COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

LABORATORY GENERAL CHECKLIST –
QUESTIONS RELATED TO REPORTING OF RESULTS ONLY

Disclaimer and Copyright Notice

The College of American Pathologists (CAP) Checklists are posted on the CAP's Web site for information only. If you are enrolled in the CAP's Laboratory Accreditation Program and are preparing for an inspection, you must use the Checklists that were mailed in your application or reapplication packet, not those posted on the Web site. The Checklists undergo regular revision and Checklists may be revised after you receive your packet.

If a Checklist has been updated since receiving your packet, you will be inspected based upon the Checklists that were mailed. If you have any questions about the use of Checklists in the inspection process, please e-mail the CAP (accred@cap.org), or call (800) 323-4040, ext. 6065.

All Checklists are ©2005. College of American Pathologists. All rights reserved.
LABORATORY GENERAL

OUTLINE

REPORTING OF RESULTS ........................................................................................................... 3
QUALITY MANAGEMENT ........................................................................................................ 12
METHOD PERFORMANCE SPECIFICATIONS ......................................................................... 15
PATIENT DATA ................................................................................................................ 16
LABORATORY GENERAL

REPORTING OF RESULTS

The laboratory must provide useful clinical data. Data must be legible, accurate, reported in clearly designated units of measurement, and promptly reported to persons authorized by law to receive and use medical information. Reference intervals (normal ranges) must be readily available to clinicians, preferably on the test report itself.

**REVISED** 03/30/2005

**REVISED** 03/30/2005

Does the laboratory director or physician designee review and approve the content and format of all patient reports at least annually?

NOTE: The laboratory director or physician designee must review and, at least annually, approve the content and format of laboratory patient reports (whether paper or computer screen images) to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff. This checklist question applies to paper and electronic medical records.

COMMENTARY:

N/A

Does the paper or electronic report include the following elements?

1. Name and address of testing laboratory (see note below)
2. Patient name and identification number, or unique patient identifier
3. Name of physician of record, or legally authorized person ordering test, as appropriate
4. Date and time of specimen collection, when appropriate
5. Date of release of report (if not on the report, this information should be readily accessible)
6. Time of release of report, if applicable (if not on the report, this information should be readily accessible)
7. Specimen source, when applicable
8. Test result(s) (and units of measurement, when applicable)
9. Reference intervals, as applicable (see Note below)

10. Conditions of specimen that may limit adequacy of testing

NOTE: The address of an outside reference laboratory may be on the report, or available in other records from the reporting laboratory. A “reference laboratory” includes outside reference laboratories as well as any affiliated or special function laboratory that is separately accredited and has a different CLIA-88 registration number than the referring laboratory. The address of the reporting laboratory should be on the report.

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

Patient reports must state the name of the physician (or other legally authorized person) ordering the test(s) or a physician of record. In those institutions where there are multiple ordering physicians and/or frequent changing of attending physicians, the ordering physician should be easily identifiable through a computer audit trail or other records of the test order.

COMMENTARY:

N/A


GEN.41250 Phase II N/A YES NO

Are reports legible?

COMMENTARY:

N/A

GEN.41300 Phase II N/A YES NO

Are copies or files of reported results retained by the laboratory in a manner that permits prompt retrieval of the information?
NOTE: The length of time that reported data are retained in the laboratory may vary; however, the reported results must be retained for that period encompassing a high frequency of requests for the data. In all circumstances, a hospital laboratory must have access to the patient's chart where the information is permanently retained.

COMMENTARY:

N/A

GEN.41302 Phase II N/A YES NO

Are laboratory records and materials retained for an appropriate time?

NOTE: The following records must be retained for at least 2 years: specimen requisitions (including the patient chart or medical record only if used as the requisition), patient test results and reports, instrument printouts, accession records, quality control records, instrument maintenance records, proficiency testing records, and quality management records. Serum and body fluid specimens should be retained for 48 hours. Urine specimens should be retained for 24 hours. Blood films, permanently stained body fluid slides, and microbiology slides should be retained for 7 days. Any deficiencies noted by the inspector must be detailed in part B of the Inspector’s Summation Report.

More stringent requirements for certain laboratory records (e.g., in anatomic pathology, cytopathology, transfusion medicine) may be found in the discipline-specific checklists.

For data transmitted by computer interface (on-line system), it is not necessary to retain paper worksheets, print-outs, etc., so long as the computer retains the data for at least two years. Manual entry of patient result data requires that all worksheets, print-outs, etc. are retained by the laboratory for at least two years.

In establishing retention requirements, care should be taken to comply with state and federal regulations.

COMMENTARY:

N/A

Is there a documented protocol in place to ensure that patient data are accessible only to those healthcare personnel who are authorized to review test results?

**NOTE:** U.S. laboratories must have procedures to ensure compliance with The Health Information Portability and Accountability Act (HIPAA).

