MINUTES

DATE: March 27, 2013
TIME: 10:00AM – 12:00PM
LOCATION: DSHS, via Webinar

Strategic Planning Committee to Eliminate Childhood Lead Poisoning

MEETING CALLED BY: Texas Childhood Lead Poisoning Prevention Program (TXCLPPP)
TYPE OF MEETING: Strategic Planning Committee (SPC) Webinar
FACILITATOR: Patrick Bloomingdale
ATTENDEES: SPC Roll Call (see page 4)

OLD BUSINESS

APPROVE FEBRUARY 27, 2013 MEETING MINUTES by Cristina Baker

DISCUSSION
TXCLPPP asked the SPC to vote “Yes” or “No” to approve the February 27, 2013 meeting minutes.

CONCLUSION
SPC - Unanimously voted “Yes” to approve the February 27, 2013 meeting minutes.

PB-109: REFERENCE FOR FOLLOW-UP BLOOD LEAD TESTING AND MEDICAL CASE MANAGEMENT by Cristina Baker

TOPIC/ITEM 1 January 30, 2013 Revisions and Options 1, 2, 3 (see pages 7-8)

DISCUSSION
• January 20, 2013 SPC Meeting - Majority voted “Yes” to accept revisions.
• February 27, 2013 SPC Meeting - SPC members voted to stop the process and make additional changes.
  o Based on the SPC suggested revisions, TXCLPPP created 3 draft Pb-109 options and emailed the SPC so they can vote via email.
• There wasn’t a majority consensus on which option to accept. TXCLPPP asked for a recall during the March 27, 2013 SPC Meeting.

CONCLUSION
Tabled until vote in Topic/Item #3

TOPIC/ITEM 2 Reviewed March 27, 2013 Revision - Option 4 (see pages 8-9)

DISCUSSION
An SPC member emailed TXCLPPP a fourth option after the 02/27/2013 meeting. TXCLPPP formulated the sample Pb-109 and presented it to the SPC. Dr. Hanfling provided a rationale for the suggested changes in the testing schedule.

CONCLUSION
A majority of SPC members voted against accepting Option 4. TXCLPPP asked SPC member to vote regarding Options 1, 2, & 3.

TOPIC/ITEM 3 SPC Voting & Recommendations

DISCUSSION
TXCLPPP asked the SPC to vote on which option to accept.

CONCLUSION
• SPC - Majority voted “Yes” to accept Option 2 (see page 10).
• The revisions to the Pb-109 will become effective on June 1, 2013.
• TXCLPPP will submit the revision to Texas Health Steps to be included in the Texas Medicaid Providers’ Procedures Manual, Child Handbook.
### NEW BUSINESS

#### THE USE OF THE TAMARAC TEST FOR TEXAS HEALTH STEPS

**By Ken Kahle[^1],
Tamarac Medical**

<table>
<thead>
<tr>
<th>PRESENTATION</th>
<th>Questions(Q) &amp; Answers(A) Generated from Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q. What is the relative cost?</td>
<td>A. There is no cost for the provider. Tamarac bills Medicaid directly and accepts the allowable billable amount. For self-pay the kit and analysis is $10.00.</td>
</tr>
<tr>
<td>Q. How does Tamarac get providers to comply with their process?</td>
<td>A. Tamarac cautions providers that the test is only as good as their ability to follow protocol.</td>
</tr>
<tr>
<td>Q. How does Tamarac provide training to ensure they are following the proper protocol?</td>
<td>A. Tamarac provides a training program using a PowerPoint presentation.</td>
</tr>
<tr>
<td>Q. Who performed the studies done on the filter paper?</td>
<td>A. Tamarac provided SPC with a paper that contained a list of studies (see pages 40-41).</td>
</tr>
<tr>
<td>Q. How does Tamarac interchange data?</td>
<td>A. Tamarac interchanges data using HL7, excel spreadsheet, secure servers, https://, and secure download from their website.</td>
</tr>
<tr>
<td>Q. What is the accuracy of results? +/- 4? +/- 2</td>
<td>A. Proficiency testing programs Tamarac participated in indicated an accuracy of +/-4, but internal tracking done by Tamarac is closer to +/- 2.</td>
</tr>
<tr>
<td>Q. How are collection kits shipped to providers?</td>
<td>A. The collection kits are shipped via FedEx Ground. The provider requests the kits via phone or fax.</td>
</tr>
<tr>
<td>Q. Do the collection kits have an expiration date?</td>
<td>A. No. The only thing that might dry out are the D-Wipes inside of the container. Tamarac also provides D-Wipe individual towels that will not dry out.</td>
</tr>
<tr>
<td>Q. What is the potential for contamination of the specimen?</td>
<td>A. The kit provides a zip lock back to prevent contamination.</td>
</tr>
</tbody>
</table>

