

Proficiency Testing – Turning Pitfalls into Positive Outcomes

Presented by:

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Learning objectives

After this webinar, you will be able to:

- Identify when PT is required
- Document PT as a staff competency assessment tool
- Identify common causes of unsuccessful performance
- Review troubleshooting unsuccessful performance
- Outline steps to resume testing after required “cease testing”

What is PT?

Inter-laboratory quality control program

Performance is compared with the performance of all participating laboratories.

Routine review of PT results will alert your laboratory director of areas that are not performing as well as expected.

PT testing is an important tool for ensuring your testing is accurate and reliable.

When is PT required?

- Moderate/High Complexity Testing
- Regulated Analytes – CMS List
- 3 events per year – 5 samples per assay

Additional Requirements

CMS requires unregulated analytes be tested 2x per year

Best Practices

Perform PT on all tests including Waived testing when available.

How is PT Performed?

- Tested with the laboratory's regular patient workload
- By personnel who routinely perform the testing
- Use the laboratory's routine methods
- Document each step of the handling, preparation, processing, and examination of the PT sample.
- The individual testing the PT sample and the laboratory director must sign an attestation statement that PT samples are tested in the same manner as patient specimens.

Attestation of Results

- “We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing materials, have as closely as practical, performed the analyses of these specimens in the same manner as these specimens in the same manner as regularly performed on patient samples.”
- Signed by
 - Testing personnel
 - Laboratory director

Best Practice:

- ✓ Alternate PT testing among all employees throughout year.
- ✓ PT samples should be run within the normal daily practice.
- ✓ Save analyzer worksheets to verify this process.
- ✓ AFTER results are received, retained specimens can be tested for training and competency of new employees.

Summary Report

You are compared to:

Peer group

- Same instrument/Same reagent
- Must contain @ least 10 to be valid

Method group

All instruments using same method

All method group

All methods testing analytes

Referee group

Subset of 'expert' laboratories

Reviewing Results

Individual report

- Your results, P/F
- Report card – last 3 events

Participant summary booklet

- How all participants performed
- Educational material
- Information on other methods / instruments

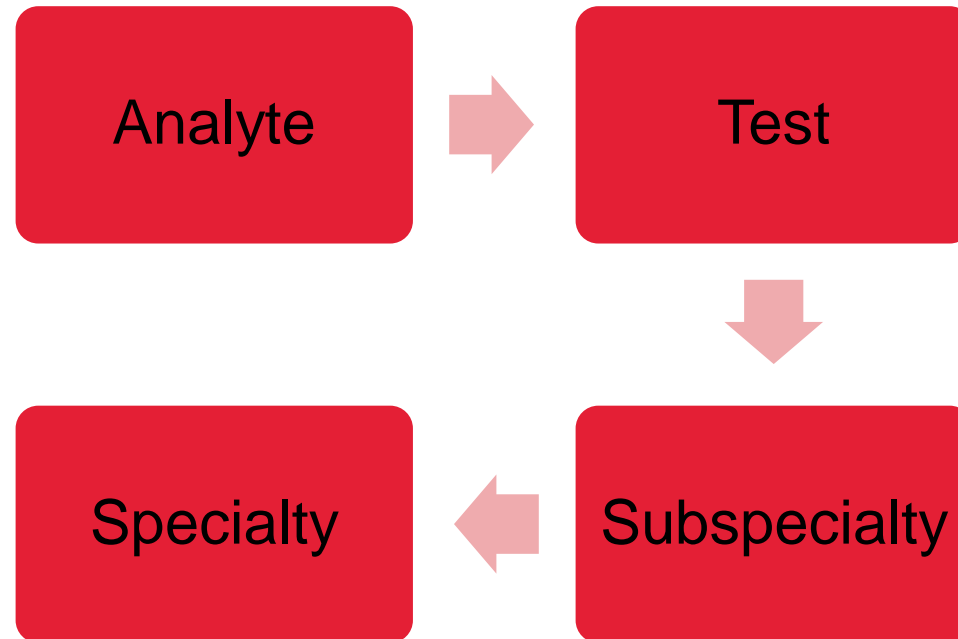
Documentation

Key points for successful documentation of PT performance:

- The laboratory director should promptly review PT results with the laboratory staff.
- Document this review and address any unsatisfactory scores.
- Initial and date the PT data to indicate that the results have been reviewed.
- Retain all records of PT participation for two years, except for immunohematology data which must be retained for ten years.

