



TAMARAC

M E D I C A L

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75

12,000

Documentation is available,
on request, for all statements
made in this presentation

Tamarac® is a specialty
laboratory

Our area of concentration is
quantitative blood lead
analysis

Laboratory/Corporate Office
Centennial, CO

Eastern Office
Collinsville, MS

CLIA-licensed, OSHA-listed

Tamarac® successfully participates in all required Proficiency Testing Programs

- Including CDC/WSLH filter paper specific PT program

Tamarac® performs all 3 CDC-accepted laboratory methodologies

- Whole venous blood
- Whole capillary blood
- Dry blood on filter paper

Primary focus:
Filter paper quantitative blood
lead analysis

Tamarac® developed a methodology for filter paper QBLA in 1995, and began providing commercial filter paper analysis in the same year

To the best of our knowledge,
Tamarac® has performed
filter paper QBLA longer than
any other laboratory in the US

To the best of our knowledge,
Tamarac® has performed
more filter paper blood lead
tests than any laboratory in
the US

Tamarac® Filter Paper
Quantitative Blood Lead Test
Characteristics

> .97 correlation with venous
analysis

- Based upon paired, simultaneously-drawn specimens in 3 published, peer-reviewed studies

< 2 Falsely-Elevated results per 1000 samples analyzed

- Based on Ohio Department of Health data from approximately 24,000 Waterless Tamarac® Test specimens collected in WIC clinics

Confirmation rate for elevated results is approximately double that for capillary tests utilizing standard prep protocols

- Comparison based on published studies and state reports from Indiana, Minnesota, Maine, Massachusetts and Rhode Island
- Based on Ohio Department of Health data from approximately 24,000 Waterless Tamarac® Test specimens collected in WIC clinics

Proprietary stick-site cleansing and de-leading protocols

- All capillary blood lead tests are subject to falsely-elevated results
- Tamarac® has developed methodologies that have proven effective in significantly reducing the incidence of FE results

Esca Tech has been producing industrial heavy metal cleaning products for over 20 years.

Products are utilized by companies in the lead industry world-wide

The logo for Esca Tech, Inc. features the company name in a large, bold, yellow, 3D-style font with a black outline. The text is set against a white background that is framed by a thick, yellow, oval-shaped border. The border has a slight gradient and a shadow effect, giving it a sense of depth.

ESCA TECH, INC.

**Contamination Control Systems,
Services & Solutions**

License Agreement grants Tamarac® exclusive use of certain Esca Tech products for use in conjunction with capillary blood lead testing of infants, children, pregnant women and lactating women in the US

- Protocols were developed by Tamarac® Medical
- Esca Tech products are technology-licensed to Tamarac® Medical
- US Patent application has been filed

Two stick-site cleansing and
de-leading protocol options
available

When hand-washing is preferred, the Standard Protocol utilizes D-Lead® Skin Cleanser and a D-Wipe® Towel for stick-site cleansing and de-leading

- Replaces conventional soap-and-water hand washing

When stick-site only cleansing is advantageous, the Waterless Protocol utilizes D-Lead® Wipe or Rinse Skin Cleaner and a D-Wipe® Towel for stick-site cleansing and de-leading

Waterless specimen collection

- Documented high accuracy
- Running water not required
- Makes specimen collection possible virtually anywhere
- Saves time
- Optimal for WIC use, health fairs, house to house screening

2-drop sample requirement – half that of capillary tube collection

- Smallest specimen of any laboratory methodology
- Reduces incidence of QNS specimens
- Smaller sample size makes collection of an adequate sample faster, more convenient and less traumatic

Lead and hemoglobin from 3 drops of blood

- Fully compatible for simultaneous lead and hemoglobin testing with HemoCue, HemoPoint or other single drop instrument
- Allows both EPSDT-mandated blood tests to be performed with a single fingerstick
- Saves providers time
- Saves children from a second stick
- Makes blood lead testing practical in WIC

Filter paper samples are stable without refrigeration for a minimum of 6 months

- No refrigeration required
- No expedited shipping required
- Facilitates specimen collection in remote areas
- Expands possible sample collection locations

