Disclosures

Relevant Financial Relationship(s):
Nothing to Disclose

Off Label Usage:
Nothing to Disclose
Objectives

Participants will:

• Distinguish differences between Proficiency Testing (PT), Alternative Assessment of Performance (AAP), and Comparison of Test Results
• Describe CLIA Regulations on PT and consequences associated with violating the regulations
• Demonstrate how to write PT related documents
• Define how to investigate PT Failures

Terms, Abbreviations, and Definitions

Centers for Medicare & Medicaid Services (CMS)

• Agency within in the US Department of Health and Human Services (HHS)
• Upholds CLIA regulations (the law) designed to ensure accuracy, reliability and timeliness of patient results
• Regulates all laboratory testing (except research)
Terms, Abbreviations, and Definitions

Clinical Laboratory Improvement Amendments (CLIA)

• Standards and Certification: Laboratory requirements: 42CFR493 (Code of Federal Regulations)
• Establishes quality standards for laboratory testing performed on humans for the purpose of diagnosis, prevention or treatment of disease or assessment of health
  • Subpart H – Participation in Proficiency Testing for Laboratories Performing Non-waived Testing (493.801 – 493.865)
  • Subpart I – Proficiency Testing Programs for Non-waived Testing (493.901 – 493.959)

Terms, Abbreviations, and Definitions

Proficiency Testing (PT)

• Testing of unknown samples sent to laboratory by CMS approved PT program
  • 3 times per year
  • 15 challenges (specimens) per year
  • Tested in same manner as patient specimens

• Quantitative
  • Assessment of amount of substance or analyte present

• Qualitative
  • Determination of presence or absence of analyte or organism
PT Program Cycle

- PT program sends samples
- Lab tests samples
- Lab submits results
- Program grades results
- Program sends grades to CMS* & lab

*Regulated analytes

PT – Regulated Analytes

- Listing of regulated analytes can be found here:
  - Clinical Laboratory Improvement Amendments (CLIA) PROFICIENCY TESTING Do’s and Don’ts

<table>
<thead>
<tr>
<th>Specialties</th>
<th>Subspecialties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry</td>
<td>Endocrinology, Routine Chemistry, Toxicology</td>
</tr>
<tr>
<td>Diagnostic Immunology</td>
<td>General Immunology, Syphilis Serology</td>
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<tr>
<td>Hematology</td>
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<tr>
<td>Immunohematology</td>
<td></td>
</tr>
<tr>
<td>Microbiology</td>
<td>Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology</td>
</tr>
</tbody>
</table>
Terms, Abbreviations, and Definitions

Alternative Assessment (of Performance) (AAP)
- CFR 493.1236
- Perform twice per year (required)
- Define acceptance criteria prior to testing
- Types of AAP
  - Chart review
  - External / internal split samples or non-CMS approved PT program provider; e.g. ERNDIM, CDC, NASCOLA, etc.
  - Patient or Quality Control blind
  - Patient pool
  - Reference material
  - Unchangeable result

Terms, Abbreviations, and Definitions

Comparison of Test Results
- CFR 493.1281
- System that evaluates and defines relationship between test results using different methodologies, instruments, or testing sites (within one CLIA laboratory)
  - Must be done twice a year
CLIA Regulations

Subpart H: Participation in Proficiency Testing (PT) for Laboratories Performing Non-waived Testing

- 493.801 Condition: Enrollment and testing of samples
- 493.803 Condition: Participation
- 493.807 Condition: Reinstatement of laboratories performing non-waived testing

493.801 Condition: Enrollment and testing of samples

**Standard; Enrollment**

The laboratory must:

- Notify HHS of PT program(s) selected for regulated analytes
- Designate CMS approved program(s) to be used for each analyte
  - Establish and maintain the accuracy of testing procedures for non-regulated analytes
- Participate in same PT program for one year for regulated analytes
493.801 Condition: Enrollment and testing of samples (continued)

**Standard; Enrollment**

The laboratory must:

- Authorize PT program to release results to HHS
  - Determine laboratory’s compliance
  - Make PT results available to public

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493.801 Condition: Enrollment and testing of samples (continued)

