What to do with Proficiency Testing Failures?

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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
The Top 10 Deficiencies
## Top 10 Deficiencies

<table>
<thead>
<tr>
<th>Rank</th>
<th>Requirement ID</th>
<th>Requirement</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>GEN.55500</td>
<td>Competency</td>
<td>1979</td>
</tr>
<tr>
<td>2</td>
<td>COM.01200</td>
<td>Activity Menu</td>
<td>1810</td>
</tr>
<tr>
<td>3</td>
<td>COM.10000</td>
<td>Procedures</td>
<td>1345</td>
</tr>
<tr>
<td>4</td>
<td>COM.01700</td>
<td>PT Evaluation</td>
<td>1178</td>
</tr>
<tr>
<td>5</td>
<td>COM.10100</td>
<td>Procedure Review</td>
<td>1137</td>
</tr>
<tr>
<td>6</td>
<td>GEN.20375</td>
<td>Document Control</td>
<td>1036</td>
</tr>
<tr>
<td>7</td>
<td>COM.30300</td>
<td>Reagent Labeling</td>
<td>1032</td>
</tr>
<tr>
<td>8</td>
<td>COM.01400</td>
<td>PT Attestation</td>
<td>968</td>
</tr>
<tr>
<td>9</td>
<td>COM.04200</td>
<td>Monthly Review</td>
<td>919</td>
</tr>
<tr>
<td>10</td>
<td>COM.30450</td>
<td>New Lot Confirmation</td>
<td>897</td>
</tr>
</tbody>
</table>
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 each “unacceptable” PT result and provide corrective action that is appropriate to the failure
Comparison

2015 Proficiency Testing Comparison*

Subspeciality

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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 each 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
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:
  o Clerical
    – Transcription error, correct method/instrument code, units, decimal place?
    – Enter results online but don’t approve?
    – Forget to submit results by due date?
  o Procedural
    – Reagents preparation, reagents acceptable, staining/interpretation steps?
Investigating PT failures

LAP investigation form continued

• Analytical
  o Calibration stable, persistent bias, within measuring range, instrument maintenance/ problems, QC and calibration review?

• Specimen handling
  o 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
  o Received on time and in good condition?
Investigating PT failures

• Reviewing PT results over time can identify
  o Persistent bias, trends, and shifts
  o Change in system and/or process
  o Systematic error
  o Evidence of corrective action
  o Training opportunities
  o Staff competencies
### Examples of Analytes Requiring Investigation due to PT Issues

<table>
<thead>
<tr>
<th>Test</th>
<th>Unit of Measure</th>
<th>Peer Group</th>
<th>Evaluation and Comparative Method Statistics</th>
<th>Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST (SGOT)</td>
<td>U/L</td>
<td>ROCHE COBAS e500 SER</td>
<td>ROCHE/37 C</td>
<td>Specimen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHM-11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHM-12</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>CHM-13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHM-14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHM-15</td>
</tr>
<tr>
<td>PO2</td>
<td>mm Hg</td>
<td>RADIOMETE AB 800 SER</td>
<td>&gt; OR = 720 mm Hg</td>
<td>Specimen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AQ-10R</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AQ-11</td>
</tr>
<tr>
<td></td>
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<td>AQ-12</td>
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<td></td>
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<td>AQ-14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AQ-15</td>
</tr>
</tbody>
</table>

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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
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.
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

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.
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%|
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%
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
  o 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.
What do the exception codes mean on my summary report?

### College Of American Pathologists Proficiency Testing Exception Summary

<table>
<thead>
<tr>
<th>LAP ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Exception Code and Description**

<table>
<thead>
<tr>
<th>Current Period</th>
<th>Previous Periods</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PT Period</td>
<td>Kit #</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P12-2015/2</td>
<td>1/3/03</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CT2-2015/1</td>
<td>3/2/106</td>
</tr>
<tr>
<td></td>
<td>CT2-2014/2</td>
<td>2/3/67</td>
</tr>
</tbody>
</table>

**Non-regulated analyte: unsatisfactory performance**

**PT Provider: CAP**

Activated Clotting Time

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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.

<table>
<thead>
<tr>
<th>Non-participation Exception Types</th>
<th>Exception Code</th>
<th>Exception Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>99</td>
<td>Non participation in proficiency testing</td>
<td>Investigate what caused the non participation and correct the problem. Return response form to CAP.</td>
</tr>
</tbody>
</table>
### 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).

<table>
<thead>
<tr>
<th>Exception Code</th>
<th>Exception Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Regulated analyte: unsatisfactory performance</td>
<td>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.</td>
</tr>
<tr>
<td>05</td>
<td>Regulated analyte: unsuccessful performance 2/3 events</td>
<td>Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.</td>
</tr>
<tr>
<td>15</td>
<td>Regulated analyte: repeat unsuccessful performance</td>
<td>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.</td>
</tr>
</tbody>
</table>
## PT Exception Types and Codes

### Non regulated Analyte Exception Types – 1 challenge

<table>
<thead>
<tr>
<th>Exception Code</th>
<th>Exception Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Non regulated analyte: unsatisfactory performance 2/3 events</td>
<td>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.</td>
</tr>
<tr>
<td>31</td>
<td>Non regulated analyte: unsuccessful performance 3/4 events</td>
<td>Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.</td>
</tr>
<tr>
<td>32</td>
<td>Non regulated analyte: critical performance 4/4 events</td>
<td>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.</td>
</tr>
</tbody>
</table>

- PT was offered at 1 challenge
- Your score was less than 100%
### Non regulated Analyte Exception Types – 2 challenges

<table>
<thead>
<tr>
<th>Exception Code</th>
<th>Exception Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>Non regulated analyte: unsatisfactory performance</td>
<td>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.</td>
</tr>
<tr>
<td>34</td>
<td>Non regulated analyte: unsuccessful performance 2/3 events</td>
<td>Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.</td>
</tr>
<tr>
<td>35</td>
<td>Non regulated analyte: critical performance 3/4 events</td>
<td>CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte.</td>
</tr>
<tr>
<td>35</td>
<td>Non regulated analyte: critical performance 4/5 events</td>
<td>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.</td>
</tr>
</tbody>
</table>

- PT was offered at 2 challenges
- Your score was less than 50%
PT Exception Types and Codes

**Non-Regulated Analytes**

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.

<table>
<thead>
<tr>
<th>Exception Code</th>
<th>Exception Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>Non regulated analyte: unsatisfactory performance</td>
<td>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.</td>
</tr>
<tr>
<td>46</td>
<td>Non regulated analyte: unsuccessful performance 2/3 events</td>
<td>Thoroughly investigate the cause of the failure, correct the problem, ensure patient results were not impacted. Submit documentation to CAP.</td>
</tr>
<tr>
<td>48</td>
<td>Non regulated analyte: critical performance 3/4 events</td>
<td>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.</td>
</tr>
<tr>
<td>48</td>
<td>Non regulated analyte: critical performance 4/5 events</td>
<td>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.</td>
</tr>
</tbody>
</table>

- 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
  o Except INR, WBG, Alcohol
• Can rotate among primary instruments for different events
• All samples from kit must be tested on same instrument
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
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.
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.
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.
• **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.
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**
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)
Questions?