Proficiency Testing: Benefits and Challenges Beyond Meeting Regulatory Requirements Session #8104

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The Division of Laboratory Programs, Standards, and Services (proposed)

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No Disclosures

- Nancy Anderson, MMSc, MT(ASCP)

  In the past 12 months, I have not had a significant financial interest or other relationship with the manufacturer(s) of the product(s) or provider(s) of the service(s) that will be discussed in my presentation.

- Heather Stang, MS, MT

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Outline

- Introduction
- CLIA PT Requirements
- Reminders when Performing PT
- Possible Changes with Respect to CLIA PT
- Use and Value of PT Beyond Meeting Regulatory Requirements

INTRODUCTION

Introduction

- **Proficiency testing (PT)**
  - A program in which multiple samples are periodically sent to laboratories for analysis and/or identification. Each laboratory's results are compared with a peer group or an assigned value, and the results are reported to the participating laboratory and others
  - Serves as a measure of external quality assessment (EQA)
- **Why is PT important?**
  - Meets regulatory requirements
  - Tool for monitoring testing performance and preventing/identifying problems
  - Mechanism for improving laboratory quality
  - Can serve as a resource for education and/or competency assessment

CLIA PT REQUIREMENTS

Statutory PT Requirements

- **CLIA law – Section 353(f)(3)**
  - Requires that a laboratory participate in proficiency testing (PT) for each examination or procedure for which PT can reasonably be developed
  - Standards shall include uniform criteria for acceptable performance based on:
    - Available technology
    - Clinical relevance of the laboratory examination or procedure
  - Standards shall include a system for grading PT
- **Section 353(f)(4)(B)(iv) – addresses cytology PT of individuals**

Regulatory Requirements

- CLIA PT requirements (including analytes and required microbiology PT) were included in the final CLIA rule published January 28, 1992
- Required PT for all laboratories (including those not previously regulated) was implemented January 1, 1994
- Required PT analytes and tests and their criteria for acceptable performance have not changed since that time

CLIA PT Regulations

- Requirements for laboratories and annual PT program approval
- For each required analyte, test or specialty without specific analytes/tests, laboratories must:
  - Enroll in approved PT program
  - Analyze 5 challenges per event
  - Obtain 80% for satisfactory score (most analytes)
  - Perform satisfactorily on 2 out of 3 testing events
- For analytes, tests or specialties not listed in regulations, laboratories must verify testing accuracy twice per year – PT is one way to do this

REMINDERS WHEN PERFORMING PT

Testing PT Samples

- Test PT samples and report results in the same manner as patient samples, to the extent possible
- Avoid repeat testing of PT samples when patient samples are tested only once
- Rotate PT among personnel who test patient samples
- PT Referral
  - DO NOT send PT samples to another laboratory for analysis even if patient specimens are routinely sent for additional testing
  - DO NOT engage in inter-laboratory communications pertaining to PT until after the due date for reporting results to the PT program
  - If your laboratory receives PT samples from another laboratory for testing, notify your inspecting agency (CMS, state agency, or accreditation organization) and DO NOT test the samples

Reporting PT Results

- The laboratory director and person who tests PT samples must attest to the routine integration of the samples into the laboratory workload when reporting results to the PT program
- Follow instructions carefully when completing PT result forms or submitting results on-line to avoid common clerical, measurement unit or calculation errors
- Submit all results by the PT program due date
- Document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples

Laboratory Review of Graded PT Results

- When results are received from the PT program, the laboratory director should review and sign off
- In cases of unsuccessful performance or PT problems, document the investigation, corrective action, and ongoing monitoring
- Maintain a copy of all PT records, for at least two years from the event date, including
  - a copy of the report forms used to record PT results
  - the attestation statement provided by the PT program, signed by the analyst and laboratory director documenting that PT samples were tested in the same manner as patient samples

PT Review by Laboratory Inspectors

- Make sure all PT records are accessible and retrievable within a reasonable time during a laboratory inspection
- Inspectors may request PT records and raw data to review results
- Inspectors verify that
  - PT was performed in the same way that patient testing is performed
  - Results for microorganism identification were reported at the same level and in the same way that results are reported on patient specimens

