


<b>Name of Policy:</b> <b>Retention of Laboratory Records and Materials</b>		 <b>Effective date:</b> 01/04/2025 <b>Original effective date:</b> 05/20/1995	
<b>Policy Number:</b> 3364-107-309			
<b>Approving Officer:</b> Medical Director, Clinical Pathology			
<b>Responsible Agent:</b> Director, Clinical Pathology Administrative Director, Lab			
<b>Scope:</b> Pathology-Laboratory			
Key words: Records and materials, retention & archival, instrument maintenance, IQCP, personnel competency.			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input checked="" type="checkbox"/>	Reaffirmation of existing policy

(A) Policy statement

The clinical laboratories have a policy for retention of laboratory records or materials in accordance with CLIA, FDA, CAP, and other accrediting agency regulations.

(B) Purpose of policy

To establish a guideline for retention and archival of laboratory records and materials.

(C) Procedure

1. The following records must be maintained for at least two years: Specimen requisitions, patient test results and reports (electronic computer retrieval is acceptable), accession records, quality control records, proficiency test records, quality improvement records.
2. Blood Bank requests, release forms and transfusion forms are retained for five years.
3. Surgical pathology reports and outside consultation reports are retained for ten years.
4. Histology paraffin blocks, slides, and reports, including autopsy blocks, slides and reports are retained for ten years and may be kept longer if deemed appropriate. Bone Marrow slides are retained ten years.
5. Stock bottle specimens in Histology are retained for one month. Autopsy stock specimens are retained a minimum of six months.
6. Discontinued policies and procedures are retained for five years.

7. Instrument maintenance records including temperature charts must be retained for the life of the instrument.
8. Serum, urine, and body fluid specimens should be retained for at least 48 hours. Blood Bank specimens are retained for a minimum of 21 days (7 days' post transfusion). Each department may retain frozen aliquots of specimen as required by applicable regulations.
9. Blood films, permanently stained body fluid slides, and microbiology slides should be retained for at least seven days.
10. Individual Quality Control Plan including risk assessment and supporting data and approval of quality control plan is kept for at least two years after discontinuation of IQCP. Ongoing quality assessment data is retained at least two years.
11. Chain of custody collection, receipt, accessioning, and handling records are retained for at least two years or longer as applicable.
12. Personnel competency and training records are retained for at least two years.
13. Computer system validation records, records of changes to software, test library, and major functions of the laboratory information systems are retained two years beyond the life of the system. Ongoing system checks are retained for at least two years.

In the event that the laboratory ceases operation an outside contractor will be hired to store all records, slides, blocks, and tissue for the appropriate time that is required by the College of American Pathologists.

<p>Approved by:</p> <p>/s/</p> <hr/> <p>Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology</p> <p>1/10/2025</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by:</i></p> <p><i>Joshua Otiso, Administrative Director, Lab</i></p>	<p><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"><li>• <i>Q-09</i></li></ul> <p>Initial effective date: 05/20/1995</p> <p>Review/Revision Date: 01/04/2025</p> <p>Next review date: 01/04/2027</p>
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