CAP checklist

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For grossing and histology laboratories.

Laboratory / location: **Reviewer:** **Date:**

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43 checks | Plain-language guidance | Source references

Select one status per criterion: **Done** - reviewed and met; **Gap** - unresolved issue; **N/A** - not applicable. Notes are fillable.

Work through these 43 checks with your laboratory's current assigned CAP checklists. Each item includes practical guidance and a source from public CAP materials or CLIA requirements.

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CAP checklist

CHECKLIST

01 Checklists and laboratory services

Check, guidance, and source	Status and notes
001. Use the CAP checklist editions assigned for the current review. Guidance: Keep the assigned e-LAB Solutions Suite files together and record their editions and download dates. Give reviewers matching copies so an older version is not used by mistake. CAP: Accreditation Checklists	☐ Done ☐ Gap ☐ N/A
002. Check that the testing menu used by CAP includes all current laboratory services. Guidance: Compare the submitted menu and assigned checklists with the laboratory's service list. Include added work, such as IHC testing or frozen sections, when reviewing whether the menu is up to date. CAP: Accreditation Checklists	☐ Done ☐ Gap ☐ N/A
003. Include all applicable assigned checklists in the review. Guidance: Cover Anatomic Pathology, All Common, Laboratory General, Director Assessment, and any other assigned checklists. Include shared services such as personnel, information systems, safety, and reagent management. CAP: Public checklist scope descriptions, 2025 edition	☐ Done ☐ Gap ☐ N/A
004. Agree who will review each checklist area and any shared responsibilities. Guidance: A simple reviewer list can help prevent missed work. For shared records, such as reagent documentation, agree how histology leadership and quality management will work together. CAP: Public checklist scope descriptions, 2025 edition	☐ Done ☐ Gap ☐ N/A

01 Checklists and laboratory services (continued)

Check, guidance, and source	Status and notes
005. Record why each item marked not applicable does not apply to the laboratory. Guidance: Use the assigned requirement wording and the work actually performed to explain the decision. If testing is sent elsewhere, still consider local specimen preparation, handling, and referral duties. CAP: Accreditation Checklists	☐ Done ☐ Gap ☐ N/A

02 Procedures and records

Check, guidance, and source	Status and notes
006. For the review, match each requirement to its procedure and completed records. Guidance: A simple reference list can help reviewers find both the instructions and records of completed work. For example, connect a special-stain procedure to documented control reactions for the relevant patient slide or batch. 42 CFR 493.1273(a), (f): Histopathology	☐ Done ☐ Gap ☐ N/A
007. Have the current laboratory director approve, sign, and date procedures and revisions before use. Guidance: Compare the approval date with the first use of a new or revised procedure. For a changed processing schedule, check that approval came before the first run using that schedule. 42 CFR 493.1251(d): Procedure manual	☐ Done ☐ Gap ☐ N/A

02 Procedures and records (continued)

Check, guidance, and source	Status and notes
008. Make current approved procedures available where staff perform the work. Guidance: Compare bench shortcuts and printed copies with the approved version, and remove outdated instructions from use. Retain the required copies of superseded procedures with their dates of initial use and discontinuance. 42 CFR 493.1251(a), (e): Procedure manual	☐ Done ☐ Gap ☐ N/A
009. Check that staff follow written procedures, including the response to failed controls. Guidance: As a review step, ask staff to show how they handle an unacceptable stain control, document corrections, and decide whether affected patient work may proceed. Compare that response with the approved instructions and criteria for release. 42 CFR 493.1251(a), (b): Procedure manual	☐ Done ☐ Gap ☐ N/A
010. Check that authorized staff can find equipment maintenance and function-check records. Guidance: Try retrieving a processor service report and subsequent function checks with a supervisor other than the person who filed them. Check that required function-check results met the applicable limits before the equipment returned to patient testing. 42 CFR 493.1254: Maintenance and function checks	☐ Done ☐ Gap ☐ N/A

