



COLLEGE of AMERICAN
PATHOLOGISTS

Master

All Common Checklist

CAP Accreditation Program



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All Common Checklist



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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists 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.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES

All Common Checklist

12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
 - Modifications that may require a change in policy, procedure, or process for continued compliance; or
 - A change to the Phase
3. Deleted/Moved/Merged:
 - Deleted
 - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
 - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
COM.30695	08/24/2023

REVISED Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
COM.01200	12/26/2024
COM.01400	12/26/2024
COM.01500	12/26/2024
COM.01520	12/26/2024
COM.01600	08/24/2023
COM.01700	12/26/2024
COM.01900	08/24/2023
COM.04200	12/26/2024
COM.04250	12/26/2024
COM.04300	08/24/2023
COM.06250	12/26/2024
COM.30450	12/26/2024
COM.30575	08/24/2023
COM.30600	12/26/2024
COM.30750	12/26/2024
COM.40300	12/26/2024
COM.40325	12/26/2024
COM.40350	12/26/2024
COM.40850	08/24/2023
COM.50400	12/26/2024

DELETED/MOVED/MERGED Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
COM.29950	12/25/2024

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 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 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.

Comutable - 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 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 (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 (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 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 - Biomarker used independent of histologic findings to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy, 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

The extent of a laboratory's proficiency testing (PT) and alternative performance assessment policies and procedures must be sufficient for the extent and complexity of testing performed in the laboratory. They must address preanalytic, analytic, and post analytic processes, such as:

- Enrollment in required PT or development of alternative performance assessment processes
- Proper handling and analysis of testing materials
- Review and reporting of results
- Evaluation of results
- Investigation of each unacceptable result to evaluate the impact on patient test results and to correct problems identified in a timely manner.

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of proficiency testing policies and procedures • Sampling of evaluations of unacceptable proficiency testing results • Sampling of proficiency testing records including intermediate worksheets, instrument printouts or interfaced results, proficiency testing result forms (paper or online), signed attestation statement and laboratory director/designee review • Records of semiannual alternative performance assessment testing, if applicable • Sampling of self-evaluations of ungraded proficiency testing results, if applicable
	<ul style="list-style-type: none"> • How are testing personnel selected to perform a proficiency testing challenge? • What steps do you follow when you are assigned to perform proficiency testing? • In what situations would you repeat a proficiency testing specimen? • What do you consider unacceptable proficiency testing performance and how do you determine corrective action? • How do you evaluate ungraded proficiency testing?
	<ul style="list-style-type: none"> • Select a representative sampling of proficiency testing results and follow records from kit receipt, selection of personnel to perform testing, test performance, use of intermediate worksheets, instrument printouts or interfaced results, and completion of proficiency testing result forms (paper or online), to the submission of results to the proficiency testing provider. Determine if the specimen and results are being handled in compliance with requirements and following laboratory policies and procedures. • Select a representative sampling of unacceptable proficiency testing results and follow records from original testing to final determination of root cause. Determine if the procedures and processes produce a thorough investigation with appropriate corrective action taken • Select an analyte with an unacceptable proficiency testing event and review records for the subsequent proficiency testing event for that analyte. Closely examine the testing records to confirm that the specimens were handled and reported in the same manner as patient specimens (COM.01600) and following laboratory policy and procedure. Determine if any inappropriate actions were taken to ensure an acceptable event score such as duplicate testing of specimens when not indicated in laboratory policy. • Compare tests listed on the laboratory's CAP Activity Menu to those listed on the laboratory's test requisition(s), computer order screens, procedure manuals, instrument

list, or patient reports and discuss potential discrepancies with responsible personnel. Determine if the CAP Activity Menu accurately reflects testing and activities performed.

COM.01100 Ungraded PT Challenges

Phase II



The laboratory director or designee assesses its performance on proficiency testing (PT) challenges that are ungraded.

NOTE: Examples include, but are not limited to:

- *PT challenges that were intended to be graded, but were not, for reasons such as:*
 - *The laboratory submitted its results after the cut-off date*
 - *The laboratory did not submit results*
 - *The laboratory did not complete the result form correctly (eg, submitted the wrong method code or recorded the result in the wrong place)*
 - *The laboratory's result was not graded because of lack of consensus*
- *Educational PT challenges*

PT records must show that ungraded PT results are evaluated for acceptable performance with investigation and corrective action taken for unacceptable results as required in COM.01700. A signature on the PT report without any notation on the acceptability of ungraded results does not meet the intent of this requirement.

The laboratory must define how it assesses performance on ungraded PT challenges and how the assessments are recorded.

Evidence of Compliance:

- ✓ Records of review and evaluation of ungraded PT challenges by the laboratory director or designee

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):3705 [42CFR493.1236(a)(2)]

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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. 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 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 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. For laboratories subject to CLIA, if patient-specific results are reported, the testing is subject to the CLIA regulations and must be 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) [42CFR493.35], [42CFR493.53],[42CFR493.63].

COM.01300 PT Participation

Phase II

The laboratory participates in the appropriate required proficiency testing (PT)/external quality assessment (EQA) program accepted by CAP for the patient testing performed.

NOTE 1: 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.

NOTE 2: This checklist requirement applies to both waived and nonwaived tests.

NOTE 3: For laboratories subject to US regulations, participation in proficiency testing may be through CAP PT Programs or another proficiency testing provider accepted by CAP. Laboratories will not be penalized if they are unable to participate in an oversubscribed program. If unable to participate, however, the laboratory must implement an alternative performance assessment procedure for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, Centers for Medicare and Medicaid Services (CMS) requires the laboratory to attempt to enroll in another CMS-approved PT program.

Laboratories must participate in one CAP-accepted PT program for each required analyte for a minimum of one year before designating a different CAP-accepted PT program for PT compliance and reporting to the CMS. If a laboratory enrolls in PT mid-year due to a new application for accreditation or the introduction of new testing, the laboratory may change to another CAP-accepted PT provider at the next enrollment period without waiting a full year. If a laboratory enrolls in PT from multiple PT providers for one required analyte, it must designate only one PT provider to submit a performance score to the CMS for the year.

NOTE 4: For laboratories not subject to US regulations, participation in proficiency testing 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.

NOTE 5: Refer to COM.01520 for PT and alternative performance assessment requirements for predictive marker testing performed using immunohistochemistry and *in situ* hybridization methods.

NOTE 6: For purposes of photograph/image identification in CAP PT Programs, it is strongly recommended that current educational resources be available to the bench technologist. Examples include the bench top resource guides, color atlases, and the Surveys Hematology Glossary, as applicable.

Evidence of Compliance:

- ✓ Records such as CAP PT order confirmation indicating that the laboratory is enrolled in CAP PT Programs for all analytes that CAP requires PT **OR** record of completed/submitted result forms for all analytes on the activity menu

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]
- 2) 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.
- 3) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation*. Northfield, IL: CAP; 2023.

****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, refer to specific requirements for the qualifications of section directors/technical supervisors in the associated checklists (HSC.40000 and CYG.50000).
- For high complexity testing under the specialty of immunochemistry, 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)]

****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:

- ✓ 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, 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 (ASCO/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.

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COM.01600 PT and Alternative Performance Assessment Specimen Testing

Phase II



The laboratory integrates all proficiency testing (PT) and alternative performance assessment specimens within the routine laboratory workload, where applicable, and those specimens are analyzed by personnel who routinely test patient/client specimens, using the same primary method systems as for patient/client specimens.

NOTE: Repetitive analysis of any proficiency specimen by one or more individuals is acceptable only if patient/client specimens are routinely analyzed in the same manner. An individual may seek assistance from other on-site personnel for morphologic examinations (identification of cell types and microorganisms) or data review (eg, for electrophoretic patterns) for proficiency testing specimens only if patient specimens are handled in the same manner, as defined by the laboratory's policies and procedures.

Laboratories that are subject to regulation by the Centers for Medicare and Medicaid Services (CMS) are not permitted to test the same analyte from the same PT product on more than one instrument or method unless that is how the laboratory tests patient specimens and laboratory procedures are written to reflect that process.

If the laboratory (under one CLIA license) uses multiple methods for an analyte, proficiency specimens must be analyzed by the primary method at the time of the PT event, or be rotated among primary methods with each PT shipment. Laboratories subject to CMS regulation are not allowed to order multiple PT kits for the purpose of testing the same specimens/analyte on multiple instruments or methods prior to the due date for submitting results to the provider.

The educational purpose of PT is best served by a rotation that allows all testing personnel to be involved in the PT program. PT records must be retained and can be an important part of the competency and continuing education records in the personnel files of testing personnel. PT materials and specimens specifically used for semiannual alternative performance assessment purposes must be integrated within the routine workload, where applicable.

The US Department of Defense (DOD) and the Department of Veterans Affairs (VA) laboratories are subject to different regulations. For both the DOD and the VA, multiple proficiency testing kits may be ordered, with results reported, from the same proficiency testing provider on the same analyte; however, laboratories may not compare results from multiple kits until after the deadline for submission of results to the provider.

Laboratories not subject to US regulations may order multiple proficiency testing kits and report results from the same PT provider on the same analyte. They may not compare results from multiple kits until after the deadline for submission of results to the PT provider.

Evidence of Compliance:

- ✓ Instrument printout and/or work records

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)]
- 2) Shahangian S, et al. Toward optimal PT use. *Med Lab Observ*. 2000;32(4):32-43
- 3) Parsons PJ. Evaluation of blood lead proficiency testing: comparison of open and blind paradigms. *Clin Chem*. 2001;47:322-330

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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. The timeframe for investigation should be appropriate for the determination of any impact on patient results. 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*. 2023(Dec 28):[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.

COM.01800 PT Interlaboratory Communication

Phase II



There is no interlaboratory communication about proficiency testing specimens and results until after the deadline for submission of data to the proficiency testing provider.

NOTE: Proficiency testing (PT) must be:

- Performed by personnel at the laboratory (CAP/CLIA number) for which PT was ordered.
- Reported by personnel at the laboratory where PT was performed.

The laboratory director must define and enforce written PT policies, strictly prohibiting interlaboratory communications about PT specimens or results until after the deadline for submission of data to the PT provider. The CAP strongly recommends personnel training on the handling of PT specimens and prevention of interlaboratory communication.

The laboratory must retain records of PT events, including copies of PT program report forms, instrument printouts, and work records.

PT records must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission of results. Laboratories that share a common computer system or personnel must have strict policies and procedures to ensure that personnel do not access proficiency testing records from other laboratories.

Evidence of Compliance:

- ✓ PT records

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)(3)]

- 2) Bierig JR. Comparing PT results can put a lab's CLIA license on the line. Northfield, IL: College of American Pathologists CAP Today. 2002;16(2):84-87

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COM.01900 PT Referral

Phase II



Proficiency testing specimens are not referred to other laboratories and are not accepted from other laboratories for analysis.

