2022 CAP Top 10 Most Common Checklist Deficiencies

To ensure our accredited laboratories have the framework and direction needed to achieve and maintain accreditation, the College of American Pathologist's (CAP) Laboratory Accreditation Program offers 21 discipline-specific checklists to optimize inspection preparation, including notes and practical examples, citations, and built-in references to provide clarification and easy access to specific regulations.

To further laboratory excellence, each year we compile the 10 most common CAP checklist deficiencies cited during the previous years' laboratory inspections. This list is meant to not only share the common deficiencies but to provide further support for laboratory improvement, ensuring quality patient care.

This year, in addition to the Checklist Requirement Q&As and other helpful resources, **we have added examples of inspector comments to provide insight into why a deficiency was cited.**

Additional tools to assist your laboratory are available by visiting our Accreditation Resources in e-LAB Solutions Suite (ELSS).

Checklist Requirements

GEN.55500 Competency Assessment Elements - Nonwaived Testing

The competency of personnel performing nonwaived testing is assessed using all six elements (as applicable) on each test system.

NOTE: Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system. The laboratory must identify the test systems that testing personnel use to generate test results, including both primary and back-up methods used for patient testing. If a single test or analyte is performed using different test systems, a separate assessment is required.

A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results.

- A test system may be manual, automated, multi-channel or single use.
- It includes instructions, reagents, supplies, equipment and/or instruments required to produce test results.
- It may encompass multiple identical analyzers or devices.
- It may include multiple tests performed on the same testing platform (eg, analyzer), unless tests have unique aspects, problems, or procedures (eg, pretreatment of specimens prior to analysis. In those situations, competency must be assessed as a separate test system to ensure personnel perform those aspects correctly.

The **six required elements** of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens) or external proficiency testing specimens
6. Evaluation of problem-solving skills

The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency may be coordinated with routine practices and procedures if they are assessed by an individual qualified to assess competency (GEN.55510). Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

The following includes examples of how competency assessment can be coordinated with routine practices and procedures:

- Assessment of the recording of quality control results and instrument maintenance data in element #3 during the monthly supervisory review process of these records.
- Assessment of test performance in element #5 during reviews of proficiency testing or alternative performance assessment records.
- Assessment of problem-solving skills in element #6 from monthly reviews of corrective action logs where problems with quality control or instrument function were investigated.

The CAP provides example competency assessment templates, which can be downloaded from cap.org in e-Lab Solutions Suite - Accreditation Resources - Templates.

Evidence of Compliance:

✓ Records of competency assessment reflecting the specific skills assessed for each test system and the method of evaluation

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1065-66 [42CFR493.1451(b)], 1053-54 [42CFR493.1413], 1992 (Feb 28) 7184 [42CFR493.1713]

2) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment*. 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

Most Common Reasons for Citations

- Not documenting all six elements that apply/elements assessed were unclear
- Not assessing new personnel semiannually
- Confused about what is considered a test system (eg, lumping all manual tests under one test system)

Resources

- Personnel/Competency Templates (find in Templates in Accreditation Resources)
- Checklist Requirement Q&A—GEN.55500

COM.04250 Comparability of Instruments and Methods - Nonwaived Testing

If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results.

NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods, even if there are different reference intervals or levels of sensitivity. It includes primary and back up methods used for patient testing. The purpose of the requirement is to evaluate the relationship between test results using different methodologies, instruments, or testing sites.

This requirement is not applicable to:

- Calculated parameters
- Waived methods
- Laboratories with different CAP numbers

The following types of materials may be used to generate data for comparability studies:

- Patient/client specimens (pooled or unpooled) are preferred to avoid potential matrix effects
- Quality control materials for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number
- Alternative protocols based on quality control or reference materials for cases when availability or pre-analytical stability of patient/client specimens is a limiting factor. The materials must be validated (when applicable) to have the same response as fresh human specimens for the instruments and methods involved.

