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

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# All Common Checklist

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ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP website (www.cap.org) by logging into e-LAB Solutions. 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.

SUMMARY OF CHECKLIST EDITION CHANGES
All Common Checklist
07/28/2015 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 listing of requirements below is from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements

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UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

All checklist requirements contain a requirement number, subject header, phase, and a declarative statement. Some requirements also contain a NOTE and/or Evidence of Compliance.

The NOTE portion of a checklist requirement provides additional detail to assist in interpreting the requirement.

Evidence of Compliance (EOC) is intended to:

- Suggest specific examples of acceptable records; some elements are required
- Assist in inspection preparation and for managing ongoing compliance
- Drive consistent understanding of requirements

If a policy or procedure is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies or procedures covered in the CAP checklists must be a written document. A separate policy or procedure may not be needed for items in EOC if it is already addressed by an overarching policy.

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. In some instances, the same requirement exists in both the COM Checklist and in a discipline-specific checklist, but with a different checklist note that has a more specific requirement. In these situations, the discipline-specific requirement takes precedence over the COM requirement.

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

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

DEFINITION OF TERMS

**Alternative 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.

**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

Biennial - Every 24 calendar months

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

Calibrator, historical - The set of archived results of a single-point calibrator that demonstrates stability of the assay over time

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

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

Confirmation - Substantiation of the correctness of a value or process

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

Correlation - Establishment of agreement 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 detection or quantification of specific features in an image following enhancement and processing of that image, including immunohistochemistry, DNA analysis, morphometric analysis, and in situ hybridization

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.

FDA - In the context of checklist requirements, FDA should be taken to mean the national, state, or provincial 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 before routine use, at prescribed intervals, or after minor adjustment (e.g. base line calibration, balancing/zero adjustment, thermometer calibration, reagent delivery).

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

Instrument - An analytical unit that uses samples to perform chemical or physical assays (e.g. 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

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** - Those activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning, changing parts, fluids, tubing, lubrication, electronic checks, 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, including 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

**Nonwaived** - Tests categorized as either moderately complex (including provider-performed microscopy) or highly complex by the US Food and Drug Administration (FDA), according to a scoring system used by the FDA

**Performance verification** - The set of processes that demonstrate an instrument or an item of equipment operates according to expectations upon installation and after repair or reconditioning (e.g. replacement of critical components)

**Policy** - 1) Set of basic principles or guidelines that direct or restrict the facility's plans, actions, and decisions; 2) Statement that tells what should or should not be done

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

**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** - 1) Specified way to carry out an activity of a process (also referred to by ISO as "work instructions"; 2) Set of steps performed that tells "how to do it" to achieve a specified outcome, including decisions to be made

**Process** - 1) Set of interrelated or interacting activities that transforms inputs into outputs; 2) Series of events, stages, or phases that takes place over time that tells "what happens" or "how it works"

**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.

**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.

**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

**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 medical, technical and/or scientific oversight of a specialty or section of the laboratory.

**Semiannual** - Every 6 calendar months
Subject to U.S. 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 for the assessment of the health of human beings.

Telepathology - The practice in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or is recorded in the patient record.

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

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

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 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.

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

Inspector Instructions:

- Sampling of proficiency testing policies and procedures
- Sampling of evaluations of unacceptable proficiency testing results
- Sampling of proficiency testing records including worksheets, instrument read-outs, reporting forms, physically signed attestation statement and laboratory director/designee review
- Records of semi-annual alternative assessment testing, if applicable
- Evaluations of ungraded proficiency testing results, if applicable

- 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 sample?
- What do you consider unacceptable proficiency testing performance and how do you determine corrective action?
- How do you evaluate ungraded proficiency testing?

- Select a representative sample of proficiency testing results and follow records from original testing to the reporting of results to the proficiency testing provider. Determine if the samples and results are being handled in compliance with requirements and following laboratory policies and procedures.
- Select a representative sample 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.

COM.01000 PT Procedure

The laboratory has written procedures for proficiency testing sufficient for the extent and complexity of testing done in the laboratory.

NOTE: The laboratory must have written procedures for the proper handling, analysis, review and reporting of proficiency testing materials. There must be written procedure(s) for investigation and correction of problems that are identified by unacceptable proficiency testing results. The laboratory should also have procedure(s) for investigation of results that, although acceptable show bias or trends suggesting a problem.

CAP-accredited laboratories must participate in proficiency testing (PT) (when available through CAP or a CAP-accepted alternate provider) for all patient tests designated by CAP. The current list of analytes for which CAP requires PT is available on the CAP website [http://www.cap.org/] or by phoning 800-323-4040 (or 847-832-7000), option 1.

The CAP office audits PT participation to assure that accredited laboratories participate in PT as appropriate.

REFERENCES

COM.01100  Ungraded PT Challenges  Phase II

The laboratory has a procedure for assessing its performance on PT challenges that were intended to be graded, but were not.

NOTE: This requirement addresses PT challenges that were intended to be graded, but were not, for reasons such as: 1) the laboratory submitted its results after the cut-off date, 2) the laboratory did not submit results, 3) the laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place). Also, if possible, the laboratory should assess its performance on PT challenges that were not graded because of lack of consensus. For guidance on the approach to these situations, refer to appendix I in the CAP Laboratory Accreditation Manual for listing of PT exception codes and actions.

Evidence of Compliance:
✓ Records of review and evaluation of ungraded PT challenges

REFERENCES

**REVISED** 04/21/2014
COM.01200  Activity Menu  Phase I

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

NOTE: The Activity Menu must reflect the laboratory’s current testing, including removal of discontinued tests. The accuracy of the Activity Menu can be assessed by inquiry of responsible individuals, and by examination of the laboratory’s test requisition(s), computer order screens, procedure manuals, or patient reports.

In order to ensure proper customization of the checklists, the laboratory must also ensure that the activity menu is accurate for non-test activities, such as methods and types of services offered.

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

If any tests omitted from the laboratory’s Activity Menu are not covered by the checklists provided for the inspection, the inspector should contact the CAP (800-323-4040) for instructions and record on the appropriate section page in the Inspector’s Summation Report (ISR) whether those tests were inspected or not inspected.

REFERENCES

**REVISED** 07/28/2015
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 [http://www.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.

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 assessment procedure for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

NOTE 4: For laboratories not subject to US regulations, participation in proficiency testing must be through CAP PT Programs. 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. (This went into effect as of the 2014 Proficiency Testing Program year.) If unable to participate, however, the laboratory must implement an alternative assessment procedure for the affected analytes.

