Recommendations for Follow-up and Case Management of Children Based on Blood Lead Levels

In 2012, the Centers for Disease Control (CDC) and Prevention decreased the reference value used to identify children who have been exposed to lead and require follow up care. The current value used to identify elevated blood lead levels is greater than or equal to 5 micrograms per deciliter (≥ 5 µg/dL) which is based on the 97.5th percentile of the National Health and Nutrition Examination Survey (NHANES) blood lead distribution in children; however, there is currently *no known safe level of lead* identified in children. The Alabama Childhood Lead Poisoning Prevention Program (ACLPPP) follows these guidelines to ensure that every child identified with a blood lead level ≥ 5 µg/dL receives care coordination services which may include health education, case management, resource referrals, and a home lead assessment. Without diagnosis and treatment, lead affected children, especially those under the age of six years old, can have permanent mental and physical developmental delays.

These are the key concepts that apply to the testing and reporting of blood lead levels in Alabama:

- The ACLPPP recommends that all children receive a blood lead level (BLL) screening at 12 and 24 months[1] of age.
- All BLLs are reportable to the Alabama Department of Public Health (ADPH). The forms on pages 7-8 have been provided for reporting directly to the ACLPPP.
- According to the CDC, a confirmatory elevated BLL is defined as one venous BLL or two capillary BLLs within 12 weeks of each other that are ≥ 5 µg/dL.
- Venous testing is recommended for confirmatory testing due to the incidence of false positives that can occur with capillary testing as a result of skin surface contamination.
- Following a capillary result ≥ 5 µg/dL, confirmatory testing should be completed within 12 weeks following the CDC "Time to Confirmatory* Testing" recommendations on page 2.
- No venous testing should be performed using the Lead Care System.
- Only venous testing should be used as follow-up for a confirmed elevated BLL.
- Follow up testing should continue for a confirmed elevated BLL until two consecutive venous results are < 5 µg/dL.

[1]*The American Academy of Pediatrics (AAP) recommends targeted screening of children 12 to 24 months of age for elevated blood lead concentration "who live in communities or census block groups with >25% of housing built before 1960 or a prevalence of children's blood concentrations >5 µg/dL of 5%."*

Recommended Schedule for Obtaining a Confirmatory Venous Sample

Capillary BLL	Time to Confirmatory* Testing
5-9 µg/dL	1 – 3 months
10-44 µg/dL	1 week – 1 month (the higher the BLL on the screening test, the more urgent the need for confirmatory testing)
45-59 µg/dL	48 hours
60-69 µg/dL	24 hours
≥ 70 µg/dL	Urgently as emergency test

*A confirmatory BLL is one venous blood lead level or two capillary blood lead levels collected within 12 weeks of each other.

Recommended Schedule for Follow-up Testing of Confirmed Elevated BLLs

Venous BLL	Early follow up testing (2 – 4 tests after identification)	Later follow up testing after BLL declining
5-9 µg/dL	3 months	6 – 9 months
10-19 µg/dL	1 – 3 months	3 – 6 months
20-24 µg/dL	1 – 3 months	1 – 3 months
25-44 µg/dL	2 weeks – 1 month	1 month
≥ 45 µg/dL	As soon as possible	As soon as possible

Recommendations for Follow-up and Case Management of Children Based on Confirmed Blood Lead Levels

BLL	Recommended Follow-up Care
< 5µg/dL	• Routine assessment of nutritional and developmental milestones • Anticipatory guidance about common sources of lead exposure • Follow-up blood lead testing at recommended intervals based on child's age
5-9 µg/dL	• Routine assessment of nutritional and developmental milestones • Environmental assessment of detailed history to identify potential sources of lead exposure • Nutritional counseling related to calcium and iron intake • Follow-up blood lead testing at recommended intervals
10-19 µg/dL	• Routine assessment of nutritional and developmental milestones • Environmental assessment of detailed history and environmental† investigation including home visit to identify potential sources of lead exposure • Nutritional counseling related to calcium and iron intake; consider lab work to assess iron status • Follow-up blood lead monitoring at recommended intervals
20-44 µg/dL	• Complete history and physical exam • Neurodevelopmental assessment • Environmental investigation of the home and lead hazard reduction • Lab work: ▪ Iron status ▪ Hemoglobin or hematocrit • Abdominal X-ray (with bowel decontamination if indicated) • Follow-up blood lead monitoring at recommended intervals

BLL	Recommended Follow-up Care
45-69 µg/dL	• Complete history and physical exam • Complete neurological exam including neurodevelopmental assessment • Environmental investigation of the home and lead hazard reduction • Lab work: ▪ Iron status ▪ Hemoglobin or hematocrit • Abdominal X-ray with bowel decontamination if indicated • Oral chelation therapy; consider hospitalization, if lead-safe environment cannot be assured • Follow-up blood lead monitoring at recommended intervals
≥ 70 µg/dL	• Hospitalize and commence chelation therapy in conjunction with consultation with a medical toxicologist or a pediatric environmental health specialty unit • Proceed with additional actions according to interventions for BLLs between 45-69 µg/dL

†The ACLPPP ensures that environmental investigations are completed for confirmed elevated BLLs ≥ 15 µg/dL. A blood lead level < 15 µg/dL requires a physician's order to complete an environmental investigation.

