Troubleshooting Guide for Proficiency Testing/External Quality Assessment Data

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Overview

The CAP Proficiency Testing/External Quality Assessment (PT/EQA) evaluation reports help laboratories identify potential problems with a visual graph of the difference between PT/EQA results and targets as percentages of allowed deviation. By reviewing graphical patterns to identify positive or negative bias, shifts, or trends from multiple program mailings, laboratory directors can initiate an investigation and, if necessary, corrective action, preventing a PT failure. This PT/EQA Troubleshooting Guide will help your laboratory to identify analytic errors and suggest corrective actions that can be taken to prevent future PT/EQA failures.

Troubleshooting Errors

When proficiency testing/external quality assessment (PT/EQA) results are outside acceptable limits, certain issues that can affect performance should be investigated by laboratories to avoid the potential impact to patient results. The investigation can include review of

- preanalytic variables such as clerical errors and specimen handling.

- analytic variables such as calibration issues, instrument issues, precision issues, and changes in the performance of reagent lots or performance over time.

- postanalytic variables such as failing to submit results by the due date.

In addition, understanding historical PT/EQA errors and their causes may prevent future PT/EQA errors.

Before investigating potential analytic issues, it is important to rule out clerical or specimen handling problems. These errors can be identified because they generally exceed the typical values. Potential causes of clerical or specimen handling mistakes include mislabeling errors, misplacing specimens in an analyzer rack, selecting the wrong units of measure, reporting the incorrect methodology, calculating errors, or using inappropriate reagents or standards.

Understanding the cause of potential errors can depend upon the number of analytes with unsuccessful PT/EQA performance, range of analyte values that demonstrate unacceptable PT/EQA, and number of PT/EQA programs with problems for a given analyte.

Errors: There are two types of analytic errors:

1. **Systematic errors** are characterized by consistent differences between participant results and target values; for example, when all results for an analyte lie on one side of the target value. More significant differences suggest a greater degree of systematic error. An example of a root cause of an analytical error is failing reagent that is used in all reactions for this analyte.

2. **Random errors** can affect some, but not all results, and are more indicative of a failure in precision of the test system. An example of a root cause of a random error is bubbles in liquid delivery tubing so that occasionally the wrong volume is delivered.

Common Causes of PT/EQA Errors, Troubleshooting Actions, and Corrective Actions

Table 1. Preanalytic errors

Potential Cause	Troubleshooting Action	Corrective Action
Clerical error	• Check original printouts for transcription errors • Check method code • Check units of measure	• Perform a self-evaluation of PT/EQA results using the correct instrument/method/reagent code in the PS • Investigate any result that fell outside the limits of acceptability for the correct peer group • Review PT/EQA reporting process • Add checks for data integrity by adding a second independent review of entered PT/EQA results • Develop a process flow to ensure any appropriate calculation is correctly performed when reporting PT/EQA results • Consider using electronic interface to send PT/EQA results • Ensure routine practice includes review of storage and stability, detailed testing instructions, and any program updates provided in each program mailing kit instructions
Specimen mix up	• Check reported results for evidence of specimen mix up • Check results against correct peer group in participant summary (PS)	
Specimen handling	• Check results against correct peer group in PS • Check specimens were received at correct temperature and stored properly according to the kit instructions	
Specimen integrity	• Check results against correct peer group in PS • Check to ensure specimens were tested according to the kit instructions	

