



# Strategic Planning Committee to Eliminate Childhood Lead Poisoning

## MINUTES

DATE: March 27, 2013

TIME: 10:00AM – 12:00PM

LOCATION: DSHS, via Webinar

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

## OLD BUSINESS

### APPROVE FEBRUARY 27, 2013 MEETING MINUTES

by Cristina Baker

<b>DISCUSSION</b>	TXCLPPP asked the SPC to vote “Yes” or “No” to approve the February 27, 2013 meeting minutes.
<b>CONCLUSION</b>	SPC - Unanimously voted “ <b>Yes</b> ” to approve the February 27, 2013 meeting minutes.

### PB-109: REFERENCE FOR FOLLOW-UP BLOOD LEAD TESTING AND MEDICAL CASE MANAGEMENT

by Cristina Baker

<b>TOPIC/ITEM 1</b>	<b>January 30, 2013 Revisions and Options 1, 2, 3 (see pages 7-8)</b>
<b>DISCUSSION</b>	<ul style="list-style-type: none"> <li>January 20, 2013 SPC Meeting - Majority voted “Yes” to accept revisions.</li> <li>February 27, 2013 SPC Meeting - SPC members voted to stop the process and make additional changes.               <ul style="list-style-type: none"> <li>Based on the SPC suggested revisions, TXCLPPP created 3 draft Pb-109 options and emailed the SPC so they can vote via email.</li> </ul> </li> <li>There wasn’t a majority consensus on which option to accept. TXCLPPP asked for a recall during the March 27, 2013 SPC Meeting.</li> </ul>
<b>CONCLUSION</b>	Tabled until vote in Topic/Item #3
<b>TOPIC/ITEM 2</b>	<b>Reviewed March 27, 2013 Revision - Option 4 (see pages 8-9)</b>
<b>DISCUSSION</b>	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.
<b>CONCLUSION</b>	A majority of SPC members voted against accepting Option 4. TXCLPPP asked SPC member to vote regarding Options 1, 2, & 3.
<b>TOPIC/ITEM 3</b>	<b>SPC Voting &amp; Recommendations</b>
<b>DISCUSSION</b>	TXCLPPP asked the SPC to vote on which option to accept.
<b>CONCLUSION</b>	<ul style="list-style-type: none"> <li>SPC - Majority voted “<b>Yes</b>” to accept <b>Option 2</b> (see page 10).</li> <li>The revisions to the Pb-109 will become effective on June 1, 2013.</li> <li>TXCLPPP will submit the revision to Texas Health Steps to be included in the Texas Medicaid Providers’ Procedures Manual, Child Handbook.</li> </ul>



# Strategic Planning Committee to Eliminate Childhood Lead Poisoning

## NEW BUSINESS

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

By Ken Kahle<sup>1</sup>,  
Tamarac Medical

<b>PRESENTATION</b>	See pages 11-41 of these minutes.
<b>DISCUSSION</b>	<p><b>Questions(Q) &amp; Answers(A) Generated from Presentation</b></p> <p><b>Q. What is the relative cost?</b>  <b>A.</b> 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.</p> <p><b>Q. How does Tamarac get providers to comply with their process?</b>  <b>A.</b> Tamarac cautions providers that the test is only as good as their ability to follow protocol.</p> <p><b>Q. How does Tamarac provide training to ensure they are following the proper protocol?</b>  <b>A.</b> Tamarac provides a training program using a PowerPoint presentation.</p> <p><b>Q. Who performed the studies done on the filter paper?</b>  <b>A.</b> Tamarac provided SPC with a paper that contained a list of studies (see pages 40-41).</p> <p><b>Q. How does Tamarac interchange data?</b>  <b>A.</b> Tamarac interchanges data using HL7, excel spreadsheet, secure servers, https://, and secure download from their website.</p> <p><b>Q. What is the accuracy of results? +/- 4? +/- 2</b>  <b>A.</b> Proficiency testing programs Tamarac participated in indicated an accuracy of +-4, but internal tracking done by Tamarac is closer to +/- 2.</p> <p><b>Q. How are collection kits shipped to providers?</b>  <b>A.</b> The collection kits are shipped via FedEx Ground. The provider requests the kits via phone or fax.</p> <p><b>Q. Do the collection kits have an expiration date?</b>  <b>A.</b> 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.</p> <p><b>Q. What is the potential for contamination of the specimen?</b>  <b>A.</b> The kit provides a zip lock back to prevent contamination.</p>

