## EDUCATIONAL COMMENTARY – FAILURE OF A PROFICIENCY TESTING EVENT: NOW WHAT?

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### LEARNING OBJECTIVES

On completion of this exercise, the participant should be able to

- define the criteria for satisfactory proficiency testing (PT) performance.
- describe the consequences of unsatisfactory performance of a PT event.
- take the appropriate steps to investigate a PT failure.
- discuss the advantages of a standardized form for corrective action.

### Introduction

Before passage of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), participation in proficiency testing (PT) was voluntary for many labs and the standards for these tests were not addressed (presentation by Judith Yost, CMS, October 12, 2011). With passage of CLIA '88, proficiency testing evolved from an educational self-assessment and improvement tool to the primary measure of continued reimbursement and licensure.[1] Performance on PT has been found to be an indicator of the quality of patient testing.[2]

By CLIA standards, clinical laboratories are required to enroll in a CMS-approved PT program for all regulated nonwaived testing, and their performance is compared to a target value using statutory criteria for acceptable performance. For nonregulated, nonwaived testing or for tests that have no formal PT available, CLIA requires alternative assessment, twice per year. The latter requirement is generally met by subscribing to a formal program that offers testing for that particular analyte or by split testing of samples for interlaboratory comparison.[3] The target value is determined either by the mean of all peer participant responses after removal of outliers, or by referee consensus. Acceptable performance is considered to be 80% for most analytes. Only immunohematology differs: the criterion for acceptable performance is 100% for some testing.[2] Performance criteria for all regulated analytes may be found in the Code of Federal Regulations at 42 CFR, Chapter IV – Centers for Medicare and Medicaid Services, Part 493 – Laboratory Requirements, Subpart I – Proficiency Testing Programs for Nonwaived Testing, beginning at section 493.901.

## EDUCATIONAL COMMENTARY – FAILURE OF A PROFICIENCY TESTING EVENT (cont.)

### Failure of an Event and Consequences

It is good practice to review all satisfactory proficiency testing results and note if there are any trends or bias in your facility's proficiency testing performance. Results that are consistently below or above the mean of the reporting group for a certain analyte may indicate instability, even though a satisfactory grade was received.[4]

A failed event is a less than 80% satisfactory performance for most analytes or less than 100% for immunohematology analytes. It is recommended that any unacceptable result be investigated even if considered a successful event, as this may detect system problems.[5] A documented investigation into processes must be completed for any unsuccessful PT event.

Both CLIA and some accrediting organizations (e.g., the College of American Pathologists) also require that documented follow-up be completed for nongraded results to facilitate laboratory education and future improved performance (Yost, 2011).[5] The College of American Pathologists requires that any result not graded due to nonconsensus (lack of agreement) be internally analyzed against survey results using CLIA limits.[6]

Failure of a single event (<80%, or <100% for immunohematology) requires an investigation to ensure that processes were followed correctly throughout all phases of testing: preanalytic, analytic, and postanalytic. This type of unsuccessful performance does not require that a response be returned to the PT program or to the facility's accreditation agency. However, if two consecutive events or two out of three consecutive events for the same analyte receive an unsuccessful grading, consequences are more severe. The laboratory must take steps to discontinue testing for that analyte. It is best to notify the accrediting agency of the voluntary discontinuance before the accrediting agency notifies the laboratory. Next, the problem should be investigated, corrective action implemented, and two consecutive successful PT events must be performed. The events may be independently obtained through most approved PT programs. Finally, the accrediting agency must be notified of the corrective action and the intent to reinstate testing.[6]

### Investigation of PT Failure, Nongraded or Nonconsensus

Unsatisfactory PT performance makes up approximately 3.2% of all CMS survey deficiencies. Inappropriate PT enrollment makes up 1.8%, and failure to perform alternative assessment of nonregulated testing makes up 6% of deficiencies (Yost, 2011). The suggested steps for investigating a PT failure are listed below. A standardized approach to root out the cause of the failure is recommended, and using a corrective action form assists in ensuring that no critical steps are overlooked.[7,8]

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**1. Survey Materials:** On receipt of the survey materials, verify that they were received in acceptable condition by viewing for breakage, hemolysis, and contamination and that they were appropriately stored for shipping when they arrived. For microbiology samples, take into consideration any conditions that may render the sample nonviable. Document all findings at the time of receipt. Taking the time now will save time later in the event of an unsatisfactory performance. Should any unacceptable conditions or criteria be noted, notify the PT program as soon as possible for shipment of replacement samples. Ensure that the samples are stored according to the manufacturers' instructions until analysis.

