Every patient deserves the GOLD STANDARD ...

All Common Checklist

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07.11.2011
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All Common Checklist

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SUMMARY OF CHECKLIST EDITION CHANGES  
All Common Checklist  
07/11/2011 Edition  

The following requirements have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory’s activity menu. The listing below is comprehensive; therefore some of the requirements included may not appear in the customized checklist. Such requirements are not applicable to the testing performed by the laboratory.

*Note: For revised checklist requirements, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.*

**NEW Checklist Requirements**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>COM.01400</td>
<td>07/11/2011</td>
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<tr>
<td>COM.40200</td>
<td>07/11/2011</td>
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**REVISED Checklist Requirements**

<table>
<thead>
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<td>07/11/2011</td>
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<tr>
<td>COM.10200</td>
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**DELETED Checklist Requirements**

None
UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

To provide laboratories with a better means to engage in and meet their accreditation requirements, the CAP has enhanced the checklist content and updated its design. New components containing additional information for both the laboratory and inspectors include Subject Headers, Declarative Statements and Evidence of Compliance. See below for a definition of each new feature as an example of how they appear in the checklists.

**Subject Header**
A phrase that provides the key concept of the requirement.

**Declarative Statement**
Checklist questions are reworded as declarative statements to better convey the regulatory nature of requirements.

**Evidence of Compliance**
Information that highlights what is needed to prove that a laboratory is in compliance with the requirement.

**HEM. 20050 Numeric QC**

For numeric QC data, Gaussian or other quality control statistics (e.g. SD and CV) are calculated monthly to define analytic imprecision.

*NOTE:* For CBC data where stabilized whole blood is not used for quality control, such statistics may be generated from previous patient samples using the standard deviation of duplicate pairs.

- ✓ Written procedure for monitoring analytic imprecision including statistical analysis of data
- ✓ QC records showing monthly monitoring of imprecision

**Using Evidence of Compliance (EOC)**

This component, which appears with several checklist requirements, is intended to:

1. Assist a laboratory in preparing for an inspection and managing ongoing compliance
2. Drive consistent understanding of requirements between the laboratory and the inspector
3. Provide specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc.)

In addition to the Evidence of Compliance listed in the checklist, other types of documentation may be acceptable. Whenever a policy/procedure/process is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies/procedures/processes covered in the CAP checklists must be documented. A separate policy is not needed for each item listed in EOC as it may be referenced in an overarching policy.
HOW TO INSPECT USING R.O.A.D INSPECTION TECHNIQUES
(Read, Observe, Ask, Discover)

CAP has streamlined the inspection approach used during onsite inspections and is now offering guidance to inspectors by providing assessment techniques to facilitate a more efficient, consistent, and effective inspection process. Specific inspector instructions are listed at the beginning of a grouping of related requirements.

Rather than reviewing each individual requirement, CAP inspectors are encouraged to focus on the Inspector Instructions for a grouping of related requirements. Once an area of concern has been identified through "Read," "Observe," "Ask," "Discover," or a combination thereof, inspectors are encouraged to "drill down" to more specific requirements, when necessary and review more details outlined in the Evidence of Compliance statements. If a requirement is non-compliant, circle the requirement number to later list on the Inspector Summation Report. Inspectors may also make notes in the margins of the checklist document.

Inspection Instructions and Icons used to evaluate a laboratory's performance now appear in several areas throughout the Inspector Checklists. Please note that all four R.O.A.D elements are not always applicable for each grouping, or sections of related requirements.

