COLLEGE of AMERICAN PATHOLOGISTS

December 2024 Changes

All Common Checklist

CAP Accreditation Program

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

12.26.2024

Disclaimer and Copyright Notice

CAP inspections are performed with the edition of the Checklists mailed to a facility at the completion of the application or reapplication process, not necessarily those currently posted on the website. The checklists undergo regular revision and a new edition may be published after the inspection materials are sent.

For questions about the use of the Checklists or Checklist interpretation, email accred@cap.org or call 800-323-4040 or 847-832-7000 (international customers, use country code 001).

Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text**. Changes appear in a track changes format that compares the previous checklist edition to the December 26, 2024 edition.** Requirements with significant revisions will display a "Revised" flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a "Revised" flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that are new or have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

2024 CHECKLIST EDITION CHANGES
NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement		Action Taken	2024 Requirement	
COM	22950	Merged	GEN	41096
		New	COM	30695

*Deleted – Removed the requirement from the checklist edition
*Merged – Combined the requirement with a similar requirement in the same or different checklist
*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists ~~from the CAP website (cap.org)~~ by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

All checklist requirements contain a requirement number, subject header, phase, and a declarative statement. Some requirements also contain the following:

- Policy/Procedure Icon:
  - The placement of the icon next to a checklist requirement indicates that a **written policy or procedure is required to demonstrate compliance with the requirement.**
  - The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.
- NOTE:
  - Additional detail used to assist in interpreting the requirement. Information in the NOTE is considered integral to the requirement and must be complied with as part of the declarative statement itself, unless it is expressed as a ~~best practice or~~ recommendation or best practice.

- Evidence of Compliance (EOC):
  - A listing of suggested ways to demonstrate compliance with the requirement; some elements are required.

The Master version of the checklist also contains references and the inspector R.O.A.D. instructions (Read, Observe, Ask, Discover), which can provide valuable insight for the basis of requirements and on how compliance will be assessed.

INTRODUCTION

The All Common Checklist (COM) contains a core set of requirements that apply to all areas performing laboratory tests and procedures. It is to be used in conjunction with the discipline-specific checklist to inspect each section. In some instances, the same requirement exists in both the COM Checklist and in a discipline-specific checklist, but with more specificity in the discipline-specific checklist. In these situations, the discipline-specific requirement takes precedence.

One COM Checklist is provided for inspection of each laboratory section or department. If more than one inspector is assigned to inspect a section, each inspector must be familiar with the COM requirements and ensure that all testing is in compliance.

Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

The use of the term "patient" within checklist requirements ~~when referring to specimens, records, testing, reports, and other required elements~~ is intended to apply broadly to the population served by the laboratory and may also include donors, clients, and study participants.

 *Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.*

Laboratories not subject to US regulations: *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

DEFINITION OF TERMS

Addendum - Information appended to a final report with no changes to the original test result(s); original report is intact and unchanged, the addendum is added as an attachment or supplement to the original report.

Alternative performance assessment - A system for determining the reliability of laboratory examinations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization.

Amended/amendment - Any change in a previously issued anatomic pathology or cytopathology report intended to correct an inaccuracy, including changes in the diagnosis, narrative text, clinical history, pre- and post-operative diagnoses, patient identification, or other content.

Analytical performance characteristics - For a specific test, the properties of a test identified from data collected during analytical validation or analytical verification studies.

Analytical validation - The process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application.

Analytical verification - The process by which a laboratory determines that an unmodified FDA-cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed.

Annual - Every 12 calendar months.

Authority - The power to give orders or make decisions: the power or right to direct someone or control a process.

Biennial - Every 24 calendar months.

Biorepository - An entity that collects, processes, stores, manages, and distributes biospecimens for research purposes. The term laboratory may also be used in the checklist to generically refer to a biorepository participating in the CAP's Biorepository Accreditation Program.

Calculated test result - A reportable patient test result that is not directly measured but rather calculated from one or more directly measured results.

Check - Examination to determine the accuracy, quality or presence of any attribute of a test system.

Clinical performance characteristics - For a specific test, the properties of a test identified from data collected during studies of clinical validation, clinical utility, or clinical usefulness.

Clinical validation - The determination of the ability of a test to diagnose or predict risk of a particular health condition or predisposition, measured by sensitivity, specificity, and predictive values.

Commutable - The property of a reference material that yields the same numeric result as would a patient's specimen containing the same quantity of analyte in the analytic method under discussion (ie, matrix effects are absent).

Confirmation - Substantiation of the correctness of a value or process.

Corrected/correction - A change in a previously issued clinical pathology test report intended to correct an inaccuracy, including changes in test results, patient identification, reference intervals, interpretation, or other content.

Corrective Action - Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

Correlation - Establishment of ~~agreement~~a relationship between two or more measured values.

Credentialing - The process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care in a health care organization.

Device - Any reagent, reagent product, kit, instrument, apparatus, equipment or related product, whether used alone or in combination, intended by the manufacturer to be distributed for use in vitro for the examination of human specimens.

Digital image analysis - The computer-assisted software detection or quantification of specific features in an image following enhancement and processing of that image, including analysis of immunohistochemistry samples, DNA analysis, morphometric analysis, and in situ hybridization.

Distributive testing - Laboratory testing performed on the same specimen, or aliquot of it, that requires sharing between two or more laboratories (with different CLIA/CAP numbers) to provide a final, reportable result for the originally-ordered test. The laboratories involved may perform separate steps of "wet" testing, or may perform calculations, data analysis/informatics processing, or interpretive processes; all such models fall under the term distributive testing.

Equipment - Single apparatus or set of devices or apparatuses needed to perform a specific task.

Examination - In the context of checklist requirements, examination refers to the process of inspection of tissues and samples prior to analysis. An examination is not an analytical test.

External quality control - A stable material designed to simulate a patient specimen for monitoring the performance of a test procedure or system to ensure reliable results. Common examples include positive and negative liquid materials or swabs provided with test kits; assayed and unassayed liquid controls provided by an instrument manufacturer, third party supplier or prepared by the laboratory; and control slides purchased or prepared by the laboratory to demonstrate appropriate reactivity or staining characteristics. In contrast to internal quality control processes, external quality control materials are not built into the performance of the clinical assay. External quality control materials are not to be confused with external quality assessment (EQA) program materials (external proficiency testing).