Possible PT Penalties

- **Failure to participate successfully in PT**
  - CMS or the accrediting agency may direct the laboratory to undertake training or obtain technical assistance
  - CMS may impose sanctions
- **PT referral, whether intentional or not, results in the most serious CLIA penalties**
  - Loss of CLIA certificate for one year
  - Includes cancellation of Medicare/Medicaid payment
  - Laboratory director unable to direct ANY laboratory for two years
  - Listing on CLIA annual Laboratory Registry – CMS website

Taking Essential Steps for Testing Act of 2012 Pub. L. 112-202, the "TEST Act"

- Clarifies that sending a PT sample to another laboratory for analysis is prohibited despite the requirement that PT samples be treated like patient specimens
- Gives the Department of Health and Human Services Secretary discretion as to whether to
  - revoke a laboratory's CLIA certificate for one year in the event of a PT referral violation and
  - substitute intermediate sanctions in lieu of a mandatory two-year ban on a laboratory director and laboratory owner if the CLIA certificate is revoked
- Regulations to implement the TEST Act being developed by CMS

POSSIBLE CHANGES WITH RESPECT TO CLIA PT

Proposed CLIA Revisions for Microbiology PT

- **Possible changes being considered by CMS and CDC based on CLIAC recommendations**
  - Levels of Service
  - Required Categories of Tests
  - Major Groups of Microorganisms
  - Gram Stain PT
  - Mixed Culture Requirements
  - Antimicrobial Susceptibility Testing
  - Direct Antigen Testing
  - Monitoring Performance over Time

Proposed CLIA Revisions for PT in Other Laboratory Specialties

- CLIAC recommended criteria for determining a list of required analytes; CMS and CDC considering the following
  - PT availability
  - Test volume
  - Medical relevance
  - Considerations of cost/impact
- Proposed criteria for acceptable performance (grading criteria) will also be developed

USE AND VALUE OF PT BEYOND MEETING REGULATORY REQUIREMENTS

For the problems that PT can identify, which is most important to you?

1. Identification of pre-analytical problems such as mislabeled or improperly transported samples, and inappropriate sample handling or storage

2. Identification of analytical problems such as calibration errors, incorrect test reagent storage, instrumentation problems, and sample extractions errors

3. Identification of post-analytical problems such as delayed reporting to PT program, incorrect calculations, incorrect test result interpretation, and transcription errors

APHL Focus Groups

- CDC funded a cooperative agreement with APHL to assess the perceived value of PT
- In all focus groups conducted, participants shared information concerning the relationship of PT to overall quality assurance including: the analytical process, personnel competency, and satisfaction with PT program services

Focus Group Participant Demographics				
Demographics	**Large Laboratories**	**Small Laboratories**	**Microbiology Laboratories**	**Public Health Laboratories**
State Public Health Laboratory	0	0	0	8
Local Public Health Laboratory	0	0	1	2
State Agricultural Laboratory	0	0	0	1
Manufacturing Industry Laboratory	1	0	0	0
Independent/Commercial Laboratory	1	2	0	0
Physician Office Laboratory (POL)	2	5	0	0
University/Medical School Laboratory	1	0	4	0
Large Hospital/Clinic Laboratory	13	6	13	0
CLIA Certificate of Compliance	0	4	0	5
CLIA Certificate of Accreditation	18	9	18	6

What do you consider as the best benefit provided by performing PT beyond meeting regulatory requirements?

1. Tool to assess competency, source of education and training
2. Indicator to evaluate and improve quality
3. Resource for assessing methodology/instrumentation
4. Monitor to check for trending of results and problem detection

Proficiency Testing Benefits Beyond Meeting Regulatory Requirements

Topic	Benefits	Examples
PT Use in Quality Management	Competency, Education and Training	· Results can be used to identify staff that may require more training · Remainder samples can be used to assess staff competencies · Remainder samples can be used for staff education and training · Samples can provide an important source of rarely seen organisms
	Quality Evaluation and Improvement	· Scores can indicate areas where improvement may be needed · Scores can be used in defense of quality of testing and results with upper management · Scores can be used to defend the quality of laboratory results when occasionally challenged by a clinician
	Assess Methodology/ Instrumentation	· Remainder samples can be used to test the accuracy of various systems, validate new instrumentation, verify accuracy with laboratory-developed tests, and troubleshoot analyzers · Summary reports can be used to obtain information on PT performance to change or recommend a change in methodology or instrument o Compare instruments when results are peer grouped o Identify methodologies/instrumentation used by the majority of laboratories
	Trending	· Results can be used to monitor trends in performance over time · Trends can be used to identify a problem before it becomes significant

