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

In 2012, the Centers for Disease Control and Prevention (CDC) adopted a blood lead reference value (BLRV) as a way of identifying the 2.5% of U.S. children ages 1–5 years old at greatest risk of lead exposure. The BLRV is based on the 97.5th percentile of the blood lead level (BLL) distribution among children 1–5 years old in the U.S. from the two most recent cycles of data from the National Health and Nutrition Examination Survey (NHANES). Based on NHANES data from 2015 to 2018, CDC accepted the Lead Exposure and Prevention Advisory Committee recommendation to update the BLRV to 3.5 micrograms per deciliter (μ g/dL). The Alabama Childhood Lead Poisoning Prevention Program (ACLPPP) follows these guidelines to ensure that every child identified with a BLL equal to or greater than 3.5 μ g/dL receives care coordination services which may include health education, case management, resource referrals, and/or a home lead assessment. Without diagnosis and treatment, lead affected children, especially those less than six years old, can have permanent mental and physical developmental delays.

What clinicians should know about BLL testing and reporting in Alabama:

- The ACLPPP recommends that all children receive a BLL screening at 12 and 24 months¹ of age.
- Per CDC recommendations, capillary screening results equal to or greater than the BLRV of 3.5 μ g/dL should be confirmed with blood drawn by venipuncture following the schedule in Table 1.
- Venous testing, following the schedule in Table 2, is recommended for follow-up testing as long as a child continues to demonstrate a BLL above the BLRV.
- Follow up testing should continue for a confirmed elevated BLL until at least one venous result is less than 3.5 mcg/dL; however, a child with fluctuating results should receive two *consecutive* results less than 3.5 µg/dL.
- No venous testing should be performed using the LeadCare point-of-care testing system.
- All BLL results are reportable to the Alabama Department of Public Health (ADPH). The forms on pages 8-9 have been
 provided for reporting directly to the ACLPPP when electronic reporting has not been established.

 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 μ g/dL of 5%."

Table 1: Recommended Schedule for Obtaining a Confirmatory Venous Sample

Capillary BLL	Time to Confirmation Testing*
3.5-9 μg/dL	Within 3 months
10-19 μg/dL	Within 1 month
20-44 μg/dL	Within 2 weeks
≥ 45 μg/dL	Within 48 hours

^{*}The higher the BLL on the initial screening capillary test, the more urgent it is to get a venous sample for confirmatory testing.

Table 2: Schedule for Follow-Up Blood Lead Testing

Venous BLL	Early follow up testing (2 – 4 tests after identification)	Later follow up testing after BLI decreasing			
3.5-9 μg/dL	3 months**	6 – 9 months			
10-19 μg/dL	1-3 months**	3 – 6 months			
20-44 μg/dL	2 weeks - 1 month	1-3 months			
<u>></u> 45 μg/dL	As soon as possible	As soon as possible			

^{**}Healthcare providers may choose to repeat blood lead tests on all new patients within a month. Repeated testing may ensure that the patient's BLL is not rising more quickly than expected.

Initial Screening Blood Lead Level

Healthcare providers may use a capillary or venous sample for initial BLL screening. If the capillary results are equal to or greater than CDC's <u>BLRV</u>, providers should collect a venous sample. If a venous sample was taken during the initial screening test, skip to *Confirmed Venous Blood Lead Level* recommendations.

If the patient's BLL is ≥3.5 μg/dL:

