

## PT Failure Corrective Action Worksheet

Year: Event Name: Sample ID(s): Analyte(s):  Sample Storag Yes		<ul> <li>□ Were the samples received on time and in an acceptable condition?</li> <li>□ Were the samples stored according to the instructions?</li> <li>□ Were the samples hemolyzed (if whole blood)?</li> <li>□ Did the samples contain excessive precipitate, turbidity, or bacterial contamination?</li> <li>□ Were the samples at the proper temperature before analysis (per instructions)?</li> <li>□ Were the samples properly mixed?</li> <li>□ Were the samples tested according to the instructions?</li> </ul>	
Clerical Err	ors:		
Yes	NO D	Were the correct samples used and/or reported (sample mix-up)?  Were the results reported under the correct analyte?  Were the results reported with the correct instrument/kit?  Was the correct method principle and reagent selected (if applicable)?  Was there a dilution/calculation error?  Were the results reported in the designated units?  Were all the samples reported with a result or exception code (not left blank) for each listed analyte?	
Quality Co Yes	ntrol (C No D No D	Were the QC results within range on the date the PT samples were tested?	



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Popo	gent/K	/i+·						
_	gent/k	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?				
Note	es:							
Calib	ration	n·						
Yes		No		Were there any problems with the most recent calibration?				
1.03	_	110	_	How often is the calibration required?				
				When was the date of the last calibration?				
				-				
	_	N1 -	_	When was the last calibration verification/linearity performed?				
Yes		No		Did the calibrator lot change?				
		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 S	SDI val	lue oi	n 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	s, che	ck the	e calib	ration records and determine if it is time to recalibrate.				
Note	es:							
	umen							
Chec	k if th	e ma		ance is up to date.				
	k if th			Daily Maintenance?				
Chec	k if th	e ma		Daily Maintenance? Weekly maintenance?				
Chec Yes	k if th	e ma No		Daily Maintenance?				
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## PT Failure Corrective Action Worksheet

Training/Competency:	
Yes □ No □ Is the training & compete	with technical competency or personnel performing the testing. ency file up to date for the personnel who performed the testing? to be trained/retrained in areas of the lab (preanalytical, analytical, postanalytical)?
Summary of Findings:	
	, Technical etc.). If applicable, rerun the PT sample. If the sample stability is eplacement sample.
Were patient results affected? Yes / No Expla For example, splitting patient specimens with a the PT specimens or indicates a problem with p Notes:	nother lab that offers the same tests may assist to determine if the PT failure is related to
Corrective Action(s):  Determine a corrective action plan to prevent to Notes:	he source of the failure from occurring in the future.
Person Performing the Investigation: Lab Director/Designee:	Date: 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.