Table 2. Analytic errors

Potential Cause	Troubleshooting Action	Corrective Action
Reagent lot performance change	• Check whether laboratory changed reagent lots before PT/EQA program, especially for small peer groups or when switching to a lot that is not yet in widespread use • Review last lot to lot comparison data to determine if new lot caused significant bias in results	• Ensure that process for testing new reagent lots uses patient samples (rather than quality control [QC] or calibrators) and has defined and appropriate acceptance criteria that will detect lot to lot changes beyond defined acceptable limits • For higher volume laboratories, consider evaluating mean patient results in the weeks before and after new lot is placed in service, to determine impact on patient results
Instrument technical problem	• Ensure QC ranges are based upon observed (correctly calculated) mean and standard deviation (SD) of QC material over long (> 1 month) period • Check that observed means are within acceptable limits of target means • Check for loss of precision over on-board life of reagents using correct (calculated) SD for QC rules • Review last analytical measurement range (AMR) verification to ensure that instrument is performing as expected	• Contact manufacturer for troubleshooting assistance if claimed precision or AMR verification cannot be reproduced in laboratory
Bad calibration	• Check whether all PT/EQA results demonstrate positive or negative bias (> 2 SDI from peer mean, or very low or high results > 3 SDI from peer mean) • Check for change in mean QC values between lots or shipments of reagent	• Ensure that process for testing new reagent lots uses patient specimens (rather than QC or calibrators) and has defined and appropriate acceptance criteria that will detect lot to lot changes beyond defined acceptable limits • Ensure calibrator values are correctly entered into the instrument • Consider establishing an in-house procedure for validation of manufacturer-provided calibrator values • If recalibration is necessary for corrective action, rerun any remaining stable PT/EQA specimen to evaluate against peer group • If recalibration is necessary for corrective action, consider (for higher volume laboratories) evaluating mean patient results in the weeks before and after suspect calibration, to determine impact on patient results

Table 3. Postanalytic errors

Potential Cause	Troubleshooting Action	Corrective Action
Failure to perform/submit PT/EQA results by the due date **OR** **no PT/EQA results submitted**	• Check that all PT/EQA results were submitted online to PT/EQA provider by stated due date	• Perform a self-evaluation of PT/EQA results using the correct instrument/method/reagent code in the PS • Perform Alternative Performance Assessment if PT/EQA was not tested or submitted to the CAP • Document confirmation online result submission (eg, maintain hard or electronic copy) • Train staff to efficiently enter and submit PT/EQA results by the due date provided in e-LAB Solutions Suite

Incorporating Daily Quality Control into the Interpretation of PT/EQA Performance

When reviewing PT/EQA performance, it is essential to identify current and potential failures by inspecting the Standard Deviation Index (SDI) and graphs of relative distances. Evaluation of your QC data preceding the challenge, at the time of the challenge, and following the challenge can also help identify possible problems and solutions. The QC records should indicate when recalibration and reagent log changes occurred. All other laboratory records used to evaluate the PT/EQA specimens and report results should also be collected and examined when reviewing possible sources of problematic PT/EQA results.

Quantitative PT Reports

Analysis of PT/EQA results can reveal a problem(s) before there is a future PT/EQA failure. The PT/EQA evaluation reports help laboratories identify potential problems with a visual graph of the difference between PT/EQA results and targets as percentages of allowed deviation. By reviewing graphical patterns from multiple program mailings, laboratory directors can initiate an investigation and, if necessary, corrective action, preventing a future PT/EQA failure.

Quantifying Deviations from the Peer Group Target

The evaluation reports list normalized results as an SDI. The SDI is obtained by subtracting the peer group mean from your laboratory's result and then dividing by the peer group SD. Monitoring rules based on SDIshave been shown to provide helpful information for self-interpretation of PT/EQA data.[1]

The evaluation reports also include a graphical summary using the relative distance of your results from the target. We refer to this distance as the percent allowed deviation. Typically, the range of acceptable results is the target +/- the PT/EQA allowable error. For example, this could be the group mean +/- 20%.

To calculate the percent allowed deviation, the target value is subtracted from your result, and the difference is divided by the PT/EQA allowable error. As a final step, this ratio is multiplied by 100 so that differences from the target value are on a percent scale ranging from -100 to +100.