NOTE 1: "Other laboratories" refers to external laboratories that are not covered under the same CAP/CLIA number.

NOTE 2: The laboratory director must define and enforce written proficiency testing policies that strictly prohibit referral or acceptance of proficiency testing specimens for analysis from other laboratories until after the PT submission due date. This applies even if the second laboratory is in the same health care system. This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens. For example, a laboratory's routine procedure for review of patient abnormal CBC blood smears might be referral of the smear to a pathologist located at another site (different CAP/CLIA number). For proficiency testing specimens, the laboratory must NOT follow its routine procedure to refer the specimen. If the PT specimen meets laboratory-defined criteria for referral to a pathologist prior to reporting and the pathologist is at another site, the pathologist must review the PT specimen at the physical location of the laboratory performing the PT. Alternatively, the laboratory must refer to the PT provider kit instructions on how to record a result for a test not performed in the laboratory.

NOTE 3: Laboratories that perform testing using a distributive testing model where portions of the process are performed at another laboratory with a different CAP/CLIA number must not participate in formal PT, as this is considered PT referral by CMS and is strictly prohibited. An alternative performance assessment must be performed at least semiannually in lieu of formal PT in these situations. Common examples of distributive testing include:

- In situ hybridization and slide interpretation performed at separate laboratories
- Next generation sequencing wet bench process, bioinformatics processes, and/or interpretation performed at different laboratories
- Leukemia/lymphoma flow cytometry panels and pathologist interpretation of the data at different laboratories

For laboratories that do not perform staining on site, immunohistochemistry (IHC) slides are permitted to be sent to another facility for staining only.

NOTE 4: Records of training on referral and acceptance of PT specimens is strongly recommended.

Refer to 'Tips for Avoiding Proficiency Testing Referral' on the CAP website (<http://www.cap.org>) through e-LAB Solutions Suite.

Evidence of Compliance:

- ✓ Proficiency testing records

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 1992(Feb 28): [42CFR493.801(b)(4)]
- 2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Brochure #8. Proficiency Testing, Dos and Don'ts. September 2008. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf>. Accessed December 23, 2015.

COM.01950 Cease Patient Testing for Repeat PT Failures

Phase II

If the laboratory was instructed by the CAP to cease patient testing for an analyte or subspecialty due to repeat unsuccessful proficiency testing, laboratory records demonstrate that no patient results were released until after the laboratory received approval from the CAP to resume patient testing.

NOTE: In order to resume patient testing, the laboratory must meet the conditions as outlined in the cease patient testing notification.

Evidence of Compliance:

- ✓ Records of communication notifying staff/physicians that testing is suspended for the required period of time **OR**
- ✓ LIS report verifying that no patient results were reported for the affected analyte or subspecialty during the cease testing time frame **OR**
- ✓ Patient reports indicating name and address of the referral laboratory where testing was performed during the affected period **OR**
- ✓ Send-out log to referral laboratory

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); [42CFR493.807].
- 2) Olson JD, Karon BS. PT failures: steps to preventing a cease testing. *CAP Today*. 2015;29(9):5-8.

QUALITY MANAGEMENT

GENERAL ISSUES

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of quality management system (QMS) policies and procedures • QMS pre-analytic, analytic and post-analytic quality monitoring records and corrective action when indicators do not meet threshold • Incident/error log and corrective action • Records of high school graduate high complexity test review by supervisor • Records of monthly review of instrument/equipment maintenance and function checks • Records of instrument/method comparison performed twice a year
	<ul style="list-style-type: none"> • How do you evaluate incident/error records? How do you determine appropriate corrective action? • As a staff member, what is your role in your laboratory's QMS? • How do you detect and correct laboratory errors?
	<ul style="list-style-type: none"> • Follow an incident identified in the incident/error records and follow actions including notification and resolution • Select several problems identified by the QM plan and follow tracking and corrective action. Determine if the methods used led to discovery and effective correction of the problem. • Review two or three instruments or items of equipment critical for patient testing. Determine if function check and maintenance records are adequate and if the laboratory performed the appropriate follow-up when irregularities were found.

COM.04000 Quality Management System (QMS)

Phase II



The laboratory's QMS (as described in GEN.13806) is implemented in each section (department) of the laboratory.

NOTE: The program must ensure quality throughout the pre-analytic, analytic and post-analytic phases of testing, as appropriate for each section (department) of the laboratory.

Evidence of Compliance:

- ✓ Records reflecting conformance with the QMS as designed

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1445(e)(5)]
- 2) Clinical and Laboratory Standards Institute (CLSI). *Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
- 3) 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): [42CFR493.1289]

COM.04050 Error Detection and Correction**Phase II**

The laboratory has a process to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

NOTE: One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all test results before or after reporting to the patient record. In computerized laboratories, there should be automatic "traps" for improbable results.

The process for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, ie, before results become available for clinical decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the appropriate clinical personnel or referring laboratory, as applicable.

If laboratories use delta checks as a mechanism to detect errors prior to the reporting of patient results, the laboratory must have written procedures describing the actions to be taken when acceptability criteria are exceeded and a process for approval of new or changed delta checks by the laboratory director or designee.

Error detection and correction procedures must include listings of common situations that may cause analytically inaccurate results and must address such analytic errors or interferences. This may require alternate testing methods; in some situations, it may not be possible to report results for some or all of the tests requested.

The intent of this requirement is NOT to require verification of all results outside the reference interval.

Evidence of Compliance:

- ✓ Records of review of results **OR** records of consistent implementation of the error detection processes **AND**
- ✓ Records of timely corrective action of identified errors

REFERENCES

- 1) Dufour D, et al. The clinical significance of delta checks. *Am J Clin Pathol*. 1998;110:531
- 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): [42CFR493.1281(b)]
- 3) Clinical and Laboratory Standards Institute. *Use of Delta Checks in the Medical Laboratory*; 1st ed. CLSI document EP33-ED1. Clinical and Laboratory Standards Institute, Wayne, PA; 2016.

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) 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)]

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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: 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

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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, stainlers)

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, detection of DNA versus a biochemical characteristic, 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

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COM.04300 Comparability Criteria - Nonwaived Testing

Phase II



Acceptability criteria are defined for comparability of nonwaived instruments and methods used to test the same analyte. Corrective action is taken when the criteria are not met.

NOTE: The acceptability criteria are determined by the laboratory and can vary based on the specific analyte and clinical impact of its measurement variation. Examples of data that can be useful to establish these criteria include, but are not limited to:

- Method validation or verification data
- Clinical significance of the variation between methods
- Biologic variation data
- Data from external proficiency testing providers.

These criteria may be developed from in-house data or published literature and must be vetted by the laboratory director to ensure that they are appropriate for the clinical application of the test.

Evidence of Compliance:

- ✓ Records of comparability studies with evidence of review and action taken, as appropriate

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): [42CFR493.1282(A)]
- 2) Clinical and Laboratory Standards Institute (CLSI). *Protocol for the Evaluation, Validation, and Implementation of Coagulometers: Approved Guideline*. CLSI document H57-A (ISBN 1-56238-656-5).Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2008.
- 3) 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.

SPECIMEN COLLECTION AND HANDLING

Inspector Instructions:

	<ul style="list-style-type: none"> Sampling of specimen collection and handling policies and procedures Sampling of specimen rejection records/log
	<ul style="list-style-type: none"> Sampling of patient specimens and derivatives of the primary specimen used during testing (specimen labeling, presentation, integrity) Determine if the aliquoting process and procedure are adequate to prevent cross-contamination and specimen mix up
	<ul style="list-style-type: none"> What is your course of action when you receive unacceptable or sub-optimal specimens? How does your laboratory ensure specimen integrity throughout processing and testing? What identifiers are in place on specimens (eg, slides, aliquots, etc.) derived from the primary specimen? What is your process for preparing aliquots from a primary specimen?

COM.06000 Specimen Collection Manual

Phase II



The specimen collection manual defines methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, and conditions for transportation and storage before testing, consistent with good laboratory practice.

NOTE: The proximity of the patient to the test site does not preclude the need for proper identification systems to prevent reporting of one patient's result to another's record. Refer to the Specimen Collection section of the Laboratory General Checklist for additional information on patient identification. The specimen collection manual may be in paper or electronic format.

REFERENCES

- 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):1034 [42CFR493.1242(a)]

COM.06100 Primary Specimen Container Labeling

Phase II



All primary specimen containers are labeled with at least two patient-specific identifiers.

NOTE: A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, cup, syringe, swab, slide or other form of specimen storage. Data files received from other laboratories for analysis are considered a specimen and must contain acceptable patient identifiers. Criteria for acceptable specimen labeling and the handling of sub-optimal specimens must be defined.

Examples of acceptable identifiers include, but are not limited to: patient name, date of birth, hospital number, social security number, requisition number, accession number, unique random number. A location (eg, hospital room number) is not an acceptable identifier. Identifiers may be in a machine readable format, such as a barcode.

For prepared slides submitted to the laboratory, if the slides are labeled with only one identifier, they must be securely submitted in a container labeled with two identifiers.

In limited situations, a single identifier may be used if it can uniquely identify the specimen. For example, in a trauma situation where a patient's identification is not known, a specimen may be submitted for testing labeled with a unique code that is traceable to the trauma patient. Other examples may include forensic specimens, coded or de-identified research specimens, or donor specimens labeled with a unique code decryptable only by the submitting location.

For specimens where site of origin is critical to the analysis (eg, site specific cultures, surgical and cytology specimens), the primary specimen container and/or the requisition must clearly identify the site of origin, and as appropriate, the laterality of the specimen (right versus left). If more than one specimen container is submitted with one requisition, each container must be labeled in a manner to ensure linkage of the specimen to the site of origin and laterality.

*This requirement does not apply to the labeling of specimens collected for **immediate** bedside patient testing performed in the presence of the patient. If the specimens are (or may be) utilized for testing away from the patient, the labeling criteria defined in this requirement apply.*

REFERENCES

- 1) Clinical and Laboratory Standards Institute. *Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.* CLSI document AUTO12-A. Clinical and Laboratory Standards Institute. Wayne, PA; 2011.
- 2) Kiechle FL. So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy, 15th edition. Northfield, IL: College of American Pathologists, 2017.

COM.06200 Secondary Specimen Container Labeling

Phase II



Adequate specimen identification is provided on specimen containers throughout all phases of testing, including, but not limited to aliquots, dilution, tubes, slides, blocks, culture plates, reaction units, nucleic acids and other extracts, data extract files, images, and other secondary specimens created during the processing or testing of a specimen.

NOTE: A single, unique identifier may be used to label materials derived from the primary specimen for use in subsequent phases of testing. The specimen identification system used must provide reliable identification of the secondary specimen and be linked to the full particulars of patient identification, collection date, specimen type, etc. The specimen identifier(s) must be indelible, legible, and able to withstand all stages of processing and conditions of storage. Identification may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory.

