

## GUIDELINES

### Guidelines on retention of pathology records and materials (Version 2/2022)

Yin Ping WONG<sup>1\*</sup>, Farveen Marican ABU BACKER<sup>2</sup>, Geok Chin TAN<sup>1</sup>, Lai Meng LOOI<sup>3</sup>, Mohd Jamsani MAT SALLEH<sup>4</sup>, Palani Ammal A. SUBRAMANIAM<sup>5</sup>, Razuin RAHIMI<sup>6,7</sup>, Roziana ARIFFIN<sup>8,9</sup>, Ruzi Hamimi RAZALI<sup>10</sup>, Sheue Feng SIEW<sup>11</sup>, Soon Keng CHEONG<sup>12</sup>, Subashini C. THAMBIAN<sup>13</sup>, Suhaila MD HANAPIAH<sup>14</sup>, Thatcheiany KUMARIAH<sup>15</sup>, Yee Loong TANG<sup>1</sup>, Zetti ZAINOL RASHID<sup>16\*\*</sup>

<sup>1</sup>Department of Pathology, Faculty of Medicine, Universiti Kebangsaan Malaysia, 56000 Kuala Lumpur, Malaysia; <sup>2</sup>Department of Pathology, Hospital Sultan Abdul Halim, 08000 Sungai Petani, Kedah, Malaysia; <sup>3</sup>Department of Pathology, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia; <sup>4</sup>Department of Pathology, Hospital Seberang Jaya, 13700 Permatang Pauh, Penang, Malaysia; <sup>5</sup>Palani Ammal & Co., Suite 7-5, 2 Rio Tower, 47100 Puchong, Selangor, Malaysia; <sup>6</sup>Department of Forensic Pathology, Faculty of Medicine, Universiti Teknologi MARA, 47000 Sungai Buloh, Selangor, Malaysia; <sup>7</sup>Department of Forensic Medicine, Hospital Sungai Buloh, 47000 Sungai Buloh, Selangor, Malaysia; <sup>8</sup>Genetics Laboratory, Department of Pathology, Hospital Tunku Azizah, 50300 Kuala Lumpur, Malaysia; <sup>9</sup>Cytogenetics & Molecular Diagnostics Laboratory, Pantai Premier Pathology, Pantai Hospital Kuala Lumpur, 59100 Kuala Lumpur, Malaysia; <sup>10</sup>Department of Pathology, Faculty of Medicine, Universiti Teknologi MARA, 47000 Sungai Buloh, Selangor, Malaysia; <sup>11</sup>National Institute of Forensic Medicine, Hospital Kuala Lumpur, 50586 Kuala Lumpur, Malaysia; <sup>12</sup>Faculty of Medicine and Health Sciences, Universiti Tunku Abdul Rahman, 43000 Kajang, Selangor, Malaysia; <sup>13</sup>Department of Pathology, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia; <sup>14</sup>Department of Pathology, National Cancer Institute, 62250 Putrajaya, Malaysia; <sup>15</sup>Department of Pathology, Hospital Kuala Lumpur, 50586 Kuala Lumpur, Malaysia; <sup>16</sup>Department of Medical Microbiology and Immunology, Faculty of Medicine, Universiti Kebangsaan Malaysia, 56000 Kuala Lumpur, Malaysia.

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#### Members of the Committee

<b>Chairperson</b>	Associate Professor Dr. Wong Yin Ping	(CPath/UKM)
<b>Advisors</b>	Distinguished Professor Datuk Dr. Looi Lai Meng Emeritus Professor Dr. Cheong Soon Keng	(CPath/UM) (CPath/UTAR)
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<b>Haematology</b>	Dr. Tang Yee Loong Dr. Thatcheiany A/P Kumariah	(CPath/UKM) (MOH)
<b>Medical Microbiology and Immunology</b>	Associate Professor Datin Dr. Noor Zetti Zainol Rashid Dr. Suhaila Md Hanapiah	(CPath/UKM) (MOH)

\*Address for correspondence: Yin Ping Wong, Department of Pathology, Faculty of Medicine, Universiti Kebangsaan Malaysia, Malaysia.  
Tel: +603- 6145 5364. Email: ypwong@ppukm.ukm.edu.my

