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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ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP Web site (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
04/21/2014 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;
   - 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 is intended to:

- Suggest specific examples of acceptable documentation; 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 documented. 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

Annual - Every 12 calendar months

Biennial - Every 24 calendar months

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

Confirmation - Substantiation of the correctness of a value or process
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

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; intent, rules, guidelines
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"

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

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 document 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.

Validation - A defined process by which a laboratory confirms that a laboratory-developed or modified FDA-cleared/approved test performs as intended or claimed.

Verification - The process by which a laboratory determines that an FDA-cleared/approved test performs according to the specifications set forth by the manufacturer.

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.
**Definitions:**

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory’s results with those of other laboratories in the group and/or with an assigned value... (adapted from Clinical Laboratory Standards Institute Harmonized Terminology Database; available at [http://www.clsi.org/](http://www.clsi.org/)).

Alternative assessment is defined as determination of laboratory testing performance by means other than PT—for example, split-sample testing, testing by a different method, etc.

**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 do you ensure proficiency testing samples are rotated among all testing personnel?
- 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?

**Phase II

<table>
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<th>PT Procedure</th>
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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.

COM.01100 Ungraded PT Challenges

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

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

NOTE: The Activity Menu should at all times reflect the laboratory’s current testing. 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. All tests listed on the CAP Master Activity Menu performed by the laboratory must be reflected on its activity menu, and those that have been discontinued must have been removed.

In order to ensure proper customization of the checklists, the laboratory should 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.

REFERENCES

COM.01300 PT Participation

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: 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. A laboratory’s participation in proficiency testing must include all analytes on this list for which it performs patient testing.

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 is method specific. If the laboratory performs HER2 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 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
The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing.

NOTE: Physical signatures must appear on the original paper attestation form. A listing of typed names on the attestation statement does not meet the intent of the requirement.

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

REFERENCES

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, 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, alternative assessment may be performed by method and specimen type, rather than for each tested abnormality (i.e. one program for all FISH cytogenetics tests performed on cell suspensions). Additionally, for sequencing based testing such as Sanger, pyrosequencing and next generation, alternative assessment may be performed by method and specimen type. For tests such as allergen testing, alternative assessment may be performed in batches of analogous tests.

NOTE 3: Semi-annual 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
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 technologists 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 semi-annual 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

**REVISED** 07/29/2013

COM.01700  PT Evaluation

Phase II

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

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 documentation of follow-up/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 “unacceptable” PT and alternative assessment results including records of corrective action that is appropriate to the nature and magnitude of the problem

REFERENCES
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:** There is a strict prohibition against interlaboratory communications about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider. The laboratory director is responsible for enforcing this prohibition. Documentation of training on the handling of PT samples and prevention of interlaboratory communication is strongly recommended.

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

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 of “test 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.

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

Refer to ‘Tips for Avoiding Proficiency Testing Referral’ on the CAP website (e-LAB Solutions, Laboratory Accreditation, LAP Resources for Laboratories) for further information.

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
- Biannual 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 involvement with 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.

**COM.04000 Documented QM/QC Plan**

**Phase II**

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/preventive 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**


**COM.04050 Unusual Laboratory Results**

**Phase II**

There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

**NOTE:** One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data for single analyte 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 must 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 defined protocol for dealing with 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
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24); [42CFR493.1281(b)]

COM.04100 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)(A)(B) 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 review process and personnel whose results require review AND
✓ Records of result review for specified personnel

REFERENCES

COM.04150 Specimen Collection Manual

There is a documented procedure 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.

Identification requirements apply to aliquots as well as to primary specimens.

REFERENCES

**REVISED** 04/21/2014
COM.04200 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.

**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 protocol for this check that includes acceptance criteria.

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

**NEW** 04/21/2014

COM.04300 Comparability Criteria/Corrective Action Phase II

Acceptability criteria are defined for comparability of instruments/methods used to test the same analyte, with documentation of corrective actions 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 corrective action, as appropriate

REFERENCES
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 protocol 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:

- Read:
  - Representative sample of procedures for completeness, laboratory director approval, and review. Current practice must match contents of procedures/policies.
  - Validation study of modified FDA-cleared/approved test, if applicable

- Ask:
  - 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?

- Discover:
  - 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, policy/procedure 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 procedure manual must be clearly documented.

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 is documentation of biennial review). Documentation of review of electronic procedures may be accomplished by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

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

**REVISED** 07/29/2013

COM.10100 Procedure Manual Review  Phase II

There is documentation 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 protocols 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 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 of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

Only policies and procedures are addressed in this requirement. Biennial review is not required for other controlled documents.
**REVISED** 07/29/2013

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/electronic signature review is required. A secure electronic signature is desirable, but not required.