[^1]: Ken Kahle, Director of Extra-Laboratory Affairs for Tamarac Medical, is a current SPC member.
<table>
<thead>
<tr>
<th>TOPIC/ITEM 1</th>
<th>Determine when to test children who resides in a Targeted Area (see page 43)</th>
</tr>
</thead>
</table>
| DISCUSSION | If child lives in a Targeted Area, then administer a venous or capillary blood lead test:  
°CURRENT SCHEDULE:  
• Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years  
PROPOSED SCHEDULE:  
• Age 6, 12, and 24 months; and ages 3 and 4 years  
• Any further blood lead test only if abnormal blood lead test or change in risk exposure history |
| CONCLUSION | SPC - Majority voted “Yes” to approve proposed schedule for Targeted Area (see page 45). |

<table>
<thead>
<tr>
<th>TOPIC/ITEM 2</th>
<th>Determine when to administer a Lead Risk Questionnaire (Pb-110) to children who resides in a Non-Targeted Area (see pages 43-44)</th>
</tr>
</thead>
</table>
| DISCUSSION | If child lives in a Targeted Area, then administer a venous or capillary blood lead test:  
°CURRENT SCHEDULE:  
• Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years  
°PROPOSED SCHEDULE:  
• Age 6, 12, and 24 months; and ages 3 and 4 years  
• Any further blood lead test only if abnormal blood lead test or change in risk exposure history |
| CONCLUSION | SPC - Majority voted “Yes” to approve proposed schedule for Non-Targeted Area (see page 45). |

2 The SPC requested changes to the QRG screening schedule.
## Meeting Roll Call - by Alphabetical Order

<table>
<thead>
<tr>
<th>First Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabel Granado</td>
<td>Clinical Chemistry Laboratory</td>
</tr>
<tr>
<td>Cristina Baker</td>
<td>Texas Childhood Lead Poisoning Prevention Program</td>
</tr>
<tr>
<td>Dan Rosenbaum</td>
<td>Tamarac Medical, Inc.</td>
</tr>
<tr>
<td>Genny Carrillo Zuniga</td>
<td>School of Rural Public Health, Texas A&amp;M Health Science Center</td>
</tr>
<tr>
<td>Jennifer Karnik</td>
<td>Adult Blood Lead Epidemiology and Surveillance Program</td>
</tr>
<tr>
<td>Jyothi R Domakonda</td>
<td>Healthy Homes and Lead Poisoning Prevention Program - Houston</td>
</tr>
<tr>
<td>Ken Kahle</td>
<td>Tamarac Medical, Inc.</td>
</tr>
<tr>
<td>Linda Kaufman</td>
<td>Healthy Homes and Lead Poisoning Prevention Program - San Antonio</td>
</tr>
<tr>
<td>Marcus Hanfling</td>
<td>Texas Pediatric Society</td>
</tr>
<tr>
<td>Nancy M. Crider</td>
<td>University of Texas School of Public Health</td>
</tr>
<tr>
<td>Patrick Bloomingdale</td>
<td>Texas Childhood Lead Poisoning Prevention Program</td>
</tr>
<tr>
<td>Randy Valcin</td>
<td>Galveston County Health District</td>
</tr>
<tr>
<td>Stephanie Shirley</td>
<td>Texas Commission on Environmental Quality</td>
</tr>
<tr>
<td>Teresa Willis</td>
<td>Blood Lead Surveillance Group</td>
</tr>
<tr>
<td><strong>Terri Sparks</strong></td>
<td><strong>Texas Health Steps</strong></td>
</tr>
<tr>
<td>Veronica Cuellar</td>
<td>Texas Childhood Lead Poisoning Prevention Program</td>
</tr>
</tbody>
</table>