\*\*The authors names are listed according to alphabetical order

<b>Chemical Pathology</b>	Associate Professor Dr. Subashini C. Thambiah Dr. Mohd Jamsani Mat Salleh	(CPath/UPM) (MOH)
<b>Genetic Pathology</b>	Dr. Ruzi Hamimi Razali Dr. Roziana Ariffin	(CPath/UiTM) (MOH/Private)
<b>Forensic Pathology</b>	Dr. Siew Sheue Feng Associate Professor Dr. Razuin Rahimi	(CPath/MOH) (UiTM/MOH)
<b>Medico-Legal Advisor</b>	Ms. Palani Ammal A. Subramaniam @ P A Sharon	Medicolegal Society Malaysia

## INTRODUCTION

This is an updated version of the *Guidelines on Retention of Pathology Records and Materials (version 1/2005)*. This document outlines the recommendations for best practices for the retention of laboratory records and diagnostic materials in Malaysia. The purpose of the updated guidelines is to standardise best practices and to ensure that the medical retention practices comply with current medical and national regulatory requirements. It may be appropriate for individual laboratories to retain pathology records and/or materials exceeding the minimum requirements, when necessary, adjusted to suit institutional policy and local settings. This document does not intend to address issues related to research and teaching after the diagnostic use of materials. University laboratories with intention of using archived tissue samples for research should consider extending the duration of retention based on their storage capabilities.

### Key updates in this edition

- Guidance for storage of electronic records
- Address retention duration of pathology records and diagnostic materials pertaining to
  - Final reports in a laboratory with and without laboratory information system (LIS)
  - Digital records and reports
  - Electron microscopy
  - Records and reports obtained from minors and individuals without capacity
  - Donors' samples and records
  - Genetic pathology
- A separate section for forensic autopsy, set apart from that of clinical autopsy

Records and/or diagnostic materials are retained for a period of time for the best interest of the patient, which includes (1) allowing additional testing to be performed on the original existing specimen if required, and (2) serving as a form of physical audit trail against possible future litigation and allegations of professional misconduct. Ideally, tissue samples should be stored indefinitely, however, practical issues such as storage space constraints in the laboratory and the deterioration of archival samples may not permit so. One size does not fit all. The time needed to store specimens, records, and data varies according to the discipline of pathology that is practiced. For instance, some specimens degrade following removal from the human body and are no longer useful for re-analysis. Hence, these specimens will be discarded following the release of the report. On the contrary, permanently prepared samples such as formalin-fixed paraffin-embedded tissue blocks can be stored for as long as the storage facilities allow. Therefore, the committee has agreed that the guidelines for the storage of specimens and the retention of relevant records are to be set by the respective disciplines of pathology based on their priorities and justifications.

Worth mentioning, detailed guidance on the physical storage conditions is beyond the scope of these guidelines. Generally, tissue samples and records are to be kept in secure and optimum storage conditions (depending on specimen stability), to ensure the long-term integrity of the specimens and records so that they remain intact and accessible until their retention period expires.

State-of-the-art technologies make the development of laboratory information management systems in many governments and private hospitals in Malaysia possible,

where increasing amounts of patients' data and records are being stored and shared electronically. These technology advancements create new requirements relating to the retention of digitalised medical records. Additionally, some areas which were not previously addressed such as with regard to storage for electron microscopy samples, donors' samples and records, and materials generated for molecular diagnostic testing are further elaborated in the current guidelines. Unless specifically mentioned, all records can be stored either in the form of soft copy or hard copy as long as they are readily accessible at any point in time. The duration for keeping simple request forms that do not contain patients' information/data is revised to a much shorter duration. Noteworthily, with reference to the Limitation Act 1953, the National Archives Act 2003, and the Private Healthcare Facilities and Services Act 1998, all medical records from all public and private health-related facilities shall be retained for a minimum period of seven (7) years from the date of issuance of reports,

with exceptions for psychiatric and paediatric cases.

According to the Age of Majority Act 1971, special attention should be paid to records and reports for minors, as the retention duration should be extended for another seven (7) years after they reach maturity, i.e. until the age of 25 years. Similarly, for individuals without capacity, it is strongly advisable that the patients' data and reports be kept indefinitely, in alignment with our local legal requirements.

