



Nebraska Department of Health and Human Services
HEALTH ALERT NETWORK
Update



To: Primary care, Laboratories, Pediatricians, Hospitals, Clinics and Public Health

From: Derry Stover, MPH, CPH
Occupational Health Epidemiologist
Phone: 402-471-2937

Matthew Donahue, MD
Acting State Epidemiologist
Phone: 402-471-8566

Gary Anthonie, MD
Director/CMO Public Health
Phone: 402-471-8566

Re: Expansion of Recall of LeadCare® Blood Lead Tests Due to Risk of Falsely Low Results

Date: November 2, 2021

The Centers for Disease Control and Prevention (CDC) released a Health Alert Network (HAN) Health Update about the expansion of Magellan Diagnostics' recall of LeadCare® Blood Lead Tests. The expanded recall has reduced the availability of supplies needed for point-of-care lead testing. Healthcare providers should not delay required blood lead testing for children. For facilities and providers affected by the recall, Nebraska DHHS recommends alternative testing methods using reference laboratories to ensure recommended and required lead testing is performed.

Background

Childhood lead poisoning is still a public health problem today, and children in Nebraska are at risk for exposure to lead. Nebraska has a relatively high percentage of homes built before 1978, where lead-based paint exposure risks are most common. Children are also exposed to lead from contaminated soil, consumer products, and occupational take-home exposures. Of the 33,747 children in Nebraska under 6 years old that were tested for lead in 2020, 296 (0.9%) had a confirmed elevated blood lead level.

Blood lead testing is a critical tool to identify children with lead exposure so they get treatment and an appropriate public health response. Per Nebraska's Blood Lead Testing Plan, most children in Nebraska need a screening blood lead test at ages 1 and 2 years old. Lead testing is recommended annually through age 5 for children at risk for exposure. All children enrolled in Medicaid are required to receive blood lead screening tests at ages 12 months and 24 months.

Nebraska has seen a significant decrease in the number of child lead screening tests performed, first due to COVID-19 in 2020 and then due to the LeadCare® test kit recall in 2021. In the first three months following the original recall in June 2021, the number of lead tests performed were 13% lower than the same three-month period in 2019. This decline suggests children may not be getting the necessary testing to detect lead exposure.

Recommendations

Despite the unavailability of LeadCare® testing kits, children must continue to receive their required blood lead tests. Nebraska DHHS and CDC strongly recommend that healthcare providers not delay required blood lead testing for children. By delaying blood lead testing for children, children exposed to lead will not be identified and receive necessary treatment and services.

Providers affected by the recall, or experiencing supply shortages, should contact Nebraska Public Health Laboratory (NPHL) or a reference laboratory to arrange for higher-complexity testing. For screening blood lead tests, specimen types include a capillary blood sample collected in a capillary blood tube or blood lead filter paper collection using capillary blood (also known as blood lead spot test). Confirmatory blood lead tests are collected by venous puncture. Refer to testing laboratory for specimen collection requirements.

More Information:

- Nebraska DHHS Blood Lead Testing Plan/Recommendations:
 - <https://dhhs.ne.gov/Lead%20Documents/DHHSBloodLeadTestingPlan.pdf>
- Nebraska DHHS: Lead Exposure Management Recommendations:
 - <https://dhhs.ne.gov/Lead%20Documents/Medical%20Management%20Recommendations%20for%20Children.pdf>
- Nebraska DHHS: Childhood Lead Poisoning: Information For Health Professionals:
 - <https://dhhs.ne.gov/Pages/Lead-Resources-for-Health-Care-Professionals.aspx>

This is an official **CDC HEALTH UPDATE**

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Expansion of Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results

Summary

Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have issued notifications about the expansion of Magellan Diagnostics' recall of LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests, which were distributed from October 27, 2020, to August 19, 2021. Additional LeadCare II product lots, including lots previously reported to be unaffected, were recalled due to a significant risk of falsely low results. The use of these devices may cause serious injuries because they might underestimate blood lead levels. FDA has identified this as a Class I recall, the most serious type of recall.

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Update to notify healthcare providers and state and local health departments about the expansion of the recall notice and to recommend appropriate follow-up actions in the shortage of LeadCare Lead Tests. This HAN Health Update is an update to [HAN Health Advisory 445: Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results](#) that CDC issued on July 6, 2021.