- Provide education about common sources of lead exposure and information on how to prevent further lead exposure.
 - Common sources of exposure include paint in homes built before 1978, contaminated soil, and contaminated drinking water. In addition to these sources of lead, there are several <u>other sources</u> that exist and can be harmful to children.
 - Adults can help reduce children's lead exposure by:
 - Frequently washing children's hands, especially before meals.
 - Frequently wiping and cleaning children's toys.
- For children living in or visiting homes or structures built before 1978, adults can reduce lead-based paint exposure by:
 - Regularly wet-wiping windows and windowsills and wet-mopping floors.
 - Avoiding repairs and construction projects that may create lead-based paint dust.
 - Covering chipping or peeling paint to keep lead from spreading to surrounding areas.
 - Using approved methods for removing lead hazards from the home (abatement) and using contractors certified by the ADPH when repairs or renovations are needed. Visit the <u>Alabama Lead Contractors</u> <u>Certification Program</u> to locate a certified firm.
- Obtain a confirmatory venous sample for blood lead testing. Use the schedule shown in Table 1.
 - CDC recommends that healthcare providers use a venous draw for confirmatory BLL screening. If the initial screening test used a venous sample, the patient does not need a confirmatory venous draw. Follow the schedule shown in Table 2.

Confirmed Venous Blood Lead Level

BLL	Recommended Follow-up Care
<3.5 μg/dL	 Provide education about common sources of lead exposure and information on how to further prevent exposure. During well-child visits, check development to make sure age-appropriate milestones are being met. During well-child visits, discuss diet and nutrition with a focus on iron and calcium intake. Conduct follow-up blood lead testing at recommended intervals based on the child's age. Centers for Medicare and Medicaid Services requires all children enrolled in Medicaid to get tested for lead at ages 12 and 24 months, or age 24–72 months if they have never been screened. For children not enrolled in Medicaid, CDC recommends focusing screening efforts on high-risk neighborhoods and children. Identify risk for lead poisoning based on the age of housing and social and demographic risk factors. Public health personnel and healthcare workers should use local data to develop screening plans that are responsive to local conditions. In the absence of such plans*, CDC recommends universal blood lead testing. Report test result to the ACLPPP.
3.5-19 μg/dL	 Follow the recommendations above for BLL < 3.5 μg/dL. Obtain an environmental exposure history to identify potential sources of lead. Arrange for an environmental investigation of the home to identify potential sources of lead†, as required. During an environmental investigation, professionals check the child's environment for possible causes of lead exposure and recommend ways to prevent further lead exposure. Ensure the child does not have iron deficiency using testing and treatment. Follow testing and treatment guidelines from the American Academy of Pediatrics (AAP). Discuss the child's diet and nutrition with a focus on calcium and iron intake. Refer caregivers to supportive services, as needed (e.g., Special Supplemental Nutrition Program for Women, Infants and Children). Check the child's development to ensure appropriate milestones are being met per AAP guidelines. Refer caregivers to supportive services, as needed (e.g., developmental specialists, Early Intervention Program). Provide follow-up BLL testing at recommended intervals. See schedule shown in Table 2. Report test result to the ACLPPP.

BLL	Recommended Follow-up Care
20-44 μg/dL	 Follow the recommendations above for BLL is 3.5–19 μg/dL.
	 Perform a complete history and physical exam, assessing the child for signs and symptoms related to lead exposure.
	 Arrange for or refer the family for an environmental investigation of the home and a lead hazard reduction program.
	 Consider performing an abdominal X-ray to check for lead-based paint chips and other radiopaque foreign
	bodies. This is important for young children who tend to swallow or eat non-food items. Children may also put their mouths on surfaces that could be covered with lead dust. Initiate bowel decontamination, if indicated.
	 Contact a Pediatric Environmental Health Specialty Unit (PEHSU) or the Poison Control Center
	(1-800-222-1222) for guidance.
	 PEHSUs provide information on protecting children and reproductive-age adults from environmental hazards.
	PEHSUs work with healthcare professionals, parents, schools, and community groups.
	Report test result to the ACLPPP.
≥ 45 μg/dL	 Follow recommendations for BLL 20–44 μg/dL.
	 Perform a complete history and physical exam including a detailed neurological exam.
	Perform an abdominal X-ray and, if needed, initiate bowel decontamination.
	 If the patient exhibits signs or symptoms of lead poisoning, including confusion, weakness, seizures, coma, nausea, vomiting, and abdominal pain, admit them to a hospital as soon as possible.
	 Consider admitting the patient to a hospital if one of these conditions exist:
	 The patient's home is not lead-safe, and they are unable to find a lead-free living space.
	 The source of lead exposure has not been identified, and the potential for further lead exposure is still possible.
	 The healthcare provider is consulting with a medical toxicologist or pediatrician with experience in treating lead poisoning to initiate:
	 Gastrointestinal decontamination (removal of swallowed lead using laxatives) or
	 Chelation therapy (a treatment that uses a medication to remove lead from the body when BLLs are very high).
	 Contact a PEHSU or Poison Control Center (1-800-222-1222) for assistance.
	Report test result to the ACLPPP.

