CLIA checklist for lab managers

CONTENTS

For grossing and histology laboratories.

Laboratory / location: _____ **Name:** _____ **Date:** _____

Table of contents

Topic	Part 1: Checklist	Part 2: Audits
01 Laboratory services and paperwork	2	40
02 Staff qualifications	6	42
03 Grossing	9	44
04 Competency checks	12	45
05 Specimens and labeling	16	47
06 Procedures	20	49
07 Method checks	22	51
08 Stains and controls	25	53
09 Equipment and reagents	27	54
10 Accuracy checks	30	55
11 Reports and retention	33	57
12 Problems and follow-up	38	59

Part 1 - Action checklist. Put each task in place. Mark Done or N/A and use the ruled space for notes.

Part 2 - Audit worksheets. Use the sample checks separately to see whether those arrangements are working.

Click a contents page number, a related task number, or a source citation to open it. All writing lines are fillable.

PART 1 / ACTION CHECKLIST

01 Laboratory services and paperwork

Task	Rule and exact wording	Status and notes
001. Ensure the examination menu matches the CMS-116 application and its updates. List the current examinations and methods, including applicable histopathology and IHC services. Clearly identify work performed at this laboratory and work sent to another laboratory.	42 CFR §493.43(c)(3) “the examinations and other test procedures performed by the laboratory” 42 CFR §493.55(c)(3)	☐ Done ☐ N/A
002. Maintain the appropriate CLIA certificate for the complexity of testing performed. Diagnostic gross examination requires coverage for high-complexity testing. Obtain the appropriate authorization before providing that service; a Certificate of Waiver does not cover it.	42 CFR §493.25(a) “A laboratory must obtain a certificate for tests of high complexity”	☐ Done ☐ N/A
003. Ensure every testing location has the required application and certificate coverage. Submit a separate application for a new testing site unless a specific location exception applies. For example, common ownership alone does not place an off-campus grossing suite under a hospital’s certificate.	42 CFR §493.43(a)-(b) “all laboratories performing nonwaived testing must file a separate application for each laboratory location.” 42 CFR §493.55(a)(2)-(b)	☐ Done ☐ N/A

01 Laboratory services and paperwork (continued)

Task	Rule and exact wording	Status and notes
004. Maintain all applicable state and local laboratory approvals. Keep required licenses current for the operating name, address and authorized services. Assign responsibility for renewals and required changes; requirements depend on the laboratory's location and services.	42 CFR §493.1101(c) "applicable Federal, State, and local laboratory requirements."	☐ Done ☐ N/A
005. Define specimen-preparation services separately from diagnostic examinations. List embedding, cutting, staining and coverslipping without diagnostic interpretation as preparation. Describe diagnostic grossing and microscopic interpretation separately so CLIA scope reflects the actual work.	CMS guidance: Appendix C, §493.1242(a)(6), PDF page 139 "specimen processing does not constitute a CLIA test." 42 CFR §493.1242(a)(6)	☐ Done ☐ N/A
006. For a Certificate of Compliance, notify HHS or its designee of listed administrative changes within 30 days. Send notice of ownership, name, location, director or high-complexity technical-supervisor changes. Retain the change's effective date and the dated notice.	42 CFR §493.51(a) "Notify HHS or its designee within 30 days of any change"	☐ Done ☐ N/A

01 Laboratory services and paperwork (continued)

Task	Rule and exact wording	Status and notes
007. For a Certificate of Compliance, notify HHS of a new specialty or subspecialty within six months of its first examination. This applies when the specialty or subspecialty is absent from the certificate. Record the first examination date and retain the notice; adding a stain does not necessarily add a specialty.	42 CFR §493.51(b) “Notify HHS no later than 6 months after performing any test or examination”	☐ Done ☐ N/A
008. For a Certificate of Compliance, notify HHS of applicable test deletions or method changes within six months. Document the change and send the required notice for testing within a covered specialty or subspecialty. This notification period does not replace requirements for using a changed method.	42 CFR §493.51(c) “Notify HHS no later than 6 months after any deletions or changes in test methodologies”	☐ Done ☐ N/A
009. For a Certificate of Accreditation, notify both HHS and the accreditor of listed administrative changes within 30 days. Send both recipients notice of ownership, name, location or director changes. Retain dated notices and follow any earlier applicable accreditor requirement.	42 CFR §493.63(a) “Notify HHS and the approved accreditation program within 30 days of any changes”	☐ Done ☐ N/A

01 Laboratory services and paperwork (continued)

Task	Rule and exact wording	Status and notes
010. For a Certificate of Accreditation, notify the accreditor of a new specialty or subspecialty within six months of its first examination. When adding a specialty absent from the laboratory's accreditation, document the first examination date and send the required notice. Follow any earlier applicable accreditor requirement.	42 CFR §493.63(b) "Notify the approved accreditation program no later than 6 months"	☐ Done ☐ N/A
011. For a Certificate of Accreditation, notify the accreditor of applicable test deletions or method changes within six months. Send the required notice for changes within covered specialties or subspecialties. Retain the change date and notice, and meet any shorter accreditor deadline.	42 CFR §493.63(c) "Notify the accreditation program no later than 6 months"	☐ Done ☐ N/A

02 Staff qualifications

Task	Rule and exact wording	Status and notes
012. Ensure the director assigns each person's authorized duties and supervision requirements in writing. Specify permitted examinations, required supervision and any approval needed before results are reported. Include travelers, managers who perform testing, and qualified coverage during absences.	42 CFR §493.1445(e)(15) "which examinations and procedures each individual is authorized to perform"	☐ Done ☐ N/A
013. Document the applicable high-complexity qualification route for each person performing delegated grossing. Identify the relevant §493.1489 paragraph and retain its supporting education and training records. A PA(ASCP) card alone does not document the degree route. A grandfather route requires the applicable qualifying-service and continuity records.	42 CFR §493.1489(b) "Meet one of the following requirements:" 42 CFR §493.1461(e) CMS Appendix C, grossing guidance for §493.1461(e), PDF pages 346-347	☐ Done ☐ N/A
014. Ensure personnel hold current state licenses for assigned work wherever licensing is required. Keep the applicable license category and scope aligned with the assignment. For example, provide cytology screening through a properly licensed cytotechnologist where the state requires that license; national certification is a separate credential.	42 CFR §493.1489(a) "Possess a current license issued by the State in which the laboratory is located, if such licensing is required;" 42 CFR §493.1483(a) - cytotechnologists	☐ Done ☐ N/A

02 Staff qualifications (continued)

Task	Rule and exact wording	Status and notes
015. Provide qualified technical supervision for each pathology specialty performed. Document the applicable medical license, board certification and specialty route. General histopathology, dermatopathology, ophthalmic pathology and oral pathology have distinct provisions; any resident delegation must meet the relevant rule.	42 CFR §493.1449(b), (f), (g) “provide technical supervision for each of the specialties and subspecialties of service” 42 CFR §493.1461(e)	☐ Done ☐ N/A
016. Ensure the laboratory director meets and documents an applicable director qualification route. For the physician-pathologist route in §493.1443(b)(1), retain the state medical license and anatomic or clinical pathology board certification. Other routes have different experience, continuing-education or continuity requirements. Document any additional technical-supervisor role separately.	42 CFR §493.1443(a)-(b) “Be certified in anatomic or clinical pathology, or both”	☐ Done ☐ N/A
017. Ensure the high-complexity laboratory director completes the required onsite visits. Complete visits at least once every six months, with at least four months between the minimum two visits. Record actual attendance dates; for example, January 15 and July 15 fit those intervals.	42 CFR §493.1445(c)(1) “Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits.”	☐ Done ☐ N/A

