Checklist for Corrective Action

Year/Testing Event_____ Analyte_____ Sample number_____

Date Sample Tested_____ Person Performing Test_____

Specimen Handling

Were specimens received in an acceptable condition? Yes ☐ No ☐
Were specimens stored according to the instructions on the result forms? Yes ☐ No ☐
Were the samples hemolyzed? Yes ☐ No ☐
Were samples tested within the time allowed for sample stability? Yes ☐ No ☐
If applicable, were the samples reconstituted correctly? Yes ☐ No ☐
Notes:_____
_____
_____

Clerical Errors

Were the results transcribed onto the forms correctly? Yes ☐ No ☐
Were the results recorded on the correct result form? Yes ☐ No ☐
Was the correct instrument/reagent/kit selected? Yes ☐ No ☐
Were the results recorded in the correct units? Yes ☐ No ☐
Were the results on your evaluation the same as the results you reported? Yes ☐ No ☐
Notes:_____
_____

Quality Control

Were controls in range on the date the proficiency samples were tested? Yes ☐ No ☐
Is there any indication of trending or shifting of the control results? Yes ☐ No ☐
Notes:_____
_____

Calibration

Were there any problems with the most recent calibration? Yes ☐ No ☐
When was the last calibration performed? _____
How often is a calibration performed? _____
When was the last calibration verification performed? _____
Notes:_____
_____

Instrument

Were instrument problems noted the day the samples were tested? Yes ☐ No ☐
Has there been any recent maintenance on the analyzer? Yes ☐ No ☐
Have you contacted your analyzer manufacturer for assistance? Yes ☐ No ☐
Notes:_____
_____

Reagents

Were the reagents stored properly? Yes ☐ No ☐
Were the reagents expired or was the open vial stability exceeded? Yes ☐ No ☐
Have there been any changes in reagent manufacturer or formulation? Yes ☐ No ☐
Notes:_____
_____

Culture

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

Findings:_____
_____
_____

Could patient results have been affected? If so, explain course of action:_____
_____
_____

Corrective Action:_____
_____
_____
_____
_____

Person Performing Investigation_____ Date_____
Lab Director_____ Date_____

Completed correction action forms do not need to be sent to American Proficiency Institute. Keep all documentation with your records. You will be required to show them to your inspector at your next onsite inspection. You may also need to send a copy to your state or accrediting agency. This form is designed to offer assistance to the laboratory in investigation and troubleshooting proficiency testing failures. It is the laboratory's responsibility to effectively troubleshoot and resolve all proficiency testing failures. Completion of this form does not guarantee future successful performances with proficiency testing. Call 800-333-0958 for assistance.