Slides prepared from specimens in the laboratory are considered secondary specimen containers. Slides prepared in the patient setting and brought to the laboratory (eg, fine needle aspiration, bone marrow preparations) are considered primary specimen containers and must follow the labeling requirements for primary specimen containers.

For histology specimens, each block of tissue must be identified by a unique identifier traceable to the primary specimen (eg, accession number) assigned to the case and by any descriptive letter(s)/number(s) added by the prosector during the dissection. If additional blocks are prepared later, all lists and logs must reflect these additions. Identification number and letter(s)/number(s) must be affixed to all blocks in a manner that remains legible. Each slide must be identified by the unique identifier traceable to the primary specimen and descriptive letters unique to the block from which it is cut. Other appropriate identifiers should be included as applicable (eg, levels of sectioning). Automated prelabeling systems are acceptable.

REFERENCES

- 1) Clinical and Laboratory Standards Institute. *Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.* CLSI document AUTO12-A. Clinical and Laboratory Standards Institute. Wayne, PA; 2011.
- 2) Clinical and Laboratory Standards Institute. *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard. 2nd ed.* CLSI document AUTO02-A2. Clinical and Laboratory Standards Institute. Wayne, PA; 2006.
- 3) 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):1034 [42CFR493.1242(a)]

****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: This requirement applies to both in-house shared specimens and specimens 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 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.

COM.06300 Specimen Rejection Criteria

Phase II



The laboratory defines and follows criteria for the rejection or special handling of specimens that do not meet established laboratory criteria for the requested test(s). The laboratory retains records of these specimens in the patient/client report and/or quality management records.

NOTE: The test report must indicate information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability for the specific test(s) requested.

If there is a pre-analytic problem with a specimen, there must be a mechanism to notify clinical personnel responsible for patient care and record the deviation from the collection instructions. If the responsible clinical individual (eg, physician) desires the result and the laboratory agrees to perform testing, the laboratory must note the condition of the specimen on the report and inform the individual that results from these specimens must be interpreted with caution as some or all of them may be inaccurate. The laboratory must retain a record of this communication (eg, in patient report or another laboratory record). For referral laboratories, this may be performed by the referring laboratory as part of the service agreement.

Examples of specimens not meeting established pre-analytic parameters include:

- *Improperly collected, handled (eg, specimen leakage), or stored specimens*
- *Desiccated specimens, if appropriate*
- *Specimens submitted beyond their stability time limits*
- *Insufficient quality/quantity of specimen*
- *Inadequate specimen labeling or requisition information*
- *Broken slides*
- *Hemolyzed, lipemic, or grossly contaminated specimens*
- *Tissue specimens with inadequate or inappropriate fixation or processing for the specific test(s) ordered (eg, frozen section specimen submitted for IHC HER2 testing).*

For surgical pathology/cytology specimens, some types of specimens may be acceptable for some types of analysis and not for others. For example, a breast tissue specimen processed for frozen section would not be acceptable for HER2 IHC testing but is acceptable to use for breast cancer diagnosis.

For newborn screening specimens, rejection criteria must be consistent with the criteria defined in the current edition of the CLSI NBS01 Standard, Blood Collection on Filter Paper for Newborn Screening Programs.

Evidence of Compliance:

- ✓ Records of rejected specimens **AND**
- ✓ Records of communications with clinical personnel for specimen deviations **AND**
- ✓ Records of disposition of unacceptable specimens

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):7183 [42CFR493.1249(a) and (b)]
- 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): [42CFR493.1283(a)(3)]
- 3) Clinical and Laboratory Standards Institute (CLSI). *Patient and Laboratory Specimen Identification Processes*. 1st ed. CLSI standard PRE01. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.
- 4) Clinical and Laboratory Standards Institute. *Blood Collection on Filter Paper for Newborn Screening Programs*. 7th ed. CLSI standard NBS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2021.
- 5) Clinical and Laboratory Standards Institute. *Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline*. 2nd ed. CLSI document H42-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2007.
- 6) Karcher DS, Lehman CM. Clinical consequences of specimen rejection: a College of American Pathologists Q-Probes analysis of 78 clinical laboratories. *Arch Pathol Lab Med*. 2014; 138(8):1003-1008.
- 7) Nakhleh RE, Souers RJ, Bashleben CP, Talbert ML. Fifteen years' experience of a College of American Pathologists program for continuous monitoring and improvement. *Arch Pathol Lab Med*. 2014;138(9):1150-1155.
- 8) Compton CC, Robb JA, Anderson MW, et al. Preanalytic and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med*. 2019;143(11):1346-63.

POLICY AND PROCEDURE MANUAL

All laboratory testing, functions, and/or processes must be defined in written policies and/or procedures, with appropriate approval, to assure clarity and consistency.

The manual must address relevant pre-analytic and post-analytic considerations, as well as the analytic activities of the laboratory. The specific style and format of procedure manuals are at the discretion of the laboratory director.

Inspector Instructions:

	<ul style="list-style-type: none"> • Representative sample of policies and procedures for completeness, laboratory director approval, and review. Procedures must be consistent with current laboratory practice.
	<ul style="list-style-type: none"> • How do you access policies and procedures? • What procedure has most recently been implemented or modified? • How do you ensure all copies of policies and procedures are up to date? • How are changes in procedures documented and communicated to staff? • How are discontinued policies and procedures removed from general access? • Show me how you access procedures when your network is down
	<ul style="list-style-type: none"> • Identify a newly-implemented procedure in the prior two years and follow the steps through authoring, laboratory director approval, and staff training



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 steps in the laboratory's testing and other technical processes must be defined in written policies and/or procedures. **Procedures must 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.

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). *Developing and Managing Laboratory Documents*. 7th ed. CLSI guideline QMS02. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

COM.10050 Procedure Manual Elements

Phase II

The procedure manual includes the following elements, when applicable to the test procedure:

- Principle and clinical significance
- Requirements for patient preparation; specimen collection, labeling, handling storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection
- Microscopic examination, including the detection of inadequately prepared slides
- Step-by-step performance of the procedure, including test calculations and interpretation of results
- Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing
- Calibration and calibration verification procedures
- The analytic measurement range for test results for the test system, if applicable
- Control procedures

- **Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability**
- **Limitations in the test methodology, including interfering substances**
- **Reference intervals (normal values)**
- **Imminently life-threatening (critical) test results**
- **Pertinent literature references**
- **The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the procedure for reporting imminently life-threatening (critical) results**
- **Description of the course of action to take if a test system becomes inoperable**

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)].
- 2) Clinical and Laboratory Standards Institute (CLSI). *Developing and Managing Laboratory Documents*. 7th ed. CLSI guideline QMS02. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

COM.10100 Policy and Procedure Review**Phase II**

The laboratory director or designee reviews all technical policies and procedures at least every two years.

NOTE: The laboratory director must ensure that the collection of testing policies and technical procedures is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant.

To minimize the burden on the laboratory and reviewer(s), the CAP suggests using a schedule whereby roughly 1/24 of all technical policies and procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index is not a sufficient record that each policy or procedure has been carefully reviewed. Signature or initials on each page of a policy or procedure is not required.

The laboratory may record review of electronic procedures by:

- *Including statements such as "reviewed by [name of reviewer] on [date of review]" in the electronic record*
- *Using a secure electronic signature*
- *Using paper review sheets.*

Only technical policies and procedures are addressed in this requirement. Biennial review is not required for other controlled documents.

Evidence of Compliance:

- ✓ Records of policy or procedure review

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1407(e)(13)]
- 2) Borkowski A, et al. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod Pathol*. 2001;14:1-5

COM.10200 New Policy and Procedure Approval**Phase II**

The laboratory director reviews and approves all new technical policies and procedures, as well as substantial changes to existing documents, before implementation.

NOTE: This review may not be delegated to designees in laboratories subject to the CLIA regulations.

Paper or electronic signature review of records is acceptable. A secure electronic signature is desirable, but not required.

Evidence of Compliance:

- ✓ Records of new policy or procedure approval

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(d)]

COM.10250 New Policy and Procedure Approval (Not Subject to US Regulations) Phase II

For laboratories not subject to US regulations, the laboratory director or designee who meets CAP director qualifications reviews and approves all new technical policies and procedures, as well as substantial changes to existing documents before implementation.

NOTE: Paper or electronic signature review of records is acceptable. A secure electronic signature is desirable, but not required.

Evidence of Compliance:

- ✓ Records of new policy or procedure approval

COM.10300 Knowledge of Policies and Procedures Phase II

The laboratory has records indicating that all personnel are knowledgeable about the contents of the policies and procedures (including changes) relevant to the scope of their testing activities.

NOTE: The form of this system is at the discretion of the laboratory director. Annual procedure sign-off by testing personnel is not required.

Evidence of Compliance:

- ✓ Records indicating that the testing personnel have read the policies and procedures, new and revised, **OR** records of another written method approved by the laboratory director

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): [42CFR493.1251(a)]

COM.10500 Discontinued Policies and Procedures Phase II

The laboratory retains a paper or electronic copy of discontinued policies and procedures with dates of initial use and retirement for at least two years (five years for transfusion medicine).

NOTE: The laboratory must follow its document control system to archive discontinued policies and procedures.

Discontinued policies and procedures must generally be inaccessible to the working areas of the laboratory (GEN.20375).

For testing on minors (under the age of 21), stricter national, federal, state (or provincial), or local laws and regulations may apply to retention of discontinued policies and procedures.

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 [42CFR493.1105(a)(2)], [42CFR493.1251(e)]

RESULTS REPORTING

Inspector Instructions:

 READ	<ul style="list-style-type: none"> Sampling of critical patient results/logs
 ASK	<ul style="list-style-type: none"> How do you record the reporting of critical results? Who do you contact?
 DISCOVER	<ul style="list-style-type: none"> Follow a critical result from testing, reporting and recording of notification

COM.30000 Critical Result Notification

Phase II



The laboratory immediately notifies physicians or other clinical personnel responsible for patient care when results of designated tests exceed established "critical" values. Records of notification are retained.

NOTE: Alert or critical results are those results that may require prompt clinical attention to avert significant patient morbidity or mortality. The laboratory director, in consultation with the clinicians served, must define the critical values and critical results that pertain to its patient population. The laboratory may establish different critical results for specific patient subpopulations (for example, dialysis clinic patients).

An appropriate notification includes a direct dialogue with the responsible individual or an electronic communication (eg, secure email or fax) with confirmation of receipt by the responsible individual.

For communication of significant and unexpected surgical pathology and cytopathology findings, refer to ANP.12175 and CYP.06450 instead.

Allowing clinicians to "opt out" of receiving critical results is strongly discouraged.

Records must show prompt notification of critical results to the appropriate clinical individual and include the following:

- Date of communication
- Time of communication
- Responsible individual communicating the result
- Person notified using identifiers traceable to that person (a first name alone is inadequate)
- Test results.

Any problem encountered in accomplishing this task must be investigated to prevent recurrence.

