A Novel Rapid and Flexible Blood Lead Testing System
LeadCare Ultra® Versus the Reference Method

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Background

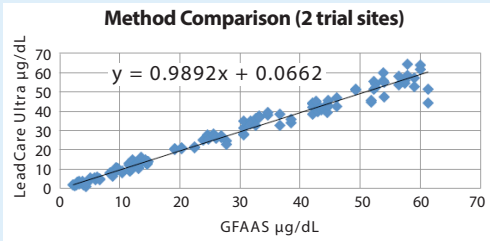
According to the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), over 500,000 U.S. children have elevated blood lead levels and 120 million people are exposed worldwide, the vast majority in developing countries. Even low levels of lead exposure cause neurological deficits, such as decreased cognitive performance and Attention Deficit Disorder, as well as adverse effects on the cardiovascular, renal and immune systems. Because most individuals have no overt clinical symptoms, the only way to determine exposure is through a blood lead test. In this study, we evaluated the performance of the LeadCare Ultra® System, a new blood lead testing system designed for use in the clinical laboratory.*

Method Comparison

Method comparison of the LeadCare Ultra® was conducted at two hospital laboratory sites. Samples collected in EDTA collection tubes were run in duplicate on Graphite Furnace Atomic Absorption Spectroscopy (GFAAS), the reference method, and the LeadCare Ultra System. One hundred forty eight (148) results within the claimed analytical range were generated.

The average of the two GFAAS results was plotted against the LeadCare Ultra result for each sample. The method comparison study produced a regression equation of $y = 0.9892x + 0.0662$, $R^2 = 0.977$.

LeadCare Ultra vs. GFAAS (avg)
(n = 148 data points)



Predicted Bias

The predicted bias was calculated using linear regression at the Limit of Quantification (LoQ) and eight (8) other points across the analytical range.

Predicted Bias
based on the regression equation
(n=148 data points)

GFAAS (µg/dL)	LeadCare Ultra (µg/dL)	Bias (µg/dL)	Bias (%)
1.9	1.95	0.05	2.4%
5	5.01	0.01	0.2%
10	9.96	-0.04	-0.4%
20	19.85	-0.15	-0.7%
30	29.74	-0.26	-0.9%
40	39.64	-0.36	-0.9%
50	49.53	-0.47	-0.9%
60	59.42	-0.58	-1.0%
65	64.37	-0.63	-1.0%

Precision

Precision of the LeadCare Ultra was performed using bovine blood standards at three lead concentrations. Eighty (80) data points were collected per concentration level over a twenty (20) day period. Samples were prepared two times per day and each sample was run in duplicate on alternating channels of the six-channel analyzer such that all channels were used equally during the study. Data from three separate lots of sensors are shown in the table below.

Precision Data

Level	Lot #	n	Avg. LeadCare Ultra Conc. (µg/dL)	Total SD (µg/dL)	Total % CV
1	1208A	80	4.8	0.34	7.10%
	1211B	80	4.2	0.58	13.60%
	1301A	80	4.6	0.53	11.60%
2	1208A	80	6.5	0.58	9.00%
	1211B	80	6.2	0.57	9.10%
	1301A	80	6.4	0.65	10.10%
3	1208A	80	60.8	2.53	4.20%
	1211B	80	62.0	4.22	6.80%
	1301A	80	63.4	2.53	4.00%

LoB, LoD, LoQ

Seventy (70) replicates of a near blank and low blood sample were analyzed over five days to establish the Limit of Blank (LoB) and Limit of Detection (LoD). Limit of Quantification (LoQ) was calculated using the Standard Deviation (SD) at the LoD and the average bias from multiple low samples using the Total Error Method.

Limit of Blank ..... 1.5 µg/dL
Limit of Detection ..... 1.9 µg/dL
Limit of Quantification ..... 1.9 µg/dL
Analytical Range ..... 1.9-65 µg/dL

Conclusion

The LeadCare Ultra System is an accurate and precise system for the quantification of lead in whole blood samples. The studies included in this evaluation demonstrate the clinical equivalence of LeadCare Ultra to established blood lead testing methods. Upon reviewing these results, the FDA cleared LeadCare Ultra as a quantitative blood lead testing system.

Magellan Diagnostics

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* LeadCare Ultra has been cleared by the U.S. Food and Drug Administration.