Another consideration for preanalytic conditions is the proper reconstitution of the samples. Carefully follow the instructions for reconstitution and handling of the survey materials before analysis. CLIA requires that samples be processed as a patient sample would be: entered into the routine workload and processed by staff who routinely perform testing. Repeating test results before submission is not allowed unless it is part of the procedure for patient reporting, such as in the case of a critical value or nonlinear result. However, if samples are stored properly, the ability to retrieve the samples and repeat the unsatisfactory testing after results are received can add valuable information to the corrective action investigation.[4]

**2. Clerical Error:** Errors of this type are the most commonly reported and may be of various types. They include typographical errors as well as errors related to interpretation, transcription, transposition, misidentification, answer-form coding, miscalculation, or acceptance of a nonlinear result.[1] Manual entry offers more chance for transcription or transposition errors. Electronic entry still allows for incorrect keystrokes and/or options to be submitted. The PT submission forms require accurate indication of the instrument, method and/or reagent code for the analyte. Incorrect data may cause the facility's results to be graded according to a different peer group or method/reagent group. It is important to avoid these types of errors, and the review of data entry by a second person may detect errors before they become a failure.[9] As described by one writer:

> [S]ometimes [when a clerical error occurs] the only corrective action is to counsel the individual technologist, but no preventative action is taken. When that happens, there are no safeguards in place to keep the error from happening again; after all, these types of errors can happen to anyone, not just a specific employee. There should be an investigation for the root cause of the event.[10]

This author also wrote:

> Clerical errors in the clinical setting could bring serious harm to the patients and therefore, should be avoided and mitigated. Risk of patient safety within the three month period of the failed test event period should also be assessed after each unsuccessful PT event and education for personnel need [sic] to be conducted.[10]

Clerical errors that are the fault of the PT program may be corrected, but often there is a time limit for such a request. Clerical errors made by the survey participant cannot be corrected and performance cannot be amended. Finally, ensure that your results are submitted on time! Late returns will be graded unsatisfactory and cannot be reassessed.[11]

**3. Technical Problems:** The most common assumption when assessing technical issues is that the reagent and/or instrumentation reported an inaccurate result. This may be exhibited by the quality control value falling out of the acceptable range for the analyte and the run being accepted. Quality control results that demonstrate excessive repeats, shifts, or trends may also affect PT results and should be carefully scrutinized in the investigation. Was the calibration of the analyte current and acceptable? Was the result within the linear range of the assay? If not, was the proper procedure followed for verification of that result? Diluting or pipetting errors may have been the cause of the unsatisfactory test result. Another cause to consider is a calculation error when a dilution protocol was followed. Assess the interpretation of the results by reviewing instrument data and/or printed materials. Use of laboratory information system (LIS) identification and interface will also aid in averting this type of error. Laboratory information system identification will not correct a sample mix-up. Finally, review the handling protocol for the samples. Was the PT sample diluted correctly? Was the sample at the correct temperature when reconstituted? Was the timeframe between reconstitution and analysis within the sample stability, as stated by the PT manufacturer guidelines? Review your results and assess the presence of possible interfering substances (such as matrix effect).

**4. Method Problems:** These types of errors include instrument problems, maintenance issues, or faulty reagents and/or standards. Verify that the instrument was within performance guidelines the day of PT. Were there repairs or component replacements recently done that could have affected the PT results? Repairs or replacement components may affect quality control, leading to reporting errors in PT and patient testing. Was the manufacturer's suggested maintenance completed as required? Lapses in maintenance schedules may result in inaccurate test values. Verify that the reagents and/or standards on board at the time of PT analysis were prepared per protocol and within the expiration date, and were working properly.

### Final Analysis and Actions

The final steps of the investigation are to determine the problem(s) and summarize the findings in your documentation. Include any supporting documents for the findings. These may include proficiency report records, instrument data, quality control records, calibration records, maintenance logs, and any other records found to be of assistance. Document the corrective action taken to remedy the problem and that steps that will be taken to prevent the problem from recurring. Finally, ask, "Could this error affect patient

results?"[4,7] If this is likely, document the actions taken to ensure that the patient testing reported at the time of the unsatisfactory PT was valid or whether amendment is needed. It is necessary to notify providers if any inaccurate results were reported. Included as appendices are two examples of standardized investigation forms that may be used to document and report corrective actions.

If required, perform two consecutive successful proficiency testing events. Finally, report the documentation and corrective actions to the accrediting agency and, if applicable, the intent to reinstate testing.

