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Retention time for records and samples – Medical Laboratories

Mauritius Accreditation Service

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Foreword

The MAURITIUS ACCREDITATION SERVICE (MAURITAS) is a governmental body established in 1998 to provide a national, unified service for the accreditation of Conformity Assessment Bodies (CABs) such as calibration/testing laboratories, certification bodies and inspection bodies. Organizations that comply with the MAURITAS requirements are granted accreditation by MAURITAS.

About MAURITAS publications

MAURITAS publications are categorized as follows:

- R series — Publications containing general policy and requirements related to MAURITAS accreditation.
- G series — Publications providing guidance on MAURITAS requirements.
- A series — Publications related to assessment procedures.
- P series — MAURITAS Quality System procedures
- F series — MAURITAS Forms
- Directories — Classified listing of accredited organizations.

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Retention time for records and samples – Medical Laboratories

1 Purpose

1.1 This document may be used as a guidance for establishing retention time for records and samples.

2 Scope and Responsibilities

2.1 This guidance document sets the retention time for records and samples and is meant for use by Medical Laboratories.

3 References

The following documents contain provisions which, through reference in this text, constitute provisions of the MAURITAS accreditation system. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated MAURITAS references, the latest edition of the document referred to, applies. MAURITAS maintains a register of the current valid MAURITAS accreditation documents.

3.1 ISO 15189 Medical Laboratories: Requirements for quality and competence.

3.2 Ontario Association of Medical Laboratories Guidelines - Guidelines for the Retention of Laboratory Records & Materials CLP020-001

3.3 Royal College of Pathologists, Best practice recommendations; Storage and retention of tissues and records

3.4 National pathology accreditation advisory council - Requirements for the retention of laboratory records and diagnostic material

4 Definitions

4.1 Aspirates

Aspirate refers to fluid, tissue, or other substance that is withdrawn from a body cavity, cyst, or tumor.

4.2 Museum Specimen

A specimen of sufficient age or interest to be kept in a museum

4.3 Teaching specimen

A biological specimen that enables the teacher to approach his subject while training students.

4.4 Penside

Pen-side diagnostic testing provides real time information about the health status of an individual through point of care devices.

5 Retention time for records and samples

5.1 It is recommended that medical laboratories make use of the following table in determining the retention times for records and samples.

Quality Management System (QMS) Records	Retention time
Pre-examination	
Request for examination	3 months after the test report issued
Laboratory work books or work sheets	5 years or as long as the associated sample is kept
Examination	
Manufacturer's instruction on purchased reagents and materials used for examination	At least 5 years since last use
Instrument printouts/Raw data	At least 5 years
Retained data and information	At least 5 years
Records of in-house reagent production or assay validation	At least 5 years
Validation/verification records	Lifetime of the instrument/method plus a minimum of 4 years
Post-Examination	
Examination results and reports	5 years or as long as medically relevant
Receipt of Samples	
Plasma and serum	At least 48 hours after the examination report is issued
Body fluids, aspirates and swabs	At least 48 hours after the examination report is issued
Wet tissue	At least 48 hours after the examination report is issued
Fixed tissue/Biopsy specimens	At least 1 year after the examination report is issued
Museum specimens	May be retained permanently
Teaching specimens	May be retained permanently
DNA and RNA	At least ten years, where applicable
Microbiological cultures	At least 24–48 hours after the examination report is issued
Stained slides	At least 48 hours after the examination report is

	issued
Whole blood	At least 48 hours after the examination report is issued
Whole blood (refrigerated)	At least 48 hours after the examination report is issued
Slides for cytology	At least 10 years
Slides for histopathology	At least 10 years
Embedded blocks for histopathology	At least 10 years
Others (related to QMS records)	
Supplier selection and performance and changes to the approved supplier list	At least 4 years
Staff qualifications, training and competency records	As long as Staff is working in the laboratory plus 4 years
Instrument maintenance records, including internal and external calibration records	Lifetime of the instrument plus a minimum of 4 years
Calibration functions and conversion factors	Lifetime of the instrument plus a minimum of 4 years
Quality control records	At least 4 years
Incident records and action taken	At least 4 years
Accident records and action taken	At least 4 years
Risk management records	At least 4 years
Non-conformities identified and immediate or corrective action taken	At least 4 years
Preventive action taken	At least 4 years
Complaints and action taken	At least 4 years
Records of internal and external audits	At least 4 years
Interlaboratory comparisons of examination results	At least 4 years
Records of quality improvement activities	At least 4 years
Minutes of meeting that record decisions made about the laboratory's quality management activities	At least 4 years
Records of management reviews	At least 4 years
Point-of-care 'penside' test data	Lifetime of the instrument or 5 years, whichever is the longer
Photographic or other digital records	At least 10 years
Temperature records (e.g. fridge, freezer, room, carrier/sample box)	Daily records for at least 2 months and summarised records for at least 4 years
Obsolete documents and records	At least 2 years
Equipment manuals, logbooks and certificates	As long as equipment is in use

6. Related Forms

Appendix A: Amendment Table

SN	Section	Amendment

