



The All-Commons Checklist

All-Commons Checklist

- ▶ 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 more specificity in the discipline-specific checklist.
- ▶ In these situations, the discipline-specific requirement takes precedence.

Proficiency Testing

- ▶ Proficiency testing - Evaluation of participant (laboratory or individual) performance against pre-established criteria by means of interlaboratory comparisons.
- ▶ Select a representative sample of proficiency testing results and follow records from kit receipt, selection of personnel to perform testing, test performance, use of intermediate worksheets, instrument printouts or interfaced results, and completion of proficiency testing result forms (paper or online), to the submission of results to the proficiency testing provider.
- ▶ Determine if the samples and results are being handled in compliance with requirements and following laboratory policies and procedures.

Proficiency Testing

- ▶ COM.01000 PT Procedure Phase II
- ▶ 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 procedures for investigation and correction of problems that are identified by unacceptable proficiency testing results. The laboratory should also have procedures for investigation of results that, although acceptable show bias or trends suggesting a problem.

Proficiency Testing

- ▶ 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.

Proficiency Testing

- ▶ 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.

Proficiency Testing

- ▶ 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.
- ▶ 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.

Proficiency Testing

- ▶ ****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: 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.

Proficiency Testing

- ▶ NOTE : This checklist requirement applies to both waived and nonwaived tests.
- ▶ NOTE : 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 (ex. hCG), if the CAP and CAP-accepted PT programs are oversubscribed, CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

Proficiency Testing

- ▶ **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

Proficiency Testing

- ▶ **REVISED** 08/17/2016
- ▶ COM.01400 PT Attestation Statement Phase II
- ▶ The proficiency testing attestation statement is signed by the laboratory director or qualified 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 as defined in the Personnel section of the Laboratory General Checklist.
 - ▶ For high complexity testing, it may be delegated to an individual meeting the qualifications of a technical supervisor or section director (GEN.53400) For moderate complexity testing, it may be delegated to an individual meeting the qualifications of a technical consultant (GEN.53625).
 - ▶ Evidence of Compliance:
 - ▶ ✓ Appropriately signed attestation statement from submitted PT result forms

Proficiency Testing

- ▶ COM.01500 Alternative Performance Assessment Phase II
- ▶ 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: 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 referral or other laboratories, split sample analysis with an established in-house method, use of assayed materials, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice.
- ▶ 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.

Proficiency Testing

- ▶ Semiannual alternative performance assessment must be performed on tests for which external PT is not available.
- ▶ 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 or by phoning 800-323-4040, option 1.
- ▶ Evidence of Compliance:
 - ▶ ✓ List of tests defined by the laboratory as requiring alternative assessments AND
 - ▶ ✓ Records of those assessments

Proficiency Testing

- ▶ ****REVISED**** 08/17/2016
- ▶ COM.01 600 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.
 - ▶ 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

Proficiency Testing

- ▶ Repetitive analysis of any proficiency sample by one or more individuals is acceptable only if patient/client specimens are routinely analyzed in the same manner.
- ▶ If the laboratory (under one CLIA license) uses multiple methods for an analyte, proficiency samples must be analyzed by the primary method at the time of the PT event, or rotated among primary methods each PT shipment. Laboratories subject to CMS regulation are not allowed to order multiple PT kits for the purpose of testing the same sample/analyte on multiple instruments or methods prior to the due date for submitting results to the provider.
- ▶ 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 records in the personnel files of the individuals.

Proficiency Testing

- ▶ ****REVISED**** 08/17/2016
- ▶ COM.01700 PT Evaluation Phase II
- ▶ There is ongoing evaluation of PT and alternative assessment results, with **appropriate corrective action** taken for each unacceptable result
 - ▶ Evidence of Compliance:
 - ▶ ✓ Records of ongoing 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.