Referral laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The referral laboratory must have a written agreement with the referring laboratory that indicates to whom the referral laboratory reports critical results.

In the point-of-care setting, the identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be a record of the critical result, date, and time in the test report or elsewhere in the medical record.

Evidence of Compliance:

- ✓ Records of notification within the established timeframe

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); [42CFR493.1291(g)]
- 2) Clinical and Laboratory Standards Institute. *Management of Clinical- and Significant-Risk Results*. 1st ed. CLSI Guideline GP47. Clinical and Laboratory Standards Institute. Wayne, PA; 2015.
- 3) Howanitz PJ, Steindel SJ, Heard NV. Laboratory critical values policies and procedures: a College of American Pathologists Q-Probes study in 623 institutions. *Arch Pathol Lab Med*. 2002; 126:663-669. (92-04).
- 4) Wagar EA, Stankovic AK, Wilkinson DS, Walsh M, Souers RJ. Assessment monitoring of laboratory critical values. A College of American Pathologists Q-Tracks study of 180 institutions. *Arch Pathol Lab Med*. 2007; 131:44-49. (QT10).
- 5) Wagar EA, Friedberg RC, Souers R, Stankovic AK. Critical values comparison: a College of American Pathologists Q-Probes survey of 163 clinical laboratories. *Arch Pathol Lab Med*. 2007; 131:1769-1775. (QP054).

COM.30100 Critical Result Read-Back

Phase I



For verbally communicated critical results, personnel communicating results request and record “read-back” of the results.

NOTE: If critical results are transmitted electronically (eg, secure email or fax), the laboratory must confirm receipt by the responsible individual; however, no read-back is necessary.

Evidence of Compliance:

- ✓ Records of critical result notification, including read-back as necessary

REAGENTS

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of test procedures for reagent handling • Sampling of new reagent/shipment confirmation of acceptability records • Sampling of ambient temperature logs (if reagents stored at ambient temperature)
	<ul style="list-style-type: none"> • Sampling of reagents (expiration date, labeling, storage)
	<ul style="list-style-type: none"> • How do you store the reagents and controls used in test procedures? • How do you confirm the acceptability of new reagent lots? • If you identify a problem with a reagent in use (eg, expired vial, unacceptable storage conditions, etc.), what is your process for evaluating the potential impact on patients? • What are your laboratory's criteria for mixing components from one lot number of reagent kit with components from another lot number of kit? • How does your laboratory manage and control reagent inventory?

COM.30250 Reagent Storage and Handling - Waived Tests

Phase II



For waived tests, the laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, etc.

NOTE: There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.

If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature.

If the laboratory identifies a problem with a reagent that was used for patient testing (eg, expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

Evidence of Compliance:

- ✓ Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring

The remaining checklist requirements in the REAGENTS section do not apply to waived tests.

COM.30300 Reagent Labeling - Nonwaived Tests

Phase II

The laboratory labels all reagents, calibrators, controls, stains, chemicals, and solutions, as applicable and appropriate, with the following elements:

- Content and quantity, concentration or titer
- Storage requirements
- Date prepared, filtered or reconstituted by laboratory
- Expiration date.

NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so they are traceable to the appropriate data in the log.

While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc. For containers with multiple individual reagent units (eg, cartridges), the expiration date must be recorded on each unit if stored outside of the original container.

This requirement also applies to the labeling of chemicals used in the laboratory to prepare reagents or during the preanalytic and analytic phases of the testing process. Requirements relating to precautionary labeling for hazardous chemicals are included in the Chemical Safety section of the Laboratory General Checklist.

Evidence of Compliance:

- ✓ Properly labeled reagents OR logs traceable to the reagents

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 [42CFR493.1252(c)]

COM.30350 Reagent Storage and Handling - Nonwaived Tests

Phase II



All reagents (chemicals, stains, controls, media, antibodies, test strips, testing cartridges, etc.) are stored and handled as defined by the laboratory and following the manufacturer's instructions.

NOTE: Reagents must be stored and handled in a manner that will prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents must be properly stored, mixed, when appropriate, and discarded when stability parameters are exceeded.

If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature.

If the laboratory identifies a problem with a reagent that was used for patient testing (eg, expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

Evidence of Compliance:

- ✓ Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring

REFERENCES

- 1) Gonzales Y, Kampa IS. The effect of various storage environments on reagent strips. *Lab Med*. 1997;28:135-137
- 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)]
- 3) Clinical and Laboratory Standards Institute (CLSI). *One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (aPTT) Test*; 3rd ed. CLSI document H47. Clinical and Laboratory Standards Institute, Wayne, PA, 2023.

COM.30400 Reagent Expiration Date - Nonwaived Tests Phase II



All reagents (chemicals, stains, controls, media, antibodies, test strips, testing cartridges, etc.) are used within their indicated expiration date.

NOTE: Expiration dates assigned by a manufacturer must be observed. The laboratory must assign an expiration date if an expiration date is not provided by the manufacturer. The laboratory must base the assigned expiration date on known stability, frequency of use, storage conditions, and risk of deterioration.

Transfusion service laboratories may use rare reagents (ie, rare antisera and selected panel red cells to determine the specificity of red cell antigens and antibodies) beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. The laboratory must have in-date reagents for routine antigen typing and antibody panel testing

For histology and cytology, laboratories may satisfy confirmation of ongoing acceptable performance of stains until the expiration date by technical assessment of case material containing suitable material for evaluation of stains, or by use of suitable control specimens.

Laboratories not subject to US regulations and military laboratories in overseas locations, may use expired reagents only under the following circumstances: 1) The reagents are unique, rare or difficult to obtain; or 2) Delivery of new shipments of reagents is delayed through causes not under control of the laboratory. The laboratory must retain records of verification of the performance of expired reagents in accordance with written laboratory procedure. The laboratory must also retain records of its efforts to obtain reagents in a timely manner and the rationale for continuing to perform the test instead of referring it to another laboratory.

Laboratories subject to US regulations must not use expired reagents.

Evidence of Compliance:

- ✓ Records confirming acceptability of any reagent used beyond its expiration date (in jurisdictions where allowed)

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 [42CFR493.1252(d)]
- 2) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Equipment, Supplies and Reagents. Washington, DC: US Government Printing Office, 2023(Mar 30);[21CFR606.65(e)].
- 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24);[42CFR493.1271(a)(1)(e)].

****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 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 automated analyzers that use reservoirs for testing reagents and cleaning/decontaminating solutions (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.

COM.30500 Reagent Kit Components - Nonwaived Tests

Phase II



If there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.

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): [42CFR493.1252(e)]

INSTRUMENTS AND EQUIPMENT

A variety of instruments and equipment are used to support the performance of analytical procedures. Examples of equipment include, but are not limited to centrifuges, microscopes, incubators, heat blocks, refrigerators, freezers, biological safety cabinets, fume hoods, glassware, pipettes, etc. This section contains general requirements that apply to most laboratory sections and types of testing and is used in conjunction with the discipline-specific checklist for inspection. The laboratory is also responsible for any additional method-specific instrument and equipment requirements found in the discipline-specific checklists, as applicable.

INSTRUMENT AND EQUIPMENT MAINTENANCE/FUNCTION CHECKS

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Sampling of instrument/equipment policies and procedures • Sampling of function check and performance verification records for instruments/equipment • Sampling of instrument/equipment maintenance logs and repair records • Records of ocular micrometer calibration • Records of biological safety cabinet certification
 OBSERVE	<ul style="list-style-type: none"> • Instrument/equipment records (promptly retrievable) • Microscopes (proper working condition) • Microscope filters - used as indicated by manufacturer • Ocular micrometer • Use of biological safety cabinet based on biosafety level, occupational risk, and as defined in laboratory policies and procedures

COM.30525 Maintenance and Function Checks - Waived Tests

Phase II



For waived tests, the laboratory follows manufacturer's instructions for instrument and equipment maintenance and function checks.

Evidence of Compliance:

- ✓ Manufacturer's instrument/equipment instructions for each waived test **AND**
- ✓ Records of instrument/equipment maintenance and function checks as required by the manufacturer

The remaining checklist requirements in the INSTRUMENT AND EQUIPMENT MAINTENANCE/FUNCTION CHECK section do not apply to waived tests.

COM.30550 Instrument/Equipment Performance Verification

Phase II



The laboratory verifies the performance of all instruments and equipment prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations.

NOTE: Instrument/equipment performance verification (NOT to be confused with validation or verification of the test method performance specifications) includes processes to verify that the instruments and equipment perform according to expectations for the intended use and within defined tolerance limits.

If instruments or equipment are moved, the laboratory must perform appropriate function checks to ensure that they were not adversely affected by the relocation process or changes due to the new environment. This does not apply to portable equipment used following the manufacturer's instructions.

Evidence of Compliance:

- ✓ Records of appropriate function checks

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.

****REVISED** 08/24/2023**

COM.30575 Instrument/Equipment Operation

Phase II



Written procedures for start-up, operation, maintenance, and shutdown of instruments and equipment, as applicable, are available in a paper-based, electronic, or web-based format at the workbench or in the work area.

NOTE: The procedures must include steps to perform an emergency shutdown and handling of workload during instrument downtime, as applicable. These may be separate approved procedures or be included in the testing procedure for a specific analyte.

****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.

COM.30625 Function Check Tolerance Limits

Phase II

The laboratory takes and records corrective action when tolerance limits for acceptable function of instruments and equipment are exceeded.

NOTE: The defined tolerance limits must follow the manufacturer's specified limits. Function checks must be within the defined tolerance limits prior to use for testing patient samples.

The action 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.).

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]

COM.30650 Instrument Troubleshooting

Phase II

Instructions are provided for minor troubleshooting and repairs of instruments (such as manufacturer's service manual).

COM.30675 Instrument and Equipment Records

Phase II

Instrument and equipment maintenance, function check, performance verification, and service and repair records (or copies) are promptly available to, and usable by, the technical staff operating the equipment.

NOTE: Effective utilization of instruments and equipment by the technical staff depends upon the prompt availability of the records (copies are acceptable) to detect trends or malfunctions. Off-site storage, such as with centralized medical maintenance or computer files, is acceptable if the inspector is satisfied that the records can be promptly retrieved.

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.

COM.30680 Microscope Maintenance

Phase II

Microscopes are clean, adequate (eg, low, high dry and oil immersion lenses as appropriate for the intended use), optically aligned, and properly maintained with records of preventive maintenance at least annually.

NOTE: Koehler illumination must be maintained for optimal resolution. Phase contrast microscopy should be available when indicated (eg, manual platelet counting, urinalysis microscopy).

REFERENCES

- 1) Vetter JP. Solving problems with illumination, focus, and detail in color photomicrography. *Lab Med*. 1997;28:719-723.

COM.30685 Microscopes for Fluorescence Testing**Phase II**

The microscopes used for fluorescence testing are monitored to ensure sufficient light source intensity, and are used with filters and slides appropriate to, and verified in conjunction with, the test(s) being performed.

