COLLEGE of AMERICAN PATHOLOGISTS

CAP Accreditation Programs
Self-Inspection Instructions & Verification Form

You **must** return this form to CAP within **60** calendar days. Perform the following steps to complete your self-inspection.

STEP 1: Review your laboratory's activity menu for accuracy.

Review and update the activity menu that CAP has on record for your laboratory through e-LAB Solutions Suite at www.cap.org. Your inspection checklists are customized based upon the activity menu you have provided in your reapplication.

STEP 2: Develop a plan for performing the self-inspection.

Self-inspection tools are available through e-LAB Solutions. To access the tools from your laboratory's dashboard: click on CAP Accreditation Resources, located under CAP Accreditation, and select Accreditation Forms and Instructions.
Begin your plan by selecting a "team" to perform the self-inspection. Teams may include bench techs, lead techs, supervisors, residents/fellows as well as neighboring laboratories interested in participating in reciprocal simulated inspections.

STEP 3: Select a date for the self-inspection.

Consider an unannounced, mock inspection to assess preparedness and readiness. Allow enough time to perform an effective self-inspection. Keep in mind that a thorough self-inspection will improve the outcome of your routine inspection.

STEP 4: Review all necessary laboratory documentation.

☐ **Policy and procedure manuals** (Administrative, Technical, Safety, Chemical Hygiene, etc).

- Do they reflect current practice and are they appropriately reviewed?

☐ **Complete personnel records.**

- Has the laboratory updated the Personnel Roster and verified each employee's educational qualifications? Is educational documentation readily available if needed?
- Is there an established competency assessment program that includes who is qualified to assess competency? Have competency assessments been performed on all testing personnel using applicable elements of competency for each test system?

☐ **Proficiency Testing or alternative assessment for each test/activity on the laboratory's test activity menu.**

- Is there documentation of evaluation of all results and corrective action for each unacceptable result?
- Does the attestation form include physical signatures and are designees qualified?
- Is PT rotated among all personnel?
- Is PT treated the same as a patient specimen (eg, duplicate testing only if patient samples are routinely run in duplicate)?

☐ **Quality Management Plan and monitors.**

- Do quality monitors include pre-analytic, analytic and post-analytic processes and reflect the scope of services provided by the laboratory?
- Is the QM Plan reviewed annually for effectiveness and are action plans documented?

☐ **Maintenance records** (instrument, temperatures, pipettes, centrifuges, etc).

- Do records include defined acceptance criteria?
- Are they reviewed monthly by the laboratory director or designee?

☐ **Quality Control records for all sections.**

- Is QC performed as required, defined in QC policy and is corrective action documented?

☐ **Test method validations and verifications** including accuracy, precision, reportable range, calibrations, analytic measurement ranges, etc.

- Does the summary statement include the evaluation of validation/verification studies and approval of each test for clinical use?

☐ **Information System requirements.**

- Have all programs been appropriately tested and approved prior to implementation?
- Are there records of training for all users?

☐ **Laboratory Reports.**
- Do all laboratory reports include required elements (eg, laboratory name, address, reference ranges)?

☐ **Laboratory Director Oversight.**
- Does the delegation policy specify the delegated individual or job title that meets regulatory qualification requirements?
- Does the laboratory director ensure sufficient number of qualified personnel?
- Did the laboratory director ensure follow-up action for QM/QC/PT failures?

Suggested Option: Consider creating "books of evidence" for each individual checklist and includes how the checklist requirement is met and where this information is located.

STEP 5: Spend time in the laboratory to ensure actual practice matches documented procedure.

STEP 6: Document all deficiencies on the enclosed form. Develop an action plan and document the corrective measures implemented. Retain the forms for review by the inspection team at your next onsite inspection.

STEP 7: Document that personnel responsible for each laboratory section have reviewed the findings of the interim self-inspection and ensure that corrective measures have been implemented.

STEP 8: Return the signed, Self-Inspection Instructions & Verification Form to CAP within 60 calendar days.

Please do not return the paper checklists to CAP. You may mail or fax your completed form. (FAX 847-832-8171)

Self-Inspection Date:	**Laboratory name:**	**CAP or AU#:**

All deficiencies noted will be corrected; documentation will be retained and provided to the inspection team at the next on-site inspection. Attested by my signature:	
Laboratory Director's Name:	**Laboratory Director's Signature:**