**Note:** Bolded members denote voting privileges

**Date:** 03/27/2013
Old Business

Texas Childhood Lead Poisoning Prevention Program

Presented by:
Cristina Baker, Program Coordinator

Date: March 27, 2013    Phone: 1-800-588-1248

Webinar Demonstration

Date: March 27, 2013    Phone: 1-800-588-1248

CenturyLink Web Meeting
Chat Feature

- Use the **CHAT** feature to submit your questions
  
  Example: **Slide 8 – Can you explain...**

Objectives

- Approve February 27, 2013 Meeting Minutes
- Review progress on actions items assigned at the February 27, 2013 SPC Meeting
  - Vote on Pb-109 Revisions
- Assign follow-up actions as necessary

Action Item #1

- Your approved changes to the Texas Administrative Code Chapter 37 (TAC 37)
  - Revised line 61 of the TAC 37, Rule §37.337 to read the following:
    
    1. obtaining a diagnostic venous blood lead test result;
    and

    Revised line 17 of the TAC 37, Rule §37.335 to read “facility” instead of “facilities”
Action Item #2

- Clarification on Texas Health Steps’ process for presenting proposed changes to Texas Health Steps Advisory Panel.
  - Response: There was nothing sent to the THSteps Advisory Panel. Texas Health Steps supported the reference level 5 as a trigger for providing follow-up testing and is changing the 10 language to 5.

Action Item #3

Review January 30, 2013 Revisions & Pb-109 Options 1, 2, 3, 4

- Review revisions made to the Pb-109
  - January 30, 2013 Version – Majority voted “Yes” to accept revisions
  - Option 1 –
  - Option 2 –
  - Option 3 –
  - Response: There wasn’t a majority consensus on which version to accept. TXCLPPP is asking for a recall.
**Capillary Screening Test Result (mcg/dL)**

- **Perform Venous Diagnostic Test Within**
  - 5 – 9 weeks
  - 10 – 44 weeks
  - 45 – 59 weeks
  - 60 – 69 weeks
  - 70 and up

### Venous Blood Lead Level (mcg/dL)

#### Early Follow-up (first 2-4 tests after identification)
- 5 – 9 weeks
- 10 – 14 weeks
- 20 – 24 weeks
- 25 – 44 weeks
- 45 and up

#### Late Follow-up (after BLL begins to decline)
- 3 months
- 6 months
- 1 year

### Table 2: Schedule for Follow-Up Venous Blood Lead Testing

<table>
<thead>
<tr>
<th>BLL Range (mcg/dL)</th>
<th>Early Follow-up (weeks after identification)</th>
<th>Late Follow-up (first 2-4 tests after identification)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>1 week</td>
<td>3 months</td>
</tr>
<tr>
<td>5 – 9</td>
<td>5 weeks</td>
<td>6 months</td>
</tr>
<tr>
<td>10 – 44</td>
<td>1 week</td>
<td>1 year</td>
</tr>
<tr>
<td>45 – 59</td>
<td>1 week</td>
<td></td>
</tr>
<tr>
<td>60 – 69</td>
<td>48 hours</td>
<td></td>
</tr>
<tr>
<td>70 and up</td>
<td>24 hours</td>
<td></td>
</tr>
</tbody>
</table>

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**March 27, 2013 Option**

Date: March 27, 2013    Phone: 1-800-588-1248
Table 1: Schedule for Obtaining a Diagnostic Venous Sample

<table>
<thead>
<tr>
<th>Capillary Screening Test Result (mcg/dL)</th>
<th>Perform Venous Diagnostic Test Weekly</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 9</td>
<td>Within 5 - 9 weeks</td>
</tr>
<tr>
<td>10 - 19</td>
<td>Lead Risk Questionnaire (Pb-110)</td>
</tr>
<tr>
<td>50 - 59</td>
<td>1 week - 3 weeks</td>
</tr>
<tr>
<td>60 - 90</td>
<td>6 weeks</td>
</tr>
<tr>
<td>65 - 90</td>
<td>12 weeks - 24 weeks</td>
</tr>
<tr>
<td>70 and up</td>
<td>1 week - 3 weeks</td>
</tr>
</tbody>
</table>

