

DATE

November 8, 2021

SUBJECT

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

INSTRUCTIONS

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For LOCAL HEALTH
DEPARTMENT reference only
DPHHS Subject Matter Resource for
more information regarding this HAN,
contact:

PHHS PHSD

Toxicologist

Dawn M. Nelson
1 (406) 417-9848

For technical issues related to the HAN
message contact the Emergency
Preparedness Section
at 1-406-444-0919

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Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory

DPHHS HAN

Information Sheet

DATE

November 8, 2021

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

BACKGROUND

See CDC HAN 457

INFORMATION

See CDC HAN 457

RECOMMENDATIONS

See CDC HAN 457



This is an official
CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
November 5, 2021, 10:00 AM ET
CDCHAN-00457

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

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Update as an update to [HAN Update 454: Expansion of Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results](#) that CDC issued on October 14, 2021. The purpose of this HAN Update is to clarify options for retesting children who were tested with the recalled LeadCare lead test kits. The information in this HAN Update remains the same as [HAN Update 454](#), except for the new information added below in bold in the **Recommendations for Clinicians** section.

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.

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](#).

- 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.
- **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 [blood lead reference value \(BLRV\)](#) from 5 µg/dL to 3.5 µg/dL in response to the Lead Exposure Prevention and Advisory Committee recommendation made on May 14, 2021.¹**
- 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 False 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](#)

References

1. Ruckart PZ, Jones RL, Courtney JG, et al. Update of the Blood Lead Reference Value — United States, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1509–1512. DOI: <https://dx.doi.org/10.15585/mmwr.mm7043a4>.

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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##