FDA - 1) For laboratories subject to US regulations, FDA refers to the US Food and Drug Administration, which is the regulatory body under Health and Human Services (HHS) with authority to regulate *in vitro* diagnostic products such as kits, reagents, instruments, and test systems; 2) For laboratories not subject to US regulations, FDA refers to the national, state or provincial, or local authority having jurisdiction over *in vitro* diagnostic test systems.

Function Check - Confirmation that an instrument or item of equipment operates according to manufacturer's specifications prior to initial use, at prescribed intervals, or after minor adjustment (~~e.g.~~eg, base line calibration, balancing/zero adjustment, thermometer calibration, reagent delivery).

High complexity - Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health. Tests in this category are seen to have the highest risks to public health.

Instrument - An analytical unit that uses samples to perform chemical or physical assays (~~e.g.~~eg, chemistry analyzer, hematology analyzer).

Instrument platform - Any of a series of similar or identical analytical methods intended by their manufacturer to give identical patient results across all models.

Internal quality control - Processes integrated into the testing instrument and/or test system designed to monitor the performance of a test to ensure reliable results. Internal quality control may include electronic, built-in, or procedural control systems. On instruments/test systems with internal QC processes, performing the internal QC is typically a physical requirement of performance of the assay on clinical specimens.

Laboratory - Term used to refer to a clinical laboratory, biorepository, forensic drug testing laboratory, or reproductive laboratory participating in the CAP accreditation programs.

Laboratory Director - The individual who is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable and clinically relevant test results and compliance with applicable regulations and accreditation requirements. This individual is listed on the laboratory's CAP and CLIA certificate (as applicable).

Maintenance - Activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning, lubrication, electronic checks, or changing parts, fluids, or tubing, etc.

Moderate complexity - Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health.

Modification of manufacturer's instructions - Any change to the manufacturer's supplied ingredients or modifications to the assay as set forth in the manufacturer's labeling and instructions. It may include a change to specimen type, instrumentation or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results.

For laboratories subject to US regulations, this includes modifications to FDA-cleared/approved tests. For laboratories not subject to US regulations, it also includes modifications to tests approved by an internationally recognized regulatory authority (eg, CE marking).

Non-conforming event - An occurrence that: 1) deviates from the laboratory's policies or procedures; 2) does not comply with applicable regulatory or accreditation requirements; or 3) has the potential to affect (or has affected) patients, donors, the general public, or personnel safety.

Nonwaived - Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity according to a scoring system used by the FDA.

Pathologist - A physician who has successfully completed an approved graduate medical education program in pathology.

In the US, a physician is defined as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine who is licensed by the state to practice medicine, osteopathy, or podiatry within the state in which the laboratory is located. In jurisdictions not subject to US regulations, a physician is defined as an individual who has a primary medical school degree (eg, MBBS, MBChB, MD, DO) in keeping with the standards of that particular jurisdiction.

Performance verification - The set of processes that demonstrate an instrument or an item of equipment operates according to expectations prior to initial use and after repair or reconditioning (eg, replacement of critical components~~)~~).

Personnel - The collective group of employees and contractors employed ~~in~~by the laboratory organization. Contractors may include those individuals contracted by the laboratory, such as pathologists, clinical or medical laboratory scientists, medical technologists, and non-laboratory individuals, such as respiratory therapists or nurses who perform patient testing. It would not include those individuals contracted outside the authority of the laboratory, such as medical waste disposal contractors, instrument service representatives, or cleaning contractors.

Policy - Written statement of overall guidelines, strategy, approach, intentions and directions endorsed by laboratory leadership that direct or restrict a facility's plans, actions, and decisions.

Predictive marker ~~testing - Immunohistochemical, immunocytochemical, and in situ hybridization tests~~ - Biomarker used ~~to predict responsiveness to a specific treatment~~ independent of ~~other histopathologic~~histologic findings~~. Rather than confirming a specific diagnosis, these tests differentiate predicted responsiveness to a~~ to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy ~~among cases of~~, compared to individuals with the same diagnosis lacking the biomarker.

Preventive action - Action taken to eliminate the cause of a potential nonconformity or any other undesirable potential situation.

Primary source verification report - A document, usually prepared by a third party agent or company that confirms that a job applicant's degree, certificate, or diploma is authentic, licenses were granted, and reported work history (company names, locations, dates and positions held) is accurate. The confirmation is obtained through direct contact with an institution, former employer, or their authorized agents.

Primary specimen - The body fluid, tissue, or sample submitted for examination, study or analysis. It may be within a collection tube, cup, syringe, swab, slide, data file, or other form as received by the laboratory.

Procedure - Set of specific instructions that describe the stepwise actions taken to complete a process, operation, activity, or task.

Process - 1) A set of related tasks or activities that accomplishes a work goal; 2) A set of interrelated or interacting activities that transforms inputs into outputs.

Proficiency testing - Evaluation of participant (laboratory or individual) performance against pre-established criteria by means of interlaboratory comparisons. In some countries, the PT programs for clinical laboratories are called "external quality assessment" programs.

Qualified pathologist - A pathologist who has training in the specific functions to be performed (eg, an anatomic pathologist for anatomic pathology functions, a clinical pathologist for clinical pathology functions, or an anatomic pathologist or dermatopathologist for skin biopsies).

Quality management system (QMS) - A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.

Reagent - Any substance in a test system other than a solvent or support material that is required for the target analyte to be detected and its value measured in a sample.

Reference interval - The range of test values expected for a designated population of individuals.

Report errors - A report element (see GEN.41096) that is either incorrect or incomplete.

Responsibility - A duty or task that an individual is required or expected to do.

Root cause analysis (RCA) - A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.

Scope of Service - The scope of service is the description of the tests/services that the laboratory provides to its customers/clients (eg, tests offered, hours of operation, turnaround times).

Secondary specimen - Any derivative of the primary specimen used in subsequent phases of testing. It may be an aliquot, dilution tube, slide, block, culture plate, reaction unit, data extract file, image, or other form during the processing or testing of a specimen. (The aliquots or images created by automated devices and tracked by internal electronic means are not secondary specimens.)

