COLLEGE of AMERICAN PATHOLOGISTS

Fast Focus on Compliance

12 Inspector Tools To Make Your Inspection Go More Smoothly

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Version no.

12 Inspector Tools to Make Your Inspection Go More Smoothly

Purpose of this Fast Focus on Compliance module is to provide you with tip sheets to help you become a more confident, efficient, and effective inspector ensuring consistent inspection findings.

Instructions: Please click on the title in the table of contents to bring you to the appropriate section.

Although these documents are provided as an aid, they are not intended nor should you use them in lieu of the checklists provided in the Inspector's Inspection Packet.

Additional information
Email: accred@cap.org
Phone: 1-800-323-4040
Additional information can be found in the Online Inspection Team Leader Training and Inspection Team Member Training (www.cap.org).

Table of Contents

Team Leader Inspection Guide

Purpose of this document:

- To provide guidelines for all inspection team leaders to ensure consistent and efficient inspections.

Instructions

- As you prepare for the upcoming CAP laboratory inspection, refer to this document as needed. Each of the major tasks or responsibilities is outlined below. Each section also provides space to include your own reminders, notes, etc. and lessons learned for future inspections.
- Do not hesitate to contact CAP with specific questions or concerns at 800-323-4040.

Phase	Tasks

Accept the assignment	• If you are unable to personally accept the inspection assignment, consider other pathologists in your practice as the team leader
	• Create Calendar of Events
	  o Inspector's Inspection Packet: 3 – 6 months prior to lab's anniversary date
	  o Inspection: within 3 month window of anniversary date
	• **Ensure training is up-to-date**
	
	NOTES:

Receive the Inspector's Inspection Packet/Select the team	• **Open the packet as soon as it arrives.**
	• Review the Activity Menu (type and complexity of testing per section unit) and instrumentation list
	• Use these and the Inspection Assignment Worksheet by Laboratory form to determine the number and type of inspectors needed
	  o Contact Assigning Commissioner for assistance if needed
	  o Check specialty inspector list in packet and/or contact CAP Inspection Assignment Specialist (847-832-7380) if you need assistance in locating appropriate inspectors, especially specialty inspectors: eg, clinical biochemical genetics, cytogenetics, flow cytometry, histocompatibility, molecular pathology, next generation sequencing

Team Leader Inspection Guide (cont.)

Phase	Tasks
Receive the Inspector's Inspection Packet/Select the team (cont.)	o Compare CAP INI to number of supervisors to determine ideal team size (do not exceed INI without prior CAP approval). If portions of the inspection require travel from one site to another, additional inspectors may be needed. o Check if this is an AABB coordinated inspection o Determine if a smaller team inspecting over a longer time period would be more efficient (eg, 5 inspectors for 1.5 days vs. 7 – 8 inspectors for 1 day); consider using cross-trained inspectors, eg, a. Flow cytometry inspector may pick up hematology. b. Team could divide Laboratory General Checklist vs. taking an additional person • Determine and report any conflicts of interests for all team members • Insist that all team members complete online Inspection Team Member Training NOTES:
Plan the inspection	• Call the laboratory director before you select an inspection date to determine logistics of the inspection such as distance between sites, preferred number of inspectors, order of laboratories to inspect if multiple facilities, preferred parking, any changes to org chart, etc. • Do **not discuss** inspection date with laboratory director (unannounced inspections) • Verify anniversary date (3 – month window), blackout dates, local holidays, hours of operation • Contact CAP with planned inspection date • Verify any security measures (photo ID) NOTES:

Team Leader Inspection Guide (cont.)

Phase	Tasks

Inspection logistics	• Arrange travel through the CAP Travel Desk (800-323-4040 ext. 7800)
	• **Distribute team member packets one month prior to inspection**
	• Conduct at least one team meeting to resolve any questions and review the schedule
	• If you have new inspectors on your team, consider asking them to conduct a mock inspection in their own laboratory of the section they will be inspecting
	• Encourage team members to use resources:
	  o CAP central office 1-800-323-4040
	  o accred@cap.org
	  o Experienced team member
	• Use the checklists provided in the Inspector's Inspection Packet
	• Provide team with list of cell phone numbers (laboratory and your team), directions, parking, meeting time/place
	• Consider arriving at the lab on the afternoon prior to the arrival of the full team or have one team member go ahead of the team (no more than 2 weeks prior to full team) eg, specialty inspector, POCT, Lab General Inspector to do safety inspection
	• Ensure all team members have completed training
	
	NOTES:

Opening Conference	• Notify laboratory 1 hour prior to arrival (unannounced inspections) • Plan to arrive by 7:30 – 8:00 am on the day of the inspection • Present the inspection announcement letter • **Introduce team to laboratory personnel and emphasize the purpose of the inspection and the role of the team**

Team Leader Inspection Guide (cont.)