For forensic autopsies, as the cases are always associated with medico-legal implications, the materials and records obtained during the procedure including the laboratory investigation results also carry a similar possibility. Therefore, a separate section for forensic autopsy is deemed indicated in this revision, to set it apart from the clinical autopsy. Unless there is an appropriate order from higher authorities, retention of specimens obtained during the forensic autopsy examination is subjected to the Human Tissue Act 2004.

## Definitions

Document	Matter in written, printed or electronic form that gives information or instruction, which serves as an official record e.g. forms, standard operating procedures (SOP), manuals, policy statements, charts, notices, biological reference intervals and work instructions.
Record	Document that contains data such as request forms, worksheets, results, laboratory reports, duty rosters, quality control, and quality assurance records, personnel files, minutes of meetings etc.
Result	An outcome/data of a laboratory analysis without interpretation.
Laboratory report	A formal interpretative record issued (usually by a competent medical officer or pathologist), that contains inferences from test results.
Retention period	Retention period refers to the length of time for which records/diagnostic materials should be kept.
Minors	Individuals less than 18 years of age.
Individual without capacity	An individual who is unable to make a decision for him/herself in relation to a matter, because of an impairment of, or a disturbance in the function of, the mind or brain.
Indefinite	Lasting for a lifetime, i.e. – 110 years (maximum life expectancy) + 6 years OR – Entire lifetime of an individual + 6 years
Medico-legal case	A case in which legal action has been initiated or is anticipated.

**1. General**

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

	<b>Record/Material</b>	<b>Minimum Retention Period</b>
<b>1.1</b>	Personnel records	Period of employment + 3 years
<b>1.2</b>	Quality management records	
	1.2.1 All quality control and quality assurance records	3 years
	1.2.2 External quality assessment (EQA) end-of-cycle summary	5 years
	1.2.3 Remedial action log	5 years
<b>1.3</b>	Equipment management logs	
	1.3.1 Maintenance, service, repair, and calibration records	Lifetime of machine/instrument + 1 year
	1.3.2 Daily, weekly, and monthly maintenance log	1 year
	1.3.3 Temperature records	1 year
<b>1.4</b>	Discontinued laboratory methods/procedures (manuals)	1 year after discontinuation
<b>1.5</b>	Laboratory management documents and records	
	1.5.1 Accident and incident reports	Indefinite
	1.5.2 Staff training records	Period of employment (including those on "on call" duties)
	1.5.3 Staff competency records	7 years
	1.5.4 Feedback/suggestions	7 years
	1.5.5 Laboratory statistics	7 years
	1.5.6 Day book/sample receiving records	7 years
	1.5.7 Duty rosters	7 years
	1.5.8 Protocols of SOP	Lifetime of SOP in use + 1 year
	1.5.9 Technical procedure manual	Lifetime of manual in use + 1 year
	1.5.10 Records of inspection	2 accreditation cycles
	1.5.11 Accreditation documents	2 accreditation cycles
<b>1.6</b>	All records and reports known to have medico-legal implications or individuals without capacity upon receipt of specimen	Indefinite <sup>¥</sup>
	All records and reports for minors	Until the child is 25 years of age <sup>¥</sup>
<b>1.7</b>	All specimens, unless specified otherwise under the specialty concerned	Retain specimens under appropriate storage conditions for 2 days after issuance of report/results
<b>1.8</b>	Records relevant to diagnostic products or equipment: records on procurement, use, modification, and supply	2 accreditation cycles or duration of use of products or equipment + 1 year
<b>1.9</b>	Records of assay validation and verification for the methods used and results obtained	2 accreditation cycles or duration of use of methods used + 1 year
<b>1.10</b>	Point-of-care testing	
	1.10.1 Worksheets/test record/log/data	Lifetime of the instrument or test platform + 1 year
	1.10.2 Specimens	Discard after issuance of report/result
	1.10.3 Strips/cartridges/kits etc.	Discard after issuance of report/result

<sup>¥</sup> applicable only to centre(s) with relevant storage facilities, and only if the status of the patient is known to the laboratory upon reception.