Revisions highlighted in yellow

Table 2: Schedule for Follow-Up Venous Blood Lead Testing

<table>
<thead>
<tr>
<th>Venous Blood Lead Level (mcg/dL)</th>
<th>Early Follow-Up (First 2-4 Tests after Identification)</th>
<th>Late Follow-Up (After BLL Begins to Decline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 - 9</td>
<td>4 months - 6 months</td>
<td>6 months - 9 months</td>
</tr>
<tr>
<td>10 - 14</td>
<td>6 months</td>
<td>6 months - 9 months</td>
</tr>
<tr>
<td>15 - 19</td>
<td>3 months - 3 months</td>
<td>3 months - 6 months</td>
</tr>
<tr>
<td>20 - 24</td>
<td>1 month - 3 months</td>
<td>1 month - 3 months</td>
</tr>
<tr>
<td>25 - 44</td>
<td>2 weeks - 1 month</td>
<td>1 month</td>
</tr>
<tr>
<td>45 and up</td>
<td>As soon as possible</td>
<td>Chelation with subsequent follow-up</td>
</tr>
</tbody>
</table>

Date: March 27, 2013    Phone: 1-800-588-1248

Pb-104: Checklist

Environmental Interventions (supplementary hardware: H104, H105, H106)
- Change water sources
- Use non-fluoride toothpaste
- Use non-fluoride mouthwash
- Use non-fluoride drinking water
- Use non-fluoride bottled water
- Use non-fluoride cooking utensils
- Use non-fluoride food containers

Pb-104: Checklist

Vital Observations (supplementary software: H102)
- Blood lead levels
- Blood lead levels
- Blood lead levels
- Blood lead levels
- Blood lead levels
- Blood lead levels

SPC Voting & Recommendations

Date: March 27, 2013    Phone: 1-800-588-1248
Reference for Follow-up Blood Lead Testing and Medical Case Management

Healthcare Provider:
- Immediately retest the child if the blood lead test result is invalid due to “Clotted” or “Insufficient Quantity.”
- Follow the flowchart below to determine if or when follow-up testing and medical case management is necessary.

**Table 1: Schedule for Obtaining a Diagnostic Venous Sample**

<table>
<thead>
<tr>
<th>Capillary Screening Test Result (mcg/dL)</th>
<th>Perform Venous Diagnostic Test Within</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 - 9</td>
<td>1 week - 12 weeks&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>10 - 44</td>
<td>1 week - 4 weeks</td>
</tr>
<tr>
<td>45 - 59</td>
<td>48 hours</td>
</tr>
<tr>
<td>60 - 69</td>
<td>24 hours</td>
</tr>
<tr>
<td>70 and up</td>
<td>Immediately as an emergency lab test</td>
</tr>
</tbody>
</table>

<sup>b</sup> The higher the BLL on the screening test, the more urgent the need for diagnostic testing.

**Table 2: Schedule for Follow-Up Venous Blood Lead Testing**

<table>
<thead>
<tr>
<th>Venous Blood Lead Level (mcg/dL)</th>
<th>Early Follow-up (first 2-4 tests after identification)</th>
<th>Late Follow-up (after BLL begins to decline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 - 9</td>
<td>3 months - 6 months</td>
<td>6 months - 9 months</td>
</tr>
<tr>
<td>10 - 14</td>
<td>3 months</td>
<td>6 months</td>
</tr>
<tr>
<td>15 - 19</td>
<td>1 month - 3 months</td>
<td>3 months - 6 months</td>
</tr>
<tr>
<td>20 - 24</td>
<td>1 month - 3 months</td>
<td>1 month - 3 months</td>
</tr>
<tr>
<td>25 - 44</td>
<td>2 weeks - 1 month</td>
<td>1 month</td>
</tr>
<tr>
<td>45 and up</td>
<td>As soon as possible</td>
<td>Chelation with subsequent follow-up&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

**Table 3: Medical Case Management for Children with a Diagnostic Elevated Blood Lead Levels**

<table>
<thead>
<tr>
<th>5 - 9 mcg/dL</th>
<th>10 - 14 mcg/dL</th>
<th>15 - 19 mcg/dL</th>
<th>20 - 44 mcg/dL</th>
<th>45 - 69 mcg/dL</th>
<th>70 or higher mcg/dL</th>
</tr>
</thead>
</table>
| 1. Lead Education: Dietary & Environmental  
2. Follow-up BLL monitoring  
3. Environmental Lead Investigation if:  
   • Follow-up BLLs persist at least 12 weeks after diagnostic venous test  
4. Complete history and physical exam  
5. Lab work: Hemoglobin or hematocrit, Iron status  
6. Environmental Lead Investigation  
7. Lead hazard reduction  
8. Neurodevelopmental monitoring  
9. Abdominal X-ray (if particulate lead ingestion is suspected) with bowel decontamination if indicated  
10. Chelation therapy<sup>c</sup>  
11. Hospitalize and commence chelation therapy<sup>c</sup>  
12. Proceed according to actions for 45-69 mcg/dL. |

<sup>c</sup> Healthcare providers should consult with an expert in the management of these lead levels before administering chelation. Chelation therapy should never be administered before a venous diagnostic is obtained.