**Inspector Instructions:**

| **READ** | Review a sampling of laboratory documents. Information obtained from this review will be useful as you observe processes and engage in dialogue with the laboratory staff. (Example of the complimentary inspector instructions for Quality Management/Quality Control General Issues section appearing across checklists):
| **OBSERVE** | Laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures. (Example)
| **ASK** | Ask open-ended, probing questions that start with phrases such as "tell me about..." or "what would you do if..." This approach can be a means to corroborate inspection findings that were examined by other techniques, such as Read & Observe. Ask follow-up questions for clarification. Include a variety of staff levels in your communication process. (Example)
| **DISCOVER** | A technique that can be used to "drill down" or further evaluate areas of concern uncovered by the inspector. "Follow the specimen" and "teach me" are two examples of Discovery. Utilizing this technique will allow for the discovery of pre-analytic, analytic, and post-analytic processes while reviewing multiple requirements simultaneously. (Example) |

- Sampling of QM/QC policies and procedures
- Incident/error log and corrective action
- Observe the settings/QC range limits established in the laboratory LIS/HIS to ensure that the laboratory’s stated ranges are accurately reflected
- As a staff member, what is your involvement with quality management?
- How do you detect and correct laboratory errors?
- Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action
INTRODUCTION

The propose of the All Common Checklist (COM) is to group together those requirements that were redundant in Laboratory General and the discipline-specific checklists. Therefore, the CAP centralized all requirements regarding: proficiency testing, procedure manuals, test method validation, and critical results into one checklist, the COM checklist.

The Laboratory General Checklist applies to all sections of the laboratory. An inspection of a laboratory section, or department will include the discipline-specific checklist(s) (e.g. Anatomic Pathology), the Laboratory General Checklist, and the All Common Checklist.

If a section unit should require more than one inspector, each inspector must ensure that each area within the section unit is in compliance with the requirements in COM.

ALL COMMON CHECKLIST

PROFICIENCY TESTING

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/).

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, attestation statement and director 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?

- Select a representative sample of unacceptable proficiency testing results and follow
documentation from original testing to final determination of root cause. Determine if the procedures and processes produce a thorough investigation with appropriate corrective action taken

COM.01000  PT Procedure

**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 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-approved alternate provider) for all patient tests designed 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

**Phase II**

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

**NOTE:** This requirement addresses PT challenges that were intended to be graded, but were not, for reasons such as: 1) the laboratory submitted its results after the cut-off date, 2) the laboratory did not submit results, 3) the laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place). Also, if possible, the laboratory should assess its performance on PT challenges that were not graded because of lack of consensus. For guidance on the approach to these situations, refer to appendix 1 in the CAP Laboratory Accreditation Manual ([http://www.cap.org/apps/docs/laboratory_accreditation/checklists/checklist_reference_links.doc](http://www.cap.org/apps/docs/laboratory_accreditation/checklists/checklist_reference_links.doc)).

**Evidence of Compliance:**

✓ Records of review and evaluation of ungraded PT challenges

**REFERENCES**


COM.01200  Activity Menu

**Phase I**

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 performed by the laboratory should be listed on the Activity Menu, and vice versa.

Please note that unusual or esoteric tests performed in the laboratory section may not be
specifically listed on the laboratory’s activity menu but may be identified on the activity menu as a miscellaneous code. Further information may be found with the laboratory’s instrumentation list. Some activities are also 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.

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 Phase II

The laboratory participates in the appropriate required CAP Surveys or another proficiency testing (PT) 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. Participation in proficiency testing may be through CAP Surveys 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 2: HER2 PT is method specific and laboratories performing HER2 testing by multiple methods must participate in PT for each method.

NOTE 3: If the laboratory interprets HER2 test results from immunohistochemical (IHC) stains prepared at another facility, the laboratory must:

A. Enroll in an appropriate PT survey
B. Send PT materials to the staining facility for preparation, and
C. Interpret the resulting stains using the same procedures that are used for patient specimens

NOTE 4: If the laboratory interprets FISH (or ISH) stains for HER2 prepared at another facility, the laboratory must not participate in PT, but must perform an alternative assessment of the test twice annually.

NOTE 5: For purposes of photomicrograph identification in CAP Surveys, 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 Surveys 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
USA, 2004


**NEW** 07/11/2011

COM.01400 Attestation Page

The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing.

