COLLEGE of AMERICAN PATHOLOGISTS

CAP Policy Manual

Policy PP. Minimum Period of Retention of Laboratory Records and Materials

The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). It may be appropriate for laboratories to retain records and/or materials for a longer period of time when required for patient care, education, quality improvement, medical/legal, or other needs, or if required by institutional policy. Some state regulations as well as other federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA 88 regulations. For testing on minors (under the age of 21), stricter state regulations may apply. Therefore, any applicable national, federal, state (or provincial) or local laws should be reviewed carefully when individual laboratories develop their record retention policies.

Material/Record	Period of Retention
GENERAL LABORATORY	
Accession records	2 years
Specimen requisitions (including the patient chart or medical record if used as the requisition)	2 years
Chain-of-custody collection, receipt, accessioning, and handling records	2 years (or longer as applicable)
Quality management records	2 years
Instrument/equipment maintenance and function check records (including temperature charts	2 years
Proficiency testing records	2 years
Policies and procedures	2 years following discontinuance
Test method validation/verification records (method performance specifications)	Length of time the test is in use, plus 2 additional years
Quality control records	2 years
Individualized Quality Control Plan (IQCP), including risk assessment and supporting data, and approval of quality control plan	Length of time the test is in use, plus 2 additional years following discontinuation of the IQCP
Ongoing IQCP quality assessment data	2 years
Laboratory Computer Services	
Computer system validation records	2 years beyond the life of the system
Records of changes to software, the test library, and major functions of laboratory information systems	2 years beyond the life of the system
Ongoing computer system checks (eg, calculation verification)	2 years
Personnel Records	
Competency assessment records	2 years
Training records	2 years

Material/Record	Period of Retention
SURGICAL PATHOLOGY (including bone marrows)	
Wet tissue	2 weeks after final report
Paraffin blocks (including cell blocks)	10 years
Reports	10 years
Slides	
Immunohistochemistry batch control slides	2 years
Surgical pathology slides	10 years
Bone marrows slides with associated peripheral blood smear(s) included in the bone marrow report	10 years
Fluorochrome-stained slides	At the discretion of the laboratory director
In situ hybridization images (refer to NOTE 1) or permanent slides	10 years - Neoplastic disorders 20 years - Constitutional disorders
Digital images used for primary diagnosis	10 years (if original glass slides are not available)
Digital images for Circulating Tumor Cells	10 years
Datasets from ex-vivo microscopy (EVM) or in-vivo microscopy (IVM) systems used to aid in interpretation or diagnosis	10 years (data must be retrievable for this period)
ELECTRON MICROSCOPY	
Wet tissue	2 weeks after final report
Resin blocks	10 years
Pictures and reports	10 years
CYTOLOGY	
Reports	10 years
Slides	
Immunochemistry batch control slides	2 years
Gynecologic cytology glass slides	5 years
Non-gynecologic cytology glass slides (including fine needle aspiration (FNA) slides	10 years
NON-FORENSIC AUTOPSY	
Wet tissue	3 months after final report
Paraffin blocks	10 years (refer to ANP.12500 for further detail)
Slides	10 years
Reports	10 years
Autopsy consent	10 years
FORENSIC AUTOPSY	
Wet stock tissue	1 year
Paraffin blocks	10 years
Reports	Indefinitely
Slides	50 years or 30 years if a DNA sample is available
Gross photographs/images	Indefinitely

Material/Record	Period of Retention
Accession records	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative sample suitable for DNA Analysis	Indefinitely
Autopsy consent	10 years
CLINICAL PATHOLOGY	
Testing Records	
Instrument printouts (not interfaced with laboratory computer system) and worksheets	2 years
Patient test results and reports, including original and corrected reports, and referral laboratory reports	10 years
Direct-to-consumer testing results, including reference intervals	10 years
Patient Specimens	
Serum and plasma	48 hours; exceptions may be made at the discretion of the laboratory director. Longer storage requirements may be necessary for patients admitted for suspected drug overdoses.
Citrated plasma	At the discretion of the laboratory director (see HEM.36940)
CSF and body fluids (except urine)	48 hours
Whole blood specimens, including blood gas specimens	At the discretion of the laboratory director
Urine	24 hours; exceptions may be made at the discretion of the laboratory director
Clinical Pathology Slides	
Peripheral blood films	7 days
Permanently stained body fluid slides	7 days
Permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles)	7 days
CYTOGENETICS	
Final reports	10 years - neoplastic disorders 20 years - constitutional disorders
Images (in situ hybridization (ISH) or non-ISH) (refer to NOTE 1)	10 years - neoplastic disorders 20 years - constitutional disorders
Chromosomal microarray data Original scan	2 weeks after the final report is released
Sufficient original data to support primary results generated and re-analysis	2 years
Slides	
Permanently stained slides	3 years
Fluorchrome stained slides	At the discretion of the laboratory director
Chromosomal microarray slides	At the discretion of the laboratory director

