

DATE:	September 15, 2021
TO:	Health Alert Network
FROM:	Alison Beam, JD, Acting Secretary of Health
SUBJECT:	Expanded Recall of LeadCare® II Testing Supply Kits Due to Risk of Falsely Low Results
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a “Health Advisory” provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE; LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE; PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

Summary

- Magellan Diagnostics, Inc. has expanded their product recall involving the LeadCare® blood test kits to include all its LeadCare II Blood Lead Test Kits, LeadCare Plus Blood Lead Test Kits, and LeadCare Ultra Blood Lead Test Kits because they could potentially underestimate blood lead levels when processing patient blood samples.
- Providers and healthcare organizations should discontinue the use of all LeadCare® II testing supply kits and quarantine the remaining inventory.
- Magellan Diagnostics has temporarily stopped shipments of LeadCare® test kits and has not issued a definitive date to resume shipments.
- Providers and healthcare organizations should identify and contact patients tested with recalled test kit lots. All results tested on impacted lots should be confirmed with an alternative lead testing option analyzed using a high complexity testing method, such as Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or Graphite Furnace Atomic Absorption Spectroscopy (GFAAS) at a high complexity, CLIA-certified, reference laboratory.
- Please call DOH at 1-877-PA-HEALTH or your local health department if you have any questions.

Please see the previous health advisory below on “Recall of LeadCare® Blood Lead Tests Due to Risk of Falsely Low Results” provided by the Centers for Disease Control and Prevention.

Summary

Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have issued a recall notice concerning the use of some LeadCare® Blood Lead Tests (certain LeadCare II, LeadCare Plus, and LeadCare Ultra test kit lots). These lots were distributed between October 27, 2020, and June 15, 2021. The use of these devices may cause serious injuries because they might underestimate blood lead levels. The FDA has identified this as a Class I recall, the most serious type of recall.

The purpose of this Health Alert Network (HAN) Health Advisory is to notify healthcare providers and state and local health departments about this recall notice and to recommend appropriate follow-up actions.

Background

Magellan Diagnostics, Inc. is recalling its LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests due to a significant risk of falsely low blood lead level results. The 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 inappropriate follow-up assessments, which may result in patient harm, including delayed puberty, reduced postnatal growth, decreased IQ, and inattention and behavior problems in children.

The FDA notified CDC on June 24 that some Magellan Diagnostics blood lead test kits were undergoing a voluntary recall by the manufacturer. The FDA is now recommending that Magellan Diagnostics customers discontinue the use of all affected test kit lots identified as part of the recall and quarantine remaining inventory.

Recommendations

- Discontinue use of all [affected test kit lots](#) identified as part of the recall.
- Retest children who were tested with the recalled LeadCare test kits whose results were less than 5µg/dL, the current CDC-recommended 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.
- Priority for retesting should be given to—
 - 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, and
 - Individuals who are pregnant or breastfeeding.
- If retesting indicates blood lead levels in excess of the current CDC [Blood Level Reference Values \(BLRV\)](#) or state or local action level, the healthcare provider or public health official should refer to [CDC guidelines](#) or state/local guidelines for appropriate follow-up action.
- Discuss the recall and retesting recommendations with a parent and/or caregiver of children who meet the retesting criteria.

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

More information about blood lead testing can be found by visiting—

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

More information about the recall can be found by visiting—

- [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 | Meridian Bioscience \(magellandx.com\)](#)
- [Magellan-Expanded-Recall-vFINAL.pdf \(magellandx.com\)](#)

If you have questions about this guidance, please call your local health department or 1-877-PA-HEALTH (1-877-724-3258).

Individuals interested in receiving further PA-HANs are encouraged to register at <https://han.pa.gov/>.

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.

This information is current as of September 15, 2021 but may be modified in the future.