**Standard; Testing of proficiency testing samples**

The laboratory must:

- Test PT samples in the same manner as patient specimens
  - Test at same time as patient specimens using routine method
  - Test same number of times as patient specimens
- Not engage in inter-laboratory communications until PT program due dates
493.801 Condition: Enrollment and testing of samples (continued)

**Standard; Testing of proficiency testing samples**

The laboratory must:

- Not send PT samples to other labs for analysis
- Document handling, preparation, processing, testing, and report of results for all PT samples
  - Maintain a copy of all records
  - **Exception:** Do **NOT** send PT samples to another lab for reflex or confirmatory testing
- PT is required on the primary method used for patient testing

493.803 Condition: Successful participation

The laboratory must:

- Successfully participate in a CMS approved PT program
  - If laboratory fails to participate successfully, CMS may impose sanctions, as specified in subpart R
  - CMS may direct laboratory to train personnel or obtain technical assistance or both, rather than imposing alternative or principle sanctions, except when one of following exists:
    - Immediate jeopardy to patient health and safety
    - Lab fails to provide satisfactory evidence to correct problem
    - Lab has poor compliance history
493.807 Condition: Reinstatement of laboratories performing non-waived testing

If a laboratory’s certificate is suspended or limited due to failed successful proficiency testing; the laboratory must:

- Demonstrate sustained performance on 2 consecutive PT events
- Suspension or limited certification period will be for a period not less than 6 months

Proficiency Testing by Specialty and Subspecialty

Standards present for specialties and subspecialties

- 493.821 Condition: Microbiology
- 493.833 Condition: Diagnostic immunology
- 493.839 Condition: Chemistry
- 493.849 Condition: Hematology
- 493.853 Condition: Pathology
- 493.857 Condition: Immunohematology
CLIA regulations

Subpart I: Proficiency Testing Programs for Non-waived Testing
• 493.901 Approval of proficiency testing programs
• 493.903 Administrative responsibilities
• 493.905 Nonapproved proficiency testing programs

CLIA regulations

Subpart K: Quality System for Non-waived Testing
• 493.1236 Standard: Evaluation of proficiency testing performance
• 493.1281 Standard: Comparison of test results

Subpart M: Personnel for Non-waived Testing
• 493.1407 Standard: Laboratory director responsibilities
493.1236 Standard: Evaluation of proficiency testing performance

Laboratory must:
• Review and evaluate results obtained on PT
• Verify accuracy of
  • Analytes or subspecialty without analytes listed in subpart I that is not evaluated or scored by CMS approved program
  • Analyte, specialty, subspecialty assigned a score that does not meet required minimum score

493.1236 Standard: Evaluation of proficiency testing performance (continued)

Laboratory must:
• At least twice annually, verify accuracy
  • Analytes not included in subpart I
  • Analytes included in subpart I where compatible PT samples are not offered by CMS approved program
• Document all PT evaluation and verification activities
493.1281 Standard: Comparison of test results

Laboratory must have a system in place to:

• Evaluate and define relationship of results between methods and instruments at least twice a year

• Identify and assess patient test results that appear inconsistent with relevant criteria, when possible:
  • Age
  • Sex
  • Diagnosis or pertinent clinical data
  • Distribution of test results
  • Relationships with other test parameters
  • Document all test result comparison activities

493.1407 Standard; Laboratory director responsibilities

Responsible for overall operation and administration of laboratory

• Ensures
  • Appropriate enrollment in PT program
  • Samples tested as required
  • Results returned on time
  • Reports reviewed appropriately
  • Corrective action is taken for unacceptable results
CLIA Regulations Summary

• PT Referral
  • Never send PT to OR test PT samples from another laboratory
  • Report inappropriate referrals to CMS

• PT Testing
  • Test same number of times as patient specimens
  • Include in normal work, using primary method
  • Rotate among testing personnel
  • EXCEPTION: Do NOT send PT samples to other labs for reflex or confirmatory testing

• Communication
  • Avoid inappropriate communication with other labs

CLIA Regulations Summary (continued)

1 kit per analyte per CLIA laboratory

• When several lab sections perform same testing under same CLIA number, one lab section should designated as primary lab
• This satisfies all PT requirements for CLIA laboratory
• NOTE: Laboratories must meet “Comparison of test results 493.1281” requirement if multiple sections perform same testing
Consequences of regulation violations

Taking Essential Steps for Testing (TEST) was signed into law in December 2012.

