


College of American Pathologists
Laboratory Accreditation Program

**Getting the Most Out of Your
Proficiency Testing**

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Thank you for your kind introduction, and hello to all of you participating today.

My name is Bruce Williams. I am a pathologist practicing in Shreveport, Louisiana and am the chair of the CAP Commission on Laboratory Accreditation.

Let's take a minute to orient you to the materials in your handout.

The handout consists of :

1. The PowerPoint handout, with lines for taking notes
2. Various Attachments that follow immediately behind the PowerPoint handout pages.

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**



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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



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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



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Enrollment

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



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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

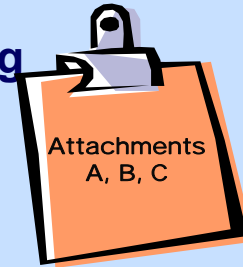
To identify any deviation in proficiency testing from external requirements or facility's expectations that requires investigation and follow-up



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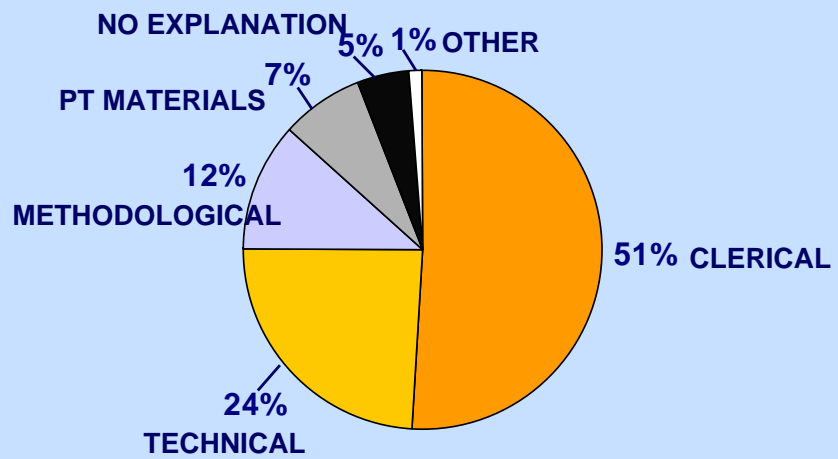
Reading the Report

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



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Reported Causes of PT Failures



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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**



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Methodologic Issues

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



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Issues with PT Testing Materials

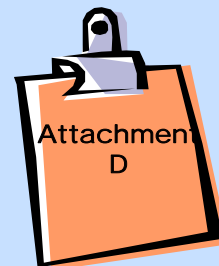
- Hemolyzed, contaminated
- Unstable PT materials
- Perceived bias
- Matrix effect incompatible with method
- Late shipment



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Investigating PT Failures

- See Attachment “D”
Investigation Flowchart



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STATE:

Let's look at a typical Evaluation Report for a quantitative CAP survey.

ASK:

- What is meant by “SDI”? What do the numbers and pound signs mean on the graph?
- Is intervention necessary?
- What are some of the data sources needed to evaluate a PT failure?

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



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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"



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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



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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



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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



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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



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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



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Slide 25 begins a discussion of acceptable corrective action plans.

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?)

2005-B: + bias, all acceptable

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

2006-A: - bias, 60% acceptable

(calibrator problem)

2006-B: ok



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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]”



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STATE:

The lab may prefer to do the entire evaluation in house

- By comparison with a reference method, or
- By testing additional samples provided by a manufacturer or otherwise assayed
 - Not ones that were used in routine QC!

In some cases, such as Schillings test or bleeding times, clinical correlation or reproducibility studies may be necessary.

Anyone who wants more information should refer to GP-29A for a more complete discussion.

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



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STATE:

The previous slide addressed quantitative testing.

- What about qualitative results?

Here is a simple 2x2 table describing the agreement between two labs on a set of six split samples.

- The labs agreed that three were positive and three were negative.
- By Fisher's exact test, this will occur on once in 20 attempts by chance alone.

Note, however, that if only 5 of the 6 match (for example, if one lab reported two positives and four negatives), the p value increases to .20.

- The lab's procedures in this case might specify a larger sample size.

Again, there is no requirement to use any

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



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Objective of PT: Quality patient care



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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



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Instructor Note: These points summarize the session.

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**



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Instructor Note: Bring the session to a close with these final additional tips.



Technical Assistance

<http://www.cap.org>

e-mail: accred@cap.org

800-323-4040, ext. 6065

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While we're waiting for you to signal your questions, I'll direct your attention to Slide 46, which contains information about how to access the technical specialists at the College, who can assist you in interpreting the intent of a checklist question.

<http://www.cap.org> home page – “Contact Us”

e-mail: accred@cap.org and your question will go directly to the Laboratory Accreditation Program area.

Or you may call 800-323-4040, ext. 6065 8:30 – 5:00 CENTRAL time Monday through Friday, except national holidays. You will be connected to a medical technologist in the accreditation department. Call while preparing for your inspection, while preparing to inspect, and even during the inspection.

Thank You



Questions and Answers



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This concludes my remarks. I'm now ready to answer your questions.