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

REFERENCES

**REVISED** 07/29/2013

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/electronic signature review is required. A secure electronic signature is desirable, but not required.

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

COM.10300  Knowledge of Procedures  Phase II

The laboratory has a system documenting that all personnel are knowledgeable about the contents of procedure manuals (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 procedures, new and revised, OR records of another documented method approved by the laboratory director

REFERENCES

COM.10500  Discontinued Procedure  Phase II

When a 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, procedures related to donor collection, transfusion, and administration of tissues and progenitor cells, procedures (paper or electronic) 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 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 document critical results? Who do you contact?

- Follow a critical result from testing, reporting and recording of notification

**NEW** 07/29/2013
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

COM.30000 Critical Result Notification

The laboratory has procedures for immediate notification of a physician (or other clinical personnel responsible for the patient's care) when results of designated tests exceed established "alert" or "critical" values that are important for prompt patient management decisions.
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 should 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 documented when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be documentation of the critical result, date, and time in the test report or elsewhere in the medical record.

REFERENCES

COM.30100 Critical Result Read-Back

When critical results are communicated by phone, there is a policy that “read-back” of the results is requested and documented.

NOTE: Transmission of critical results by electronic means (FAX or computer) is acceptable. If critical results are transmitted electronically, the laboratory should 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 with documentation of read-back

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)
**REvised** 07/29/2013

**COM.30250 Reagent Handling/Storage - Waived Tests**

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 documented (recording the initials of the individual is 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. The functionality of the system must be documented daily.

**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.

**COM.30300 Reagent Labeling**

Reagents, calibrators, controls, 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 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 as to be 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.

**Evidence of Compliance:**
✓ Written policy defining elements required for reagent labeling
**REVISED** 04/21/2014

COM.30350  Reagent Storage  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 ambient storage temperature is indicated, there must be documentation that the defined ambient temperature is maintained and corrective action taken when tolerance limits are exceeded.

A frost-free freezer may not 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 be able to document 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, as applicable

**REVISED** 07/29/2013

COM.30400  Reagent Expiration Date  Phase II

All reagents 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.

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 document verification of the performance of expired reagents in accordance with written laboratory policy.

Laboratories subject to US regulations must not use expired reagents.

Evidence of Compliance:

✓  Written policy for evaluating reagents and media lacking manufacturer's expiration date

REFERENCES

New reagent lots and/or 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 the new reagent lot or shipment does 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 if the material is documented in the package insert or by 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 prior to use

AND

✓ Records of acceptability study of new reagents/shipments

**REFERENCES**


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 documentation 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

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** 04/21/2014
COM.30550 Instrument/Equipment Performance Verification

The performance of all instruments and equipment is verified upon installation and after repair or reconditioning 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

**NEW** 04/21/2014
COM.30575 Instrument/Operation

There are documented standard 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. 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

Appropriate maintenance and function checks are performed and documented 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 have 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** 04/21/2014
COM.30625 Function Check Tolerance Limits

Tolerance limits for acceptable function are documented for specific instruments and equipment wherever appropriate, with documented corrective 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.

REFERENCES

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

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
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.

THERMOMETERS

Inspector Instructions:

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

**NEW** 04/21/2014

Phase II

COM.30700  Thermometric Standard Device

An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer 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 should be rechecked for continued use.

Evidence of Compliance:

✓ Thermometer certificate of accuracy AND
✓ Policy for the continued use of certified thermometers

**NEW** 04/21/2014

Phase II

COM.30725  Non-certified Thermometers

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

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

Phase II Temperature Checks

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 documentation 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 documented (recording the initials of the individual is adequate).

The use of automated (including remote) temperature monitoring systems is acceptable, providing 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. The daily functionality of the system must be documented.

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

**NEW** 04/21/2014

Phase II Temperature Range

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

Phase II Temperature Corrective Action

There is evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment are exceeded, including evaluation of contents of refrigerators and freezers for adverse effects.
NOTE: If acceptable temperature ranges for refrigerators and/or freezers are exceeded, stored reagents, controls, calibrators, etc. must be checked to confirm the accuracy or quality of the material before use and documented. The check should follow a defined protocol or procedure.

TEST METHOD VALIDATION/VERIFICATION

Inspector Instructions:

- Policies and procedures for the introduction of new tests/methods/instruments
- Sampling of assay validation/verification studies, including signed summary statements and data, for tests with emphasis on tests introduced in the past two years
- Sampling of assay validation studies for laboratory-developed tests (LDTs), including tests that are not FDA-cleared/approved and FDA-cleared/approved tests modified by the laboratory, with emphasis on tests introduced since the last on-site inspection
- Sampling of patient reports for laboratory-developed assays

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**REVISED** 04/21/2014

COM.40000 Method Validation/Verification Approval Phase II

There is a summary statement, signed by the laboratory director (or designee who meets CAP director qualifications) prior to use in patient testing, documenting 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.

