CLIA Records Retention Requirements

CLIA (Clinical Laboratory Improvement Amendments) regulations require laboratories to retain specific records for designated time periods to ensure compliance, facilitate inspections, and maintain quality control. Below is a summary of the key retention requirements:

Test Records & Patient Reports
- Retain for at least 2 years from the date of reporting.
- Cytology slides must be retained for at least 5 years.
- Histopathology slides must be retained for at least 10 years.

Quality Control (QC) Records
- Retain for at least 2 years.
- Includes instrument calibration, maintenance logs, reagent records, and QC test results.

Proficiency Testing (PT) Records
- Retain for at least 2 years.
- Includes PT results, corrective actions, and documentation of participation.

Personnel Records
- Retain for at least 2 years after an employee leaves.
- Includes competency assessments, training records, and qualifications.

Instrument Maintenance & Calibration Records
- Retain for at least 2 years.
- Covers equipment maintenance logs, service records, and calibration data.

Test System Performance Records
- Retain for at least 2 years.
- Includes method validation, verification, and analytical performance studies.

Corrective Action & Incident Reports
- Retain for at least 2 years.
- Documents errors, troubleshooting, and remedial actions taken.

Inspection & Accreditation Records
- Retain for at least 2 years.
- Includes CLIA certificates, accreditation reports, and regulatory inspection findings.

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