

GUIDELINES ON RETENTION OF PATHOLOGY RECORDS AND MATERIALS, PART I (VERSION 1/2005)

Developed jointly by College of Pathologists, Academy of Medicine of Malaysia and Ministry of Health Malaysia

INTRODUCTION

1. Formation of the Joint Committee

A Joint Committee of the College of Pathologists, Academy of Medicine Malaysia (CPath) and the Ministry of Health of Malaysia (MOH) was established in early 2004 to develop guidelines on the minimum requirements for retention of pathology records and materials for Pathology Laboratories in Malaysia. In order to cover a broad perspective and maintain a practical approach, the Committee comprised pathologists from the various pathology specialties, from University Hospitals, Ministry of Health public hospitals and Private laboratories, as well as a nominee from the Medico-Legal Society of Malaysia. Each Committee member further consulted other pathologists and technical personnel in their specialty and brought their views to the discussion table.

Members of the Committee

Chairperson	: Professor Dr. Looi Lai Meng	(CPath)
Secretary	: Dr. Joshua M Daniel	(MOH)
Anatomical Pathology	: Dr. Navinbhai Patel Dr. Wahidah Abdullah	(CPath) (MOH)
Haematology	: Professor Dr. Ainoon Othman Dr. Azizon Othman	(CPath) (MOH)
Chemical Pathology	: Professor Dr. Yap Sook Fan Dr. Tengku Norita Tengku Yazid	(CPath) (MOH)
Medical Microbiology	: Professor Dr. Yasmin Malik Dr. Zubaidah Abdul Wahab	(CPath) (MOH)
Forensic Pathology	: Professor Dr. Kasinathan Nadesan Dr. Mohd Shah Mahmood	(CPath) (MOH)
Medico-Legal Society	: Assoc. Professor Dr. Norchaya Talib	

2. Purpose of the Guidelines

Part I of these guidelines are intended to reflect best laboratory practice for the benefit of patients. This was completed in March 2005. In developing these guidelines, prime considerations were given to time that should be allowed for review of test results and reports by the requesting doctor, the possibility of further testing on existing samples without having to inconvenience the patient for another sample, medico-legal implications, the deterioration of samples and the constraints of storage space in the laboratory. It is emphasized that the recommendations of these guidelines represent the minimum requirements. It is recognized that many laboratories in Malaysia have retained their records and materials for longer periods and will continue to do so.

Part II of the guidelines will address retention of records and materials (in particular) for other purposes, such as training and education, quality control usage, professional development and research. These will be developed in the near future.

3. Definitions

The General Section of the guidelines (Part I) applies to all specialties of pathology. Thereafter, the guidelines reflect requirements according to the specialties of pathology specified.

A **document** is any information or instruction (e.g. forms, procedures, policy statements, charts, notices, biological reference intervals, work instructions).

A **record** is a document containing data (e.g. analytical results, laboratory reports, personnel files, duty rosters, minutes of meetings).

Laboratory or test **results** refer to data without interpretation.

A laboratory **report** refers to the interpretative report issued (usually by a pathologist) containing inferences from test results or analytical findings.

1. GENERAL

Applicable to all specialties of pathology unless otherwise specified in the specialty concerned

	Record/Material	Retention duration
1.1	Personnel records	Duration of employment + 3 years
1.2	1.2.1 All QC and QA Records 1.2.2 External QA end-of-cycle summary 1.2.3 Remedial action log	3 years 5 years 5 years
1.3	Equipment 1.3.1 Maintenance, service, repair and calibration records 1.3.1 Daily, weekly, monthly maintenance log 1.3.2 Temperature records	Life of machine + 3 years 6 months 6 months
1.4	Discontinued laboratory methods/ procedures (manuals)	3 years after discontinuation
1.5	Management 1.5.1 Accident and incident reports 1.5.2 Records of Department training activities 1.5.3 Feedback suggestions 1.5.4 Laboratory statistics 1.5.5 Duty rosters	Indefinite 5 years 5 years 5 years 1 year
1.6	1.6.1 Referring doctor's request. 1.6.2 All laboratory records	3 years, unless otherwise specified under the specialty concerned.
1.7	All specimens, unless specified otherwise under the specialty concerned.	Retain specimens under appropriate storage conditions for 2 days after issue of report/result
1.8	All records and reports known to have medico-legal implications upon receipt of specimen	Indefinite

RETENTION OF PATHOLOGY RECORDS AND MATERIALS

2. ANATOMICAL PATHOLOGY

	Record/Material	Retention duration
2.1	Request form accompanying specimen	As long as the corresponding report is kept.
2.2	Report duplicates/ records/ block keys/ diagrams and copies of any representative images prepared	20 years
2.3	2.3.1 Immunofluorescence slides 2.3.2 All other slides including special stains and frozen sections	2 days after issue of report 7 years
2.4	Blocks, including paraffin blocks from frozen section tissue	20 years
2.5	Frozen tissue blocks for immunofluorescence studies	3 months
2.6	2.6.1 Unblocked tissue removed at surgery 2.6.2 Unblocked tissue retained at autopsy	1 month after issue of report 3 months after issue of autopsy report
2.7	Autopsy 2.7.1 Registers and report duplicates 2.7.2 Tissue blocks 2.7.3 Slides 2.7.4 Records of tissue and organ disposal	Indefinite 20 years 7 years Indefinite