<sup>1</sup> Ken Kahle, Director of Extra-Laboratory Affairs for Tamarac Medical, is a current SPC member.

by Cristina Baker

## TEXAS CHILDHOOD BLOOD LEAD SCREENING GUIDELINES: QUICK REFERENCE GUIDE (QRG)<sup>2</sup>

<b>TOPIC/ITEM 1</b>	<b>Determine when to test children who resides in a Targeted Area (see page 43)</b>
<b>DISCUSSION</b>	<p>If child lives in a Targeted Area, then administer a venous or capillary blood lead test:</p> <p><b><u>Current Schedule:</u></b></p> <ul style="list-style-type: none"> <li>• Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years</li> </ul> <p><b><u>Proposed Schedule:</u></b></p> <ul style="list-style-type: none"> <li>• Age 6, 12, and 24 months; and ages 3 and 4 years</li> <li>• Any further blood lead test only if abnormal blood lead test or change in risk exposure history</li> </ul>
<b>CONCLUSION</b>	SPC - Majority voted "Yes" to approve proposed schedule for Targeted Area (see page 45).
<b>TOPIC/ITEM 2</b>	<b>Determine when to administer a Lead Risk Questionnaire (Pb-110) to children who resides in a Non-Targeted Area (see pages 43-44)</b>
<b>DISCUSSION</b>	<p>If child lives in a Targeted Area, then administer a venous or capillary blood lead test:</p> <p><b><u>Current Schedule:</u></b></p> <ul style="list-style-type: none"> <li>• Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years</li> </ul> <p><b><u>Proposed Schedule:</u></b></p> <ul style="list-style-type: none"> <li>• Age 6, 12, and 24 months; and ages 3 and 4 years</li> <li>• Any further blood lead test only if abnormal blood lead test or change in risk exposure history</li> </ul>
<b>CONCLUSION</b>	SPC - Majority voted "Yes" to approve proposed schedule for Non-Targeted Area (see page 45).

<sup>2</sup> The SPC requested changes to the QRG screening schedule.



# Strategic Planning Committee to Eliminate Childhood Lead Poisoning

## Meeting Roll Call - by Alphabetical Order

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

**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

MEETING

- WEBCAM
- PARTICIPANTS (3)
- Settings
- Park's Blotting...
- ABLES Program PC

CHAT

Everyone

3:24 PM - ABLES Program  
WELCOME TO CENTURYLINK WEB

SEND

WELCOME TO CENTURYLINK WEB

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

## Chat Feature



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

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

## 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

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

## 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"

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

## 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**.

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

## Action Item #3

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

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

## Action Item #3

- 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.

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

# January 30, 2013 Revision

Revisions highlighted in yellow

**Initial Test Capillary Sample**

Less than 5 mcg/dL

To determine when additional screening is necessary, use the *Blood Lead Screening and Testing Guidelines for Texas Children's Quick Reference Guide*

Less than 5 mcg/dL

**Initial Test Venous Sample**

5 mcg/dL or greater

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

Capillary Screening Test Result (mcg/dL)	Perform Venous Diagnostic Test Within
5 - 9	12 weeks
10 - 44	1 week - 4 weeks
45 - 59	48 hours
60 - 69	24 hours
70 and up	Immediately as an emergency lab test

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

Venous Blood Lead Level (mcg/dL)	Early Follow-up (first 2-4 tests after identification)	Late Follow-up (after BLL begins to decline)
5 - 9	3 months	6 months
10 - 14	3 months	6-9 months
15 - 19	1-3 months	3-6 months
20 - 24	1-3 months	1-3 months
25 - 44	2 weeks - 1 month	1 month
45 and up	As soon as possible	Chelation with subsequent follow-up