Section Director - The individual who is responsible for the technical and/or scientific oversight of a specialty or section of the laboratory.

Semiannual - Every 6 calendar months.

Sentinel event - An unexpected occurrence that reaches a patient and results in death, permanent harm, or severe temporary harm, unrelated to the natural cause of the patient's illness or underlying condition.

Subject to US Regulations - Laboratories located within the United States and laboratories located outside of the US that have obtained or applied for a CLIA certificate to perform laboratory testing on specimens collected in the US and its territories for the assessment of the health of human beings.

Telepathology - The practice of pathology and cytology in which digitized or analog video, still image(s), or other data files are examined and an interpretation is rendered that is included in a formal diagnostic report in the patient record. It also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record.

Test - A qualitative, quantitative, or semiquantitative procedure for detecting the presence of, or measuring of an analyte~~.~~.

Testing personnel - Individuals responsible for performing laboratory assays and reporting laboratory results.

Test system - 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 and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

Visitor - An individual entering the laboratory who is not considered personnel.

Waived - A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result." Laboratories performing waived tests are subject to minimal regulatory requirements.

ALL COMMON CHECKLIST

PROFICIENCY TESTING

***REVISED** 12/26/2024*

COM.01200 Activity Menu **Phase I**

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~~.~~ and regardless of PT provider. This includes remote review and interpretation of digitized images and data under the laboratory's CAP/CLIA certificate. ~~Testing performed under a separate CLIA certificate must not be listed on the laboratory's activity menu.~~ ***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 CAP accreditation checklists, the laboratory must also ensure its activity menu is accurate for ~~non-test activities~~other related information, such as methods used and types of services offered. This requirement does not apply to the instrument list.*

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

Testing performed under a separate CLIA certificate must not be listed on the laboratory's activity menu.

*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~~For laboratories subject to CLIA, if patient-specific results are reported ~~from the laboratory~~, the testing is subject to the CLIA regulations and must be ~~reported to~~listed on the CAP Activity Menu.*

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]~~ 35], [42CFR493.53],[42CFR493.63].

*****REVISED** 12/26/2024***

COM.01400 PT Attestation Statement **Phase II**

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~~,~~ and Cytogenetics~~, and Transfusion Medicine~~, refer to specific requirements for the qualifications of section directors/technical supervisors in the associated checklists (HSC.40000~~,~~ and CYG.50000~~, and TRM.50050~~).*
- *For high complexity testing under the specialty of immunohematology, refer to TRM.50050 for the qualifications of the transfusion service medical director (technical supervisor) and designees.*
- *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.~~

***REVISED** 12/26/2024*

COM.01500 Alternative Performance Assessment **Phase II**

For tests for which CAP does not require proficiency testing (PT), the laboratory at least semiannually exercises an alternative performance assessment system for determining the reliability of analytic testing.

NOTE 1: Appropriate alternative performance assessment processes include participation in an external PT program not required by CAP; participation in an ungraded/educational PT program; split sample analysis with another laboratory, split sample analysis with an established in-house method, use of assayed materials, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define alternative performance assessment processes and the criteria for successful performance in accordance with good clinical and scientific laboratory practice. Specimens used for alternative performance assessment must be integrated into the routine workload, where applicable (refer to COM.01600).

NOTE 2: For in situ hybridization testing other than predictive marker testing, and other complex molecular and sequencing-based tests (including but not limited to microarray-based tests, multiplex PCR-based tests, and next generation sequencing-based tests), alternative performance assessment may be performed by method or specimen type rather than for each analyte or tested abnormality. For tests such as allergen testing, alternative performance assessment may be performed using a rotating subset of tests in the menu provided that the subset reflects the handling and testing procedure for the entire menu.

NOTE 3: Semiannual alternative performance assessment must be performed on tests for which external PT is not available.

NOTE 4: This checklist requirement applies to both waived and nonwaived tests.

NOTE 5: Calculated test results derived from directly measured test results (eg, O2 saturation) do not require PT or alternative assessment, with the exception of nonwaived calculated INR, calculated hematocrit, and estimated hemoglobin. PT or alternative performance assessment requirements apply to the measured analytes used to obtain the calculated result.

The list of analytes for which CAP requires enrollment and participation in a CAP-accepted PT program is available on cap.org through e-LAB Solutions Suite under CAP Accreditation Resources, Master Activity Menu Reports. Also, the inspection packet includes a report with this information for each laboratory section/department.

A form, Alternative Performance Assessment (APA) Test List, is available on cap.org through e-LAB Solutions Suite to help laboratories track compliance with this requirement.

Evidence of Compliance:

~~✓ List of tests defined by the laboratory as requiring alternative performance assessments~~ **~~AND~~**

✓ Records of review and evaluation of assessments by the laboratory director or designee

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):7184 [42CFR493.1236(c)(1)]

2) Shahangian S, *et al*. A system to monitor a portion of the total testing process in medical clinics and laboratories. Feasibility of a split-specimen design. *Arch Pathol Lab Med*. 1998;122:503-511
3) Shahangian S, Cohn RD. Variability of laboratory test results. *Am J Clin Pathol*. 2000;113:521-527
4) 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.
5) Schrijver I, Aziz N, Jennings L, Richards CS, Voelkerding KV, Weck KE. Methods-Based Proficiency Testing in Molecular Genetic Pathology. *J Mol Diagn*. May 2014;16(3):283-287.

***REVISED** 12/26/2024*

COM.01520 PT and Alternative Performance Assessment for IHC, ICC, and ISH Predictive Markers **Phase II**

The laboratory participates in the appropriate required proficiency testing (PT) program/external quality assessment (EQA) program accepted by CAP or performs alternative performance assessment for all predictive markers performed using immunohistochemistry (IHC), immunocytochemistry (ICC), and in situ hybridization (ISH) methods, as required in the note.

NOTE: Information on analytes that require enrollment and participation in a CAP-accepted PT program is available on the CAP website [cap.org] through e-LAB Solutions Suite under CAP Accreditation Resources, Master Activity Menu Reports. Also, the inspection packet includes a report with this information for each laboratory section/department. The CAP Office audits PT participation to assure that accredited laboratories participate in appropriate PT.

