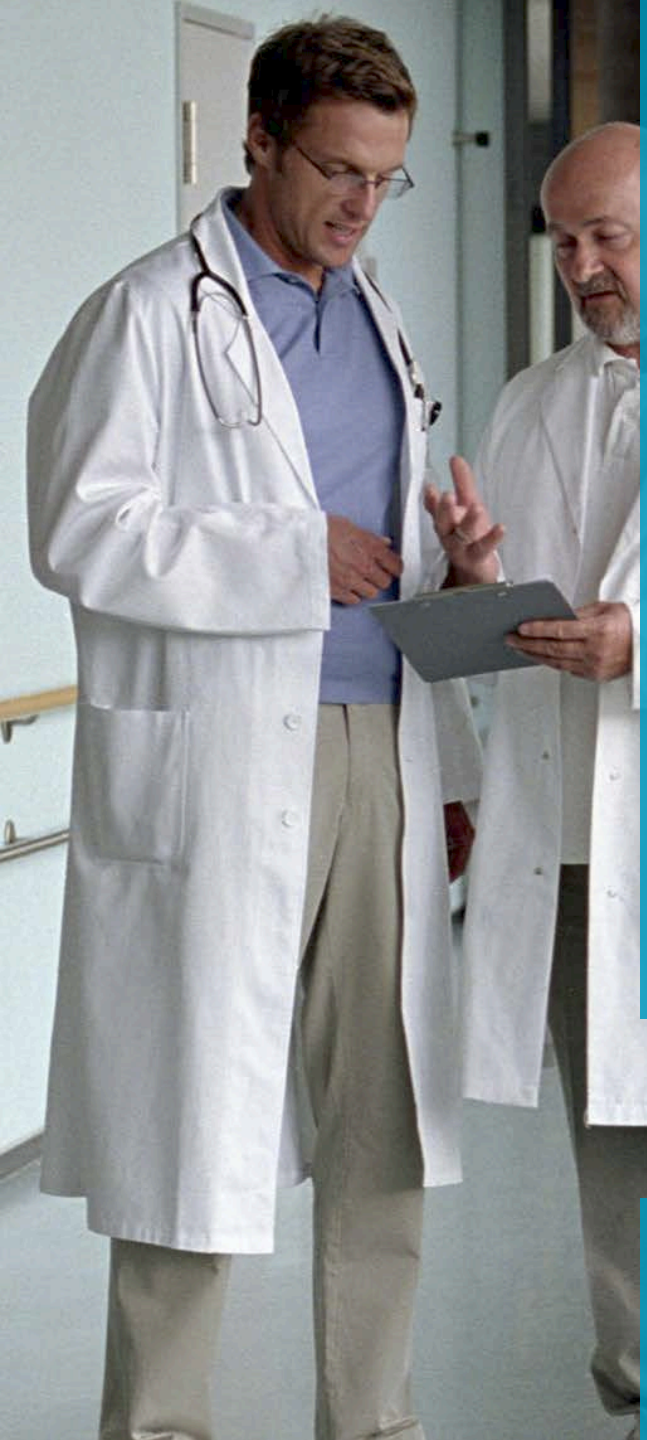


COLLEGE of AMERICAN PATHOLOGISTS

What to do with Proficiency Testing Failures?

Dottie Hautman, MT(ASCP)SC
Inspection Analyst
Laboratory Accreditation
College of American Pathologists

March 22, 2016

Objectives

- Identify the common causes of PT failures
- Discuss corrective actions for PT failures
- Discuss PT Best Practices
- Explain cease testing
- Define multiple kit ordering

CAP

The Top 10 Deficiencies

Top 10 Deficiencies

	All CAP Laboratories Deficiencies 2014-2015		
Rank	**Requirement ID**		**Grand Total**
1	GEN.55500	Competency	1979
2	COM.01200	Activity Menu	1810
3	COM.10000	Procedures	1345
4	**COM.01700**	**PT Evaluation**	**1178**
5	COM.10100	Procedure Review	1137
6	GEN.20375	Document Control	1036
7	COM.30300	Reagent Labeling	1032
8	COM.01400	PT Attestation	968
9	COM.04200	Monthly Review	919
10	COM.30450	New Lot Confirmation	897

CAP

PT Evaluation COM.01700

There is ongoing evaluation of PT and alternative assessment(AA) results, with prompt corrective action taken for unacceptable results.