Phase	Tasks
Opening Conference (cont.)	• Ask the key lab directors/supervisors to introduce themselves • Determine who should be notified of any deficiencies • Review the schedule for the day • Notify staff of when the team will stop accepting documentation for review (eg, prior to Pre-summation, during Summation, as long as the team is in the laboratory) • If multiple laboratories will be inspected, determine if single or joint Summation Conferences are preferred • Discuss with the lab director the audience and format of Summation Conference (see Summation Conference tip sheet for options) • Keep lab tour to 15 – 30 minutes depending on the size of the facility NOTES:
Time Management	• Team leader should manage time to be available to answer questions and complete interviews (inspect with 1 – 2 small checklists) • Use a working lunch as time to do a status check with the team • Check on team frequently to determine progress and if adjustments to schedule or assignments should be made • Encourage team members to document deficiencies throughout the day rather than waiting until the Pre-summation Conference; Your team members should be aware of the need to **inform supervisors** as deficiencies are cited (clearly state that a deficiency is being cited and why)

Team Leader Inspection Guide (cont.)

Phase	Tasks
Time Management (cont.)	• Team members should be willing to discuss deficiencies with laboratory staff but prolonged discussions should be avoided with the understanding that the team will review all proposed deficiencies during their pre-Summation Conference. NOTES:
Inspection	• Encourage team members to use R-O-A-D and interact with laboratory staff o Focus on major topics first, then delve into details in problematic or questionable areas o Spend twice as much time observing and asking questions as reviewing/reading documentation such as procedure manuals • Use the Decision Flow Chart as a guide to determine when to cite, to remove, and to mark deficiencies as corrected on-site o Items listed under Evidence of Compliance (EOC) are examples of documentation that could demonstrate compliance; these are not mandatory o Details listed in the NOTES carry the same weigh as the requirement itself o Focus on trends, not isolated incidents; were corrective actions implemented? • Call CAP central office regarding interpretation of requirements phone: 847-832-7000 or 800-323-4040 • Review compliance with previously cited deficiencies (Previous ISR pages) • Use checklists to take notes NOTES:

Team Leader Inspection Guide (cont.)

Phase	Tasks
TLC/Interviews	• Plan to interview the lab director after lunch if possible. • **If systemic issues are discovered, cite the appropriate TLC deficiencies and provide explanation on ISR Part A Comments page** • Discuss TLC deficiencies privately with Laboratory director and explain that these will not necessarily be presented at the Summation Conference. NOTES:
Pre-summation Conference	• Use the time to discuss any questions**, systemic issues**, etc. (Systemic issues may be indicated if the same All Common Checklist items are cited in multiple lab sections) and ensure consistency (deficiency vs. recommendation) for similar findings • Ensure all ISR pages (all pink and yellow) are accounted for; never discard any pink or yellow pages • Ensure all **supervisors have been informed of deficiencies**, especially if changes are made during the Pre-summation • **Ensure deficiencies clearly indicate why the laboratory is not in compliance (include dates, analytes, section units, etc.)** • Ensure all deficiencies are cited on appropriate ISR pages (section unit/checklist) • Mark deficiencies Corrected on-site only when minor corrective actions were required • Remove deficiencies when documentation is found and is in compliance NOTES:

Team Leader Inspection Guide (cont.)

Phase	Tasks
Summation Conference	• Explain that there are approximately 3000 requirements (and estimate the percent of deficiencies based on that) • **Offer positive feedback as well as noting any areas for improvement** • Do not verbally present recommendations • Encourage dialogue but do not allow confrontations. It is important to state explicitly that the team is a fact-finding team and that the lab may challenge any deficiency by providing supporting documentation. The final decision will be up to the Regional or Accrediting Commissioner and, eventually, the Accreditation Committee. • Maintain educational focus • Have laboratory director sign Part A of ISR; leave a copy of Part B. • Remind the lab director about the 30 day response time and leave the envelope with the Deficiency Response Instructions and forms • Discuss the proper response method and documentation for phase I, II and recommendations NOTES:

Post-inspection	• Complete page 1 of Part A of ISR
	• Include comments to explain any “no” answers on the 5 Part A questions
	• **Use the Comments page to provide explanation/details regarding:**
	  o **any systemic issues,**
	  o **results of a compliant investigation/non-routine inspection,**
	  o **TLC deficiencies,**

Team Leader Inspection Guide (cont.)

Phase	Tasks
Post-inspection (cont.)	o **the overall evaluation of the quality of laboratory services and involvement/effectiveness of lab director** • Return ISR pages within 24 hours using pre-paid mailer • Return reimbursement forms (with receipts) and evaluation forms within 90 days. • Dispose of any inspection-related materials in manner that maintains confidentiality (eg, shred) NOTES:

General notes/lessons learned:

Team Member Inspection Guide

Purpose of this document:

- To provide guidelines for all inspection team leaders to ensure consistent and efficient inspections

Instructions

- As you prepare for the upcoming CAP laboratory inspection, refer to this document as needed. Each of the major tasks or responsibilities is outlined below. Each section also provides space to include your own reminders, notes, etc. and lessons learned for future inspections

- Do not hesitate to contact CAP with specific questions or concerns at 800-323-4040

Phase	Tasks

Preparing	• Review the materials as soon as you receive them
	• **Become familiar with:**
	  o **the Activity Menu and instrumentation list**
	  o **Section Synopsis Report**
	  o **PT Performance Report**
	  o **Previous ISR**
	  o **Customized checklists**
	• Ensure your inspector training is up-to-date
	• Review pertinent sections of Laboratory Accreditation Manual
	• Discuss any questions with the inspection Team Leader prior to the inspection
	• If unfamiliar with instrumentation, consider doing an internet search
	• If you have question about interpretation of Checklist items, email a question to the CAP (accred@cap.org), or phone 847-832-7000 or 800-323-4040
	• Determine any possible conflicts of interests and report to the team leader

Team Member Inspection Guide (cont.)

