

Guidelines for the Retention of Laboratory Records & Materials CLP020-001

Revised June 2006

This OAML Guideline for community laboratories in Ontario lists recommended periods of retention, for specific laboratory records and materials.

Records and materials shall be stored in a suitable environment to prevent loss, unauthorized access, damage or deterioration due to the effects of factors such as temperature, water or fire.

Community laboratories are to be aware of their obligations as health information custodians under the *Personal Health Information Protection Act, 2004*.

A source for the recommended retention period for each specimen or record is provided in parenthesis. Where the source is the OAML, this indicates a consensus among OAML laboratories as to the appropriate minimum retention period, in the absence of a more authoritative source.

1. Records:

General Laboratory Records

OHIP Requisition (Laboratory Claim)	Seven years (MOHLTC Laboratory Verification Agreement) or until MOHLTC audit complete
Analytical Incident Reports	2 years (CLIA & CAP)
Result Communication Records	1 year (OAML)
Clinical Trials Records	25 years (ICH)
Daily Patient Logs	1 year (MOHLTC)
Laboratory Worksheet/Work List	2 year (CAP)
Instrument Maintenance Records	Life of instrument plus 2 years (OAML)
Method Manuals (obsolete)	2 years (CAP)
Method Manuals (obsolete - Immunohematology)	Indefinitely (OLA)
Patient Test Results (other than Cytology/Histology)	7 years (OAML)
Reportable Infectious Diseases Reports	7 years (OAML)

Quality Control Records

It is recommended that all Quality Control Records be kept for a period of two years (except Immunohematology).

All QC records (Levey-Jennings, cumulative summaries, QC corrective actions, temperature charts, environmental monitoring, etc.)	2 years (OLA)
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Quality Improvement Records

Management Review Records	2 years (CLIA & CAP)
Training, Qualifications and Competency	3 years past last day of employment (OAML)
Signature/ID Traceability	10 years (OAML)
Software Application Validation Records	Life of instrument plus 2 years (OAML)
Supplier Qualification Records	2 years (CLIA & CAP)
Records of External Inspections, Self and Peer Assessments	2 years (CLIA & CAP)
Method/Process Validation Records	Life of instrument plus 2 years (OLA)
Annual Review of Policies, Processes and Procedures	2 years (CLIA & CAP)
Register of Referred Specimens	3 months (OAML)
Referral Lab Arrangements and Contracts	Duration of Contract plus 2 years (OAML)
Specimen Rejection Log	3 months (OAML)
Analyzer Correlation Results	Life of the instrument plus 2 years (OAML)
Record of Destruction of Records Containing Personal Health Information	2 years (CLIA & CAP)
Equipment Calibration Records (e.g. Thermometers, Balances, Pipettes)	2 years (CLIA & CAP)

Safety Records

Waste Disposal	Current year plus 2 years (OAML)
Transportation of Dangerous Goods (TDG) ground shipping records	2 years (TDG Act)
TDG air shipping records	3 months (IATA)

Cytology Records

Normal Reports	5 years (OLA)
Abnormal Reports	20 years (OLA)

Flow Cytometry Records

Histograms	2 years (OLA)
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Histology Records

Histology Reports (adult)	20 years (OLA)
Histology Reports (<18 years)	50 years (OLA)

Immunohematology Records

Retention periods for Immunohematology records are based on recommendations for transfusion medicine.

Patient Records	Indefinitely (OLA)
Signature/ID Traceability	10 years (OLA)
Quality Control Records	5 years (OLA)
Antibody investigation reports	Indefinitely (OLA)
Non-transfusion serological test results	3 years (OLA)
EQA Reports	5 years (OLA)

Proficiency Testing Records

QMP-LS (EQA)/CAP Raw Data, QMP-LS (EQA)/CAP Work Sheets/Reports	2 years (OLA)
QMP-LS (EQA)/CAP Raw Data, QMP-LS (EQA)/CAP Work Sheets/Reports (Immunohematology)	5 years (OLA)
Blind Control Reports	2 years (OLA)

2. Materials:

Proficiency Testing Materials

Proficiency Testing Materials	Until final participant results are received (OAML)
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Chemistry Specimens

Routine serum/plasma (2-8°C)	3 days (OAML)
Hepatitis A, B, C (2-8°C)	7 days after reporting (OAML)
Aliquots of 24-hour urine (2-8°C)	Until testing completed plus 3 days (OAML)
Electrophoresis & immunofixation gels (room temp.)	1 year (OAML)