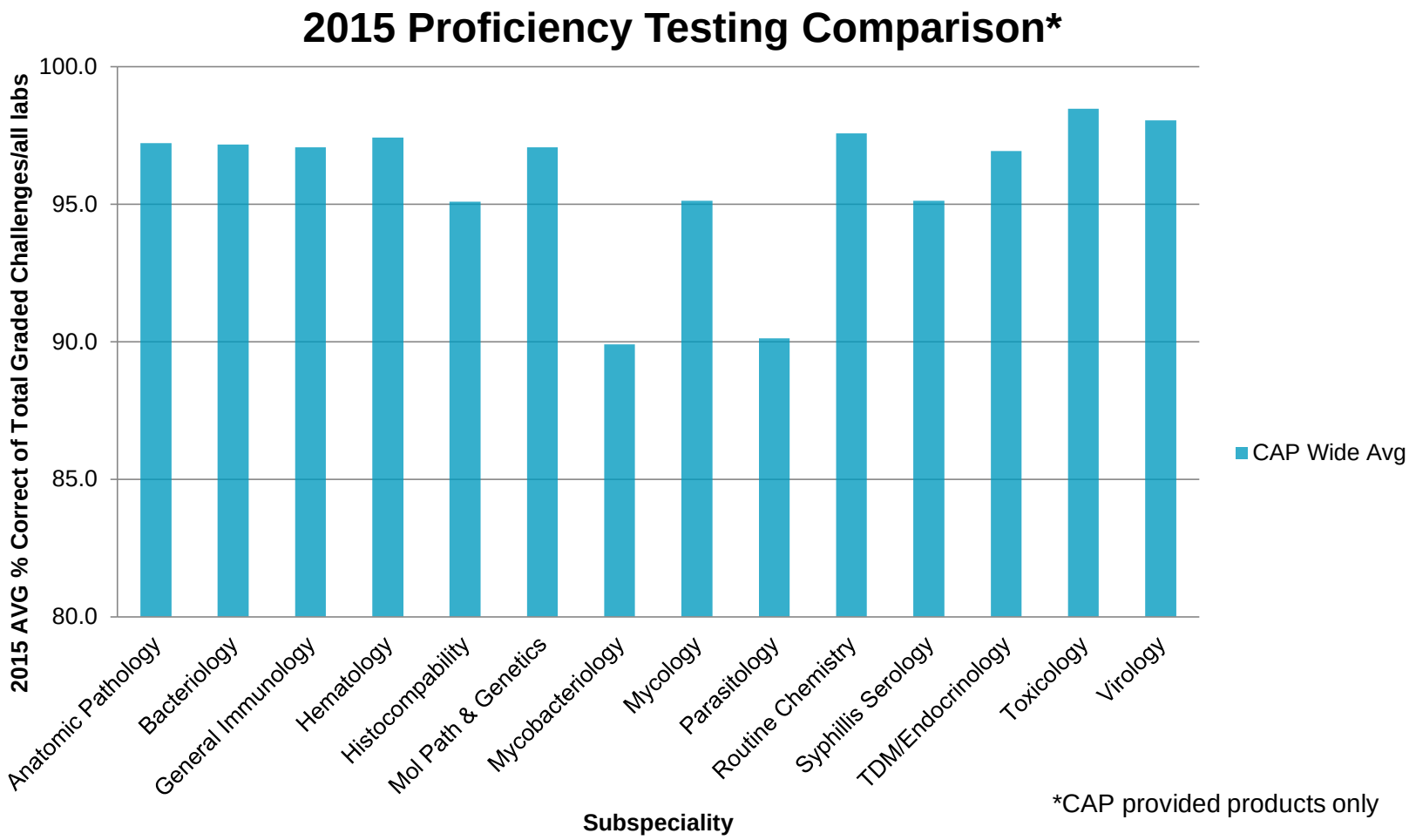
- Note: AA not applicable for regulated analytes

Key point:

- **Investigate <u>each</u> "unacceptable" PT result and provide corrective action that is appropriate to the failure**

CAP

Comparison



*CAP provided products only

What is your PT telling you?