This requirement only applies when the instruments/reagents are producing the same reportable result. For example, some laboratories may use multiple aPTT reagents with variable sensitivity to the lupus anticoagulant to perform different tests, such as aPTT for heparin monitoring and a lupus-like anticoagulant screen. If these are defined as separate tests, this requirement does not apply unless each type of aPTT test is performed on more than one analyzer.

For Microbiology testing, this requirement applies when two instruments (same or different manufacturers) are used to detect the same analyte. Two or more detectors or incubation cells connected to a single data collection, analysis and reporting computer need not be considered separate systems (eg, multiple incubation and monitoring cells in a continuous monitoring blood culture instrument, two identical blood culture instruments connected to a single computer system, or multiple thermocycler cells in a real time polymerase chain reaction instrument). This checklist requirement does not apply to multiple analytical methods (eg, antigen typing versus culture or detection of DNA versus a biochemical characteristic) designed to detect the same analyte.

Evidence of Compliance:

✓ Records of comparability studies reflecting performance at least twice per year with appropriate specimen types

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register*. 2003(Jan 24):5236 [42CFR493.1281(a)]

2) Ross JW, *et al*. The accuracy of laboratory measurements in clinical chemistry: a study of eleven analytes in the College of American Pathologists Chemistry Survey with fresh frozen serum, definitive methods and reference methods. *Arch Pathol Lab Med*. 1998;122:587-608

3) Miller WG, Myers GL, Ashwood ER, et al. State of the Art in Trueness and Inter-Laboratory Harmonization for 10 Analytes in General Clinical Chemistry. *Arch Pathol Lab Med* 2008;132:838-846

4) Clinical and Laboratory Standards Institute. *Verification of Comparability of Patient Results within One Healthcare System: Approved Guideline (Interim Revision)*. CLSI document EP31-A-IR. Clinical and Laboratory Standards Institute, Wayne, PA; 2012.

5) Miller WG, Erek A, Cunningham TD, et al. Commutability limitations influence quality control results with different reagent lots. *Clin Chem*. 2011;57:76-83

Most Common Reasons for Citations

- Not performed twice a year (eg, due to COVID)
- Lack of acceptance criteria
- Lack of understanding that this doesn't just apply to identical instruments

Resources

- Checklist Requirement Q&A—COM.04250
- Method/Instrument Comparison Template (find in Templates in Accreditation Resources)

COM.01200 Activity Menu

The laboratory's current CAP Activity Menu accurately reflects the testing performed.

NOTE: The laboratory's CAP Activity Menu must include all patient/client testing performed by the laboratory.

- For laboratories with a CLIA certificate, it includes all testing and activities performed under that CLIA certificate.
- For laboratories not subject to CLIA, it includes all testing and activities meeting all of the following criteria: 1) performed under the same laboratory director, 2) under the same laboratory name, and 3) at the same physical premises (contiguous campus).

The testing and activities must be listed on the laboratory's CAP Activity Menu regardless of whether it is also accredited by another organization. **The laboratory must update its CAP Activity Menu when tests are added or removed by logging into e-LAB Solutions Suite on cap.org and going to Organization Profile - Sections/ Departments**. In order to ensure proper customization of the checklists, the laboratory must also ensure its activity menu is accurate for non-test activities, such as methods and types of services offered.

Some activities are included on the Master Activity Menu using more generic groupings or panels instead of listing the individual tests. The Master Activity Menu represents only those analytes that are directly measured. Calculations are not included, with a few exceptions (eg, INR, hematocrit).

Laboratories are not required to include testing performed solely for the purpose of research on their activity menus, but may opt to include such testing if the laboratory wants it to be inspected by the CAP. Testing performed for research is defined as laboratory testing on human specimens where **patient-specific** results are **not** reported for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. If patient-specific results are reported from the laboratory, the testing is subject to CLIA and must be reported to the CAP.