Reminder to Users of LeadCare Testing Systems

On May 17 2017, Magellan Diagnostics Inc. sent a "Customer Safety Communication" letter to all affected customers. The letter provided the following information:

- Do NOT use venous blood samples with any LeadCare Blood Lead Testing Systems.
- All LeadCare Blood Lead Testing Systems can be used with capillary blood samples, for example:
    - Capillary tubes shipped in LeadCare II test kits
    - RAM Scientific SAFE-T-FILL capillary collection tubes

The U.S. Food and Drug Administration (FDA) recommends laboratories and health care professionals take the following actions:

- Discontinue using Magellan's LeadCare System Testing Systems with venous blood samples.
- At this time, all LeadCare systems can be used with capillary blood samples.
- Report any adverse events to the FDA and to Magellan Diagnostics.
- If laboratories or health care professionals are concerned about using the LeadCare Test Systems, the alternative options are mass spectrometry or atomic absorption methods. These are not point-of-care tests, and may be available only from larger-capacity laboratories such as reference labs.

Alabama Reporting Requirements for Lead Levels

According to the Administrative Code of the Alabama Department of Public Health (ADPH), all lead results are reportable. Based on Chapter 420-4-1, Notifiable Diseases, "Each physician, dentist, nurse, medical examiner, hospital administrator, nursing home administrator, laboratory director, school principal, and child care center/Head Start director shall be responsible to report cases or suspected cases of notifiable diseases and health conditions. Reports by laboratories as outlined in 420-4-1-.04(3) shall not substitute for reports by persons responsible for reporting cases or suspected cases of notifiable diseases and health conditions. Said report shall contain such data as may be required by the rules of the State Board of Health."

Please use the forms on the following two pages to report elevated and non-elevated blood lead levels to the ACLPPP.

References:

[1]Hagan, J. F., Shaw, J. S., & Duncan, P. M. (2017). *Bright futures: Guidelines for health supervision of infants, children, and adolescents* (4th ed.). Elk Grove Village, IL: Bright Futures/American Academy of Pediatrics.

Online References:

https://www.cdc.gov/nceh/lead

https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm

https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-inc-expands-recall-leadcare-testing-systems-due-inaccurate-test-results

https://emergency.cdc.gov/han/han00403.asp

http://www.adph.org/epi/assets/Final_ND_Rules.pdf

http://www.alabamapublichealth.gov/aclppp/

Alabama Childhood Lead Poisoning Prevention Program
Phone: 1-833-667-1495
Fax: 1-334-206-3726

Use this form to report all **elevated blood lead levels** greater than or equal to 5 µg/dL. Please print.
Fax to (334) 206-3726 within 5 days of testing. Please call (334) 206-3883 with any questions.
Blood lead levels less than 5 µg/dL should be reported on the non-elevated lead reporting form within 30 days of testing.

Name: Last, First			
Date of Birth / Sex / Race	/	/	
Street Address			
City, State, Zip, Phone			
Lead Result	Collection Date / /	Venous or Capillary (circle one)	Blood Lead Level _____ µg/dL
Medicaid Number, if applicable/ Guardian name	/		

Name: Last, First			
Date of Birth / Sex/ Race	/	/	
Street Address			
City, State, Zip, Phone			
Lead Result	Collection Date / /	Venous or Capillary (circle one)	Blood Lead Level _____ µg/dL
Medicaid Number, if applicable/ Guardian name	/		

Reporting Facility_____

Name of Sender_____ Phone_____

Use this form to report all **non-elevated blood lead levels** less than 5 µg/dL. Please print.

Fax to (334) 206-3726 within 30 days of testing. Please call (334) 206-3883 if you have any questions.

Elevated blood lead levels of 5 µg/dL or more should be reported on the elevated lead reporting form within 5 days of testing.

Last Name, First Name	**Date of Birth**	**Sex (M or F)**	**Race (list all if multiple)**	**Street Address City, State, Zip**	**County**	**Collection Date**	**Venous or Capillary**	**Blood Lead Level**

Reporting Facility_____

Name of Sender_____ Phone_____