**COMMENTARY:**

N/A

Is there a system whereby the identity of the analyst performing or completing the test and the date of the test can always be established?

**NOTE:** The system should also be capable of identifying those test results that have been autoverified.

**COMMENTARY:**

N/A


Is there a documented system to ensure that all revised reports for previously reported incorrect (erroneous) patient results are identified as revised, corrected, or amended on all forms of patient reports (paper, video displays, etc.)?

**NOTE:** "Revisions" includes any changes to accompanying reference intervals and interpretations, but not minor typographical errors of no clinical consequence. Reports that display "corrected" results must clearly indicate that the new result is a change from a previously reported result.

**COMMENTARY:**

N/A
GEN.41310        Phase II        N/A YES NO

When revised results are reported, are the revised and original data clearly identified as such, and are the original data readily accessible to the user for comparison?

NOTE: As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the revised information. The previous information and the revised information must be identified as such, and the original data must be present in the revised report (for paper reports), or linked electronically or logically to the revised information (in electronic reports). The precise format of corrected reports is at the discretion of the laboratory. Unless specifically endorsed by the medical staff/clients, it is not acceptable to simply indicate that a result has been revised, with the expectation that the reader will look up the previous result somewhere in the laboratory chart. For extensive interpretive or textual data (e.g., surgical pathology reports), replicating the entire original and corrected pathology reports may be cumbersome and render the revised report format difficult to interpret. In such cases, a comment in the corrected report summarizing the previous information and the reason for the correction may be more appropriate than repeating the entire original report.

COMMENTARY:

N/A

GEN.41312        Phase I        N/A YES NO

When there are multiple sequential corrections of a single test result, are all corrections referenced in sequential order on subsequent reports?

NOTE: When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the "true" result. All corrections should be referenced in the patient report.

COMMENTARY:

N/A

GEN.41320        Phase II        N/A YES NO

Does the laboratory have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when results of certain tests fall within established "alert" or "critical" ranges?
NOTE: This includes results received on specimens sent to reference laboratories for testing. Alert or critical values are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. These values should be defined by the laboratory director, in consultation with the clinicians served.

COMMENTARY:

N/A


**GEN.41330 Phase II**

Is there documentation of notification of the appropriate clinical individual of all critical values?

NOTE: 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 and test results. Any problem encountered in accomplishing this task should be investigated to prevent recurrence.

COMMENTARY:

N/A

**NEW**  03/31/2004

GEN.41340  Phase I  N/A YES NO

Does the laboratory have a policy with respect to a verification “read-back” of critical values that are communicated verbally or by phone?

NOTE: This question applies both to 1) results of in-house tests, and 2) results received by the laboratory from outside reference laboratories.

COMMENTARY:

N/A

GEN.41345  Phase II  N/A YES NO

Has the laboratory defined turnaround times (i.e., the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and does it have a policy for notifying the requester when testing is delayed?

NOTE: This does NOT imply that all instances of delayed reporting for all tests must lead to formal notification of clinical personnel. Rather, clinicians and laboratory must have a jointly agreed upon policy for when such notification is important for patient care.

COMMENTARY:

N/A


GEN.41350  Phase II  N/A YES NO

Does the laboratory have a documented process for evaluating and selecting reference laboratories?

NOTE:
1. Selection of reference laboratories must be based primarily upon the quality of performance of such laboratories.

2. "Referred Specimens" includes any for which intermediate processing is performed at another facility, such as histopathology/cytology preparation.

3. Laboratories subject to CLIA-88 must refer specimens for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

4. It is the responsibility of the laboratory director or designee to monitor the quality of test results received from reference laboratories.

The laboratory director should ensure that the reference laboratories provide turnaround times that meet clinical needs.

COMMENTARY:

N/A


GEN.41370 Phase II N/A YES NO

Is the laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), responsible for selecting referral laboratories?

COMMENTARY:

N/A

GEN.41430 Phase II N/A YES NO

For samples referred to another laboratory, is the original or an exact copy of the testing laboratory's report retained by the referring laboratory?
NOTE: For results received directly from the testing laboratory's computer, there may not be a paper copy, which is acceptable.

COMMENTARY:

N/A


GEN.41440 Phase II N/A YES NO

Are the essential elements of referred test results reported by the referring laboratory as received from the reference laboratory, without alterations that could affect clinical interpretation?

NOTE: This does not mandate that the referring laboratory report every word nor retain the exact format of the reference laboratory report. Beyond faithful transcription of any direct testing data, the referring laboratory director may elect to edit interpretive remarks provided by the reference laboratory, in the context of patients’ clinical status and the local medical environment. There is no requirement to fully replicate the complete content of the reference laboratory report.

COMMENTARY:

N/A

QUALITY MANAGEMENT

**NEW**  03/30/2005

GEN.20262     Phase I     N/A     YES     NO

Does the laboratory summarize and review its records of errors and incident reports at defined intervals to identify trends and initiate corrective/preventive actions as appropriate?