Proficiency Testing Benefits Beyond Meeting Regulatory Requirements

Topic	Benefits	Examples
PT Program Satisfaction	Turnaround Times	· Time from PT sample receipt to submission of test results to PT program was adequate to perform and report testing
	Technical Advice	· Programs provide educational challenges with added information · Programs provide additional information on their website regarding ungraded challenges · Technical experts were knowledgeable

What do you consider as the most challenging aspect of performing PT?

1. Inability to truly treat PT samples as patient specimens
2. Large number of ungraded challenges
3. PT program subscription cost
4. Staff time involved in the PT process (i.e., purchasing, analyzing and/or interpreting)

Proficiency Testing Challenges Experienced by Clinical Laboratory Professionals

Topic	Challenge	Examples
PT Sample Identification/ Handling	PT Samples treated the same as Patient Specimens	· PT samples do not physically resemble patient specimens which makes it difficult to handle and treat them the same · Samples require additional instruction on handling and safety precautions, reconstitution, testing, and reporting results than patient specimens · Additional documentation required for PT samples may lead to potential for transcription errors · Entering PT information into an electronic laboratory information system (LIS) may result in errors in computation and conclusions for non-analytical purposes
PT Use in Quality Management	Total Testing Process Evaluation	· Limited value of PT in the pre- and post-analytic phases of testing
	Methodology/ Instrumentation Assessment	· Determination as to which analyzer should be designated for analysis and for reporting when the test is performed on multiple analyzers may result in additional tracking and paperwork
	Competency, Education, and Training	· Fear of failure is a concern · Staff are held accountable for the results by management and consequences of failure can be serious for laboratorians
	Trending	· PT results at the extreme high and low ends of the analytical range may result in data that is less useful for methodology and instrument monitoring · Trending is not useful in microbiology because samples are repeated less frequently

Proficiency Testing Challenges Experienced by Clinical Laboratory Professionals

Topic	Challenge	Examples
Technical Challenges	PT Sample Unavailability	· Developing an alternative PT program when samples or analytes are not available commercially can be challenging · There is sometimes a lag time until the PT program provides tests for new instruments or methodologies
	Matrix Effect	· PT sample matrices are unlike patient specimens and can lead to testing issues
	Ungraded PT Challenges	· Corrective action with documentation is necessary and involves extended staff time
Administrative Challenges	PT Program Costs	· Expense of PT can be difficult to justify in the budget · Sometimes it is necessary to purchase multiple modules to cover all analytes tested
	Staff Time	· PT is time consuming and difficult to incorporate into daily workload · Extensive time is needed for documentation, ordering PT, reporting results, managing paperwork volume, clerical review · LIS may handle PT data differently than patient data and extra time is needed to process it

Proficiency Testing Challenges Experienced by Clinical Laboratorians

Topic	Challenge	Examples
PT Program Satisfaction	PT Sample Quality/Quantity	· Poorly stained slides · Distorted images in photomicrographs · Quantity not enough for a repeat test · Complex reconstitution instructions · Lack of sample source information with microbiology samples · Susceptibility testing issues due to number of passes of an organism
	PT Reporting Unit Consistency	· PT reported in units that are different from those used to report patient specimens · Need to perform unit conversions · PT program changes reporting units
	PT Reporting Format	· Different reporting format for each PT program · Process different from how patient specimens would be reported
	Customer Service	· Automated telephone response system does not provide opportunity to talk with a live person · Difficult to reach a technical expert
	Turnaround Times	· Unable to rerun labile samples