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 analytic performance specifications, including analytic 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.

ANALYTIC VALIDATION/VERIFICATION
Laboratories are required to perform analytic 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 analytic validation/verification of test systems 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 data from manufacturers' information or published reports, but the laboratory must verify outside data 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, analytic sensitivity, interferences, analytic 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 analytic accuracy, precision, analytic sensitivity, analytic 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 all of the following characteristics:

1. The test is neither FDA-cleared nor FDA-approved, or the laboratory has made a modification to manufacturer's instructions for an FDA-cleared/approved test
2. The test is performed by the clinical laboratory that developed the test. A laboratory is considered to have developed a test irrespective of whether the test or critical components of the test were originally developed elsewhere or reagents (including ASRs), equipment, or technology integral to the test were purchased, adopted, or licensed from another entity, or if the test was validated by another laboratory.
3. The test was first used for clinical testing after April 23, 2003
Phase II

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.

Phase I

LDT List

The laboratory documents the list of laboratory-developed tests (LDTs) it has implemented during the previous 2 years.

NOTE: This list will help the inspector review the analytic validation data for these tests.

This includes tests developed in-house, and for laboratories subject to US regulations, tests using ASRs, and FDA-cleared/approved tests that have been modified by the laboratory.

**REVISED** 04/21/2014

Phase II

Manufacturer Instructions

The laboratory follows manufacturer instructions or provides documentation of validation 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 tests, if manufacturer instructions are modified, the test is no longer considered waived, and requirements for high complexity testing apply.

Evidence of Compliance:

✓ Documentation of validation of established performance specifications (accuracy, precision, analytic sensitivity, analytic specificity, interferences, reference range, and reportable range) of any test that has been modified.

REFERENCES

Phase II

Analytic Accuracy/Precision

The laboratory verifies or establishes analytic 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/precision AND
✓ Records of verification or establishment of analytic accuracy and precision for each test

REFERENCES

**REVISED** 04/21/2014

Analytic Sensitivity

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

Evidence of Compliance:
✓ Written procedure for determining method performance characteristics, including analytic sensitivity AND
✓ Records of establishment of analytic sensitivity for each assay

REFERENCES

**NEW** 07/29/2013

Analytical Specificity/Interfering Substances

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
The laboratory understands the analytic 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 analytic interferences **AND**
- ✓ Document listing known interferences for each test and plan of action when they are present

**REFERENCES**

Testing of body fluid specimens using methods intended for other specimen types (e.g. blood or other fluid) have been validated by the laboratory for accuracy, precision, analytic sensitivity, analytic specificity, interferences, and reportable range.

**NOTE:** This requirement applies directly to body fluid testing that the laboratory offers as a routine, orderable test. If the test is routinely performed on the fluid, there must be a written procedure. The laboratory director determines the extent of the method performance specifications relevant for clinical purposes. 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.

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. Protein and lipid content can vary considerably from specimen to specimen. "Normal" fluid samples may not be obtainable. 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

**NEW** 07/29/2013
COM.40630 LDT Reporting

Reports for laboratory-developed tests (LDTs) contain a description of the method, a statement that the assay was developed by the laboratory, and appropriate performance characteristics.

NOTE: 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."

REFERENCES

**NEW** 07/29/2013
COM.40640 LDT Clinical Claims Validation

All clinical claims made by the laboratory about a laboratory-developed test (LDT) are validated.

NOTE: Clinical claims may 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. The laboratory should validate claims through a clinical study, but for rare conditions or well-accepted uses of a test, reference to published peer-reviewed literature is acceptable.

Evidence of Compliance:
✓ Records of clinical studies performed by the laboratory OR peer-reviewed literature that reasonably substantiate all claims made by the laboratory about a test

COM.40700 Method Performance Specifications Availability
The laboratory's current test methods, including performance specifications and supporting validation/verification data (analytic accuracy, precision, analytic sensitivity, interferences, reference range, and reportable range, as applicable), are available to clients of the laboratory and to the inspection team upon request.

NOTE: The laboratory must also provide data on clinical performance claims to clients upon request if clinical performance claims are made. The laboratory may at its option require clients to agree to treat such data as confidential and not to share such data with any other party except as required by law.

The CAP inspection team is instructed to use the data solely for accreditation purposes.

REFERENCES

COM.40800 Analytic Methodology Changes Phase II

If the laboratory changes its analytic 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

**REVISED** 07/29/2013

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 documentation 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
Phase II

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