



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: 4

Subject: **Update - Magellan Diagnostics resumes distribution of LeadCare® II test kits - March 09, 2022**

Message ID: 3/9/2022 4:30:00 PM

Recipients: HAN Community Members.

From: TRI-COUNTY HEALTH DEPARTMENT

Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: **Tri-County Health Department is forwarding you the attached HAN. You may have already received this broadcast if you are on the CDPHE distribution list, however, we wanted to ensure you did not miss this important information. No response is required.**

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: 03092022 15:15

FROM: CO-CDPHE

SUBJECT: HAN Update - Magellan Diagnostics Resumes Distribution of LeadCare® II Test Kits

RECIPIENTS: Local Public Health Agencies / Clinical Labs

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

HEALTH UPDATE | Magellan Diagnostics resumes distribution of LeadCare® II test kits | March 09, 2022

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,” and provides reminders regarding lead screening.
- Magellan Diagnostics has identified and resolved the defect causing the blood lead test kit recall.
- Clinics should discard all affected test kits identified by the recall.
- Providers can purchase replacement LeadCare® II test kits and use the new products to screen at-risk children for lead.
- Screen Medicaid and CHP+ -eligible children at ages 12 and 24 months. Screen other children using CDPHE’s risk-based questionnaire.
- CDPHE encourages providers to follow CDC-recommended actions for elevated blood lead case management based on the updated blood lead reference value of 3.5 micrograms per deciliter.

Background information

Magellan product recall

Beginning in June, 2021, 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. The FDA and CDC recommended Magellan Diagnostics customers discontinue the use of all affected test kit lots and quarantine remaining recalled inventory.

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.

On Feb. 16, 2022, Magellan Diagnostics notified CDC that the paperboard material used to package treatment reagent tubes was the source of the contaminant. Magellan has replaced the packaging materials and resumed shipments of its test kits.

Food recalls

In early February, two companies recalled snack foods potentially contaminated with lead. These recalls are a reminder that there are many potential sources of lead and highlight the importance of asking parents and guardians about those sources using CDPHE's risk-based questionnaire.

Updated blood lead reference value

In October 2021, CDC lowered its blood lead reference value for children from 5 micrograms per deciliter ($\mu\text{g}/\text{dL}$) to 3.5 $\mu\text{g}/\text{dL}$. The blood lead reference value is a screening tool to identify children who have higher levels of lead in their blood compared with most children. Children who have blood lead test results above the blood lead reference value may need early intervention to prevent lead poisoning.

Recommendations / guidance

- Discard all affected Magellan test kit lots identified as part of the recall. A complete list of affected test kit lots can be found at <https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk>
- Screen at-risk children for lead using a point-of-care test (Magellan LeadCare II), venous test, or a capillary test processed in a laboratory.
- Children eligible for Medicaid or the Child Health Plan Plus (CHIP+) are **required** to be screened at 12 and 24 months.
- Ask parents and guardians of other children about potential sources of lead using CDPHE's risk-based questionnaire, available at https://drive.google.com/file/d/1kWhJ1QNXTy2d73lZEduNjTOE_ySLpeZf/view. Screen children who meet any of the criteria for lead.
- CDPHE encourages Colorado health care providers to follow CDC-recommended actions for elevated blood lead case management (<https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm>).
- Report all lead tests, not just elevated tests, for children aged 18 years and younger. Timely reporting allows public health to take steps to help families prevent ongoing lead exposure.
- Lead can pass from a pregnant person to the unborn baby. Evaluate if pregnant people have risk factors that indicate a need for blood lead testing during pregnancy. (<https://www.cdc.gov/nceh/lead/docs/publications/leadandpregnancy2010.pdf>)

More information

Magellan recall

- Recall resolution press release: <https://www.prnewswire.com/news-releases/magellan-diagnostics-resumes-distribution-of-leadcare-ii-test-kits-301483264.html>
- Recall press release: <https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk>

Guidance

- CDPHE EBL Case Management for State & Local Public Health: <https://drive.google.com/file/d/1QmH34cdDZyVMJHSSDzKyvnMwb0-fF-sB/view?usp=sharing>
- CDPHE EBL Case Management Guidance for Health Care Providers: <https://drive.google.com/file/d/1KkBO6pWxj5ETogQ89rP-C5nl-14DenJp/view?usp=sharing>
- CDPHE lead reporting: <https://cdphe.colorado.gov/lead-health>

Food recalls associated with lead contamination

- El Chavito: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/el-chavito-inc-recalls-saladitos-dried-salted-plums-and-saladitos-enchilados-salted-plums-chili?utm_medium=email&utm_source=govdelivery#recall-announcement
- A&E Corrales: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ae-corrales-llc-recalls-saladitos-dried-salted-plums-chili-because-possible-health-risk?utm_medium=email&utm_source=govdelivery#recall-announcement

Contact the Colorado Childhood Lead Poisoning Prevention Program at cdphe_leadreports@state.co.us with questions.