Recommendations for Improvement

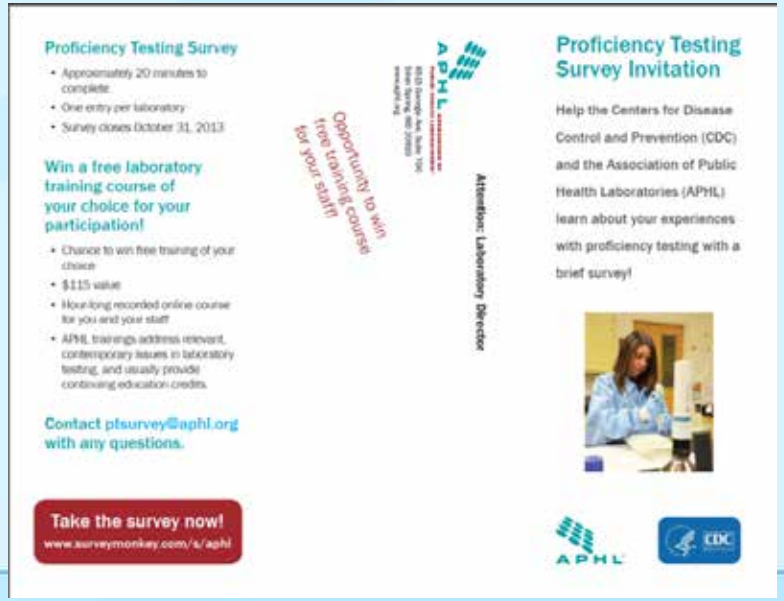
- Provide customized modules to help reduce PT cost
- Provide PT samples that more closely resemble patient specimens
- Decrease number of negative samples
- Provide more complex organism samples
- Reduce paperwork
- Provide uniform reporting procedures across modules and PT programs

Recommendations for Improvement Provided by Clinical Laboratory Professionals

PT Cost	· Provide customized modules
Sample/PT Modules	· Provide PT samples that more closely resemble patient specimens · Decrease number of negative samples · Provide more complex organism samples · Resolve CLSI and FDA susceptibility testing breakpoint differences
PT Reporting	· Reduce paperwork · Provide uniform reporting procedures across modules

National Proficiency Testing (PT) Survey

- Anonymous survey conducted in collaboration with APHL now open!
- Purpose
  - Gather information to understand how laboratories use PT and perceive its value
  - Identify the kinds of laboratories that would benefit from additional information regarding PT
  - Determine if there is a need for educational materials



National PT Survey (cont.)

- Invitational letters sent to directors of approximately 34,000 Certificate of Accreditation/Certificate of Compliance laboratories in late July 2013
- One entry per laboratory
- Promotion
  - Articles to be published in MLO and Clinical Microbiology Newsletter
  - Advertisements in CAP Today and MLO
- Access survey at:
  - **www.surveymonkey.com/s/aphl**
- Email inquiries to:
  - **ptsurvey@aphl.org**

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

CDC

www.surveymonkey.com/s/aphl

Dear Laboratory Director,

The Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC) invite you or the person directly responsible for the oversight of proficiency testing (PT) in your laboratory to participate in an important survey about PT. The results of the survey will help us to understand how PT is used by laboratories throughout the country. The survey requires a computer with Internet access and should take no more than 20 minutes of your time.

To access the survey enter www.surveymonkey.com/s/aphl **into your browser.** If you need a paper copy of the survey, please email ptsurvey@aphl.org.

Once in the survey, you will be asked to enter either the 6-digit number shown on the address label that accompanied this letter or the 10-digit CLIA number for your laboratory, as indicated on your CLIA certificate. *Please note: An independent contractor will use the CLIA number to assure that there is only one response per laboratory and to characterize the laboratory using existing data. The CLIA number will not be used to identify any laboratory or individual. The summary report will not contain any identifying information, preventing the linkage of laboratories with survey results.*

As a token of our appreciation for completing the survey, you and your staff will have the opportunity to win an hour-long live or recorded course addressing relevant, contemporary issues in laboratory testing. The training session is valued at $105. If you wish to enter the random drawing, please provide your email address after completing the survey (your email address will not be linked to your survey answers and will only be used for the drawing before being deleted from our files). All 50 prizes will be awarded and a list of winners may be requested by sending an email to ptsurvey@aphl.org with "Winners List" in the subject line after November 30, 2013.

Thank you for your participation! If you have any questions please email ptsurvey@aphl.org.

Sincerely,

Karen Breckenridge

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Questions?

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