NOTE 5: Proficiency testing for HER2 (ERBB2) is method specific. If the laboratory performs HER2 (ERBB2) testing by multiple methods, the laboratory must participate in PT for each method.

A. HER2 interpretation by immunohistochemistry (IHC): If the laboratory interprets its HER2 test results from IHC stains prepared at another facility, the laboratory must:
• Enroll in an appropriate PT Program
• Send PT materials to the staining facility for preparation, and
• Interpret the resulting stains using the same procedures that are used for patient specimens

B. HER2 (ERBB2) interpretation by FISH (or ISH): If the laboratory sends its FISH (or ISH) slides for hybridization to another facility, the laboratory must perform an alternative assessment of the test twice annually and may not participate in formal (external) PT.

NOTE 6: For purposes of photograph/image identification in CAP PT Programs, it is strongly recommended that the current CAP Surveys Hematology Glossary be readily available to the bench technologist in the hematology and urinalysis sections.

Evidence of Compliance:
✓ Records such as CAP order form or purchase order 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
2) Tholen DW. Reference values and participant means as targets in proficiency testing. Arch Pathol Lab Med. 1993;117:885-889
**REVISED** 07/28/2015

COM.01400 PT Attestation Statement

The proficiency testing attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.

NOTE: Physical signatures must appear on a paper version of the attestation form. 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.

- For high complexity testing, it may be delegated to an individual meeting the qualifications of a technical supervisor or section director.
- For moderate complexity testing, it may be delegated to an individual meeting the qualifications of a technical consultant.

Evidence of Compliance:
✓ Appropriately signed attestation statement from submitted PT result forms

REFERENCES

COM.01500 Alternative Performance Assessment

For tests for which CAP does not require PT, the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing.

NOTE 1: Appropriate alternative performance assessment procedures include participation in an external PT program not required by CAP; participation in an ungraded/educational PT program; split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed materials, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice.

NOTE 2: For FISH 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 assessment may be performed by method or specimen type rather than for each analyte or tested abnormality. For tests such as allergen testing, alternative assessment may be performed in batches of analogous tests.

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.

The list of analytes for which CAP requires proficiency testing is available on the CAP website [http://www.cap.org/] or by phoning 800-323-4040 (or 847-832-7000), option 1.

Evidence of Compliance:
✓ List of tests defined by the laboratory as requiring alternative assessments AND
✓ Records of those assessments

REFERENCES


COM.01600 PT Integration Routine Workload Phase II

The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples.

NOTE: Duplicate analysis of any proficiency sample is acceptable only if patient/client specimens are routinely analyzed in the same manner. With respect to morphologic examinations (identification of cell types and microorganisms; review of electrophoretic patterns, etc.), group review and consensus identifications are permitted only for unknown samples that would ordinarily be reviewed by more than one person in an actual patient sample.

If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method. The educational purposes of proficiency testing are best served by a rotation that allows all testing personnel to be involved in the proficiency testing program. Proficiency testing records must be retained and can be an important part of the competency and continuing education documentation in the personnel files of the individuals. When external proficiency testing materials are not available, the semiannual alternative performance assessment process should also be integrated within the routine workload, if practical.

Evidence of Compliance:
✓ Written policy describing proper handling of PT specimens AND
✓ Instrument printout and/or work records AND
✓ Completed attestation pages from submitted PT result forms

REFERENCES

COM.01700 PT Evaluation Phase II

There is ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for each unacceptable result.

NOTE: Primary records related to PT and alternative assessment testing are retained for two years (unless a longer retention period is required elsewhere in this checklist for specific analytes or disciplines). 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 proficiency testing specimens.

Evidence of Compliance:
✓ Records of ongoing, timely review of all PT reports and alternative assessment results by the laboratory director or designee AND
✓ Records of investigation of each “unacceptable” PT and alternative assessment result including records of corrective action appropriate to the nature and magnitude of the problem

REFERENCES
**REVISED** 07/28/2015

COM.01800  PT Interlaboratory Communication  Phase II

There is a policy that prohibits interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider.

NOTE: Results must be reported by personnel within the laboratory. There is a strict prohibition against interlaboratory communications about proficiency testing samples or results until after the deadline for submission of data to the proficiency testing provider. The laboratory director is responsible for enforcing this prohibition. Records of training on the handling of PT samples and prevention of interlaboratory communication are strongly recommended. The laboratory must maintain the records of the proficiency testing event, including a copy of the proficiency testing program’s report forms. Copies of such records must not be shared with and should be inaccessible to personnel of any laboratory including an affiliated laboratory until after the deadline for submission of results.

REFERENCES
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

**REVISED** 04/21/2014

COM.01900  PT Referral  Phase II

There is a policy that prohibits referral of proficiency testing specimens to another laboratory or acceptance from another laboratory.

NOTE: 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 abnormal blood smears might be referral of the smear to a pathologist located at another site. For proficiency testing specimens, the referring laboratory must NOT follow its routine procedure in this situation. Rather, the laboratory must submit a PT result indicating that the test is not performed since the review does not occur within the referring laboratory.

For laboratories subject to US regulations, this applies even if the second laboratory is in the same health care system. It is the responsibility of the laboratory director to ensure that this prohibition is enforced.

Records of training on referral and acceptance of PT samples is strongly recommended.


REFERENCES
QUALITY MANAGEMENT

GENERAL ISSUES

Inspector Instructions:

- Sampling of QM policies and procedures
- QM/QC program, including pre-analytic, analytic and post-analytic monitor 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
- Semiannual instrument/method comparison records

- How do you evaluate data on the incident/error log? How do you determine appropriate corrective action?
- As a staff member, what is your role in quality management?
- How do you detect and correct laboratory errors?

- Follow an incident identified on the incident/error log 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 Written QM/QC Plan

The laboratory has a written quality management/quality control (QM/QC) program.

NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory’s systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective action based on data from its QM system.

All QM requirements in the Laboratory General Checklist pertain to the laboratory.

Evidence of Compliance:

- Records reflecting conformance with the program as designed AND
- Results of quality surveillance

REFERENCES

Unusual Laboratory Results

There is a written procedure for the detection and correction of 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 reported data for tests that do not include interpretation. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results should provide for timely correction of errors, i.e. before results become available for clinical decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ordering physician or referring laboratory, as applicable.

Each procedure must include a listing of common situations that may cause analytically inaccurate results, together with a procedure to 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 (normal) range.

