Preventing Critical Proficiency Testing Failures

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Disclosures

- **COI: none**
- **Off-label use: none**
- **Chair, CAP Continuous Compliance Committee**

Learning objectives

- Review the rationale and requirements for proficiency testing (PT), including CLIA requirements
- Differentiate PT requirements for regulated vs. nonregulated analytes
- Define the adverse consequences of unsuccessful PT performance
- List steps to avoid poor PT performance and associated adverse outcomes

Outline

- Regulating agency PT requirements (CMS)
- Accrediting agency PT requirements
- Responding to PT failures
- Changes and future direction in PT

Proficiency Testing is an important, integral part of your quality program!

What Doesn't Proficiency Testing Accomplish?

- PT does not test the quality of the laboratory
- PT usually does not test pre and post analytical steps
- Limitations in the evaluation of the analytical step (testing accuracy)
  - Special treatment is often given to PT sample by the laboratory
  - The specimen and its handling are not the same as a clinical specimen
- External PT does not test laboratory efficiency

What does (can) Proficiency Testing Accomplish?

- Assess the current state-of-the-art in laboratory medicine
- Provide information to assist in method selection
- Improve Laboratory Practice/Patient Care
  - Provide information on analyte accuracy
- Educational aspects of the programs: peer comparison
- Satisfaction of regulatory and accrediting requirements

CMS PT Requirements

- **Clinical Laboratory Improvement Amendments (CLIA)**
  - **http://www.cms.gov/CLIA/03_Interpretive_Guidelines_for_Laboratories.asp#TopOfPage**
  - **Appendix C, Interpretive Guidelines**
    - *Subpart H, PT requirements for non-waived testing*
  - **83 regulated non-waived tests require PT**
  - **Regulated analytes defined by discipline (specialty)**
  - **Enrollment by analyte (chemistry, immunology, immunohematology)**
  - **Enrollment by subspecialty (microbiology)**

CMS PT Requirements

- **CLIA PT rules, con't**
  - **Enrollment required for each "lab" (CLIA number)**
  - **Enrollment required for primary instrument/method each analyte**
    - *Minimum each analyte, best practice demands commonly used secondary methods to be evaluated*
  - **Regulated analyte PT 5 samples X 3/year**
  - **Must be CMS-approved PT provider**
  - **Passing score 80% (100% immunohematology)**

CMS PT Requirements

- **CLIA PT rules, con't**
  - **One failed PT test (< 80%) = unsatisfactory performance**
    - *Must investigate cause*
    - *CMS can direct cease testing if patient danger*
  - **2 cons or 2/3 failed = unsuccessful performance**
    - *CMS may permit technical assistance or retraining, or cease testing*
  - **3 cons or 3/4 failed = cease testing (regulated analytes)**

CMS PT Requirements

CLIA PT rules, con't

- **What about all other non-waived testing?**
- **Non-regulated, non-waived testing**
  - *Twice annually verify accuracy of results*
- **What about waived testing?**
  - *No CLIA/CMS requirements for PT or accuracy verification*
- **PT handling**
  - *Handle as patient specimen*

CMS PT Requirements

- **CMS focus on PT referral**
  - **CLIA defines harsh penalties for "cheating" on PT**
    - *Intentional referral of PT material to another lab*
    - *1 year suspension of testing and lab director is prohibited from directing for 2 years*
  - **Accidental PT referral most common**
    - *Confirmation of results as patient specimen*
    - *Clerical or send-out error*
  - **PT Referral bill (TEST) gives CMS greater discretion**
    - *Unclear how CMS will implement TEST*
    - *Still high risk, don't let down your guard*

CMS PT Requirements

- **CMS focus on PT referral**
- **CMS proposed rule for TEST Act interpretation**
  - **Category 1: Revocation of CLIA certificate, intentional or repeat PT referral**
  - **Category 2: Suspension or limitation of CLIA certificate, intermediate category, applied to many labs that refer unintentionally**
  - **Category 3: General sanctions, least severe, apply to labs that refer PT which does not get tested, civil penalty and corrective action plan**

Accrediting agency PT requirements

- **Accrediting agencies must at min meet CLIA**
  - **Frequency, scoring of *regulated* analyte PT**
  - **Each agency puts its own "spin" on PT**
    - *Best practice*
    - *Focus of accrediting agency*
    - *Scientific/medical input on sig of testing*