Samples sent through mail with no external bio-hazard label required

- Each kit contains prepaid, self-addressed envelope to return specimen to the lab
- No need for extensive packaging
- Makes shipping convenient

Comprehensive specimen collection kit and de-leading products provided at no charge

- Each kit contains all required supplies
- Makes specimen collection faster and easier
- No need to locate and assemble supplies
- No need for providers to purchase supplies
- De-leading products provided for each collection

Samples normally analyzed within 2 business days of receipt

- Results $\geq 5\mu\text{g/dL}$ are reported to submitter immediately by phone or fax
- All results provided by secure web download, fax or mail

Test results reported per state DOH requirements

- Tamarac® reports test results to state departments of health
- We are frequently able to accommodate special reporting requests from state departments of health

Tamarac® background and qualifications

To the best of our knowledge,
Tamarac® holds, or has held
all state department of health
filter paper blood lead testing
contracts available to private
labs

Tamarac® was selected as
the laboratory for all state
WIC filter paper pilot
programs conducted to this
date

Tamarac® has been awarded
all state WIC filter paper blood
lead testing contracts to this
date

Use of The Tamarac® Test in states adjacent to Texas

Louisiana

- Tamarac® has been performing all Louisiana Department of Health and Hospitals pediatric blood lead testing since 2006
- Tamarac® performs 40 to 50% of all Louisiana pediatric blood lead testing

Oklahoma

- Tamarac® has been performing all Oklahoma Department of Health pediatric blood lead testing since 2002
- Tamarac® performs approximately 30% of total Oklahoma pediatric blood lead testing

So why is The Tamarac® Test
virtually unheard of in Texas?

Pediatric blood lead testing is Medicaid-centered

- The vast majority of pediatric blood lead tests are billed to Medicaid
- It's impractical for Tamarac® to offer services in a state where Medicaid billing is not possible

Under current regulations all
Texas Health Steps first
(screening) laboratory blood
lead tests are required to be
submitted to the Texas DSHS
laboratory

Why Texas may want to
reconsider this requirement

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Currently, 75% of all Texas elevated capillary blood lead results are determined to be falsely-elevated

- The highest state-wide FE % we have observed nationally
- Significant negative implications for all parties involved

2011 Texas DSHS Data

- 1701 capillary results $\geq 10\mu\text{g/dL}$
- 990 received a confirmatory venous test
- 249 (25.15%) capillary results were confirmed $\geq 10\mu\text{g/dL}$
- 741 (74.84%) capillary results were not confirmed $\geq 10\mu\text{g/dL}$

Based upon an analysis of 24,000 Waterless Tamarac® Tests, the expected falsely-elevated rate is between 23.4% and 31.25%

- Source: Ohio Department of Health Surveillance data
- Specimens collected in Ohio WIC clinics

When all specimens
submitted are considered, the
Tamarac® Test FE rate is
31.25%

However: Two clinics that submitted only 6.5% of total specimens, submitted 51.11% of total FE specimens

- Reason to believe that these clinics were not using the Tamarac® protocol properly, if at all

When results from these two clinics are removed from the data, the FE rate is 23.40%

Nearly opposite numbers

- Texas state-wide

25.15% confirmed

74.84% falsely elevated

- Tamarac

76.60% confirmed

23.40% falsely elevated

Why do FE percentages for Texas and Tamarac® vary by such a wide margin?

The primary cause of falsely-elevated results is pre-analytic specimen contamination by residual skin-surface lead

- Lead from the skin surface becomes incorporated into the specimen during collection
- Instead of measuring lead in the blood, the laboratory analysis measures lead in the blood PLUS lead picked up from the skin surface

The high incidence of FE
results in Texas is not a
reflection on laboratory
analysis

It is a reflection on specimen
collection

With minor exceptions, the
Tamarac® stick-site prep
protocol is currently
unavailable in Texas

Virtually all Texas specimens are collected after the patient's hands are washed with soap and water