3. CYTOLOGY

	Record/Material	Retention duration
3.1	Request form accompanying specimen	As long as corresponding report is kept
3.2	Report duplicates/ records/ block keys/ diagrams and copies of any representative images prepared	20 Years
3.3	Exfoliative and Fine Needle Aspiration Cytology (FNAC) 3.3.1 Slides 3.3.2 Cell blocks	7 years 20 years
3.4	Sputum, urine, cerebrospinal fluid and other body fluids	2 days after issue of report
3.5	Specimens received in liquid based fixative	1 month after issue of report

4. HAEMATOLOGY

	Record/Material	Retention duration
4.1	Request form accompanying specimen 4.1.1 Routine test 4.1.2 Test with interpretative report	1 month after issue of result 3 years after issue of report
4.2	Reported blood film (i.e. slide)	3 years after issue of report
4.3	4.3.1 Blood samples 4.3.2 Urine samples (e.g. for haemosiderin)	2 days after test is done 24 hrs after test is done
4.4	Bone marrow slides	7 years after issue of report
4.5	Reports 4.5.1 Bone marrow 4.5.2 Haemoglobin analysis 4.5.3 Special coagulation tests (e.g. Factor assays, platelets) 4.5.4 Special tests (e.g. Osmotic fragility test, Ham's test, Sickling test, Sucrose lysis test) 4.5.5 G6PD assay 4.5.6 Immunophenotyping 4.5.7 Full blood picture	20 years 20 years 20 years 20 years 7 years 20 years 7 years
4.6	Results 4.6.1 Full blood count 4.6.2 Routine coagulation tests (e.g. Disseminated intravascular coagulation, Prothrombin time.) 4.6.3 G6PD Screening	3 years 3 years 7 years

5. CLINICAL CHEMISTRY/ CHEMICAL PATHOLOGY

	Record/Material	Retention duration
5.1	Request form accompanying specimen 5.1.1 Routine test 5.1.2 Special test	1 month after issue of report /result 12 months after issue of report/result
5.2	Report duplicates 5.2.1 Neonatal screening and inborn error of metabolism 5.2.3 Drug of abuse testing (confirmatory or screening) 5.2.4 Therapeutic drug monitoring 5.2.5 All other reports	25 years 7 years 7 years 7 years
5.3	Results	3 years
5.4	Samples 5.4.1 Serum, plasma, blood, frozen urine and other frozen body fluids 5.4.2 Other body fluids e.g. urine, cerebrospinal fluid, pleural fluid	2 days after issue of report/ result 24 hours after test is done

6. IMMUNOLOGY

	Record/Material	Retention duration
6.1	Request form accompanying specimen 6.1.1 Routine Test 6.1.2 Special Test	1 month after issue of report/result 12 months after issue of report/result
6.2	Report duplicates	7 years
6.3	Samples (serum, plasma, cerebrospinal fluid, urine, etc.)	7 days after issue of report/result
6.4	Frozen tissue blocks	3 months
6.5	Immunofluorescence slides	2 days after issue of report/result

7. TRANSFUSION (BLOOD BANK)

	Record/Material	Retention duration
7.1	Request form accompanying specimen	20 years
7.2	Report duplicates and records	7 years In case of children, retain until the child reaches the age of 25 years
7.3	Samples of materials examined	7 days after test is done
7.4	Laboratory records of blood donations and administration of blood and blood products	20 years

8. MEDICAL MICROBIOLOGY

	Record/Material	Retention duration
8.1	Request form accompanying specimen for Bacteriology, Parasitology, Virology and Mycology	1 month after issue of report/result
8.2.	Specimens for culture & sensitivity 8.2.1 All specimens except urine & blood 8.2.2 Urine 8.2.3 Blood (including fungal culture)	2 days after issue of report/result Discard after issue of report/result Negative - Discard after issue of report/result Positive - 7 days after issue of report/result
8.3	Serum/plasma for serology	Negative - Discard after issue of report/result Positive - 7 days after issue of report/result

8.4	Slides 8.4.1 Wet preparation 8.4.2 Stained/ Immunofluorescence slides	Discard after issue of report/result Negative- Discard after issue of report/result Positive- 2 days after issue of report/result
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9. GENETICS

	Record/Material	Retention duration
9.1	Request form accompanying specimen	As long as the corresponding report is kept.
9.2.	9.2.1 Report duplicates 9.2.1 Records/ block keys/ diagrams/ copies of any representative images prepared	Indefinite 3 years
9.3	Patient information/ karyotypes	3 years
9.4	Microscopic slides 9.4.1 Chromosome metaphase slides 9.4.2 Other slides	Fluorescence-stained slides - 3 months. Standard stained slides -18 months. 7 years
9.5	Fixed chromosome preparation (blood & bone marrow) in suspension	6 months
9.6	Tissue cultures	6 months
9.7	Plasma, serum and urine for testing (other than DNA) for biochemical genetics	3 months
9.8	DNA extracts for molecular Genetics	1 month after analysis. If part of a study, retain at least 1 month after study completed.
9.9	Guthrie's Test 9.9.1 Neonatal screening 9.9.2 Other cases	Until child reaches the age of 25 years. 7 years