PROFICIENCY TESTING ACTION FORM

AMERICAN ASSOCIATION OF BIOANALYSTS
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LABORATORY NAME: _____

Section: _____

_____

Completed by: _____

Core lab Manager / Department Supervisor: _____

Problem: _____

_____

Attach documents as needed

Corrective Action/Preventive Action: _____

_____

Attach documents as needed

Reviewed by:

Laboratory Manager _____ Date: _____

Medical Director _____ Date: _____

PROFICIENCY TEST CORRECTIVE ACTION CHECKLIST FORM

Laboratory Name: _____ CLIA #: _____

Testing Event: _____ Year: _____

Proficiency Testing Module: _____ Analyte: _____

Date PT Sample Rcvd: ___/___/___ Test Date: ___/___/___ Report Date: ___/___/___

Sample #: _____ Reported Results: _____ Expected Range: _____

Expected Results: _____ Repeat Analysis Result _____ (Original or new specimen)

Sample #: _____ Reported Results: _____ Expected Range: _____

Expected Results: _____ Repeat Analysis Result _____ (Original or new specimen)

Sample #: _____ Reported Results: _____ Expected Range: _____

Expected Results: _____ Repeat Analysis Result _____ (Original or new specimen)

Sample #: _____ Reported Results: _____ Expected Range: _____

Expected Results: _____ Repeat Analysis Result _____ (Original or new specimen)

Sample #: _____ Reported Results: _____ Expected Range: _____

Expected Results: _____ Repeat Analysis Result _____ (Original or new specimen)

I. Does this failure represent unsatisfactory performance for this analyte, specialty, or subspecialty? Y / N

2. Does this failure represent unsuccessful performance for this analyte, specialty, or subspecialty? Y / N

(Unsatisfactory performance for two events in a row or two out of three consecutive testing events:

PT Failure Classification:

	Submitted Late	Lack of Consensus	Failure to Submit
	Clerical Error	Equipment Error	Educational Challenge
	Trend / Bias	Other	

FINDINGS: _____

_____

CORRECTIVE ACTION: _____

_____

COULD THIS ERROR AFFECT PATIENT RESULTS? Y / N

If yes, state course of action: _____

[Review process to be modified by each lab to what is appropriate for that lab]

Investigated by: _____ Date: ___/___/___

Technical Consultant/Supervisor: _____ Date: ___/___/___

Laboratory Director: _____ Date: ___/___/___

PROFICIENCY TEST CORRECTIVE ACTION CHECKLIST FORM continued

This form is to be used as a guide to assist in investigating, documenting, and correcting proficiency test failure or unacceptable results. Identify the reasons for failure or unacceptable results in proficiency testing and take appropriate corrective measure. Complete Proficiency Testing Corrective Action Form and attach copies of all records reviewed to this form.

1) SPECIMEN HANDLING
   a) Were proficiency test specimens checked for acceptability when received? (Review notes made at the time proficiency test was received). Y / N / NA
   b) Were the specimens handled properly? (Review instruction for specimen preparation). Y / N / NA

2) CLERICAL ERRORS
   a) Verify correct value was transcribed from instrument printout to report form, or that the correct response was entered from the list of results. Y / N / NA
   b) Verify that decimal point and units of measure were honored on the report form. Y / N / NA
   c) Verify that the correct code from the instrument or reagent list was entered on the report form. Y / N / NA
   d) Verify that the correct testing method information was provided. Y / N / NA
   e) Verify that any calculations were performed correctly. (even if automated calculation) Y / N / NA
   f) Check summary report to verify value on report form was honored by the PT service. Y / N / NA

3) QUALITY CONTROL
   a) Were quality control materials within the acceptable range on the date of PT testing? (Verify the quality control acceptable range in use.) Y / N / NA
   b) Any evidence of trends or shifts in the periods just before and just after PT was tested? Y / N / NA

4) CALIBRATION
   a) What was the date of the last calibration? ____/____/____
   b) How often is calibration to be performed? ____/____/____
   c) When was last calibration verification performed? ____/____/____
   d) Were any calibration problems noted? Y / N / NA

5) INSTRUMENT
   a) Were instrument parameters entered correctly? Y / N / NA
   b) Was daily maintenance performed on the date of PT testing? Y / N / NA
   c) Was special maintenance performed just prior to PT? Y / N / NA
   d) Were instrument problems noted when PT was performed? Y / N / NA

6) REAGENTS
   a) Check reagent / instrument log for notation of recent problems. Y / N / NA
   b) Check reconstitution instructions in package insert versus procedure -any changes? Y / N / NA
   c) Verify that open stability of reagent was not exceeded by reviewing procedure with testing personnel. Y / N / NA

7) TESTING PERSONNEL
   a) Date of last competency assessment for testing personnel. ____/____/____
   b) Review assay procedure and proficiency test sample preparation instructions with testing personnel to ensure that instructions were followed Y / N / NA
   c) Review with testing personnel how samples were loaded to rule out misidentification or transposition of samples. Y / N / NA
   d) Was retraining of testing personnel required and if so is this completed? Y / N / NA

8) PROCEDURE
   a) Review procedure versus manufacturer's most current recommendation for any changes. Y / N / NA
   b) If retained frozen or refrigerated specimens were retested, were the results the same as those reported? Y / N / NA
   c) Call instrument or reagent manufacturer for input if cause is not readily identified. Y / N / NA

9) INTERPRETATION ERRORS
   a) Was PT challenge beyond the scope and extent of the testing routinely performed in your lab? Y / N / NA
   b) Has summary report been reviewed for an explanation of key features of the element presented in the photomicrographs and/or pictures? Y / N / NA
   c) Have textbook references been consulted for additional information? Y / N / NA
   d) (Microbiology) Compare the test characteristics found in your laboratory with the characteristics of the correct identification. Review your results and procedure for the key to distinguish the correct identification from the incorrect identification. Y / N / NA