Phase	Tasks

Preparing (cont.)	• Participate in the team meeting
	  o Review inspection schedule and responsibilities (especially All Common requirements in section units with multiple inspectors)
	  o Share list of cell phone numbers (laboratory and your team),
	  o Review directions, parking, meeting time/place
	
	NOTES:

Opening Conference	• Plan to arrive by 7:30-8:00 am on the day of the inspection • Team leader should introduce the team to laboratory personnel; key lab directors/supervisors should introduce themselves • **Notify staff of when the team will stop accepting documentation for review (eg, prior to Pre-summation, during Summation, as long as the team is in the laboratory)** • Keep lab tour to 15-30 minutes depending on the size of the facility NOTES:
Inspection	• Review activity menu with supervisor of discipline being inspected • Use a working lunch as time to do a status check with the team • Document deficiencies throughout the day rather than waiting until the Pre-summation Conference after reviewing them with the appropriate supervisor/manager

Team Member Inspection Guide (cont.)

Phase	Tasks

Inspection (cont.)	• **Use R-O-A-D and interact with laboratory staff**
	  o **Focus on major topics first, then delve into details in problematic or questionable areas**
	  o **Spend twice as much time observing and asking questions as reviewing/reading documentation such as procedure manuals**
	• Maintain a professional attitude at all times!
	• Review proficiency records, especially investigation and corrective actions for unsuccessful events (any event less than 100%)
	• Determine which instruments or methods are new since the last inspection and review method validation data
	• If inspecting more than one section, develop a schedule with the section supervisors
	• For each section, review documentation (procedures) and observe actual testing
	• Use the Decision Flow Chart as a guide to determine when to cite, to remove, and to mark deficiencies as corrected on-site
	  o Items listed under Evidence of Compliance (EOC) are examples of documentation that could demonstrate compliance; these are not mandatory
	  o Details listed in the NOTES carry the same weigh as the requirement itself
	  o Focus on trends, not isolated incidents; were corrective actions implemented?
	• Review compliance with items cited as deficiencies at the last on- site inspection, paying particular attention to recurring deficiencies

Team Member Inspection Guide (cont.)

Phase	Tasks
Inspection (cont.)	• Discuss all deficiencies with the supervisor/laboratory representative as they are identified and summarize them at the end of the section inspection; Clearly state that a deficiency I being cited and why • If uncertain about the interpretation of a checklist requirement, discuss with the Team Leader. If still uncertain, call the CAP at 1-800-323-4040 NOTES:
Pre-summation Conference	• Use the time to discuss any questions, systemic issues, etc. (Systemic issues may be indicated if the same All Common Checklist items are cited in multiple lab sections); ensure appropriate Team Leader Checklist deficiencies are cited to reflect the systemic issues • Ensure all ISR pages (all pink and yellow) are accounted for; never discard any pink or yellow page • Ensure all deficiencies are written on the appropriate section unit/checklist Deficiency (pink) page for each checklist. For each citation, record the checklist number and the specific reason the laboratory is deficient ie, include dates, analytes, section units, etc.) • If no deficiencies, check the “This lab section had no deficiencies” box at the top of the page • Ensure all deficiencies are cited on appropriate ISR pages (section unit/checklist) including All Common

Team Member Inspection Guide (cont.)

