COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

TEAM LEADER ASSESSMENT OF DIRECTOR & QUALITY CHECKLIST

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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.

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TEAM LEADER ASSESSMENT OF DIRECTOR & QUALITY

OUTLINE

SUMMARY OF CHANGES .................................................................3
INSPECTION TECHNIQUES – KEY POINTS ........................................4
INSTRUCTIONS ..............................................................................6
LABORATORY DIRECTOR ASSESSMENT ...........................................9
   TECHNICAL CONSULTANT (PATHOLOGIST, OTHER QUALIFIED PHYSICIAN OR DOCTORAL
   SCIENTIST) ...........................................................................17
SUMMARY OF CHANGES
TEAM LEADER ASSESSMENT OF DIRECTOR & QUALITY Checklist

The following questions 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 questions included may not appear in the customized checklist. Such questions are not applicable to the testing performed by the laboratory.

Note: For revised checklist questions, 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 Questions

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REVISED Checklist Questions

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CONTINUING EDUCATION INFORMATION

Beginning January 2008, you may earn continuing education credits (CME/CE) by completing an online Inspection Preparation activity that includes review of this checklist.

Prior to reviewing the checklist, log on to the CAP Web site at `<http://www.cap.org>`, click the Education Programs tab, then select Laboratory Accreditation Program (LAP) Education Activities, and Inspection Preparation for complete instructions and enrollment information.

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INSPECTION TECHNIQUES – KEY POINTS

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I. READ – OBSERVE – ASK – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

READ = Review of Records and Documents
Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation.

OBSERVE – ASK = Direct Observation and Asking Questions
Observing and asking questions accomplish the following:

1. Verifies that the actual practice matches the written policy or procedure
2. Ensures that the laboratory processes are appropriate for the testing performed
3. Ensures that outcomes for any problem areas, such as PT failures and issues/problems identified through the quality management process, have been adequately investigated and resolved
4. Ensures that previously cited deficiencies have been corrected

Use the following techniques:

- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written
policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures.

- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you’ve seen and observations you’ve made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.

- Ask open-ended questions that start with phrases such as “show me how…” or “tell me about …” or “what would you do if…” By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen transport policy and show me how you ensure optimum specimen quality?” This will help you to determine how well the technical staff is trained, whether or not they are adhering to the lab’s procedures and policies, and give you a feel for the general level of performance of the laboratory.

- Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question “Is there documentation of corrective action when control results exceed defined tolerance limits?” ask, “What would you do if the SD or CV doubles one month?” A follow-up probing question could be, “What would you do if you could not identify an obvious cause for the change in SD or CV?”

### II. Evaluate Selected Specimens and Tests in Detail

**For the Laboratory General Checklist: Follow a specimen through the laboratory.** By following a specimen from collection to test result, you can cover multiple checklist questions in the Laboratory General checklist: questions on the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including appropriate reference ranges, retention of test records, maintaining confidentiality of patient data, and proper handling of critical results and revisions to reports.

**For the individual laboratory sections:** Consult the laboratory’s activity menu and focus on tests that potentially have the greatest impact on patient care. Examples of such tests include HIV antibodies, hepatitis B surface antigen, urine drugs of abuse, quantitative beta-hCG, cultures of blood or CSF, acid-fast cultures, prothrombin time and INR reporting, and compatibility testing and unexpected antibody detection. Other potentially high-impact tests may be identified by looking at very high or low volume tests in the particular laboratory, or problems identified by reviewing the Variant Proficiency Testing Performance Report.

*To evaluate preanalytic and postanalytic issues:* Choose a representative specimen and “follow” the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories.

*To evaluate analytic processes:* Choose 2 or 3 analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records and method performance validations for the last 2 years, selecting timeframes at
the beginning, mid-point, and end of this timeframe. Compare instrument print-outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

III. Verify that proficiency testing problem have been resolved: From the inspector’s packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Correlate any PT problems to QC or maintenance records from the same time period. Be thorough when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.

IV. Review correction of previous deficiencies: Review the list of deficiencies from the previous on-site inspection provided in the inspector’s packet. Ensure that they have been appropriately addressed.

*********************************************************************************************************************************************
INSTRUCTIONS
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The purpose of this checklist is to evaluate the qualifications of the laboratory director and the effectiveness of the director in implementing the Standards of the Laboratory Accreditation Program, including the laboratory’s quality management plan.

This checklist must be completed by the team leader or a team member who is qualified and trained to be a team leader.

The following activities will provide the information needed to complete the questions in this checklist:

1. Interview with the laboratory director.
2. Interviews with laboratory supervisory personnel, and other laboratory personnel as appropriate.
3. Observation of the operation of the laboratory during the on-site inspection.
4. Review of the laboratory organizational chart, quality management plan and records, committee minutes, and other relevant documents.
5. Interview with the hospital administrator. If the laboratory is an independent organization, an executive from the organization should be interviewed.
6. Interview with the chief of the medical staff (for laboratories associated with a medical staff).