NOTE: Having a process to track the length of time the bulb is in use and limit bulb usage based on the manufacturer's recommendations (as applicable), is an example of an acceptable process to monitor the adequacy of the source intensity.

The use of filters or slides not matched properly to the assay(s) performed can lead to erroneous results. Written procedures must specify the excitation and emission filters used for fluorescence microscopy. Fluorescence microscopes should be used in an area where ambient lighting can be minimized.

Evidence of Compliance:

- ✓ Records of microscope monitoring

REFERENCES

- 1) Schutzbach TE, McGuire R. Immunofluorescence. In: Specter S, Hodinka RL, Young SA, editors. *Clinical Virology Manual*. Third Edition ed. Washington: ASM Press;2000. p. 69-78.
- 2) Clinical and Laboratory Standards Institute . *Fluorescence In Situ Hybridization Methods for Clinical Laboratories; Approved Guideline*. 2nd ed. CLSI document MM07-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2013.

COM.30690 Calibration/Recalibration - Ocular Micrometer**Phase II**

The ocular micrometer (when required) is calibrated for the microscope(s) and the specific objective(s) with which it is used.

NOTE: An ocular micrometer is required for certain types of testing, including:

- Parasitology identification when determining the size of eggs, larvae, cysts, trophozoites, and microfilaria or other bloodborne parasites
- Sperm morphology for use of certain sperm morphology classification methods (Kruger Strict and World Health Organization (WHO) methods references in the 3rd and 4th editions).
- Surgical pathology when accurate microscopic measurements are needed (eg, measuring depth or extent of invasion and margins in various cancers, extent of involvement in needle core biopsies, size of organisms or other microscopic findings)

Calibrations must be checked against a calibrated stage micrometer slide or other object(s) of known dimensions appropriate to the use of the ocular micrometer.

Any change in the optics of the microscope (eg, change in objective or ocular lens) requires recalibration. If there are no changes to a particular microscope's optical components, there is no need to recheck calibration.

Evidence of Compliance:

- ✓ Records of initial calibration and recalibration, if applicable

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):7167 [42CFR493.1264(b)]

****NEW** 08/24/2023**

COM.30695 Biological Safety Cabinet**Phase II**

A certified biological safety cabinet (BSC) is available and used when appropriate.

NOTE: The biological safety cabinet must be certified when installed, whenever moved, and at least annually to ensure that filters are functioning properly and that airflow rates meet specifications.

A BSC is used when protection of personnel, product, and/or the environment is needed for certain types of testing or procedures, including:

- Handling specimens potentially containing infectious pathogens considered highly transmissible by airborne routes or with potential for aerosolization or risk of splashes
- Prevention of DNA/RNA contamination for molecular testing procedures
- Maintaining sterility of cell cultures.

The laboratory director is responsible for ensuring a risk assessment is conducted, and for defining and implementing work practice controls to minimize identified risks, including installation and proper use of the appropriate type of biological safety cabinet.

The 6th edition of [Biosafety in Microbiological and Biomedical Laboratories](#) provides guidance for safe conduct of work from a biosafety perspective. It can be used as a tool for assessing and mitigating risk. Refer to Section II - Biological Risk Assessment, Appendix N - Clinical Laboratories, Section IV - Laboratory Biosafety Level Criteria and Table 1. Summary of Laboratory Biosafety Levels (BSLs) for specific information.

Evidence of Compliance:

- Defined work practice controls appropriate for the assessed level of risk **AND**
- Maintenance and function check schedule **AND**
- Records of testing and certification

REFERENCES

- Department of Health and Human Services. [Biosafety in Microbiological and Biomedical Laboratories](#), 6th ed. June 2020.

THERMOMETERS

Inspector Instructions:

	<ul style="list-style-type: none"> Records of traceability to NIST Standards Sampling of verification records for non-certified thermometers Sampling of policies and procedures for thermometer verification
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COM.30700 Thermometric Standard Device

Phase II

An appropriate thermometric standard device of known accuracy (certified to meet National Institute of Standards and Technology (NIST) Standards or traceable to NIST Standards) is available.

NOTE: Thermometric standard devices must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration or they are subject to requirements for non-certified thermometers.

Thermometers should be periodically evaluated for damage (eg, separation of columns). Thermometers with obvious damage must be rechecked for continued use.

Evidence of Compliance:

- Thermometer certificate of accuracy

REFERENCES

- 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.

COM.30725 Non-certified Thermometers

Phase II

All non-certified thermometers are checked against an appropriate thermometric standard device before initial use and as defined by laboratory policy.

NOTE: Non-certified thermometers used in transfusion medicine, including blood-warmer thermometers, must be checked at least annually.

If digital or other displays of temperatures on equipment are used for daily monitoring, the laboratory must verify that the readout is accurate. The display must be checked initially and following manufacturer's instructions.

Evidence of Compliance:

- ✓ Records of verification

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.

TEMPERATURE-DEPENDENT INSTRUMENTS, EQUIPMENT, AND ENVIRONMENTS

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Sampling of temperature logs (refrigerator, freezer, water bath, heat block, incubator ambient, etc.)
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****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.*

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)].

COM.30775 Temperature Range

Phase II

Acceptable ranges are defined for all temperature-dependent storage devices, equipment, and environments (including test-dependent ambient temperature) in accordance with the manufacturer's instructions.

Evidence of Compliance:

- ✓ Temperature log or record with defined acceptable range

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):[42CFR493.1252(b)].

COM.30800 Temperature Corrective Action

Phase II

The laboratory takes corrective action when acceptable temperature ranges for temperature-dependent storage devices, equipment, and environments are exceeded, including evaluation for adverse effects.

NOTE: If acceptable temperature ranges are exceeded, stored reagents, controls, calibrators, or other materials must be checked to confirm the accuracy or quality of the material before use, with records retained.

Evidence of Compliance:

- ✓ Records of corrective action for unacceptable temperatures

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):[42CFR493.1252(b)].

VOLUMETRIC GLASSWARE AND PIPETTES

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Pipette verification procedure • Sampling of records of pipette/dilutor checks
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- What is your laboratory's course of action prior to using non-certified volumetric glassware?
- How are you assured your automatic pipetting systems exhibit no carryover effects?

COM.30810 Volumetric Glassware Accuracy and Reproducibility

Phase II



Glass volumetric pipettes and other glassware used for volumetric dispensing are of certified accuracy (Class A); or if non-Class A pipettes and glassware are used, they are checked for accuracy and reproducibility initially and according to the manufacturer's recommended interval, or at least annually if not specified, and the results are recorded.

NOTE: The following Table shows the American Society for Testing and Materials' calibration (accuracy) specifications for Class A volumetric pipettes:

Nominal Capacity (mL)	Variation (\pm mL)
0.5 - 2	0.006
3 - 7	0.01
8 - 10	0.02
15 - 30	0.03
40 - 50	0.05
100	0.08

For Non-Class A pipettes: Pipette checks must be performed following manufacturer's instructions, at minimum and as defined in laboratory procedure. Such checks may be done by gravimetric, colorimetric or other validation procedures. Alternative approaches include spectrophotometry and the use of commercial kits.

If initial calibration is performed by the manufacturer or other outside facility, sufficient information must be provided to justify acceptance of the pipette's calibration based on the laboratory's written specifications of acceptable bias and imprecision. The outside facility must also provide a record of the technique used to check calibration and ship the pipette in a manner that protects it from damage in transit.

Evidence of Compliance:

- ✓ Pipettes and glassware marked Class A **OR** a NIST certificate **OR**
- ✓ Records of initial and ongoing verification of non-Class A pipette and glassware accuracy and reproducibility

REFERENCES

- 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-9
- 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-17
- 3) Perrier S, et al. Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S183
- 4) American Society for Testing and Materials. Standard specification for glass volumetric (transfer) pipets, designation E 969-95. Philadelphia, PA: ASTM, 1995
- 5) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):14
- 6) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News.* 1999;31(13):20-22
- 7) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479

COM.30820 Quantitative Pipette Accuracy and Reproducibility

Phase II



Pipettes used for quantitative dispensing (eg, adjustable volume, micropipettes, dilutors, and analytic instruments with integral automatic pipettors) are checked for accuracy and

reproducibility initially and according to the manufacturer's recommended interval, or at least annually if not specified, and the results are recorded.

NOTE: The initial calibration may be performed by the manufacturer or other outside facility, but in such cases the laboratory must have a record from the manufacturer or other facility that includes the technique used to check calibration, the method of shipment to prevent damage in transit, and the bias and precision of the pipette(s). The bias and imprecision must meet the specification established by the laboratory.

If the facility performs pipette checks in house, they must be performed following manufacturer's instructions, at minimum, and as defined in laboratory procedure. Such checks may be done by gravimetric, colorimetric or other validation procedures. Alternative approaches include spectrophotometry and the use of commercial kits.

For analytic instruments with integral automatic pipettors, this checklist requirement applies, unless such checks are not practical for end-user laboratory. Manufacturers' recommendations must be followed.

This requirement is not applicable for pre-calibrated inoculation loops that are used in the direct plating of clinical specimens such as urine cultures.

Evidence of Compliance:

- ✓ Records of initial and ongoing verification of pipette accuracy and reproducibility

COM.30830 Measuring Devices

Phase I



The use of less precise measuring devices such as serological plastic pipettes and graduated cylinders are limited to situations where the accuracy and precision of calibrated glass pipettes are not required.

NOTE: In contrast with the more stringent accuracy requirements of glass pipettes, ASTM requirements for plastic pipettes are $\pm 3\%$ of the stated volume. The procedure manual must specify when the use of non-class A measuring devices is permissible.

REFERENCES

- 1) American Society for Testing and Materials. Standard specification for serological pipets, disposable plastic, designation E 934-88, In 1993 Annual Book of ASTM Standards, section 14 (general methods and instrumentation). Philadelphia, PA: ASTM, 1993:14.02:485-486

COM.30840 Pipette Carryover

Phase II



The laboratory evaluates its automatic pipetting systems for carryover.

NOTE: This requirement applies to both stand-alone pipette systems and to sample pipettes integrated with analytic instruments.

One suggested method to study carryover is to run known high patient samples, followed by known low samples to see if the results of the low-level material are affected. If carryover is detected, the laboratory must determine the analyte concentration above which subsequent samples may be affected, and define this value in the procedure. Results of each analytical run must be reviewed to ensure that no results exceed this level. If results that exceed the defined level are detected, then the appropriate course of action must be defined (repeat analysis of subsequent samples, for example).

Carryover studies must be performed, as applicable, as part of the initial evaluation of an instrument and be repeated after major maintenance or repair of the pipetting assembly of the instrument. The laboratory may use the data from carryover studies performed by instrument manufacturers, as appropriate.

In practice, carryover is a problem only for analytes with a wide clinical range of analyte concentration, such that a minute degree of carry-over could have significant clinical implications.