03 Staff qualifications, duties, and competency

Check, guidance, and source	Status and notes
011. Include permanent, temporary, and relief staff in personnel and duty records. Guidance: Compare the roster with staffing schedules, grossing assignments, and written authorizations. Include agency staff and people who cover another bench only occasionally. 42 CFR 493.1445(e): Laboratory director responsibilities	☐ Done ☐ Gap ☐ N/A
012. Verify each person's qualifications and required license for the assigned work. Guidance: Document the applicable qualification route with education, training, experience, and licensing records before relying on the person's testing work. A job title or credential alone may not establish eligibility for the assigned high-complexity duties. 42 CFR 493.1445(e): Laboratory director responsibilities	☐ Done ☐ Gap ☐ N/A
013. Keep grossing assignments within each person's written duties and required supervision. Guidance: Compare assigned biopsy and resection cases with the individual's authorization and demonstrated abilities. Make clear when a specimen must be referred to a qualified supervisor or another authorized person. 42 CFR 493.1445(e)(12), (15): Laboratory director responsibilities	☐ Done ☐ Gap ☐ N/A
014. Make qualified supervisory help accessible whenever the relevant work is performed. Guidance: Keep evening and weekend contact instructions current so staff know whom to ask about unexpected findings. Technical supervision may be provided onsite, by phone, or electronically as needed; meet any separate onsite supervision requirements that apply. 42 CFR 493.1451(a): Technical supervisor responsibilities	☐ Done ☐ Gap ☐ N/A

03 Staff qualifications, duties, and competency (continued)

Check, guidance, and source	Status and notes
015. Assess and document competency for each person's assigned testing. Guidance: For applicable high-complexity testing, include observation of patient testing; monitoring of result recording and reporting; review of intermediate, QC, proficiency-testing, and maintenance records; observation of instrument maintenance and function checks; testing of known, blind, or proficiency samples; and problem solving. Training attendance alone does not demonstrate competency. 42 CFR 493.1451(b)(8): Technical supervisor responsibilities	☐ Done ☐ Gap ☐ N/A
016. Complete competency assessments on time with qualified assessors, and reassess after method or instrument changes. Guidance: For high-complexity testing, assess at least semiannually in the first year and annually afterward, using an appropriately qualified assessor. After a method or instrument change, reassess performance with the new method or instrument before the person reports patient results. 42 CFR 493.1451(b)(8), (9): Technical supervisor responsibilities	☐ Done ☐ Gap ☐ N/A

04 Specimen tracking and reports

Check, guidance, and source	Status and notes
017. Match each specimen part to its order, labeled container, source, and accession record. Guidance: For a multipart biopsy, check that each container remains linked to the correct patient, anatomic source, and part designation during accessioning. Resolve differences under the laboratory's specimen policies. 42 CFR 493.1232: Specimen identification and integrity	☐ Done ☐ Gap ☐ N/A
018. Match gross descriptions and block keys to submitted cassettes and resulting blocks. Guidance: For example, follow an A1-A4 block key through processing and embedding to the stored blocks. Resolve missing or extra identifiers so each tissue sample remains linked to its described site. 42 CFR 493.1232: Specimen identification and integrity	☐ Done ☐ Gap ☐ N/A
019. Keep every slide, level, and recut linked to the correct block, specimen part, and case. Guidance: To check the process, follow a recut or additional-level request from the block through slide labeling, staining, and delivery. Confirm that the material reaches the intended case for review. 42 CFR 493.1232: Specimen identification and integrity	☐ Done ☐ Gap ☐ N/A
020. Resolve and record specimen discrepancies under the acceptance and rejection policy. Guidance: For a container with a source discrepancy, record the confirmed information, who resolved it, and the decision to accept or reject the specimen. Record any remaining limitations before proceeding under the laboratory's policy. 42 CFR 493.1242: Specimen submission, handling, and referral	☐ Done ☐ Gap ☐ N/A