02 Staff qualifications (continued)

Task	Rule and exact wording	Status and notes
018. Document the director's activities during each onsite visit. Record the visit date and work within the director's responsibilities, such as resolving an IHC control problem, updating staff authorization or discussing quality-assessment findings. A sign-in entry alone does not describe that work.	42 CFR §493.1445(c)(2) "including evidence of performing activities that are part of the laboratory director responsibilities."	☐ Done ☐ N/A

03 Grossing

Task	Rule and exact wording	Status and notes
019. Ensure each person performing delegated grossing has written authorization for that work. The technical supervisor's delegation should identify the qualified person and permitted work. Authorize the relevant specimen types and tasks before assigning them.	CMS guidance: Appendix C, §493.1461(e), PDF pages 346-347 "The delegation should be in writing." 42 CFR §493.1461(e)	☐ Done ☐ N/A
020. Ensure case block keys match the cassette contents, gross descriptions and authorized specimen protocols. A block key identifies the tissue placed in each cassette. For example, entries such as 'A1: superior tip' and 'A2: central section' should describe the actual submitted sections and remain consistent with recorded orientation and ink colors.	CMS guidance: Appendix C, §493.1461(e), PDF page 346 "mechanical procedures for which a specific written protocol has been developed." 42 CFR §493.1461(e)	☐ Done ☐ N/A
021. Ensure the test record identifies the person who performed the gross examination. Record the performer's name or a traceable individual identifier, including traveling staff. A shared 'gross room' login is insufficient by itself. The identifier may be elsewhere in the test record rather than on the final report.	42 CFR §493.1283(a)(4) "including the identity of the personnel who performed the test(s)." 42 CFR §493.1461(e) CMS Appendix C, grossing identity guidance for §493.1461(e), PDF page 347	☐ Done ☐ N/A

03 Grossing (continued)

Task	Rule and exact wording	Status and notes
022. Ensure the gross examination and its date are documented in the test record. Create a dated entry for the gross examination itself. Preserve that testing date when correcting or transferring the record; collection and final-report dates do not replace it.	42 CFR §493.1283(a)(4) "The records and dates of all specimen testing"	☐ Done ☐ N/A
023. Arrange technical-supervisor review of gross examinations performed during the supervisor's absence. CMS guidance recommends this review within 24 hours. Document the examination and review times. Apply any additional supervision requirement tied to the employee's qualification route; the guidance is not a universal final-report deadline.	CMS guidance: Appendix C, §493.1461(e), PDF page 347 "should be reviewed within 24 hours by the technical supervisor." 42 CFR §493.1461(e) 42 CFR §493.1495(b)(7), (c)	☐ Done ☐ N/A
024. Ensure staff obtain appropriate help for specimens or problems outside their authorized work. Provide a consultation procedure naming the responsible supervisor or director. Staff should follow the required hold, notification and documentation steps. Grossing authorization alone does not authorize diagnostic microscopic interpretation.	42 CFR §493.1495(b)(5) "either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;" 42 CFR §493.1489(b)(7) - histopathology qualifications	☐ Done ☐ N/A

03 Grossing (continued)

Task	Rule and exact wording	Status and notes
025. Ensure the responsible qualified technical supervisor signs the examination report. The technical supervisor retains responsibility for the diagnosis and report. The grossing employee's entry identifies their portion of the work and does not replace the examination-report signature.	CMS guidance: Appendix C, §493.1461(e), PDF page 347 "must sign the examination report." 42 CFR §493.1461(e)	☐ Done ☐ N/A

04 Competency checks

Task	Rule and exact wording	Status and notes
026. Ensure each person's competency plan covers their actual testing duties. Apply the six testing-assessment elements to applicable testing work, including delegated diagnostic grossing. Do not automatically impose that same federal testing assessment on preparation-only duties; provide appropriate training and monitoring for all assigned work.	CMS guidance: Appendix C, §493.1242(a)(6), PDF page 139 "specimen processing does not constitute a CLIA test." 42 CFR §493.1451(b)(8) 42 CFR §493.1445(e)(13) 42 CFR §493.1242(a)(6)	☐ Done ☐ N/A
027. Assign competency assessments to personnel who meet the applicable assessor qualifications. For high-complexity testing, the technical supervisor may delegate assessment in writing to an appropriately qualified general supervisor. Apply histopathology's specialty provisions and any additional accreditor requirements; a manager's title alone does not establish eligibility.	CMS guidance: CMS - Assessing Personnel Competency, PDF page 5 "a TS may delegate the responsibility, in writing, to a GS if they meet the regulatory qualification requirements." 42 CFR §493.1463(b)(4) 42 CFR §493.1461(e)	☐ Done ☐ N/A
028. Complete and document high-complexity testing competency assessments at the required intervals. Assess personnel at least semiannually during their first year of patient testing and at least annually afterward. Schedule from the actual testing start date. Training attendance and annual employment evaluations do not substitute for the six assessment elements.	42 CFR §493.1451(b)(9) "at least semiannually during the first year the individual tests patient specimens."	☐ Done ☐ N/A

04 Competency checks (continued)

Task	Rule and exact wording	Status and notes
029. Complete and document direct observation of routine test performance during competency assessment. Record the procedure observed, date, assessor and outcome. For someone who performs grossing, include relevant specimen identification, handling, examination and documentation tasks.	42 CFR §493.1451(b)(8)(i) “Direct observations of routine patient test performance”	☐ Done ☐ N/A
030. Document assessment of the person’s recording and reporting of test results. Assess the employee’s actual reporting task, including correct measurements, units and specimen parts. Record the assessed work, outcome and response to errors; a dictated measurement of ‘2.3 cm’ should remain accurate in the saved description.	42 CFR §493.1451(b)(8)(ii) “Monitoring the recording and reporting of test results;”	☐ Done ☐ N/A
031. Include the applicable testing-record assessment in each person’s competency documentation. Document assessment of the person’s worksheets or intermediate results, quality-control records, proficiency-testing results and preventive-maintenance records, as applicable to their work. Identify the records assessed, outcome and any needed follow-up.	42 CFR §493.1451(b)(8)(iii) “Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;”	☐ Done ☐ N/A

04 Competency checks (continued)

Task	Rule and exact wording	Status and notes
032. Complete and document direct observation of applicable maintenance and function checks. For example, when balance checks are part of testing duties, document the employee's use of a check weight, result and response to an unacceptable reading. Assess actual performance rather than documenting only that a log was read.	42 CFR §493.1451(b)(8)(iv) "Direct observation of performance of instrument maintenance and function checks;"	☐ Done ☐ N/A
033. Assess and document test performance using an appropriate test challenge. Use a suitable previously analyzed specimen, internal blind sample or external proficiency sample. Record expected and observed results for the method assessed. A single challenge does not automatically cover unrelated methods or all six competency elements.	42 CFR §493.1451(b)(8)(v) "testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples;"	☐ Done ☐ N/A
034. Assess and document the person's ability to resolve testing problems. Use a suitable scenario or documented event, such as a jar and requisition with conflicting laterality. Record whether the person applies the required hold, documentation and consultation steps; a real discrepancy must not be resolved by guessing.	42 CFR §493.1451(b)(8)(vi) "Assessment of problem solving skills;"	☐ Done ☐ N/A

