

# Product Bulletin

## Proficiency Testing with the LeadCare® Technology

# LeadCare® II

### What is Proficiency Testing?

Proficiency testing is an excellent way to monitor the quality of results generated by laboratories throughout the country.

Proficiency programs typically have 3 surveys per year. For each survey, the proficiency test sponsor sends 5 blood samples to each participating laboratory. Each lab is responsible for analyzing the 5 samples and reporting the results back to the proficiency test sponsor. Proficiency is determined based upon the accuracy of the individual laboratory's results compared to the other participating labs.

Several blood lead proficiency testing programs are available. However, it must be noted that proficiency programs use processed, non-human blood. Many test systems, including the LeadCare technology, are sensitive to the difference between fresh human blood and blood lead proficiency samples. This is referred to as a matrix effect.

### LeadCare Technology – Matrix Effect

The LeadCare and LeadCare® II Systems are designed and calibrated for the analysis of fresh human blood, this being reflective of true patient samples. The methodology is sensitive to differences between fresh human blood and other forms of blood, including frozen and thawed, often used for controls or proficiency samples. We refer to this sensitivity as a "matrix effect."

The matrix effect has 3 characteristics:

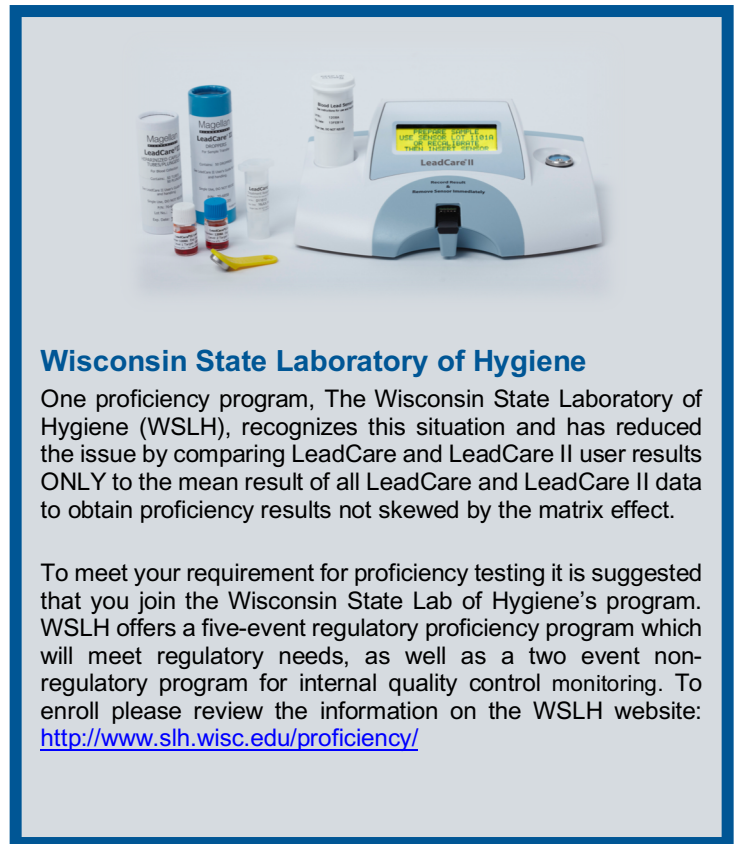
- The LeadCare or LeadCare II test value will tend to be slightly higher than the reference method value used for comparison in proficiency testing.
- It is more apparent on test samples with higher lead concentrations.
- It is not present with fresh, whole blood.

Typically, the results from all laboratories who participate in a proficiency testing program are pooled together, regardless of the testing methodology utilized. The results of each individual laboratory are then compared to the mean value for each sample. This type of comparison does not account for the matrix effect.

The matrix effect generally is visible when testing proficiency samples with a target value greater than 25 µg/dL.

It is important to note the matrix effect **does not apply to patient samples** tested with the LeadCare or LeadCare II technology as these systems are calibrated for accurate analysis of fresh, whole blood samples.

For more information about proficiency testing with LeadCare II, visit <http://www.leadcare2.com/Product-Support>.



### Wisconsin State Laboratory of Hygiene

One proficiency program, The Wisconsin State Laboratory of Hygiene (WSLH), recognizes this situation and has reduced the issue by comparing LeadCare and LeadCare II user results ONLY to the mean result of all LeadCare and LeadCare II data to obtain proficiency results not skewed by the matrix effect.

To meet your requirement for proficiency testing it is suggested that you join the Wisconsin State Lab of Hygiene's program. WSLH offers a five-event regulatory proficiency program which will meet regulatory needs, as well as a two event non-regulatory program for internal quality control monitoring. To enroll please review the information on the WSLH website: <http://www.slh.wisc.edu/proficiency/>

### Blood Lead Proficiency Programs

#### Wisconsin State Laboratory of Hygiene (WSLH)

To sign up, call (800) 462-6252.

#### College of American Pathologist (CAP)

To sign up, call (800) 323-4040 or go to [www.cap.org](http://www.cap.org).

#### American Proficiency Institute (API)

To sign up, call (800) 333-0958 or go to [www.api-pt.com](http://www.api-pt.com).

**Pennsylvania:** All laboratories in the state of Pennsylvania are required to participate in the Pennsylvania State Department of Health Blood Lead Proficiency Testing Program. To sign up, call (610) 280-3464.

