

Summary of Tamarac Medical Filter Paper Quantitative Blood Lead Test Characteristics

1. Documented accuracy. The correlation between paired, simultaneously drawn extraction method filter paper and venous samples is $>.970$. Additionally, undetected-elevated and, falsely-elevated rates may be considered clinically insignificant. These findings are documented by three published, peer-reviewed studies involving 363 paired, simultaneously drawn extraction method filter paper and venous sample comparisons.

References:

Hugh Y. Yee et al. Capillary Blood Collection by Paper for Lead Analysis by Graphite Furnace Atomic Absorption Spectrometry. Microchemical Journal, 52: 370-375 (1995).

Keyrati Srivuthana et al. A New Filter Paper Method to Measure Capillary Blood Lead Level in Children. Arch. Pediatr. Adolesc. Med., 150: 498-502 (1996).

Hugh Y. Yee. An Improved Capillary Blood-Filter Paper-Graphite Furnace Atomic Absorption Spectrometric Method For Lead Screening. Journal of Analytical Toxicology, Vol. 21: 142-148 (1997).

2. Proprietary stick site cleansing and prep products. A significant threat to the accuracy of any capillary blood lead test is pre-analytic contamination caused by residual skin-surface lead being incorporated into the specimen during collection, and, thereby, causing a falsely-elevated result. D-Lead® Soap, D-Lead® Dry or Wet Skin Cleaner and D-Wipe® Towels have demonstrated substantial efficacy in removing lead from the skin. Use of these products for stick site cleansing and preparation may provide protection against falsely-elevated results. These products are provided by Tamarac Medical, Inc. at no additional charge, and their use is MANDATORY with The Tamarac Test. Esca Tech, Inc. has, by a technology license agreement, granted to Tamarac Medical, Inc. exclusive use rights for the use of D-Lead® Soap, D-Lead® Dry or Wet Skin Cleaner, and D-Wipe® Towels in conjunction with capillary blood lead or other heavy metals testing of infants, children and pregnant or lactating women in the United States.

3. Acceptance by the Centers For Disease Control And Prevention. CDC acceptance requires participation in the CDC Filter Paper Proficiency Testing Program, which is administered by the Wisconsin State Laboratory of Hygiene. Tamarac Medical successfully participates in this program.

4. Minimal sample size requirement. The Tamarac Medical Filter Paper Quantitative Blood Lead Test requires only two drops of fingerstick, earstick, or heelstick blood, the smallest amount of any methodology. This is important in pediatric use where collection of larger capillary or venous samples is frequently difficult or impossible.

5. High compatibility with simultaneous hemoglobin testing. CMS requires both lead and hemoglobin testing for Medicaid EPSDT physicals. Hemoglobin is typically measured with a HemoCue® or similar instrument which requires that the first two drops of blood from the stick site be discarded. When The Tamarac Medical Filter Paper Quantitative Blood Lead Test is used in conjunction with the HemoCue® instrument, or other single-drop hemoglobin instrument, the first two drops from the stick site are used for the lead test, with the third drop used for hemoglobin measurement. As a result, both mandated EPSDT blood tests can be performed with a total of only 3 drops of blood from the same stick site. This is the same amount of blood that would be required if hemoglobin testing was done alone.

6. Samples can be collected quickly and easily. Filter paper samples are significantly faster and easier to collect than capillary tube samples. When compared to venous collection the difference in ease of collection is even more dramatic.

7. Minimal clinical expertise is required for sample collection. With minimal training, virtually anyone is capable of collecting an acceptable filter paper sample.

8. Sample stability and handling. Once a blood sample has dried on the filter paper, it is stable at room temperature for at least 6 months. Filter paper samples require no special handling or refrigeration. They can be sent to the laboratory by mail or any other carrier with no bio-hazard warning.

9. Reduced patient trauma. Since the sample collection procedure is minimally invasive, and can be performed quickly, little patient trauma is normally experienced. Further reduction in discomfort can be expected when the earlobe is used as the stick site.

10. Economy. Tamarac Medical bills Medicaid and CHIP directly and accepts the allowable amount. We also bill private health insurance directly. There is no charge to the submitter for publicly or privately insured patients. For self-pay/uninsured patients, we bill the submitter \$10.00 per specimen submitted.

11. We provide a complete collection kit for each test at no charge. Each kit contains all supplies needed to collect and submit a sample:

- * Collection instructions
- * D-Lead® Soap (4 oz. bottles) or D-Lead® Dry or Wet Skin Cleaner (8 oz. bottles) and D-Wipe® Towels (40 ct. canisters) for stick site prep (U.S. patent application pending)
- * Alcohol wipe
- * Gauze pad
- * Sealed, sterile, OSHA approved retractable lancet
- * Tamarac Medical filter paper in a sealed and re-sealable plastic bag
- * Latex-free adhesive bandage
- * Paper Towel
- * Blood Lead Test Request Form
- * Prepaid mailing envelope
- * Preprinted “peel-and-stick” ID/return address label

12. Rapid turn-around time and complete reporting. Samples are normally analyzed within one business day of receipt by the laboratory. If the first of the two required samples yields an elevated result, an additional 24 hours is required for confirmatory duplicate analysis of the second sample. Elevated results are phoned or faxed to the ordering office immediately. Results for all tests can be provided by fax, mailed hard copy or downloaded from a secure website. Test results are provided to the state department of health per their requirements.

TO ORDER A SUPPLY OF FREE TAMARAC TEST KITS, AND D-LEAD® AND D-WIPE® STICK SITE CLEANSING AND PREPARATION PRODUCTS CALL TOLL FREE 1-800-842-7069

FOR ADDITIONAL INFORMATION ON THE TAMARAC MEDICAL FILTER PAPER QUANTITATIVE BLOOD LEAD TEST CONTACT:

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