CPAL

Central **P**ennsylvania **A**lliance
Laboratory

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Blood Lead
- New Platform -

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Ordering Information and Suggested Codes:

Mnemonic:	Lead
Test Name:	Lead, Whole Blood
Test Number:	1750180
Specimen:	Whole Blood EDTA Room temp 26 days; 2-8°C 31 days
LOINC Codes	5671-3
CPT Codes	83655

Effective Date: Testing offered beginning on Thursday, June 29, 2017.

Performed: Monday and Thursday, dayshift

Reference Range:

Age	Previous Range	New Range
0 – 6	0 – 4 ug/dL	0 – 4 ug/dL
≥ 7	0 – 9 ug/dL	0 – 9 ug/dL

Background:

   Lead is a heavy metal commonly found in the environment. Lead is toxic and can cause neurological damage, especially among children, at any detectable level. Lead is associated with a wide range of toxicity in children across a very broad band of exposures, down to the lowest blood lead concentrations yet studied, both in animals and people. These toxic effects extend from acute, clinically obvious, symptomatic poisoning at high levels of exposure down to subclinical (but still very damaging) effects at lower levels. Lead poisoning can affect virtually every organ system in the body. The principal organs affected are the central and peripheral nervous system and the cardiovascular, gastrointestinal, renal, endocrine, immune, and hematological systems.

   Adults who are exposed to a dangerous amount of lead can experience anemia, nervous system dysfunction, weakness, hypertension, kidney problems, decreased fertility, an increased level of miscarriages, premature deliveries, and low birth weight of their child.

Principle of Test:

   The PinAAcle 900Z spectrometer from PerkinElmer is a compact, high performance atomic absorption spectrometer incorporating a burner system for flame atomization and/or a graphite furnace for electrothermal

atomization. The CPAL system incorporates the gas furnace only option. The spectrometer is capable of fully automatic single-element and sequential multielement analyses. The complete system is operated from the associated computer using the software.

Validation Data:
Precision:
Two levels of control were run ten times each, within the same run and on two different days. The %CVs fall within the Manufacturer's claim of ≤ 10.0% for both within run precision and between run precision. (Table 1)
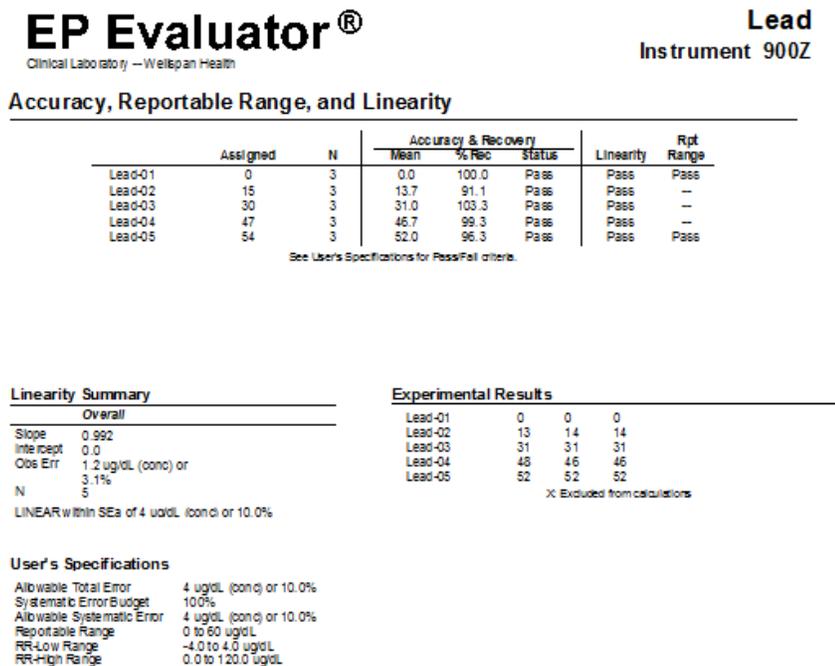
Table 1: Precision

Test	Within Run Precision				Between Run Precision				Accept
	Level 1 Mean	%CV	Level 3 Mean	%CV	Level 1 Mean	%CV	Level 3 Mean	%CV	
Lead	6.0	0.00	43.7	1.11	6.5	7.89	45	3.01	Yes

Linearity:
To verify the AMR and linearity of the assay, patient samples were run in triplicate. The results were entered into EP Evaluator. Please see the EP Evaluator results below (Figure 1). The calculated slope is 0.992 with an intercept of 0.0 and an observed error of 1.2 ug/dL or 3.1 %. The assay is linear within Allowable Systematic Error of 4 ug/dl or 10.0%. The linearity validation is acceptable and the AMR of the assay verified.

Figure 1: Linearity

EP Evaluator®
Clinical Laboratory – Wellspan Health

Lead
Instrument 900Z

Accuracy, Reportable Range, and Linearity

	Assigned	N	Accuracy & Recovery			Linearity	Rpt Range
			Mean	% Rec	Status		
Lead-01	0	3	0.0	100.0	Pass	Pass	Pass
Lead-02	15	3	13.7	91.1	Pass	Pass	--
Lead-03	30	3	31.0	103.3	Pass	Pass	--
Lead-04	47	3	46.7	99.3	Pass	Pass	--
Lead-05	54	3	52.0	96.3	Pass	Pass	Pass

See User's Specifications for Pass/Fail criteria.