Background

Magellan Diagnostics, Inc. is recalling LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Test kits due to a significant risk of falsely low blood lead level results. FDA has concerns that the falsely low results may contribute to health risks in special populations such as young children and pregnant individuals. A pregnant or lactating individual's exposure to lead is concerning because it may cause health problems for the parent and the developing baby. Obtaining falsely low blood lead level results may lead to patients not receiving appropriate follow-up assessments, which may result in patient harm, including delayed puberty, reduced postnatal growth, decreased IQ, and attention and behavior problems in children.

FDA initially notified CDC on June 24, 2021, that some Magellan Diagnostics blood lead test kits were undergoing a voluntary recall by the manufacturer. FDA recommended that Magellan Diagnostics customers discontinue using all affected test kit lots identified as part of the recall and quarantine remaining inventory. On August 31, 2021, Magellan Diagnostics began notifying customers that the recall was expanded to include additional LeadCare II product lots. The recall now includes the majority of all test kits distributed since October 27, 2020. Product distribution has been paused until further notice, and replacement product is currently unavailable. It is unknown when replacement product will be available.

Recommendations for Clinicians

- Continue to schedule and perform required blood lead tests for patients. A venous or capillary blood sample analyzed using higher complexity methods such as inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectroscopy (GFAAS) from a CLIA compliant clinical laboratory should be used if LeadCare lead test kits are unavailable.
- Discontinue using all [test kit lots](#) identified as part of the recall.
- Retest children who were tested with the recalled LeadCare lead test kits whose results were less than CDC's [blood lead reference value](#). Retesting should be done with a venous blood sample analyzed with higher complexity testing.

- 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.
- Prioritize testing for:
 - Children where there is clinical concern that symptoms or developmental problems may be related to lead exposure,
 - Populations at higher risk of elevated blood lead levels, such as children tested due to Medicaid-required screening or due to other state or local requirements,
 - Individuals who are pregnant or breastfeeding, and
 - Children who are immigrants, refugees, or recently adopted from outside of the United States.
- Discuss the recall and retesting recommendations with a parent or caregiver of children who meet the retesting criteria.
- Follow recommendations for [best practices](#) when collecting a capillary blood sample for lead testing.

Recommendations for Public Health Professionals

- Work with healthcare providers in their jurisdictions to ensure patients receive their required blood lead tests. This outreach should include making providers aware of the need to conduct a capillary or venous test analyzed using higher complexity methods if LeadCare lead test kits are unavailable.
- Make providers aware that:
 - By delaying blood lead testing for children due to the unavailability of LeadCare lead test kits, children exposed to lead risk are not being identified and receiving necessary treatment and services.
 - If blood lead testing indicates blood lead levels are above the current [CDC blood lead reference value](#) or state or local action level, the healthcare provider or public health professional should refer to CDC guidelines or state/local guidelines for appropriate follow-up action.
 - [State and public health laboratories](#) may be able to help with additional demands for higher complexity testing.
- Follow recommendations for [best practices](#) when [collecting a capillary blood sample](#) for lead testing.
- Per [CDC guidance](#), children with blood lead levels at or greater than CDC's [blood lead reference value](#) should have had a subsequent test with a venous blood sample for confirmation. LeadCare instruments are currently approved for use only with capillary or finger/heel stick samples.
 - Venous blood confirmation levels are performed with higher complexity testing such as inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectroscopy (GFAAS) and are generally considered more accurate and are available from CLIA-compliant clinical laboratories.

For More Information about Blood Lead Testing

- [CDC's Lead Poisoning Prevention Program](#)
- [CDC's Lead and Multi-element Proficiency Program](#)

For More Information about the Recall

- [Magellan Diagnostics Recalls LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests Due to Risk of Falsely Low Results](#)
- [Information on the LeadCare Test Kit "Controls Out of Range-Low" \("COOR-LO"\) Recall](#)

For More Information about Laboratory-related Resources

- [Blood Lead Testing in Public Health Laboratories](#)
- [Video: What is the Laboratory Response Network for Chemical Threats \(LRN-C\)?](#)
- [Best Practices for Sampling and Testing Blood for Lead](#)
- [Lead Testing at Environmental Health Laboratories](#)

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention, highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##