WSLH Proficiency Testing
WISCONSIN STATE LABORATORY OF HYGIENE
UNIVERSITY OF WISCONSIN–MADISON

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:

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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 incubater temperature/gas/humidity within acceptable limits?
Yes ☐ No ☐ If applicable, have you contacted your kit manufacturer for assistance?
Notes:

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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.

Notes:

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.

Notes:

Corrective Action(s):

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

Notes:

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.

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