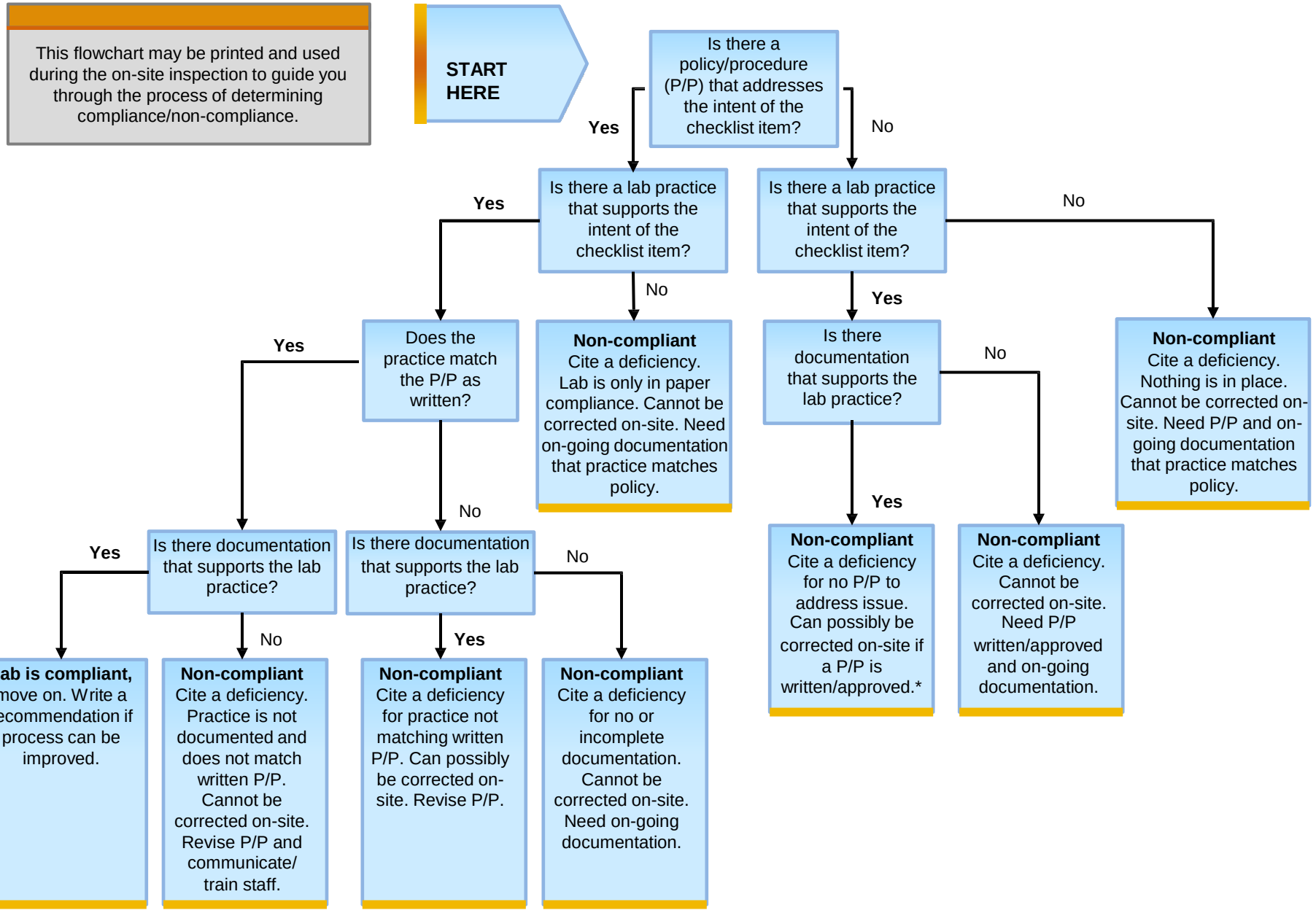
Pre-summation Conference (cont.)	• Mark deficiencies Corrected on-site only when minor corrective actions were required • Remove deficiencies when documentation is found and is in compliance • Ensure supervisors are notified of all deficiencies especially if changes are made during the Pre-summation • Sign and date each ISR deficiency and recommendation page for your checklist responsibilities NOTES:
Summation Conference	• Thank the staff that you worked with, especially the supervisor by name • Offer positive feedback as well as noting any areas for improvement; this sets a favorable tone • Emphasize systemic issues • Do not verbally present recommendations • Team leader should encourage dialogue but not allow confrontations • Return all pink and yellow pages to the team leader for copying; never discard any pink or yellow pages NOTES:

Team Member Inspection Guide (cont.)

Post-inspection	• Return reimbursement forms (with receipts) and evaluation forms within 90 days • Dispose of any inspection-related materials in a manner that maintains confidentiality (eg, shred the paperwork at the lab being inspected) NOTES:

General notes/lessons learned:

Compliance Decision Flowchart



Inspecting Proficiency Testing

QUESTIONS TO ASK

REVIEW **PT Policy**

Does the PT policy include:

- Instructions for review and evaluation of each unacceptable result?
- Ungraded PT challenges?
- Proper handling of PT products from receipt to reporting?
- Prohibition of interlaboratory communication?
- Referral of samples to another laboratory?
- Investigation of bias and trends?

REVIEW **Delegation Policy**

Does the delegation policy authorize another individual or job title to:

- Sign the attestation statements?
- Review final reports?
- Perform corrective actions?

REVIEW **Activity Menu**

- Does the Activity Menu include all tests currently performed by the laboratory?
- Is the laboratory enrolled in PT for all activities for which the LAP *requires* enrollment and participation?
- Is the laboratory performing alternative performance assessments (APA) for activities that do not require enrollment in PT? (Participation in proficiency testing meets the requirement for alternative performance assessment)

WHAT TO CITE

No policy	COM.01000

Delegation	TLC.11425

If delegated duty not performed, cite specific checklist requirement in addition to TLC.11425

Activity menu	COM.01200
Enrollment	COM.01300
APA	COM.01500

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QUESTIONS TO ASK (cont.)

REVIEW **PT Performance <100% Report**

- Are there outliers (result <100%; eg, 4/5)?
- Is there an increased number of outliers per discipline?
- Based on outliers, are there specific records to be reviewed later?
- Are there non participations to review?

WHAT TO CITE

Cite, if necessary, after reviewing records

REVIEW **PT Records**

- Are records (instrument printouts, worksheets, raw data, PT evaluations) available for two years (five years for transfusion medicine)?
- Are PT samples tested the same as patients (multiple instruments, multiple users, repeat testing)?
- Is there adequate rotation of testing amongst staff?
- Does raw data documentation include signed attestation by the director or designee that meets defined regulatory requirements for the complexity of testing?

