< REPLACE WITH NAME OF LAB >

PROFICIENCY TEST CORRECTIVE ACTION CHECKLIST FORM

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 :

____

Investigated by: ____ Date: __________

Technical Consultant/Supervisor: ____ Date: __________

Laboratory Director: ____ Date: __________

Attached Supporting Documents :

____

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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.

RESET

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

COMMENTS :

IDENTIFICATION OF LABORATORY PROBLEM/ PREVENTABLE ERROR

Previous trends/unacceptable results for this test?
☐ NO - Skip to next question
☐ YES –Corrective action/investigation noted:

Quality control results reviewed?
☐ Yes ☐ Acceptable
☐ Not Acceptable-Indicate Corrective Action

Clerical /Transcription Review:
☐ Acceptable
☐ Not Acceptable-Indicate Corrective Action

Was patient data affected?
☐ NO
☐ YES – Indicate Corrective Action

INVESTIGATION

Was sample retested?
☐ YES Result of retesting:
Was there agreement between original result and retested result? ☐ NO ☐ YES
☐ NO Reason why retesting not performed

Was procedure reviewed with the analyst?
☐ YES Provide documentation of review
☐ NO Reason why review not performed _____

If procedure was reviewed with analyst, were errors in technique identified?: ☐ NO ☐ YES

Was the analyst retrained?
☐ YES Provide documentation of retraining
☐ NO Reason why retraining not performed

Written narrative of investigation:

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INVESTIGATION SUMMARY: ROOT CAUSE

Pre-analytic Phase of Testing	Analytic Phase of Testing	Post-Analytic Phase of Testing
☐ PROBLEM WITH PT SAMPLE	☐ METHODOLOGICAL PROBLEM	☐ CLERICAL ERROR
☐ SAMPLE PROCESSING	☐ TECHNICAL PROBLEM	☐ REPORTING PROBLEM
☐ DATA ENTRY	☐ REAGENT PROBLEM	☐ NO EXPLANATION AFTER INVESTIGATION
☐ OTHER (SPECIFY): _____	☐ CALIBRATOR PROBLEM	☐ OTHER (SPECIFY): _____
	☐ OTHER (SPECIFY): _____	

PREVENTION

Describe policies and practices to be implemented by the laboratory as a result of the investigation of this problem/preventable error

Describe how the laboratory will monitor itself to ensure the effectiveness of newly implemented policies and practices

Identify the individual(s) responsible for monitoring the effectiveness of implemented policies and practices

Date	Testing Personnel
Date	Laboratory Director/Technical Consultant

Review by Staff

Name	Date	Name	Date

Upon Completion - This Record Must be Kept for Two Years for CLIA Testing

Continuous Quality Improvement Form
Investigation of Unacceptable Proficiency Tests: Instructions for Use

This form must be used whenever the laboratory is notified by the laboratory director or technical consultant that a proficiency test result is unacceptable. An investigation must be conducted to determine the root cause of the failure. If there is a discrepancy, the laboratory must identify the cause and implement an appropriate response to prevent the error from reoccurring. Laboratory errors may occur at any of the three phases of testing: pre-analytic, analytic, and post-analytic

a. **Pre-analytic (pre-examination) phase of testing:** includes all activities from the time the lab test was ordered through the time the sample was processed and ready to be tested. **Problems that require completion of this form.** Errors associated with transport, receipt and accessioning, or processing of PT samples

b. **Analytic (examination) phase of testing:** includes the activities of performing the test, verifying the test results, interpreting the findings, and recording the results.
Problems that require completion of this form (the examples given below are not meant to be an exhaustive list. The laboratory may encounter errors not listed below which require investigation)
1) Methodological Problem: Procedure not performed correctly, 2) Technical problem: examples include the instrument is not functioning properly, there was an error in instrument calibration, and the instrument was not cleaned properly, 3) Reagent Problem: Expired reagents or controls used, reagents stored at wrong temperature or not brought to proper temperature before testing, or invalid control results accepted and client results reported

c. **Post-analytic (post-examination) phase of testing:** includes activities related to reporting results and archiving results. **Problems that require completion of this form:** Transcriptional errors and reporting errors.

2. Document the investigation

a. **Documentation:** Document the ungraded (reported) result, and the expected result/range in the appropriate box. Determine if the non-graded result matches the expected result. If the expected result matches the reported result, no further action is required. Complete the remainder of the form if there is a discrepancy between the reported result and the expected result.

b. **Identification:** The laboratory must recognize that an error in testing has occurred. (Provide a complete yet concise description of the laboratory error, including lot #'s, expiration dates, etc, and attach documentation if necessary. Answer each question contained in the "Identification of Laboratory Problem" section.

c. **Investigation:** Describe the steps taken to identify the source of the error. If needed retest the sample or controls, review the procedure with the analyst, and retrain the analyst. Identify the root cause of the error or problem (i.e., clerical, technical, personnel, etc.).

c. **Prevention:** Describe the steps for corrective action taken by the laboratory to prevent recurrence of the error (i.e., personnel training/education, need for technical assistance, development of new policies/procedures, etc.). The laboratory must also identify a mechanism to establish an ongoing system to monitor that the action(s) taken have been effective in preventing recurrence of the original problem.

3. Review with staff: The completed CQI form must be reviewed with all staff involved with testing. This may be done as part of staff meetings. Include a statement in the minutes of the meeting that the CQI form was reviewed with staff. Have all staff involved with testing initial and date the completed form.

Acknowledgements:

1) **http://www.aab-pts.org/**
2) **http://resources.psmile.org/resources**
3) **Dan Leighton, (Dan@smartlabtools.com)**