signed attestation statements sent or transmitted to the PT providers ▪ PT results and scores from the provider ▪ Documentation of review ▪ Records of any corrective action	2 years
Safety Records	
Waste disposal	Current year plus 2 years (OAML)
Transportation of Dangerous Goods (TDG) ground shipping records	2 years (TDG)
TDG air shipping records	2 years (TDG)
TDG Training Records	2 years
TDG certificates	Discarded upon expiry
IATA training records	2 years
IATA certificates	Discarded upon expiry

Records / Materials	Period of Retention
MSDS/SDS	30 years
Workplace H&S Meeting Minutes	5 years (WSH Regulations)
Safety Meeting Minutes	5 years (WSH Regulations)
Eyewash (plumbed/portable)/Emergency Shower Log	7 years (WSH Regulations/ANSI)
Monthly Fire Extinguisher Inspection Log	2 years (MB Fire Code)
Annual electrical checklist	5 years (MB Electrical Code)
Personnel Records	
Competency assessment records	2 years (CAP)
Training records	2 years (CAP)
Signature / ID traceability	10 years (OAML)
Qualifications	3 years past last date of employment (OAML)
Lab Computer Services	
Computer system validation records	2 years beyond the life of the system (CAP)
Records of changes to software, the test library, and major functions of laboratory information systems	2 years (CAP)
Ongoing computer system checks (ie. calculation verification)	2 years (CAP)

7.0 Clinical Biochemistry & Toxicology Retention Guidelines

Records / Materials	Period of Retention
Routine serum / plasma (2-8°C)	3 days (OAML)
Aliquots of 24-hour urine (2-8°C)	Until testing is complete plus 3 days (OAML)
Electrophoresis & immunofixation gels (room temp) *This includes hemoglobinopathy electrophoresis (see Hematology)	1 year (OAML) See Hematology re: bone marrows, as gels or instrument generated curves/plots may be required for follow-up
Urine for urinalysis (2-8°C)	Until testing complete (OAML)
Electrophoresis specimens	Minimum one (1) month
Rejected specimens	As per period of retention outlined for requested procedure
Toxicology	
Medical Examiner Samples	120 days after final report issued unless other arrangements made -

Records / Materials	Period of Retention
Medical Examiner Case work (screens, quantitations, dockets)	5 years (ANAB)
Quality Control	5 years (ANAB)
Proficiency Testing Records Note: includes all information regarding the PT event: ▪ Test records ▪ Signed attestation statements sent or transmitted to the PT providers ▪ PT results and scores from the provider ▪ Documentation of review Records of any corrective action	3 years (ANAB)

8.0 Hematology Retention Guidelines

Records / Materials	Period of Retention
Coagulation plasma (room temperature)	36 hours
EDTA bloods (2-8°C or room temp)	36 hours
Peripheral blood smears – normal (room temp)	7 days (OAML)
Peripheral blood smears reviewed by a pathologist (includes fluid cytospin slides and slides for malaria/blood borne parasites)	10 years (CPSA)
Bone marrow slides and records	Adults (≥18 years) – 10 years (CAP) Children (<18 years) – 50 years (CPSS)
Rejected specimens	Replaceable – not retained
	Irreplaceable – not retained
	Time Sensitive – as per policy, samples are processed, therefore are retained as per routine practice
HIT Tests (negative and positive samples)	1 year @ -70ºC

9.0 Clinical Microbiology Retention Guidelines

Records / Materials	Period of Retention
Original Specimens:	
Rejected specimens	As per period of retention outlined for requested procedure
Specimens from sterile sites (2-8°C)	7 days after specimen processed

Records / Materials	Period of Retention
Specimens from non-sterile sits (i.e. wounds, etc) (2-8°C)	5 days after specimen processed
EDTA Whole Blood for MONO	72 hours after specimen collected
Urine samples (2-8°C)	2 days after specimen processed
Smears from Original Specimen (stored at room temperature):	
Routine microbiology slides (including blood cultures)	7 days after specimen processed (Micro)
Urethral smears from Gram negative diplococci but having negative culture	1 year
Positive smears from sterile sites (negative culture)	1 year
Acid Fast Bacilli positive smears	1 year
Microbial Isolates - storage at -70°C (or minimally at -20°C): ***Note: Inventory of pathogens, toxins and other regulated infectious material in long term storage to be maintained including location and risk group***	
"Reportable" isolates sent to CPL/NML	Store as frozen stock culture until final report received from referral laboratory
Sterile site isolates of potential pathogenic significance (other than blood cultures and CSF's)	Store as frozen stock culture 1 month after reporting
Isolates from blood cultures and CSF's	Microorganisms isolated from blood cultures should be stocked and stored at -70**°C** for a minimum of one year Note: Risk Group Level III organisms should not be stocked
MRSA – first MRSA isolate/patient	MRSA – Isolates should be stocked and stored at -70°C for a minimum of one year after reporting
Flu/RSV/SARS-CoV-2 samples	Positive and Negative Flu/RSV/SARS-CoV-2 samples should be kept a minimum of 7 days. HSC, SBH, WL- If space permits, samples may be stored up to 2 years at -70°C. Other sites, store samples at 4-8°C or -20°C.
Other isolates as applicable	Store as frozen stock culture 1 month after reporting
PFGE gels (electronic copies)	Indefinitely
Isolates stored as frozen stocks as part of study requirement for Clinical Trial	10 years (can be discarded 3 months after study coordinator notified. A copy of company notification and a record of the date that frozen stocks were discarded should be kept for 10 years)
Isolates stored as frozen stocks as part of Research Study	5 years (may be discarded earlier if