- Develop processes to investigate and avoid repeat PT performance failures

Responding to PT failures

Use proficiency testing results to monitor performance in your laboratory:

- **Investigation is required for <u>each</u> unacceptable PT result**
- **Monitor performance for each event and over time looking for trends**
  - **Major categories of investigation**
    - ***Clerical***
    - ***Analytical***
    - ***Procedural***
    - ***Specimen handling***
    - ***PT Material***

CAP

Investigating PT failures

PT Exception Investigation Checklist (www.cap.org)

- **Leads laboratory through stages of investigation to determine reasons for unacceptable PT results which include:**
  - **Clerical**
    - **Transcription error, correct method/instrument code, units, decimal place?**
    - **Enter results online but don't approve?**
    - **Forget to submit results by due date?**
  - **Procedural**
    - **Reagents preparation, reagents acceptable, staining/interpretation steps?**

CAP

Investigating PT failures

LAP investigation form continued

- Analytical
  - Calibration stable, persistent bias, within measuring range, instrument maintenance/ problems, QC and calibration review?
- Specimen handling
  - Reconstitute PT samples according to instructions, storage per instruction, perform correct test on correct vial, follow specific kit instructions?
    - — eg, Poor blood gas sample handling is common and results in a PT failure
- PT material
  - Received on time and in good condition?

CAP

Investigating PT failures

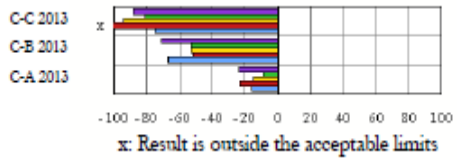
- **Reviewing PT results over time can identify**
  - **Persistent bias, trends, and shifts**
  - **Change in system and/or process**
  - **Systematic error**
  - **Evidence of corrective action**
  - **Training opportunities**
  - **Staff competencies**

CAP

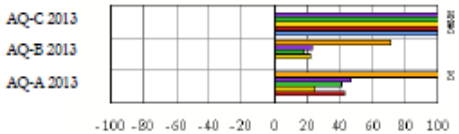
Examples of Analytes Requiring Investigation due to PT Issues

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
AST (SGOT)	**CHM-11**	32	39.9	2.1	515	-3.8	31	48	Acceptable
U/L	**CHM-12**	86	103.7	5.3	515	-3.3	82	125	Acceptable
ROCHE COBAS c500 SER	**CHM-13**	71	88.1	4.3	516	-4.0	70	106	Acceptable
ROCHE/37 C	**CHM-14**	78	101.1	6.0	518	-3.9	80	122	Unacceptable
	CHM-15	155	183.3	9.7	516	-2.9	146	220	Acceptable
PO2	**AQ-10R**	170	143.4	3.1	1112	+8.6			[26]
mm Hg	**AQ-11**	110	98.4	2.4	1113	+4.8	91	106	Unacceptable
RADIOMETER ABL 800 SER	**AQ-12**	135	119.1	2.6	1122	+6.2	111	127	Unacceptable
> OR = 720 mm Hg	**AQ-13**	135	118.2	2.5	1123	+6.6	110	126	Unacceptable
	AQ-14	105	94.0	2.3	1124	+4.7	86	102	Unacceptable
	AQ-15	87	80.0	2.2	1122	+3.1	73	87	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation



x: Result is outside the acceptable limits



x: Result is outside the acceptable limits

Proficiency Testing Recommendations

Common Causes of PT Failures:

- **Failure to return results (participate) by the due date**
- **Clerical errors count**
- **Instrument/method codes**
- **Calibration bias**

14

Preventing repeat PT failures

Develop a strategy and implement

- **Timely Investigation**
- **Perform patient impact analysis**
- **Develop a corrective action plan and implement**
- **Review current procedures and provide in-service**
- **Analyze records for instrument/method calibration, QC, reagent checks, and scheduled maintenance**
- **Consider purchasing additional PT material/off-cycle**

Investigate the effect of a PT failure on patient results

- **How has the laboratory confirmed if patient/client results were affected during the time of the identified PT failure?**
- **Supporting documentation is required to assess the effectiveness of the documentation submitted. If the documentation is not sufficient the laboratory will be asked for additional documentation.**

CAP

Investigate impact of PT failure on patient results

- **Re-test preserved patient specimens after issue is corrected**
- **Review results from same patient before and after issue is corrected (stable or low biologic variability tests)**
- **Review selected patient results for consistency with other diagnostic information in medical record**
- **Calculate patient mean/median (after filtering outliers) before and after issue is corrected (high volume tests)**
- **Re-assay stable PT material after issue is corrected (PT results do not always reflect patient result trends)**
- **Review calibration curves or internal QC from before and after issue is corrected (QC trends may be smaller or larger than effects on patient results)**
- **Review internal/instrument QC to external QC peer groups (QC trends may be smaller or larger than effects on patient results)**

Proficiency Testing Tool Box (www.cap.org)

Proficiency Testing Toolbox

Related Information

- If you add a new test...add the activity code and update your CMS Analyte Reporting Selection.
- Remember to update your accreditation personnel records if necessary.

Resources

- Escalation Process for PT Failures – Tip Sheet (PDF, 241 KB)
- Definitions
- Proficiency Testing Compliance FAQs
- Analyte Specific PT Troubleshooting Guides
- PT Exception Investigation Checklist (PDF, 141 KB)
- Troubleshooting Guide for Proficiency Testing Data (July 2009) (PDF, 174 KB)
- Review of Patient Results in Response to a PT Failure (PDF, 135 KB)
- Responding to a Missing Enrollment E-mail

Contact the Compliance Group

Operations Specialist, CAP PT Compliance Group

- Phone: 800-323-4040, ext. 6052
- Fax: 847-832-8174
- Email: ptcn@cap.org

Or you may send your response to the following address:

CAP 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 please contact Customer Service at 800-323-4040.

CAP

Cease Testing

CMS/CAP PT performance monitoring for regulated analytes

"Unsatisfactory" PT performance for a regulated analyte/ subspecialty within 3 PT events is an initial PT failure

Example: |**2015/1 20%** | 2015/2 100% | 2015/3 100% |

"Unsuccessful" PT performance is unsatisfactory performance for the same analyte/subspecialty in 2 consecutive or 2 out of 3 testing events

Example: |**2015/1 20%**| 2015/2 100%| **2015/3 60%**|

CAP

CMS/CAP PT performance monitoring for regulated analytes

"Repeat unsuccessful" PT performance is unsatisfactory PT performance in 3 consecutive, 3 out of 4, or 2 sets of 2 out of 3 PT events identified for the same regulated analyte/ subspecialty.

Example: **2015/1 20%|2015/2 60%|**2015/3 100%

|2016/1 20%|2016/2 100%|2016/3 100%

Example: **2015/1 20%|2015/2 60%|**2015/3 100%

|2016/1 100%|**2016/2 20%|2016/3 0%**

CAP

When a cease testing notice is received

- **Laboratory Director must sign an acknowledgement form stating that patient/client testing will cease for that analyte for 6 months**
  - **Regardless of medical importance (including critical analytes such as pO2, compatibility testing, Protime, etc.).**
- **Failure to acknowledge a cease testing notice and/or execute the cease testing directive may lead to more serious sanctions up to and including revocation of accreditation.**
- **Laboratory must provide evidence they ceased testing during the applicable dates.**
- **Next inspection team will be notified to verify cease testing dates.**