04 Competency checks (continued)

Task	Rule and exact wording	Status and notes
035. Reevaluate performance with a changed method or instrument before patient results are reported using it. Document competency with the new method or instrument, including relevant operation, result entry and checks. Complete this assessment before the employee reports patient results using the change.	42 CFR §493.1451(b)(9) “prior to reporting patient test results, the individual's performance must be reevaluated”	☐ Done ☐ N/A
036. Address identified skill gaps with appropriate retraining and documented follow-up. Document the original problem, instruction provided and subsequent demonstration of the corrected skill. For a specimen-part entry error, retain the retraining and corrected-performance record rather than merely relabeling the original assessment as complete.	42 CFR §493.1445(e)(13) “identify needs for remedial training or continuing education to improve skills;”	☐ Done ☐ N/A

05 Specimens and labeling

Task	Rule and exact wording	Status and notes
037. Obtain written or electronic test requests from authorized persons. Record the ordering person's identity with the request. For an oral request, solicit written or electronic authorization within 30 days and retain the authorization or documentation of efforts to obtain it.	42 CFR 493.1241(a) “a written or electronic request for patient testing from an authorized person.” 42 CFR 493.1241(b)	☐ Done ☐ N/A
038. Record patient identifiers accurately on specimen labels and in the accession record. The request, container, and accession record must identify the same patient. Carry the supplied patient identifier and sex and age or date of birth accurately into the laboratory information system (LIS). Resolve discrepancies through the laboratory's procedure.	42 CFR 493.1241(e) “the laboratory must ensure the information is transcribed or entered accurately.” 42 CFR 493.1241(c)(2) 42 CFR 493.1241(c)(3) 42 CFR 493.1242(a)(3)	☐ Done ☐ N/A
039. Record each requested examination and applicable specimen source accurately in the accession record. For a skin excision with a separately submitted margin, record both parts, their source descriptions, and their requested examinations without exchanging the part assignments.	42 CFR 493.1241(c)(4) “The test(s) to be performed.” 42 CFR 493.1241(c)(5) 42 CFR 493.1241(e)	☐ Done ☐ N/A

05 Specimens and labeling (continued)

Task	Rule and exact wording	Status and notes
040. Record collection details and relevant clinical information accurately in the case record. The request process must solicit the collection date, time when appropriate, and information needed for the specific test. Transcribe supplied information accurately and handle missing or conflicting information through the laboratory's procedure.	42 CFR 493.1241(c)(6) “The date and, if appropriate, time of specimen collection.” 42 CFR 493.1241(c)(8) 42 CFR 493.1241(e)	☐ Done ☐ N/A
041. Maintain patient and specimen-part identity through testing and the final report. Use identifiers that consistently connect the container, gross description, block key, cassettes, blocks, slides, and report. For case S26-01452, A1 remains the skin excision and B1 remains the separate margin throughout the case.	42 CFR 493.1232 “from the time of collection or receipt of the specimen through completion of testing and reporting of results.”	☐ Done ☐ N/A
042. Preserve source-block identity on every recut, level, and replacement label. A deeper level cut from B1 must identify B1 on the new slide and in the case record. Handle and document label corrections through the laboratory's procedure so the original specimen identity remains clear.	42 CFR 493.1232 “ensure positive identification and optimum integrity of a patient's specimen”	☐ Done ☐ N/A

05 Specimens and labeling (continued)

Task	Rule and exact wording	Status and notes
043. Record the date and time each specimen reaches the laboratory. The accession record should contain the laboratory arrival timestamp. Keep it distinct from the specimen collection time and the time of any later test order.	42 CFR 493.1242(b) “The laboratory must document the date and time it receives a specimen.”	☐ Done ☐ N/A
044. Document the condition and disposition of specimens that fail acceptance criteria. For a leaking or mislabeled jar, record the condition and what happened to the specimen. Include the notification, resolution, and rejection or authorized exception required by the laboratory's written acceptance procedure.	42 CFR 493.1283(a)(3) “The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.” 42 CFR 493.1242(a)(7)	☐ Done ☐ N/A
045. Follow written collection, preservation, transport, and processing instructions for each intended examination. Use the fixative, transport conditions, and any fixation timing required for that specimen and test. Make the necessary preservation information available to staff; one assumed fixation interval does not cover every examination.	42 CFR 493.1242(a)(4) “Specimen storage and preservation.” 42 CFR 493.1242(a)(2) 42 CFR 493.1242(a)(5) 42 CFR 493.1242(a)(6)	☐ Done ☐ N/A

05 Specimens and labeling (continued)

Task	Rule and exact wording	Status and notes
046. Refer specimens only to CLIA-certified laboratories or laboratories meeting CMS-recognized equivalent requirements. Use the receiving testing laboratory's actual identity and certification status to select an eligible referral destination. The courier's name or a trading name alone does not establish the testing laboratory's certification.	42 CFR 493.1242(c) “only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.”	☐ Done ☐ N/A
047. Prepare send-out specimens and paperwork according to the written referral procedure. Use the receiving laboratory's submission instructions for patient and specimen identifiers, requested examination, container, preservation, and packaging. Keep the tracking or receipt information required by your referral procedure.	42 CFR 493.1242(a)(8) “Specimen referral.” 42 CFR 493.1242(d)	☐ Done ☐ N/A
048. Provide referring clients with current written specimen submission instructions. For clinics sending biopsies, make the applicable labeling, preservation, transport, and rejection instructions available. Include the other patient-preparation and specimen-handling information that applies to the examinations offered.	42 CFR 493.1242(d) “written instructions must be available to the laboratory's clients”	☐ Done ☐ N/A

06 Procedures

Task	Rule and exact wording	Status and notes
049. Make current written procedures available to the staff performing the work. Provide access that staff can use at the work location. Keep printed and electronic working copies current so personnel can follow the approved instructions.	42 CFR 493.1251(a) “must be available to, and followed by, laboratory personnel.”	☐ Done ☐ N/A
050. Perform bench procedures according to the laboratory's current written instructions. Write usable steps for the stain sequence, reagent preparation, instrument program, acceptance decisions, and result entry. Keep the instructions aligned with the procedure staff are authorized to perform.	42 CFR 493.1251(b)(3) “Step-by-step performance of the procedure, including test calculations and interpretation of results.” 42 CFR 493.1251(a) 42 CFR 493.1251(b)(4) 42 CFR 493.1251(b)(13)	☐ Done ☐ N/A
051. Supply laboratory instructions for applicable procedure requirements missing from the manufacturer's material. Add local instructions such as specimen rejection criteria when the manufacturer's material omits them. Provide the laboratory's reporting and downtime procedures. Textbooks may supplement the written procedure but do not replace it.	42 CFR 493.1251(c) “not provided by the manufacturer must be provided by the laboratory.” 42 CFR 493.1251(a) 42 CFR 493.1251(b)	☐ Done ☐ N/A