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

REFERENCES

COM.01500 Alternative Performance Assessment

For tests for which CAP does not require PT, the laboratory at least semi-annually 1) participates in external PT, or 2) exercises an alternative performance assessment system for determining the reliability of analytic testing.

NOTE 1: Appropriate alternative performance assessment procedures may include: split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice. Participation in ungraded/educational proficiency testing programs also satisfies this checklist requirement.

NOTE 2: For FISH testing, alternative assessment may be performed by method and specimen type, rather than for each tested abnormally (i.e. one program for all FISH cytogenetics tests performed on cell suspensions).

NOTE 3: Semi-annual alternative assessment must be performed on tests for which 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:
✓ Records of completed external PT OR alternative assessments

REFERENCES
4) CLSI. Assessment of Laboratory Tests When Proficiency Testing is not Available; Approved Guideline- Second Edition. CLSI
COM.01600  PT Integration Routine Workload  Phase II

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

**NOTE:** Replicate 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**

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:** Compliance with this item can be examined by selecting a sample of PT evaluation results and alternative assessment records. Special attention should be devoted to unacceptable results.

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.

**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**
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement


COM.01800 PT Interlaboratory Communication

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: Under CLIA regulations, 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.

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

COM.01900 PT Referral

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

NOTE: Under CLIA regulations, there is a strict prohibition against referring proficiency testing specimens to another laboratory. In other words, the laboratory may not refer a proficiency testing specimen to a laboratory with a different CLIA number (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.

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 (i.e. with a different CLIA number than the referring laboratory). 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.

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 AND QUALITY CONTROL

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 and director review. Current practice must match contents of procedures/policies.
  - Validation study of modified FDA-approved/cleared 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, director review and staff training

COM.10000 Procedure Manual Phase II

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, 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 annual 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
2) van Leeuwen AM. 6 Steps to building an efficiency tool. Advance/Laboratory. 1999:8(6):88-91

**REVISED** 07/11/2011

COM.10100 Procedure Manual Review Phase II

There is documentation of review of all policies and procedures by the current laboratory director or designee at least every two years.

NOTE: The director must ensure that the collection of 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.

REFERENCES
**REVISED** 07/11/2011

COM.10200 New Procedure Review  Phase II

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

NOTE: Current practice must match the policy and procedure documents.

REFERENCES

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

COM.10400 New Director Procedure Review  Phase II

If there is a change in directorship, the new director ensures (over a reasonable period of time) that laboratory procedures are current and have been appropriately reviewed.

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, it is recommended to meet the requirements of some states relating to the testing of minors (under the age of 21); laboratories should retain procedures (paper or electronic) for at least 23 years (to cover the interval from fetal period to age 21).

REFERENCES

COM.10600 Manufacturer Instructions  Phase II

For FDA approved/cleared tests, the laboratory follows manufacturer instructions or provides documentation of validation study(ies) if the test has been modified.
NOTE: For example, the laboratory must verify the established performance specifications of FDA-approved assays (accuracy, precision, analytic sensitivity, interferences, reference range, and reportable range, as applicable).

If the laboratory modifies manufacturer instructions, the test is categorized as a non-FDA approved/cleared test, and the modification must be validated by the laboratory. A change in the specimen type or collection device is considered a modification.

For waived tests, if manufacturer instructions are modified, the test is no longer considered waived, and requirements for high complexity testing apply.

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

COM.30000 Critical Result Notification Phase II

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. 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.
COM.30100 Critical Result Read-Back

When critical results are communicated verbally or by phone, there is a policy that laboratory personnel ask for a verification “read-back” of the results.

NOTE: Laboratory personnel should document the read-back.

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 documented read-back

TEST METHOD VALIDATION

Inspector Instructions:
- Documentation of the test method validation (method comparison study, precision study, analytic sensitivity, interferences, AMR, and director approval). Emphasize tests that have been implemented in the past two years, particularly those tests that are not FDA-cleared/approved (including FDA-cleared/approved tests modified by the laboratory)
- What laboratory test has been implemented in the past two years, particularly those that are not FDA-cleared or approved? How has your laboratory verified/established the reportable range for the test validation?
- How does your laboratory establish or verify reference intervals?