Evidence of Compliance:
✓ Records of review of results OR records of consistent implementation of the error detection system(s) defined in the procedure AND
✓ Records of timely corrective action of identified errors

REFERENCES

Supervisory Result Review

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 patient records. Rather, this requirement is intended to address only that situation for "high complexity testing" performed by trained high school graduates qualifying under the CLIA regulation 42CFR493.1489(b)(5)(i) when a qualified supervisor/general supervisor is not present.

The qualifications to perform high complexity testing can be accessed using the following link: CAP Personnel Requirements by Testing Complexity.

Evidence of Compliance:
✓ Written policy defining the personnel and test results requiring review AND
✓ Records of result review for specified personnel

REFERENCES

Instrument/Equipment Record Review

Instrument and equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.
NOTE: The review of the records related to tests that have an approved IQCP must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.).

**NEW** 04/21/2014

COM.04250 Comparability of Instruments/Methods

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

NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods. The purpose of the requirement is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. This comparison is required only for nonwaived instruments/methods accredited under a single CAP number. The laboratory must establish a written procedure for this check that includes acceptance criteria. This requirement is not applicable to calculated parameters.

Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number.

Otherwise, the use of human samples, rather than stabilized commercial controls, is preferred to avoid potential matrix effects. The use of pooled patient samples is acceptable since there is no change in matrix. In cases when availability or pre-analytical stability of patient/client specimens is a limiting factor, alternative protocols based on QC or reference materials may be necessary but the materials used should be validated (when applicable) to have the same response as fresh human samples for the instruments/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. If these are defined as separate tests, then 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 (e.g. 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 (e.g. antigen typing versus culture or detection of DNA versus a biochemical characteristic) designed to detect the same analyte.

Evidence of Compliance:
✓ Written procedure for performing instrument/method comparison AND
✓ Records of comparability studies reflecting performance at least twice per year with appropriate specimen types

REFERENCES
Acceptability criteria are defined for comparability of instruments/methods used to test the same analyte, with records of action when the criteria are not met.

NOTE: Statistically defined acceptability limits should be used for quantitative assays.

Evidence of Compliance:
✓ Records of comparability studies with evidence of review and action taken, as appropriate

REFERENCES

SPECIMEN COLLECTION AND HANDLING

Inspector Instructions:

- Sampling of specimen collection and handling policies and procedures
- Sampling of specimen rejection records/log

- Sampling of patient specimens and derivatives of the primary specimen used during testing (specimen labeling, presentation, integrity)

- 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 (e.g. slides, aliquots, etc.) derived from the primary specimen?

COM.06000 Specimen Collection Manual

There are written procedures describing 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 procedure may be in paper or electronic form.

REFERENCES
All Common Checklist

Phase II

**COM.06100** Primary Specimen Container Labeling

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 in laboratory policy.

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 (e.g. hospital room number) is not an acceptable identifier. Identifiers may be in a machine readable format, such as a barcode.

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.

Evidence of Compliance:
- Written policy with criteria for acceptable labeling of primary specimen containers AND
- Specimen collection procedures with defined labeling specifications OR
- Records of compliance audits for specimen labeling

REFERENCES

**NEW** 07/28/2015

**COM.06200** Secondary Specimen Container Labeling

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 and must be defined in laboratory procedure.

Slides prepared from specimens in the laboratory are considered secondary specimen containers. Slides prepared in the patient setting and brought to the laboratory (e.g. 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 (e.g. 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 (e.g. levels of sectioning). Automated prelabeling systems are acceptable.

REFERENCES

**NEW** 07/28/2015

**COM.06300 Specimen Rejection Criteria**

**Phase II**

There are written criteria for the rejection of unacceptable specimens, instructions for the special handling of sub-optimal specimens, and records of disposition of all unacceptable 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.

This requirement applies to specimens received for all types of testing and does not imply that all “unsuitable” specimens are discarded or not analyzed. If there is a problem with a specimen (e.g. improperly collected or stored, insufficient quality/quantity of specimen, inadequate labeling or requisition information, broken slides, hemolysis, lipemia, gross contamination, etc.), there must be a mechanism to notify clinical personnel responsible for patient care. If the treating physician desires the result, then the laboratory must note the condition of the specimen on the report. Some or all tests may be incorrect on such a specimen. The laboratory may wish to record that a dialogue was held with the physician, when such occurs.

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
✓ Instructions for special handling of sub-optimal specimens 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)]
PROCEDURE MANUAL

The procedure manual should be used by personnel at the workbench and must include the following elements, when applicable to the test procedure:

1. Principle and clinical significance
2. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection
3. Microscopic examination, including the detection of inadequately prepared slides
4. Step-by-step performance of the procedure, including test calculations and interpretation of results
5. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing
6. Calibration and calibration verification procedures
7. The analytic measurement range for test results for the test system, if applicable*
8. Control procedures
9. Corrective action to take when calibration or control results fail to meet the laboratory’s criteria for acceptability
10. Limitations in the test methodology, including interfering substances
11. Reference intervals (normal values)
12. Imminently life-threatening (critical) test results
13. Pertinent literature references
14. 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
15. Description of the course of action to take if a test system becomes inoperable

(*The analytic measurement range may not apply to qualitative or semi-quantitative tests.)

The manual should 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:

- Representative sample of procedures for completeness, laboratory director approval, and review. Current practice must match contents of policies and procedures.
- Validation study of modified FDA-cleared/approved test, if applicable
- How do you access procedures?
- What procedure has most recently been implemented or modified?
- How do you ensure all copies of 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?
- Identify a newly-implemented procedure in the prior two years and follow the steps through authoring, laboratory director approval, and staff training
A complete procedure manual is available at the workbench or in the work area.

NOTE 1: 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. In all cases, procedures must match the laboratory’s practice, the laboratory’s practice must follow written procedure, and appropriate reviews must occur.

NOTE 2: 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 3: 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 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic versions of procedures must be subjected to proper document control (i.e. only authorized persons may make changes, changes are dated/signed (manual or electronic), and there are records of biennial review). Review of electronic procedures may be recorded by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Records of review by a secure electronic signature are NOT required. Alternatively, paper review sheets may be used to record review of electronic 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 [42CFR493.1251(a) (b) (1-14)(c)(d)(e)]
2) van Leeuwen AM. 6 Steps to building an efficiency tool. Advance/Laboratory. 1999:8(6):88-91

COM.10100 Procedure Manual Review Phase II

There are records of review of all technical policies and procedures by the current laboratory director or designee 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), it is suggested that a schedule be developed 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.
Only technical policies and procedures are addressed in this requirement. Biennial review is not required for other controlled documents.