Proficiency Testing

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

Proficiency Testing

- ▶ ****REVISED**** 08/17/2016
- ▶ COM.01800 PT Interlaboratory Communication Phase II
- ▶ There is no interlaboratory communication about proficiency testing samples until after the **deadline** for submission of data to the proficiency testing provider.
- ▶ Evidence of Compliance:
 - ▶ ✓ Written policy prohibiting interlaboratory communication about PT specimens AND
 - ▶ ✓ Proficiency testing records

Proficiency Testing

- ▶ Results must be reported by personnel within the laboratory.
- ▶ The written proficiency testing policies must strictly prohibit 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, instrument printouts, and work records.
- ▶ Proficiency testing records must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission of results.
- ▶ Laboratories that share a common computer system must take appropriate steps to ensure that records are not readily accessible by other laboratories.

Proficiency Testing

- ▶ **REVISED** 08/17/2016
- ▶ COM.01900 PT Referral Phase II
- ▶ Proficiency testing specimens are not referred to other laboratories and are not accepted from other laboratories for analysis.
 - ▶ NOTE: The written proficiency testing policies must strictly prohibit referral or acceptance of proficiency testing specimens for analysis from other laboratories. **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 morphology might be referral of the smear to a technologist 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.
- ▶ 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.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written policy prohibiting PT specimen referral or acceptance from other laboratories AND
 - ▶ ✓ Proficiency testing records

Proficiency Testing

▶ ****NEW** 08/17/2016**

▶ COM.01950 Cease Patient Testing for Repeat PT Failures

Phase II

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

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

▶ Evidence of Compliance:

▶ ✓ Records of communication notifying staff/physicians that testing is suspended for the required period of time OR

▶ ✓ LIS report verifying that no patient results were reported for the affected analyte during the cease testing time frame OR

▶ ✓ Patient reports indicating name and address of laboratory where testing was performed during the affected period OR

▶ ✓ Send-out log to referral laboratory

Quality Management

- ▶ Review QM policies and procedures
- ▶ Review QM/QC program, including pre-analytic, analytic and post-analytic monitor records and corrective action when indicators do not meet threshold
- ▶ Review Incident/error log and corrective action
 - ▶ Remember you are bound to respect confidentiality – do unto others....
- ▶ 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
- ▶ 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.

Quality Management

- ▶ **REVISED** 08/17/2016
- ▶ COM.04000 Written QM Program Phase II
- ▶ The laboratory has a written quality management (QM) program.
 - ▶ 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

Quality Management

- ▶ **REVISED** 08/17/2016
- ▶ COM.04050 Error Detection and Correction Phase II
- ▶ There is a written procedure for the detection and correction of significant clerical and analytical errors, and unusual laboratory results, in a timely manner.
 - ▶ A 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

Quality Management

- ▶ COM.04100 Supervisory Result Review Phase II
- ▶ In the absence of on-site supervisors, high complexity testing performed by trained high school graduates qualifying as high complexity testing personnel is reviewed by the laboratory director or supervisor/general supervisor within 24 hours.
- ▶ NOTE: The CAP does NOT require supervisory review of all test results before or after reporting to 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:
http://www.cap.org/apps/docs/laboratory_accreditation/build/pdf/personnel_requirements_by_testing_complexity.pdf
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written policy defining the personnel and test results requiring review AND
 - ▶ ✓ Records of result review for specified personnel

Quality Management

- ▶ ****REVISED**** 07/28/2015
- ▶ COM.04200 Instrument/Equipment Record Review Phase II
- ▶ Instrument and equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.

Quality Management

- ▶ COM.04250 Comparability of Instruments and Methods - Nonwaived Testing Phase II
- ▶ If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a 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.

Quality Management

- ▶ 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.
- ▶ Quality control material 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 and methods involved.
- ▶ This requirement only applies when the instruments/reagents are producing the same reportable result.

Quality Management

- ▶ COM.04300 Comparability Criteria - Nonwaived Testing Phase II
- ▶ Acceptability criteria are defined for comparability of nonwaived instruments and methods used to test the same analyte, 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

Specimen Collection And Handling

- ▶ Review the specimen collection and handling policies and procedures
 - ▶ Criteria for rejection may differ for different procedures e.g. Wash versus Semen Analysis
- ▶ Review the specimen rejection records/log
- ▶ COM.06000 Specimen Collection Manual Phase II
- ▶ 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: 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.