The TEST Law gives CMS greater discretion at defining penalties for PT Referrals.

- **Category 1**: Revocation of CLIA certificate and civil monetary penalty, intentional or repeat PT referral.
- **Category 2**: Suspension and 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 but results are received after the event cut-off date, civil penalty and corrective action plan would be required.
Consequences of regulation violations

Examples

• Lose CLIA certificate – 1 year minimum
• Lose Medicare/Medicaid reimbursement
• Monetary penalty
• Owner / operator loses ability to own/operate laboratory – 2 years
• Laboratory Director not permitted to direct laboratory – 2 years

Laboratory compliance with regulations

• Create standard operating policies and procedures
  • Include CLIA regulations related to PT and how lab addresses and meets each regulation
  • Investigate any and all PT failures and ungraded PT challenges
  • Perform PT or Alternative Assessment on all tests / analytes
  • Report inappropriate PT referrals
• Train all staff about the CLIA rules related to PT (yearly)
Writing proficiency testing documents

Determine the documents needed:

• Policy
  • Set of basic principles that direct or restrict the laboratory’s plans, actions, and decisions
  • Goals and intentions
  • What happens and why

• Process
  • Set of interrelated or interacting activities
  • Shows sequence of events
  • How it happens

Writing proficiency testing documents

Determine the documents needed:

• Procedure (& job aids)
  • Specific way to carry out an activity or process
  • Step by step instructions
  • How to do it

• Forms
  • Paper or electronic document used for recording results
  • Captures information and results generated
  • Becomes a Record of what was done
Writing proficiency testing documents - Policy

Sections of a policy

• Purpose – what document is meant to achieve
• Scope – who the document applies to
• Responsibility – who is responsible for carrying out the policy
• References – what sources was information obtained from
• Policy statements – what happens and why
  • Use CLIA regulations and accreditation standards to write policy statements

Writing proficiency testing documents – Policy example

Proficiency Testing / Alternative Assessment of Performance and Comparison of Test Results Policy [DOC ID: VER] Effective date:
Acme Laboratories
Compliance City, USA

Proficiency Testing / Alternative Assessment of Performance and Comparison of Test Results Policy

PURPOSE
This document provides a mechanism for the Acme Laboratories to have the necessary information to understand the requirements for proficiency testing, alternative assessment of performance, and comparability of instruments/methods/sites.

The Clinical Laboratory Improvement Amendments (CLIA) states that only one proficiency testing kit may be tested per analyte per CLIA number.

When there are several laboratory sections performing testing for the same analyte and they are under the same CLIA/CAP number, one laboratory section is designated as the primary laboratory and performs the proficiency testing. All laboratory sections must compare to the primary laboratory twice a year to meet the requirements of CAP’s COM.04250.

RESPONSIBILITIES
It is the responsibility of the laboratory supervisor or designee to ensure these policy statements are followed for all employees in the work unit.
Writing proficiency testing documents – Policy example

Proficiency Testing / Alternative Assessment of Performance and Comparison of Test Results Policy [DOC ID.VER]  Effective date:

POLICY STATEMENTS

<table>
<thead>
<tr>
<th>Element</th>
<th>Policy Statement</th>
</tr>
</thead>
</table>
| Proficiency Testing            | • Laboratory has written procedures for proficiency testing.  
• Laboratory has a procedure for assessing its performance on PT challenges that were intended to be graded, but were not.  
• Laboratory prohibits interlaboratory communication about proficiency testing samples until after due date of results assigned by PT program.  
• Laboratory ensures PT samples are not sent to another CLIA laboratory or used for other purposes until after due date of results to the program. |
| Alternative Assessment of Performance (AAP) | • Must be performed twice per year on tests for which external PT is not available.  
• Acceptability criteria are defined prior to sample analysis.  
• Applies to both waived and non-waived tests. |
| Comparison of Results         | If the laboratory uses more than one non-waived instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for comparability of results. |

Laboratory should address all CLIA regulations and accrediting agencies’ standards related to PT, AAP, and Comparison of Results in the policy document.