REFERENCES

COM.10200 New Procedure Review 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 required. A secure electronic signature is desirable, but not required.

Evidence of Compliance:
✓ Policy on procedure review AND
✓ Records of new policy or procedure approval

REFERENCES

COM.10250 New Procedure Review (Not Subject to US Regulations) Phase II
For laboratories not subject to US regulations, the laboratory director or designee 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 required. A secure electronic signature is desirable, but not required.

Evidence of Compliance:
✓ Policy on procedure review AND
✓ Records of new policy or procedure approval

COM.10300 Knowledge of Policies and Procedures Phase II
The laboratory has a defined process and 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 specifically 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

COM.10500 Discontinued Policies and Procedures Phase II
When a policy or procedure is discontinued, a paper or electronic copy is maintained for at least 2 years, recording initial date of use, and retirement date.
NOTE 1: In transfusion medicine, policies and procedures (paper or electronic) related to donor collection, transfusion, and administration of tissues and progenitor cells must be maintained for 5 years.

NOTE 2: For genetic testing, in order to meet the requirements of some states relating to the testing of minors (under the age of 21), it is recommended that laboratories retain policies or procedures (paper or electronic) for at least 23 years (to cover the interval from fetal period to age 21).

REFERENCES

RESULTS REPORTING

Inspector Instructions:

- Sampling of critical patient results/log
- How do you record the reporting of critical results? Who do you contact?
- Follow a critical result from testing, reporting and recording of notification

COM.29950 Reference Intervals

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

NOTE: The laboratory must report reference (normal) intervals or interpretations with patient/client results, where such exist. This is important to allow proper interpretation of patient/client data. Age- and/or sex-specific reference ranges (normal values) or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags (generally available with a computerized laboratory information system) is recommended. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions, which are based on the test result.

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable.

REFERENCES
Critical Result Notification

Phase II

The laboratory has written procedures for immediate notification of a physician (or other clinical personnel responsible for the patient’s care) when results of designated tests exceed established "critical" values that are important for prompt patient management decisions. Records of notification are maintained.

NOTE: Alert or critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. Each laboratory may 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). Critical results should be defined by the laboratory director, in consultation with the clinicians served.

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

Records must be maintained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records must include: date, time, responsible laboratory individual, person notified (the person’s first name alone is not adequate documentation), and test results. Any problem encountered in accomplishing this task should be investigated to prevent recurrence.

Reference laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The reference laboratory should have a written agreement with the referring laboratory that indicates to whom the reference 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.

REFERENCES


Critical Result Read-Back

Phase I

When critical results are communicated by phone, “read-back” of the results is requested and recorded.

NOTE: Transmission of critical results by electronic means (FAX or computer) is acceptable. If critical results are transmitted electronically, the laboratory must confirm receipt of the result by the intended recipient (e.g. by a phone call); however, no read-back is necessary.

Evidence of Compliance:

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

Inspector Instructions:

- 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)

- Sampling of reagents (expiration date, labeling, storage)

- 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 (e.g. 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 Handling/Storage - 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 and recorded daily. The two acceptable ways of recording temperatures are: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). The identity of the individual recording the temperature(s) must be recorded (initials of the individual are adequate).

The use of automated (including remote) temperature monitoring systems is acceptable, providing that laboratory personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. There must be records showing daily functionality of the system.

Evidence of Compliance:
✓ Written procedure consistent with manufacturer’s instructions for each waived test

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

**REVISED** 07/28/2015

COM.30300  Reagent Labeling  Phase II
Reagents, calibrators, controls, stains, chemicals, and solutions are properly labeled, as applicable and appropriate, with the following elements.

1. Content and quantity, concentration or titer
2. Storage requirements
3. Date prepared, filtered or reconstituted by laboratory
4. 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.

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:
✓ Written procedure defining elements and requirements for reagent labeling

REFERENCES

**REVISED** 07/28/2015
COM.30350 Reagent Storage and Handling Phase II

All reagents and media are stored and handled as recommended by the manufacturer.

NOTE: Reagents and media must be stored and handled as recommended by the manufacturer to 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 laboratory identifies a problem with a reagent that was used for patient testing (e.g. expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and maintain records of the evaluation and actions taken.

If ambient storage temperature is indicated, there must be records that the defined ambient temperature is maintained and corrective action taken when tolerance limits are exceeded.

A frost-free freezer may be used to store reagents and controls provided that the function of these materials is not compromised. Storage conditions must remain within the specifications of the manufacturer of the reagent or control. Temperatures may be recorded using a continuous monitoring system or a maximum/minimum thermometer. Thermal containers within the freezer may be used.

Patient samples may be stored in a frost-free freezer only if protected from thawing. The laboratory must maintain records showing that the temperatures stay within the defined range.

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

REFERENCES
**REVISED** 07/28/2015

COM.30400  Reagent Expiration Date  Phase II

All reagents, chemicals, and media are used within their indicated expiration date.

NOTE: The laboratory must assign an expiration date to any reagents and media that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions, and risk of deterioration.

This requirement also applies to the labeling of chemicals used in the laboratory. Requirements relating to precautionary labeling for hazardous chemicals are included in the Chemical Safety section of the Laboratory General Checklist.

Separate requirements for rare blood banking reagents are included in the Transfusion Medicine Checklist.

For laboratories not subject to US regulations and military laboratories in overseas locations, expired reagents may be used 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 maintain records of verification of the performance of expired reagents in accordance with written laboratory procedure. The laboratory must also maintain 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:

✓ Written procedure for evaluating reagents and media lacking manufacturer’s expiration date

✓ Records of reagents used beyond their expiration date (as applicable)

REFERENCES


COM.30450  New Reagent Lot Confirmation of Acceptability  Phase II

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

NOTE: The purpose of this check is to confirm that the use of new reagent lots and shipments 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.

Qualitative: For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative sample with known reactivity against the new reagent lot. A weakly positive sample should also be used in systems where patient results are reported in that fashion.

Examples of suitable reference materials for qualitative tests include:

1. Positive and negative patient samples tested on a previous lot;
2. Previously tested proficiency testing materials;
3. External QC materials tested on the previous lot;
4. Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms.

For flow cytometry reagents, please refer to the Reagents section of the Flow Cytometry Checklist.