06 Procedures (continued)

Task	Rule and exact wording	Status and notes
052. Obtain the current laboratory director's signed, dated approval before using any new or changed procedure. A revised stain procedure scheduled for first use on September 10 needs approval before that use. Keep the approval with the procedure's controlled record.	42 CFR 493.1251(d) “approved, signed, and dated by the current laboratory director before use.”	☐ Done ☐ N/A
053. Write corrective-action instructions for unacceptable calibration or control results. State what work or reporting is held, how the problem is addressed, and how acceptable performance is established before affected patient results are reported.	42 CFR 493.1251(b)(8) “Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.”	☐ Done ☐ N/A
054. Provide written instructions for an inoperable test system. For a stainer outage, define how staff hold work, use an approved alternative or referral when appropriate, and handle delayed reporting. Make the instructions accessible during the outage.	42 CFR 493.1251(b)(14) “Description of the course of action to take if a test system becomes inoperable.” 42 CFR 493.1251(b)(13)	☐ Done ☐ N/A
055. Retain each discontinued procedure for at least two years after discontinuance. Include its initial-use and discontinuance dates. A procedure discontinued September 10, 2026 remains available through at least September 10, 2028 under this rule; apply longer requirements when applicable.	42 CFR 493.1105(a)(2) “Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued.”	☐ Done ☐ N/A

07 Method checks

Task	Rule and exact wording	Status and notes
056. Determine and document whether each test system requires verification or establishment of performance specifications. Use verification for an applicable unmodified FDA-cleared or approved system; establish specifications for modified and other systems covered by paragraph (b)(2). When the pre-April 24, 2003 exception applies, document the actual system's qualifying use.	42 CFR 493.1253(b)(1) “Each laboratory that introduces an unmodified, FDA-cleared or approved test system” 42 CFR 493.1253(a) 42 CFR 493.1253(b)(2)	☐ Done ☐ N/A
057. Verify local performance of each applicable unmodified FDA-cleared or approved test system. Document the laboratory's accuracy, precision, and reportable-range results against the manufacturer's specifications. Verify that the manufacturer's reference intervals suit the laboratory's patient population. The record must show the laboratory's performance.	42 CFR 493.1253(b)(1)(i) “Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer” 42 CFR 493.1253(b)(1)(ii) 42 CFR 493.1253(c)	☐ Done ☐ N/A
058. Establish applicable performance specifications for modified and other test systems covered by §493.1253(b)(2). Document accuracy, precision, analytical sensitivity, specificity and interferences, reportable range, reference intervals, and other needed characteristics as applicable. Use a study appropriate to the qualitative or quantitative method, with results and a documented decision on whether the defined criteria were met.	42 CFR 493.1253(b)(2) “establish for each test system the performance specifications for the following performance characteristics, as applicable:” 42 CFR 493.1253(c)	☐ Done ☐ N/A

07 Method checks (continued)

Task	Rule and exact wording	Status and notes
059. Complete and document required performance work before reporting patient results. The study record should show the work performed, results, acceptance decision, and completion before the first patient report. Select study material appropriate to the method; this section does not prescribe one universal IHC case count.	42 CFR 493.1253(b)(1) “before reporting patient test results” 42 CFR 493.1253(b)(2) 42 CFR 493.1253(c)	☐ Done ☐ N/A
060. Have the technical supervisor evaluate method changes and establish the performance evidence needed for the configuration in use. Address changes to retrieval, reagents, detection, instruments, or specimen preparation. Complete the supporting performance work needed for the changed method and keep the current procedure and controls aligned with it.	42 CFR 493.1451(b)(2) “Verification of the test procedures performed and establishment of the laboratory's test performance characteristics” 42 CFR 493.1451(b)(1) 42 CFR 493.1451(b)(4) 42 CFR 493.1253(b)	☐ Done ☐ N/A
061. Set calibration and control procedures from the method's verified or established performance specifications. For a new IHC method, use the study's supported control acceptance criteria in the written procedure. Define calibration procedures where they apply to the test system.	42 CFR 493.1253(b)(3) “based upon the performance specifications verified or established”	☐ Done ☐ N/A

07 Method checks (continued)

Task	Rule and exact wording	Status and notes
062. Reevaluate each testing person's performance after method or instrument changes, before that person reports patient results using the change. Provide needed training and document the person's performance with the new methodology or instrument. The reevaluation must cover the changed work rather than relying only on the previous method's assessment.	42 CFR 493.1451(b)(9) “prior to reporting patient test results, the individual's performance must be reevaluated” 42 CFR 493.1451(b)(7)	☐ Done ☐ N/A
063. Evaluate and document the relationship between results twice a year when the same test uses different methods, instruments, or sites. Define how results from the different systems relate and document the comparison activities. For a stain performed on two instruments, record both comparison rounds and the evaluation of differences. This requirement applies when the described multiple-system situation exists.	42 CFR 493.1281(a) “twice a year evaluates and defines the relationship between test results” 42 CFR 493.1281(c)	☐ Done ☐ N/A

08 Stains and controls

Task	Rule and exact wording	Status and notes
064. Check IHC and fluorescent stains for positive and negative reactivity each time of use. Document the controls and observed reactions for that use under an identifiable run or equivalent record. Apply the laboratory's acceptance criteria to the reactions.	42 CFR 493.1273(a) “fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use.” 42 CFR 493.1273(f)	☐ Done ☐ N/A
065. Stain a known-reactivity control with each patient slide or group for other differential or special stains. For a fungal-stain group, include the appropriate control in that staining group and identify the control in the group record.	42 CFR 493.1273(a) “a control slide of known reactivity must be stained with each patient slide or group of patient slides.”	☐ Done ☐ N/A
066. Document the reaction of each special-stain control. Record the observed reaction and whether it meets the laboratory's acceptance criteria. The record needs the reaction, not merely confirmation that a control slide was present.	42 CFR 493.1273(a) “Reaction(s) of the control slide with each special stain must be documented.”	☐ Done ☐ N/A
067. Ensure control results meet laboratory and applicable manufacturer acceptance criteria before reporting patient results. When controls are unacceptable, hold the affected patient results while the problem is addressed. Establish acceptable control performance before reporting the supported patient results.	42 CFR 493.1256(f) “criteria for acceptability before reporting patient test results.”	☐ Done ☐ N/A

08 Stains and controls (continued)

Task	Rule and exact wording	Status and notes
068. Document every control procedure, including failed runs and repeats. If run 041 fails and run 042 repeats the work, keep both control results intact and identifiable. The successful repeat does not erase the failed result.	42 CFR 493.1256(g) “The laboratory must document all control procedures performed.”	☐ Done ☐ N/A
069. Check and document H&E stain response each day it is used. Record the daily check of intended response and expected staining characteristics. Apply the laboratory's criteria for features such as nuclear detail and stain balance; this daily H&E statement is CMS interpretive guidance.	CMS guidance: CMS Appendix C, interpretive guidance for 42 CFR 493.1256(e)(2), PDF page 194 “must check routine stain Hematoxylin and Eosin each day for intended response” 42 CFR 493.1256(e)(2)	☐ Done ☐ N/A
070. Identify and address inadequately prepared slides under the laboratory's written procedure. Provide instructions for problems such as poor nuclear staining, folds, and suspected contamination. Record the recut, restain, communication, or other response required by the laboratory's procedure.	42 CFR 493.1251(b)(2) “Microscopic examination, including the detection of inadequately prepared slides.”	☐ Done ☐ N/A