## 2. Anatomical Pathology: Histopathology

	Record/Material	Minimum Retention Duration
2.1	Request form (hard copy or electronic equivalent) with written clinical information not transcribed into report or not readily available in the patients' notes	As long as the corresponding report is kept
2.2	Final reports (hard copy or electronic equivalent) 2.2.1 Minors 2.2.2 Normal adults 2.2.3 Individuals without capacity	Until the child is 25 years of age <sup>‡</sup> 10 years* Indefinite <sup>‡</sup>
2.3	Physical or digital scanned slides 2.3.1 Surgical pathology slides including all permanent stained slides (H&E, frozen section, special stains, immunohistochemistry, chromogenic in-situ hybridisation) 2.3.2 Electron microscopy slides/grids 2.3.3 Fluorochrome stained slides	7 years  7 years 2 days after issuance of report
2.4	Blocks 2.4.1 Paraffin-embedded blocks including residual tissue from frozen sections 2.4.2 Resin-embedded blocks, for ultrastructural study 2.4.3 Frozen tissue blocks for special stains/immunofluorescence studies 2.4.4 Special paediatric cases including paediatric cancers, inherited genetic diseases, etc.	20 years or until the child is 25 years old (whichever is greater) 20 years or until the child is 25 years old (whichever is greater) 3 months Indefinite
2.5	Unblocked surgical wet tissues	1 month after issuance of report
2.6	Clinical/non-coronial autopsy 2.6.1 Register/consent form/images/gross photographs/results/reports 2.6.2 Unblocked wet tissues/organs retained during autopsy with consent 2.6.3 Tissue blocks 2.6.4 Slides	10 years 3 months after issuance of report 20 years 7 years

<sup>‡</sup> applicable only to centre(s) with relevant storage facilities, and only if the status of the patient is known to the laboratory upon reception.

\* for laboratory with LIS – in both physical and electronic copies for 5 years and kept in electronic copies only for another 5 years; for laboratory without LIS – in physical copies for 10 years.

Note: It is suggested to retain tissue blocks for a longer period of years for research use depending on the laboratory storage capacity.

## 3. Anatomical Pathology: Cytopathology

	Record/Material	Minimum Retention Period
3.1	Request forms (hard copy or electronic equivalent) with written clinical information not transcribed into report or not readily available in the patients' notes	As long as the corresponding report is kept

<b>3.2</b>	Final reports (hard copy or electronic equivalent) 3.2.1 Minors 3.2.2 Normal adults 3.2.3 Individuals without capacity	Until the child is 25 years of age <sup>‡</sup> 10 years* Indefinite <sup>‡</sup>
<b>3.3</b>	Exfoliative and fine needle aspiration cytology (FNAC) 3.3.1 Slides 3.3.2 Cell blocks	7 years 20 years
<b>3.4</b>	Gynae/non-gynae slides	7 years
<b>3.5</b>	Male fertility slides	1 year
<b>3.6</b>	Residual specimen of sputum, urine, cerebrospinal fluid, and other body fluids after slides preparation	7 days from date of receipt or until 2 days after the final report is issued (whichever date is later)
<b>3.7</b>	Specimens received in liquid-based fixative	1 month after issuance of report
<b>3.8</b>	Digital images used for diagnostic analysis e.g. semi-automated Pap screening images	6 years (to cover at least 1 recall visit)

<sup>‡</sup> applicable only to centre(s) with relevant storage facilities, and only if the status of the patient is known to the laboratory upon reception.

\* for laboratory with LIS – in both physical and electronic copies for 5 years and kept in electronic copies only for another 5 years; for laboratory without LIS – in physical copies for 10 years

#### 4. Forensic Pathology

	<b>Record/Material</b>	<b>Minimum Retention Period</b>
<b>4.1</b>	Mortuary registers	Indefinite Electronic copies after 30 years
<b>4.2</b>	Autopsy drafts	Indefinite Electronic copies after 30 years
<b>4.3</b>	Autopsy reports and duplicates	Indefinite Electronic copies after 30 years
<b>4.4</b>	Photographic records	Indefinite Electronic copies after 30 years
<b>4.5</b>	Tissue blocks	20 years
<b>4.6</b>	Stained slides	7 years
<b>4.7</b>	Histological/laboratory reports	Indefinite Electronic copies after 30 years
<b>4.8</b>	Unblocked tissues	3 months after issuance of histological reports
<b>4.9</b>	Records of organ and body disposal	Indefinite Electronic copies after 30 years