<sup>b</sup> To determine when additional screening is necessary, use the Blood Lead Screening and Testing Guidelines for Texas Children: Quick Reference Guide.
<sup>c</sup> Healthcare providers should consult with an expert in the management of these lead levels before administering chelation. Chelation therapy should never be administered before a venous diagnostic is obtained.
Ken Kahle  
Director, Extra-Laboratory Affairs  
Tamarac Medical, Inc.
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.

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 ≥ 5µg/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
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 ≥ 10µg/dL
- 990 received a confirmatory venous test
- 249 (25.15%) capillary results were confirmed ≥ 10µg/dL
- 741 (74.84%) capillary results were not confirmed ≥ 10µg/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 5µg/dL reference level will magnify the significance and implications of FE results.
From 2010 Texas data: 15,552 children had a BLL ≥ 5 µg/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:

- Ken Kahle
- Director, Extra-Laboratory Affairs
- Tamarac Medical, Inc.
- Email: kkahle@tamaracmedical.com
- Cell: 601-880-3578
- Toll-free: 1-800-842-7069
Summary of Tamarac® Test Characteristics

1. Documented accuracy.
In an analysis of approximately 24,000 Waterless Tamarac® Tests, 99.77% of the test results were deemed accurate based on pre-determined accuracy criteria. Based on this analysis, the documented falsely-elevated (false positive) rate is less than 2 per thousand tests. Based on this analysis, the documented confirmation rate of elevated Waterless Tamarac® Test results is approximately two times higher than the average capillary blood lead confirmation rate demonstrated in published state department of health surveillance data for the states of Indiana, Minnesota, Maine, and Massachusetts/Rhode Island.

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:


2. Proprietary stick site cleansing and prep protocols.
Standard and waterless protocols are available. Pre-analytic contamination of the specimen by residual skin-surface lead is the most frequent cause of falsely-elevated (false positive) results. 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 at no additional charge. Esca Tech, Inc. has, by a technology license agreement, granted to Tamarac® Medical the exclusive right to use the 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 States1.
3. **Full compatibility with simultaneous hemoglobin testing.**
   When The Tamarac® 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, and the third drop is used for hemoglobin measurement. As a result, both mandated EPSDT blood tests are performed with a total of only 3 drops of blood from a single stick – the same amount of blood that would be required if hemoglobin testing was done alone.

4. **Filter paper blood lead testing is accepted by the Centers for Disease Control and Prevention (CDC).**
   Tamarac® Medical is also CLIA licensed, OSHA listed, and participates successfully in required proficiency testing programs.

5. **Minimal sample size requirement.**
   The Tamarac® Test requires only two drops of finger stick, ear stick, or heel stick blood.

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

7. **Economy.**
   Tamarac® Medical bills Medicaid and CHIP directly and accepts the allowable amount. We can submit billing claims to all insurance companies; claims are processed by insurance companies according to individual plan terms. There is no charge to the submitter when reimbursement is made by public or private insurance payers. Charges for self-pay/uninsured patients are billed to the submitting facility at an economical group rate on a monthly basis.

8. **We provide a complete collection kit for each test at no charge.**
   Each kit contains all supplies and stick-site prep products needed to collect and submit a sample. A prepaid mailing envelope to ship the specimen to the lab is also included.

9. **Rapid turn-around time and complete reporting.**
   Samples are normally analyzed within one to two business day of receipt. 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 flagged and are phoned or faxed to the ordering office daily. Results for all tests can be provided by secure website download, fax, or mailed hard copy. Tamarac® Medical works directly with state departments of health to electronically report test results to their format and frequency specifications.