Further information is given below regarding the interviews with the laboratory director, hospital administrator, and representative of the medical staff. These interviews are essential parts of the inspection. If for any reason an interview cannot be conducted, the team leader should discuss the circumstances in the Inspector’s Summation Report.
**Meeting with the Laboratory Director**

**Purpose:** To help determine if the laboratory director has sufficient responsibility and authority for operation of the laboratory. A minimum of 15-20 minutes should be allowed for the meeting.

The interview is an opportunity to:

- Evaluate the director’s activities as listed in the Standards for Laboratory Accreditation
- Review any problems that the inspection experience might serve to resolve (e.g., space problems, staffing shortages)

**Meeting with the Hospital Administrator/Chief Executive Officer (CEO)**

For hospital-based laboratories, the inspector should meet with the hospital administrator/CEO. Approximately 15-20 minutes should be allowed for the meeting. It is a good idea not to schedule the meeting for early in the day, since the team leader should have a sense of the laboratory’s operations first. For independent laboratories, the inspector should meet with an executive from the laboratory organization.

**Purpose:** To extend the College’s appreciation for participating in the accreditation program and to record an evaluation of the laboratory from the administration’s viewpoint.

Points to communicate during the interview are:

- The goals of the CAP Laboratory Accreditation Program: education and laboratory improvement; establishing best practices in laboratory medicine, based on input from national experts
- Inspection method: two-year accreditation cycle; use of active laboratorians as inspectors; educational value to inspector and inspected laboratory
- The role of proficiency testing in the program
- Laboratory director: the laboratory director is responsible for the overall operation of the laboratory, under the requirements of both the CAP Laboratory Accreditation Program and CLIA-88 regulations

The interview is an opportunity to:

- Ascertain the administration’s perception of the laboratory service
- Discuss administration’s view of the laboratory director’s role in ensuring high quality laboratory services to fulfill the needs of the institution’s patients and clinicians
- Determine if the institution gives the director the authority to fulfill the director’s responsibilities under CAP and CLIA-88
- Address the effectiveness of the working relationship among the laboratory, its director and administration
- Identify any areas of conflict

The interview should include a discussion of all laboratories being inspected. Discussion of the laboratory’s financial and/or contractual arrangements is **prohibited**.
When speaking with the hospital administrator, the team leader should ask if the laboratory service level is appropriate to the requirements of the institution. The team leader should ask how the pathologists participate in hospital-wide committees, how effective they are in working with the medical and administrative staffs, and if they meet the expectations of the administration.

The inspector may record information from this interview in Part A of the Inspector’s Summation Report.

Meeting with a Representative of the Medical Staff

For laboratories associated with organized medical staffs, it is important for the team leader to interview the chief of the medical staff (or other knowledgeable medical staff representative, such as the chief medical officer, or a physician who uses the laboratory’s services frequently).

The team leader should allow for a 15-20 minute discussion, and should have an understanding of the laboratory’s operations beforehand.

Purpose: To determine whether the director and the laboratory staff have established an effective working relationship with the medical staff and are effectively supporting patient care.

The interview is an opportunity to:

- Evaluate how effectively the scope, quality, and timelines of the laboratory services meet the patient care needs of the hospital
- Assess the contribution of the pathologist and laboratory staff to teaching conferences and meetings
- Determine the cooperation of medical staff and pathologist in problem resolution
- Judge the medical community’s perception of the effectiveness of the laboratory director and other pathologists, and determine if the laboratory director has sufficient authority to fulfill the needs of the medical staff and patients

When meeting with the chief or other active member of the medical staff, the team leader should ask questions about the scope, quality and timeliness of laboratory services. The team leader should ask the medical staff representative for input on pathologist participation in medical staff committees, participation in institutional quality management (performance improvement) and patient safety activities, and participation in teaching conferences. The discussion should include all laboratories being inspected, including special function and satellite laboratories.

The inspector may record information from this interview in Part A of the Inspector’s Summation Report.
**REVISED** 10/31/2006

TLC.10100     Phase II     N/A  YES  NO

Does the laboratory director satisfy the personnel requirements of the College of American Pathologists?

