State of Illinois
CLIA Laboratory
Certification Program

CLIA LABORATORY RECORD RETENTION REQUIREMENTS

(As of 2013 and stated in The Code of Federal Regulations, CFR42 Part 430, Appendix C, Subpart J, §493.1105 Standard: Record Retention requirements)

Listed are the CLIA requirements for retaining patient and testing records, specimens and slides. Use the table below as a guideline when establishing your laboratory's policies and procedures for record retention.

Note: If your laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are maintained and available for the time frames specified below.

Type of Record	*Specialty/Subspecialty*	*Retention Time*
Test Requisitions and Authorizations Including patient's chart or medical record if used as the test requisition or authorization	**ALL**	**2 years**
Test Procedures Including dates of initial use and discontinuance	**ALL**	**2 years after the procedure has been discontinued**
Analytic Systems Records Quality control and patient test records, including instrument printouts, if applicable Analytical systems activities (Test systems, equipment, instruments, reagents, materials, and supplies; Establishment and verification of performance specifications; Maintenance and function checks; Calibration and calibration verification procedures; Control procedures; Comparison of test results; Corrective actions)	**Immunohematology (Transfusion-Related Only)**	As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(v), & (d): **10 years** (After processing records are completed or six months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.)
	All Others	**2 years**
Proficiency Testing Records • Includes all information regarding the PT event: test records, signed attestation statements sent or transmitted to the PT providers, PT results and scores from the provider, documentation of review and records of any corrective actions	**All**	**2 years**
Laboratory Quality System Assessment	**All**	**2 years**
Test Reports • Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports)	**Pathology Subspecialties & Immunohematology (Transfusion-Related Only)**	**10 years**
	All Others	**2 years**
Slides	**Cytology**	**5 years**
	Histopathology	**10 years**
	All Others	**No Requirements**
Specimen Blocks	**Pathology**	**2 years**
Tissue Remnants	**Pathology**	**Completion of Diagnosis**