Material/Record	Period of Retention
Original specimens and cultures	Until release of the final report
Processed specimens or cell pellets	2 weeks after final report
MOLECULAR PATHOLOGY	
Fluorochrome stained slides	At the discretion of the laboratory director
Chromosomal array slides	At the discretion of the laboratory director
In situ hybridization images* (see Note 1) or permanent slides	10 years - neoplastic disorders 20 years - constitutional disorders
Reports	10 years - neoplastic disorders 20 years - constitutional disorders
Next generation sequencing data	2 years
Sequence read files (eg, FASTQ, uBAM, BAM, CRAM) and variant calling files (eg, VDF, gVCF)	2 years
Array Data	
Original scan	2 weeks after the final report is released
Sufficient original data to support primary results generated and re-analysis	2 years
FLOW CYTOMETRY	
Data for evaluation of hematolymphoid neoplasia, PNH, and congenital immunodeficiency	10 years
Data for routine lymphocyte subset and CD34+ enumeration	2 years
TRANSFUSION MEDICINE	
Policies and procedures, including approval, review, and discontinuance	5 years
Quality Management Records	
Proficiency testing records	5 years
Management reviews for the effectiveness of the quality system	5 years
Blood supplier agreements	5 years
Irradiation dose delivery	5 years
Control systems for patient testing	10 years
Control systems for donor testing	10 years
Instrument and equipment maintenance and function checks	10 years
Temperature monitoring (eg, graphs, logs) of refrigerators, freezers, and platelet incubator	10 years
Inspections of blood/critical materials	10 years
Inspection of weld for completeness	10 years
Specimens	
Patient pretransfusion testing specimens	7 days post-transfusion
Specimens from blood donors units	7 days post-transfusion
Patient Records	
Orders and requests for blood/blood components	5 years
Transfusion administration records	10 years
Final unit disposition	10 years

Material/Record	Period of Retention
Patient pre-transfusion testing results/interpretation	10 years
Immediate evaluation/interpretation of transfusion reactions	10 years
Final inspection and verification of blood before issue	10 years
Evaluation/interpretation of delayed transfusion reactions	10 years
Emergency release of blood, including signature of requesting physician	10 years
Therapeutic phlebotomy/apheresis records	10 years
Transfusion problems such as transfusion reactions, unexpected antibodies, and special transfusion requirements.	Indefinitely
Donor Records	
Blood/component donor information, consent and collection	10 years
Donor blood testing	10 years
Retyping of donor units	10 years
Donor notification of significant findings	10 years
Component production	10 years
Look back investigation/disease reporting	10 years
Final unit disposition	10 years
Irradiation of cellular components	10 years
Acceptability of returned units into inventory	10 years
Indefinitely and permanently deferred donors	Indefinitely
Donors placed under surveillance (for recipient protection)	Indefinitely
Personnel	
Competency records	5 years
Training records † (see Note 2)	5 years
Records of employee signatures, initials, identification codes, and inclusive dates of employment	10 years
Other Records	
Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components	10 years
Traceability of blood, blood components and critical materials	10 years
Container qualification/process validations	10 years
Tissue Records (including hematopoietic progenitor cells)	
Daily temperature monitoring	10 years
Investigation of adverse events	10 years
Discontinued policies, procedures and other controlled documents	10 years beyond tissue's disposition or expiration, whichever is longest
Collection, transportation, processing, issuing, and disposition	10 years beyond tissue's disposition or expiration, whichever is longest

* *Note 1: There is no retention requirement for images of glass slide preparations when the source slides remain readable for the required retention period. A scanned image may not take the place of the source slides.*

† *Note 2: The five-year retention requirement for transfusion medicine training records aligns with the AABB Standards to provide consistency for laboratories that have coordinated CAP/AABB inspections and for labs in states that are required to follow AABB regulations (eg, California). Reference Table 6.2C in the AABB Standard lists: Standard 2.1.2 - Training Records of Personnel – minimum retention time (in years) – 5.*

REFERENCES

1. Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1105].
2. Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1): [21CFR606.160].
3. Fanaoff J. Retention of Pediatric Medical Records. American Academy of Pediatrics. March 2016. https://www.aap.org/en-us/professional-resources/practice-transformation/managing-practice/Pages/Retention-of-Pediatric-Medical-Records.aspx. Accessed April 15, 2019.

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