Specimen Collection And Handling

- ▶ ****NEW/REVISED** 08/17/2016**
- ▶ COM.06100 Primary Specimen Container Labeling Phase II
- ▶ All primary specimen containers are labeled with at least two patient-specific identifiers.
 - ▶ NOTE: A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, cup, syringe, swab, slide or other form of specimen storage. Criteria for acceptable specimen labeling and the handling of sub-optimal specimens must be defined in laboratory policy.

Specimen Collection And Handling

- ▶ ****NEW** 07/28/2015**
- ▶ COM.06200 Secondary Specimen Container Labeling Phase II
- ▶ Adequate specimen identification is provided on specimen containers throughout all phases of testing, including, but not limited to aliquots, dilution, tubes, slides, blocks, culture plates, reaction units, nucleic acids and other extracts, data extract files, images, and other secondary specimens created during the processing or testing of a specimen.
 - ▶ NOTE: A single, unique identifier may be used to label materials derived from the primary specimen for use in subsequent phases of testing. The specimen identification system used must provide reliable identification of the secondary specimen and be linked to the full particulars of patient identification, collection date, specimen type, etc. The specimen identifier(s) must be indelible, legible, and able to withstand all stages of processing and conditions of storage. Identification may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory 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) are considered primary specimen containers and must follow the labeling requirements for primary specimen containers.

Specimen Collection And Handling

▶ ****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.

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

Procedure Manual

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

Procedure Manual

- ▶ 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

Procedure Manual

- ▶ Read representative samples of procedures for completeness, laboratory director approval, and review. Current practice must match contents of policies and procedures.
- ▶ Identify a newly-implemented procedure in the prior two years and follow the steps through authoring, laboratory director approval, and staff training

Procedure Manual

- ▶ ****REVISED**** 08/17/2016
- ▶ COM.10000 Procedure Manual Phase II
- ▶ A complete procedure manual is available in a paper-based, electronic, or web-based format at the workbench or in the work area.
 - ▶ 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.
 - ▶ 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.
 - ▶ 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

Procedure Manual

- ▶ Electronic manuals accessed by computer are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, as long as the electronic versions are readily available to all personnel and personnel have been trained on how to access them. However, procedure manuals must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain paper copies, electronic copies on CD or other digital media, or have an approved alternative mechanism to access web-based files during network downtimes. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.
- ▶ Electronic procedure manuals and electronic copies of procedures are subject to proper document control (see GEN.20375), and there must be 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.

Procedure Manual

- ▶ 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.

Procedure Manual

- ▶ 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

Procedure Manual

- ▶ 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

Procedure Manual

- ▶ ****REVISED**** 08/17/2016
- ▶ 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 two years (five years for transfusion medicine), recording initial date of use, and retirement date.
 - ▶ NOTE: For testing on minors (under the age of 21), stricter state regulations may apply.

Results Reporting

- ▶ COM.29950 Reference Intervals Phase II
- ▶ All patient/client results are reported with reference (normal) intervals or interpretations as appropriate.
 - ▶ NOTE: The laboratory must report reference intervals or interpretations with patient/client results, where such exist. This is important to allow proper interpretation of patient/client data. Age and/or sex-specific reference intervals or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags (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.**

Results Reporting

- ▶ ****REVISED**** 08/17/2016
- ▶ COM.30000 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. 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.
- ▶ Referral laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The referral laboratory should have a written agreement with the referring laboratory that indicates to whom the referral laboratory reports critical results.

