



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: [Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results](#) that was 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

- 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.
- Per [CDC guidance](#), children with blood lead levels at or greater than 5 µg/dL 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.

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](#)

DHEC contact information for reportable diseases and reporting requirements

Reporting of blood lead testing results (all results, regardless of test type, test result, or age of patient) is required by SC Statute requiring the reporting of diseases and conditions to your state or local public health department. See SC Code of Laws § 44-53-1310 et seq.) as per the DHEC 2021 List of Reportable Conditions available at: <https://www.scdhec.gov/sites/default/files/Library/CR-009025.pdf>

All blood lead results are reportable within 30 days. Any elevated results (5 mcg/dL or greater) are reportable within 7 days.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Blood Lead Test Reporting

**Mail, Fax, Email, or Send via secure FTP all blood lead testing results to
DHEC Bureau of Population Health, Data Analytics, and Informatics.**

Reporting

- **Submit electronically via DHEC's web-based reporting system; or**
- **Mail to:**
Bureau of Population Health, Data Analytics, and Informatics, Lead Surveillance
Sims-Aycock Building
2600 Bull Street
Columbia, SC 29201
- **Fax Lead reports to: (803) 898-3236; or**
- **Email: scionlead@dhec.sc.gov to establish electronic reporting**

For further information, contact:

**DHEC Bureau of Maternal and Child Health
Division of Children's Health and Perinatal Services**

Childhood Lead Poisoning Prevention Program

Mills Jarrett Building

2100 Bull Street

Columbia, SC 29201

Toll-Free Phone:

1-866-4NO-LEAD (866-466-5323)

Division Main Number: (803) 898-0767

For information on reportable conditions, see <https://www.scdhec.gov/ReportableConditions>

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.
Info Service	Provides general information that is not necessarily considered to be of an emergent nature.