

MLE Corrective Action Record

MLE Shipment: _____ MLE Specimen #: _____ Analyte: _____

Your Result: _____ Acceptable Range/Correct Answer: _____

Data Entry Error

- Clerical error by testing personnel when completing the test result form? Yes No

If yes, attach instrument printouts or other supporting documentation. Describe steps taken to prevent recurrence.

- Data processing error by MLE? Yes No

If yes, call MLE immediately upon receipt of your evaluation.

Describe incident below.

Specimen-Handling Error

- Did you handle the specimens properly? Yes No

Review the handling instructions in the test result form. If you did not follow the instructions in the test result form, describe the error and the steps you have taken to prevent recurrence.

Instrumentation or Test System Error

- Have you identified problems with your instrumentation or test system? Yes No

Describe any problems with your instrumentation or test system that resulted in this PT failure and/or incorrect patient testing. State what you have done to correct the situation and to prevent recurrence.

Procedure and Interpretation Error

- Did you follow each step in the MLE Test Result Form specimen instructions? Yes No

- Did you follow each step in your procedure manual/package insert? Yes No

Review the instructions and your test procedure thoroughly. Make sure that you performed all steps exactly as written. Make sure that there were no special procedures for specimen preparation and handling. Describe any handling, technique, and/or procedural errors.

- Did you incorrectly identify a cell or microorganism? Yes No

Review technical critiques in MLE's Participant Summary, and/or textbooks or other literature.

Refer to pages 56-57 of this guide for recommended texts. Describe any educational review or additional training performed.

Quality System Assessment

- Did the reason for the error affect patient results? Yes No

If yes, identify volume of patient results affected and follow-up action taken.

Testing Personnel Signature _____

Date _____

Laboratory Director
Signature _____