Examples include immunoassays such as hCG, certain enzymes (eg, CK), and certain drugs of abuse (eg, benzoylecgonine [cocaine metabolite], which may be present in high concentrations). The laboratory should select representative examples of such analytes for carryover studies.

Evaluation for carryover is not required for automatic pipettes that use disposable tips.

Evidence of Compliance:

- ✓ Record of carryover studies, as applicable

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.

ANALYTICAL BALANCES

An analytical balance is a class of balance designed to measure mass accurately in the milligram to sub-milligram range. They are typically used for measuring chemicals used to prepare standards.

For other types of balances or weight measurement devices (eg, scales), refer to the Instrument and Equipment Maintenance/Function Checks section and to discipline-specific requirements, as applicable (eg, ANP.32450 for autopsy pathology, TRM.32200 for blood volume standardization).

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of analytical balance service records • Sampling of analytical balance accuracy check records
	<ul style="list-style-type: none"> • Analytical balances (placement) • Standard weights (maintained, appropriate class)

COM.30860 Analytical Balance Maintenance

Phase I

Analytical balances are cleaned, serviced and checked at least annually by qualified service personnel.

Evidence of Compliance:

- ✓ Records of analytical balance maintenance **AND**
- ✓ Service contract or records of technical training of in-house personnel

COM.30870 Analytical Balance Placement

Phase I

Analytical balances are placed in locations that permit accurate and precise measurements. If subject to vibrations that may interfere with readings, they are placed on vibration-damping tables or surfaces.

NOTE: This requirement applies to analytical balances used to measure mass in the milligram and sub-milligram range.

REFERENCES

- 1) General European OMCL Network (GEON). Quality Management Document PA/PH/OMCL (12) 77 R11 Qualification of Equipment Annex 8: Quantification of Balances. Updated September 2020.

COM.30880 Analytical Balance Accuracy**Phase II**

Standard weights of the appropriate American National Standards Institute (ANSI)/ASTM Class are available and used for verifying accuracy of analytical balances at defined intervals, with records retained.

NOTE: The verification of accuracy of the analytical balance must be performed at a defined interval to ensure accurate creation of analytical calibrators and/or weighed-in controls from standard materials, as well as when gravimetrically checking the accuracy of pipettes.

Accuracy must be verified at least every six months if used for weighing materials to make standard solutions for method calibration. Accuracy must be verified at the time of installation and whenever a balance is moved. Acceptable ranges must be defined.

External verification of accuracy requires the appropriate class of ASTM specification weights. ASTM Class 1 weights are appropriate for calibrating high precision analytical balances (0.01 to 0.1 mg limit of precision). ASTM Class 2 weights are appropriate for calibrating precision top-loading balances (0.001 to 0.01 g precision). ASTM Class 3 weights are appropriate for calibrating moderate precision balances, (0.01 to 0.1 g precision).

Laboratories located outside of the United States may use equivalent certified weights if ANSI/ASTM class standard weights are not available.

REFERENCES

- 1) ASTM E617-18. Standard Specification for Laboratory Weights and Precision Mass Standards, ASTM International 2018.
- 2) ASTM E898-20. Standard Test Method of Testing Top-Loading, Direct-Reading Laboratory Scales and Balances. ASTM International. 2020.
- 3) General European OMCL Network (GEON). Quality Management Document PA/PH/OMCL (12) 77 R11 Qualification of Equipment Annex 8: Quantification of Balances. Updated September 2020.

COM.30890 Weight Maintenance**Phase II**

Calibration weights for analytical balances are well-maintained (clean, in a covered container, free of corrosion) and appropriate lifting or handling devices are available.

NOTE: Weights must be well-maintained (covered when not in use, free of corrosion) and only be handled by devices that will not leave residual contaminants on the weights. Certified weights will only meet their specifications if maintained in pristine condition.

WAIVED TEST IMPLEMENTATION

This section applies to waived testing performed following the manufacturer's instructions, without modification. The current list of tests waived under CLIA may be found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>.

Inspector Instructions:

	<ul style="list-style-type: none"> • Which waived tests or instruments have been implemented in the past two years? • Are all manufacturers' instructions followed exactly for all waived test kits and devices?



- Review written procedures and manufacturer's instructions for a sampling of tests. Confirm that procedures follow manufacturer's instructions.

COM.30980 Waived Test Implementation and Approval

Phase II

The laboratory director or designee meeting CAP director qualifications approves the introduction of new waived tests.

NOTE: After initial approval, the introduction of additional identical waived instruments performing identical previously approved waived tests does not require approval by the director or designee, providing manufacturer instructions for instrument verification are followed and recorded.

Waived testing must be performed following the manufacturer's instructions. If the laboratory modifies a waived test, the checklist requirements for high complexity testing apply, including the requirements for validation of the method performance specifications.

The laboratory director's signature on the written test procedure may be used to show approval of the test for use in patient testing.

This requirement also applies to tests with FDA emergency use authorization (EUA) specifically designated by the FDA or other entities as designated by the US Department of Health and Human Services (HHS) Secretary for use in patient care settings in the EUA Letter of Authorization. Such tests are deemed to be CLIA waived tests.

Evidence of Compliance:

- ✓ Records of test approval

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.

LABORATORY-DEVELOPED TESTS:

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.

Inspector Instructions:

	<ul style="list-style-type: none"> • Policies and procedures for the introduction of new tests, methods, or instruments • Sampling of assay validation and verification studies with emphasis on tests introduced in the past two years, especially high volume tests and tests with the highest risk to patients • Sampling of patient reports for laboratory-developed assays
	<ul style="list-style-type: none"> • Which laboratory tests or instruments have been implemented in the past two years, particularly those that are not FDA-cleared/approved? • Do you follow the manufacturer's instructions exactly for all FDA-cleared/approved diagnostic kits or devices? • For laboratories not subject to US regulations, do you follow the manufacturer's instructions exactly for tests approved by an internationally recognized regulatory authority? • How does your laboratory validate or verify assay performance prior to test implementation? • How does your laboratory verify or establish reference intervals?

- How does your laboratory validate clinical performance characteristics of LDTs?



- Select at least one validation or verification study performed for each type of instrument or method introduced during the past two years.
- In addition, select assays for evaluation if recurrent problems have been identified in proficiency testing results, quality control, competency assessment, or physician complaints regardless of how long the assay has been in place.
- Review validation or verification records to confirm that appropriate studies were performed using an adequate number of cases, and a written assessment of the data was performed. If the data showed discordances or unacceptable variations, investigate how they were resolved. If a study was not performed or is missing required components, cite the appropriate related requirement(s) (eg, COM.40300, COM.40325, COM.40350).
- Confirm that the written assessment of each component (accuracy, precision, interferences, etc.) of the validation or verification studies has been approved by the laboratory director (or qualified designee) prior to the initiation of clinical testing. If the study assessment was not signed by the laboratory director or designee, cite COM.40475.
- Review examples of patient reports for laboratory-developed tests to identify clinical claims being made by the laboratory for the testing. Confirm that studies for the clinical performance specifications were performed.

COM.40250 Manufacturer's Instructions

Phase II



The laboratory follows manufacturer's instructions for all test systems or provides validation records if the test has been modified.

NOTE: Following manufacturer's instructions includes performing quality control, calibration, calibration verification, and related functions as applicable to the scope of testing. Reagents, fluids, and disposable materials supplied by the laboratory must meet the specifications in the instructions.

If the laboratory modifies manufacturer's instructions, the test is no longer FDA-cleared/approved, and the modification(s) must be validated by the laboratory. This requirement also applies to laboratories not subject to US regulations for tests approved by an internationally recognized regulatory authority that are modified by the laboratory.

Changes in the specimen type or collection device are examples of common modifications (see "modification of manufacturer's instructions" in the Definition of Terms). Additional requirements for validation/verification may be found in the discipline-specific checklists.

For waived and moderately complex tests, if manufacturer instructions are modified, requirements for high complexity testing apply.

Evidence of Compliance:

- ✓ Validation records of established performance specifications (accuracy, precision, analytical sensitivity, analytical specificity, interferences, reference interval(s), and reportable range) of any test that has been modified

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): [42CFR493.1252]

****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 Medical Laboratory Measurement Procedures*. 4th ed. CLSI guideline EP10. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.
- 3) Clinical and Laboratory Standards Institute (CLSI). *A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods*. 3rd ed. CLSI report EP19-Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 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 Medical Laboratory Measurement Procedures*. 4th ed. CLSI guideline EP10. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.
- 2) Clinical and Laboratory Standards Institute (CLSI). *A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods*. 3rd ed. CLSI report EP19-Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 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: 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

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 to Evaluate Medical Laboratory Test Methods*. 3rd ed. CLSI report EP19-Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 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.

COM.40475 Method Validation and Verification Approval - Nonwaived Tests Phase II

Prior to clinical use of each nonwaived test, the laboratory director, or designee meeting CAP director qualifications, has signed the laboratory's written assessment of the validation or verification study (accuracy, precision, etc.) to confirm the acceptance of the study data and written assessment, and to approve each nonwaived test for clinical use.

NOTE: This checklist requirement is applicable only to nonwaived tests implemented after June 15, 2009; however, all nonwaived tests must have records of completed analytical validation or verification, regardless of their implementation date.

The approval must include: 1) review of the written assessment of the validation or verification study, including the acceptability of the data and investigation of any discordant results; 2) signed approval statement, such as, "I have reviewed the verification (or validation) data for the performance specifications listed below for the (insert instrument/test name), and the performance of the method is considered acceptable for patient testing."

If a validation or verification study (accuracy, precision, reportable range, etc.) was not performed or is missing required components, the appropriate, related checklist requirements must also be cited (eg, COM.40300, COM.40350).

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/verified for each test and instrument or device.

Evidence of Compliance:

- ✓ Records of approval of validation and verification studies and approval for clinical use

REFERENCES

- 1) Lawrence Jennings, Vivianna M. Van Deerlin, Margaret L. Gulley (2009) Recommended Principles and Practices for Validating Clinical Molecular Pathology Tests. *Archives of Pathology & Laboratory Medicine*: Vol. 133, No. 5, pp. 743-755
- 2) Labawan FL, Weck KE, Kant JA, Feldman GL, Schrijver; Biological and Molecular Genetic Resource Committee of the College of American Pathologists. Verification of performance specifications of a molecular test: cystic fibrosis carrier testing using the Luminex liquid bead array. *Arch Pathol Lab Med*. 2012. Jan; 136(1):14-9.
- 3) 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]

COM.40500 Analytical Interferences Phase II



The laboratory understands the analytical interferences for each test, and has an appropriate plan of action when they are present.

NOTE: Interfering substances may pose a significant problem to the clinical laboratory and healthcare providers who may be misled by laboratory results that do not reflect patient clinical status. The laboratory must be aware of common interferences by performing studies or referencing studies performed elsewhere (such as by the instrument-reagent manufacturer).

