



Health Alert Network

Tri-County Health Department

Serving Adams, Arapahoe and Douglas Counties

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John M. Douglas, Jr., M.D. Executive Director

The pages that follow contain information critical to protecting the health of your patients and the citizens of Colorado.

HAN UPDATE

Number of pages including cover: 3

Subject: **Update - LeadCare® blood lead test kit recall - October 1, 2021**

Message ID: 10/1/2021 2:45:00 PM

Recipients: HAN Community Members.

From: TRI-COUNTY HEALTH DEPARTMENT

Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: **For your information. No response required. Please distribute widely in your office.**

You have received this message based upon the information contained within our Health Alert Network Notification System. If you have a different or additional e-mail or fax address that you would like us to use, or if you have additional questions, call 720-200-1477.

Categories of Health Alert Network 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/Public Health Brief: Provides general information that is not necessarily considered to be of an emergent nature.

You may download a copy of this HAN from the TCHD website at

<http://www.tchd.org/259/Health-Alert-Network>



HEALTH ALERT NETWORK BROADCAST

MESSAGE ID: 10012021 13:00

FROM: CO-CDPHE

SUBJECT: HAN Update - LeadCare® blood lead test kit recall

RECIPIENTS: Local Public Health Agencies / Clinical Labs

RECIPIENT INSTRUCTIONS: Local Public Health Agencies - Please forward to primary healthcare providers in your jurisdiction

HEALTH UPDATE | LeadCare® blood lead test kit recall | October 1, 2021

Health care providers: Please distribute widely in your office

Key points

- This Health Alert Network (HAN) broadcast updates a HAN distributed on July 9, 2021, “Recall of LeadCare® blood tests due to risk of falsely low results.”
- Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have expanded a recall notice concerning the use of some LeadCare® Blood Lead Tests (certain LeadCare II, LeadCare Plus, and LeadCare Ultra test kit lots) to include additional LeadCare II sublots.
- These lots were distributed between Oct. 27, 2020 and Aug. 19, 2021.
- Childhood lead screening rates in Colorado decreased 15% from June to August 2021, compared with the same time last year. CDPHE strongly recommends providers continue to screen at-risk children for lead at 12 and 24 months with a venous test OR capillary test processed in a laboratory (see below).
- Unaffected Magellan point-of-care lead testing products (if available) also may be used for routine lead screenings.
- CDPHE will provide updates when more information becomes available.

Background information

The FDA notified CDC on June 24, 2021 that Magellan Diagnostics was voluntarily recalling some blood lead test kits. On Sept. 28, 2021, Magellan Diagnostics, Inc. expanded the recall to include additional LeadCare II sublots. The FDA recommends that Magellan Diagnostics customers discontinue the use of all affected test kit lots and quarantine remaining recalled inventory.

Magellan Diagnostics, Inc. recalled its LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests due to a risk of tests returning false low blood lead level results. False low blood lead level results may lead to inappropriate follow-up assessments that may result in patient harm, including delayed puberty, reduced postnatal growth, decreased IQ, and inattention and behavior problems in children. False low results may contribute to health risks in special populations

such as young children and pregnant or lactating individuals. Pregnant or lactating individuals' exposure to lead is concerning because it may cause health problems for both the parent and the developing baby.

Recommendations / guidance

- Discontinue use of all affected test kit lots identified as part of the recall. An updated list of affected test kit lots can be found here:
<https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk>
- Follow previous CDPHE guidance for retesting children affected by recalled products, available here:
https://drive.google.com/file/d/1tImGgJ-54JgX3YOY0dBjhw8kY1NISKF_/view
- Continue to screen at-risk children for lead. Children eligible for Medicaid or the Child Health Plan Plus (CHIP+) are **required** to be screened at 12 and 24 months. Other children should be screened if they meet one of the criteria in CDPHE's risk-based questionnaire:
<https://drive.google.com/file/d/1qcJ8C5dPvGBI8tA1yJVvrFctONjevq9E/view>
- Retesting and routine screening should be done with a venous OR capillary blood sample analyzed with higher complexity testing OR with an unaffected Magellan point-of-care product (if available).
- Examples of acceptable capillary testing in a laboratory setting can be found here*:
 - <https://ltd.aruplab.com/Tests/Pub/0020745>
 - <https://www.labcorp.com/tests/717016/lead-capillary-fingerstick-blood-pediatric>
 - <https://testdirectory.questdiagnostics.com/test/test-detail/39027/lead-capillary?cc=STL>

*This is not a comprehensive list nor a CDPHE endorsement of acceptable laboratory providers.

More information

- CDPHE-issued HAN: https://drive.google.com/file/d/1tImGgJ-54JgX3YOY0dBjhw8kY1NISKF_/view
- CDC-issued HAN: <https://emergency.cdc.gov/han/2021/han00445.asp>
- Blood lead testing:
 - CDC's Lead Poisoning Prevention Program: <https://www.cdc.gov/nceh/lead/>
 - CDC's Lead and Multi-element Proficiency Program: <https://www.cdc.gov/labstandards/lamp.html>
- Magellan recall:
 - Magellan Diagnostics Recalls LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests Due to Risk of Falsely Low Results:
<https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk>
- Lead in Colorado:
 - <https://cdphe.colorado.gov/lead-health>
- Contact the Colorado Childhood Lead Poisoning Prevention Program at cdphe_leadreports@state.co.us with questions.