**Quantitative:** For quantitative nonwaived tests, patient specimens should be used to compare a new lot against the old 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 samples confirms the absence of matrix interference. Other than patient samples, the following materials may also be used:

1. Reference materials or QC products provided by the method manufacturer with method specific and reagent lot specific target values;
2. Proficiency testing materials with peer group established means;
3. QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories;
4. Third party general purpose reference materials with the method manufacturer to be commutable with patient specimens for the method.
5. QC material used to test the current lot is adequate alone to check a new shipment of the same reagent lot, as there should be no change in potential matrix interactions between the QC material and different shipments of the same lot number of reagents.

For hematology analyzers, reservoirs containing testing reagents and cleaning/decontaminating solutions must be checked according to manufacturer's instructions.

**Evidence of Compliance:**
- Written procedure for the confirmation of acceptability of new lots and shipments **AND**
- Records of acceptability studies for new reagent lots and shipments

**REFERENCES**

### COM.30500 Reagent Kit Components

**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.

**Evidence of Compliance:**
- Written policy defining allowable exceptions for mixing kit components from different lots

**REFERENCES**

### 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. The laboratory is also responsible for any additional instrument and equipment requirements found in the discipline-specific checklists, as applicable.
INSTRUMENT AND EQUIPMENT MAINTENANCE/FUNCTION CHECKS

Inspector Instructions:

- 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
- Instrument/equipment records (promptly retrievable)

**NEW** 04/21/2014
COM.30525 Maintenance and Function Checks - Waived Tests  
Phase II

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

Evidence of Compliance:
✓ Written procedure consistent with manufacturer's instructions for each waived test AND
✓ Records for 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.

**NEW/REVISED** 07/28/2015
COM.30550 Instrument/Equipment Performance Verification  
Phase II

The performance of all instruments and equipment is verified upon installation and after major maintenance or service to ensure that they run according to expectations.

NOTE: Performance verification is necessary after repairs or replacement of critical components of an instrument or item of equipment.

Evidence of Compliance:
✓ Written procedure for performance verification AND
✓ Records of performance verification

REFERENCES

**NEW/REVISED** 07/28/2015
COM.30575 Instrument/Operation  
Phase II

There are written procedures for start-up, operation and shutdown of instruments and equipment, as applicable.

NOTE: These procedures must readily be available to the operator in the immediate vicinity of the instrument, and ideally should include a procedure for emergency shutdown and for handling workload during instrument downtime. These may be separate approved procedures or included in the testing procedure for a specific analyte.
**NEW** 04/21/2014
COM.30600  Maintenance/Function Checks  Phase II

Appropriate maintenance and function checks are performed and records maintained for all instruments (e.g. analyzers) and equipment (e.g. centrifuges) following a defined schedule, at least as frequent as specified by the manufacturer.

NOTE: There must be a schedule and procedure at the instrument for appropriate function checks and maintenance. These may include (but are not limited to) cleaning, electronic, mechanical and operational checks. The procedure and schedule must be as thorough and as frequent as specified by the manufacturer.

Function checks should be designed to detect drift, instability, or malfunction, before the problem is allowed to affect test results.

For equipment that has no standard frequency or requirement for maintenance and function checks, each laboratory should establish a schedule and procedure that reasonably reflects the workload and specifications of its equipment.

REFERENCES

**NEW/REVISED** 07/28/2015
COM.30625  Function Check Tolerance Limits  Phase II

Tolerance limits for acceptable function are defined for specific instruments and equipment wherever appropriate, with records of action when the limits 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 (e.g. trending for repeat failures, etc.).

REFERENCES

**NEW** 04/21/2014
COM.30650  Instrument Troubleshooting  Phase II

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

**NEW** 04/21/2014
COM.30675  Instrument/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. Offsite 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
THERMOMETERS

Inspector Instructions:

- Records of traceability to NIST Standards
- Sampling of verification records for non-certified thermometers
- Sampling of policies and procedures for thermometer verification

**NEW** 04/21/2014

COM.30700  Thermometric Standard Device  Phase II

An appropriate thermometric standard device of known accuracy (certified to meet 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 (e.g. separation of columns). Thermometers with obvious damage must be rechecked for continued use.

Evidence of Compliance:

✓ Thermometer certificate of accuracy AND
✓ Policy for the use of thermometers after the date of expiration of the guarantee of calibration

REFERENCES

**NEW** 04/21/2014

COM.30725  Non-certified Thermometers  Phase II

All non-certified thermometers in use 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:

✓ Written procedure defining verification of non-certified thermometers AND
✓ Written policy for rechecking of non-certified thermometers AND
✓ Records of verification

REFERENCES
TEMPERATURE-DEPENDENT INSTRUMENTS, EQUIPMENT, AND ENVIRONMENTS

Inspector Instructions:

- Sampling of temperature logs (refrigerator, freezer, water bath, heat block, incubator ambient, etc.)

**NEW** 04/21/2014
COM.30750 Temperature Checks Phase II

Temperatures are checked and recorded each day of use for all temperature-dependent equipment and environments using a calibrated thermometer.

NOTE: Temperature-dependent equipment (e.g. refrigerators, freezers, incubators) containing reagents and/or patient/client specimens must be monitored daily, as equipment failures could affect accuracy of patient/client test results. Items such as water baths and heat blocks used for procedures need only be checked on days of patient/client testing.

If specific instruments, equipment, kits, or supplies have specified ambient temperature ranges for proper operation or use, there must be records that the specified ambient temperature is maintained and corrective action taken when tolerance limits are exceeded.

The two acceptable ways of recording temperatures are: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). The identity of the individual recording the temperature(s) must be recorded (initials of the individual are adequate).

The use of automated (including remote) temperature monitoring systems is acceptable, providing that laboratory personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. There must be records showing daily functionality of the system.

For heat blocks or dry baths, thermocouple probes may be used as an alternative method for checking the temperature.

REFERENCES

**NEW** 04/21/2014
COM.30775 Temperature Range Phase II

Acceptable ranges have been defined for all temperature-dependent equipment and environments (including test-dependent ambient temperature) in accordance with the manufacturer instructions.

Evidence of Compliance:
✓ Temperature log or record with defined acceptable range

**NEW** 04/21/2014
COM.30800 Temperature Corrective Action Phase II
There is evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment and environmental temperatures are exceeded, including evaluation of contents of refrigerators and freezers for adverse effects.

NOTE: If acceptable temperature ranges are exceeded, stored reagents, controls, calibrators, etc. must be checked to confirm the accuracy or quality of the material before use and records maintained. The check should follow a defined procedure.