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

5 - 9 mcg/dL	10 - 14 mcg/dL	15 - 19 mcg/dL	20 - 44 mcg/dL	45 - 69 mcg/dL	70 or higher mcg/dL
<ol style="list-style-type: none"> <li>Lead Education: Dietary &amp; Environmental</li> <li>Follow-up BLL monitoring</li> <li>Environmental Lead Investigation if:                             <ul style="list-style-type: none"> <li>Follow-up BLLs persist at least 12 weeks after diagnostic venous test</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>Lead Education: Dietary &amp; Environmental</li> <li>Follow-up BLL monitoring</li> <li>Environmental Lead Investigation if:                             <ul style="list-style-type: none"> <li>Follow-up BLLs persist at least 12 weeks after diagnostic venous test</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>Lead Education: Dietary &amp; Environmental</li> <li>Follow-up BLL monitoring</li> <li>Proceed according to actions for 20-44 mcg/dL, if:                             <ul style="list-style-type: none"> <li>Follow-up BLLs persist at least 12 weeks after diagnostic venous test</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>Lead Education: Dietary &amp; Environmental</li> <li>Follow-up BLL monitoring</li> <li>Complete history and physical exam</li> <li>Lab work: Hemoglobin or hematocrit; Iron status</li> <li>Environmental Lead Investigation</li> <li>Lead hazard reduction</li> <li>Neurodevelopmental monitoring</li> <li>Abdominal X-ray if particulate lead ingestion is suspected with bowel decontamination if indicated</li> </ol>	<ol style="list-style-type: none"> <li>Lead Education: Dietary &amp; Environmental</li> <li>Follow-up BLL monitoring</li> <li>Complete history and physical exam</li> <li>Complete neurological exam</li> <li>Lab work: Hemoglobin or hematocrit; Iron status; FEP or ZPP</li> <li>Environmental Lead Investigation</li> <li>Lead hazard reduction</li> <li>Neurodevelopmental monitoring</li> <li>Abdominal X-ray with bowel decontamination if indicated</li> <li>Chelation therapy</li> </ol>	<ol style="list-style-type: none"> <li>Hospitalize and commence chelation therapy</li> <li>Proceed according to actions for 45-69 mcg/dL</li> </ol>

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

# February 27, 2013 Options

Revisions in red

**Option 1**

Table 1: Schedule for Obtaining a Diagnostic Venous Sample

Capillary Screening Test Result (mcg/dL)	Perform Venous Diagnostic Test Within
5 - 9	12 weeks
10 - 44	1 week - 4 weeks
45 - 59	48 hours
60 - 69	24 hours
70 and up	Immediately as an emergency lab test

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

Venous Blood Lead Level (mcg/dL)	Early Follow-up (first 2-4 tests after identification)	Late Follow-up (after BLL begins to decline)
5 - 9	3 months - 6 months	6 months - 9 months
10 - 14	3 months	6 months - 9 months
15 - 19	1 month - 3 months	3 months - 6 months
20 - 24	1 month - 3 months	1 month - 3 months
25 - 44	2 weeks - 1 month	1 month
45 and up	As soon as possible	Chelation with subsequent follow-up

**Option 2**

Table 1: Schedule for Obtaining a Diagnostic Venous Sample

Capillary Screening Test Result (mcg/dL)	Perform Venous Diagnostic Test Within
5 - 9	1 week - 12 weeks
10 - 44	1 week - 4 weeks
45 - 59	48 hours
60 - 69	24 hours
70 and up	Immediately as an emergency lab test

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

Venous Blood Lead Level (mcg/dL)	Early Follow-up (first 2-4 tests after identification)	Late Follow-up (after BLL begins to decline)
5 - 9	3 months - 6 months	6 months - 9 months
10 - 14	3 months	6 months - 9 months
15 - 19	1 month - 3 months	3 months - 6 months
20 - 24	1 month - 3 months	1 month - 3 months
25 - 44	2 weeks - 1 month	1 month
45 and up	As soon as possible	Chelation with subsequent follow-up

**Option 3**

Table 1: Schedule for Obtaining a Diagnostic Venous Sample

Capillary Screening Test Result (mcg/dL)	Perform Venous Diagnostic Test Within
5 - 9	12 weeks - 24 weeks
10 - 44	1 week - 4 weeks
45 - 59	48 hours
60 - 69	24 hours
70 and up	Immediately as an emergency lab test