^{*}The ACLPPP does not have a current strategic screening plan in place; therefore, universal testing is recommended. Data collected through universal testing and reporting will be used to develop a strategic screening plan.

[†]The ACLPPP refers children with a venous BLL of \geq 15 µg/dL for an environmental home investigation. A venous blood lead level < 15 µg/dL requires a physician's order to refer for an environmental home investigation. An elevated venous blood lead result is required for an environmental home investigation to be completed.

Reminder to Users of LeadCare Testing Systems

On May 17, 2017, Magellan Diagnostics Inc. sent a "Customer Safety Communication" letter to all affected customers stating:

- 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.

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

- Discontinue using Magellan's LeadCare System Testing Systems with venous blood samples.
- 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 which are not point-of-care tests.

On <u>July 6, 2021</u>, the CDC issued a Health Alert Network Health Advisory regarding certain Magellan Diagnostics, Inc. LeadCare Blood Test Kits distributed between October 27, 2020 and June 15, 2021. Magellan Diagnostics, Inc. recalled its <u>LeadCare II</u>, <u>LeadCare Plus</u>, and <u>LeadCare Ultra</u> Blood Lead Tests due to a significant risk of falsely low blood lead level results. Recommendations include:

- Discontinue use of all affected test kit lots.
- Retest children who were tested with the recalled LeadCare test kits whose results were less than 5 μg/dL.
- Retest children who were previously tested with a LeadCare test kit if the lot number of the initial test kit is unknown and the test was done after October 27, 2020 through July 6, 2021.
- Priority for retesting should be given to:
 - o Children where there is clinical concern that symptoms or developmental problems may be related to lead exposure.
 - o Populations at higher risk of elevated blood lead levels, such as children tested due to Medicaid-required screening.

On November 5, 2021, the CDC added the additional recommendation:

Retesting should be done by higher complexity testing (ICP-MS or GFAAS) with either a venous or a capillary blood sample.
 Capillary screening results above the blood lead reference value should be confirmed with blood drawn by venipuncture.
 Please note that effective October 28, 2021, CDC has updated its BLRV from 5 μg/dL to 3.5 μg/dL in response to the Lead Exposure Prevention and Advisory Committee recommendation made on May 14, 2021.

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 all necessary information for both elevated and non-elevated blood lead levels.

References:

¹Hagan, 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:

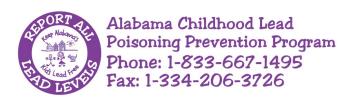
https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm

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

 $\underline{https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/magellan-diagnostics-inc-expands-voluntary-recall-leadcarer-test-kits}$

https://www.alabamapublichealth.gov/blog/assets/notifiablediseases.pdf

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



Use this form to report all **elevated blood lead levels** greater than or equal to 3.5 μ g/dL. <u>Please print or type</u>. Fax to (334) 206-3726 within 5 days of testing. Please call (334) 206-3883 with any questions. Blood lead levels less than 3.5 μ g/dL should be reported on the non-elevated blood lead reporting form within 5 days of testing.

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Use this form to report <u>all</u> non-elevated blood lead levels less than 3.5 $\mu g/dL$. <u>Please print or type</u>.

Fax to (334) 206-3726 within 5 days of testing. Please call (334) 206-3883 if you have any questions. *Elevated blood lead levels* greater than or equal to 3.5 μ g/dL should be reported on the elevated blood lead reporting form within 5 days of testing.

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