

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 collected prior to the survey and placed in a room with an electrical outlet. 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.
- A completed Annual Test Volume (ATV) form plus documentation (calculations) to support your declaration. A blank ATV form has been attached to this letter for your convenience.
- 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), and MD/DO Licenses.
 - MT & MLTS **must** have either copies or transcripts of the advanced degrees (AS, BS, MS). ASCP or other professional society cards or certificates cannot be accepted as the only proof of qualification.
 - Medical Assistants, LPNs, and RNs **must** have either high school diplomas or advanced degrees available. Licenses cannot be accepted as the only proof of qualification.
 - Those employees with only foreign educational documents **must** have them evaluated for equivalency to a US high school diploma, or college degree. (Please contact COLA for a list of evaluation organizations).
 - In those states that license laboratory personnel, a copy of a current state license can be accepted. It is advisable to have copies of the corresponding educational degree as well.
 2. Written performance evaluations and/or technical skill competencies. New employees must be evaluated at 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.)

QUESTIONS AND ANSWERS ABOUT YOUR UPCOMING COLA SURVEY

Q: How much time will the survey take?

A: The length of time necessary to complete your survey depends on your test menu, ATV and the extent of any noncompliances identified during the survey. Smaller physician office labs are often surveyed in 3-4 hours. Large labs and hospital labs may take several days to complete the survey. Our experience shows that the survey is completed faster and with fewer citations if the following actions are taken by your lab:

- The laboratory has performed its own self-assessment by reviewing the Section III COLA Criteria for Quality Laboratory Performance in your *COLA Accreditation Manual*.
- All materials indicated on the "Documents Necessary for the Survey" form are organized in a room with an electrical outlet prior to the Surveyor's arrival.

Q: Will my laboratory be able to operate during the survey?

A: The COLA survey consists of a review of your processes and an audit of your records. We encourage you to conduct normal laboratory operations during the survey, so the surveyor can observe actual work in progress. The surveyor will conduct a walkthrough of your laboratory, and talk with laboratory staff to gain an understanding of the path of workflow in your facility. This interaction and opportunity to observe the laboratory in action is a critical part of the survey. COLA surveyors are all trained laboratorians, who are dedicated to providing education for you and your staff throughout the survey process. Many laboratories find it helpful to arrange extra coverage for that day, so that their staff can take advantage of the educational opportunities provided by the surveyor. The surveyors make every effort to minimize disruptions so that patient care is not compromised during the survey.

Q: How should my laboratory prepare for the COLA survey?

A: You should review your laboratory's information by logging on to www.colacentral.com and making any necessary personnel or test menu updates as soon as possible. Laboratories are required to notify COLA of any changes to test menu, instrumentation, personnel, and ownership within 60 days of the change. If you have additions the surveyor was not aware of, this will extend the time the individual is onsite and could impact the survey schedule for other laboratories. It is strongly recommended that the

laboratory complete the Self-Assessment found in Section III of your *COLA Accreditation Manual*. These are the exact same questions the surveyor will use when conducting the on-site survey, so chances of success will be greatly enhanced. If this is done, there should be no surprises when the surveyor arrives.

Q: Who should be present at the time of survey?

A: It is essential that the individual(s) most familiar with the laboratory's policies and procedures be present. This includes supervisors, consultants, and/or testing personnel. The director's role and participation is very important, as the director is ultimately responsible for all phases of the laboratory's operation. COLA encourages the laboratory director to take an active role in the process; however, his/her presence during the survey is not mandatory. Nor is his/her absence a valid reason for canceling or rescheduling a survey. If the director cannot be available, the surveyor will be happy to speak with him/her by phone prior to the summary conference, or at a mutually convenient time, to review the survey findings. At the conclusion of the survey, your surveyor will hold a summary conference with all staff that would like to participate. At this time the surveyor will review the findings and discuss the next steps in the accreditation process.

Q: When will my laboratory receive COLA accreditation?

A: The surveyor will check for compliance with all COLA criteria delineated in Section III, Criteria for Quality Laboratory Performance, in your *COLA Accreditation Manual*. The results of your survey will be outlined in a Plan of Required Improvement (PRI). Upon agreement to this plan and after submission of any required documentation, your laboratory will be granted full accreditation status and your accreditation certificate will follow.

If you have other questions, please contact **COLA** at **800-981-9883**.