**Summary**

The investigation of unacceptable PT results and certainly the ramifications of a discontinuation of testing may be intimidating. A logical approach and use of a standardized investigation form may be a reassurance that possible critical steps in the investigative process were not overlooked, and variables were examined for the root cause of unsatisfactory proficiency testing performance.

**Notes**

A complete list of CMS-approved proficiency testing providers may be found at the CMS website:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ptlist.pdf

The following proficiency testing and accrediting agencies offer proficiency testing investigation forms or checklists to assist in correction.

| Agency | Document | Comment |
|---|---|---|
| AAB-PTS | http://www.yourdigitalpublication.com/PTS/2014ProgramGuide/ | pages 30-34 |
| AAFP-PT | http://www.aafp.org/dam/AAFP/documents/practice_management/office_lab_pt/AAFP-PTHandbook.pdf | PDF, pages 24-25 |
| API | http://www.api-pt.com/reference/forms/cachecklist.pdf | |
| CTS | http://www.calthoracic.org/sites/default/files/pdfs/CTS%20PT%20Troubleshooting%20Guide.pdf | |
| CAP | http://www.cap.org/apps/docs/proficiency_testing/pt_exception_investigation_checklist.doc | requires MS Word |
| COLA | Laboratory Accreditation Manual, no longer available online | page 69 |

**Appendices A and B appear on the next four pages.**

**Laboratory Name:** _____

**Section:** _____

**Investigated by:**_____

# Investigation of Proficiency Testing Results

For quality assessment of unsatisfactory, ungraded or non-consensus proficiency testing results. Document all corrective action and keep this documentation with the PT results.

**Proficiency Testing Event/ Year:** _____ **Date Received:** _____

**Date Tested:** _____ **Date Submitted:** _____

| **Analyte:** | | | | | |
|---|---|---|---|---|---|
| **Result reported:** | | | | | |
| **Acceptable Range:** | | | | | |
| **Repeat Result (if possible):** | | | | | |

**Problem/Explanation of Findings:**

Attach documents as needed.

**Corrective Action/Preventive Action:**

Attach documents as needed.

- **Could this error affect Patient Results? Y/N (if yes, state course of action) :**

Reviewed by:

Laboratory Manager/Supervisor: Date: Medical Director/Pathologist: Date:

| Item | Y/N | Explanations/Comments | Initials / Date |
|---|---|---|---|
| **Check for problems with survey materials.** | | | |
| Hemolysis, bacterial contamination, freezing, cracked vials: | Y / N | | |
| Improper storage upon receipt: | Y / N | | |
| Improper reconstitution or handling : | Y / N | | |
| Improper shipping (shipped according to schedule and at proper temperature): | Y / N | | |
| **Clerical Error:** | | | |
| Transcription error: | Y / N | | |
| Transposition error: | Y / N | | |
| Wrong instrument, method and/or reagent code(s) reported to the program: | Y / N | | |
| Failure to return results to the program within specified time: | Y / N | | |
| **Technical Problems:** | | | |
| Misinterpretation/misidentification of results: | Y / N | | |
| Dilution or pipetting error: | Y / N | | |
| Time delay between reconstitution and analysis: | Y / N | | |
| Calculation error: | Y / N | | |
| Run accepted in nonlinear range: | Y / N | | |
| Run accepted even though controls were out-of-range: | Y / N | | |
| Quality control results demon-strating excessive repeats, shifts or trends : | Y / N | | |
| Run accepted even though calibration was out-of-range or overdue: | Y / N | | |
| Sample mix-up: | Y / N | | |
| **Method problems:** | | | |
| Instrument problem identified : | Y / N | | |
| Instrument repaired or replaced : | Y / N | | |
| Faulty reagents or standards: | Y / N | | |
| Maintenance performed as required: | Y / N | | |

# Checklist for Corrective Action

Year/Testing Event_____ Analyte_____ Sample number_____

Date Sample Tested_____ Person Performing Test_____

## Specimen Handling

Were specimens received in an acceptable condition? Yes □ No □
Were specimens stored according to the instructions on the result forms? Yes □ No □
Were the samples hemolyzed? Yes □ No □
Were samples tested within the time allowed for sample stability? Yes □ No □
If applicable, were the samples reconstituted correctly? Yes □ No □
Notes:_____
_____
_____

## Clerical Errors

Were the results transcribed onto the forms correctly? Yes □ No □
Were the results recorded on the correct result form? Yes □ No □
Was the correct instrument/reagent/kit selected? Yes □ No □
Were the results recorded in the correct units? Yes □ No □
Were the results on your evaluation the same as the results you reported? Yes □ No □
Notes:_____
_____