For laboratories not subject to US regulations, participation in PT must be through CAP PT programs only. Laboratories may use acceptable alternatives when the CAP is unable to deliver PT due to oversubscribed programs, stability issues or customs denial, contingent on CAP approval. If unable to participate, however, the laboratory must implement an alternative performance assessment procedure for the affected analytes.

The following table includes requirements for participation in PT or alternative performance assessment that must be followed for each predictive marker tested by IHC, ICC, or ISH:

Extent of Service	Requirement
Predictive marker IHC stain and interpretation performed at the same laboratory	*The laboratory must participate in CAP-accepted PT when required (refer to the Activity Menu).*
Predictive marker IHC stain and interpretation performed at different laboratories	*Both the stain only and interpretation only laboratories must perform alternative performance assessment at least semiannually, which may be satisfied by participation in a PT program~~.~~ *.*
Predictive marker hybridization and ISH interpretation performed at the same laboratory	*The laboratory must participate in CAP-accepted PT when required (refer to the Activity Menu).*
Predictive marker hybridization and ISH interpretation performed at different laboratories	*Both hybridization only and interpretation only laboratories must perform alternative performance assessment at least semiannually.* *The laboratory must not participate in formal (external) PT if the hybridization and interpretation are performed at different laboratories. Participation in formal PT would constitute PT referral.*
Other predictive marker testing performed by IHC, ICC, and ISH for which the CAP does not require proficiency testing (eg, ~~PD-L1.~~DNA MMR)	*The laboratory must perform alternative performance assessment at least semiannually.*

**For laboratories that do not perform IHC staining on site, IHC slides are permitted to be sent to another facility for staining only. This is not permitted for ISH slides.*

Laboratories interpreting HER2 for breast predictive marker testing by multiple methods must participate in the required PT or perform alternative performance assessment as described above for each method.

Evidence of Compliance:

✓ Records such as CAP PT order confirmation for predictive markers where CAP-accepted PT programs are required **OR** record of completed/submitted result forms **OR**

✓ Records of alternative performance assessment for IHC, ICC, and ISH predictive markers for which the CAP does not require participation in a PT program

REFERENCES

1) Wolff AC, Somerfield MR, Dowsett M, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. *Arch Pathol Lab Med.* Published online June 7, 2023. doi: 10.5858/arpa.2023-0905-SA.
2) Nakhleh RE, Grimm EE, Idowu MO, *et al*. Laboratory compliance with the American Society of Clinical Oncology/College of American Pathologists (ASC/CAP) guidelines for human epidermal growth factor 2 (HER2) testing: a College of American Pathologists survey of 757 laboratories. *Arch Pathol Lab Med* 134:728-34, 2010.
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) Allison KH, Hammond ME, Dowsett M, et al. Estrogen and progesterone receptors in breast cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. *Arch Pathol Lab Med.* 2020;144(5):545-63.

*****REVISED** 12/26/2024***

COM.01700 PT and Alternative Performance Assessment Result Evaluation Phase II

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 timeframe for investigation should be appropriate for the determination of any impact on patient ~~test~~ results ~~and correct problems identified. It is recommended that~~. The CAP recommends, but does not require, the laboratory to investigate acceptable results that show significant bias or trends.

For guidance on investigating unacceptable PT/alternative performance assessment results, refer to the Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox on the CAP website (www.cap.org) through e-LAB Solutions Suite.

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~~2023(Dec 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.

QUALITY MANAGEMENT

GENERAL ISSUES

COM.04100 Supervisory Review for High Complexity Testing **Phase II**

In the absence of on-site supervisors, high complexity testing performed by trained high school graduates qualifying as high complexity testing personnel is reviewed by the laboratory director or supervisor/general supervisor within 24 hours.

NOTE: The CAP does NOT require supervisory review of all test results before or after reporting to the patient record. Rather, this requirement is intended to address only that situation for "high complexity testing" performed by trained high school graduates qualifying under the CLIA regulation 42CFR493.1489(b)(5~~)(i~~) when a qualified supervisor/general supervisor is not present.

A detailed listing of personnel qualifications to perform high complexity testing can be found in e-Labs Solution Suite on cap.org (log-in required) under Accreditation Resources.

Evidence of Compliance:
✓ Records of result review for specified personnel

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):7182 [42CFR493.1463(a)(3) and 42CFR493.1463(c)]: 7183 [42CFR493.1489(b)(1)] and [42CFR493.1489(b)(5)]

*****REVISED** 12/26/2024***

COM.04200 Instrument/Equipment Record Review **Phase II**

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

~~*NOTE:*~~*NOTE: Appropriate evidence of review includes both the reviewer's signature or initials and the review date. 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

***REVISED** 12/26/2024*

COM.04250 Comparability of Instruments and Methods - Nonwaived Testing Phase II

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 calendar 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*
- *Instruments/equipment that do not provide a reportable result (eg, microscopes, stainers)*

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 which identify an organism by detecting different analyte characteristics (eg, antigen typing versus culture ~~or~~, detection of DNA versus a biochemical characteristic~~) designed to detect the same analyte.~~, MALDI-TOF versus phenotypic/biochemical microbial identification).

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

SPECIMEN COLLECTION AND HANDLING

***REVISED** 12/26/2024*

COM.06250 Specimen Aliquoting and Shared/Residual Samples **Phase II**

The process used for aliquoting specimens or use of shared or residual specimen for additional or reflex testing prevents cross-contamination and mix up of specimens and aliquots.

NOTE: ~~Aliquots must not be returned~~This requirement applies to ~~the original specimen container for~~ both in-house shared specimens ~~to be used for molecular-based testing or forensic drug testing, or for biorepository storage. For~~ and specimens ~~used for other types of testing, the~~referred to another laboratory. Laboratories referring specimens for testing must follow the specimen handling instructions provided by the referral laboratory.

The laboratory must consider contamination and the potential for specimen mix up when defining its ~~procedure.~~

aliquoting procedures. If previously aliquoted specimens are used for additional testing, the procedure must define when and how they can be used. Aliquots must not be returned to the original specimen container.

Common examples of situations where specimens are sent for additional testing by molecular-based methods include the use of liquid based cervical cytology specimens for HPV, C. trachomatis, or N. gonorrhoeae testing, and HCV or HIV antibody testing specimens for reflex to nucleic acid amplification testing. These situations need to be carefully evaluated to prevent specimen alteration or contamination during processing and testing.