Records available	COM.01700
PT tested as patients	COM.01600
Rotate testing among staff	COM.01600
Attestation	COM.01400

REVIEW **PT Evaluations**

Is there evidence of timely review for the following:

- Bias?
- SDI $\geq \pm 2.0$?
- Ungraded challenges?
- All unacceptable results?
- Enrollment in multiple kits for same analyte?

Bias	COM.01700
SDI $\geq \pm 2.0$	COM.01700
Ungraded	COM.01700
Unacceptable	COM.01700
Enrollment	COM.01600
Review	COM.01700
Handling	COM.01000
Interlaboratory	COM.01800
Referral	COM.01900

CAP

QUESTIONS TO ASK (cont.)

WHAT TO CITE

REVIEW **Corrective Actions**

Does the investigation include a timely review of:

- Clerical errors?
- Procedural errors?
- Specimen handling errors?
- Analytical/interpretation errors?
- Preanalytical errors – shipping, storage, reconstitution?
- Impact on patient testing?
- Implementation of the corrective actions?
- Assessment of future risk?
- Documented review by director or designee?
- Corrective action appropriate to the nature and magnitude of the problem?

Review	COM.01700

REVIEW **Alternative Performance Assessment Records**

- Does the laboratory participate in alternative performance assessment at least twice per year?
- Does the laboratory participate in an external PT program, if available, OR laboratory defined process?
- Are PT samples tested the same as patient samples?
- Is there adequate rotation amongst staff?
- Is there defined acceptability criteria?
- Documented review and corrective action if required?
- Does the raw data include the name of the testing personnel?

Same as patients	COM.01600
Rotation	COM.01600
Acceptability criteria	COM.01500
Review	COM.01700
Name of testing personnel	COM.01700
Frequency	COM.01500

Summation Conference Tip Sheet

Always

- Leave adequate time for the Summation Conference
- Highlight the educational and peer review objectives of the Accreditation Program
- Introduce the inspection team
- Be open, positive and supportive
- Allow laboratory to find missing documents and correct deficiencies while the team is on-site
- Encourage constructive dialogue
- Explain the post-inspection process including how to ask for an expungement
- Finish the conference again on a positive note, thanking the staff for their work in preparing for the inspection and their co-operation during the inspection
- Have the Laboratory Director sign the Signature Page of the Inspector's Summation Report, assemble all pages of the Summation Report and have someone make copies of Part B. These copies will remain with the laboratory and the originals will be sent back to the CAP office per the instructions

Never

- Leave a copy of the ISR pages without giving the laboratory an opportunity to discuss
- Leave Part A of the ISR with the laboratory director/staff
- Be rushed
- Debate the appropriateness of Checklist requirements
- Allow confrontation between the inspection team members and laboratory
- Surprise the laboratory with "new" deficiencies at the Summation Conference
- Solicit business
- Breach a confidence

Format

- Discuss the format of the Summation Conference (see Options 1 & 2 below) with the laboratory director and **jointly determine** the best option for this laboratory

Summation Conference Tip Sheet (cont.)

Format (cont.)

- Start out positively; thank the staff for their hospitality and for the educational benefits of visiting their laboratory
- Acknowledge Administration and other personnel attending the Summation Conference from outside the Laboratory if applicable
- Review the 2 phases of deficiencies and how to respond to each. Also, point out (but do not present verbally) the recommendation pages noting that it is not necessary to respond to these
- Reinforce that the laboratory has 30 days to respond to deficiencies from the inspection date and that no further deficiency report will be sent
- It is helpful for putting things into perspective to determine before the summation how many total deficiencies there are as an estimated percentage of total checklist requirements. This is true particularly if the facility administrator is attending the conference
- Have a separate discussion with the laboratory director regarding any Team Leader Checklist deficiencies; do not present these deficiencies at the full summation conference

Option 1	Option 2
• Have each team member present all deficiencies in a straightforward manner with concrete information	• Before convening the formal summation conference, meet with the laboratory director and laboratory management to discuss the full list of deficiencies and answer any questions
• Summarize by highlighting systemic issue and areas for improvement	• Present a high-level summary of deficiencies and emphasize systemic issues; do not verbally repeat all the deficiencies

- Allow time for questions. However, do not get into confrontations about specific deficiencies. Remind the inspected laboratory that the final decision on any deficiency is that of the Regional Commissioner. If the laboratory feels a deficiency is not just, they can contest it in their deficiency response. Remind them that it is essential that they include adequate documentation to support their claim
- If time permits, allow your team to briefly thank the laboratory for their help during the inspection
- Finish the conference again on a positive note

Inspecting All Common

Proper Use

- One per lab section – specific packet
- Contains requirements that are applicable to the entire section regardless of the number of discipline-specific checklists and is to be used in conjunction with the discipline-specific checklists
- If more than one inspector is inspecting the same section (e.g. core laboratory), inspectors will need to share the All Common Checklist and **record their findings** on the **All Common Checklist ISR Deficiency** page for that section
- Never discard any pink or yellow All Common ISR pages; there must be one set for each lab section unit