If an inspector identifies that a laboratory is performing tests or procedures not included on the laboratory's CAP Activity Menu, the inspector must do the following:

- Cite COM.01200 as a deficiency
- Contact the CAP (800-323-4040) for inspection instructions as requirements may be missing from a laboratory's customized checklist
- Record whether those tests/procedures were inspected on the appropriate section page in the Inspector's Summation Report (ISR)

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2004(Oct 1): 985 [42CFR493.51]

Most Common Reasons for Citations

- Didn't update activity menu after an instrument change that affected the activity menu (eg, test went from waived to nonwaived)
- Inspector packet activity menu not matching the laboratory's current activity menu
- Activities not listed under the correction section unit

Resources

- Master Activity Menu (also found on Activities pages in Organization Profile)
- Checklist Requirement Q&A—COM.01200

COM.10000 Policy and Procedure Manual

A complete policy and procedure manual is available in a paper-based, electronic, or web-based format at the workbench or in the work area.

NOTE 1: All laboratories testing, functions and/or processes must be defined in written policies and/or procedures. **Procedures must match the laboratory's practice**.

NOTE 2: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed or electronic procedure must be detailed in the procedure manual.

NOTE 3: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the manufacturer's manual must be clearly recorded and approved.

NOTE 4: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

- A complete manual is available for reference
- The card file or similar system corresponds to the complete manual and is subject to document control

NOTE 5: Electronic manuals accessed by computer are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, as long as the electronic versions are readily available to all personnel and personnel have been trained on how to access them. However, procedure manuals must be available to laboratory personnel when the electronic versions are inaccessible (eg, during laboratory information system or network downtime); thus, the laboratory must maintain paper copies, electronic copies on CD or other digital media, or have an approved alternative mechanism to access web-based files during network downtimes. All policies and procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic manuals and electronic copies of policies and procedures are subject to proper document control (see GEN.20375).

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1251(a) (b) (1-14) (c)(d)(e)]

2) Borkowski A, et al. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5

3) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Development and Management of Laboratory documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6 (ISBN 1-56238-869-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2013.

Most Common Reasons for Citations

- Not following policy/procedure (eg, changed process but failed to update procedure)
- Failure to archive a procedure not in use
- Printed procedures don't match electronic documents (version control)

Resources

- Checklist Requirement Q&A—COM.10000

COM.01700 PT and Alternative Performance Assessment Result Evaluation

There is ongoing evaluation of proficiency testing (PT) and alternative performance assessment results by the laboratory director or designee with appropriate corrective action taken for each unacceptable result.

NOTE: Each unacceptable PT or alternative performance assessment result (any result or specimen not meeting defined acceptability criteria) must be evaluated in a timely manner to determine the impact on patient test results and correct problems identified. It is recommended that the laboratory investigate acceptable results that show significant bias or trends.

Primary records related to PT and alternative performance assessment testing are retained for at least two years (five years for transfusion medicine). These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and records of follow-up or corrective action.

For laboratories outside the US, PT failures relating to problems with shipping and specimen stability should include working with local customs and health regulators to ensure appropriate transit of PT specimens.

Evidence of Compliance:

- ✓ Records of ongoing review of all PT reports and alternative performance assessment results by the laboratory director or designee **AND**
- ✓ Records of investigation of each "unacceptable" PT and alternative performance assessment result including records of corrective action appropriate to the nature and magnitude of the problem

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7173 [42CFR493.1407(e)(4)(iv)]

2) Steindel SJ, et al. Reasons for proficiency testing failures in clinical chemistry and blood gas analysis. A College of American Pathologists Q-Probes study in 655 laboratories. *Arch Pathol Lab Med*. 1996;120:1094-1101

3) Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality*. 3rd ed. CLSI guideline QMS24. Clinical and Laboratory Standards Institute. Wayne, PA; 2016.