Important Facts: Lessons Learned

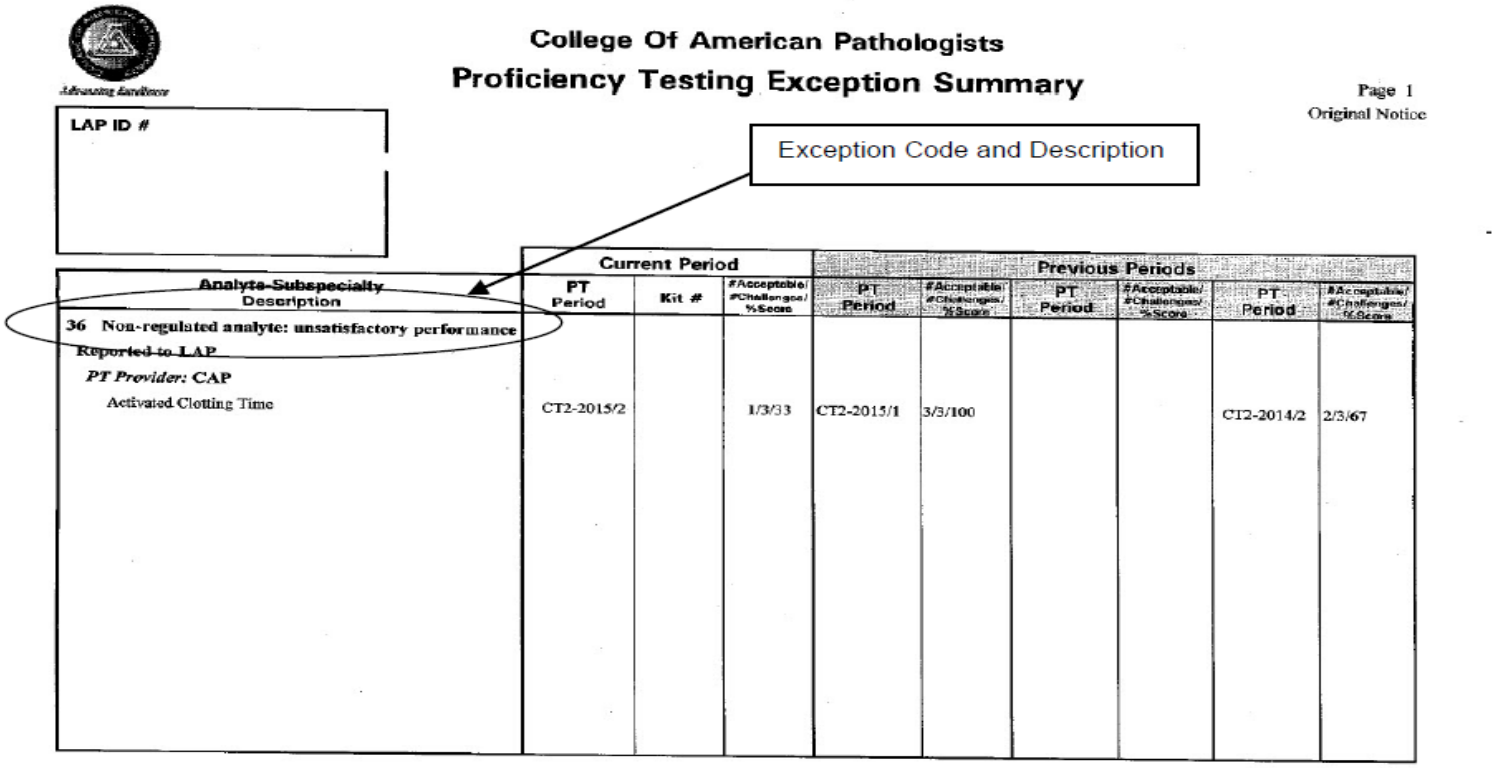
Remember, a cease testing directive is effective at the analyte level.