09 Equipment and reagents

Task	Rule and exact wording	Status and notes
071. Perform and document required equipment maintenance. Set tasks and intervals from the manufacturer's instructions, or establish laboratory protocols where required for modified equipment or missing instructions. For processor TP-1, record the task, instrument ID, completion date, and service details.	42 CFR 493.1254(a)(1) “Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.” 42 CFR 493.1254(b)(1)	☐ Done ☐ N/A
072. Complete required function checks within acceptable limits before patient testing. Record actual results against the manufacturer's or laboratory's established limits. If a check is outside those limits, resolve it before testing patients. Complete any required return-to-use checks after service.	42 CFR 493.1254(a)(2) “Function checks must be within the manufacturer's established limits before patient testing is conducted.” 42 CFR 493.1254(b)(2)	☐ Done ☐ N/A
073. Define, monitor, and document required storage and operating conditions. Set conditions consistent with applicable manufacturer instructions. For a reagent refrigerator, document its acceptable temperature range and monitoring results. Address water quality, humidity, and protection from electrical interruptions where applicable.	42 CFR 493.1252(b) “These conditions must be monitored and documented”	☐ Done ☐ N/A

09 Equipment and reagents (continued)

Task	Rule and exact wording	Status and notes
074. Resolve and document storage conditions outside approved limits. After a refrigerator excursion, assess the affected reagents or specimens, decide their disposition, restore acceptable storage, and record the corrective action. Include when acceptable conditions resumed.	42 CFR 493.1282(b) "The laboratory must document all corrective actions taken" 42 CFR 493.1282(b)(3)	☐ Done ☐ N/A
075. Label reagents and prepared solutions with the required use information. For a prepared stain, include identity, significant strength or concentration, storage requirements, preparation date, expiration date, and other information needed for proper use. Use clear labels that staff can interpret.	42 CFR 493.1252(c) "Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled" 42 CFR 493.1252(c)(1) 42 CFR 493.1252(c)(2) 42 CFR 493.1252(c)(3) 42 CFR 493.1252(c)(4)	☐ Done ☐ N/A
076. Keep expired, deteriorated, and substandard reagents out of use. Remove an expired stain or a visibly deteriorated solution from the working supply. Replace it with material that meets its expiration and quality requirements before proceeding.	42 CFR 493.1252(d) "must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality."	☐ Done ☐ N/A

09 Equipment and reagents (continued)

Task	Rule and exact wording	Status and notes
077. Use components from different reagent-kit lots only when the manufacturer permits it. Keep kit components associated with their lot numbers. If the manufacturer permits a particular combination, use that combination according to its instructions.	42 CFR 493.1252(e) “Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.”	☐ Done ☐ N/A
078. Perform required batch, lot, and shipment reactivity checks when prepared or opened. For a new stain lot, document the expected reaction, observed result, and acceptance decision when it is opened. Include positive, negative, and graded reactivity where applicable.	42 CFR 493.1256(e)(1) “when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.”	☐ Done ☐ N/A

10 Accuracy checks

Task	Rule and exact wording	Status and notes
079. Establish an accuracy-assessment method for every test or procedure. Assign each menu item its required regulated PT program or applicable accuracy-verification method. Keep routine histopathology separate from gynecologic cytology PT. Maintain staff competency assessments separately from laboratory accuracy assessment.	42 CFR 493.801(a)(2)(ii) “a laboratory must establish and maintain the accuracy of its testing procedures” 42 CFR 493.1236(c)	☐ Done ☐ N/A
080. Verify applicable test accuracy at least twice annually. Complete accuracy verification for tests outside Subpart I and listed tests without compatible samples from a CMS-approved PT program. Document the material tested, comparison result, actual result, acceptance criteria, date, and evaluation.	42 CFR 493.1236(c) “At least twice annually, the laboratory must verify the accuracy of the following:” 42 CFR 493.1236(c)(1) 42 CFR 493.1236(c)(2) 42 CFR 493.1236(d)	☐ Done ☐ N/A
081. Handle regulated PT samples in the same manner as patient specimens. Use routine testing personnel, methods, workload, and repeat frequency. Document the testing and reporting steps, with the analyst's and laboratory director's signed attestation to routine handling.	42 CFR 493.801(b)(2) “The laboratory must test samples the same number of times that it routinely tests patient samples.” 42 CFR 493.801(b)(1) 42 CFR 493.801(b)(6)	☐ Done ☐ N/A

10 Accuracy checks (continued)

Task	Rule and exact wording	Status and notes
082. Prevent interlaboratory and cross-site PT result discussions until after the reporting due date. Tell staff when the event's reporting due date has passed before allowing discussion with other laboratories or separate sites. Keep PT results out of cross-site chats and shared result discussions until then.	42 CFR 493.801(b)(4) “must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s)”	☐ Done ☐ N/A
083. Prevent referral of regulated PT samples to another laboratory for analysis. Stop the PT workflow before the point at which a patient specimen would normally be referred for further testing. A laboratory receiving another laboratory's PT sample for testing must notify CMS.	42 CFR 493.801(b)(5) “The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory” 42 CFR 493.801(b)	☐ Done ☐ N/A
084. Evaluate each PT event's results and document required follow-up. Record the laboratory's assessment of the provider report. Investigate unacceptable performance and document the corrective action needed to maintain accurate and reliable patient results.	42 CFR 493.1236(a) “The laboratory must review and evaluate the results obtained on proficiency testing” 42 CFR 493.1236(d) 42 CFR 493.1282(a)	☐ Done ☐ N/A
085. Verify accuracy when PT results are unscored or do not reflect test performance. Perform and document verification when required by § 493.1236(b), such as when the program cannot score a challenge or a score reflects late submission rather than laboratory performance.	42 CFR 493.1236(b)(1) “Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored” 42 CFR 493.1236(b)(2) 42 CFR 493.1236(d)	☐ Done ☐ N/A

10 Accuracy checks (continued)

Task	Rule and exact wording	Status and notes
086. Maintain complete records of accuracy evaluations and verification. Keep the underlying results, comparison or expected values, acceptance criteria, evaluation, and follow-up together. For example, an assessment packet can identify the tested cases or materials, date, reviewer, and outcome.	42 CFR 493.1236(d) “All proficiency testing evaluation and verification activities must be documented.”	☐ Done ☐ N/A

11 Reports and retention

Task	Rule and exact wording	Status and notes
087. Send complete and accurate reports to the final report destination. Include required patient identification, performing laboratory name and address, date, examination, appropriate specimen source, result or interpretation, and relevant specimen-acceptability information. Send every specimen part and its corresponding diagnosis accurately through manual and electronic reporting.	42 CFR 493.1291(a) “to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry” 42 CFR 493.1291(c)	☐ Done ☐ N/A
088. Have tissue pathology reports signed by an appropriately qualified individual. Authorize tissue-report signers who meet the qualification provisions referenced in § 493.1273(b), or the specific neuromuscular-pathology provision in paragraph (c), as applicable.	42 CFR 493.1273(d) “Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b)” 42 CFR 493.1273(b) 42 CFR 493.1273(c)	☐ Done ☐ N/A
089. Obtain electronic-signature authorization from the examiner who made the diagnosis. Use a reporting workflow in which the diagnosing examiner authorizes the electronic signature. For example, individual sign-out authorization can identify that examiner and the report they approved.	42 CFR 493.1273(d) “it must be authorized by the individual who performed the examination and made the diagnosis.”	☐ Done ☐ N/A