- An electrostatic bond exists between lead and skin
- Washing hands with soap and water is largely ineffective in removing lead from the skin
- Typical soaps, such as Ivory Liquid remove only approximately 72% of lead
- 28% of lead remains on the skin surface, and is available for specimen contamination

Tamarac® Stick-Site Cleansing and De-Leading Protocols

- Standard --- D-Lead® Skin Cleanser, D-Wipe® Towel, alcohol wipe
- Waterless – D-Lead® Wipe or Rinse Skin Cleaner, D-Wipe® Towel, alcohol wipe

D-Lead® Skin Cleanser
removes 99.87% of lead from
the skin



D-Lead® Wipe or Rinse Skin Cleaner removes 99.63% of lead from the skin



D-Wipe® Towel removes 98.82% of lead from the skin



Each Tamarac® prep protocol
uses **TWO** of these products
prior to an alcohol wipe

Less lead remaining on the skin results in a reduced possibility of specimen contamination and subsequent FE results

Comparison:
75% current TX FE rate
vs
23.4%-31.25% Tamarac®
Waterless FE rate

The 5 μ g/dL reference level
will magnify the significance
and implications of FE results

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From 2010 Texas data:
15,552 children had a BLL \geq 5
 $\mu\text{g/dL}$.

At a FE percentage at the
current FE rate of 74.84%,
there would be 11639 FE
results

Nearly 12,000 FE results per
year will:

Place a major burden on public health

- Significant staff time and energy will be required to assure unnecessary confirmatory testing of nearly 12,000 children
- May require resources that are not available

Place a major burden on Texas healthcare providers

- Each unnecessary confirmatory test adds to the workload of a practice

Place a major burden on Texas Medicaid

- Medicaid will pay for unnecessary confirmatory venous tests, patient transportation and other costs

Place a major burden on parents

- Nearly 12,000 parents will be needlessly concerned about their child's health
- Each of these parents will be unnecessarily inconvenienced by taking their child to a provider for a confirmatory venous test

Place a major burden on children

- Nearly 12,000 children will needlessly undergo the trauma of a venous collection

Additional reasons to consider
The Tamarac® Test for Texas
Health Steps

Opens the possibility of blood lead testing in WIC

- WIC testing offers the most significant, and most practical, opportunity to rapidly increase Medicaid and overall screening rates
- Significant overlap of Medicaid and WIC populations
- Blood lead testing in WIC has demonstrated a 24% increase in Medicaid screening rates
- Whole blood specimen collection is not practical in the WIC environment

Opens the possibility of blood lead testing in WIC

- Filter paper specimen collection utilizes blood that is currently discarded when hemoglobin testing is performed
- It takes no more blood to do lead and hemoglobin than it does to do hemoglobin alone
- The Tamarac® Waterless Protocol was developed for WIC use
- Blood lead specimen collection adds only 3 to 5 minutes to the certification/recertification protocol

Use of The Tamarac® Test
has been shown to increase
state-wide screening rates

Mississippi results: 114.5% increase in 2.5 years

- When the Mississippi State Department of Health switched from capillary tube collection and analysis in all public health clinics to The Tamarac® Test, state-wide screening numbers increased by nearly 115% in less than two and a half years

Kansas results: 150% increase in 2 years

- When the Kansas Department of Health and Environment switched from capillary tube collection and analysis in all public health clinics to The Tamarac® Test, state-wide screening numbers increased by 150% in two years

Increased provider compliance

- The faster and easier it is to collect and submit a specimen, the more likely it is that the sample will be collected and submitted
- We believe that The Tamarac® Test is the most provider-friendly blood lead test available

We suggest that making The Tamarac® Test available to Texas Health Steps providers would have significant positive implications for Texas and Texans:

1. A major reduction in the incidence of falsely-elevated capillary blood lead test results

2. A probable increase in
statewide blood lead testing
rates

3. A probable increase in provider compliance with EPSDT blood lead testing requirements

4. A significant reduction in Medicaid blood lead testing expenditures

5. A realistic opportunity to expand blood lead testing into the Texas WIC population

6. And, most importantly, a significant reduction in the number of children who must needlessly undergo the trauma of a venous collection

For questions, requests and additional information please contact:

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