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

Venous Blood Lead Level (mcg/dL)	Early Follow-up (first 2-4 tests after identification)	Late Follow-up (after BLL begins to decline)
5 - 9	3 months - 6 months	6 months - 9 months
10 - 14	3 months	6 months - 9 months
15 - 19	1 month - 3 months	3 months - 6 months
20 - 24	1 month - 3 months	1 month - 3 months
25 - 44	2 weeks - 1 month	1 month
45 and up	As soon as possible	Chelation with subsequent follow-up

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

# March 27, 2013 Option

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

## March 27, 2013 Option

### Revisions highlighted in yellow

Table 1: Schedule for Obtaining a Diagnostic Venous Sample

Capillary Screening Test Result (mcg/dL)	Perform Venous Diagnostic Test Within
5 - 9	<ul style="list-style-type: none"> <li>* 12 weeks – 24 weeks</li> <li>* Lead Risk Questionnaire (Pb-110)</li> <li>* Lead Education</li> </ul>
10 - 44	1 week – 4 weeks
45 - 59	48 hours
60 - 69	24 hours
70 and up	Immediately as an emergency lab test

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

Venous Blood Lead Level (mcg/dL)	Early Follow-up (first 2-4 tests after identification)	Late Follow-up (after BLL begins to decline)
5 - 9	3 months - 6 months	6 months - 9 months
10 - 14	3 months	6 months
15 - 19	1 month - 3 months	3 months - 6 months
20 - 24	1 month - 3 months	1 month - 3 months
25 - 44	2 weeks - 1 month	1 month
45 and up	As soon as possible	Chelation with subsequent follow-up

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

## Pb-104: Checklist

**Environmental Interventions** (supply parent with educational materials #1-307, #1-308, #1-309)

- Potential sources of lead
  - Lead paint
  - Lead contaminated dust and soil
  - Lead contaminated water from lead pipes or lead solder
  - Imported mini-blinds
  - Home remedies (Azarcon or Greta)
  - Lead contaminated food from storage in ceramic pottery, leaded crystal, and lead soldered cans
  - Occupations and hobbies
- Certified professionals should conduct lead abatement
- Methods to reduce their child's lead exposure
  - Create barriers between living/play areas and lead sources (i.e. tape over lead painted windowsills or doorframes, plant grass in bare soil areas)
  - Wash child's hands and face before meals and at bedtime
  - Wash child's toys, pacifiers, and bottles often
  - Wet mop floors regularly and wet wipe window components
  - Vacuum carpeted areas before wet mopping floors
  - Keep child from eating nonfood items
  - Keep child away from peeling, chipping, or flaking paint
  - Prevent child from playing in bare soil areas
  - Keep child away from areas where lead is being used (i.e. hobbies, occupations)
  - Relocate if lead contamination is extensive and not easily remediable
- Potential water hazards
  - Do not cook with or allow children to drink hot tap water
  - Run cold tap water for 1-2 minutes in the morning and fill a pitcher with the water.
  - Use this water for drinking, cooking, and formula preparation
  - Use bottled water if drinking water is contaminated

**Nutritional Interventions** (supply parent with educational material #12-22)

- Feed child foods rich in absorbable iron, vitamin C, and calcium
- Feed child three healthy meals and two nutritious snacks each day
- Use glass, plastic, or stainless steel containers for storing, preparing, or serving food