11 Reports and retention (continued)

Task	Rule and exact wording	Status and notes
090. Immediately alert the requester and applicable result user to life-threatening or alert results. When a result indicates an imminently life-threatening condition or a panic or alert value, immediately contact the requesting individual or entity and, when applicable, the person responsible for using the result.	42 CFR 493.1291(g) “The laboratory must immediately alert the individual or entity requesting the test”	☐ Done ☐ N/A
091. Determine whether clinical urgency requires notification when a report is delayed. When an established reporting time frame cannot be met, decide whether the appropriate person needs notification based on the urgency of the requested testing. Apply the laboratory's notification process to that decision.	42 CFR 493.1291(h) “the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify”	☐ Done ☐ N/A
092. Promptly notify the appropriate people when a reporting error is discovered. Notify the authorized person who ordered the test and, when applicable, the person using the result. For an incorrect specimen designation, communicate the error promptly through the laboratory's established process.	42 CFR 493.1291(k)(1) “Promptly notify the authorized person ordering the test”	☐ Done ☐ N/A

11 Reports and retention (continued)

Task	Rule and exact wording	Status and notes
093. Issue corrected reports promptly to the appropriate people. Send the corrected report to the authorized ordering person and, when applicable, the person using the result. Ensure that electronic interfaces and manual delivery convey the corrected information accurately.	42 CFR 493.1291(k)(2) "Issue corrected reports promptly to the authorized person ordering the test" 42 CFR 493.1291(a)	☐ Done ☐ N/A
094. Retain both the original and corrected reports. Preserve a duplicate of each version in the retained record. Correcting a report must not erase the original version.	42 CFR 493.1291(k)(3) "Maintain duplicates of the original report, as well as the corrected report."	☐ Done ☐ N/A
095. Retain pathology reports and materials for the applicable minimum periods. Keep reports for 10 years after reporting; histopathology slides for 10 years after examination; blocks for 2 years after examination; and preserved tissue remnants until diagnosis. Apply longer periods when otherwise required.	42 CFR 493.1105(a)(7)(i)(B) "Retain histopathology slides for at least 10 years from the date of examination." 42 CFR 493.1105(a)(6)(ii) 42 CFR 493.1105(a)(7)(ii) 42 CFR 493.1105(a)(7)(iii) 42 CFR 493.1273(b)	☐ Done ☐ N/A

11 Reports and retention (continued)

Task	Rule and exact wording	Status and notes
096. Retain supporting laboratory records for at least two years. Keep requisitions and authorizations, quality-control and patient-test records, analytic-system records, PT records, and quality-assessment records for their applicable minimum periods. Include instrument printouts where applicable.	42 CFR 493.1105(a)(3) “Retain quality control and patient test records (including instrument printouts, if applicable)” 42 CFR 493.1105(a)(1) 42 CFR 493.1105(a)(4) 42 CFR 493.1105(a)(5)	☐ Done ☐ N/A
097. Retain discontinued procedures for at least two years after discontinuance. Archive each discontinued procedure with its dates of initial use and discontinuance. Keep that copy available throughout the required retention period.	42 CFR 493.1105(a)(2) “Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued.”	☐ Done ☐ N/A
098. Retain performance studies throughout test-system use, with a minimum retention of two years. Keep establishment and verification records while the laboratory uses the system. A system used for five years needs its studies retained throughout those five years.	42 CFR 493.1105(a)(3)(i) “for the period of time the laboratory uses the test system but no less than 2 years.”	☐ Done ☐ N/A

11 Reports and retention (continued)

Task	Rule and exact wording	Status and notes
099. Arrange continued retention and access if the laboratory ceases operation. Provide for records, slides, blocks, and tissue to remain retained and available for their required periods. Identify the custodian, storage location, and access process in the closure arrangements.	42 CFR 493.1105(b) “the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available”	☐ Done ☐ N/A

12 Problems and follow-up

Task	Rule and exact wording	Status and notes
100. Maintain an ongoing process to assess and correct specimen-handling problems. Follow written quality-assessment procedures and document the work. For example, define a local mislabeled-specimen measure, record incidents consistently, assess their causes, and act on identified problems.	42 CFR 493.1249(a) “an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems” 42 CFR 493.1249(c)	☐ Done ☐ N/A
101. Correct equipment or testing failures and document the actions taken. When a processor operates outside established limits, follow the corrective-action procedure. Record the problem, investigation, correction, and decision about returning the equipment to use.	42 CFR 493.1282(b)(1)(i) “Equipment or methodologies that perform outside of established operating parameters or performance specifications;” 42 CFR 493.1282(a)	☐ Done ☐ N/A
102. Assess patient results and specimens affected by a testing failure. For failed controls or calibration, evaluate all results in the unacceptable run and since the last acceptable run. For processor or storage failures, assess affected specimens and results under the laboratory's procedure and document their disposition.	42 CFR 493.1282(b)(2) “All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated” 42 CFR 493.1282(a) 42 CFR 493.1282(b)(1) 42 CFR 493.1282(b)(3)	☐ Done ☐ N/A

12 Problems and follow-up (continued)

Task	Rule and exact wording	Status and notes
103. Document whether corrective actions resolved the problem. After changing a cassette-labeling step, assess later results or incidents using a follow-up method suited to the problem. Record the outcome and take further action if the problem continues.	42 CFR 493.1289(b) “a review of the effectiveness of corrective actions taken to resolve problems” 42 CFR 493.1249(b) 42 CFR 493.1299(b)	☐ Done ☐ N/A
104. Revise procedures when needed to prevent a problem from recurring. If an interface problem requires a new report-checking step, put that step into the procedure staff use. Document the quality assessment and any necessary changes.	42 CFR 493.1299(b) “revision of policies and procedures necessary to prevent recurrence of problems” 42 CFR 493.1249(b) 42 CFR 493.1289(b)	☐ Done ☐ N/A
105. Discuss reporting-quality findings and follow-up with the appropriate staff. Include relevant amendments, delays, or interface problems in the reporting-quality review. Document the review and staff discussion so those involved understand the problem, response, and follow-up.	42 CFR 493.1299(b) “discussion of postanalytic systems quality assessment reviews with appropriate staff.” 42 CFR 493.1299(a) 42 CFR 493.1299(c)	☐ Done ☐ N/A

01 Laboratory services and paperwork

Audit exercise	Findings and follow-up
01.1 Current services and testing locations **1.** Choose a current service, such as diagnostic grossing or IHC, and identify its methods and the location where each part of the work occurs. **2.** Compare the current service list with CMS-116 and its updates; distinguish examinations performed here from work sent elsewhere. **3.** For each testing address in this example, identify its certificate coverage or the specific location exception being used. **4.** Record any mismatch between actual work, complexity or location and the laboratory's paperwork. Related checklist tasks: 001, 002, 003, 005	
01.2 Location-specific approvals **1.** Choose one operating location and list the state or local laboratory approvals applicable to its actual services. **2.** Compare the issued approvals with the current name, address, testing scope and renewal dates. **3.** Record any expired approval or unreported change and assign follow-up. Related checklist tasks: 004	