Evidence of Compliance:

- ✓ Document listing known interferences for each test and plan of action when they are present

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI guideline EP07. Clinical and Laboratory Standards Institute. Wayne, PA; 2018.
- 2) Ho C-H. The hemostatic effect of packed red cell transfusion in patients with anemia. *Transfusion*. 1998;38:1011-1014
- 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1253]

COM.40605 Reference Intervals**Phase II****The laboratory verifies or establishes its reference intervals.**

NOTE: Reference intervals are important to allow a clinician to assess patient results against an appropriate population. The reference intervals must be established or verified for each analyte and specimen source (eg, blood, urine, cerebrospinal fluid), when appropriate. For example, a reference interval can be verified by testing samples from 20 healthy representative individuals; if no more than two results fall outside the proposed reference interval, that interval can be considered verified for the population studied.

If a formal reference interval study is not possible or practical, then the laboratory should carefully evaluate the use of published data for its own reference intervals, and retain records of this evaluation. For many analytes (eg, therapeutic drugs, cholesterol, and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.

Evidence of Compliance:

- ✓ Record of reference interval study **OR** records of verification of manufacturer's stated interval when reference interval study is not practical (eg, unavailable normal population) **OR** other methods approved by the laboratory/section director

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):7164 [42CFR493.1253]
- 2) Van der Meulen EA, et al. Use of small-sample-based reference limits on a group basis. *Clin Chem*. 1994;40:1698-1702
- 3) 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.

COM.40615 Reference Interval Evaluation**Phase II****The laboratory evaluates the appropriateness of its reference intervals and takes corrective action if necessary.**

NOTE: Criteria for evaluation of reference intervals include:

1. Change of analytic methodology
2. Change in patient population

If it is determined that the range is no longer appropriate for the patient population, corrective action must be taken.

Evidence of Compliance:

- ✓ Records of evaluation and corrective action, if indicated

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):7164 [42CFR493.1253]
- 2) Van der Meulen EA, et al. Use of small-sample-based reference limits on a group basis. *Clin Chem*. 1994;40:1698-1702
- 3) 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.
- 4) 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): [42CFR493.1282(b)(1)(iii)]

COM.40620 Body Fluid Analysis**Phase II****Methods for body fluid analysis have been validated or verified and metrics for interpretation have been established.**

NOTE: This requirement applies directly to body fluid testing that the laboratory offers as a routine, orderable test. If the test is routinely performed on the fluid, there must be a written procedure. The requirement COM.40475 for a method validation or verification approval applies. Method performance specifications for blood specimens may be used for body fluids if the laboratory can reasonably exclude the existence of matrix interferences affecting the latter either by reference in the procedure manual to published literature or by evaluation for interferences

due to matrix effects by performing an appropriate study (eg, a dilution study using admixtures of samples, spiking samples, further dilution).

The reference intervals must be defined and reported with the results, unless the concentration of the analyte is reported in comparison to its concentration in a contemporaneously collected blood specimen. If the result is to be interpreted by comparison to the patient's blood, serum, or plasma, such results must be accompanied by an appropriate comment such as, "The reference interval(s) and other method performance specifications are unavailable for this body fluid. Comparison of this result with the concentration in the blood, serum, or plasma is recommended." Reference interval citations from the manufacturer's insert or published literature citations may be used to determine the reference interval (COM.40605). However, reference intervals have not been published for many body fluid analytes and obtaining normal fluids to establish reference intervals may not be feasible.

A request for a test on a body fluid specimen that is not listed on the laboratory's test menu that requires clearance by the section director or designee is considered a clinically unique specimen, rather than a routine, orderable test. Typically, these specimens are submitted due to an unusual clinical concern in a specific patient or situation (eg, pathologic states where the analyte is not normally found in the fluid type) and it may not be possible to establish a comparative metric. In such cases, the result must be accompanied by a comment such as, "The reference interval(s) and other method performance specifications have not been established for this body fluid. The test result must be integrated into the clinical context for interpretation."

Evidence of Compliance:

- ✓ Records of validation or verification studies with evaluation and approval **AND**
- ✓ Records of reference interval study **OR** records of verification of manufacturer's stated interval or published literature **OR** other methods approved by the laboratory/section director

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Analysis of Body Fluids in Clinical Chemistry*. 2nd ed. CLSI guideline C49. Clinical and Laboratory Standards Institute, Wayne, PA, 2018
- 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); [42CFR493.1253]
- 3) Block DR, Algeciras-Schimmeck A. Body fluid analysis; clinical utility and applicability of published studies to guide interpretation of today's laboratory testing in serous fluids. *Crit Rev Clin Lab Sci*. 2013 July-Oct;50(4-5):107-24. doi: 10.3109/10408363.2013.844679.
- 4) Owen WE, Thatcher ML, Crabtree KJ, et al. Body fluid matrix evaluation on a Roche cobas 8000 system. *Clin Biochem*. 2015; 48(13-14):911-4.

COM.40625 Clinical Claims Validation - FDA-cleared/approved Tests

Phase II



For FDA-cleared/approved tests, the laboratory validates clinical claims not included in the manufacturer's instructions.

NOTE: For laboratories not subject to US regulations, this requirement also applies to tests that are approved by an internationally recognized regulatory authority.

A clinical claim is a communication from the laboratory to its users (including but not limited to clinicians and patients) regarding a test's sensitivity and specificity, predictive values for a disease or condition, clinical usefulness, cost-effectiveness or clinical utility.

To adequately support a clinical claim, the laboratory must perform a clinical validation study, unless the clinical validity of the test is documented in peer-reviewed literature or textbooks. The clinical validation study must include at least 20 samples and must include both positive and negative samples. If the laboratory uses fewer samples, the laboratory director or designee meeting CAP director qualifications must record the criteria used to determine the appropriateness of the sample size.

Evidence of Compliance:

- ✓ Records of clinical studies performed by the laboratory **OR** peer-reviewed literature that reasonably substantiates all claims made by the laboratory about a test

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods*. 3rd ed. CLSI report EP19-Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

COM.40640 Clinical Performance Characteristics Validation - Laboratory-developed Tests Phase II



The laboratory validates clinical performance characteristics for laboratory-developed tests.

NOTE: Clinical performance characteristics include statements about a test's sensitivity and specificity, and may include determining predictive values for relevant disease(s) or condition(s), as applicable.

These characteristics must be established by the laboratory unless the clinical validity of the test is documented in peer-reviewed literature or textbooks. The clinical validation study must include at least 20 samples and must include both positive and negative samples. If the laboratory uses fewer samples, the laboratory director must record the criteria used to determine the appropriateness of the sample size.

Evidence of Compliance:

- ✓ Records of clinical studies performed by the laboratory **OR** peer-reviewed literature that reasonably substantiates all claims made by the laboratory about a test

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods*. 3rd ed. CLSI report EP19-Ed3. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

COM.40700 Method Performance Specifications Availability Phase II



For current test methods, the laboratory makes the following available to clients and the inspection team upon request:

- **Summary of the analytical performance specifications for each method, validated or verified by the laboratory to include analytical accuracy, precision, analytical sensitivity, analytical specificity (test method interferences), reference interval, and reportable range, as applicable; and**
- **Summary of clinical validation or peer-reviewed literature, as applicable, for laboratory-developed tests and FDA-cleared/approved tests where a laboratory makes a clinical claim not in the manufacturer's instructions.**

NOTE: Information may be provided to clients in a summary format referring to the supporting data, statistics, and published studies, as appropriate. Clients include healthcare entities, other laboratories, and licensed independent practitioners. This requirement does not apply to patients or their authorized representatives.

The laboratory may require clients to treat the data as confidential and not to use such proprietary information for its own test development or share such data with any other party except as required by law. The CAP inspection team is instructed to treat all such data as confidential and to review them solely for accreditation purposes.

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):7163 [42CFR493.1291(e)]

COM.40800 Analytical Methodology Changes Phase II



If the laboratory changes its analytical methodology so that test results or their interpretations may be significantly different, the change is explained to clients.

NOTE: This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the test report itself.

Common examples of assays where changes to the method may significantly affect results include tumor markers and high-sensitivity troponin assays.

Evidence of Compliance:

- ✓ Records such as directed mailings, laboratory newsletters or comment on the patient report advising of the change

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):7163 [42CFR493.1291(e)]
- 2) National Academy of Clinical Biochemistry, Sturgeon, CM, Diamandis, EP. (Eds.). *Laboratory Medicine Practice Guidelines. Use of tumor markers in clinical practice: quality requirements*. American Association for Clinical Chemistry, 2009.

COM.40805 Intermittent or Seasonal Testing**Phase II**

For tests taken out of production for a period of time (eg, seasonal testing for influenza), the laboratory meets the following requirements prior to resuming patient testing, as applicable:

1. PT or alternative assessment performed within 30 days prior to restarting patient testing
2. Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing
3. Competency assessed for analysts within 12 months prior to restarting patient testing

NOTE: A test is considered to be taken out of production when (1) patient testing is not offered AND (2) PT or alternative assessment, as applicable, is suspended. It does not apply to situations where a proficiency testing challenge is not performed due to a temporary, short-term situation, such as a reagent back order or an instrument breakdown. In those situations, the laboratory must perform alternative assessment for that testing event.

For tests for which PT is required by CAP, if a PT challenge is not offered during the 30-day period prior to restarting patient testing, the laboratory may perform an alternative assessment of the test. The laboratory must participate in the next scheduled PT event, if the Laboratory Accreditation Program requires external PT for that analyte.

COM.40830 Test List - Modified FDA-cleared/approved Tests and LDTs**Phase I**

The laboratory maintains a list of laboratory-developed tests (LDTs) and modified FDA-cleared/approved tests implemented by the laboratory.

NOTE: For laboratories not subject to US regulations, the list must also include tests approved by an internationally recognized regulatory authority that have been modified by the laboratory.

A form is available on the CAP website that may be used for maintaining this list and can be downloaded from the CAP website (cap.org) through e-LAB Solutions Suite.

COM.40840 Calibration and Quality Control Procedures - Modified FDA-cleared/approved Tests and LDTs**Phase II**

For laboratory-developed tests and modified FDA-cleared/approved tests, the laboratory defines written procedures for calibration and quality control based on the studies performed to evaluate the method performance specifications.

NOTE: The procedures must define the frequency, number, and concentration of calibrators and controls to be used.

For laboratories not subject to US regulations, this requirement also applies to tests that are not approved by an internationally recognized regulatory authority and to approved tests that have been modified by the laboratory.

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(b)(3)]

****REVISED** 08/24/2023****COM.40850 LDT Reporting****Phase II****Reports for laboratory-developed tests (LDTs) contain the following:**

- A statement that the assay was developed by the laboratory AND
- A brief description of the method and performance characteristics needed for clinical use, unless the information is readily available to the clinician in another format (eg, test catalog, policy to provide upon request).