Writing proficiency testing documents - Process

Sections of a process

• Purpose – what sequence of activities carries out policy’s intent

• Process – describes sequential steps in a flow chart or table

Proficiency Testing / and Alternative Assessment of Performance Process [DOC ID.VER]  Effective date:

Acme Laboratories  
Compliance City, USA

Proficiency Testing / and Alternative Assessment of Performance Process

PURPOSE

This document describes how PT and AAP are processed in the department.
Writing proficiency testing documents – Process example

Proficiency testing documents – procedures to consider

- Order proficiency testing from PT program
- Create a survey schedule for all surveys ordered
- Order PT in lab info system
- PT Handling
  - Receipt and inspection of kit
  - Test kit
  - Report results
  - Review evaluation
- Investigate unacceptable results
- Respond to PT Program requests for additional information
Proficiency testing documents – training to consider

- CLIA regulations
  - Rules
  - Consequences of non-compliance
- Accreditation standards
- PT, AAP, Comparison of results processes
- Investigation of unacceptable results

Proficiency Testing (PT) Failures

OH NO!
You’ve failed PT- now what?

Start before the failure;
with a systematic approach to investigation.
Systematic approach for investigation

Checklist or Process:

• It is easier to start with a checklist of things to consider when PT fails
• This helps your staff to follow a consistent process
• Many PT vendors have excellent PT Investigation Checklists; review these prior to creating your own checklist

Examples of PT Failure Investigation Checklists

• American Academy of Family Physicians (AAFPPT) “Proficiency Testing Failure Checklist”
• American Proficiency Institute (API), “Checklist for Corrective Action”
• College of American Pathologists (CAP), “PT Exception Investigation Worksheet”
• New York State permitted labs: For unsuccessful performance, a Root Cause Analysis is required
Systematic approach for investigation

Create a PT Failure Investigation Procedure

Proficiency Testing Failure Investigation Procedure [DOC ID: VER] Effective date:

Acme Laboratories
Compliance City, USA

Proficiency Testing Failure Investigation

PURPOSE
This procedure provides instructions for laboratory staff on how to perform and complete an investigation when an unacceptable PT result occurs.

PROCEDURE
(next page)

<table>
<thead>
<tr>
<th>Responsible</th>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert title of appropriate person(s) in laboratory</td>
<td>01</td>
<td>Initiate the investigation record on the PT Investigation Checklist form. (This can become part of the review documentation). This applies to AAP and ungraded challenges as well.</td>
</tr>
<tr>
<td></td>
<td>02</td>
<td>Review all PT records (PT material receipt/condition, accession records, instrument worksheets/tapes, LIS records/reports, QC &amp; calibration records, saved Adobe file of the PT online entry (e.g. screenshot) etc.)</td>
</tr>
<tr>
<td></td>
<td>03</td>
<td>Complete all items on the PT Investigation Checklist.</td>
</tr>
<tr>
<td></td>
<td>04</td>
<td>Perform Root Cause Analysis (if appropriate). Establish failure cause.</td>
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<td></td>
<td>05</td>
<td>Review past PT performance (minimum 6 events). Evaluate “Cease Testing” risk.</td>
</tr>
<tr>
<td></td>
<td>06</td>
<td>Determine if PT failure could affect patient results, and if so, implement patient result review. If necessary, update results with corrected reports.</td>
</tr>
<tr>
<td></td>
<td>07</td>
<td>Analyze corrective/preventive action (CAPA) to prevent failure recurrence. Implement document revisions, quality improvements, re-training and/or competency assessment.</td>
</tr>
<tr>
<td></td>
<td>08</td>
<td>Complete documentation of PT failure event, including review and signature of Laboratory Director.</td>
</tr>
</tbody>
</table>
Major Categories of PT Failures

**Clerical:** Number one cause of PT failures!

Includes:
- Math errors in calculations
- Transcription errors – either pre-analytical or post-analytical
- Incorrect code used – double check instrument/method and other codes with each survey

**Clerical** (continued)

- Incorrect decimal point placement
- If handwritten – unclear printing or incomplete entry
- Incomplete, or late entry
- Wrong unit of measure used
Other Major Categories of PT Failures

Specimen handling

- Storage conditions
- Reconstitution and dilution errors
- Identification error

PT material

- If there were issues with the kit when it was received, replace it immediately – do not test
- Contamination
- Remember matrix effects!