## Quality Control

Were controls in range on the date the proficiency samples were tested? Yes □ No □
Is there any indication of trending or shifting of the control results? Yes □ No □
Notes:_____
_____

## Calibration

Were there any problems with the most recent calibration? Yes □ No □
When was the last calibration performed? _____
How often is a calibration performed? _____
When was the last calibration verification performed? _____
Notes:_____
_____

## Instrument

Were instrument problems noted the day the samples were tested? Yes □ No □
Has there been any recent maintenance on the analyzer? Yes □ No □
Have you contacted your analyzer manufacturer for assistance? Yes □ No □
Notes:_____
_____

## Reagents

Were the reagents stored properly? Yes □ No □
Were the reagents expired or was the open vial stability exceeded? Yes □ No □
Have there been any changes in reagent manufacturer or formulation? Yes □ No □
Notes:_____
_____

## Culture

Was the media stored according to manufacturer's instructions? Yes □ No □
Was the media expired? Yes □ No □
Was the appropriate QC performed on the media? Yes □ No □
Was the incubator temperature/gas/humidity within acceptable limits? Yes □ No □
If applicable, have you contacted your kit manufacturer for assistance? Yes □ No □
Notes:_____
_____

Findings:_____
_____
_____

Could patient results have been affected? If so, explain course of action:_____
_____
_____

Corrective Action:_____
_____
_____
_____
_____

Person Performing Investigation_____ Date_____
Lab Director_____ Date_____

Completed correction action forms do not need to be sent to American Proficiency Institute. Keep all documentation with your records. You will be required to show them to your inspector at your next onsite inspection. You may also need to send a copy to your state or accrediting agency. This form is designed to offer assistance to the laboratory in investigation and troubleshooting proficiency testing failures. It is the laboratory's responsibility to effectively troubleshoot and resolve all proficiency testing failures. Completion of this form does not guarantee future successful performances with proficiency testing. Call 800-333-0958 for assistance.

***References***

1. O'Sullivan DC. Proficiency testing: error prevention and correction. *Med Lab Observ*. 1994;26(4):28-31.

2. Astles JR, Stang H, Alspach T, et al. CLIA requirements for proficiency testing: the basics for laboratory professionals. *Med Lab Observ.* 2013;45(9):8.

3. Centers for Medicare and Medicaid Services. *Clinical Laboratory Improvement Amendments (CLIA): Proficiency Testing DOs and DON'Ts*. Baltimore, MD: Centers for Medicare and Medicaid Services, 2008. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf. Accessed July 2, 2014.

4. University of California at Santa Cruz. Proficiency testing. In: *Student Health Center Lab Manual*. Santa Cruz: University of California; 2012. http://shs-manual.ucsc.edu/policy/proficiency-testing. Effective May 1, 2012. Reviewed March 3, 2014. Accessed July 2, 2014.

5. COLA. Evaluation grouping: proficiency testing. In: *COLA Laboratory Accreditation Manual*. April 2014 ed. Columbia, MD: COLA; 2014:66-72.

6. National Cancer Institute Center for Cancer Research. Proficiency testing policy. In: *Laboratory of Pathology Online Policy Manual*. Bethesda, MD: Center for Cancer Research. http://home.ccr.cancer.gov/lop/intranet/policymanual/generalpolicy/default.asp. Updated January 27, 2014. Accessed July 2, 2014.

7. Investigation of Proficiency Testing Results [form]. Willmar, MN: Rice Laboratory; 2012.

8. American Proficiency Institute. Checklist for Corrective Action [form]. Traverse City, MI: American Proficiency Institute; 2006. http://www.api-pt.com/reference/forms/cachecklist.pdf. Accessed July 2, 2014.

9. Shearer M. How to reduce clerical errors: run proficiency testing as if testing a patient specimen [case study]. Northfield, IL: College of American Pathologists; 2012. http://www.cap.org/apps/docs/laboratory_accreditation/elab_connect_case_study.pdf. Accessed July 2, 2014.

10. Satyadi C. Are clerical errors acceptable in proficiency testing? April 22, 2014. In: *Lab Medicine Lablogatory: a blog for medical laboratory professionals* [Internet].Chicago, IL: American Society for Clinical Pathology; 2013 - http://labmedicineblog.com/2014/04/22/are-clerical-errors-acceptable-in-proficiency-testing/.

11. Edson DC, Russell D, Massey L. Proficiency testing: a guide to maintaining successful performance. *Lab Medicine*. 2007;38(3):184-186.