Cytology Slides

Gyne or non-gyne, negative or unsatisfactory	5 years (OLA)
Gyne or non-gyne, suspicious - positive (\geq ASC/AGC)	20 years (OLA)
Fine needle aspiration	10 years (CAP)

Hematology Specimens

Coagulation plasma (2-8°C)	Until testing is complete (OAML)
EDTA bloods (2-8°C or room temp.)	Until testing is complete (OAML)
Peripheral blood smears /abnormal (room temp.)	1 year (OAML)
Peripheral blood smears /normal (room temp.)	7 days (OAML)

Histology Specimens

Wet tissue	4 weeks after final report (OLA)
Blocks (Adult) (< 36°C)	20 years (OLA)
Blocks (<18 years) (< 36°C)	50 years (OLA)
Slides (Adult)	10 years (OLA)
Slides (<18 years)	10 years post 18 th birthday (OLA)

Immunohematology Specimens

ABO, DAT, Negative Antibody Screen (2-8°C)	6 days (OAML)
Positive Antibody Screen (less than or equal to -20°C)	1 year (OAML)

Microbiology Materials

Specimens:	
Culture & sensitivity (except sterile sites) (2-8°C)	Until testing complete (OAML)
Culture & sensitivity (sterile sites) (room temp.)	7 days after testing (OAML)
Chlamydia - positive (< -20°C)	30 days (OAML)
Chlamydia - negative (2-8°C)	5 days (OAML)
Urine for urinalysis (2-8°C)	Until testing complete (OAML)
Smears: (room temperature)	
Routine microbiology slides	7 days (OAML)
Gram negative diplococci smears-male urethral (negative culture)	1 year (OAML)
Positive smears from sterile sites (negative culture)	1 year (OAML)
Isolates: (storage temp. dependent on organism)	
Isolates from MOH reportable positive cultures	Keep viable until final report received from referral laboratory (OAML)
Sterile site isolates of potential pathogenic significance	1 month after reporting (OAML)
MRSA/VRE	3 months (OAML)

Other Specimens

Parasitology Specimens (room temp.)	Until reporting complete (OAML)
Mycology Specimens (temp. dependent on specimen type)	Until reporting complete (OAML)

3. References

CAP: College of American Pathologists
 CLIA: Clinical Laboratory Improvement Amendments (US)
 ICH: International Council on Harmonization
 MOHLTC: Ministry of Health and Long-term Care, Ontario
 OAML: Ontario Association of Medical Laboratories
 OLA: Ontario Laboratory Accreditation (Quality Management Program - Laboratory Services) version 3
 IATA: International Air Transportation Association

Acknowledgements

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The Ontario Association of Medical Laboratories

The Ontario Association of Medical Laboratories (OAML) represents Ontario's community laboratories.

Our mission is to promote excellence in the provision of laboratory services and, as an essential component of the health care system, to contribute to shaping the future of health care in Ontario.

The OAML encourages the highest level of professional and ethical integrity and technical excellence among laboratory owners, operators and staff, in the provision of laboratory services for the benefit of the people of Ontario.

Guidelines for Clinical Laboratory Practice

The OAML, through its Quality Assurance and Clinical Laboratory Practice Committee (Committee), coordinates the development and dissemination, implementation and evaluation of Guidelines for Clinical Laboratory Practice.

The proposed Guideline is developed by a working group of the Committee. The Guideline is then submitted to the Committee as a whole. The comments of the Committee are considered and a final version of the Guideline is submitted to the OAML Board of Directors for approval.

The comments of end users are essential to the development of Guidelines. You are strongly encouraged to submit your comments on this or any other OAML Guideline to:

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Warning & Disclaimer for Laboratory Resources

This Guideline was prepared to assist community laboratories. Users must ensure that their own record & specimen retention practices comply with all specific legislative, government policies or accreditation requirements that apply to their organizations. The Guideline is not meant to be construed as legal advice or meant to address all matters pertaining to the specimen & record retention. Given the complexity of legal requirements, laboratorians are reminded that whenever there is uncertainty regarding whether some aspect of the Guideline is appropriate for their facility or organization, they are advised to seek advice from the Medical Director and/or legal counsel of their organization.