01 Laboratory services and paperwork (continued)

Audit exercise	Findings and follow-up
01.3 A recent laboratory change **1.** Choose a real administrative, specialty or method change and record its effective date or first examination date, as appropriate. **2.** Identify whether the laboratory holds a Certificate of Compliance or Certificate of Accreditation and select the applicable notification rule. **3.** Compare the notice dates and recipients with that rule and any shorter applicable state or accreditor deadline. **4.** Document missing notices or other discrepancies for follow-up; no change means this sample exercise can be omitted. Related checklist tasks: 006, 007, 008, 009, 010, 011	

02 Staff qualifications

Audit exercise	Findings and follow-up
02.1 One employee's assigned work **1.** Choose an employee who performs delegated grossing and identify the specimen types and tasks assigned on a recent shift. **2.** Match those tasks to the director's written authorization and any stated supervision requirements. **3.** Trace the person's recorded CLIA qualification route to its diploma, transcript, training or applicable continuity records. **4.** Where a state personnel license is required, compare its category, scope and validity with the assignment. Related checklist tasks: 012, 013, 014	
02.2 Director and specialty-supervisor qualifications **1.** Identify the person assigned as director and the person providing technical supervision for a pathology specialty the laboratory performs. **2.** For each role, follow the documented qualification route to the required medical license, board certification and other applicable records. **3.** If one person fills both roles or a resident has delegated duties, verify each role or delegation separately. Related checklist tasks: 015, 016	

02 Staff qualifications (continued)

Audit exercise	Findings and follow-up
02.3 Director visits **1.** Use the high-complexity laboratory's completed onsite-visit records to determine whether the required intervals were met. **2.** For a selected visit, locate the dated record of the director's activities and the associated work, such as a documented quality discussion. **3.** Record any interval or documentation gap for follow-up. Related checklist tasks: 017, 018	

03 Grossing

Audit exercise	Findings and follow-up
03.1 Follow a completed gross examination **1.** Choose a recent case, such as a skin excision, and identify the recorded grossing performer and examination date. **2.** Compare the person's written delegation with the specimen type and tasks described in the case. **3.** Trace the gross description's orientation and ink colors through the block key to cassette entries such as A1 and A2. **4.** Record any missing identity, date, authorization or inconsistent tissue description for follow-up. Related checklist tasks: 019, 020, 021, 022	
03.2 Coverage during an absence **1.** Choose a gross examination performed during the technical supervisor's absence. **2.** Compare the examination and subsequent review times with the laboratory's procedure and the applicable CMS guidance; consider any additional personnel-specific supervision obligation. **3.** Identify the responsible technical supervisor's signature on the examination report. Related checklist tasks: 023, 025	
03.3 A specimen requiring consultation **1.** Choose a documented case involving an unfamiliar specimen or a problem outside the grossing employee's authorized work. **2.** Compare the case's hold, notification and consultation record with the laboratory's procedure. **3.** Record any missing response or unclear responsibility that needs correction. Related checklist tasks: 024	

04 Competency checks

Audit exercise	Findings and follow-up
04.1 Competency scope, assessor and timing **1.** Choose one person who performs testing and list their actual examinations and methods. **2.** Compare that work with the competency plan, the assessor's qualifications and any required written delegation. **3.** Use the person's first patient-testing date and completed assessments to check the applicable first-year and subsequent intervals. Related checklist tasks: 026, 027, 028	
04.2 One completed competency assessment **1.** Select a completed assessment for an actual test or examination the employee performs. **2.** Identify its documentation of direct observation, result recording/reporting and the applicable testing-record assessment. **3.** Identify the documented maintenance/function-check observation, suitable test challenge and problem-solving assessment. **4.** Record any missing applicable element, unclear outcome or unsupported completion entry; this exercise checks existing assessments and does not replace them. Related checklist tasks: 029, 030, 031, 032, 033, 034	

04 Competency checks (continued)

Audit exercise	Findings and follow-up
04.3 A changed method or corrected skill gap **1.** Choose a recent method/instrument change or a documented competency problem. **2.** For a change, compare the completed reassessment date with the first patient result reported using the new method or instrument. **3.** For a skill gap, follow the original finding through retraining and the recorded demonstration of corrected performance. Related checklist tasks: 035, 036	

05 Specimens and labeling

Audit exercise	Findings and follow-up
05.1 Trace one multipart case **1.** Select a completed case with at least two specimen parts, such as an excision and a separate margin. **2.** Compare the original request and container-label records with the entered patient details, examinations, sources, collection details, and relevant clinical information. **3.** Follow each part through the gross description, block key, cassette, block, slide, and report; record any broken connection. **4.** If the case has recuts, levels, or corrected labels, trace those to their source blocks and correction records. Related checklist tasks: 037, 038, 039, 040, 041, 042	
05.2 Review a specimen-handling exception **1.** Choose a specimen with a recorded handling issue, or use a clearly labeled hypothetical example if none is available. **2.** Compare its receipt timestamp, condition, and disposition with the written acceptance procedure. **3.** Compare the documented fixative and transport conditions with the instructions for the intended examination, including any required timing. Related checklist tasks: 043, 044, 045	

05 Specimens and labeling (continued)

Audit exercise	Findings and follow-up
05.3 Follow a referral in each direction **1.** Choose an outgoing specimen and identify the actual receiving testing laboratory and its certification or recognized equivalent. **2.** Compare the send-out record with that laboratory's instructions for identifiers, examination, container, preservation, and packaging. **3.** Using the access offered to an outside clinic, obtain your laboratory's current incoming-specimen instructions and identify any missing applicable information. Related checklist tasks: 046, 047, 048	

06 Procedures

Audit exercise	Findings and follow-up
06.1 Use the procedure from the workbench **1.** Ask a staff member to open the procedure through the access normally available at the work location. **2.** Observe a suitable portion of the work and compare its sequence, materials, instrument settings, and result-entry steps with the current instructions. **3.** For instructions supplied by a manufacturer, identify where the laboratory provides applicable local information omitted from those instructions. Related checklist tasks: 049, 050, 051	
06.2 Follow one procedure revision **1.** Choose a revised procedure and compare the current director's signed approval date with its first-use date. **2.** Retrieve the retired version and its initial-use and discontinuance dates. **3.** Use the discontinuance date to confirm that the laboratory's retention arrangement covers at least the required two years and any applicable longer period. Related checklist tasks: 052, 055	

06 Procedures (continued)

Audit exercise	Findings and follow-up
06.3 Rehearse a control failure and an outage **1.** Use a hypothetical unacceptable control and ask staff to identify the written action for holding work and addressing the result. **2.** Use a hypothetical stainer outage and ask staff to identify the approved alternatives, referral arrangements, and delayed-reporting instructions that apply. **3.** Confirm that the instructions can be accessed with the affected system unavailable; record any missing or unclear steps for correction. Related checklist tasks: 053, 054	