**Medical Care** (supply parent with educational materials #1-310 and #1-311)

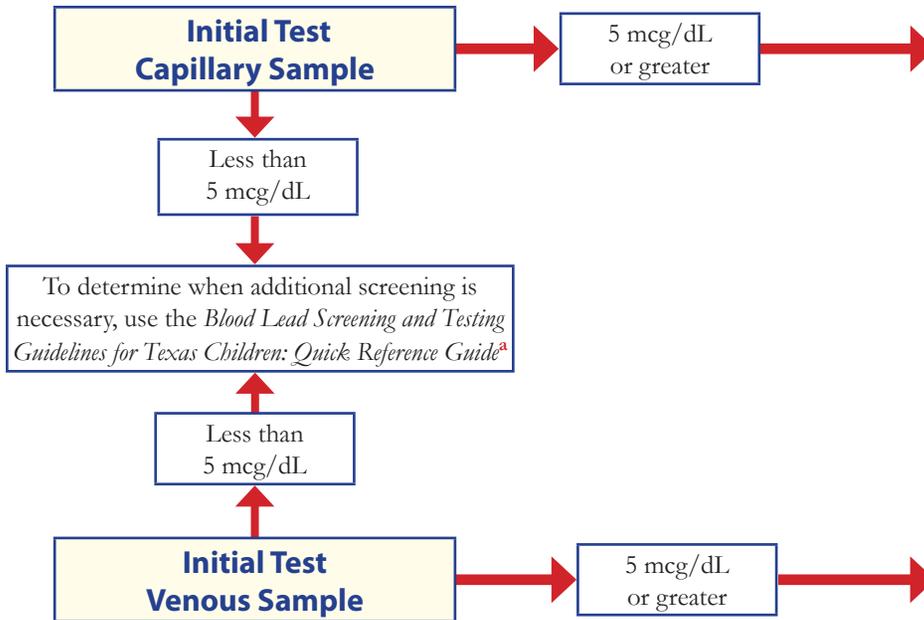
- The importance of recommended medical follow-up
  - After the blood lead level goes below 10 µg/dL, screen children for lead at least once a year up to the age of 6
- Risks associated with elevated blood lead levels

## SPC Voting & Recommendations

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

**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**

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

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

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

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

5 - 9 mcg/dL	10 - 14 mcg/dL	15 - 19 mcg/dL	20 - 44 mcg/dL	45 - 69 mcg/dL	70 or higher mcg/dL
<ol style="list-style-type: none"> <li>1. Lead Education: Dietary &amp; Environmental</li> <li>2. Follow-up BLL monitoring</li> </ol>	<ol style="list-style-type: none"> <li>1. Lead Education: Dietary &amp; Environmental</li> <li>2. Follow-up BLL monitoring</li> <li>3. Environmental Lead Investigation if:                             <ul style="list-style-type: none"> <li>• Follow-up BLLs persist at least 12 weeks after diagnostic venous test</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Lead Education: Dietary &amp; Environmental</li> <li>2. Follow-up BLL monitoring</li> <li>3. Proceed according to actions for 20-44 mcg/dL if:                             <ul style="list-style-type: none"> <li>• Follow-up BLLs persist at least 12 weeks after diagnostic venous test</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Lead Education: Dietary &amp; Environmental</li> <li>2. Follow-up BLL monitoring</li> <li>3. Complete history and physical exam</li> <li>4. Lab work: Hemoglobin or hematocrit; Iron status</li> <li>5. Environmental Lead Investigation</li> <li>6. Lead hazard reduction</li> <li>7. Neurodevelopmental monitoring</li> <li>8. Abdominal X-ray (if particulate lead ingestion is suspected) with bowel decontamination if indicated</li> </ol>	<ol style="list-style-type: none"> <li>1. Lead Education: Dietary &amp; Environmental</li> <li>2. Follow-up BLL monitoring</li> <li>3. Complete history and physical exam</li> <li>4. Complete neurological exam</li> <li>5. Lab work: Hemoglobin or hematocrit; Iron status; FEP or ZPP</li> <li>6. Environmental Lead Investigation</li> <li>7. Lead hazard reduction</li> <li>8. Neurodevelopmental monitoring</li> <li>9. Abdominal X-ray with bowel decontamination if indicated</li> <li>10. Chelation therapy<sup>f</sup></li> </ol>	<ol style="list-style-type: none"> <li>1. Hospitalize and commence chelation therapy<sup>e</sup></li> <li>2. Proceed according to actions for 45-69 mcg/dL</li> </ol>

<sup>a</sup>Blood Lead Screening and Testing Guidelines for Texas Children: Quick Reference Guide. Go to: [www.dshs.state.tx.us/lead](http://www.dshs.state.tx.us/lead). <sup>b</sup>The higher the BLL on the screening test, the more urgent the need for diagnostic testing. <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.



