EVALUATING YOUR PROFICIENCY TESTING RESULTS

The role of proficiency testing (PT) has traditionally been one of an external quality assurance check. However, since successful PT performance has become an assessment tool for determining regulatory compliance, effectively evaluating your PT results is imperative.

This CLIAFacts addresses the process to follow when evaluating your PT results. Feel free to incorporate this outline into your policy/procedure manual, and use it to evaluate previous PT reports or when you get your next set of PT results. If you aren't already preserving your PT specimens, then consider retaining them for use in this evaluation process.

A Beneficial Process for Evaluating Your PT Results

Once you receive your PT results, review the CMS summary page to determine if all regulated analytes were scored for CLIA (regulatory) purposes. If you performed PT on a regulated analyte and this analyte does not appear on the summary page, then contact your PT provider.

Check to be sure the CLIA number for the lab is included and/or correct on the report, along with the name and identifier of any other regulatory or accrediting body (i.e.,CMS/State/COLA) that should receive copies of your PT report. If the CLIA number and/or regulatory information are lacking or incorrect, then your regulatory or accrediting agency will have problems receiving and monitoring your PT enrollment and scores. Notify your PT provider of any corrections to this information.

Review your scores for the individual analytes and review the overall specialty scores. Criteria for satisfactory performance is a minimum score of 80% for all analytes (except a minimum score of 100% for ABO/Rh and compatibility testing). For analytes in the same specialty the scores are averaged to obtain the overall specialty score. "Unsatisfactory" PT performance occurs when there is a failure in one event. PT performance is "unsuccessful" if there are two consecutive PT event failures or two out of three PT event failures. If repeated analyte/specialty scores indicate unsuccessful PT performance, then the lab is at risk of losing its ability to continue to test the analyte and/or specialty. After completing this initial review, continue with the more extensive review that follows:

I. All results were passing. Congratulations! But wait, you should...

A. Review the report.

1. Are three of five results for an analyte outside +/- 1.5 Standard Deviations, if this information is provided?
2. Are three results for an analyte outside +/- 50% of mean?
3. Do the five results for the analyte range from -50 to +50% of mean?
4. Did any analytes receive an automatic 100% because they could not be graded?

B. If conditions 1,2, or 3 exist, then take corrective action since it identifies gradual long-term trends and indicates test instability.

C. If condition 4 exists, perform a self evaluation, since the score does not reflect actual laboratory performance.

D. If none of these conditions exist, document this review.

[Stop review here.]

II. If PT results for any analytes are unsatisfactory:

A. Check your original documentation for discrepancies. Look for:

1. Transcription, transposition, method coding errors.
2. PT program errors.

B. Check testing records for technical processing errors. Look for:

1. Misidentification of specimen.
2. Misinterpretation of results.
3. Results mistakenly reported outside the reportable range or when QC was out of range.

C. If any of the above appear to be the reason for the PT problems:

1. Document the causes and the corrective action taken to prevent them from happening in the future.

[Stop review here.]

III. If the reason for the problems is still not apparent, then evaluate the test systems affected.

A. Expand the scope of the inquiry by asking:

1. Is the problem affecting more than one test on an instrument?
   a. If yes, expect an instrument-related problem.
2. Is the problem affecting only tests results in a certain range, e.g., only specimens with high values are affected?
   a. If yes, this could be due to a linearity/calibration problem.
3. Are several tests affected from the same PT specimen?
   a. If yes, it could be a problem of PT specimen integrity or reconstitution.

B. Evaluate status of the affected tests at the time of initial testing and determine:

1. Has maintenance been performed appropriately?
2. Are controls in range, or starting to trend or shift?
3. When was the last calibration?
4. Is temperature a factor?
5. Are all reagents or controls in date?

C. Retest PT specimens retained specifically for this purpose. Serum specimens may be frozen; however, check to determine the time period your PT program's hematology specimens will be stable when refrigerated (they cannot be frozen). If the results in question are now in range **and**:

1. One test or specimen was affected, it is termed "random analytical error" that may have been due to:
   a. Aliquot evaporation.
   b. Pipetting error/dilution error.
   c. Instrument instability/power surge.
2. Two or more poor results for the same test were biased in the same direction, it is referred to as "short-term systematic analytical error" that may have been due to:
   a. Improper instrument maintenance.
   b. Reagent deterioration.
   c. Improper calibration.
3. If all of the PT problems were explained by the above, then check for possible effects on patient results since the PT specimens were done. If the effect could have been clinically significant, then document appropriate corrective action. Take steps to prevent the problems from recurring.

[Stop review here.]

IV. **If the results of the retest are NOT in range,** obtain a new sample of the PT material in question from your PT program and test it. Availability of these specimens varies greatly. If they aren't available, then consider performing split-specimen testing on several patient specimens instead.

A. If the new specimens are in range,then the problem could have been due to:

1. Problems with the PT material specimen itself, such as:

a. Bacterial/fungal contamination.

b. Delay or temperature damage in shipment.

c. Hemolysis of specimen.

e. Evaporation of the specimen.

f. Reconstitution error or delay in testing.

B. Document the cause of the errors and the corrective action taken to prevent future problems.

[Stop review here.]

V. **If the results of these newly obtained specimens are out of range as well,** then it's most likely due to a "long-term systematic error."

A. Examples of some of these problems and their solutions are:

1. Miscalibration--recalibrate the instrument.

2. Repetitive procedural error--reread procedure/retrain staff.

3. Infrequent performance of the test--retrain staff or consider discontinuing the test.

4. Major instrument maintenance problem--call for service.

5. Matrix effect/incompatibility with your method--call PT provider.

B. If the problems are corrected by any of the above reasons, then check the effect of the problem on patient results since the PT was originally performed. If the effect was clinically significant, then take appropriate corrective action. Document the corrective action taken to prevent them from happening again.

VI. **Perform a scheduled QA follow-up review of the effectiveness of all corrective actions** taken to prevent future PT problems. Document this review.

[Stop review here.]

Proficiency Testing is a well-justified laboratory expense. Taking the time to evaluate the results according to the above outline will aid in your efforts to attain successful proficiency testing results, as well as produce quality laboratory test results.