The following message was sent to you through the Alaska Public Health Alert Network (AK PHAN). Please share this information with others who may be interested.

Note: Contact information for the Alaska Section of Epidemiology can be found at the end of this message.

The Alaska Section of Epidemiology (SOE) is forwarding this U.S. Centers for Disease Control and Prevention (CDC) Health Advisory to Alaska health care providers for their immediate attention. Resources specific to Alaska are at the bottom of this Advisory.

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
July 6, 2021, 12:00 PM ET
CDCHAN-00445

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 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 Centers for Disease Control and Prevention (CDC) 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 5 µg/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 and July 6, 2021, the date of this health advisory.
- 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 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.

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

Alaska-Specific Information

For questions on prior testing using these products and recommended actions, please contact the Alaska Section of Epidemiology, Environmental Public Health Program, by phone (907-269-8000) or email (eph@alaska.gov).

Alaska Public Health Alert website: http://dhss.alaska.gov/dph/Epi/Pages/phan/default.aspx