

	<i>The American Association for Laboratory Accreditation</i>	
	P604 – POLICY FOR MEDICAL RECORD AND MATERIAL RETENTION	Document Issued: March 30, 2010
		Page 1 of 3

A2LA has established the minimum requirements for the retention of laboratory records and materials. These requirements are equal to or more stringent than the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

Some states and or countries promulgate regulations requiring retention of records and/or materials for longer periods than are specified in this policy. It is recommended that each laboratory carefully review state or national laws when developing their individual record retention policies.

A2LA accredited laboratories must also have a written plan describing the process for sample retention should the laboratory go out of business. This plan will require that retained items be maintained secure until the posted retention period is reached.

Please note: It may be appropriate for laboratories to retain records and/or materials for longer periods of time when required for patient or operational purposes.

#### **PERIOD OF RETENTION**

<b><i>General Laboratory</i></b>	
Accession log	2 years or between full assessments whichever is longer
Instrument records including maintenance records, printouts, calibration and verification records	2 years or between full assessments whichever is longer
Quality control records including performance data, instrument printouts, and corrective action.	2 years or between full assessments whichever is longer
Proficiency Testing results including corrective actions	2 years or between full assessments whichever is longer
Management Review documentation	2 years or between full assessments whichever is longer
Reports of internal audits	2 years or between full assessments whichever is longer
Corrective Action Reports	2 years or between full assessments whichever is longer
Preventative Action Reports	2 years or between full assessments whichever is longer
Quality Assurance Records and QA meeting minutes(Except as notated elsewhere in this guideline)	2 years or between full assessments whichever is longer
Records of employee signatures, initials, and identification codes	10 years
<b><i>Surgical Pathology (including bone marrows)</i></b>	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years



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**P604 – POLICY FOR MEDICAL RECORD  
AND MATERIAL RETENTION**

Document Issued:  
March 30, 2010  
Page 2 of 3

<b><i>Cytology(GYN)</i></b>	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Quality Assurance studies	5 years
Reports	10 years
<b><i>Cytology(non-GYN)</i></b>	
Fine needle aspiration slides	10 years
Body Fluid slides	10 years
Reports	10 years
Quality Assurance studies	10 years
Note: Cytology slides may be loaned to proficiency testing (PT) programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of the slides by the PT program and maintains the acknowledgment to document the loan of these slides. Documentation of slides loaned or referred for purposes other than PT testing must be maintained and all slides must be retrievable upon request.	
<b><i>Non-Forensic Autopsy</i></b>	
Wet tissue	3 months after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
<b><i>Forensic Autopsy</i></b>	
Wet stock tissue	1 year
Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative tissue suitable for DNA Analysis	Indefinitely
<b><i>Clinical Pathology</i></b>	
Patient test records	2 years
Urine	24 hours
Serum/CSF/Body fluids (except urine)	48 hours
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides – microbiology (i.e.gram stains).	7 days
Reports	10 years
<b><i>Cytogenetics</i></b>	
Permanently stained slides	3 years



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P604 – POLICY FOR MEDICAL RECORD  
AND MATERIAL RETENTION

Document Issued:  
March 30, 2010  
Page 3 of 3

Fluorochrome stained slides	3 years or longer at the discretion of the laboratory director
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images(digitized, prints or negatives)	20 years
<b><i>Flow Cytometry</i></b>	
Gated dot plots and histograms	10 years
<b><i>Blood Bank</i></b>	
Donor and recipient records	10 years
Patient records	10 years
Quality control records	5 years
Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipient's protection (e.g., those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)	Indefinitely
Specimens from and potential and confirmed recipients	7 days post-transfusion
blood donors units	7 days post-transfusion