< REPLACE WITH NAME OF LAB >
Continuous Quality Improvement:
Investigation of Ungraded Proficiency Testing

Name of PT Agency: _____ Analyte:_____

PT Set Identification	Date PT Set Received	Date of Testing

Ungraded (Reported) Result:	Expected Result / Range
Reason for non-grading ☐ Lack of Consensus ☐ Other	Did non-graded result = Expected Result? ☐ Yes – No further action required ☐ No – complete the rest of this form

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 retesting 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:

RESET FORMS

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	
☐ OTHER (SPECIFY):	☐ CALIBRATOR PROBLEM	☐ NO EXPLANATION AFTER INVESTIGATION
	☐ 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 Ungraded 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 ungraded. An investigation must be conducted to determine whether or not the expected result was obtained by the testing laboratory. No additional action is required if the reported result is the same as the expected result. 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.