4) Shahangian S, et al. Toward optimal PT use. *Med Lab Observ*. 2000;32(4):32-43

5) Zaki Z, et al. Self-improvement by participant interpretation of proficiency testing data from events with 2 to 5 samples. *Clin Chem*. 2000;46:A70

6) Stavelin A, Riksheim BO, Christensen NG, Sandberg S. The Importance of Reagent Lot Registration in External Quality Assurance/Proficiency Testing Schemes. *Clin Chem*. 2016;62(5):708-15.

Most Common Reasons for Citations

- Not having a standardized way to investigate the failure
- Misunderstanding about the need to review missed challenges when the laboratory receives an overall passing score (eg, 80%)
- Inspector disagrees with the level of assessment/corrective action performed

Resources

- Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox
- "Proficiency Testing (PT) Failures: Getting to the 'Root' of the Causes" webinar (find in Focus on Compliance in Accreditation Resources)
- Checklist Requirement Q&A—COM.01700

COM.30600 Maintenance/Function Checks

The laboratory performs and records appropriate maintenance and function checks for all instruments (eg, analyzers) and equipment (eg, centrifuges) following a defined schedule, at least as frequent as specified by the manufacturer.

NOTE: Maintenance and function checks may include (but are not limited to) cleaning, electronic, mechanical and operational checks.

The purpose of a function check is to detect drift, instability, or malfunction, before the problem is allowed to affect test results.

For equipment without manufacturer's instructions defining maintenance and function check requirements, the laboratory must establish a schedule and procedure that reasonably reflects the workload and operating specifications of its equipment.

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1254]

2) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline*. CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.

Most Common Reasons for Citations

- Missing records (daily, weekly, or monthly function check)
- Not following manufacturer's defined frequency
- Employees not documenting performed maintenance

Resources

- Checklist Requirement Q&A—COM.30600

COM.04200 Instrument/Equipment Record Review

The laboratory director or designee reviews and assesses instrument and equipment maintenance and function check records at least monthly.

NOTE: If problems are identified (eg, maintenance not performed as scheduled), the reviewer must record corrective action. The review of the records related to tests that have an approved individualized quality control plan (IQCP) must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:

✓ Records of monthly review

Most Common Reasons for Citations

- Missing evidence of review due to staffing shortages (eg, COVID, supervisors pulled to work the bench)
- Not performed for less frequently used equipment (eg, osmometer)
- Completed several months of review on the same date (not timely)

Resources

- Checklist Requirement Q&A—COM.04200

COM.01400 PT Attestation Statement

The proficiency testing attestation statement is signed (physical or electronic signature) by the laboratory director or qualified designee and all individuals involved in the testing process.

NOTE: If electronic signatures are used for the PT attestation, the laboratory must be able to show that they are traceable to the event (eg, electronic record with a date/time stamp for the activity) and are only used by the authorized person (eg, password protected account). A listing of typed names on the attestation statement does not meet the intent of the requirement. The signature of the laboratory director or designee need not be obtained prior to reporting results to the proficiency testing provider.

Designees must be qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing as defined in the Personnel section of the Laboratory General Checklist.

- For high complexity testing, it may be delegated to an individual meeting the qualifications of a technical supervisor or section director (GEN.53400). For the specialties of Histocompatibility, Cytogenetics, and Transfusion Medicine, refer to specific requirements for the qualifications of section directors/technical supervisors in the associated checklists (HSC.40000, CYG.50000, and TRM.50050).
- For moderate complexity testing, it may be delegated to an individual meeting the qualifications of a technical consultant (GEN.53625).

Evidence of Compliance:

✓ Appropriately signed attestation statement from submitted PT result forms

References

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801(b)(1)]

2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. QSO-21-10-CLIA. Clinical laboratory improvement amendments of 1988 (CLIA) Laboratories Surveyor Guidance for New and Modified CLIA Requirements Related to SARS-CoV-2 Test Result Reporting. January 8, 2021. https://www.cms.gov/files/document/qso-21-10-clia.pdf. Accessed February 3, 2021.