The allowed deviation may be calculated as follows:

If your result is greater than the target mean:

$$\text{Percentage of Acceptable Deviation} = 100 \times \frac{\text{your result - target}}{\text{upper limit - target mean}}$$

If your result is less than the target mean:

$$\text{Percentage of Acceptable Deviation} = 100 \times \frac{\text{your result - target}}{\text{target mean - lower limit}}$$

If results are beyond -100% or +100%, an "x" is printed at that limit, indicating that results exceed the evaluation limit and are beyond the graphical limitations. Monitoring rules based on the percent allowed deviations have been shown to provide helpful information for the self-interpretation of PT/EQA data.[2]
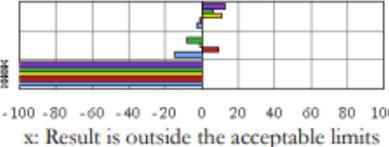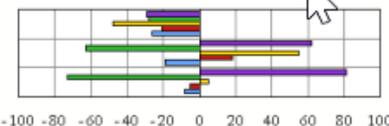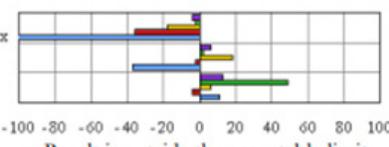
Interpreting Deviations from the Peer Group Target

Table 4 provides performance examples based on the percent allowed deviations displayed in the graphical summaries. In some cases, the identification of time-dependent trends can provide additional diagnostic information.

Table 4. Guidelines for monitoring PT/EQA performance using the evaluation graphs

Time Trends in PT Evaluation Graphs over Multiple Mailings		
Pattern	**Example**	**Action**
Persistent results on one side of the target values	Shows persistent bias, even if small; recalibration should have occurred within this time frame	See listing of suggested actions for evidence of systematic error
Results flip from one side of the target to the other by mailing	Shows impact of system and/or process changes; longer bars are of more concern	See listing of suggested actions for evidence of systematic error
Over time, length of bars increased on both sides of 0	A sudden shift may show impact of system and/or process changes; may reveal new source of either systematic or random error	See listing of suggested actions for evidence of random error
Over time, lengths of the bars increase primarily on one side	A gradual increase in bar length may reveal a systematic error. x: Result is outside the acceptable limits	See listing of suggested actions for evidence of systematic error

Over time, length of bars decrease	Shows impact of system and/or process changes, particularly as a result of corrective action	Retain as documentation that corrective action has been successful
	PT-C PT-B PT-A -100 -80 -60 -40 -20 0 20 40 60 80 100 x: Result is outside the acceptable limits	
Large positive and negative differences	Large differences may indicate random error	See listing of suggested actions for evidence of random error
	PT-C PT-B PT-A -100 -80 -60 -40 -20 0 20 40 60 80 100	
One result in a mailing exceeds ±75% of the allowed deviation	The one value out of range was the result of a transcription error.	See Issues due to general causes
	PT-C PT-B PT-A -100 -80 -60 -40 -20 0 20 40 60 80 100 x: Result is outside the acceptable limits	

Suggested Actions if There is Evidence of Systematic Error

1. Review internal QC performance. Look for trends or shifts that may not yet trigger your rejection rules. Assess the process of setting and changing QC target values.

2. If recalibration has not already occurred, recalibrate the instrument.

3. If participating in an external QC performance program, review comparative reports for QC performance. Further investigation is warranted if the laboratory performance on a lot of QC material is at consistent variance with the group performance mean.

4. Use assayed control material to evaluate performance.

Suggested Actions if There is Evidence of Random Error

1. Rule out errors from nonanalytical sources (eg, transcription error, misplaced specimens, calculation error).

2. Investigate components of the analytical system (eg, specimen probes, reaction cells, reagents).

3. Review internal QC performance. Look for trends or shifts that may not yet trigger your rejection rules. Assess the process of setting and changing QC target values.

4. Use assayed control material to evaluate performance.

References

1. Carey RN, Cembrowski GS, Garber CC, Zaki Z. Performance characteristics of several rules for self-interpretation of proficiency testing data. *Arch Pathol Lab Med.* 2005;129:997-1003.

2. Jenny RW, Jackson-Tarentino KY. Causes of Unsatisfactory performance in proficiency testing. *Clin Chem.* 2000;46: 89-99.Grannis GF, Gruemer H-D, Lott JA, et al. Proficiency evaluation of clinical chemistry laboratories. *Clin Chem.* 1972;18:222-236.

3. Northam BE. Whither automation? *Ann Clin Biochem.* 1981;18:189-190.