04 Specimen tracking and reports (continued)

Check, guidance, and source	Status and notes
021. Send reports accurately to intended recipients and promptly notify them of reporting errors. Guidance: Compare a released report with the received version as a practical transmission check. For reporting errors, promptly notify the authorized ordering person and, when applicable, the result user; promptly issue the corrected report and keep both versions. 42 CFR 493.1291(a), (k): Test report	☐ Done ☐ Gap ☐ N/A
022. Keep blocks and slides retrievable for every applicable retention period. Guidance: Federal minimums include 10 years for histopathology slides and 2 years for pathology blocks, measured from examination. Check archive retrieval and planned disposal dates against any applicable longer CAP, state, or institutional periods. 42 CFR 493.1105: Retention requirements	☐ Done ☐ Gap ☐ N/A

05 Equipment, reagents, and slide quality

Check, guidance, and source	Status and notes
023. Complete and record equipment maintenance on the required schedule. Guidance: For unmodified equipment, follow the manufacturer's maintenance instructions at least as often as specified. Use documented laboratory protocols when equipment is developed or modified locally, or when the manufacturer provides no protocol. 42 CFR 493.1254: Maintenance and function checks	☐ Done ☐ Gap ☐ N/A
024. Check equipment performance before returning it to patient testing. Guidance: Document function checks that meet the applicable manufacturer's or laboratory's limits before resuming patient testing. Keep those results with the repair record and the decision to return the equipment to use. 42 CFR 493.1254: Maintenance and function checks	☐ Done ☐ Gap ☐ N/A
025. Document the response when storage or operating conditions fall outside limits. Guidance: Record the duration, affected specimens or reagents, corrective action, and decision about using or discarding affected material, following applicable storage or stability instructions. Restoring the temperature alone does not establish that the material remains suitable. 42 CFR 493.1282(b)(3): Corrective actions	☐ Done ☐ Gap ☐ N/A

05 Equipment, reagents, and slide quality (continued)

Check, guidance, and source	Status and notes
026. Label, date, and store reagents correctly, and use only suitable materials. Guidance: Include identity, strength or concentration when significant, preparation and expiration dates, storage requirements, and other information needed for correct use. Do not use expired, deteriorated, or substandard materials, or mix kit lots unless the manufacturer permits it. 42 CFR 493.1252(c)-(e): Reagents, materials, and supplies	☐ Done ☐ Gap ☐ N/A
027. Run and document the required controls for special stains and IHC. Guidance: Check IHC for positive and negative reactivity each time of use; stain a control slide with known reactivity with each patient slide or group for other special stains. Record control results so they can be linked to the patient slide or batch. 42 CFR 493.1273(a), (f): Histopathology	☐ Done ☐ Gap ☐ N/A
028. Investigate recurring slide defects and document whether corrective actions worked. Guidance: Use the laboratory's slide-acceptance criteria to review defects such as folds, chatter, or poor staining. Recut logs and later slide checks can help show whether a change improved quality. 42 CFR 493.1289: Analytic systems quality assessment	☐ Done ☐ Gap ☐ N/A

06 IHC validation and clinical use

Check, guidance, and source	Status and notes
029. Keep the required validation or verification records for each active IHC assay. Guidance: Match each active assay to its applicable performance study, completion date, and first patient-report date. Complete required validation or verification before reporting patient results. 42 CFR 493.1253: Establishment and verification of performance specifications	☐ Done ☐ Gap ☐ N/A
030. Confirm that IHC studies support the specimen preparations and fixatives used. Guidance: Compare clinical specimens with those in the validation study, including alternative fixatives and cytology preparations. Use CAP's recommendations to plan any additional studies, and check the current assigned checklist for accreditation requirements. CAP: Principles of Analytic Validation of Immunohistochemical Assays	☐ Done ☐ Gap ☐ N/A
031. Document how IHC study results support clinical use. Guidance: Keep the study plan, acceptance criteria, results, and explanations of discrepancies together. Record the final assessment showing whether the assay met the laboratory's criteria before clinical use. 42 CFR 493.1253(b), (c): Establishment and verification of performance specifications	☐ Done ☐ Gap ☐ N/A
032. Match each predictive IHC assay and scoring system to its supporting studies. Guidance: Review the intended tumor site, indication, and scoring method together. CAP recommends separate validation or verification for assays with distinct scoring systems; apply the current assigned checklist's requirements. CAP: Principles of Analytic Validation of Immunohistochemical Assays	☐ Done ☐ Gap ☐ N/A