Processes/Areas for Observation

- Patient specimen processing (walk through process with lab staff)
- Procedure manuals available in work areas
- Lab practice matches procedure/ follows manufacturers' instructions
- Critical results notification process
- Reagents
  - Used within expiration date
  - Labeled appropriately
  - Stored according to manufacturer requirements
- System to detect unusual results

Key Documents to Review

- Proficiency Testing (PT)
  - Complete procedure
  - CAP-accepted PT including raw data, worksheets, etc. and corrective actions for any result less than 100%
  - Alternative performance assessment data/corrective actions
  - CAP Activity Menu Report
  - Signed PT attestation statements
- Quality Management
  - Documented QM/QC Plan
  - Specimen collection manual, including container labeling procedure
  - Monthly evaluation of instrument maintenance

CAP

Inspecting All Common (cont.)

Key Documents to Review (cont.)

- Procedure Manual
  - Reviewed biennially
  - Laboratory Director approves all new and substantially revised procedures
  - All personnel are knowledgeable
  - Discontinued procedures
- Results Reporting
  - Critical result notification with feedback
- Reagents
  - New lots and shipments verified
- Test Method Validation
  - Signed summary statement by laboratory director or designee
  - Validation data
  - Listing of Lab Developed Tests
- Instruments and equipment
  - Sampling of instrument/equipment policies, procedures, function checks, and performance verification records
  - Sampling of maintenance logs and repair records
  - (Thermometers) Records of traceability of NIST Standards
  - Sampling of temperature logs (refrigerator, freezer, water bath, heat block, incubator ambient, etc.), including corrective actions
- IQCP
  - List of tests using IQCP and a summary for each
  - Risk assessment for each IQCP
  - Signed Quality Control plan defining all elements being monitored

Inspecting Forensic Drug Testing Laboratories

In addition to the All Common, General, and Team Leader Requirements

Processes/Areas for Observation

- Specimen collection, instructions to patient or referring lab, identification of the specimen once collected, chain of custody, packaging and transport to testing lab
- Central specimen processing to observe specimen handling and storage prior to testing. Specimen must be maintained in the original container and aliquots cannot be returned to original container
- Ensure specimen identification is adequate, specimen security seal condition or secured specimen container integrity is maintained, and the external chain of custody is complete upon receipt
- All urine specimens tested for validity
- Internal chain of custody accounts for all specimens and aliquots at all points of testing
- Access to specimens, aliquots, and extracts is restricted to authorized lab personnel
- Specimen retention and disposition are identified and documented. Specimens must be retained for **one year**:
    - Positive urine specimens.
    - Positive hair specimens within the original container.
    - Positive specimens are retained frozen in original container for one year.
    - Aliquots are not returned to original container.
    - Whole blood specimens must be stored at least 30 days.
- Record retention must meet client, legal, regulatory and accreditation requirements and stored for at least two years and be easily accessible
- Reagents/Standards/Calibrators/Controls (RSCC) must be validated, labeled (may be traceable to a paper or electronic log), matrix matched or validated against the matrix, and DEA and/or State licenses as required for controlled substances
- Calibrators and quality control if prepared in house must be prepared from different lot numbers or sources
- Use of expired reagents must be defined in a policy that includes circumstances for use, qc, and personnel authorized to extend the usage of RSCC
- Walk through lab to check for:
    - Chemical, biologic, fire, electrical and other safety hazard
    - Eye wash stations and spill kits appropriate PPE available and in use Adequate work space
    - Refrigerators, freezers, room temperature monitoring system

Key Documents to Review

- Proficiency survey results from previous two years
- Procedures- ensure activity menu/proficiency testing and SOP match

CAP

Inspecting Forensic Drug Testing Laboratories (cont.)

Key Documents to Review (cont.)

- Initial procedures are approved by the scientific director prior to use
- Training records are available for all new procedures
- Procedures are reviewed by frequency defined by lab/at least every two years. Changes must be signed and dated by the scientific director.
- Forms in use are under document control
- New method validations since last inspection include accuracy, precision, analytical sensitivity (LOD), analytical specificity, linearity for quantitative methods (LOQ), and carryover potential
- Method performance annual verification must include precision, analytical sensitivity (LOD), linearity (LOQ) and carryover potential
- Quality Management- indicators are appropriate for testing and results known to staff
- Interpretive consultations are available to clients
- Quality control for screening tests- drug free, 25% above and below cutoff, blind at least 1% of batch and at least one per batch, controls are at least 10% of run, and include one fortified control is at the end of the batch
- Quality control for confirmatory tests with single point calibration – drug free, 25% below cut-off or near limits of quantitation (LOQ), 25% above cut-off and controls compromise at least 10% of the samples in the batch
- Quality control for confirmatory tested with multiple point calibration – drug free, positive at concentration to challenge cutoff(s) in use, and controls compromise 10% of the batch
- Conjugated drug controls used where conjugates are hydrolyzed
- Internal blind QC- at least one specimen per screening batch and at least 1% of the screening samples must be blind controls. For forensic testing- 20% positive samples are needed
- Weekly QC review by the scientific director or designee, in addition to monthly review that must include confirmation assay precision assessment
- Testing methods – see instrument listing in inspection packet
- Hair specimens have a validated procedure to control potential external contamination: wash procedure and/or metabolite identification
- Results certification: chain of custody documents, results of calibrators, results of quality control, identification of specimens tested in each batch, testing sequence of calibrators, controls, and unknowns, results of specimens, and identity of analyst(s) performing the test, along with identification of the reviewer and date of certifying review

CAP

Inspecting Forensic Drug Testing Laboratories (cont.)