75  
12,000

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

**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

75

12,000

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 5µg/dL reference level will magnify the significance and implications of FE results

75

12,000

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:

- Ken Kahle
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- Tamarac Medical, Inc.
- Email: [kkahle@tamaracmedical.com](mailto: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:

*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 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 States<sup>1</sup>.

**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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# 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

## Texas Childhood Blood Lead Screening Guidelines: Quick Reference Guide (QRG)

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

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

## Non-Targeted Area

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

■ **Current Schedule:**

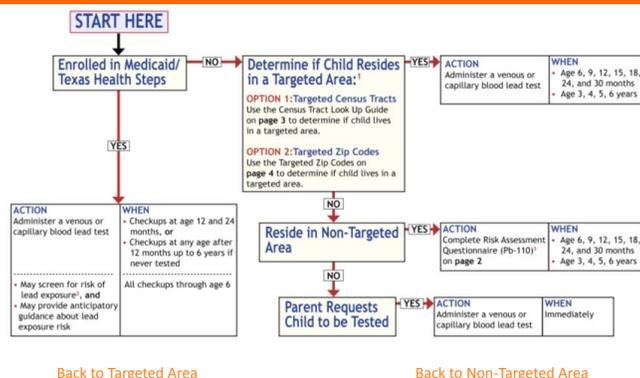
- Age 6, 9, 12, 15, 18, 24, 30 months; and age 3, 4, 5, 6 years

■ **Proposed Schedule:**

- Age 6, 12, and 24 months; and ages 3 and 4 years

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

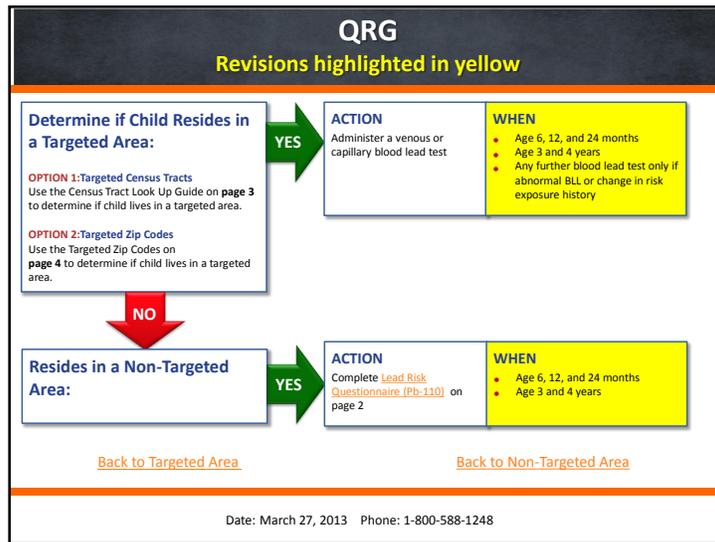
## QRG – Current Version



[Back to Targeted Area](#)

[Back to Non-Targeted Area](#)

