This is an official

CDC Health Advisory

Distributed via Health Alert Network
July 6, 2021 6:00 PM
10493-CAD-07-06-2021-LEAD

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 between 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

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.