Key Documents to Review (cont.)

- Cutoff values are defined for screening and confirmatory tests
- Unconfirmed results statement
- Confirmation of positives – by different method from screening testing
- Confirmatory testing may be performed In house or by CAP – FDT accredited lab or SAMSHA – certified lab
- Lab re-screens and confirms presence of screen-positive drugs. Ethanol retesting is done on separate aliquots of original specimen (one test must be by gas chromatography)
- Referral process includes initial screening, specimen aliquoting, chain-of-custody, receipts of reference lab results, and reporting of results
- Results review includes evidence of any repeat injections, reanalysis, secondary screening or rescreening, evidence of potential carryover review, and evidence of comparison of initial and confirmatory testing to ensure consistent results
- Results reporting – only confirmed positives are reported as positive, results are confidential and can be communicated by phone or electronic per protocol
- Instruments and equipment: pipette accuracy and precision at least annually, analytical balance services annually. Liquid chromatography – monitor LC column by retention time, relative retention time, separation of closely eluting compounds, chromatography quality and detector response. Gas chromatography – includes checking gas lines
- Mass spectrometry – tune each day of use and evaluate identification criteria/relative ion intensity
- Personnel – certifying scientists must be appointed by scientific director Scientific Director – qualifications reviewed/approved at CAP

** focus on areas that are critical, frequently cited, frequently overlooked, and unique to the checklist

Inspecting Laboratory General

Processes/Areas for Observation

- Specimen Collection
  - Observation of an in-patient and out-patient phlebotomy if performed by laboratory staff
  - Patient ID confirmed
  - Specimens labeled properly
  - Supplies within expiration date
- Central Specimen Processing
  - Observe specimen handling/processing
  - Send out tests
- Safety Walk Through Entire Laboratory
  - Chemical, biologic, fire, electrical and other safety hazards
  - Availability/use of personal protective devices
  - SDS sheets
  - Sufficiency of the physical space
  - Compliance with HIPAA regulations
  - Posting of official CAP sign for reporting quality concerns
- Audit Personnel Records
  - Academic degree or transcripts
  - Initial training records
  - Competency records
  - Visual color discrimination

Key Documents to Review

- Quality Management (QM)
  - Written QM plan
  - Defined quality indicators
  - Records of quality indicator monitoring/evaluation
  - Annual evaluation for effectiveness
  - Interim self-Inspection findings/corrective actions
- Document Control System for Policies/Procedures/Forms

Inspecting Laboratory General (cont.)

Key Documents to Review (cont.)

- Specimen Collection Manual
  - Complete specimen collection and handling procedures
- Specimen Requisitions (electronic and paper)
- Processing Area Equipment Maintenance Records
- Patient Reports (electronic and paper versions)
  - Approval of report format and content
  - Corrected reports
  - Reference laboratory reports
- Water Quality Procedures and Testing Records
- Laboratory Information System (LIS) Procedures and Records
  - LIS testing at installation/upgrades
  - System maintenance records
  - System security
  - Calculation checks
  - Autoverification
  - Telepathology
- Safety Procedures and Records
  - Review of safe work practices/incident reports
  - Bloodborne pathogen procedures/training
  - Fire policies/procedures
  - Fire drill records
  - Electrical safety equipment inspection
  - Chemical hygiene plan
  - Chemical inventory evaluation
  - Eyewash testing records

Inspecting the Reproductive Laboratory

Processes/Areas for Observation

- Semen analysis and therapeutic insemination specimens
  - Collection instructions posted/provided for off-site collection
  - Requisition and collection records
  - Specimen labeling and rejection criteria – 2 identifiers
  - Chain of custody for therapeutic insemination specimens
  - Andrology section director – 2 years of experience in a lab performing andrology procedures
- Embryology
  - Monitoring of incubators and other temperature dependent equipment
  - Culture media receipt, examination, and QC (if applicable)
  - Specimen identification throughout the entire process
  - Sterile technique/environment
  - Culture of oocytes and embryos
  - Chain of custody
  - Oocyte retrieval and embryo transfer
    - Documented time-out process
  - Embryology section director – 2 years of experience in a lab performing IVF/ART related procedures
- Cryopreservation
  - Specimen processing
  - Specimen labeling – 2 identifiers
  - LN2 storage monitoring
  - Inventory control and specimen tracking process

Key Documents to Review

- Manual semen analysis procedures and records

Inspecting the Reproductive Laboratory (cont.)

Key Documents to Review (cont.)