Results Reporting

- ▶ COM.30100 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.
 - ▶ “OK/Received” on fax report is not sufficient – must make human contact
- ▶ Evidence of Compliance:
 - ▶ ✓ Records of critical result notification, including read-back as necessary

Reagents

- ▶ Ask: How do you confirm the acceptability of new reagent lots?
 - ▶ Review procedures for reagent handling
 - ▶ Review new reagent/shipment confirmation of acceptability records
- ▶ Review ambient temperature logs (if reagents stored at ambient temperature)
- ▶ Review actual reagents (expiration date, labeling, storage)

Reagents

- ▶ ****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

Reagents

- ▶ **REVISED** 08/17/2016
- ▶ COM.30350 Reagent Storage and Handling Phase II
- ▶ All reagents and media are stored and handled as defined by the laboratory and following the manufacturer's instructions.
 - ▶ NOTE: Reagents and media must be stored and handled in a manner that will prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents must be properly stored, mixed, when appropriate, and discarded when stability parameters are exceeded.
 - ▶ If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature.
 - ▶ If the laboratory identifies a problem with a reagent that was used for patient testing (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.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Records of reagent and media storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring

Reagents

- ▶ ****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
 - ▶ Evidence of Compliance:
 - ▶ ✓ Written procedure for evaluating reagents and media lacking manufacturer's expiration date
 - ▶ AND
 - ▶ ✓ Records confirming acceptability of any reagent used beyond its expiration date (in jurisdictions where allowed)

Reagents

- ▶ 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;

Reagents

- ▶ Evidence of Compliance:
- ▶ ✓ Written procedure for the confirmation of acceptability of new lots and shipments, with defined acceptability criteria AND
- ▶ ✓ Records for the introduction of new lots and shipments, including lot number(s) tested and comparison of results to the acceptability criteria

Reagents

- ▶ 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

Instruments And Equipment

- ▶ Review instrument/equipment policies and procedures
- ▶ Review function check and performance verification records for instruments/equipment
- ▶ Review instrument/equipment maintenance logs and repair records

Instruments And Equipment

- ▶ ****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

Instruments And Equipment

- ▶ ****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.
 - ▶ Microscope, centrifuge, vortex,
 - ▶ ? Laser

Instruments And Equipment

- ▶ 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.

Instruments And Equipment

- ▶ ****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.

Instruments And Equipment

- ▶ COM.30650 Instrument Troubleshooting Phase II
- ▶ Instructions are provided for minor troubleshooting and repairs of instruments (such as manufacturer's service manual).

- ▶ COM.30675 Instrument and Equipment Records Phase II
- ▶ Instrument and equipment maintenance, function check, performance verification, and service and repair records (or copies) are promptly available to, and usable by, the technical staff operating the equipment.
- ▶ NOTE: Effective utilization of instruments and equipment by the technical staff depends upon the prompt availability of the records (copies are acceptable) to detect trends or malfunctions. 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

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

Thermometers

- ▶ 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 noncertified 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 and records of recertification

Thermometers

- ▶ 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: 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

- ▶ ****REVISED**** 08/17/2016
- ▶ 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.
 - ▶ 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. For heat blocks or dry baths, thermocouple probes may be used as an alternative method for checking the temperature.
 - ▶ If specific instruments, equipment, kits, or supplies have specified ambient temperature ranges for proper operation, storage, or use, there must be records that the specified ambient temperature is maintained and corrective action taken when tolerance limits are exceeded.

Temperature-dependent Instruments, Equipment, and Environments

- ▶ If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (e.g. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.
- ▶ 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.
 - ▶ Biopsy specimens, serum for hormone or antibody analysis

Temperature-dependent Instruments, Equipment, and Environments

- ▶ 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's instructions.
 - ▶ Evidence of Compliance:
 - ▶ ✓ Temperature log or record with defined acceptable range
- ▶ 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 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, with records maintained. The check should follow a defined procedure.

Take home points...

- ▶ A deficiency is an opportunity for improvement, not a Scarlett Letter
- ▶ There is no room in the inspection process for “the good old boys club” attitude
- ▶ RLAP is under the scrutiny of CMS and the LAP program
- ▶ The second inspector comes from a world much tighter than most of our labs so we need to prepare better and inspect better
- ▶ If we want to eliminate the outside inspector, we need to do a better job of adhering to and enforcing the standards
- ▶ We may have better outcomes because of it.