Unsatisfactory Performance

Failure to attain the minimum satisfactory score for:

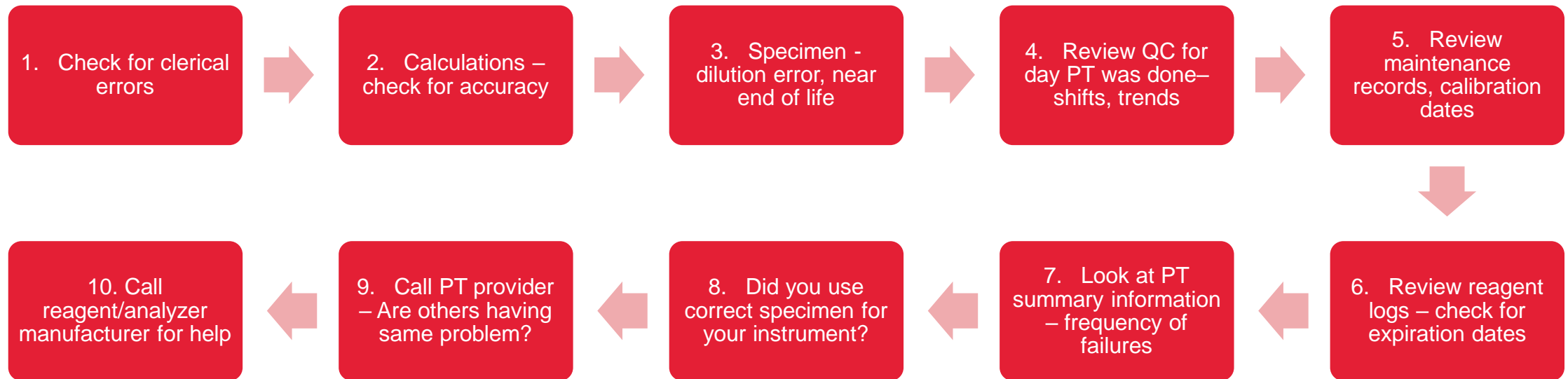


Unsuccessful Performance

- Unsatisfactory performance for the same analyte in 2 consecutive or 2 of 3 testing events (Score less than 80%)
- Repeated unsatisfactory overall testing event scores in 2 consecutive or 2 of 3 testing events
- Unsatisfactory testing event score for subspecialties not graded by analyte
 - Microbiology (all subsets)
 - Compatibility testing
 - Unexpected antibody detection/ID

Troubleshooting Unsuccessful Performance

- If you fail -- you MUST determine why, correct problem, and document



Document... Document... Document... Document

Is your testing accurate and reliable?

Quality Assessment

1. Evaluate every step of testing process
2. Ensure policies and procedures are effective
 - Learn if procedures and policies are being followed
3. Look for opportunities for improvement
4. Implement corrective actions
5. Re-evaluate (go to step 1) to determine if corrective actions fixed problem

Educational Challenges

- Non-graded for regulatory purposes
- Case history included
- Review required by COLA, CAP and other accreditation agencies
- Beneficial training tool

Best Practice

- ✓ Use educational challenges as inhouse group training session.
- ✓ Review case history
- ✓ Discuss in group setting
- ✓ Review correct result
- ✓ Discuss all results submitted by respondents

Employee Competency Assessment Tool

**Review of worksheets, QC, PT &
maintenance records**

Assessment of test performance
(PT / blind samples)

What Happens if Your Lab is Required to Cease Testing?

Pass two CONSECUTIVE events for that analyte

- 1 or more of the events may be off-cycle PT
- At least 6 months after cease testing

Off-cycle PT

- Specimens other than usual event specimens
- REQUESTED/PURCHASED from PT provider

After passing 2 consecutive –

- Request CMS/COLA approve for testing to resume

Proposed Changes to PT Regulations

Add 29 analytes as regulated

Remove 5 regulated analytes with low test volume

Revise the score for acceptable performance due to improved accuracy and precision of testing

In microbiology specify broad categories of tests. Enable flexibility for new technologies and be appropriate for future technologies

Enable CMS to apply the same sanctions for PT referral for waived testing when performed in moderate and high complexity laboratories

Review

Common Pitfalls

- Not treating proficiency testing samples the same as patient samples
- Not ensuring all testing personnel has an opportunity to participate
- Attestation forms not being signed
- Corrective action not being performed

Positive Outcomes

- PT tests entire process – pre-analytical, analytical and post analytical
- All personnel are competent and records to support are available
- Lab director responsibility is now being met
- Opportunity to improve quality of lab

Remember, Proficiency Testing serves as a test of your laboratory's processes, the competency of your staff and is a good indicator of the level of quality in your lab.

Helpful Resources

AAFP- Investigation Checklist of Unsatisfactory Proficiency Testing
https://www.aafp.org/dam/AAFP/documents/practice_management/office_lab_pt/unsatisfactory-pt-checklist%20.PDF

A complete list of CMS-approved proficiency testing providers may be found at the CMS website: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ptlist.pdf>

American Proficiency Institute. Checklist for Corrective Action
<http://www.api-pt.com/reference/forms/cachechecklist.pdf>

Centers for Medicare and Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA): Proficiency Testing DOs and DON'Ts.

<https://www.cms.gov/Regulations-andGuidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf>



Questions?



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