TEST METHOD VALIDATION/VERIFICATION

Inspector Instructions:

- Policies and procedures for the introduction of new tests/methods/instruments
- Sampling of assay validation/verification studies with emphasis on tests introduced in the past two years
- Sampling of patient reports for laboratory-developed assays

- 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 implemented in the past two years?
- How does your laboratory validate/verify assay performance prior to test implementation?
- How has your laboratory verified/established the reportable range (AMR) for the test?
- How does your laboratory establish or verify reference intervals?
- How does your laboratory validate clinical claims made by the laboratory about LDTs?

- Select a representative sampling of new assays introduced during the past two years for evaluation.
- In addition, select assays in place greater than two years if recurrent problems have been identified in proficiency testing results, quality control, competency assessment, or physician complaints for evaluation, as applicable.
- Review summary statements and supporting validation/verification data to confirm that studies were performed using an adequate number of cases, data were evaluated, and summary statements were approved prior to implementation. If the data showed discordances or unacceptable variations, investigate how they were resolved.

**REVISED** 07/28/2015

COM.40000 Method Validation/Verification Approval

There is a summary statement, signed by the laboratory director (or designee who meets CAP director qualifications) prior to use in patient testing, that includes the evaluation of validation/verification studies and approval of each test for clinical use.

NOTE: This checklist item is applicable only to tests implemented after June 15, 2009; however, all tests must have records of completed analytical validation/verification, regardless of their implementation date.
If multiple identical instruments or devices are in use, there must be records showing that the method performance specifications have been separately verified for each test and instrument/device.

The summary statement must include a written assessment of the validation/verification study, including the acceptability of the data. The summary must also include a statement approving the test for clinical use with the approval signature such as, "This validation study has been reviewed, and the performance of the method is considered acceptable for patient testing."

For an FDA-cleared/approved test, a summary of the verification data must address analytical performance specifications, including analytical accuracy, precision, interferences, and reportable range, as applicable.

In addition, for modified FDA-cleared/approved tests or LDTs, the summary must address analytical sensitivity, analytical specificity, and any other parameter that is considered important, to assure that the analytical performance of a test (e.g. specimen stability, reagent stability, linearity, carryover, and cross-contamination, etc.), as appropriate and applicable.

If the laboratory makes clinical claims about its tests, the summary must address the validation of these claims.

See the Method Performance Specifications section for details concerning validation/verification.

Evidence of Compliance:
✓ Summary of validation/verification studies with review and approval

REFERENCES

METHOD PERFORMANCE SPECIFICATIONS

NOTE: This subsection on METHOD PERFORMANCE SPECIFICATIONS does not apply to waived tests.

ANALYTICAL VALIDATION/VERIFICATION

Laboratories are required to perform analytical validation/verification of each nonwaived test/method/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/verification of tests introduced prior to a specific date. The laboratory must have data for the validation/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.

The method performance specifications must be validated or verified in the location in which patient testing will be performed. If an instrument is moved, the laboratory must verify the method performance specifications (i.e. accuracy, precision, reportable range) after the move to ensure that the test system was not affected by the relocation process or any changes due to the new environment (e.g. temperature, humidity, reagent storage conditions, etc.). The laboratory must follow manufacturer's instructions for instrument set up, maintenance, and system verification.

Not all method performance specifications apply to qualitative tests. For qualitative tests, the laboratory must establish/verify 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 and reportable range.

• For tests that are not FDA-cleared or approved (including tests developed in-house), or for FDA-cleared/approved tests modified by the laboratory, the laboratory must establish accuracy, precision, analytical sensitivity, interferences, analytical specificity, and reportable range, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable.

LABORATORIES NOT SUBJECT TO US REGULATIONS:

• The laboratory must verify or establish analytical accuracy, precision, analytical sensitivity, analytical specificity (interfering substances) and reportable range for each test. Laboratories may use information from manufacturers, published literature, or studies performed in other laboratories, but should verify such outside information, whenever practical.

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.

COM.40100 Intermittent Testing

When a test is put back into production, the following requirements must be met:

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: This requirement applies to tests that are taken out of production for a time (for example, seasonal testing for influenza). 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.

The laboratory should have written procedures for putting intermittent tests into production.

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.

**REVISED** 07/28/2015
COM.40200 LDT and Modified Test List

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

NOTE: The list must include tests developed in-house, and for laboratories subject to US regulations, tests using analyte-specific reagents (ASRs), and FDA-cleared/approved tests 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 (http://www.cap.org) through e-LAB Solutions Suite.

**REVISED** 04/21/2014

**COM.40250** Manufacturer Instructions
Phase II

The laboratory follows manufacturer instructions or provides validation records if the test has been modified.

NOTE: Following manufacturer 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 instructions, the test is no longer an FDA-cleared/approved test, and the modification(s) must be validated 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 range, and reportable range) of any test that has been modified.

REFERENCES

**COM.40300** Accuracy and Precision
Phase II

The laboratory verifies or establishes analytical accuracy and precision for each test.

NOTE: Where current technology permits, accuracy is established by comparing results to a definitive or reference method, or may be verified by comparing results to an established comparative method. Use of reference materials or other materials with known concentrations or activities is suggested in establishing or verifying accuracy. Precision is established by repeat measurement of samples at varying concentrations or activities within-run and between-run over a period of time.

Evidence of Compliance:
✓ Written procedure for determining method performance characteristics, including accuracy and precision AND
✓ Records of verification or establishment of accuracy and precision for each test

REFERENCES
All Common Checklist

COM.40350  Accuracy - Modified FDA-cleared/approved and LDTs  Phase I

For modified FDA-cleared/approved and laboratory-developed tests (LDTs), validation of analytical accuracy includes testing with an appropriate number of samples.

NOTE: An appropriate number of samples 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 (e.g. next-generation sequencing, FISH, 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 modified FDA-cleared/approved tests and 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, and quality control.

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

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

Evidence of Compliance:

✓ Written procedure for determining method performance characteristics, including accuracy

✓ Records of establishment of analytical accuracy for each test

REFERENCES

**REVISED** 04/21/2014
COM.40400  Analytical Sensitivity  Phase II

For modified FDA-cleared/approved tests or laboratory-developed tests (LDTs), the laboratory establishes the analytical sensitivity (lower detection limit) of each assay, as applicable.

