LeadCare[®] II

Key Tips to Success with Blood Lead Proficiency Testing (PT)

Skills Review Checklist

- 1. Proper handling of the PT samples upon receipt.
 - Read the storage and handling instructions. Follow the PT program's recommendations.
 - Retain copies of all PT paperwork, including attestation forms, worksheets, result forms submitted to the PT provider (paper or electronic), and the instructions that came from the PT provider.
- 2. Sample integrity
 - Were PT samples received in satisfactory condition?
 - Do NOT test samples that have leaked during shipment.
 - Do NOT test samples that show signs of product deterioration.
 - Do NOT test samples that have clots present.
- 3. Technique related concerns include:
 - Proper filling of capillary tubes. The accuracy of the test system depends on an accurate fill volume of 50 µL.
 - Be sure to wipe off any excess sample on the outside of the capillary tube.
 - Make sure that there are no clots or air bubbles in the capillary tube.
 - o Always mix the sample with treatment reagent.
 - o Invert the sample/treatment reagent mixture thoroughly before placing onto the sensor.
- 4. <u>Special note for CLIA-Waived laboratories</u>: **Patient samples** with blood lead levels greater than or equal to 5 µg/dL should be confirmed with a venous sample by a reference laboratory. **Proficiency samples** with blood lead levels greater than or equal to 5 µg/dL should <u>not</u> be confirmed by a reference laboratory. Simply report the results generated for each sample on the proficiency reporting form. If you have questions about proficiency, please call LeadCare Product Support at 800-275-0101 or email LeadCareSupport@magellandx.com.

Investigating a PT Failure

Check for the following:

- 1. Clerical errors
 - Transcription error, correct method code, correct units of measure, decimal place.
 - Forgetting to enter the results online and approving them after entry.
 - Did you submit by the due date?



LeadCare[®] II

Key Tips to Success with Blood Lead Proficiency Testing (PT)

- Reread the instruction sheets that came with the PT samples (e.g. storage/handling/testing sequence/dilution, etc.) to eliminate or confirm pre-analytical mistakes. Compare the PT report with your answer sheet to check for PT program clerical errors. PT programs make mistakes too! Contact provider immediately for a corrected report.
- 2. Sample integrity
 - Does the sample look appropriate for testing? (no clots present, at proper temperature)
 - Does the sample matrix have anything to do with the failure?
- 3. Procedural errors
 - Capillary collection technique: follow all instructions in the package insert or quick reference guide.
 - Is the analyzer calibrated to the lot number in use?
 - Was the sample added to treatment reagent prior to testing?
 - Use lead-free testing supplies. Are the supplies certified lead-free?
 - Cleanliness: are the benches cleaned each day of testing to limit the possibility of environmental contamination?
- 4. Analytical errors
 - Is a trend or bias noted?
 - Did you review Quality Control to see if it was within range?
 - Check to see if there is any remaining PT sample. If so, perform repeat testing. If the failure is reproduced, reach out to the manufacturer for assistance.

Corrective Measures to Consider Once You Have Determined Root Cause

- 1. Determine if PT failure indicates problems with technical competency of personnel performing the testing. Retrain staff and document the retraining for clerical errors, sample integrity, and procedural issues. Make sure all testing personnel are trained to the instructions for use.
- 2. Keep an action log to document any problems prior to or immediately after running PT samples.
- 3. Consider annual retraining to review key elements to success.
- 4. Perform calibration verification and/or validate your system's performance. Determine if patient samples need to be retested.

