Proficiency Testing
Corrective Action Investigation Checklist

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Completed by: _____

Date: _____

PT Study ID: _____

Sample ID: _____

Analyte/Method.: _____

The following checklist defines the items that may be reviewed when evaluating a "Not Acceptable" in order to prepare an efficient corrective action and preventive action procedure. This checklist may be filed with other associated PT records as determined by your laboratory's Quality Management System. Note: Multiple causes may contribute to an out-of-control PT result.

	Yes	No	Comments
Sample Prep			
Were the sample(s) properly prepared by following Phenova's work instructions (i.e., dilution volumes, properly preserved)? Please refer to your documented quality records.	☐	☐	
Was the sample prepared (i.e., digested or extracted) and analyzed within the recommended hold time? (Hold time for ampulated samples begins once the vial is opened).	☐	☐	
Reporting			
Please review reporting documents to determine any transcription errors. Were there any erronous reporting of the results?	☐	☐	
Were dilution schemes performed correctly and applied correctly in the calculation of the final result?	☐	☐	
For any dilution schemes performed (i.e., original result exceeded the calibration range), did they provide detection above the mid-range of the calibration?	☐	☐	
Identification			
Was the reported value confirmed using a second analytical column, if applicable?	☐	☐	
If both a primary and confirmation column were used, was there a significant difference between the two results?	☐	☐	
Primary Column Value: _____ Confirmation Column Value: _____ Reported Value: _____			
Review and confirm the following are accurately represented in the reporting for sample/compound in question:			
Identification	☐	☐	
Integration	☐	☐	
Quantitation	☐	☐	
Method Sensitivity			
Does the laboratory's MDL and RL support the concentration of the sample?	☐	☐	
RL Value: _____ MDL Value: _____ Sample Concentration Value: _____			
Calculations			
For the following values please verify that all calculations were performed correctly and that their values are within prescribed acceptance criteria:			
Sample Concentration	☐	☐	
Matrix QC	☐	☐	
Initial Calibration	☐	☐	
Continuing Calibration	☐	☐	
Method Blank	☐	☐	
Lab Control Sample (LCS)	☐	☐	
Second Source QC Standards	☐	☐	
Surrogates Standards	☐	☐	
Internal Standards	☐	☐	
Other: _____	☐	☐	
Other: _____	☐	☐	

	Yes	No	Comments
Calibration			
Verify that the standards and reagents used in the analysis were valid (i.e., not expired; second source where required).	☐	☐	
Has standard stability been established and demonstrated?	☐	☐	
Verify that the following for the standard curve is appropriate:			
Number of points	☐	☐	
Dispersion	☐	☐	
Low Level Standards Readability	☐	☐	
Linear Regression Adequate (where applicable)	☐	☐	
Residuals	☐	☐	
Other Curves	☐	☐	
Was the elution order correct? (This is particularly important for isomeric pairs)	☐	☐	
Were the chromatographic peaks identified correctly?	☐	☐	
Method Capability			
Review the laboratory's historical performance over past PT studies for this analyte by the specific method and determine any positive or negative biases, even in acceptable results.			
Are There Any Trends?	☐	☐	
Provide the vendors study ID numbers:			
Study ID _____ Study ID _____ Study ID _____ Study ID _____ Study ID _____ Study ID_____			
Review the laboratory's historical performance using statistical control charts for atypical patterns or variation and determine any positive or negative biases, even in acceptable results. Any trends?	☐	☐	
Method			
Were any deviations made to the Standard Operating Procedure?	☐	☐	
Are the deviations (if applicable), consistent with the reference method?	☐	☐	
Quality Control			
If the result is biased-high, can this bias be attributed to detection/ contamination within any of the QC indicators found under method capability (above)? (Clearly define in the comments section.)	☐	☐	
Assess lab limits for acceptability to method and program requirements.			
Are lab allowed QC or calibration limits wider than the PT acceptance limits?	☐	☐	
Are these lab allowed limits consistent with the method limits?	☐	☐	
If lab allowed limits are wide, did the reported results fall outside the PT limits but within the lab allowed limits?	☐	☐	
Were there any situations that required corrective action at the time of analysis?	☐	☐	
Are there any situations detected in this investigative process that should have prompted corrective action at the time of analysis?	☐	☐	
Based on this investigative process, does the data support the reported value for this analyte?	☐	☐	

Investigation Summary

What To Do Next

Contact Phenova to Help You Validate Your Corrective Action Procedure
Phone: **1-866-942-2978**
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Enroll in a Rapid Return™ Study to Maintain Your Accreditation

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