

Proficiency Testing (PT) Failure Corrective Action Worksheet

Year:	Date Samples Received:
Event Name:	Date Samples Tested:
Sample ID(s):	Date Results Submitted:
Analyte(s):	Date Results Due to PT provider:
	Personnel Who Performed the Testing:

Sample Storage and Handling:

Yes No Were the samples received on time and in an acceptable condition?

Yes No Were the samples stored according to the instructions?

Yes No Were the samples hemolyzed (if whole blood)?

Yes No Did the samples contain excessive precipitate, turbidity, or bacterial contamination?

Yes No Were the samples at the proper temperature before analysis (per instructions)?

Yes No Were the samples properly mixed?

Yes No Were the samples tested according to the instructions?

Yes No Was there a time delay before or during analysis?

Notes:

Clerical Errors:

Yes No Were results submitted by the due date?

Yes No Were the correct samples used and/or reported (sample mix-up)?

Yes No Were the results reported under the correct analyte?

Yes No Were the results reported with the correct instrument/kit?

Yes No Was the correct method principle and reagent selected (if applicable)?

Yes No Was there a dilution/calculation error?

Yes No Were the results reported in the designated units?

Yes No Were all the samples reported with a result or exception code (not left blank) for each listed analyte?

Yes No Do the results on your evaluation report match the results from the instrument printout and/or worksheet?

Notes:

Quality Control (QC):

Yes No Were the QC results within range on the date the PT samples were tested?

Yes No Were there any shifts or trends in the QC values the week before, on the day, or after the PT samples were tested?

Notes:

Reagent/Kit:

- Yes No Was the reagent/kit stored and handled properly?
- Yes No Was the reagents/kit expired or was the open vial stability exceeded?
- Yes No Was there a reagent lot change (did QC shift after the lot change)?
- Yes No Have there been any changes in reagent/kit manufacturer or formulation (are you looking at the most current package insert)?
- Yes No If applicable, have you contacted the reagent/kit manufacturer for further assistance?

Notes:**Calibration:**

- Yes No Were there any problems with the most recent calibration?
- How often is the calibration required? _____
- When was the date of the last calibration? _____
- When was the last calibration verification/linearity performed? _____
- Yes No Did the calibrator lot change?
- Yes No Do the calibrator values on the package insert match those in the instrument?
- The SDI (Standard Deviation Index) value on the evaluation report is a measurement of how close your result is to the mean result. Check the SDI value on your evaluation report.
- Yes No Are the SDI values all negative or all positive, ± 2 ?
- Yes No Are more than half of your results ± 1.5 ?
- If yes, check the calibration records and determine if it is time to recalibrate.

Notes:**Instrument:**

- Check if the maintenance is up to date.
- Yes No Daily Maintenance?
- Yes No Weekly maintenance?
- Yes No Monthly maintenance?
- Yes No Quarterly maintenance?
- Yes No Yearly maintenance?
- Yes No Has there been any recent maintenance on the analyzer?
- Yes No Were any instrument problems noted before, on the day, or after the samples were tested?
- Yes No Are the pipetting/measurement devices dispensing correctly?
- When was the last calibration check performed on the pipettes/measuring devices? _____
- Yes No If applicable, have you contacted the instrument manufacturer for further assistance?

Notes:**Culture:**

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

Notes:

Training/Competency:

Determine if the PT failure indicates problems with technical competency or personnel performing the testing.

Yes No Is the training & competency file up to date for the personnel who performed the testing?

Yes No Does the personnel need to be trained/retrained in areas of the lab (preanalytical, analytical, postanalytical)?
If yes, which area(s)? _____

Notes:

Summary of Findings:

Summarize the source of the PT failure (Clerical, Technical etc.). If applicable, rerun the PT sample. If the sample stability is expired/compromised, contact WSLH PT for a replacement sample.

Were patient results affected? Yes / No Explain the course of action:

For example, splitting patient specimens with another lab that offers the same tests may assist to determine if the PT failure is related to the PT specimens or indicates a problem with patient test results.

Corrective Action(s):

Determine a corrective action plan to prevent the source of the failure from occurring in the future.

Person Performing the Investigation: _____ Date: _____

Lab Director/Designee: _____ Date: _____

The corrective action worksheet is a tool to assist laboratories with troubleshooting PT failures. Completion of this worksheet does not guarantee future successful performances. It is the laboratory's responsibility to effectively troubleshoot and resolve all PT failures. Completed corrective action worksheets should not be submitted to WSLH PT. Keep all documentation as part of your event record as you may be required to provide documentation to an inspector or agency. If you should have any questions, contact WSLH PT at (800) 462-5261.