NOTE: The qualifications required by CAP for the position of laboratory director depend on the testing performed in the laboratory.*

1. For laboratories that perform high complexity testing (as defined under CLIA-88), or for laboratories performing only moderately complex and/or waived testing whose annual test volume exceeds 500,000, the qualifications for the director are equivalent to the requirements for directors of high complexity laboratories under CLIA-88, as follows:

   The director must:

   a. Be an M.D. or D.O. licensed to practice (if required) in the jurisdiction where the laboratory is located
   b. Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification

   OR

   a. Be an M.D., D.O. or D.P.M. licensed to practice (if required) in the jurisdiction where the laboratory is located
   b. Have at least one year of laboratory training during residency, or at least two years of experience supervising high complexity testing

   OR

   a. Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution
   b. Be certified and continue to be certified by a board approved by HHS**

2. Laboratories in which high-complexity testing is limited to a particular specialty (e.g., hematology, dermatopathology, oral pathology, neuromuscular pathology, ophthalmic pathology) may be directed by an M.D. or D.O. who is certified in that specialty by one of the
following boards, or who possesses qualifications equivalent to those required for certification***:

a. A board that is a member of the American Board of Medical Specialties
b. The American Board of Oral and Maxillofacial Pathology
c. An American Osteopathic board

3. For laboratories in which the annual test volume does not exceed 500,000, and in which testing is limited to moderately complex tests alone (including provider-performed microscopy [PPM], as defined by U.S. federal regulations), or with waived tests, the director must:

a. Be qualified as in paragraph (1) above, OR
b. Be an M.D., D.O. or D.P.M., licensed to practice in the jurisdiction where the laboratory is located (if required), with at least 20 hours of continuing medical education credit hours in laboratory medicine, or equivalent training during medical residency; or with at least one year of experience supervising nonwaived laboratory testing, OR
c. Be a doctoral scientist with at least one year of experience supervising nonwaived laboratory testing

4. For laboratories in which the annual test volume does not exceed 500,000, and in which testing is limited to waived tests and provider-performed microscopy (PPM) (as defined by U.S. federal regulations), the director must:

a. Be qualified as in paragraphs (1), (2) or (3) above, OR
b. Be an M.D. or D.O., or D.P.M., licensed to practice in the jurisdiction in which the laboratory is located, if required.

Additional qualifications for grandfathered individuals and for the subspecialty of oral pathology may be found in the CLIA-88 regulations (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=de25c80f02191defdb049d6f4f722531&rgn=div8&view=text&node=42:4.0.1.5.29.13.223.23&idno=42).

With respect to laboratories subject to CLIA-88 that perform moderately complex or highly complex tests: a single individual may direct no more than 5 such laboratories.

*Qualifications for director of the embryology laboratory, and for scientific director of the forensic drug testing laboratory, are given in the Reproductive Laboratory and Forensic Drug Testing checklists, respectively.

**A list of boards approved by CMS for doctoral scientists may be found at http://www.cms.hhs.gov/CLIA/16_Certification_Boards_Clinical_Consultants_&_Laboratory_Directors.asp

***Specific requirements under CLIA-88 for neuromuscular pathology may be found in http://ecfr.gpoaccess.gov/cgi/t/text/text-
TLC.10150 Phase II N/A YES NO

**NEW**  10/31/2006

Are anatomic pathology services provided by a pathologist certified in anatomic pathology, or possessing qualifications equivalent to those required for certification?

NOTE: In facilities where anatomic pathology services are provided, a pathologist certified in anatomic pathology (or possessing qualifications equivalent to those required for certification) must perform such services. The services of a consulting anatomic pathologist shall be retained if necessary.

At the discretion of the director, subspecialties of anatomic pathology may be provided by physicians who are qualified under paragraph 2 of the Note to TLC.10100, above.

COMMENTARY:

N/A

If the laboratory director is not qualified to direct any of the individual sections of the laboratory, does the laboratory retain the services of individuals qualified to direct those sections?

**COMMENTARY:**

N/A

Does the laboratory director have sufficient responsibility and authority to implement and maintain the standards of the College of American Pathologists?

**NOTE:** Examples of how the team leader may obtain information on the director’s responsibility and authority include: interviews with the laboratory director, institution’s administration, medical staff, laboratory management and laboratory supervisory staff; review of the laboratory organizational chart; and review of minutes of quality management and other laboratory meetings.

**COMMENTARY:**

N/A


If the laboratory director has delegated some functions (e.g., review of QC data, procedure manuals, proficiency testing performance, etc.) to others, is there documentation of which individuals are authorized to act on his/her behalf for specific activities?

**NOTE:** The director is responsible for ensuring that delegated functions are properly carried out. It is the responsibility of the laboratory director to ensure that persons performing delegated functions are qualified to do so.

**COMMENTARY:**

N/A
TLC.10500 Phase II N/A YES NO

Does the director ensure communication of laboratory data?

COMMENTARY:

N/A


TLC.10600 Phase II N/A YES NO

Does the director ensure provision of anatomic pathology procedures as appropriate?