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

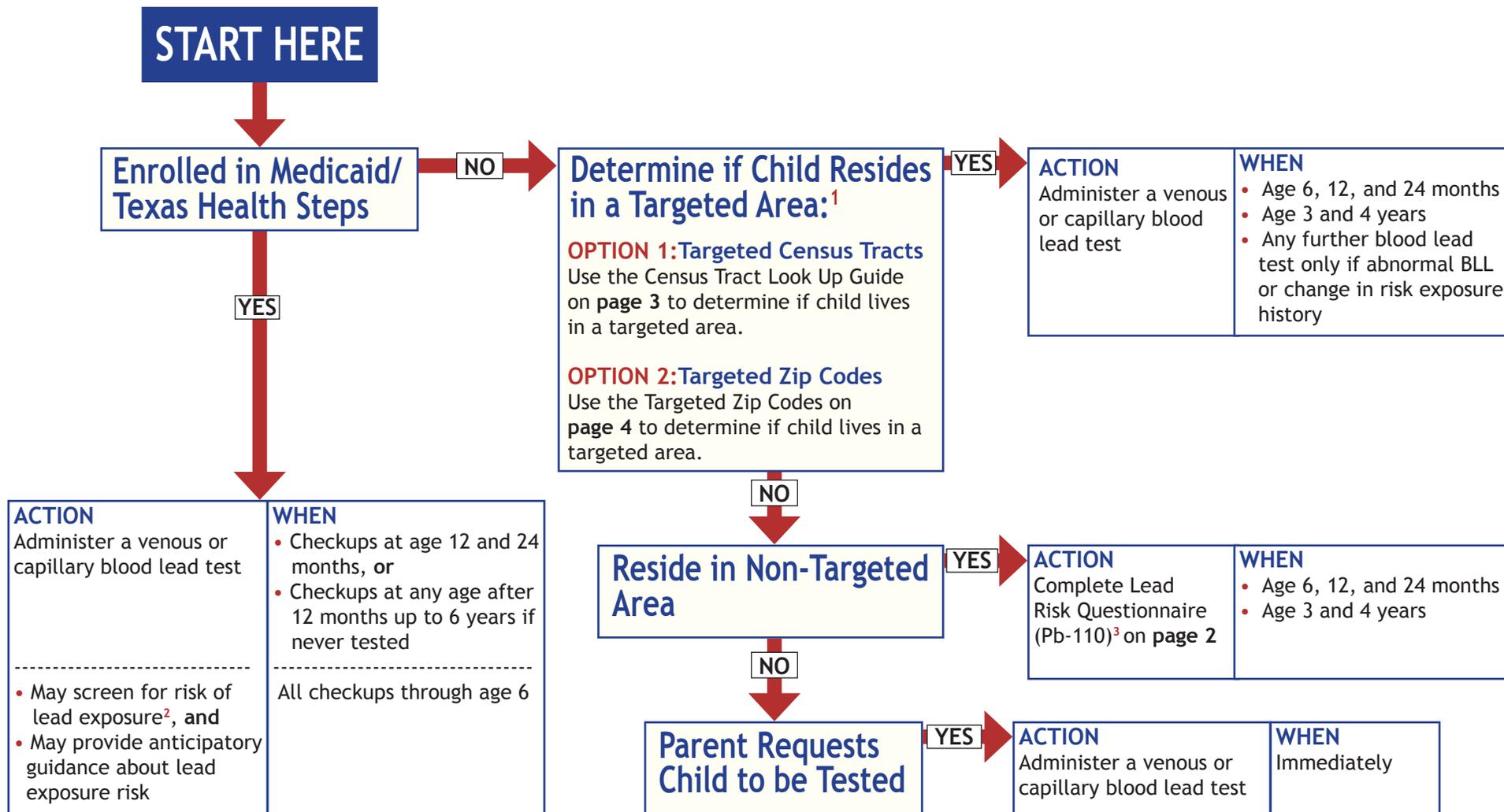


**Does the SPC accept the proposed revisions to the QRG?**

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

<p><b>Presenter</b></p> <p>Cristina Baker, Program Coordinator</p> <p>Texas Childhood Lead Poisoning Prevention Program 1100 W. 49<sup>th</sup> St., Austin, TX 78756 PO Box 149347, MC1964, Austin, TX 78714</p> <p><a href="http://www.dshs.state.tx.us/lead">www.dshs.state.tx.us/lead</a></p>	<p><b>Meeting Dates</b></p> <ul style="list-style-type: none"> <li>▪ April 24, 2013</li> <li>▪ May 29, 2013 – <b>if necessary</b></li> <li>▪ September 2013</li> </ul>
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Date: March 27, 2013 Phone: 1-800-588-1248



**NOTE:** After a blood lead test is administered and you receive the results; use Pb-109 Form<sup>4</sup>, *Reference for Follow-up Testing and Medical Case Management*, to determine if or when follow-up testing and medical case management is necessary.

<sup>1</sup>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. <sup>2</sup>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](http://www.dshs.state.tx.us/thsteps/forms.shtm). <sup>3</sup>The *Lead Risk Questionnaire* (Pb-110) is recommended for children who reside in a non-targeted area. <sup>4</sup>The Pb-109 and other TX CLPPP forms are available online at [www.dshs.state.tx.us/lead](http://www.dshs.state.tx.us/lead).