#### 5. Haematology

##### a. General haematology and haemostasis

	<b>Record/Material</b>	<b>Minimum Retention Period</b>
<b>5.1</b>	Peripheral blood films (i.e. slides) 5.1.1 without digital images 5.1.2 with digital images	1 year 1 week

<b>5.2</b>	Body fluid slides 5.2.1 without digital images 5.2.2 with digital images	1 year 1 week
<b>5.3</b>	Samples 5.3.1 Blood/body fluid/bone marrow 5.3.2 Urine 5.3.3 DNA extracts for molecular testing	1 week from date of receipt or until 2 days after the final result/report is issued 24 hours after the test is done 1 year at $\leq -20^{\circ}\text{C}$
<b>5.4</b>	Plasma for special haemostasis test	1 month at $\leq -20^{\circ}\text{C}$
<b>5.5</b>	Request form 5.5.1 Hard copy 5.5.1.1 Routine test or test without interpretative report 5.5.1.2 Testing requiring interpretative report 5.5.2 Electronic form	1 month after issuance of result 3 years after issuance of report 4 years
<b>5.6</b>	Final reports (hard copy or electronic equivalent) 5.6.1 Minors 5.6.2 Normal adults 5.6.3 Individuals without capacity	Until the child is 25 years of age <sup>‡</sup> 10 years Indefinite <sup>‡</sup>
<b>5.7</b>	Bone marrow slides (used for bone marrow reporting) Bone marrow slides/peripheral blood slides (used for flow cytometry reporting)	7 years 7 years
<b>5.8</b>	Digital images	10 years
<b>5.9</b>	Flow cytometry data including digital images or graphical output 5.9.1 For general and neoplastic disorders 5.9.2 For lymphocyte subset and CD34 enumeration	10 years after issuance of report 2 years after issuance of report
<b>5.10</b>	Molecular genetic analysis including digital images and data	3 years
<b>5.11</b>	Stem cell reports, request forms, worksheets, and data analysis	10 years

<sup>‡</sup> applicable only to centre(s) with relevant storage facilities, and only if the status of the patient is known to the laboratory upon reception.

## b. Transfusion

	<b>Record/Material</b>	<b>Minimum Retention Period</b>
<b>5.12</b>	Patients' blood specimens for testing	1 week
<b>5.13</b>	Donors' blood specimens for testing 5.13.1 Negative microbiology result 5.13.2 Positive microbiology result Blood grouping	1 day after the test is done 1 week after the test is done 1 week after the test is done
<b>5.14</b>	Laboratory records of blood products received and issued	20 years
<b>5.15</b>	Laboratory records for all the immunohaematology testing	20 years

<b>5.16</b>	Donors' record	
	5.16.1 Permanently deferred donors	Indefinitely
	5.16.2 Donation date, time, and the phlebotomist identification	1 year
	5.16.3 Donation form of blood donor	7 years
	5.16.4 Laboratory records	20 years
<b>5.17</b>	Investigations and reports related to the safety of blood components	10 years
<b>5.18</b>	Records of recall and look-back/trace-back	10 years
<b>5.19</b>	Final reports (hard copy or electronic equivalent)	
	5.19.1 Minors	Until the child is 25 years of age <sup>¥</sup>
	5.19.2 Normal adults	10 years
	5.19.3 Individuals without capacity	Indefinite <sup>¥</sup>

<sup>¥</sup> applicable only to centre(s) with relevant storage facilities, and only if the status of the patient is known to the laboratory upon reception.