Accrediting agency PT requirements

- **Laboratory Accreditation Program (LAP)**
  - **College of American Pathologists (CAP)**
- **Key differences between LAP and CLIA PT**
  - **LAP does not distinguish waived vs. nonwaived**
    - *For enrollment, not necessarily scoring*
  - **PT required for predictive markers (ER/PR, Her 2)**
  - **Emphasis on evaluating ungraded or no consensus PT**
  - **PT Programs must be CAP-accepted**
    - *Currently 10 CAP-accepted PT programs*

Example of PT Evaluation-Ungraded PT Challenges

Blood Cell ID Ungraded	BCP-16	PLASMODIUM SP (MALARIA)	[26]
	BCP-17	NEUTROPHIL, SEG/BAND	[26]
	BCP-18	MONOCYTE	[26]
	BCP-19	POLYCHROMATOPHILIC RBC	[26]
	BCP-20	PLASMODIUM SP (MALARIA)	[26]

Accrediting agency PT requirements

- **LAP vs. CLIA PT, con't**
  - **PT enrollment required for more analytes**
    - *CMS 83 regulated analytes*
    - *LAP analyte/procedure index lists waived and nonwaived analytes requiring PT*
  - **How does CAP determine which analytes require CAP-accepted PT vendor enrollment?**
    - *Based upon number labs doing test, clinical importance, availability of PT material*
    - *Continuous Compliance Committee (CCC) final decision*

Accrediting agency PT requirements

- **LAP vs. CLIA PT, con't**
  - **Analytes with required PT enrollment (> 300)**
    - *Master activity menu with PT options (e-Lab solutions)*
    - *Laboratory activity menu (e-Lab Solutions)*
    - *Analyte/procedure index of PT Surveys or EXCEL catalog (www.cap.org)*
  - **Similar to CLIA by analyte**
    - *Some analytes defined by matrix (serum vs. urine hCG)*
  - **Frequency/number PT samples**
    - *5 X 3 for regulated analytes*
    - *Varies for all other analytes (5X3, 3X2, 2X3)*

Analyte/Procedure Index of Surveys and EXCEL Catalogs

Analyte/Procedure	LAP ENR
Antigen detection, bacterial (cont.)	X
	X
Antigen detection, viral	X
	X
	X
Antigliadin antibody IgA, IgG, qualitative	X
Antigliadin antibody IgA, IgG, quantitative	
Antiglomerular basement membrane, qualitative	X

Accrediting agency PT requirements

- **All other analytes require alternative assessment of performance (AAP)**
  - **All analytes not listed as requiring CAP-accepted PT**
  - **Twice annually**
  - **Must define acceptance criteria by analyte/test**
  - **Appropriate AAP may include**
    - *Split sample with outside or internal reference lab*
    - *Split sample with alternative method*
    - *Assayed material or regional pools*
    - *Clinical validation by chart review (lab director)*
    - *Participation in ungraded/graded PT*

CAP (LAP) oversight of PT performance

- **Continuous Compliance Committee (CCC)**
  - **Defines which nonregulated analytes require PT**
  - **Audits and accepts PT providers**
  - **Monitors non-enrollment, non-participation, and performance in required PT by LAP labs**
  - **Sends out notification when a laboratory must *CEASE TESTING* due to non-enrollment, non-participation or critical performance failure**

CAP (LAP) definition of critical PT failure

- **Regulated analyte: failure to perform as expected with potential impact on patient care and/or inconsistent with CMS regulation,**
  - *3/3 or 3/4 failures, no flexibility (CLIA)*
  - *Cease testing letter sent after 3rd failure*
  - *ER/PR and Her 2 handled as regulated analyte per CAP/ASCO*
- **Nonregulated analyte/required by LAP: failure to perform as expected with potential impact on patient care and/or inconsistent with CAP laboratory accreditation program requirements,**
  - *Generally 4/4 or 4/5 failures, but CCC has flexibility*

How is a laboratory notified of a problem?