POLICY AND PROCEDURE MANUAL

COM.10000 Policy and Procedure Manual **Phase II**

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~~ steps in the laboratory's testing~~, functions~~ and~~/or~~ other technical processes must be defined in written policies and/or procedures. ***Procedures must ~~match the laboratory's~~ be consistent with current laboratory 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~~

NOTE 6: 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~~*Developing and* ~~Management of~~*Managing Laboratory* ~~documents; Approved Guideline - Sixth Edition.~~*Documents*. 7th ed. CLSI ~~document~~guideline QMS02~~-A6 (ISBN 1-56238-869-X).~~. Clinical and Laboratory Standards Institute, ~~940 West Valley Road, Suite 1400,~~ Wayne, ~~Pennsylvania 19087 USA, 2013~~PA; 2024.

RESULTS REPORTING

~~**COM.29950 Reference Intervals Merged with GEN.41096 Phase II**~~

~~**All patient/client results are reported with reference (normal) intervals or interpretations as appropriate.**~~

~~*NOTE: The laboratory must report reference intervals or interpretations with patient/client results, where such exist to allow for proper interpretation of patient/client data. Age- and/or sex-specific reference intervals or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags is recommended. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions, which are based on the test result (eg, activated clotting time in cardiac surgery).*~~

~~*Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is acceptable if rigidly controlled.*~~

~~REFERENCES~~
~~1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7162 [42CFR493.1291(d)]~~
~~2) Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition.* CLSI Document EP28-A3c. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.~~

REAGENTS

***REVISED** 12/26/2024*

COM.30450 New Reagent Lot and Shipment Confirmation of Acceptability - Nonwaived Tests Phase II

New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service.

NOTE: This requirement applies to reagents that provide a chemical or biological reaction to detect and/or measure a target analyte and would not apply to inert ingredients (eg, reagent water, saline) or materials used for specimen preparation.

The purpose of this check is to confirm that the use of new analytic reagent lots and shipments (including different shipments of the same lot) do not affect patient results. Matrix interferences

between different lots of reagents may impact the calibration status of instruments and consistency of patient results. Improper storage conditions during shipping of reagents may have a negative impact on their ability to perform or exhibit the same levels of reactivity as intended.

The minimum extent of the reagent check is described below; however, the check must be at least as extensive as described in the manufacturer's instructions. The laboratory may determine the number of specimens tested.

***Qualitative**: For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative specimen with known reactivity against the new reagent lot. Utilization of a weakly positive specimen is recommended for confirmation of acceptability.*

Examples of suitable reference materials for qualitative tests include:
- *Positive and negative patient specimens tested on a previous lot;*
- *Previously tested proficiency testing materials;*
- *External QC materials tested on the previous lot (eg, antigen testing kit controls, immunohematology antisera and reagent red cells)*
- *Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms;*
- *~~If~~If there is documentation that none of the above options is available, control material provided by the assay manufacturer with the new test kit.*

There are more specific requirements in other checklists for some types of qualitative testing, such as:
- *Flow cytometry antibodies and reagents (FLO.23325)*
- *Microbiology media and stains, disks/strips, antimicrobials, and reagents (eg, MIC.11038, MIC.21540, MIC.21560, MIC.21624, MIC.21626, MIC.21910, MIC.65320)*
- *Immunohistochemistry antibody and detection system reagents (ANP.22760, CYP.04380, BAP.05363).*

***Quantitative**: For quantitative nonwaived tests, patient specimens are preferred for comparing a new lot against the previous lot, when possible. Manufactured materials, such as proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots, even if results show no change following a reagent lot change. The use of patient specimens confirms the absence of matrix interference. The following materials may be used:*
- *Patient specimens tested on a previous lot*
- *Reference materials or QC products provided by the method manufacturer with method specific and reagent lot specific target values*
- *Proficiency testing materials with peer group established means*
- *QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories*
- *Third-party general purpose reference materials if commutable with patient specimens for the method (per package insert or method manufacturer)*
- *QC material in use with the current reagent lot to check a new shipment of the same reagent lot (There should be no change in potential matrix interactions with use of the same lot number of reagent and QC material).*

For ~~hematology~~automated analyzers~~,~~ that use reservoirs ~~containing~~for testing reagents and cleaning/decontaminating solutions ~~must be checked according to~~(eg, many hematology analyzers, some urine analyzers, etc.), the laboratory must define the process for checking new lots of reagents and solutions. Any manufacturer's instructions must be followed.

Evidence of Compliance:

✓ Records for the introduction of new lots and shipments, including lot number(s) tested and comparison of results to the acceptability criteria

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Matrix Effects.* 4th ed. CLSI document EP14. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

2) 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.
3) Miller WG, Myers GL, Rej R. Why commutability matters. *Clin Chem.* 2006;52:553-554
4) Clinical and Laboratory Standards Institute (CLSI). *User Evaluation of Acceptability of a Reagent Lot Change.* 2nd ed. CLSI guideline EP26. Clinical and Laboratory Standards Institute. Wayne, PA; 2022.

INSTRUMENTS AND EQUIPMENT

***REVISED** 12/26/2024*

COM.30600 Maintenance/Function Checks **Phase II**

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.

It is up to the laboratory to determine how and where records of maintenance checks are recorded. Equipment not in use does not require maintenance or function checks, but these checks must be performed before putting the equipment back into service.

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 (CLSI). *General Laboratory Equipment Performance Qualification, Use, and Maintenance.* 2nd ed. CLSI guideline QMS23. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.

Temperature-Dependent Instruments, Equipment, and Environments

***REVISED** 12/26/2024*

COM.30750 Temperature Checks **Phase II**

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.** 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. 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~~.~~ before using any temperature-dependent equipment, kits, or supplies. 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****.* ***Temperature-dependent testing devices with built-in fail-safe technology that will disable utilization if temperatures are out of range are exempted from the daily check.*** *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. This does not require routine daily review of the system records.

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 (CLSI). *General Laboratory Equipment Performance Qualification, Use, and Maintenance.* 2nd ed. CLSI guideline QMS23. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.
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)].

