COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

Proficiency Testing/External Quality Assessment (PT/EQA) Exception Investigation Worksheet

SURVEY INFORMATION

PT Program
Name: _____ CAP No. _____

Date PT Program
Received: _____ Date Analysis Performed: _____

Date PT Program
Results Submitted: _____ Date Results Received: _____

Investigation Performed By: _____

Analyte: _____

Specimen Number	Reported Result	Intended Result/Range	Acceptable/ Unacceptable	Results of repeat testing on retained PT material (if available) after evaluation

EVALUATION OF POSSIBLE SOURCES OF ERROR

CLERICAL

	Yes	No	N/A
Were the results submitted and approved by the due date?	☐	☐	☐
Were PT results correctly transcribed from the instrument or worksheet into the CAP online reporting system (ELSS)?	☐	☐	☐
Was the correct instrument/method/reagent/manufacturer reported on the result form?	☐	☐	☐
Do the units of measure match between the result form and the instrument results?	☐	☐	☐
Is the decimal place correct?	☐	☐	☐

A response of “NO” to any of these questions may indicate a clerical error. Although reporting PT results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the PT, addition of a second reviewer, or investigation of the reporting format provided by the testing device.

PROCEDURAL

	Yes	No	N/A
Were all laboratory procedures followed for processing this PT?	☐	☐	☐
Were all test reagents prepared according to procedure?	☐	☐	☐
Were reagent(s) within the open expiration dates?	☐	☐	☐
Was culture media stored per manufacturer's instructions?	☐	☐	☐
Were dilutions performed correctly?	☐	☐	☐
Were calculations performed correctly?	☐	☐	☐

A response of “NO” to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the PT material and/or review of laboratory procedures may be required.

ANALYTICAL

	Yes	No	N/A
Was the most recent calibration acceptable and within established limits at the time PT was performed?	☐	☐	☐
Were previous PT results reviewed for shifts or trends?	☐	☐	☐
Were quality control results acceptable for the date of PT testing?	☐	☐	☐
Were quality control results from around the time of the PT event without bias/trending?	☐	☐	☐
Were microscopic examinations interpreted correctly?	☐	☐	☐
Was staining performed and interpreted correctly?	☐	☐	☐
Was the intended result within the analytical measurement range for the instrument?	☐	☐	☐
Was instrument maintenance performed per schedule?	☐	☐	☐
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the PT was performed?	☐	☐	☐

A response of “NO” to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

SPECIMEN HANDLING

	Yes	No	N/A
Were PT specimens reconstituted as indicated in the kit instructions?	☐	☐	☐
Were PT specimens stored as indicated in the kit instructions?	☐	☐	☐
Were all special instructions for specimen storage and testing provided in the kit instructions followed (ie, some analytes may require testing immediately upon receipt)?	☐	☐	☐
Were PT specimens tested as soon as possible upon receipt?	☐	☐	☐
Were the correct tests performed on the correct vial of PT material?	☐	☐	☐

A response of “NO” to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the program materials.

PT MATERIAL

	Yes	No	N/A
Was the physical condition of the PT material received in the laboratory verified and stored according to the storage and stability information in the kit instructions?	☐	☐	☐
Were your PT results graded against the appropriate peer group based on the instrument/ method reported on the result form?	☐	☐	☐

A response of “NO” to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of PT kits after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your PT provider for additional information if needed.

For additional assistance in troubleshooting unacceptable performance, review the following documents or contact your instrument/method manufacturer.

Troubleshooting Guide for Proficiency Testing Data. Available at http://www.cap.org/apps/docs/proficiency_testing/troubleshooting_guide_for_pt_data.pdf. Accessed January 26, 2011.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality; Approved Guideline – Third Edition*. CLSI document QMS24. 2016.

CONCLUSION/SUMMARY:

CORRECTIVE ACTION DOCUMENTATION:

REVIEW OF PATIENT RESULTS IN RESPONSE TO PT FAILURE:

REVIEW/APPROVAL: _____

DATE: _____