

## QUALITY ASSURANCE DEPARTMENT

DOC Number	TITLE	VERSION Number
PHDB1/QAD/FOR-2.4	INTERNAL QUALITY CONTROL INVESTIGATION CHECKLIST	4.0
EFFECTIVE DATE: 10-03-2018		SUPERSEDES VERSION: 3.0

Internal QC Information		
Equipment/Analyzer:	Department:	
QC Material:	Lot No and Expiry:	
Investigation Performed by:	Date:	
Unacceptable Result		
Analyte:	Unit:	
Unacceptable Result:	Intended Result/Range:	
Result of Rerun:		
<b>Westgard Violation:</b> <b>Random error:</b> <input type="checkbox"/> 1- 2S <input type="checkbox"/> 1-3S <input type="checkbox"/> R-4S <b>Systematic error:</b> <input type="checkbox"/> 2-2S <input type="checkbox"/> 4-1S <input type="checkbox"/> 10x <input type="checkbox"/> N/A		
Root Cause Analysis Scheme		
<b>Human Error</b> <input type="checkbox"/> Blunders (swapped QC levels) <input type="checkbox"/> Short Sample <input type="checkbox"/> Deviation of instructions <input type="checkbox"/> Others _____	<b>Instrument Failure</b> <input type="checkbox"/> Aspiration error <input type="checkbox"/> Interrupted power supply <input type="checkbox"/> Hardware error <input type="checkbox"/> Water Interruption <input type="checkbox"/> Others _____	<b>Reagent/QC/Calibration Materials</b> <input type="checkbox"/> Expired Reagent <input type="checkbox"/> Expired Reagent Stability <input type="checkbox"/> Improper Reagent Storage <input type="checkbox"/> Improper Reagent Preparation  <input type="checkbox"/> Expired QC material <input type="checkbox"/> Expired QC Stability (open vial) <input type="checkbox"/> Improper storage of QC material <input type="checkbox"/> Improper QC reconstitution  <input type="checkbox"/> Expired Calibrator <input type="checkbox"/> Expired Calibrator Stability  <input type="checkbox"/> Diluent Insufficiency <input type="checkbox"/> Others _____
<b>Monitoring Failure</b> <input type="checkbox"/> Required Daily Maintenance <input type="checkbox"/> Required Preventive Maintenance <input type="checkbox"/> Expired Calibration <input type="checkbox"/> Uneven distribution of QC data <input type="checkbox"/> Manufacturer Value Change <input type="checkbox"/> Change-over/Lot Change <input type="checkbox"/> Others _____		
Corrective Action		
<input type="checkbox"/> Re-run same QC material <input type="checkbox"/> Re-run fresh QC material <input type="checkbox"/> Others _____ <input type="checkbox"/> Calibrate and re-run QC <input type="checkbox"/> Escalate to Senior Tech/Lab Manager/Technical Service Engineer		
Preventive Action		

Remarks/Comments: .....

Reviewed by: (Lab Director/Designee) \_\_\_\_\_

Date: \_\_\_\_\_