TEST METHOD VALIDATION AND VERIFICATION - NONWAIVED TESTS

NOTE: This section does not apply to waived tests performed following manufacturer's instructions.

ANALYTICAL VALIDATION/VERIFICATION

Analytical verification is the process by which a laboratory determines that an unmodified FDA-cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed. Analytical validation is the process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application. See below for requirements for laboratories not subject to US regulations.

Laboratories are required to perform analytical validation or verification of each nonwaived test, method, or instrument system before use in patient testing, regardless of when it was first introduced by the laboratory, including instruments of the same make and model and temporary replacement (loaner) instruments. ***There is no exception for analytical validation or verification of tests introduced prior to a specific date.*** *The laboratory must have data for the validation or verification of the applicable method performance specifications and retain the records as long as the method is in use and for at least two years after discontinuation.*

If an FDA-cleared or approved method was verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must ensure that the verification correlates with its in-house test performance by showing confirmation of performance specifications by laboratory personnel testing known specimens.

The method performance specifications (ie, the applicable analytic performance characteristics of the test, such as accuracy, precision, etc.) must be validated or verified in the location in which patient testing will be performed. If an instrument is moved, the laboratory is responsible for determining that the method performance specifications are not affected by the relocation process or any changes due to the new environment (eg, refer to the manufacturer's manual regarding critical requirements, such as set-up limitations, environmental conditions, etc.). The laboratory must follow manufacturer's instructions for instrument set up, maintenance, and system verification. Separate requirements for verifying the performance of instruments and equipment to confirm that they function according to expectations for the intended use and within the defined tolerance limits are found in the Instrument and Equipment Maintenance and Function Checks section (COM.30550, COM.30600).

QUALITATIVE TESTING

Not all method performance specifications apply to qualitative tests. For qualitative tests, the laboratory must verify or establish the method performance specifications that are applicable and clinically relevant.

LABORATORIES SUBJECT TO US REGULATIONS:

- *For unmodified FDA-cleared or approved tests, the laboratory may use information from manufacturers, or published literature, but the laboratory must verify such outside information on accuracy, precision, reportable range, and reference intervals.*
- *For modified FDA-cleared or approved tests and laboratory-developed tests (LDTs), the laboratory must establish accuracy, precision, analytical sensitivity, analytical specificity (interferences), reportable range, and reference intervals, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable.*

LABORATORIES NOT SUBJECT TO US REGULATIONS:

- *For laboratories performing tests approved by an internationally recognized regulatory authority (eg, the European Union's Conformité Européenne (CE) Marking), the laboratory may use information from manufacturers, or published literature, but the laboratory must verify such outside information on accuracy, precision, reportable range, and reference intervals. Analytical verification must also follow national, federal, state (or provincial), and local laws and regulations for approval and usage of such tests. These instruments and devices are not considered laboratory-developed tests in laboratories not subject to US regulations.*
- *For tests not approved by an internationally recognized regulatory authority, the laboratory must perform analytic validation to establish accuracy, precision, analytic sensitivity, analytical specificity (interferences), reportable range, and reference intervals, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable.*

<u>LABORATORY-DEVELOPED TESTS:</u>
For the purposes of interpreting the checklist requirements, a laboratory-developed test (LDT) is defined as follows: A test used in patient management that has both of the following features:

1. *The test is performed by the clinical laboratory in which the test was developed wholly or in part;* ***AND***
2. *The test is neither FDA-cleared nor FDA-approved (or, for laboratories not subject to US regulations, the test is not approved by an internationally recognized regulatory authority).*

CONTRACT RESEARCH ORGANIZATION (CRO) LABORATORIES
For tests performed strictly for research purposes, the laboratory may accept validation/verification studies performed by the sponsor or manufacturer contracting with the laboratory. The laboratory must retain records showing:

1. *Attestation by the manufacturer (or contractor) that the test was validated/verified;* ***AND***
2. *How the test is used, and attestation that the test is used for research only and will not be accessible for clinical purposes.*

If a test result is used to render any decision that may affect the study subject, even if only to determine enrollment, continued participation of an individual in a study, or as an outcome measure in a clinical trial, the testing is considered patient testing, and the laboratory is responsible for performing on-site analytic validation or verification of the test.

EMERGENCY USE AUTHORIZATION (EUA)
For laboratories subject to US regulations, an emergency use authorization (EUA) is the legal mechanism used by the FDA or other entities as designated by the US Department of Health and Human Services (HHS) Secretary to allow the use of an unapproved medical product (eg, diagnostic device) or an unapproved use of an approved medical product during an emergency to diagnose, treat, or prevent a serious or life threatening disease condition caused by a chemical, biological, radiological, or nuclear agent (CBRN). An EUA assay is not considered a laboratory-developed test. For purposes of accreditation, laboratories using an EUA assay must follow checklist requirements for FDA-cleared/approved methods.

Laboratories must verify the test method performance specifications as applicable to the test's FDA-designed authorized setting, which can be found in the EUA Letter of Authorization.

- *For tests authorized for use in a patient care setting, the laboratory must follow manufacturer's instructions for waived test implementation (COM.30980) at minimum.*
- *For tests authorized for use in moderate or high complexity testing laboratories only, laboratories must verify the test method performance specifications as defined in COM.40300 and follow manufacturer's instructions for verification, if provided. While the objective is to fully verify the test method performance specifications, a more limited approach is acceptable if sufficient numbers and types of positive specimens and standard materials are unavailable (eg, early in an emergency disease outbreak, with outbreaks that are geographically limited, or with agents that pose a particularly high biosafety risk).*

Laboratories using an EUA assay must follow the assay or test system's protocol as authorized by the FDA without modification, except for modifications allowed by the FDA. Note that the FDA and the CAP may require studies prior to implementing certain modifications. The laboratory must document any alternative mechanism employed to ensure accurate test results.

Under emergency conditions, sampling devices and transport media may become limited and it may be necessary to obtain them from multiple sources. If EUA regulations specifically address these items, the laboratory must follow them. Otherwise, the laboratory director or designee meeting CAP director qualifications has discretion to determine which devices and media are acceptable for use; a full, formal verification study for each device or media is not necessarily required, but the laboratory must have defined criteria for specimen acceptance.

