

DOCUMENTS NECESSARY FOR THE COLA SURVEY

- The surveyor will need documentation of all laboratory functions described below, including patient charts when requested, for a two-year period prior to the survey, or from the date of the last survey/ CMS CLIA inspection.
- These records should be identified and the location communicated to the relevant staff. The list below is not all-inclusive, but represents the basic items required. Depending on individual circumstances, the surveyor may request additional records.
- Copy of current CLIA Certificate for surveyor to review and retain if required.
- Copy of current Test Volume calculations for surveyor to verify along with a copy of the completed Annual Test Volume Report that was previously sent to COLA.
- Personnel files for each laboratory employee (including physicians) performing non-waived testing. Files must include:
 1. Proof of education according to CLIA '88 requirements. The following documents are acceptable: High school diploma, GED, Transcripts (must have date graduated), college degrees (AS, BS, MS, and PhD), RN license, NP license, PA license, or MD/DO License. Medical Assistants and LPNs must have either high school or AA diplomas available in addition to their licenses. Those employees with only foreign educational documents must have them evaluated for U.S. equivalency. (Please contact COLA for a list of evaluation organizations).
 2. Written performance evaluations and/or technical skill competencies. New employees must be evaluated six months and also one year after their hire; other employees must be evaluated yearly.
 3. Records listing laboratory-related continuing education and annual OSHA/Bloodborne Pathogens training.
 4. Training documents for all new employees or some proof of their previous experience, such as resumes and prior instrument training.
 5. Job descriptions for all employees.
- Policy & Procedure Manual(s) including all Instrument Operator's Manuals.
- Current package inserts for all kit tests and reagents (including all waived methods).
- Package inserts for all controls and calibration materials used during the survey period.
- Proficiency testing (PT) records including instrument tapes, test report forms, attestation statements, graded results, and corrective actions taken for *all* unsatisfactory scores.
- Instrument/equipment/pipette calibration, maintenance, and function check records for current and discontinued instruments used during the survey period.
- Temperature and humidity records
- All quality control (QC) records, graphical representations, charts, and any other documentary logs involved.
- Test requisitions and report forms used for all laboratory testing. The surveyor may ask to review several patient charts.
- Incident Management Plan and any reports (see *COLA LabGuide 71*).
- Quality Assurance (QA) Plan and documentation of implementation - QA reviews. (For assistance consult *COLA LabGuide 70* or contact your COLA Technical Advisor.)