NOTE: For laboratories subject to US regulations, the following disclaimer statement must be included on the patient report: "This test was developed and its performance characteristics determined by <insert laboratory/company name>. It has not been cleared or approved by the US Food and Drug Administration."

A test that uses a class I ASR (analytic-specific reagent) is by definition an LDT.

Laboratories not subject to US regulations do not need to use the above disclaimer but must include a statement that the test was developed by the laboratory.

The laboratory may put a single disclaimer on the patient report for all studies (eg, immunostains, in situ hybridization, or flow cytometry) collectively used in a particular case. Separately tracking each reagent used for a case and selectively applying the disclaimer is unnecessary.

The CAP also recommends (but does not require) including additional information in the patient report, such as the following:

- The FDA does not require this test to go through premarket FDA review.
- This test is used for clinical purposes. It should not be regarded as investigational or for research.
- This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

This requirement does not apply to laboratory-developed tests that are traditional methods, such as manual microscopy, conventional microbiologic cultures, conventional cytogenetics, and manual hematology and immunology tests.

REFERENCES

- 1) CLSI. *Establishing Molecular Testing in Clinical Laboratory Environments*: CLSI document MM19-A (ISBN 1-56238-773-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2011
- 2) Department of Health and Human Services, Food and Drug Administration. Medical devices; classification/reclassification, restricted devices, analyte specific reagents. Final rule. *Fed Register*. 1997(Nov 21):62243 [21CFR809 and 864].
- 3) Caldwell CW. Analyte-specific reagents in the flow cytometry laboratory. *Arch Pathol Lab Med*. 1998; 122:861-864.
- 4) American College of Medical Genetics, Technical Standards and Guidelines for Clinical Genetics Laboratories, 2021.

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

This section applies to laboratories using an IQCP approved by the laboratory director for nonwaived testing to reduce external control analysis to a frequency less than the limits defined in the CLIA regulations and CAP checklists. Laboratories are not required to implement an IQCP; however, one is required if the laboratory decides to perform QC at a frequency less than specified in the CLIA regulations. A laboratory may not implement an IQCP that allows for quality control to be performed less frequently than indicated in the manufacturer's instructions. This section does not apply if the type and frequency of external quality control already meets or exceeds minimum quality control requirements defined in the CLIA regulations and CAP checklist requirements.

If a laboratory is located in a state that does not accept IQCP as an option for reducing the frequency of external quality control, the laboratory must follow the state regulations and perform external quality control following the frequency defined in the state regulations and CAP checklists.

Eligibility for use of an IQCP is limited to testing meeting all of the following criteria:

- Nonwaived tests that employ an internal (electronic/procedural/built-in) quality control system
 - Exception: Microbiology media and reagents used for microbial identification and susceptibility testing may implement an IQCP as defined in the Microbiology Checklist
- Tests performed in specialties other than Anatomic Pathology and Cytopathology
 - Exception: If an Anatomic Pathology or Cytopathology test can be assigned to a different CMS subspecialty, it may qualify.

Testing performed using microbiology media and reagents used for microbial identification and susceptibility testing is eligible for IQCP as defined in the Microbiology Checklist.

IQCP requirements do not apply to waived testing. A search tool is available on the FDA website to confirm the complexity of tests performed and can be accessed at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

The CAP has a variety of tools available on cap.org through e-LAB Solutions Suite under Accreditation Resources, IQCP Toolbox, including frequently asked questions, examples, forms, and links to CMS and CDC resources.

Note that development of an IQCP only impacts quality control requirements. All other checklist requirements remain unchanged and applicable. For a listing of specialties/subspecialties and general regulations which are designated as "eligible" for IQCP refer to the Centers for Medicare and Medicaid State Operations Manual (www.cms.gov) interpretive guidelines for regulation 42CFR493.1256(d), Table 1: Eligibility for IQCP.

Inspector Instructions:

	<ul style="list-style-type: none"> • Policies and procedures for the implementation of an IQCP • Completed List of Individualized Quality Control Plans form identifying all tests, instruments and devices, and test sites using an IQCP • Sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years for the following: <ul style="list-style-type: none"> ◦ Risk assessment, including laboratory data and summary of findings ◦ Manufacturer's product inserts and published data ◦ Signed quality control plan defining all aspects monitored ◦ Ongoing quality assessment monitoring records for QC, instrument/equipment maintenance and function checks, complaints, errors, and corrective actions ◦ Reapproval of quality control plan at least biennially <p>Sampling of IQCP records to include: 1) a mix of manual and automated tests using an IQCP in the last two years; 2) a mix of tests using an IQCP where there are variations in the testing environment, personnel, multiple testing devices, etc.; and 3) a mix of tests using an IQCP that has had recurring problems with proficiency testing, quality control, instrument failure, errors, or physician complaints.</p>
	<ul style="list-style-type: none"> • What sources of information did you use to perform the IQCP risk assessment? • How is the ongoing quality assessment of your IQCP performed? • How are physician complaints about the validity of test results for tests using an IQCP handled? • What is the process to review errors for tests using an IQCP? • Have there been any adverse patient events related to a test using an IQCP?
	<ul style="list-style-type: none"> • Review an IQCP and confirm that all elements of the quality control plan are being monitored

- Select a test that has an IQCP and compare the manufacturer's package insert to the quality control plan to confirm that external QC is performed at least as frequently as defined in the manufacturer's instructions
- Review an IQCP that is shared by more than one testing location to verify that the risk assessment included an evaluation of each site or location and that each location is monitored as defined in the IQCP
- Review the IQCP risk assessment summary, supporting data and approved quality control plan to confirm that the plan was approved by the laboratory director prior to implementation
- Review ongoing quality assessment data and error/incident logs to confirm that effective corrective actions have been taken

COM.50200 List of Individualized Quality Control Plans

Phase II

The laboratory has identified all tests using an IQCP on the CAP's List of Individualized Quality Control Plans form.

NOTE: The form may be downloaded from cap.org through e-LAB Solutions Suite under Accreditation Resources, IQCP Toolbox.

The use of the CAP form is required, even if standardized forms and templates are used by the laboratory.

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Brochure #12. CLIA Individualized Quality Control Plan, Considerations When Deciding to Develop an IQCP. November 2014. <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf>

COM.50300 Risk Assessment

Phase II



The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include all of the following:

- Pre-analytic, analytic, and post-analytic phases of the testing process
- Intended medical uses of the test and impact if inaccurate results are reported (clinical risk)
- Components of the tests including reagents, environment, specimen, testing personnel, and test system
- Variations in the components based on use of the tests (eg, use in different environments, by different personnel, or multiple identical devices)
- Data from the laboratory's own environment, instrument/equipment performance, and testing personnel demonstrating acceptable performance over the maximum time interval between external quality control runs defined in the IQCP
- Manufacturer's instructions and recommendations

NOTE: The risk assessment must include a process to identify the sources of potential failures and errors for a testing process, and evaluate frequency and impact of those failures and sources of error.

The laboratory director must consider the laboratory's clinical and legal responsibilities for providing accurate and reliable patient test results. Published data and information may be used to supplement the risk assessment but are not substitutes for the laboratory's own studies and evaluation. The laboratory must involve a representative sample of testing personnel in the process of conducting the risk assessment. It is not necessary for all personnel to be involved.

The risk assessment for laboratories with multiple identical devices must show that an evaluation was performed if there are differences in testing personnel or environments where testing is performed, with customization of the quality control plan, as needed.

The QC study to assess the performance and stability of the tests must support the QC frequency and elements defined in the laboratory's quality control plan. At a minimum, the study must include laboratory data representing the maximum interval between runs of external quality control. Consecutive days of data collection are not specifically required if testing is done sporadically, or is not performed seven days a week. Laboratories may use historical data for tests already in place, and may supplement the study with data from published literature. For new tests, devices, and instruments introduced into the laboratory, the laboratory must collect in-house data and may need to define a more frequent QC interval until sufficient data is available to support a longer time interval between runs of external QC. For susceptibility testing guidance, refer to MIC.21910.

For affiliated laboratories (eg, systems) with integrated procedures, each accredited laboratory must have its own IQCP approved by the laboratory director. There must be records demonstrating that risks specific to the site were evaluated involving a representative sample of local testing personnel to conduct the risk assessment and that laboratory-specific QC data were used in the study to support the defined frequency of quality control. Laboratories may use data from other sites to supplement risk assessments and to support their findings.

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Quality Control Based on Risk Management*. 2nd ed. CLSI document EP23. Clinical and Laboratory Standards Institute. Wayne, PA; 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>
- 3) Nichols JH. Laboratory quality control based on risk management. *Ann Saudi Med* 2011; 31:223-228.
- 4) Yundt-Pacheco J, Parvin CA. Validating the performance of QC procedures. *Clin Lab Med* 2013; 33:75-88.
- 5) US Department of Health and Human Services. Developing an IQCP - A Step-by-Step Guide. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf>

****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*. 2nd ed. CLSI document EP23. Clinical and Laboratory Standards Institute. Wayne, PA; 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.

COM.50500 Quality Control Plan Elements

Phase II

The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:

- The number, type (external and internal quality control systems), and frequency of quality control
- Criteria for acceptable performance
- Monitoring of the testing environment and reagents
- Specimen quality
- Instrument calibration, maintenance, and function checks
- Training and competency of testing personnel

- **Provisions for multiple identical devices and variation for uses covered under one IQCP**

NOTE: The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions, at minimum. The quality control plan must control the quality of the test process and ensure accurate and reliable test results.

External control material samples must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions.

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Quality Control Based on Risk Management*. 2nd ed. CLSI document EP23. Clinical and Laboratory Standards Institute. Wayne, PA; 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.
- 3) US Department of Health and Human Services. Developing an IQCP - A Step-by-Step Guide. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf>

COM.50600 Ongoing Quality Assessment Monitoring

Phase II



Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes records of the following:

- **Review of quality control and instrument/equipment maintenance and function check data at least monthly**
- **Evaluation of errors relating to preanalytic, analytic and post analytic phases of the testing process**
- **Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing**
- **Evaluation of corrective actions taken when problems are identified**
- **Re-evaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur**
- **Reapproval of the quality control plan by the laboratory director or designee at least biennially.**

NOTE: If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if modifications are needed to the quality control plan to mitigate potential risk. Common examples of failures include unacceptable proficiency testing results, recurrent out-of-range reagent storage or room temperatures, unacceptable quality control results, use of unvalidated specimen types, and the IQCP not being followed as written.

An example form is available on cap.org through e-LAB Solutions Suite under Accreditation Resources, IQCP Toolbox that may be used for recording ongoing assessments of the IQCP.

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Quality Control Based on Risk Management*. 2nd ed. CLSI document EP23. Clinical and Laboratory Standards Institute. Wayne, PA; 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.
- 3) US Department of Health and Human Services. Developing an IQCP - A Step-by-Step Guide. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf>