

College of American Pathologists

Laboratory Accreditation Program

Getting the Most Out of Your Proficiency Testing

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Objectives

After participating in today's session, you will be able to:

- **Discuss the regulatory aspects and impact of proficiency testing (PT)**
- **Identify approaches to effectively manage and fully utilize PT in your laboratory**
- **List investigative techniques used to determine causes of poor PT performance and describe effective corrective actions**
- **Use PT summary discussions as continuing education opportunities**



Proficiency Testing Do's

- **Enrollment**
- **Participation**
- **Evaluation of results**
- **Investigation of failures**
- **Corrective actions**
- **Maintenance of records**



Proficiency Testing Don'ts

- **Test samples differently than patient specimens**
- **Have same people always do testing**
- **Refer samples to another laboratory**
- **Discuss results before reporting**
- **Use PT samples for other purposes before submission date deadline**



Enrollment

- **Required for all analytes listed in the PT Enrollment Guide**
 - Updated annually
 - Available at CAP Web site
 - Included with order renewal forms



Participation

- **In addition to enrolling and testing samples, you must:**
 - **Ensure results are sent**
 - **Ensure they are sent by the deadline**
 - **Ensure all faxed pages are received**
- **Note: non-participation (failure to receive results) = unsatisfactory**



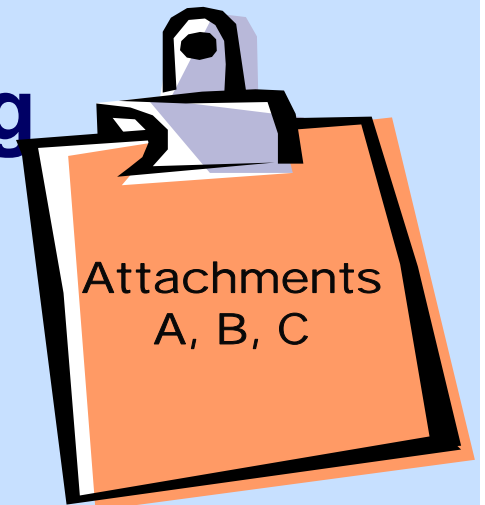
Evaluation of PT Results

To identify any deviation in proficiency testing from external requirements or facility's expectations that requires investigation and follow-up

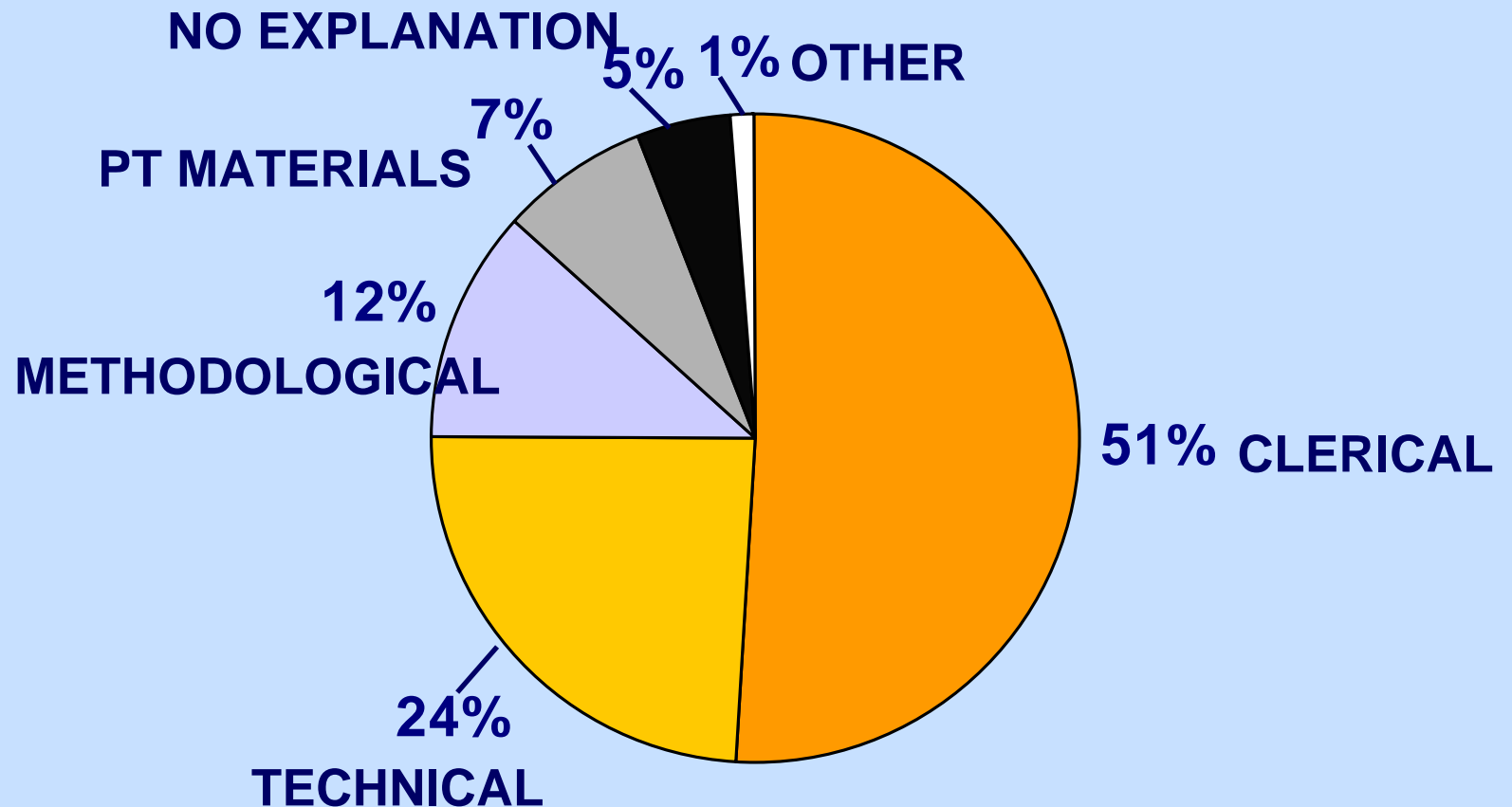


Reading the Report

- Performance on graded (acceptable vs. unacceptable)
- Ungraded results (codes)
- Bias on quantitative testing
 - Level of bias requiring action defined in procedure



Reported Causes of PT Failures



Clerical Errors

- **Postanalytic phase**
- **Same importance as testing errors**
- **Examples:**
 - **Transcription**
 - **Method/reagent/instrument codes**
 - **Missing information (TNP, etc.)**



Technical Issues

Directly attributable to human actions:

- **Reconstitution/pipetting/dilution errors**
- **Specimen mix-up**
- **Improper specimen handling**
- **Incorrect instrument set-up**
- **Failure to follow testing kit instructions**
- **Morphologic misinterpretation**



Methodologic Issues

- **Mechanical difficulties**
- **Instrument software problems**
- **Frequency of calibration**
- **Inadequate reagent performance**
- **Inadequate maintenance/function checks**
- **Other instrument malfunction
(intermittent electric problems)**



Issues with PT Testing Materials

- Hemolyzed, contaminated
- Unstable PT materials
- Perceived bias
- Matrix effect incompatible with method
- Late shipment



Investigating PT Failures

- See Attachment “D”
Investigation Flowchart



Investigation

- Review the all-participant report received from your PT Provider
- Review reporting records
- Review sample preparation/handling, testing
- Verify that the PT material was processed in the correct instrument mode
- Review results from previous survey



Investigation 2

- Review QC performance, instrument calibration, and reagent performance prior to, during, and after the original analysis of the PT challenge
- Contact the instrument/reagent manufacturer for assistance
- Retest the PT specimen(s), if possible or purchase additional specimens with different reagent lot



Corrective Actions

- **Design a process to verify clerical entries prior to PT result submission**
 - Verify instrument/method codes
- **Retrain testing personnel as to the proper procedures for sample preparation, testing, and reporting**
- **Modify (narrow) the QC acceptance range to detect problems sooner**



Corrective Actions 2

- **Evaluate/increase frequency of calibration**
- **Perform instrument function verification**
- **Revise procedure to reflect corrective actions**

***For more information, see NCCLS GP-27A “Use of Proficiency Testing to Improve the Clinical Laboratory**



Maintenance of Records

Original records

- Who performed testing/reported results
- Date/time of testing and reporting
- Worksheets/instrument tapes
- Confirmation results were received

Investigation

- QC records
 - Date of testing
 - Before/after
- Maintenance at defined frequency
- Calibration as defined by procedure

Requirement listed in GEN. 11484



Closing the Loop

- **Include:**
 - **Explanation of investigation**
 - **Documentation of external validation**
 - **Determination of whether there has been impact on patient care**
 - **Implementation of new processes/procedures to prevent recurrence**



Not Closing the Loop

- **May result in sanctions**
 - **Additional documentation**
 - **Suspension of testing**
 - **Cessation of testing**



Satisfactory PT Performance

- **Is 80% for regulated analytes**
 - **and other analytes that have at least 5 challenges per PT event)**
- **Percentage varies for analytes with fewer than 5 challenges**



Unsatisfactory PT Performance

- Laboratories that have unsatisfactory performance for 1 or more analytes on an event will receive a PT Exception Summary (PTES) report. Labs must:
 - Investigate problem
 - Determine cause
 - Implement corrective actions
- Response to LAP is not required



Unsuccessful PT Performance

- Is unsatisfactory performance on 2 of 3 PT events
- Laboratory will receive a PT Exception Summary (PTES) report
- Laboratory must suspend testing or implement plan of correction
- LAP must approve laboratory's action



Case Study

Story line:

Ineffective investigation and corrective actions led to cessation of testing:

2004-C: + bias, all acceptable

2005-A: no results received (fax problem?)

2005B: + bias, all acceptable

2005-C: + bias, 40% acceptable
(calibrator problem, almost expired)

2006-A: - bias, 60% acceptable
(calibrator problem)

2006-B: ok



Alternative Assessments

- **Participation in any formal PT program (for which enrollment is not required) including educational**
- **Split sample analysis with other laboratories**
- **Testing against an established method**



Alternative Assessments

- Testing against a reference sample
 - product calibrator
 - previously assayed material (e.g., regional pool)
- Analysis of patient data
 - clinical correlation
 - delta checking; moving averages
- See NCCLS GP-29A “Assessment of Laboratory Tests When Proficiency Testing is Not Available [2002]”



Split-Sample Testing: Quantitative

- **Determine type of statistical analysis to use**
- **Determine criteria for acceptability**
- **Test samples representing AMR**
- **Test enough samples**



Split-Sample Testing: Qualitative

- If only 2 of 3 match, the sample size must be increased to 6
- 5 of the 6 must match to achieve the same level of confidence.

95% confidence



Continuing Education

Formal CME/CE

- Contact individual PT providers for list of opportunities

Informal

- Discuss performance/investigations with all techs
- Review of summaries/critiques at staff meetings
- Pathologist led CE meeting using PT readings



Objective of PT: Quality patient care



Key Points for PT Management

- Spend more time - a lot more time - going over your PT results
- Be sure PT samples are handled as patient samples
- Be certain that every analyte is covered by formal or alternative assessments
 - Establish limits of acceptability if the provider has not



Additional Tips

- **Keep original worksheets and instrument tapes with the PT file**
- **Make sure every less-than-acceptable result is followed up and documented**
- **Resolve systematic biases**
- **Confirm that corrective actions make sense and actually fix the problem**



Technical Assistance

<http://www.cap.org>

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800-323-4040, ext. 6065



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Thank You



Questions and Answers



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