Linearity Summary

	Overall
Slope	0.992
Intercept	0.0
Obs Err	1.2 ug/dL (conc) or 3.1%
N	5

LINEAR within SEa of 4 ug/dL (conc) or 10.0%

Experimental Results

Lead-01	0	0	0
Lead-02	13	14	14
Lead-03	31	31	31
Lead-04	48	46	46
Lead-05	52	52	52

X Excluded from calculations

User's Specifications

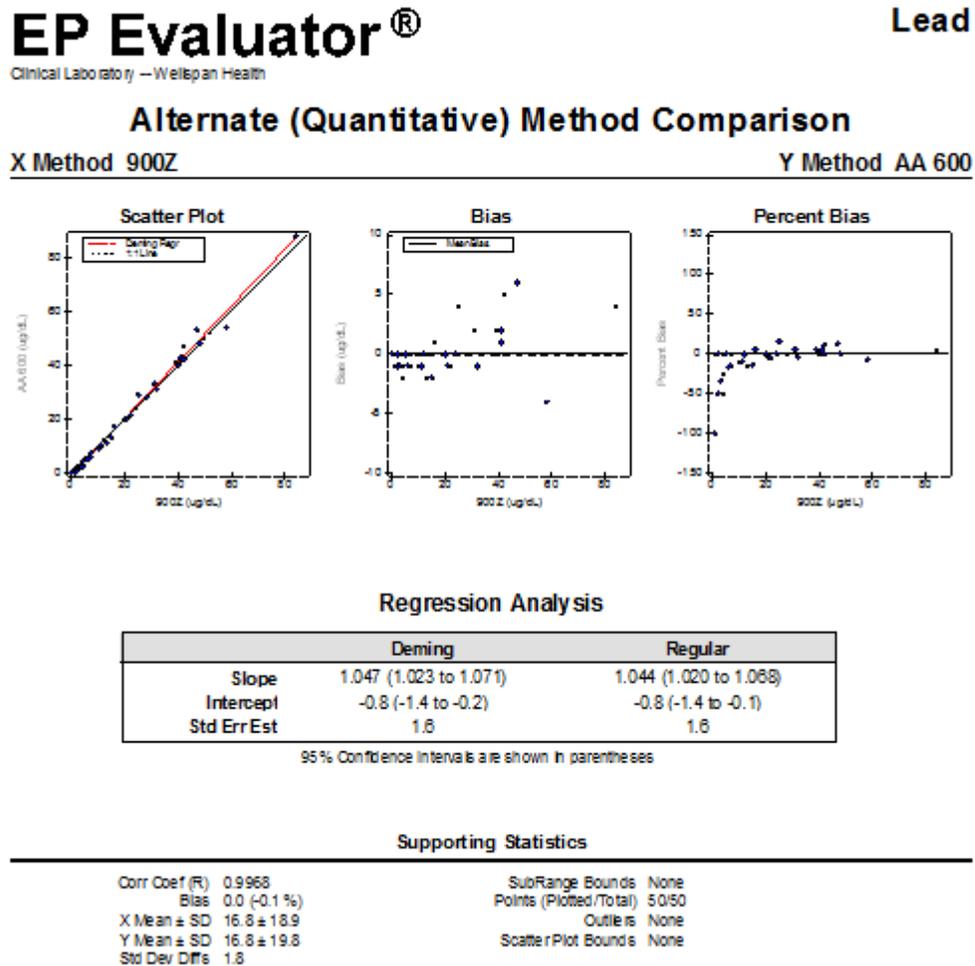| Allowable Total Error	4 ug/dL (conc) or 10.0%
Systematic Error Budget	100%
Allowable Systematic Error	4 ug/dL (conc) or 10.0%
Reportable Range	0 to 60 ug/dL
RR-Low Range	-4.0 to 4.0 ug/dL
RR-High Range	0.0 to 120.0 ug/dL

Method Comparison:

Fifty specimens were split and processed utilizing Perkin Elmer's AAnalyst 600 and Perkin Elmer's PinAAcle 900Z (Figure 2). Quantitative analysis yielded a correlation coefficient (R) of 0.9968 with a slope of 1.047 and an intercept of -0.8. Overall bias for AAnaylst 600 versus PinAAcle 900Z was -0.1%.

Figure 2: Method Comparison

EP Evaluator ®
Clinical Laboratory — Wellspan Health

Lead

Alternate (Quantitative) Method Comparison

X Method 900Z   Y Method AA 600

Regression Analysis

	Deming	Regular
Slope	1.047 (1.023 to 1.071)	1.044 (1.020 to 1.068)
Intercept	-0.8 (-1.4 to -0.2)	-0.8 (-1.4 to -0.1)
Std Err Est	1.6	1.6

95% Confidence Intervals are shown in parentheses

Supporting Statistics

Corr Coef (R)	0.9968	SubRange Bounds	None
Bias	0.0 (-0.1 %)	Points (Plotted/Total)	50/50
X Mean ± SD	16.8 ± 18.9	Outliers	None
Y Mean ± SD	16.8 ± 19.8	Scatter Plot Bounds	None
Std Dev Diffs	1.8		

References:
1. PinAAcle 900 Series IVD, Customer Hardware and Service Guide; PerkinElmer; Release C, July 2016.
2. CDC, Centers for Disease Control and Prevention, Childhood Lead Poisoning Prevention; 2012.