COM.40000 Method Validation Approval

There is a summary statement, signed by the laboratory director (or designee who meets CAP director qualifications), documenting review of validation studies and approval of each test for clinical use.

NOTE: This checklist item is applicable only to tests implemented after June 15, 2009.

An example of such a statement is: “This validation study has been reviewed and the performance of the method is considered acceptable for patient testing.”

REFERENCES
METHOD PERFORMANCE SPECIFICATIONS

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

Sound laboratory practice requires full characterization of each test/method/instrument system before its use in patient testing, without regard to when the test was first introduced by a given laboratory. For each test performed on blood, the laboratory must have data on accuracy, precision, analytic sensitivity, interferences and reportable range (i.e. analytic measurement range (AMR) as applicable.

Applicable method performance specifications must also be established for body fluids and other specimen types routinely tested by the laboratory. (For such specimens, the laboratory director should determine 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 either 1) exclude the existence of matrix interferences affecting the latter, or 2) identify and document any matrix interferences that exist. If a reference range cannot be defined for a particular type of specimen, a comment to that effect should be included in the patient report.

For fluids and other specimen types not routinely tested, it may not be possible to establish test performance characteristics to the same extent as for blood specimens (particularly for analytic accuracy and reference range). In such situations, the laboratory should include a note in the report stating, for example, "The reference range and other method performance specifications have not been established for this test in [type of fluid]. The test result should be integrated into the clinical context for interpretation." (Reference: Clinical and Laboratory Standards Institute. Analysis of Body Fluids in Clinical Chemistry; Approved Guideline. CLSI document C49-A (ISBN 1-56238-638-7). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.)

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 and reportable range, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable. (Note that testing matrices other than those listed in manufacturer instructions constitutes a modification of an FDA cleared/approved test.)

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.

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.

The laboratory must retain records of method performance specifications while the method is in use and for at least two years after discontinuation of a method.

The following checklist element applies to tests performed intermittently; i.e. tests that are taken out of production for a time (for example, seasonal testing such as influenza testing). A test is considered to be taken out of production when both of these conditions are met: 1. patient testing is not offered AND 2. PT or alternative assessment, as applicable, is suspended.
**NEW**       07/11/2011

COM.40200       Tests Not FDA-Approved/Cleared

The laboratory has a documented list of tests not approved/cleared by FDA that have been implemented during the previous two (2) years.

**NOTE:** The inspector will emphasize review of the analytic validation data for these labs.

Tests not approved/cleared by FDA include tests developed in-house, tests using ASRs, and FDA-approved/cleared tests that have been modified by the laboratory.

COM.40300       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**

COM.40400 Analytic Sensitivity Phase II

The laboratory verifies or establishes the analytic sensitivity (lower detection limit) of each assay, as applicable.

NOTE: For FDA-cleared/approved tests, documentation may consist of data from manufacturers or the published literature.

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

REFERENCES

COM.40500 Analytic Interferences Phase II

The laboratory verifies or establishes analytic interferences for each test.

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

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

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

COM.40600 Reportable Range Phase II

The reportable range (analytic measurement range) is verified/established for each analytic procedure before implementation.

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

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

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

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

REFERENCES

COM.40700 Method Performance Specifications Availability Phase II

The laboratory's current test methods, including performance specifications and supporting validation data (analytic accuracy, precision, analytic sensitivity, interferences, reference range, and reportable range, as acceptable), are available to clients of the laboratory and to the inspection team upon request.

NOTE: The laboratory must also provide data on clinical validity, if available, to clients upon request.

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

The laboratory may at its option require clients to agree to treat validation data as confidential and not to share such data with any other party except as required by law.

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

COM.50000 Reference Intervals 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 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 director

REFERENCES

COM.50100 Reference Interval Evaluation
Phase II

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

NOTE: Criteria for evaluation of reference intervals include:

1. 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