06 IHC validation and clinical use (continued)

Check, guidance, and source	Status and notes
033. Assess and approve IHC assay changes before using them for patient testing. Guidance: Document the performance checks and validation or revalidation decision for changes to the clone, retrieval, detection system, or platform. CAP's guideline recommends full revalidation for a clone change; check the current assigned checklist and obtain the laboratory director's approval of revised procedures before use. CAP: IHC validation guideline update, 2024 summary of recommendations	☐ Done ☐ Gap ☐ N/A

07 Quality review and problem follow-up

Check, guidance, and source	Status and notes
034. Define the quality measures your laboratory will review. Guidance: Choose useful measures, consistent definitions, review periods, data sources, and responsible reviewers. As a local tracking method, you can count technical recuts separately from diagnostically requested levels and use consistent workload totals for comparisons. 42 CFR 493.1289: Analytic systems quality assessment	☐ Done ☐ Gap ☐ N/A
035. Record quality concerns, follow-up actions, and staff discussions. Guidance: Review problems and trends with receiving, grossing, and other affected staff. Assign follow-up locally and document the actions taken so staff know what changed. 42 CFR 493.1249: Preanalytic systems quality assessment	☐ Done ☐ Gap ☐ N/A

07 Quality review and problem follow-up (continued)

Check, guidance, and source	Status and notes
036. Evaluate patient results affected by failed controls or calibration. Guidance: Review every result from the unacceptable run and since the last acceptable run. Document the assessment and take any corrective action needed to ensure accurate and reliable reporting. 42 CFR 493.1282(b)(2): Corrective actions	☐ Done ☐ Gap ☐ N/A
037. Correct the cause of the problem and document what changed. Guidance: Connect the investigation to changes in the work process, procedures, or system settings. Choose actions that address the identified cause and help prevent the problem from happening again. 42 CFR 493.1249: Preanalytic systems quality assessment	☐ Done ☐ Gap ☐ N/A
038. Document whether corrective actions resolved the problem. Guidance: Use later observations or quality results to check the effect of the change. Record the outcome and take further action if the problem continues. 42 CFR 493.1289(b): Analytic systems quality assessment	☐ Done ☐ Gap ☐ N/A

CAP checklist

CHECKLIST

08 Self-inspection and follow-up

Check, guidance, and source	Status and notes
039. Complete the required self-inspection and follow up on unresolved findings. Guidance: Use CAP materials in the year between on-site inspections. A local follow-up list can assign each unresolved item to a person and due date, and flag overdue work. CAP: Inspection Tools and Training	☐ Done ☐ Gap ☐ N/A
040. Check that staff follow the current written procedures. Guidance: As a local review method, observe a bench process and compare it with the procedure and related records. Record any gaps in practice or access to records. 42 CFR 493.1251(a): Procedure manual	☐ Done ☐ Gap ☐ N/A
041. Keep CAP contact details and inspection arrangements current. Guidance: Check the laboratory profile, responsible contacts, and notification telephone numbers. Follow the notification process for your program and location, including any first-inspection exceptions. CAP: Inspection Tools and Training	☐ Done ☐ Gap ☐ N/A
042. Arrange access to records and agree on any advance document review. Guidance: Consider naming primary and backup contacts to retrieve records. Advance review is optional; the laboratory director and inspection team leader must agree on its dates. CAP: Inspection Tools and Training	☐ Done ☐ Gap ☐ N/A

08 Self-inspection and follow-up (continued)

Check, guidance, and source	Status and notes
043. Submit deficiency responses with supporting records by the deadline. Guidance: CAP specifies a response within 30 days after inspection. Assign responsibility locally, follow the response instructions, and retain corrective records, requested attachments, and submission confirmation. CAP: Inspection Tools and Training	☐ Done ☐ Gap ☐ N/A