Evidence of Compliance:

✓ Written procedure for determining method performance characteristics, including analytical sensitivity

✓ Records of establishment of analytical sensitivity for each assay

REFERENCES

COM.40450 Analytical Specificity Phase II

For modified FDA-cleared/approved tests or laboratory-developed tests (LDTs), the results of each validation study include a sufficient number of samples to establish the test’s analytical specificity.

NOTE: The 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 and provided confidence intervals to estimated performance characteristics.

Evidence of Compliance:
✓ Records of validation studies and published references used to establish analytical specificity

REFERENCES

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 (during LDT validation) or referencing studies performed elsewhere (such as by the instrument-reagent manufacturer).

Evidence of Compliance:
✓ Written procedure for determining method performance characteristics, including analytical interferences AND
✓ Document listing known interferences for each test and plan of action when they are present

REFERENCES
2) Ho C-H. The hemostatic effect of packed red cell transfusion in patients with anemia. Transfusion. 1998;38:1011-1014

COM.40600 Reportable Range Phase II

The reportable range is verified or established for each analytical procedure before implementation.

NOTE: The analytical measurement range (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution or concentration.

Expanded definitions and details of the AMR are provided in some of the section-specific checklists (e.g. Chemistry). Verification of the AMR may not apply to certain assays (for example, in immunology and coagulation).

The limits of the AMR are based on meeting accuracy and precision requirements such as the minimal limit of quantification or sensitivity, when applicable. In some cases, clinically relevant
limits may be narrower than the potential analytical range, and the clinically relevant limit would be used as the limit of the reportable range.

Evidence of Compliance:
✓ Written policy for determining method performance characteristics, including reportable range AND
✓ Records of verification or establishment of reportable ranges for each test

REFERENCES

**NEW** 07/28/2015
COM.40610 Calibration and Quality Control Procedures 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.

REFERENCES

**REVISED** 07/28/2015
COM.40620 Body Fluid Testing Phase II

Methods for body fluid analysis have been validated or verified.

NOTE: This requirement applies directly to body fluid testing that the laboratory offers as a routine, orderable test. A request for a test on a body fluid sample that is not listed on the laboratory’s test menu that requires clearance by the section director or designee is considered a clinically unique sample, rather than a routine, orderable test.

If the test is routinely performed on the fluid, there must be a written procedure. The requirement COM.40000 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 (e.g. a dilution study using admixtures of samples, spiking samples, further dilution). The reference range must be defined and reported with results, unless the value is reported in comparison to its concentration in blood. Reference range citations from the manufacturer's insert or published literature citations may be used to determine the range (COM.50000).

Alternative performance assessment is required (COM.01500) and may be performed using clinical assessment by chart review.

The section director should be consulted when requests for testing of body fluids that are not listed on the laboratory’s test menu are received. For clinically unique samples where specimens are submitted with a unique request based on an unusual clinical concern in a specific patient or situation (e.g. pathologic states where the analyte is not normally found in the fluid type), it may not be possible to establish test performance characteristics. In such cases, the result must be accompanied by a comment such as, “The reference range 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.”

REFERENCES
**REVISED** 07/28/2015

COM.40630  LDT Reporting  Phase I

Reports for laboratory-developed tests (LDTs) contain a statement that the assay was
developed by the laboratory.

NOTE: This requirement does not apply to traditional methods, such as manual microscopy,
conventional microbiologic cultures, and manual hematology and immunology tests.

Requirements for reports are given in the Results Reporting sections of the checklists.
Laboratories subject to US regulations often include an LDT disclaimer as follows: "This test
was developed and its performance characteristics determined by <insert laboratory/company
name>. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA
as qualified to perform high-complexity testing. This test is used for clinical purposes. It should
not be regarded as investigational or for research."

The report should also contain a brief description of the method and any performance
characteristics needed for clinical use, unless the information is readily available to the clinician
in an equivalent form (e.g. test catalog).

REFERENCES
    and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2011

**REVISED** 07/28/2015

COM.40640  LDT Clinical Claims Validation  Phase II

All clinical claims made by the laboratory are validated for the following types of tests:
- Laboratory-developed tests (LDTs)
- FDA-cleared/approved tests for which the laboratory makes a clinical claim(s) not
  included in manufacturer instructions

NOTE: Clinical claims include statements about a test’s diagnostic sensitivity and specificity,
ability to predict the risk of a disease or condition, clinical usefulness, or cost-effectiveness.
Clinical claims may be found on the test report or in other information distributed by the
laboratory (websites, test catalogues, newsletters, memoranda, advertisements, etc.).
Laboratories are not required to make clinical claims about a test, but any claims made by the
laboratory must be validated.

In order to adequately support a claim about diagnostic sensitivity and specificity and/or ability
to predict risk of a disease or condition, 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 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

**REVISED** 07/28/2015

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 (interferences), reference range, and reportable range, as applicable; and
- Supporting data for clinical performance claims, if applicable, validated or verified by the laboratory or obtained from peer-reviewed literature.

NOTE: For the purposes of providing this information to clients, it may be presented 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

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.

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

REFERENCES

REFERENCE INTERVALS

COM.50000 Reference Intervals Established/Verified Phase II

The laboratory establishes or verifies its reference intervals (normal values).

NOTE: Reference intervals are important to allow a clinician to assess patient results against an appropriate population. The reference range must be established or verified for each analyte and specimen source (e.g. 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 2 results fall outside the proposed reference interval, that interval can be considered verified for the population studied (refer to CLSI guideline EP28-A3c, reference below).

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 ranges, and retain records of this evaluation. For many analytes (e.g. therapeutic drugs and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.
Evidence of Compliance:
✓ Record of reference range study OR records of verification of manufacturer’s stated range when reference range study is not practical (e.g. unavailable normal population) OR other methods approved by the laboratory/section director

REFERENCES

COM.50100 Reference Interval Evaluation

The laboratory evaluates the appropriateness of its reference intervals and takes corrective action if necessary.

NOTE: Criteria for evaluation of reference intervals include:
1. Introduction of a new analyte to the test repertoire
2. Change of analytic methodology
3. 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

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. Note that development of an IQCP only impacts quality control requirements. All other checklist requirements remain unchanged and applicable.

This section does not apply to tests where an IQCP was implemented, but the type and frequency of quality control defined in the plan already meets or exceeds minimum quality control requirements defined in the CLIA regulations and CAP checklist requirements. Quality control requirements in other sections of the All Common Checklist and discipline-specific checklists will be used for inspection in those situations.

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 daily 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 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 (e.g., FISH testing may be classified as either a histopathology or a cytogenetics test).