- Sperm count – 1 level of control each 8 hours of testing
- Concentration technique for azoospermic specimens OR disclaimer statement
- Sperm motility – Objective method defined with method verification every 6 months
- Sperm morphology – process to verify stain quality and method for consistent assessment of morphologic observation among technologists

- Automated semen analysis procedures and records
  - Daily quality control records (at least 2 levels)
  - Records of calibration/calibration verification
  - Procedures for handling samples that fall outside of the reportable parameters
- Semen analysis worksheets and reports with morphology classification system, reference ranges, and interpretive comments, when needed
- IUI procedures and records for maintaining the identity of the sample from collection to final disposition
- Embryology procedures defining assessment of maturity/quality and criteria for insemination
- Media and contact material quality control records
- Embryology records for each patient treatment cycle, including:
  - Timing of events
  - Outcome of insemination and culture
  - Identification of person performing each step
  - Disposition of each gamete/embryo
  - Critical reagents/supplies/equipment used for each product
- Embryologist training program and records of training
- Embryology clinical outcome data review

Inspecting the Reproductive Laboratory (cont.)

Key Documents to Review (cont.)

- Cryopreservation procedures, including the labeling of cryovials
- Inventory control procedures, including a plan for investigating specimens missing from inventory
- Emergency plan for implementing back-up capability for instruments and equipment, including provisions for emergency power (tested quarterly)
- Policy to provide back-up staffing
- Donor tissue program procedures and records, including:
  - Defined authority, responsibility, and accountability
  - Donor eligibility determination
  - Donor tissue labeling with unique identification code
  - Quarantine/release from quarantine
  - Retention of records (10 years)
  - Shipping of reproductive tissues
- Duplicate record storage reconciled annually
- Lab is FDA registered; FDA current guidelines available

IQCP INSPECTOR TIPSHEET

Processes/Areas for Observation

- Risk Assessment
- Quality Control Plan
- Quality Assessment Monitoring

Key Documents to Review

1. Policies and procedures for the implementation of an IQCP
2. Completed CAP List of Individualized Quality Control Plan(s) Form from the laboratory to sample records.
3. Review a sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years. Must include:
    a. Risk Assessment
        1) All three phases of the testing process: preanalytic, analytic, and post analytic
        2) All five required components: Specimen, Test System, Reagent, Environment, Testing Personnel
        3) Data from the laboratory's own environment, instrument/equipment performance, and testing personnel, including variations in use
        4) Review of the manufacturer's instructions and recommendations to identify potential risks and processes to mitigate risk
    b. Quality Control Plan
        1) Approval of the plan with signature of laboratory director and date before implementation
        2) Number, type (external and internal quality control systems), and frequency of quality control defined
        3) Quality control performed at least as frequent as required in manufacturer's instructions
        4) External control materials run with new lots and shipments
        5) Additional processes for monitoring the quality of the specimen, test system, reagents, environment and testing personnel defined based on risk assessment
        6) Customization of quality control plan for variations in use, including multiple identical devices, different personnel or different testing locations
        7) Quality control plan followed as written

IQCP INSPECTOR TIPSHEET (cont.)

Key Documents to Review (cont.)

c. Quality Assessment Monitoring
   1) Monthly review of quality control and instrument/equipment maintenance and function check data
   2) Evaluation of errors relating to all phases of the testing process
   3) Separate monitoring for variations in testing
   4) Evaluation of complaints on the quality of testing
   5) Evaluation of corrective actions taken if problems are identified
   6) Reevaluation of the risk assessment when failures are identified
   7) Annual reapproval of the quality control plan

COLLEGE of AMERICAN PATHOLOGISTS

Inspector IQCP Do's and Don'ts

IQCP REQUIREMENT	DO CITE IF:	DON'T CITE BECAUSE:
COM.50300	1.) Risk Assessment (RA) is missing one or more of the five required components (specimen, reagent, environment, testing personnel, test system)	1.) The format of RA is not "user-friendly" - RECOMMEND
	2.) RA doesn't cover all three phases of testing: pre-analytic, analytic, and post-analytic	2.) The RA doesn't look like the ones in YOUR lab - DISCUSS
	3.) RA did not include in-house data (previous QC records, environmental monitoring, etc.) or did not involve laboratory personnel	3.) You disagree with the acceptability of a specific risk - DISCUSS
COM.50400, COM.50500	4.) Quality Control Plan (QCP) was not signed by the laboratory director prior to implementation	4.) You disagree with the frequency of the QC being run - RECOMMEND
	5.) QC is performed less frequently than specified in manufacturer's instructions	5.) You think the QCP does not address potential risks - RECOMMEND
	6.) QCP is not followed as written	6.) You disagree with the acceptability of QC to mitigate a specific risk - DISCUSS
COM.50600	7.) Quality Assurance process does not monitor devices used in all locations	7.) You don't think that the lab has adequately addressed potential patient outcomes - RECOMMEND
	8.) Serious quality concerns or adverse patient outcomes have not been addressed – MAY ALSO NEED TO CITE TLC.10460	
Daily QC Requirement – Discipline-specific Checklists	9.) Equivalent Quality Control (EQC) is still in use without an approved IQCP – CITE DISCIPLINE-SPECIFIC CHECKLIST DAILY QC REQUIREMENT(S)	
	10.) Laboratory is using an IQCP for a test that is not eligible	
COM.50200	11.) Laboratory is not using the required CAP List of IQCPs form	