

10 Steps to Help Prepare for CAP/CLIA Inspections

1 Be familiar with the CAP/CLIA checklist that will be used

Know what inspectors will be looking for and any updated or new items. Create a book of documents to go with each checklist item to have available.

2 Review Policy and Procedure Manuals

Update all policies and procedures to be in accordance with updated or new checklist items, as well as in compliance with any changes that may have occurred in your lab. Ensure that manuals have been reviewed and signed off on.

3 Review all Documentation Forms

Check that the most current version is being used and that they are accurately filled out and up-to-date. Forms can include maintenance logs, solution rotation schedules, temperature logs, and competency and training verification.

4 Check Reagent Labels

Every reagent needs to be labeled with content, storage requirements, expiration date, and date of preparation (if done in the lab).

5 Test Method Verification and Validation

Validation/verification processes should be documented for any new test or test system. This may include new instrumentation, new antibodies or clones, staining protocols, or reagents.

6 Prepare Case and Slide Examples

Prepare cases and corresponding slides for review. These can include H&Es, IHC (both non-predictive and predictive markers), special stains, cytology, frozens, and any other testing utilized in your lab.

7 Corrective Action Procedures

Occasionally there may be tissue carryover, mislabeling, wrong stain done, or other quality issues. Corrective actions are to be put in place for when issues do occur.

8 Coach the Team

All team members need to know where to find SDS sheets, policies and procedures, be able to explain the daily workflow and what their specific tasks are. If they are asked something they are not sure of, it is okay to provide that as an answer with a follow-up that they will find out or direct to someone who can answer.

9 Clean

A clean lab is more welcoming to inspectors. Cleaning will allow you to uncover expired or mislabeled reagents, older versions of policies and procedures, and any excess clutter. Be sure to get rid of anything that should not be in the lab (food and drink, lotions, etc).

10 Relax

Remember that inspectors are peers. Relax and know that you are ready!