



INSPECTING PROFICIENCY TESTING

QUESTIONS TO ASK

REVIEW PT Policy

Does the PT policy include:

- Instructions for review and evaluation of each unacceptable result?
- Assessment of 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 CAP Accreditation Program *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)

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

Review	COM.01700
Ungraded	COM.01100
Handling	COM.01600
Interlaboratory	COM.01800
Referral	COM.01900

* It is not required that the laboratory investigate bias/trends; however, it is best practice. If the policy does not include bias/trend information, this is great opportunity to make a recommendation.

If there is a policy/procedure but the laboratory's practice does not match the policy/procedure, cite COM.10000.

Delegation	DRA.11425
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If delegated duty not permitted or performed, cite specific checklist requirement in addition to DRA.11425

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

Cite, if necessary, after reviewing records

QUESTIONS TO ASK (cont.)

WHAT TO CITE

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
Testing personnel	COM.01600
PT on primary method	COM.01600
Attestation	COM.01400

REVIEW PT Evaluations

Is there evidence of timely review for the following:

- Ungraded challenges?
- All unacceptable results?
- Enrollment in multiple kits for same analyte?

Ungraded	COM.01100
Unacceptable Enrollment	COM.01300
Review	COM.01700
Handling	COM.01600
Interlaboratory	COM.01800
Referral	COM.01900

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
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REVIEW Alternative Performance Assessment Records

- Does the laboratory define APA process and perform APA at least semiannually.
- Are APA samples tested the same as patient samples?
- Are APA samples analyzed by personnel who routinely test patient/client specimens?
- Is there defined acceptability criteria?
- Is there documented review and corrective action if required?

APA Process	COM.01500
Frequency	COM.01500
Same as patients	COM.01600
Testing personnel	COM.01600
Acceptability criteria	COM.01500
Review	COM.01700