Laboratories may develop their own model for designing an IQCP or use the Clinical and Laboratory Standards Institute (CLSI) Guideline EP23-A, the Centers for Medicare and Medicaid Services guidance, a manufacturer protocol, or use other commercially available products.

NOTE: A laboratory may not implement an IQCP that allows for quality control to be performed less frequently than indicated in the manufacturer's instructions. The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions and recommendations, at minimum.

The following table contains information on quality control related requirements that are eligible for IQCP under CAP's accreditation program and the related CLIA regulations (Title 42CFR):

<table>
<thead>
<tr>
<th>QC Requirement</th>
<th>Related CLIA Regulation (Title 42 in the CFR)</th>
</tr>
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<tbody>
<tr>
<td>Quantitative testing includes two levels of quality control at different</td>
<td>493.1256(d)(3)(i)</td>
</tr>
<tr>
<td>concentrations at least daily</td>
<td></td>
</tr>
<tr>
<td>Qualitative testing includes positive and negative controls at least daily</td>
<td>493.1256(d)(3)(ii)</td>
</tr>
<tr>
<td>Semi-quantitative testing with graded or titered results include a control</td>
<td>493.1256(d)(iii)</td>
</tr>
<tr>
<td>material of graded or titered reactivity at least daily</td>
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<tr>
<td>Tests with an extraction phase include two levels of quality control, one of</td>
<td>493.1256(d)(iv)</td>
</tr>
<tr>
<td>which goes through the extraction phase at least daily</td>
<td></td>
</tr>
<tr>
<td>Tests with molecular amplification procedures include two control materials</td>
<td>493.1256(d)(3)(v)</td>
</tr>
<tr>
<td>and a control material capable of detecting inhibition, as applicable</td>
<td></td>
</tr>
<tr>
<td>Fluorescent stains are checked for positive and negative reactivity each time</td>
<td>493.1256(e)(3)</td>
</tr>
<tr>
<td>of use - Fluorescent in situ hybridization only</td>
<td></td>
</tr>
<tr>
<td>Each new lot and shipment of reagents, disks, stains, antisera, and</td>
<td>493.1256(e)(1)</td>
</tr>
<tr>
<td>identification systems (systems using two or more substrates or two or more</td>
<td></td>
</tr>
<tr>
<td>reagents, or a combination) are checked for positive and negative reactivity,</td>
<td></td>
</tr>
<tr>
<td>as well as graded reactivity, if applicable</td>
<td></td>
</tr>
<tr>
<td>Each batch of commercially prepared media is checked for sterility, if</td>
<td>493.1256(e)(4)(i)</td>
</tr>
<tr>
<td>sterility is required for testing, before or concurrent with initial use</td>
<td></td>
</tr>
<tr>
<td>Each batch of commercially prepared media is checked for its ability to support</td>
<td>493.1256(e)(4)(ii)</td>
</tr>
<tr>
<td>growth and, as appropriate, select or inhibit specific organisms or produce a</td>
<td></td>
</tr>
<tr>
<td>biochemical response, before or concurrent with initial use</td>
<td></td>
</tr>
<tr>
<td>Antimicrobial susceptibility tests include appropriate control organism(s)</td>
<td>493.1261(b)(1)</td>
</tr>
<tr>
<td>to check the procedure each day tests are performed</td>
<td></td>
</tr>
<tr>
<td>Antifungal susceptibility tests include appropriate control organism(s) to</td>
<td>493.1263(b)(2)</td>
</tr>
<tr>
<td>check the procedure each day tests are performed</td>
<td></td>
</tr>
<tr>
<td>Blood gas testing includes one control (combination of low and high values</td>
<td>493.1267(b)(c)</td>
</tr>
<tr>
<td>used) every eight hours of patient testing and one control sample each time a</td>
<td></td>
</tr>
<tr>
<td>specimen is tested unless the method is auto-calibrated every 30 minutes</td>
<td></td>
</tr>
<tr>
<td>Automated coagulation testing includes two levels of controls every 8 hours of</td>
<td>493.1269(b)</td>
</tr>
<tr>
<td>patient testing and when a reagent is changed</td>
<td></td>
</tr>
</tbody>
</table>

Inspector Instructions:

- Policies and procedures for the implementation of an IQCP
- Sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years for the following:
  - 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
- Reassessment of quality control plan at least annually

If an IQCP is in use, the laboratory is required to complete the following forms provided by the CAP and provide a copy to the inspector:

- List of Individualized Quality Control Plans by Instrument/Device/Test - identifies all tests, instruments and devices using an IQCP
- Individualized Quality Control Plan Summary - provides key information on implementation and monitoring of the IQCP

Use the completed forms to identify an appropriate sampling of records to review.

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 have had recurring problems with proficiency testing, quality control, instrument failure, errors, or physician complaints.

**NEW** 07/28/2015

The laboratory has identified all tests using an IQCP and completed the CAP’s forms for laboratories using an individualized quality control plan.

NOTE: The CAP requires the completion of the following forms if an IQCP is in use by the laboratory: List of Individualized Quality Control Plans and the Individualized Quality Control Plan
Summary. The forms may be downloaded from the CAP website (http://www.cap.org) through e-LAB Solutions Suite.

The use of the forms is required, even if standardized forms and templates are used by the laboratory. The laboratory is responsible for maintaining the accuracy of the data on the form and for providing a current copy to the inspector during an on-site CAP inspection. The form is intended to be used as an inspector tool and does not meet the checklist requirements for documenting the IQCP risk assessment or quality control plan.

REFERENCES

**NEW** 07/28/2015

**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:

- Preanalytic, analytic, and postanalytic 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 (e.g. use in different environments, by different personnel, or multiple identical devices)
- Data from the laboratory’s own environment, instrument/equipment performance, and testing personnel
- 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 is not a substitute 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 performed to assess the performance and stability of the tests must support the QC frequency and elements defined in the laboratory’s quality control plan. The study must include data representing, at a minimum the maximum interval between runs of external quality control. The laboratory may use historical data during the risk assessment for tests already in place.

For affiliated laboratories (e.g. 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
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.

REFERENCES

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 and recommendations, 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 at least every 31 days and with new lots and shipments of reagents or more frequently if indicated in the manufacturer’s instructions.

REFERENCES
**NEW** 07/28/2015

COM.50600  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 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, and
- Evaluation of corrective actions taken if problems are identified
- Reapproval of the quality control plan by the laboratory director or designee at least annually

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.

REFERENCES