TO ORDER FREE KITS AND SUPPLIES CALL TOLL FREE 1-800-842-7069

FOR ADDITIONAL INFORMATION OR DOCUMENTATION, CONTACT:

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1 Patent Pending. Esca Tech, Inc has a published U.S. Patent Application (Pub. No. 20070016102) with pending claims directed to a method for cleansing a blood sampling site on an individual prior to collection of a blood sample. Tamarac® Medical’s current right to exclusive use of the D-Lead® and D-Wipe® product line derive from its contractual agreement with Esca Tech, Inc. and not from any existing patent or patent application.
New Business

Texas Childhood Lead Poisoning Prevention Program

Presented by:
Cristina Baker, Program Coordinator

Date: March 27, 2013    Phone: 1-800-588-1248

Moving Forward / Action Items

Date: March 27, 2013    Phone: 1-800-588-1248


Date: March 27, 2013    Phone: 1-800-588-1248
Targeted Area

If child lives in a Targeted Area, then administer a venous or capillary blood lead test:

**Current Schedule:**
- Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years

**Proposed Schedule:**
- Age 6, 12, and 24 months; and ages 3 and 4 years
- Any further blood lead test only if abnormal blood lead test or change in risk exposure history

Non-Targeted Area

If child lives in a Non-Targeted Area, then complete Pb-110: Lead Risk Questionnaire

**Current Schedule:**
- Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years

**Proposed Schedule:**
- Age 6, 12, and 24 months; and ages 3 and 4 years

QRG – Current Version

**START HERE**

- Enrolled in Medicaid/Texas Health Steps
- Determine if Child Resides in a Targeted Area?
  - Yes
    - Action: Administer a venous or capillary blood lead test
    - Checkups at age 12 and 24 months; or Checkups at any age after 12 months if 1-2 years old
  - No
    - Action: Checkups at age 12 and 30 months; or Checkups at any age after 12 months if 1-2 years old

- Residence in Non-Targeted Area
  - Yes
    - Action: Administer a venous or capillary blood lead test
    - Checkups at age 12 and 24 months; or Checkups at any age after 12 months if 1-2 years old
  - No
    - Action: Checkups at age 12 and 24 months; or Checkups at any age after 12 months if 1-2 years old

**Back to Targeted Area**

**Back to Non-Targeted Area**
QRG
Revisions highlighted in yellow

Determine if Child Resides in a Targeted Area:

OPTION 1: Targeted Census Tracts
Use the Census Tract Look Up Guide on page 3 to determine if child lives in a targeted area.

OPTION 2: Targeted Zip Codes
Use the Targeted Zip Codes on page 4 to determine if child lives in a targeted area.

NO

Resides in a Non-Targeted Area:

YES

ACTION: Administer a venous or capillary blood lead test
WHEN:
• Age 6, 12, and 24 months
• Age 3 and 4 years
• Any further blood lead test only if abnormal BLL or change in risk exposure history

YES

ACTION: Complete Lead Risk Questionnaire (Pb-110) on page 2
WHEN:
• Age 6, 12, and 24 months
• Age 3 and 4 years

Does the SPC accept the proposed revisions to the QRG?

Does the SPC accept the proposed revisions to the QRG?

Meeting Dates
• April 24, 2013
• May 29, 2013 – if necessary
• September 2013

Presenter
Cristina Baker, Program Coordinator
Texas Childhood Lead Poisoning Prevention Program
1100 W. 49th St., Austin, TX 78756
PO Box 149347, MC1964, Austin, TX 78714
www.dshs.state.tx.us/lead
Following the Centers for Disease Control and Prevention (CDC) recommendations, the following criteria was used to determine targeted areas: (a) Areas with ≥27% of housing built before 1950, and (b) Areas with ≥3% of children at ages 1 and 2 with elevated blood lead levels.

Only for Texas Health Steps Children - the use of the Lead Risk Questionnaire (Pb-110) and child health forms is optional. The child health forms are available online from Texas Health Steps at www.dshs.state.tx.us/thsteps/forms.shtm.

1 Following the Centers for Disease Control and Prevention (CDC) recommendations, the following criteria was used to determine targeted areas: (a) Areas with ≥27% of housing built before 1950, and (b) Areas with ≥3% of children at ages 1 and 2 with elevated blood lead levels.

2 Only for Texas Health Steps Children - the use of the Lead Risk Questionnaire (Pb-110) and child health forms is optional. The child health forms are available online from Texas Health Steps at www.dshs.state.tx.us/thsteps/forms.shtm.

3 The Lead Risk Questionnaire (Pb-110) is recommended for children who reside in a non-targeted area.

4 The Pb-109 and other TX CLPPP forms are available online at www.dshs.state.tx.us/lead.