07 Method checks

Audit exercise	Findings and follow-up
07.1 Review one method's introduction **1.** Choose a method and identify its intended use, actual configuration, FDA status, and applicable verification or establishment route; assess any claimed pre-2003 exception against its history. **2.** Compare the laboratory's study results with the performance characteristics and acceptance criteria applicable to that route. **3.** Compare study completion with the first patient-result report date. **4.** Compare the current written calibration and control procedures with the verified or established performance specifications. Related checklist tasks: 056, 057, 058, 059, 061	
07.2 Follow a method or instrument change **1.** Choose a change to retrieval, reagent, detection, instrument, or specimen preparation and identify the technical supervisor's evaluation. **2.** Compare the current configuration with the performance work supporting it and the current procedure and controls. **3.** For staff using changed methodology or instrumentation, compare documented reevaluation dates with their first patient reports using the change. Related checklist tasks: 060, 062	

07 Method checks (continued)

Audit exercise	Findings and follow-up
07.3 Review a test performed on multiple systems **1.** Identify a test performed using different methods, instruments, or testing sites. **2.** Review the documented twice-yearly comparison activities and the defined relationship between the results. **3.** Examine a difference identified in the comparisons and its documented evaluation; if no multiple-system situation exists, document why this task is not applicable. Related checklist tasks: 063	

08 Stains and controls

Audit exercise	Findings and follow-up
08.1 Trace controls for a stain run **1.** Select an IHC or fluorescent-stain use and identify its documented positive- and negative-reactivity checks. **2.** Select a different differential or special-stain group and identify the known-reactivity control stained with that group. **3.** Compare the recorded control reactions with the laboratory's acceptance criteria and note any record that only says a control was present. Related checklist tasks: 064, 065, 066	
08.2 Follow a failed run through reporting **1.** Select a failed-control run with follow-up, or use a clearly labeled hypothetical example. **2.** Confirm that the original failed control and any repeat are both retained and identifiable. **3.** Compare the acceptable follow-up control result with the affected patient-report timing to determine whether reporting waited for acceptable control performance. Related checklist tasks: 067, 068	
08.3 Review H&E quality and a poor slide **1.** For a selected period, compare H&E use dates with the documented daily checks of intended stain response. **2.** Choose an inadequately prepared slide, or use a clearly labeled example, and identify the laboratory's applicable written response. **3.** Review the recorded recut, restain, communication, or other response against that procedure. Related checklist tasks: 069, 070	

09 Equipment and reagents

Audit exercise	Findings and follow-up
09.1 Instrument maintenance and readiness **1.** Choose a processor or stainer and a completed patient-testing period. **2.** Compare its maintenance and function-check records with the manufacturer's requirements or applicable laboratory protocol. **3.** Trace any service event or out-of-limit function check to the documented acceptable check before patient testing resumed. Related checklist tasks: 071, 072	
09.2 Reagent preparation and use **1.** Select reagents on the working bench, including a recently prepared solution and an opened commercial lot. **2.** Compare labels, expiration dates, condition, and kit-component lot numbers with preparation records and manufacturer instructions. **3.** Trace the new batch, lot, or shipment to its required reactivity result and acceptance decision; record any missing or unacceptable evidence. Related checklist tasks: 075, 076, 077, 078	
09.3 Storage excursion follow-up **1.** Choose a storage-monitoring period and identify the approved limits that applied. **2.** Compare any out-of-range entry with its corrective-action record and the assessment of affected reagents or specimens. **3.** Confirm the record explains disposition of affected material and restoration of acceptable conditions. Related checklist tasks: 073, 074	

10 Accuracy checks

Audit exercise	Findings and follow-up
10.1 Test-menu coverage **1.** Compare the current menu with the PT or accuracy-verification method assigned to each applicable test or procedure. **2.** For procedures requiring twice-annual verification, compare the required coverage with the year's completed assessments. **3.** Open the supporting records for selected assessments and record any missing result, evaluation, or follow-up. Related checklist tasks: 079, 080, 086	
10.2 PT event handling **1.** Choose a completed regulated PT event and its handling, testing, reporting, and attestation records. **2.** Compare personnel, methods, workload integration, and repeat testing with routine patient practice. **3.** Check the documented workflow and any communication or referral incidents against the event's reporting due date and the prohibition on PT referral. Related checklist tasks: 081, 082, 083	

10 Accuracy checks (continued)

Audit exercise	Findings and follow-up
10.3 PT result follow-up **1.** Choose a provider report that contains an unacceptable, unscored, or unevaluated result, if available. **2.** Match the report to the laboratory's evaluation, any required accuracy verification, and corrective-action record. **3.** Identify any result for which required follow-up is missing and record the task needed to resolve it. Related checklist tasks: 084, 085	

11 Reports and retention

Audit exercise	Findings and follow-up
11.1 Report delivery and authorization **1.** Choose a completed multipart tissue case and obtain the source report and the version received at its final destination. **2.** Compare identifiers, specimen parts, diagnoses, and other required report information for accuracy and completeness. **3.** Match the signer to the applicable qualification record and, for an electronic signature, to the diagnosing examiner's authorization. Related checklist tasks: 087, 088, 089	
11.2 Urgent, delayed, and corrected reports **1.** Select available examples of an urgent result, a delayed report, and a reporting error; use a practice scenario for a situation with no actual example. **2.** Compare recognition and notification times with the immediate-alert, urgency-based delay, and prompt error-notification requirements. **3.** For the error case, trace the corrected report to its recipient and confirm that both the original and corrected versions remain available. Related checklist tasks: 090, 091, 092, 093, 094	

11 Reports and retention (continued)

Audit exercise	Findings and follow-up
11.3 Archive access and retention periods **1.** Select retained reports, slides, blocks, supporting records, a discontinued procedure, and a performance study. **2.** Calculate the applicable retention end dates from reporting, examination, or discontinuance dates; confirm tissue remnants were preserved until diagnosis. **3.** Request the selected items through the normal archive process, including off-site or migrated records where applicable. **4.** Check that closure arrangements identify custody and continued access for every required record and material category. Related checklist tasks: 095, 096, 097, 098, 099	

12 Problems and follow-up

Audit exercise	Findings and follow-up
12.1 Specimen-quality assessment **1.** Choose a specimen-handling measure used by the laboratory and read its local definition. **2.** Recalculate selected entries from the underlying incident records and compare them with the quality-assessment summary. **3.** Trace an identified collection or handling problem to its documented assessment and response. Related checklist tasks: 100	
12.2 Failure and affected-case review **1.** Choose a recorded equipment, control, calibration, or storage failure. **2.** Follow the event through investigation, corrective action, and the return-to-use decision where applicable. **3.** For failed controls or calibration, compare the reviewed patient results with the unacceptable run and all work since the last acceptable run; for other failures, compare affected-case review with the laboratory's procedure. Related checklist tasks: 101, 102	

12 Problems and follow-up (continued)

Audit exercise	Findings and follow-up
12.3 Effectiveness and staff follow-up **1.** Choose a corrective action recorded as completed. **2.** Compare the later result or incident review with the original problem to see whether the action was effective. **3.** Confirm any needed procedure change appears in the version staff use. **4.** Match relevant reporting-quality findings and follow-up to the documented discussion with appropriate staff. Related checklist tasks: 103, 104, 105	