Types of letters sent:

Warning letter for first failure – no response to CAP required; refer to CAP website for investigation tools

Evidence of investigation reviewed at next onsite inspection

Next level letter – *Proficiency Testing Compliance Notice* (PTCN) response form

- *Non-enrollment PTCN; Non-participation PTCN; and Performance PTCN*
- *Formal response to CAP required with root cause analysis and specific corrective action plan*
- *Occurs after 2/2 or 2/3 failure (all PT)*
- *Warning letter that next failure will result in cease testing*

  --Regulated analytes and ER/PR or Her 2

Laboratory Accreditation Program
Proficiency Testing Compliance Notice (PTCN) – *Performance* Response Form

Laboratory Name:		
CAP #:	**PT Exception For:**	**Exception Type:**
Kit #:	**PT Analyte Group:**	**PT Provider:**

1. Laboratory Action: (choose one)

☐ Laboratory investigated the PT failure, completed this form, and is providing supporting documentation as outlined below and on the reverse side of this form.

OR

☐ Laboratory has voluntarily ceased patient/client testing for this analyte/subspecialty. I understand that I must contact the CAP prior to resuming patient/client testing to determine what documentation to submit. Additionally, this activity is being removed from my Activity Menu and cannot be added until required documentation is provided.

2. Reason for unacceptable results (choose all that apply)

☐ Clerical ☐ Procedural ☐ Analytical ☐ Specimen Handling ☐ PT Material (must provide documentation from PT provider)

☐ Other (please explain):

3. During your investigation of this PT failure were any patient/client results affected?

☐ Yes ☐ No If yes, please explain what actions were taken:

4. What specific corrective actions have you taken to prevent reoccurrences? (choose all that apply)

☐ **Developed** procedures for review and reporting of PT results
☐ **Trained**/retrained personnel on testing procedures and processes
☐ **Reviewed** records for instrument/method calibration, reagent checks, maintenance, service calls and results from previous PT events
☐ Other (please explain):

5. What evidence do you have that the problem has been successfully corrected? (see reverse side for required documentation)

☐ Re-analysis of PT samples ☐ Performed reinstatement PT ☐ Verified patient or QC results with other method or laboratory

☐ Self-evaluation (for clerical errors) ☐ Other (please explain):

Laboratory Director's Signature: Date:

How is a laboratory notified of a problem?

Types of letters sent:

- **Third failure (after PTCN issued/received)**
  - **Regulated analyte: Cease testing letter**
  - **ER/PR, Her 2: Cease testing letter**
  - **Non-regulated analyte: Another PTCN**
    - *After 4th failure or 4 of 5, review by CCC to determine action (usually cease testing)*
    - *For non-regulated handled case by case*

What should a laboratory do when they receive a PTCN?

- **Determine whether error was clerical, procedural, analytical, specimen handling, or PT material issue (should have been done already)**
- **If analytical, resolve instrument/method issues as quickly as possible, ensure analytical issues *remain resolved***
- **If clerical/procedural/specimen handling, retrain staff and institute fail-safes for next survey**
- **Correct problem and file documentation for review at next onsite inspection**
- ***Avoid failing next survey***

Cease testing letter

- Lab must sign and acknowledge that testing has ceased for analyte
  - Regardless of medical importance
  - pO2, compatibility testing, Na, etc
- Failure to acknowledge cease testing letter may lead to accreditation action
- Next inspection team will be notified of cease testing dates
  - Failure to comply will jeopardize accreditation
- Cease testing is bad

Cease testing letter

- **Requirements to resume testing once in Cease testing status**
  - **Root cause analysis with specific corrective action plan developed based on the findings**
  - **Implement plan and document success**
  - **2 events of successful off-cycle/reinstatement PT**
  - **Submission of foregoing data to CAP and if acceptable, await reinstatement letter before reinstituting testing.**

You are lab manager at lab (1 CLIA#) that measures Na in three separate locations.

One location has failed 2 consecutive surveys. You know that if you fail the next survey due to clerical issues CMS/CAP will be required to…

1. Send cease testing notice for all Na testing
2. Send cease testing notice for Na testing in 1 location
3. Use discretion as errors were mainly clerical
4. Do nothing, clerical errors do not count

You are lab manager at lab (1 CLIA#) that has blood gas machines in three separate locations.

One location has failed 2 cons surveys for pO2. Your best action is to…

1. **Proceed with 3rd survey at all locations**
2. **Investigate BG machines in all locations**
3. **Voluntarily cease testing on device/location that failed and investigate cause**
4. **Investigate only device/location that failed surveys**

Your lab has failed 3 cons Troponin I (not CLIA reg analyte) surveys due to analytical and/or procedural problems. Upon next failure CAP is likely to….