What is the Impact of PT Failure on Patient Results?

- If the error was employee related, review this employee’s other patient work records
- Any errors which could have also affected patient results must be fully investigated, and patient results repeated
- If bias was found, investigate the effect on patient results - rerun patients after it has been corrected

Remember this?
What is the Impact of PT Failure on Patient Results?

• The most important part of the investigation is careful review of the potential impact to patient results

• If there is doubt, retest the patients and compare results before and after corrective action is taken

• Evaluate differences, and decide if a corrected report is necessary, a corrected report is better than an incorrect one!

Mayo Clinic primary value: “The needs of the patient come first.”

Reviewing PT Performance

• This step is frequently overlooked during PT investigation

• It is important to review, or “look back” on previous PT performance

• Review at least six (6) prior surveys

• It is helpful to understand previous failures – focus prevention efforts there!

• Your overall PT performance over this time determines your risk for “Cease Testing”
Scoring Terminology

Proficiency Testing Survey vendors may use different scoring terminology:

- Acceptable / Not acceptable
- Percent score (e.g. 80%)
- Pass / Fail
- Satisfactory / Unsatisfactory

CLIA, College of American Pathologists (CAP) and New York State terminology

Unsatisfactory – performance when a lab receives < 80% (or <100% in Transfusion Medicine) for a given analyte survey.

For example, of 5 challenges:
- 3 sample results are correct, and
- 2 sample results are incorrect.

The score is 60% and the survey event is unsatisfactory.
College of American Pathologists (CAP)

Unsuccessful – laboratory’s performance is unsatisfactory for 2 consecutive or 2 out of 3 surveys.

For example:
- 2016-A survey: 60% (unsatisfactory)
- 2016-B survey: 100% (satisfactory)
- 2016-C survey: 60% (unsatisfactory)

The performance is unsuccessful due to 2 out of 3 unsatisfactory events.

How to remember this?

1. Unsatisfactory – performance when a lab receives < 80% (or <100% in Transfusion Medicine) for a given analyte survey.
2. Unsuccessful – when a laboratory’s performance is unsatisfactory for 2 consecutive or 2 out of 3 surveys.
Repeat Unsuccessful Performance

Repeat unsuccessful PT performance is:

- Unsatisfactory PT performance in 3 consecutive events
  or

- Unsatisfactory performance in 3 out of 4 events
  or

- Unsatisfactory performance in 2 sets of 2 out of 3 PT events identified for the same regulated analyte/subspecialty.

Example:

Review six (6) past survey events:

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event score</td>
<td>3/5</td>
<td>3/5</td>
<td>5/5</td>
<td>4/5</td>
<td>3/5</td>
<td>3/5</td>
</tr>
</tbody>
</table>
**Example:**

Review six (6) past survey events:

<table>
<thead>
<tr>
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<td>4/5</td>
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<tr>
<td>Interpretation</td>
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<td>Satisfactory</td>
<td>Satisfactory</td>
<td>Unsatisfactory</td>
<td>Unsatisfactory</td>
</tr>
</tbody>
</table>

- Risk of “Cease Testing” due to repeat unsuccessful performance, two (2) sets of two (2) unsuccessful performance out of three (3) events.
Cease Testing

In 2015, CMS enforced that all PT providers must implement Cease Testing for repeat unsuccessful PT testing.

• Cease Testing is enforced for 6 months
• If the regulated analyte is performed in multiple laboratory sections, all must cease testing
• Before testing can resume, all Reinstatement Requirements must be fulfilled

Questions & Discussion