## 6. Chemical Pathology

	Record/Material	Minimum Retention Period
<b>6.1</b>	Request form (hard copy or electronic equivalent)	1 year following report validation
<b>6.2</b>	*Report duplicates:	
	6.2.1 Neonatal screening and inborn error of metabolism	25 years
	6.2.2 Drug of abuse testing (confirmatory or screening)	7 years
	6.2.3 All other reports	7 years
<b>6.3</b>	Results (hard copy or electronic equivalent)	1 year
<b>6.4</b>	6.4.1 Serum, plasma, blood, frozen urine, and other frozen body fluids	**2 days after issuance of report/result
	6.4.2 Urine and faeces	Discard after issuance of report/result
	6.4.3 Other body fluids (e.g. cerebrospinal fluid, pleural fluid), aspirates, and swabs	24 hours after the test is done
	6.4.4 Urine toxicology	5 days after issuance of report/result
<b>6.5</b>	Final reports/records/accompanied images/representative diagrams/photographs	1 year provided all results have been transcribed into a formal report
<b>6.6</b>	Protein electrophoresis (electrophoretogram/gel) and immunofixation/immunotyping (gel/digital)	3 years
<b>6.7</b>	Specimens for biochemical testing for inherited metabolic disorders	
	6.7.1 Dried blood spot	1 year
	6.7.2 Serum/plasma/urine/cerebrospinal fluid	3 months after issuance of report/result

\*Report duplicates: copy of original report or ability to reprint information content of an original report.<sup>5</sup>

\*\*2 days after issue of report/result unless additional testing is required i.e. if the final report recommends follow-up analysis done in parallel with re-analysis of the original sample.



## 7. Medical Microbiology

	Record/Material	Minimum Retention Period
7.1	Request form 7.1.1 Hard copy form  7.1.2 Electronic form 7.1.3 Request form used as laboratory worksheet	1 month after issuance of report/result  1 year Retain as part of laboratory worksheet
7.2	Worksheets 7.2.1 For permanent/semi-permanent specimens  7.2.2 For temporary specimens (such as serum, body fluid, and faecal samples) 7.2.3 Instrument print-out, graphic outputs, and digital images used for diagnostic analysis 7.2.4 Instrument output for diagnostic tests using nucleic acids	At least 1 month after issuance of report/result At least 1 month after issuance of report/result 1 year for annual analysis  1 year for annual analysis
7.3	Final report or copies (hard copy or electronic equivalent)	6 months or as needed
7.4	Specimens for microbiological investigations 7.4.1 All specimens except urine, and blood culture 7.4.2 Urine 7.4.3 Blood culture, including fungal/mycobacterial culture Negative: Positive:	2 days after issuance of report/result  Discard after issuance of report/result  Discard after issuance of report/result 7 days after issuance of report/result or blood culture positive
7.5	Microbiological cultures 7.5.1 Positive cultures including viral cultures 7.5.2 Positive cultures of clinical importance (e.g. blood culture isolates, cerebrospinal fluid isolates, enteric pathogens, with multiple or methicillin-resistant <i>Staph. aureus</i> , 'outbreak' strains, <i>M. tuberculosis</i> , Group A Streptococci, and unusual pathogens of clinical significance) 7.5.3 Isolates have been referred to reference laboratories	2 days after issuance of report/result Should be retained for at least 7 days   Until receipt of the reference laboratory's final report
7.6	Freeze-dried or other permanently preserved cultures	Retained as needed
7.7	Slides 7.7.1 Wet preparation 7.7.2 Permanently stained slides 7.7.2.1 From clinical specimens (e.g. cerebrospinal fluid preparations, blood films for malarial parasites, blood culture films, acid-fast bacilli)  7.7.2.2 From culture plates 7.7.3 Immunofluorescence slides	Discard after issuance of report/result  Negative: discard after issuance of report/result (unless negative slides are required for re-checking or EQA). Positive: 2 days after issuance of report/result  2 days after issuance of report/result 2 days after issuance of report/result

<b>7.8</b>	Electrophoretic strips and immunofixation plates	2 years (either strips/plates or digital images)
<b>7.9</b>	Serum/plasma for serology/immunology 7.9.1 Negative result 7.9.2 Positive result	Discard after issuance of report/result 7 days after issuance of report/result
<b>7.10</b>	Nucleic acids (DNA and RNA) 7.10.1 Extracted from clinical samples or derived from microbiological cultures, and the molecular diagnostic outputs from microbiology/virology laboratories - Negative - Positive 7.10.2 Original specimen remaining after nucleic acid extraction	Discard after issuance of report/result 7 days after issuance of report/result Discard 2 days after the final report has been issued by the laboratory