1. Do nothing, troponin I is not a regulated analyte
2. Ask lab for a thorough investigation of issues
3. Issue cease testing notice due to concerns over patients safety
4. Report lab to CMS

Responding to PT failures

- **Unsatisfactory (1 event) PT failure investigation**
  - **Investigation required for each unsatisfactory PT**
  - **Major categories of investigation**
    - *Clerical*
    - *Analytical*
    - *Procedural*
    - *Specimen handling*
    - *Matrix effect*

Example of Unsatisfactory PT Evaluations

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325 Waukegan Road Northfield Illinois 60093-2750
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EVALUATION
ORIGINAL

C-B 2011 Chemistry

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	Limits of Acceptability S.D.I	Lower	Upper	Your Grade	Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation
Lactate Dehydrogenase	CHM-06	225	183.1	9.1	254	+4.6	146	220	Unacceptable	Survey -100 Mean +100
U/L	CHM-07	373	312.5	15.4	255	+3.9	249	375	Acceptable	C-B 2011
BECKMAN AU SERIES	CHM-08	159	128.8	6.8	255	+4.4	103	155	Unacceptable	C-A 2011
BECKMAN AU OSR/37 C	CHM-09	254	209.5	10.4	255	+4.3	167	252	Unacceptable	C-C 2010
	CHM-10	158	128.4	6.6	255	+4.5	102	155	Unacceptable	x: Result is outside the acceptable limits
LDL, measured	CHM-06	94.41	86.708	5.037	50	+1.5	60.69	112.73	Acceptable	C-B 2011
mg/dL	CHM-07	74.31	66.618	4.853	50	+1.6	46.63	86.61	Acceptable	C-A 2011
DIRECT SURFACTANT	CHM-08	61.02	56.637	2.918	49	+1.5	39.64	73.63	Acceptable	C-C 2010
	CHM-09	114.62	102.208	5.560	49	+2.2	71.54	132.88	Acceptable	
	CHM-10	67.08	56.863	3.007	49	+3.4	39.80	73.93	Acceptable	x: Result is outside the acceptable limits
Magnesium	CHM-06	4.03	3.758	0.128	274	+2.1	2.81	4.70	Acceptable	C-B 2011
mg/dL	CHM-07	2.71	2.473	0.093	276	+2.5	1.85	3.10	Acceptable	C-A 2011
COLOR-DYE-XYLIDYL MAGO	CHM-08	5.27	5.162	0.157	273	+0.7	3.87	6.46	Acceptable	C-C 2010
BECKMAN AU SERIES	CHM-09	3.18	3.078	0.110	274	+0.9	2.30	3.85	Acceptable	
	CHM-10	5.27	5.159	0.158	275	+0.7	3.86	6.45	Acceptable	
Potassium, serum	CHM-06	5.0	4.93	0.06	323	+1.2	4.4	5.5	Acceptable	C-B 2011
mmol/L	CHM-07	3.1	3.07	0.05	324	+0.6	2.5	3.6	Acceptable	C-A 2011
ION SELECT ELECT DIL	CHM-08	6.0	5.87	0.07	321	+1.9	5.3	6.4	Acceptable	C-C 2010
BECKMAN AU SERIES	CHM-09	4.5	4.47	0.05	322	+0.6	3.9	5.0	Acceptable	
	CHM-10	6.1	5.87	0.07	319	+3.4	5.3	6.4	Acceptable	

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Responding to PT failures

- **LAP investigation form (www.cap.org)**
  - **Leads lab thru various stages of investigation**
    - *Clerical*
      - Transcription, correct method/instrument code, units, decimal place
    - *Procedural*
      - Reagents according to SOP, reagents acceptable, QC acceptable (QC review), staining/interpretation steps
    - *Analytical*
      - Calibration stable, past PT bias, within measuring range, instrument maintenance/ problems, QC and calibration review

Responding to PT failures

- **LAP investigation form, con't**
  - **Specimen handling**
    - *Reconstitute according to instruction, stored per instruction, correct test on correct vial*
  - **PT material (matrix)**
    - *PT graded with appropriate group (matrix effect), PT material received on time and in good condition*