Most Common Reasons for Citations

- Individual not qualified to sign or delegated to perform this duty (eg, blood bank needs a physician)
- Missing testing personnel signatures

Resources

- Checklist Requirement Q&A—COM.01400

COM.30750 Temperature Checks

The laboratory monitors and records temperatures using a calibrated thermometer as defined in written procedure for the following:

- **Temperature-dependent storage devices (eg, refrigerators, freezers, incubators)**
- **Temperature-dependent equipment (eg, water baths, heat blocks)**
- **Temperature-dependent environments (eg, ambient reagent or specimen storage, conditions for instrument operation and test performance)**

NOTE: Temperature-dependent storage devices and temperature-dependent environments where reagents, supplies, and patient/client specimens are stored within a specified temperature range **must be checked daily**. Please refer to more stringent requirements in the Transfusion Medicine, Reproductive Laboratory Medicine and Biorepository Checklists for storage requirements for blood components, tissues, and biorepository specimens.

Use of a continuous monitoring device or a minimum/maximum thermometer satisfies the requirement for daily temperature recording, including during laboratory closures (eg, weekends, holidays), as long as the monitoring data is evaluated on the next business day prior to use. For use of minimum/maximum thermometers during laboratory closures, this includes resetting the device prior to the monitoring period and recording both low and high temperatures. It is not necessary to record low and high temperatures on days when the laboratory is in operation if daily temperatures are recorded.

Temperature-dependent equipment and temperature-dependent environments used for procedures at a specified temperature range must be **checked on each day of use**. For heat blocks or dry baths, thermocouple probes may be used as an alternative method for checking the temperature.

Temperature-dependent environments refer to areas of the laboratory where specific instruments, equipment, kits, or supplies have manufacturer or laboratory specified ambient temperature ranges for proper operation, storage, or use.

Temperatures may be recorded either manually or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording temperatures must be recorded (initials of the individual are adequate).

If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate daily functionality of the automated system in accordance with manufacturer's instructions.

Patient specimens, reagents, and controls may be stored in a frost-free freezer only if protected from thawing. Thermal containers within the freezer may be used. The laboratory must retain records showing that the temperatures stay within the defined range.

- Repeated freeze-thaw cycles contribute to biomolecular degradation and are detrimental to biospecimen quality.
- It is prudent to avoid freeze-thaw altogether by aliquoting specimens before freezing.

References

1) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline*. CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.

2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):[42CFR493.1252(b)].

Most Common Reasons for Citations

- Missing days for manually recorded logs
- Missing corrective action for out-of-range temperatures
- Not using a minimum/maximum thermometer during lab closures in labs not open 24/7

Resources

- Checklist Requirement Q&A—COM.30750
- Temperature Chart Template (find in Templates in Accreditation Resources)
- Temperature Log Template (find in Templates in Accreditation Resources)

GEN.20450 Correction of Laboratory Records

The laboratory makes corrections to laboratory records (eg, quality control data, temperature logs, and intermediate test results or worksheets) using appropriate techniques.

NOTE: The laboratory must have a written procedure that defines how to make corrections to both paper and electronic laboratory records. Laboratory records and changes to such records must be legible and indelible. The techniques used must meet the following criteria:

- Original (erroneous) entries must be visible (ie, erasures and correction fluid or tape are unacceptable) or accessible (eg, audit trail for electronic records).
- Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit.

This requirement does not apply to changes to patient reports (refer to GEN.41310).

Evidence of Compliance:

✓ Records of corrections to laboratory records

Most Common Reasons for Citations

- Lab personnel are not following the lab's policy for record correction which should state that the original (erroneous) entries must be visible and corrected data, including the identity of the person changing the record and when the record was changed, are noted on the record. Some examples are:
  - Scratching out erroneous entries rather than simply lining through the entry
  - Not dating or initialing the change