- **If you have more than one instrument that performs an analyte (eg, iSTAT and Radiometer) and have been directed to cease testing for that analyte (eg, pO2), you are not allowed to report patient/client results from either instrument for that analyte.**
- **If you have multiple areas under the same CLIA/CAP number that perform an analyte, ALL areas are impacted and must cease testing for that affected analyte.**
  - **For example, ER, Respiratory, and Main Laboratory all perform pO2 but only one set of PT scores is sent to CMS by a PT provider. If Respiratory is the CMS reporting area, and has repeat unsuccessful scores for pO2, ALL areas must cease testing.**

CAP

PTCN Exception Types and Codes

What do the exception codes mean on my summary report?



College Of American Pathologists

Proficiency Testing Exception Summary

Page 1
Original Notice

LAP ID #

Exception Code and Description

Analyte-Subspecialty Description	Current Period PT Period	Kit #	#Acceptable/ #Challenges/ %Score	Previous Periods PT Period	#Acceptable/ #Challenges/ %Score	PT Period	#Acceptable/ #Challenges/ %Score	PT Period	#Acceptable/ #Challenges/ %Score
36 Non-regulated analyte: unsatisfactory performance Reported to LAP									
***PT Provider:* CAP**									
Activated Clotting Time	CT2-2015/2		1/3/33	CT2-2015/1	3/3/100			CT2-2014/2	2/3/67

PT Exception Types and Codes

Non participation in Proficiency Testing

If you received a PTCN notice with this exception type, the following criteria apply:

- If the analyte is regulated your PT provider did not report a score to CMS.
- If the analyte is not regulated, your PT provider did not report this score to the CAP Accreditation Programs.
- **Non-participation in PT is equivalent to receiving a PT performance score of zero if performing the activity/test.**

Non-participation Exception Types		
Exception Code	**Exception Description**	**Action**
99	Non participation in proficiency testing	Investigate what caused the non participation and correct the problem. Return response form to CAP.

CAP

PT Exception Types and Codes

Regulated Analyte – Reported to CMS

If you receive a PTCN Notice with one of these exception types, the following criteria apply:

- The analyte is **regulated** and **reported to CMS** and the CAP Accreditation Programs.
- Your PT score was less than 80% (or 100% for ABO/Rh and Compatibility Testing).

Regulated Analyte (reported) Exception Types		
Exception Code	**Exception Description**	**Action**
10	Regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
05	Regulated analyte: unsuccessful performance 2/3 events	Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.
15	Regulated analyte: repeat unsuccessful performance	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The lab may be required to cease testing for 6 months.

PT Exception Types and Codes

Non regulated Analyte Exception Types – 1 challenge		
Exception Code	**Exception Description**	**Action**
30	Non regulated analyte: unsatisfactory performance 2/3 events	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
31	Non regulated analyte: unsuccessful performance 3/4 events	Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.
32	Non regulated analyte: critical performance 4/4 events	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The lab may be required to cease testing.

- PT was offered at **1 challenge**
- Your score was **less than 100%**

CAP

PT Exception Types and Codes

Non regulated Analyte Exception Types – 2 challenges		
Exception Code	**Exception Description**	**Action**
33	Non regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
34	Non regulated analyte: unsuccessful performance 2/3 events	Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.
35	Non regulated analyte: critical performance 3/4 events	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte.
35	Non regulated analyte: critical performance 4/5 events	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The lab may be required to cease testing.

- PT was offered at **2 challenges**
- Your score was **less than 50%**

CAP

PT Exception Types and Codes

Non-RegulatedAnalytes

If you receive a PTCN Notice with one of these exception types, the following criteria apply:

- The analyte is **not regulated** and therefore is only reported to CAP Accreditation Programs.

Non regulated Analyte Exception Types – 5 challenges		
Exception Code	**Exception Description**	**Action**
45	Non regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
46	Non regulated analyte: unsuccessfulperformance2/3 events	Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.
48	Non regulated analyte: critical performance 3/4 events	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The lab may be required to cease testing.
48	Non regulated analyte: critical performance 4/5 events	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The lab may be required to cease testing.

