

Retention of specimens, records, and materials

Allina Health Laboratory complies with the retention guidelines outlined by its accreditation and government regulatory agencies. These include the College of American Pathologists (CAP), the American Association of Blood Banks (AABB), and the guidelines of the Medicare Negotiated Rule Making Committee. The retention practices meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). The minimal retention requirements are listed below.

Records and materials minimum retention requirements are as follows:

General Laboratory:

MATERIAL/RECORD	PERIOD OF RETENTION
Test Report/Patient Results (Pathology departments and Transfusion Medicine have further retention requirements)	2 years
Records of maintenance and function checks	2 years
Lot validations	2 years
Temperature records	2 years
Maintenance (e.g. Service records) records	2 years
Records of method performance specifications (i.e. method comparisons, reference range studies, initial precision and accuracy validations)	Duration method is in use + 2 years
Computer programs/application/interface testing and build records	Duration of application is in use + 2 years
Records of conditions of test system operation (e.g. temp.)	2 years
Records of calibration and calibration verification procedures	2 years
Quality control records	2 years
Reference lab requisitions	10 years
Lab/Test Requisitions- non-reference Lab	2 years
Copy of original report, including final, prelim, corrected	2 years after date of report
Proficiency testing records	2 years 5 years for Transfusion Services
Quality systems assessment records	2 years
Records of verification of test performance specifications	While test system is in use, or minimum of 2 years after service
MSDS	Duration of use plus 30 years

Surgical Pathology (including bone marrows):

MATERIAL/RECORD	PERIOD OF RETENTION
Wet tissue	2 weeks after final report
Paraffin blocks	20 years
Slides Archived slides may be utilized for the benefit of the patient, even if that use destroys the slide.	20 years
Reports	10 years
Thin Prep Pap vials	30 days
Non-GYN blocks	20 years
FNA blocks	20 years
Non-GYN slides	20 years

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Flow Cytometry:

MATERIAL/RECORD	PERIOD OF RETENTION
Gated dot plots and histograms	10 years
Data for evaluation of hematolymphoid neoplasias, PNH, and congenital immunodeficiency evaluations	10 years
Routine lymphocyte subset and CD34+ enumeration data	2 years

Hematology:

MATERIAL/RECORD	PERIOD OF RETENTION
Daily Peripheral Bloods	1 week
Blood Morphology Slides	10 years
Kleihauers Slides	10 years
Bone Marrows	10 years
Body fluid slides for QA	1 month

Molecular Diagnostics:

MATERIAL/RECORD	PERIOD OF RETENTION
Mutation Analysis	
Peripheral blood/Bone Marrow	2 weeks
CSF and other body fluids	2 weeks
Wet/Frozen tissue	2 weeks after final report
Extracted DNA (heritable)	2 weeks
Extracted DNA (pathology)	2 years
Records (heritable)	2 years
Records/Reports (pathology)	15 years
Frozen serum	1 month
Frozen plasma	1 month
eSwabs	7 days
Records	2 years

Cytogenetics:

MATERIAL/RECORD	PERIOD OF RETENTION
Original specimen and cultures	Until release of final report
Processed specimens and cell pellets	2 weeks after final report
Permanently stained slides	3 years
Fluorochrome-stained slides	At the discretion of the director
CMA slides	At the discretion of the director
Unstained slides	90 days
Images of permanent slides of ISH studies, hard copy (negative or prints) and/or in retrievable digitized formats.	10 years for neoplastic disorders, 20 years for congenital disorders
CMA data	Original scan for at least two weeks after the final report is released sufficient original data to support primary results generated and re-analysis for a minimum of two years.

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Final Report (electronic versions are acceptable)	10 years for neoplastic disorders and 20 years for constitutional conditions.
Slides	3 years
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized or negatives)	20 years

Reference: The information contained in this document is taken from the Allina Health Laboratory “*RETENTION OF SPECIMENS RECORDS AND MATERIALS POLICY*” and is not an all-inclusive list.