LeadCare[®] II

Blood Lead Proficiency Testing Overview

Proficiency Testing (PT) enrollment is generally optional for waived testing. However, performing PT can be a great way for a lab to monitor their system's performance and quality of test results. Verify the status of your LeadCare II System with your state's CLIA office to determine whether or not your state recognizes waiver.

1. Choose a Blood Lead (BL) Proficiency Testing (PT) Program:

- a. Accredited, Blood Lead PT programs include (these and others):
 - <u>Wisconsin State Laboratory of Hygiene (WSLH)</u>
 - <u>The College of American Pathologists (CAP)</u>
- b. Some states mandate participation in state run BL PT programs:
 - Pennsylvania State Department of Health
 - All laboratories licensed in Pennsylvania are required to participate in PA's Blood Lead PT Program.

2. Decide on the type of program suiting your lab's needs:

- a. Regulatory Programs: As required by your lab license; 5 samples, 3 times per year
 - The results are reported to your lab's regulatory agency.
- b. Quality Assurance Programs: FYI programs; 3 samples, 2 times per year
 - The results are sent to your lab for QA review.
 - Note: Some states (NJ/OH) ask you to submit your QA evaluations for compliance.

3. Retain all PT Enrollment Confirmation Information:

- a. Post the shipping schedule and review it with your staff to set expectations.
- b. Keep contact information in an accessible location known to all staff involved with testing.
- c. Frequently refer to the shipping schedule to ensure that:
 - Someone will be available to perform the testing within the required time limit.
 - Sufficient in-date test supplies and reagents will be available upon receipt of PT samples.
 - The expected samples arrive on-time. If not, investigate why with the supplier.

LeadCare[®] II

Blood Lead Proficiency Testing Overview

4. When the Package Arrives:

- a. Document the date of receipt and open the package immediately.
- b. Check for damage and/or completeness of samples and forms.
 - If a problem is noted that will suspend your PT testing and delay reporting until after the due date, contact the PT program immediately. They will advise you on how to proceed.
- c. Read storage information immediately and store samples as directed, or proceed with testing.

5. On the Day of Testing:

- a. Handle the PT samples as if they are true patient samples.
- b. Allow samples to come to room temperature before testing. Make sure you are testing the samples in the proper order and confirm that the sample ID matches the sample ID listed on the reporting form.
- c. Inspect the sample integrity. Do not test samples with visible clots present. Contact the supplier immediately if sample integrity is compromised.
- d. Record your blood lead result being mindful of your instrument's reportable range.
- e. Keep the samples on hand until you receive your score. Once you have a passing grade, consider storing the samples frozen for up to 12 months. These samples may be valuable in the future for any troubleshooting.

6. Reporting PT Results:

a. Follow the supplier's instructions for reporting results above or below the reportable range of the test system.

(i.e., use of > or < symbols and when to use or not use decimal places).

- b. Submit your results before the scheduled due date.
- c. Print/Save a copy of your data submission report for a minimum of 2 years.

7. Upon Receipt of Your Score:

- a. Review the entire report (evaluation, event notes and statistics) carefully noting the following:
 - Scores less than 100%.
 - "No Results Received" message.
- b. Investigate and document corrective actions taken on scores less than 100%.
- c. Perform a self-evaluation of ungraded results (e.g., "Not scored" or "Non consensus").

