

BLOOD SPOT TEST SPECIFICATIONS

Lead

Clinical Information

Lead is a toxic heavy metal implicated in severe neurological defects in developing children. Exposure of the general population to high levels of environmental lead occurred due to its use as an additive in gasoline and paint. Since these products have been discontinued, overall lead exposure and levels have declined significantly. However, lead is still found in older plumbing systems and paint, and soil contaminated before its use was banned. Lead exposure is particularly dangerous in children, in whom it can negatively affect brain development and intelligence. Children are more susceptible than adults to lead exposure by oral ingestion of lead dust or lead-based paint, and gastrointestinal absorption of lead is also more efficient in children. Current CDC guidelines recommend that there is no safe level of lead exposure in children. High lead exposure can also reduce vitamin D and hemoglobin synthesis. Lead is taken up by red blood cells and binds to hemoglobin. Therefore, measurement in whole blood provides a more accurate assessment of lead exposure than urinary lead measurements, which are not clinically useful. Measurement of lead in dried blood spots by ICP-MS is a reliable and convenient method to assess lead exposure. The reference range for blood spot lead is $<2.50 \mu\text{g/dL}$.

References:

Timko DM, Stickle DF. Measurement of filter paper bloodspot lead by inductively coupled plasma-mass spectrometry (ICP-MS). *Methods Mol Biol.* 2010;603:327-38.

Tong S, von Schirmding YE, Prapamontol T. Environmental lead exposure: a public health problem of global dimensions. *Bull World Health Organ.* 2000;78:1068-77.

Schnur J, John RM. Childhood lead poisoning and the new Centers for Disease Control and Prevention guidelines for lead exposure. *J Am Assoc Nurse Pract.* 2014;26:238-47.

Assay Method: ICP-MS

Intra-assay Precision

Intra-assay precision was determined by choosing three samples spanning the reference range, and analyzing them 20 times within the same run. Results are shown below:

Mean Lead Concentration ($\mu\text{g/dL}$)	Standard Deviation	Coefficient of Variation (C.V. %)
0.70	0.05	6.9
1.85	0.07	4.0
17.31	0.93	5.4

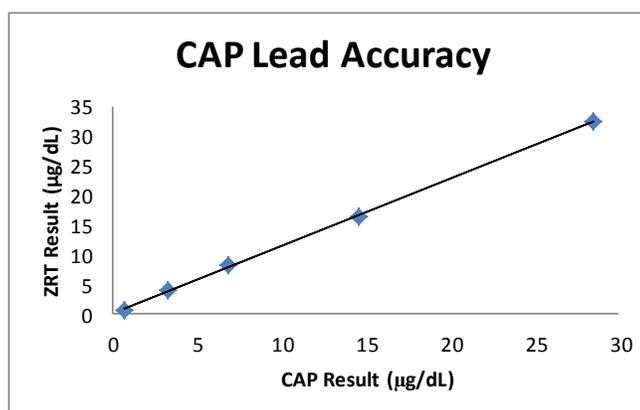
Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times throughout different runs over a 1-month period. Results are shown below:

Mean Lead Concentration ($\mu\text{g/dL}$)	Standard Deviation	Coefficient of Variation (C.V. %)
0.72	0.07	9.9
1.87	0.09	5.1
17.66	0.76	4.3

Accuracy

To test the accuracy of the dried blood spot assay for lead, proficiency samples from the College of American Pathologists (CAP) with known values for lead were spotted onto filter paper and analyzed, and the results plotted against the CAP values. Resulting correlation data are shown below ($R^2 = 1.0$):



Analyte Stability

The dried blood spot samples are stable for more than 1 month at room temperature.

Specimen Collection

Kits for blood spot collection contain a filter paper collection card, finger lancets, an alcohol prep pad, sterile gauze, a band-aid, easy-to-follow instructions, and a mailer to return the sample for analysis.