- PT was offered at **5 challenges**
- Your score was **less than 80%**

PT Multiple Kits

Proficiency Testing Multiple Kits

- **CMS Directive**
- **Treat like Patients**
- **Only allowed 1 kit of each type per CLIA/CAP number**
- **Report 1 result per analyte/kit type regardless of specimen type**
  - **Except INR, WBG, Alcohol**
- **Can rotate among primary instruments for different events**
- **All samples from kit must be tested on same instrument**

CAP

Proficiency Testing Multiple Kits

- **In August, 2015, the Centers for Medicare & Medicaid Services (CMS) reiterated that laboratories are not permitted to test proficiency testing (PT) samples on multiple instruments unless that is how the laboratory tests patient specimens and laboratory procedures are written to reflect that process.**
- **COM.01600 PT Integration Routine Workload**

CAP

Proficiency Testing Multiple Kits

- **CMS *further expanded* their interpretation to include multiple kits from the same program, as well as those containing analytes not listed in Subpart I of the CLIA regulations, including waived methods like whole blood glucose meters.**

CAP

Proficiency Testing Multiple Kits

- **One PT result per analyte per type of specimen (serum, whole blood, urine, etc.) is allowed for each individual CLIA-licensed laboratory.**
- **If a laboratory routinely uses more than one primary method/instrument for reporting the same analyte, PT can be rotated among the primary methods/instruments.**
- **All samples for one analyte within a shipment must be tested with the same instrument.**

CAP

Proficiency Testing Multiple Kits

- **In general, PT enrollment is not required for both serum/plasma and whole blood matrices if alternative performance assessment is performed at least semi-annually. However, the Continuous Compliance Committee has identified 3 analytes that do require separate PT enrollment for both serum/plasma and whole blood:**
  - **Alcohol**
  - **Glucose**
  - **INR**
- **These analytes have known physiological differences between serum/plasma and whole blood matrices. Additionally, methodologies and reference intervals often differ between whole blood and serum/plasma, which may further complicate comparisons between matrices.**

Proficiency Testing Multiple Kits Q & A

- ***Question*: Can multiple PT programs be ordered for the same analyte if the programs have different specimen types (e.g. CGL for plasma INR and WP4 for whole blood INR)?**

- ***Answer*: Yes, multiple PT programs can be ordered for the same analyte if the programs have different specimens because they have different target values and are not comparable to each other.**

Proficiency Testing Multiple Kits Q & A

- ***Question*: How does this CMS directive impact how large laboratories with multiple testing sites or separate locations in which all are under one CLIA number, order Surveys? For example, such laboratories would have previously ordered Chemistry PT kits under different sublevels.**

- ***Answer*: If a large laboratory has multiple testing sites or separate locations in which all are under one CLIA license, they will only be able to order one Chemistry (or Hematology, Immunology, Clinical Microscopy, etc.) Survey kit unless they are testing multiple instruments, all with different analytes.**

CAP

Proficiency Testing Multiple Kits Q & A

- ***Question*: If CAP PT is not reported for a second instrument/method/matrix, what type of assessment should be done?**

- ***Answer*: Biannual comparison studies must be performed if more than one instrument/method/matrix is routinely used for patient testing.**

- **COM.04250 Comparability of Instruments/Methods**

CAP

For more information

- Call 800-323-4040 ext. 6052 or 847-832-7000, or email PTCN@cap.org.
- CAP-accredited laboratories may visit cap.org/*eLAB Solutions Suite/Laboratory Accreditation/*Proficiency Testing Toolbox (Analyte Specific Troubleshooting Guides are available in the Toolbox)
- Go to www.cms.gov/Regulations and Guidance/Clinical Laboratory Improvement Amendments (CLIA)

CAP

Questions?

COLLEGE of AMERICAN PATHOLOGISTS