Information on current EUA assays can be found on the FDA website (www.fda.gov).

Laboratories not subject to US regulations may use US FDA EUA assays or other types of assays (eg, World Health Organization Emergency Use Listing) as allowed by national, federal, state (or provincial), or local regulations.

***REVISED** 12/26/2024*

COM.40300 Verification of Test Performance Specifications - FDA-cleared/approved Tests **Phase II**

Prior to clinical use of each unmodified FDA-cleared or approved test, the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

1. **Analytical accuracy**
2. **Analytical precision**
3. **Reportable range**

NOTE 1: This requirement also applies to tests with FDA emergency use authorization (EUA) in moderate or high complexity testing laboratory settings.

NOTE 2: Accuracy is verified by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to verify accuracy. The use of routine quality control materials or calibrators used to calibrate the method is not appropriate.

NOTE 3: Precision is verified by repeat measurement of samples at varying concentrations/activities within run and between run over a period of time.

NOTE 4: The reportable range of an assay is the range of test result values over which the laboratory has verified accuracy of the instrument or test system measurement response.

NOTE 5: If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device.

NOTE 6: If a method is verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must have records to show that the verification correlates with its in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens.

NOTE 7: The requirement for a written assessment applies to all tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical verification, regardless of the implementation date. The written assessment must include an evaluation of each component of the verification study, including the acceptability of the data. If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use.

Templates for analytical verification written assessment can be found on cap.org in e-LAB Solutions Suite - Accreditation Resources - Templates.

NOTE 8: For contract research organization (CRO) laboratories: For tests performed strictly for research purposes, the laboratory may accept verification studies performed by the sponsor or manufacturer contracting with the laboratory. The laboratory must retain records showing: 1) attestation by the manufacturer (or contractor) that the test was verified; and 2) how the test is used, and attestation that the test is used for research only and will not be accessible for clinical purposes.

If a test result is used to render any decision that may affect the study subject, even if only to determine enrollment, continued participation of an individual in a study, or as an outcome measure in a clinical trial, the testing is considered patient testing, and the laboratory is responsible for performing on-site analytic verification of the test.

Evidence of Compliance:

✓ Records of verification and written assessment of each component of the test method performance specifications for each test

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) [42CFR493.1253]
2) Clinical and Laboratory Standards Institute. (CLSI). *Preliminary Evaluation of Quantitative Clinical Medical Laboratory Methods; Approved Guideline.* 3rd *Measurement Procedures.* 4th ed. CLSI document guideline EP10-A3-AMD. Clinical and Laboratory Standards Institute, Wayne, PA; 2014 2024.
3) Clinical and Laboratory Standards Institute. (CLSI). *A Framework for Using CLSI documents Documents to Evaluate Clinical Medical Laboratory Measurement Procedures; 2nd Test Methods.* 3rd ed. CLSI report EP19-ED2 Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 2015 2022.
4) Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline. 3rd ed.* CLSI document EP05-A3. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.
5) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Matrix Effects.* 4th ed. CLSI document EP14. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

***REVISED** 12/26/2024*

COM.40325 Verification of Test Performance Specifications - Tests Approved by an Internationally Recognized Regulatory Authority - Laboratories not Subject to US Regulations **Phase II**

For laboratories not subject to US regulations, prior to clinical use of each test approved by an internationally recognized regulatory authority (eg, the European Union's Conformité Européenne (CE) Marking), the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

1. **Analytical accuracy**
2. **Analytical precision**
3. **Reportable range**
4. **Any other performance characteristic required to ensure analytical test performance**

NOTE 1: Accuracy is verified by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to verify accuracy. The use of routine quality control materials or calibrators used to calibrate the method is not appropriate.

NOTE 2: Precision is verified by repeat measurement of samples at varying concentrations or activities within run and between run over a period of time.

NOTE 3: The reportable range of an assay is the range of test result values over which the laboratory has verified accuracy of the instrument or test system measurement response.

NOTE 4: The laboratory must also validate analytic sensitivity (lower detection limit) and analytic specificity (interferences) if the test manufacturer has not documented these test characteristics. Data on interferences may be obtained from manufacturers or published literature, as applicable. The laboratory must validate other relevant analytic characteristics not documented by the test manufacturer, as appropriate.

NOTE 5: If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately verified for each test and instrument or device.

NOTE 6: If a method is verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must have records to show that the verification correlates with in-house test performance by showing confirmation of performance specifications by the laboratory personnel testing known specimens.

NOTE 7: The requirement for a written assessment applies to all tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical verification,

regardless of the implementation date. The written assessment must include an evaluation of each component of the verification study, including the acceptability of the data; If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use.

Templates for analytical verification written assessment can be found on cap.org in e-LAB Solutions Suite - Accreditation Resources - Templates.

NOTE 8: For contract research organization (CRO) laboratories: For tests performed strictly for research purposes, the laboratory may accept verification studies performed by the sponsor or manufacturer contracting with the laboratory. The laboratory must retain records showing: 1) attestation by the manufacturer (or contractor) that the test was verified; and 2) how the test is used, and attestation that the test is used for research only and will not be accessible for clinical purposes.

If a test result is used to render any decision that may affect the study subject, even if only to determine enrollment, continued participation of an individual in a study, or as an outcome measure in a clinical trial, the testing is considered patient testing, and the laboratory is responsible for performing on-site analytic verification of the test.