Responding to PT failures

- **Mayo internal PT failure investigation form**
  - **Investigation by path of workflow**
    - *Preanalytical, analytical, postanalytical*
  - **Categorization of PT events**
    - *Methodological problem, Clerical error, technical problem, problem with PT material, problem with PT evaluation, no explanation after investigation*
  - **Required elements of every PT investigation**
    - *QC review, calibration review, review of patient results over time period, impact on patient results (yes/no and follow-up required or done)*

Responding to PT Failures

- **Who should review the Data**
  - **Technologists involved with the testing**
  - **Laboratory supervisor/manager**
  - **Medical director**
  - **Quality Manager**
  - **Laboratory Administrator**
  - **Laboratory Director**

Access the CAP PT Toolbox

1 - Log In

Proficiency Testing Tool Box (www.cap.org)

Related Information

- Don't forget! If you add a new test... add the activity code to your CAP accreditation test menu.
- Update your accreditation personnel records to ensure the proper person receives accreditation notices.

Resources

- PT Exception Investigation Checklist (Word, 775 K)
- Definitions
- Proficiency Testing Compliance FAQs
- Troubleshooting Guide for Proficiency Testing Data (July 2009) (PDF, 174 KB)
- Getting the Most Out of Your Proficiency Testing
- Responding to a Missing Enrollment E-mail
- Analyte Specific PT Troubleshooting

Contact the Compliance Group

Operations Specialist, LAP PT Compliance Group

- Phone: 800-323-4040, ext. 6052
- Fax: 847-832-8174

Or you may send your response to the following address:

LAP PT Compliance Group
Operations Specialist
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750

For questions concerning the results your laboratory reported in this PTCN, please contact your PT provider.

For questions about your PTCN report, please contact Customer Service at 800-323-4040 option 1.

Current Toolbox Menu

- PT Exception Investigation Checklist
- Definitions
- PT Compliance FAQs
- Troubleshooting Guide for PT Data (July 2009)
- Getting the most out of PT
- Responding to a Missing Enrollment eMail
- Analyte Specific PT Troubleshooting

Analyte Specific PT Troubleshooting

- HER-2 Testing
- Blood Gas Analysis
- Coagulation-Regulated Analytes
- (coming soon) Mycology
- (in development) Endocrine

CMS/CDC Process for CLIA Update

- **Addition of tests to list of regulated (PT required) analytes**
- **Modifications to grading scheme (acceptability criteria) for many regulated analytes**
- **Criteria for adding analytes:**
  - **Availability of proficiency testing;**
  - **Test volume of a given analyte;**
  - **Clinical relevance, based on**
    - *Review of practice guidelines;*
    - *Literature, including MMWR;*
    - *FDA risk classification;*
  - **Cost**

CMS/CDC Process for CLIA Update

- **28 Analytes under consideration for inclusion in CLIA**
  - **Hgb A1c; Troponin I & T: Vitamin B12; Hepatitis C antibody; BNP and NTproBNP; INR ; CEA; Acetaminophen; Salicylate; others**
- **57 proposed grading modifications**
- **5 analytes proposed removal**
  - **Primidone, Procainamide/NAPA, Quinidine, Ethosuxomide, LD isoenzymes**
- **Significance: change PT frequency to 5 challenges, 3 events per year, change grading schemes for many**
- **Timeline?**

CMS changes for 2014

- **CMS notified PT providers that second instrument reporting would no longer be allowed on PT surveys starting with the 2014 survey cycle**
- **PT providers signed joint letter to CMS objecting**
- **CMS will consider PT providers objections**
- **If no change occurs, second instrument reporting will no longer occur starting January 2014**

Resources

- CAP Troubleshooting guide for proficiency testing data (available at www.cap.org for CAP accredited laboratories)
- CLSI Document GP27-A2, *Using Proficiency Testing to Improve the Clinical Laboratory*, 2007.
- Malone, Bill, Proficiency Testing: Making the Grade, Clin Lab News 37: No.12, December, 2011.
- Miller, WG, GRD Jones, GL Horowitz, C Weykamp, Proficiency Testing/External Quality Control Assessment: Current Challenges and Future Directions, Clin Chem 57: 1670, 2011.

CAP Resources

- **Contact the Compliance Group**
  - **LAP PT Compliance Group**
  - **Phone: 800-323-4040, ext. 6052**
  - **Fax: 847-832-8174**
- **Or you may use the following address:**
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Questions?