Records / Materials	Period of Retention
	Principle Investigator gives approval)
Inventory of regulated materials in long-term storage, including locations and risk groups.	5 years (CBS3)
Activities Involving Risk Group 2, 3 or 4 Pathogens	
Waste disposal records	5 years (CBS3)
Import, export, transfer and shipping records	5 years (CBS3)
Maintenance, repair, performance and verification records for containment and decontamination technologies (Autoclaves, BSCs, etc.)	5 years (CBS3)
Records of incidents involving pathogens, toxins, other regulated infectious material, infected animals, or losses of containment	Minimum 10 years (CBS3)
Biosafety and biosecurity training records	5 years (CBS3)

10.0 Genomics Retention Guidelines

Records / Materials	Period of Retention
Final Report (hard copy or electronic equivalent)	25 years
Representative Karyotypes (hard copy, negatives, microfiche or electronic equivalent)	20 years (CAP)
Worksheets	25 years
Accession logbooks (Molecular only)	25 years
Glass slides	3 years (CAP)
Residual Cells (fixed)	Until analysis complete or longer at laboratory director's discretion (CAP)
Culture Sheets	3 years
Requisitions	25 years
DNA & RNA Specimens	20 years
Next-Generation Sequencing Data	2 years
Microarray Data	Original scan for at least 2 weeks after the final report is released Sufficient original data to support primary results generated and reanalysis for a minimum of 2 years
Blood and Bone Marrow Cell Pellets	20 years

11.0 Immunology Retention Guidelines

Records / Materials	Period of Retention
Patient electronic List mode files	2 years or discretion of the Medical Director (CLSI) (Dr Morales – 10 years or longer depends upon the patient as is also linked to pathology/hematology requirement)
Flow cytometry quality assurance	2 years (CLSI)
Flow cytometry instrumentation / calibration records	2 years (CLSI)
Flow cytometry specimens	8 days or until work is completed
Electrophoresis & immunofixation gels (room temperature)	Minimum 2 years (OAML)
Specimens	Minimum 2 weeks either frozen or at 4°C (test dependent)
Rejected specimens	Flow cytometry – 8 days All others – minimum 1 or 2 months, depending on test

12.0 Miscellaneous Retention Guidelines

Records / Materials	Period of Retention
Clinical Genetics Records	Indefinitely except in certain circumstances where the information will be of minimal importance to future interaction in genetics with the patient or other family members. Records should be maintained as separate charts from the institution's main health record.
Clinical Trials; study records (responsibility for record retention lies with Clinical Trial Coordinator; laboratory retains testing records for time frame outlined above)	25 years (or as stipulated by study). As per Health Canada requirements for studies where a clinical trial application was filed with Health Canada.
Research study records (responsibility for record retention lies with Research Study coordinator; laboratory retains testing records for time frame outlined above)	5 years (may be discarded once results published)

13.0 References

13.1 CPSA: June 2005, Laboratory – Extended Standards & Guidelines. College of Physicians & Surgeons of Alberta

13.2 Canadian Association of Pathologists, The Retention and Use of Human Biologic Material

13.3 College of American Pathologists CAP Commission on Laboratory Accreditation, Appendix PP Retention of Laboratory Records and Materials (2001)

13.4 American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories, 2006 Edition

13.5 CSA Standards Z902-04, Blood & Blood Components

13.6 AABB Standards for Blood Banks and Transfusion Services, 25th Edition

13.7 CCMG Guidelines: Retention of Cytogenetic Records

13.8 Guidelines for the Retention of Laboratory Records & Materials CLP020-001, revised June 2006. Ontario Association of Medical Laboratories (OAML)

13.9 Collection, Retention and Disposition of Tissue and Toxicology Specimens Taken at Medico-Legal Autopsy, Officer of the Chief Medical Examiner, Manitoba Justice

13.10 Laboratory Quality Assurance Program, Laboratory Guidelines – 2010 Edition, College of Physicians & Surgeons of Saskatchewan

13.11 Canadian Biosafety Standard – 3rd Edition

14.0 Abbreviations

14.1	**CAP**	College of American Pathologists
14.2	**CAP***	Canadian Association of Pathologists
14.3	**CLIA**	Clinical Laboratory Improvement Amendments (US)
14.4	**OAML**	Ontario Association of Medical Laboratories
14.5	**OLA**	Ontario Laboratory Accreditation
14.6	**IATA**	International Air Transportation Association
14.7	**CSA**	Canadian Standards Association
14.8	**AABB**	American Association of Blood Banks
14.9	**CBS**	Canadian Blood Services
14.10	**TDG**	Transportation of Dangerous Goods
14.11	**CME**	Office of the Chief Medical Examiner, Manitoba Justice
14.12	**CPSA**	College of Physicians & Surgeons of Alberta
14.13	**CLSI**	Clinical and Laboratory Standards Institute (formerly NCCLS)
14.14	**CCMG**	Canadian College of Medical Geneticists
14.15	**CPSS**	College of Physicians & Surgeons of Saskatchewan
14.16	**CBS3**	Canadian Biosafety Standard, 3rd Edition
14.17	**ANAB**	ANSI-ASQ National Accreditation Board

15.0 Associated Documents

15.1 170-10-04, *Records & Materials Retention Policy – Pathology*
15.2 160-APP-07, *Appendix 8: Record Retention (MB Transfusion Manual)*
15.3 130-10-01, *DI Record Retention Policy*