Evidence of Compliance:

✓ Records of the test method performance specifications for each test

REFERENCES

1) Clinical and Laboratory Standards Institute. (CLSI). *Preliminary Evaluation of Quantitative Clinical Medical Laboratory Methods; Approved Guideline.* 3rd *Measurement Procedures.* 4th ed. CLSI document guideline EP10-A3-AMD. Clinical and Laboratory Standards Institute., Wayne, PA; 2014. 2024.
2) Clinical and Laboratory Standards Institute. (CLSI). *A Framework for Using CLSI Documents to Evaluate Clinical Medical Laboratory Measurement Procedures.* 2nd *Test Methods.* 3rd ed. CLSI report EP19-ED2Ed3. Clinical and Laboratory Standards Institute., Wayne, PA; 2015. 2022.
3) Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline.* 3rd ed. CLSI document EP05-A3. Clinical and Laboratory Standards Institute. Wayne, PA; 2014.
4) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Matrix Effects.* 4th ed. CLSI document EP14. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

***REVISED** 12/26/2024*

COM.40350 Validation of Test Performance Specifications - Modified FDA-cleared/approved Tests and LDTs **Phase II**

Prior to clinical use of each modified FDA-cleared or approved test and laboratory-developed tests (LDTs), the laboratory has performed a validation study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

- **Analytical accuracy**
- **Analytical precision**
- **Reportable range**
- **Analytical sensitivity (lower detection limit)**
- **Analytical specificity**
- **Any other performance characteristic required to ensure analytical test performance**

NOTE 1: For laboratories not subject to US regulations, this requirement also applies to:

- *Tests that are not approved by an internationally recognized regulatory authority*
- *Approved tests that have been modified by the laboratory*

NOTE 2: Accuracy is validated by comparing results to a definitive or reference method, or an established comparative method. Use of matrix-appropriate reference materials, patient specimens (altered or unaltered), or other commutable materials with known concentrations or activities may be used to validate accuracy. The use of routine quality control materials or calibrators used to calibrate the method is not appropriate.

For laboratory-developed tests, an appropriate number of samples to demonstrate analytical accuracy is defined as the following:

- *For quantitative tests, a minimum of 20 samples with analyte concentrations distributed across the analytical measurement range should be used. Proportionate mixtures of samples may be used to supplement the study population.*
- *For qualitative tests, a minimum of 20 samples, including positive, negative, and low-positive samples with concentrations near the lower level of detection should be used; equivocal samples should not be used.*
- *For certain methods that test multiple analytes (eg, next-generation sequencing, HPLC, GC-MS, MALDI-TOF, etc.), analytic accuracy may be established for each method (not necessarily each analyte), as appropriate.*

If the laboratory uses fewer samples, the laboratory director must record the criteria used to determine the appropriateness of the sample size. In many cases, a validation study with more samples is desirable.

For LDTs in use prior to July 31, 2016, for which limited validation studies are recorded, ongoing data supporting acceptable test performance may be used to meet the above minimum sample requirement, unless the laboratory director has recorded the criteria used to determine the acceptability of a smaller sample size. Examples of such ongoing data include records of proficiency testing, alternative performance assessment, quality control, and correlation with clinical data.

NOTE 3: Precision is validated by repeat measurement of samples at varying concentrations or activities within-run and between-run over a period of time.

NOTE 4: The reportable range of an assay is the range of test result values over which the laboratory has established accuracy of the instrument or test system measurement response

NOTE 5: Analytical sensitivity is the lowest concentration or amount of the analyte or substance that can be measured or distinguished from a blank (lower limit of detection).

NOTE 6: Analytical specificity refers to the ability of a test or procedure to correctly identify or quantify an entity in the presence of interfering or cross-reactive substances that might be expected to be present. Laboratories are encouraged to review the published literature for guidance on analytical specificity.

NOTE 7: Examples of other performance characteristics required for analytical test performance include specimen stability, reagent stability, linearity, carryover, and cross-contamination, as appropriate and applicable.

NOTE 8: If multiple identical instruments or devices are in use, there must be records (data and written assessment) showing that the method performance specifications have been separately validated for each test and instrument or device.

NOTE 9: The requirement for a written assessment applies to all tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical validation, regardless of the implementation date. The written assessment must include an evaluation of each component of the validation study, including the acceptability of the data. If data include discordant results, there must be a record of the discordance and investigation of any impact on the approval of the test for clinical use.

Templates for analytical verification written assessment can be found on cap.org in e-LAB Solutions Suite - Accreditation Resources - Templates.

~~*NOTE 10*~~*NOTE 10: For contract research organization (CRO) laboratories: For tests performed strictly for research purposes, the laboratory may accept validation studies performed by the sponsor or manufacturer contracting with the laboratory. The laboratory must retain records showing: 1) attestation by the manufacturer (or contractor) that the test was validated, and 2)*

how the test is used, and attestation that the test is used for research only and will not be accessible for clinical purposes.

If a test result is used to render any decision that may affect the study subject, even if only to determine enrollment, continued participation of an individual in a study, or as an outcome measure in a clinical trial, the testing is considered patient testing, and the laboratory is responsible for performing on-site analytic validation of the test.

NOTE 11: This checklist requirement does not apply to LDTs that employ the following methods:

- *Manual microscopy (eg, histopathologic and cytologic interpretation, microscopic examination of blood or body fluids, Gram stains)*
- *Conventional microbiologic cultures ~~and disc/broth/tube susceptibility studies~~*

Evidence of Compliance:

✓ Records of validation and written assessment of each component of the test method performance specifications

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) [42CFR493.1253]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
3) Clinical and Laboratory Standards Institute~~.~~ (CLSI). *A Framework for Using CLSI ~~documents~~Documents to Evaluate ~~Clinical~~Medical Laboratory ~~Measurement Procedures. 2nd~~Test Methods.* 3rd ed. CLSI report EP19-~~ED2~~Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2015~~2022.
4) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline. 2nd ed.* CLSI document EP17-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2012.
5) Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline.* 3rd ed. CLSI document EP05-A3. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.
6) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Matrix Effects.* 4th ed. CLSI document EP14. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

***REVISED** 12/26/2024*

COM.50400 Quality Control Plan Approval **Phase II**

The IQCP includes a written quality control plan approved by the laboratory director prior to implementation.

NOTE: The quality control plan may be part of a test procedure or be a separate written plan. As an efficiency, a single plan may address multiple tests performed on one device. A separate, quality control plan approved by the laboratory director must be in place for each laboratory with a separate CAP and CLIA number.

The approval of the IQCP may not be delegated in laboratories subject to the CLIA regulations.

REFERENCES

1) Clinical and Laboratory Standards Institute~~.~~ (CLSI). *Laboratory Quality Control Based on Risk Management~~; Approved Guideline~~.* 2nd ed. CLSI document EP23-~~A~~. Clinical and Laboratory Standards Institute. Wayne, PA; ~~2011~~2023.
2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Brochure #13. CLIA Individualized Quality Control Plan, What is an IQCP? November 2014. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf Accessed January 12, 2016.