COMMENTARY:

N/A


**REVISED** 10/31/2006

TLC.10700 Phase II N/A YES NO

Does the director ensure provision of consultations regarding the ordering of appropriate tests and the medical significance of laboratory data?

*NOTE: Only physicians or doctoral scientists may provide consultations.*

COMMENTARY:

N/A


**TLC.10800** Phase II  
N/A YES NO  
Does the director interact with government and other agencies as appropriate?  

**COMMENTARY:**

N/A

**TLC.10900** Phase II  
N/A YES NO  
Is the laboratory director actively involved in the design, implementation and oversight of the quality management system?  

**NOTE:** The director is responsible for the laboratory’s overall quality management program, including the monitoring of key indicators; investigation of problems, with corrective/preventive action as appropriate; maintenance of patient safety; analytic quality control; and ensuring the quality of tests referred to outside laboratories.

**COMMENTARY:**

N/A


**TLC.11000** Phase II  
N/A YES NO  
Does the laboratory’s quality management plan effectively monitor essential performance characteristics of the laboratory; identify, investigate and prevent recurrence of problems; and maintain patient safety?  

**NOTE:** The quality management plan must address preanalytic, analytic and post-analytic activities. The plan must include monitoring key indicators appropriate to the laboratory, as well as a program to investigate problems that may affect patient care, including implementation of corrective/preventive action as necessary.

**COMMENTARY:**
TLC.11200 Phase II N/A YES NO

Does the director ensure provision of educational programs, strategic planning, and research and development appropriate to the needs of the laboratory and institution?

COMMENTARY:

N/A


TLC.11300 Phase II N/A YES NO

Does the director ensure sufficient personnel with adequate documented training and experience to meet the needs of the laboratory?

NOTE: For laboratories subject to CLIA-88, all personnel must meet the personnel requirements of CLIA-88.

COMMENTARY:

N/A


TLC.11400 Phase II N/A YES NO

Does the director ensure implementation of a safe laboratory environment in compliance with good practice and applicable regulations?

NOTE: The director must ensure compliance with OSHA and state/local regulations, as well as other applicable safety regulations. Details may be found in the Safety and Transport Services sections of the Laboratory General checklist.
COMMENTARY:

N/A


TLC.11500 Phase I N/A YES NO

Is the laboratory director or designee directly involved in the selection of all laboratory equipment and supplies?

NOTE: The intent is to ensure that the director has appropriate control over the process. The fact that economic issues are a major factor in these selections does not relieve the director of responsibility for ensuring the quality of the technical, clinical and operational aspects of the laboratory.

COMMENTARY:

N/A

NOTE TO THE TEAM LEADER: The following three questions apply to the laboratory directors who are not present full-time at the laboratory.

TLC.11600 Phase II N/A YES NO

Is there an agreement defining the frequency of, and responsibilities for, on-site visits by the laboratory director?

COMMENTARY:

N/A

TLC.11700 Phase II N/A YES NO

Is there documentation of the activities of the director during visits to the accredited laboratory and healthcare institution?

NOTE: The inspector should review the agreed-upon list of responsibilities and activities to ensure that they are in fact completed.
COMMENTARY:

N/A

TLC.11800  Phase II  N/A YES NO

Is the frequency/duration of on-site visits, and involvement of the laboratory director in the laboratory’s activities, considered adequate by the laboratory and medical staff?

COMMENTARY:

N/A

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TECHNICAL CONSULTANT (PATHOLOGIST, OTHER QUALIFIED PHYSICIAN OR DOCTORAL SCIENTIST)

-----------------------------------------------------------------

This checklist section applies only to laboratories that perform moderately complex tests AND are directed by an individual who does not meet the qualifications in paragraphs (1) or (2) of the Note to TLC.10100. This section does NOT apply to laboratories that perform only waived and/or PPM tests or are directed by an individual meeting the qualifications in paragraphs (1) or (2) of the Note to TLC.10100.

**NEW**  10/31/2006

TLC.12550  Phase II  N/A YES NO

Does the laboratory retain an individual qualified as a technical consultant?

**NOTE:** The technical consultant must be a pathologist, other physician, or doctoral scientist qualified as a director of a laboratory performing high-complexity testing, as defined in the Note to TLC.10100.

COMMENTARY:

N/A

Is there an agreement defining the responsibilities of the technical consultant?

NOTE: The technical consultant is responsible for the technical and scientific oversight of the laboratory, including compliance with CAP checklist requirements. The technical consultant must be available to the laboratory as needed for telephone, electronic and on-site consultation.

COMMENTARY:

N/A


Is there documentation of the activities of the technical consultant?

NOTE: The inspector should review the agreed-upon list of responsibilities and activities to ensure that they are in fact completed.

COMMENTARY:

N/A