NOTE: Investigation of individual problems may not reveal trends or patterns caused by underlying system problem(s). Thus, the laboratory should periodically group errors and incident reports together for review, to detect system problem(s) that could be responsible for some errors or incidents.

COMMENTARY:

N/A

**REVISED**  09/30/2004

GEN.20316     Phase II     N/A     YES     NO

Are key indicators of quality monitored and evaluated to detect problems and opportunities for improvement?

NOTE: Key indicators are those that reflect activities critical to patient outcome, that affect a large proportion of the laboratory's patients, or that have been problematic in the past. The laboratory must document that the selected indicators are regularly compared against a benchmark, where available and applicable. The benchmark may be a practice guideline, CAP Q-PROBES data, or the laboratory's own experience. New programs or services should be measured to evaluate their impact on laboratory service. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor a single indicator; larger laboratories should monitor multiple aspects of the scope of care commensurate with their scope of service. (However, there is no requirement that an indicator(s) be assessed in every section of the laboratory during every calendar year.)

Examples of key indicators include, but are not limited to:

1. Patient/Specimen Identification. May be any of the following: percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors.

2. Test Order Accuracy. Percent of test orders correctly entered into a laboratory computer.
3. **Stat Test Turnaround Time.** May be collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a “stat” priority. May be confined to the Emergency Department or intensive care unit if a suitable reference database is available. Laboratories may monitor mean or median turnaround time or the percent of specimens with turnaround time that falls within an established limit.

4. **Critical Value Reporting.** Percent of critical values with documentation that values have been reported to caregivers.

5. **Customer Satisfaction.** Must use a standardized satisfaction survey tool with a reference database of physician or nurse respondents.

6. **Specimen Acceptability.** Percent of general hematology and/or chemistry specimens accepted for testing.

7. **Corrected Reports – General Laboratory.** Percent of reports that are corrected.

8. **Corrected Reports – Anatomic Pathology.** Percent of reports that are corrected.

9. **Surgical Pathology/Cytology Specimen Labeling.** Percent of requisitions or specimen containers with one or more errors of pre-defined type.

10. **Blood Product Wastage.** Percentage of packed red blood units or other blood products that are not transfused to patients and not returned to the blood product supplier for credit or reissue.

11. **Blood Culture Contamination.** Percent of blood cultures that grow bacteria that are highly likely to represent contaminants.

While there is no requirement that the specific key quality indicators listed above be monitored, these indicators have been field-tested and shown to be measurable in a consistent manner, to demonstrate variability from laboratory-to-laboratory, and to be important to clinicians and to patient care. For the above indicators, performance should be compared with multi-institutional performance surveys that have been conducted within ten years of the laboratory’s most recent measurement, where such surveys are available (see references below). Action plans should be developed for any indicator in which laboratory performance falls below the 25th percentile (i.e., 75% or more of the other laboratories in the study perform better). Use of the indicators listed above does not require enrollment in any quality monitoring product.

**COMMENTARY:**

N/A

**REFERENCES:**

**REVISED** 12/29/2004

GEN.20364 Phase II N/A YES NO

**Are postanalytic variables monitored?**

NOTE: Postanalytic (i.e., post-examination) variables include all steps in the overall laboratory process between completion of the analytic phase of testing and results receipt by the requesting physician. Examples are accuracy of data transmission across electronic interfaces, reflex testing, turnaround time from test completion to chart posting (paper and/or electronic), and interpretability of reports. This list is neither all-inclusive nor exclusive, providing the variables chosen are appropriate to the laboratory's scope of care.

COMMENTARY:

N/A

### METHOD PERFORMANCE SPECIFICATIONS

<table>
<thead>
<tr>
<th>GEN.42160</th>
<th>Phase II</th>
<th>N/A</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

If the laboratory changes its analytic methodology so that test results or their interpretations may be **SIGNIFICANTLY** different, is the change 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.*

**COMMENTARY:**

N/A

Does the laboratory have a process to ensure appropriate routing of patient test results to physicians?

NOTE: During the course of their medical care in a health care system, the location of a patient may change multiple times; i.e., from various inpatient locations, to outpatient, to physician office patient. The intent of the question is to ensure that patient test results are routed to the responsible physician(s) regardless of patient location. For example, after a patient is discharged from the hospital, test reports should be routed to the physician as well as the hospital medical record.

COMMENTARY:

N/A

Are manual and automated result entries verified before final acceptance and reporting by the computer?

NOTE: Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer. An example of best practices for this step is checking the result against the reportable range and critical values for the test. Depending on the local environment, this may or may not require a second person. Verification procedures must generate an audit trail.

This checklist question does not apply to autoverification procedures (see below).

COMMENTARY:

N/A