### 8. Genetic Pathology

	<b>Record/Material</b>	<b>Minimum Retention Period</b>
<b>8.1</b>	Request forms (hard copy or electronic equivalent) (Contain clinical information not readily accessible in the patient's notes but used in the interpretation of test data)	As long as the corresponding report is kept
<b>8.2</b>	Final original reports (hard copy or electronic equivalent) 8.2.1 Constitutional genetic testing 8.2.2 Somatic genetic testing	Indefinite <sup>¥</sup> 10 years*
<b>8.3</b>	Representative karyotypes (hard copy or electronic equivalent)	4 years
<b>8.4</b>	Images in-situ hybridisation (ISH) (hard copy or electronic equivalent)	4 years
<b>8.5</b>	Specimen for cytogenetic testing 8.5.1 Original specimens and cultures 8.5.2 Fixed chromosome cell suspension	1 month after issuance of report/result 6 months
<b>8.6</b>	Slides 8.6.1 Permanently stained slides 8.6.2 Fluorochrome stained slides 8.6.3 Chromosomal microarray slides	4 years 6 months At the discretion of the laboratory director
<b>8.7</b>	Nucleic acid extracts 8.7.1 Somatic or constitutive genetic testing  8.7.2 Frozen plasma for non-invasive prenatal testing	3 months after -issuance of report/result for an individual, or -completion of a family study where the proband's sample is required as a control, or -completion of testing. (whichever of the 3 periods is the longest). 12 months

<b>8.8</b>	Bioinformatic genetic data 8.8.1 Sequencing data i.e. FASTQ, BAM, CRAM) 8.8.2 Variant calling files (i.e. gVCF). 8.8.3 Microarray analysis files	4 years after issuance of report/result 10 years 4 years
<b>8.9</b>	Specimens for biochemical genetic testing (i.e. plasma, serum, urine, and others) 8.9.1 Original container 8.9.2 Analytical aliquot	7 days 3 months after issuance of report/result

<sup>‡</sup> applicable only to centre(s) with relevant storage facilities, and only if the status of the patient is known to the laboratory upon reception.

\*if the report relates to a paediatric patient, the retention period should be greater than 10 years, until the child is 25 years old, or at least 7 years from the age of maturity (whichever is greater).

## CONCLUSION

We recommend the current guidelines be embraced across all disciplines of pathology in Malaysia. This would serve as a reference to the laboratory in preparation for laboratory accreditation by local authorities. There is a constant need to keep guidelines up to date to remain valid. It is suggested that this guideline should be reviewed and revised at least once every five (5) years or as soon as new evidence or practice is/are published.

## Lists of Reviewers from Stakeholders (Names in alphabetical order)

<b>Dr. Afifah Hj. Hassan</b> Consultant Transfusion Medicine and Director, National Blood Centre, Kuala Lumpur.	<b>Prof. Datuk Dr. Ainoon Othman</b> Consultant Haematopathologist, Universiti Sains Islam Malaysia, Nilai, Negeri Sembilan.
<b>Dr. Chin Loi Khim</b> Consultant Genetic Pathologist, Genetics Laboratory, Hospital Tunku Azizah, Kuala Lumpur.	<b>Dr. Mimi Azura Aziz</b> Consultant Haematopathologist, Hospital Tunku Azizah, Kuala Lumpur.
<b>Dr. Mohamad Azaini Ibrahim</b> Director and Consultant Forensic Pathologist, National Forensic Medicine Institute, Kuala Lumpur.	<b>Dr. Nazihah Mohd Yunus</b> Consultant Genetic Pathologist, Human Genome Centre, Universiti Sains Malaysia, Kota Bharu, Kelantan.
<b>Dr. Noraini Ismail</b> Consultant Medical Microbiologist, Hospital Sultanah Bahiyah, Alor Setar, Kedah.	<b>Dr. Raudhawati Hj Osman</b> Consultant Haematopathologist, Hospital Melaka, Melaka.
<b>Dr. Tengku Norita Tengku Yazid</b> Consultant Chemical Pathologist, Hospital Selayang, Selangor.	<b>Prof. Dr. Yasmin A. Malik</b> Visiting Clinical Consultant Medical Microbiologist, Universiti Malaya Medical Centre, Kuala Lumpur.
<b>Dr. Zanariah Alias</b> Consultant Anatomical Pathologist, Hospital Kuala Lumpur, Kuala Lumpur.	

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