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 ADVISORY

Number of pages including cover: 4
Subject: **Advisory - Recall of LeadCare® blood lead tests due to risk of falsely low results - 7/9/2021**
Message ID: 7/9/2021 3:45:00 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.**

For more information:
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.
- CDPHE: 303-692-2700 or 303-370-9395 (after hours)

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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

COLORADO
Department of Public Health & Environment

HEALTH ALERT NETWORK BROADCAST
MESSAGE ID: 070921 11:20
FROM: CO-CDPHE
SUBJECT: HAN Advisory – Recall of LeadCare® Blood Lead Tests Due to Risk of Falsely Low Results
RECIPIENTS: Local Public Health Agencies / Clinical Labs
RECIPIENT INSTRUCTIONS: Local Public Health Agencies – Please forward to primary healthcare providers in your jurisdiction

HEALTH ADVISORY | Recall of LeadCare® blood lead tests due to risk of falsely low results | 7/9/2021

Health care providers: Please distribute widely in your office

Key points

- 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.
- Providers should discontinue use of all affected test kit lots (see link below).
- The use of these devices may underestimate blood lead levels.
- The timeframe for replacement product availability is currently unknown.
- CDC recommends retesting potentially impacted individuals (those with results less than 5 µg/dL) with a venous test.
- CDPHE additionally recommends retesting potentially impacted individuals with a venous test OR an unaffected LeadCare II product (if available).
- CDPHE will provide updates when more information becomes available.

Background information

Magellan Diagnostics, Inc. is recalling 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, which 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.

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 now recommends that Magellan Diagnostics customers discontinue the use of all affected test kit lots identified as part of the recall and quarantine remaining inventory.

Recommendations / guidance

- Discontinue use of all affected test kit lots identified as part of the recall.
    - 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
- Retest individuals 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 OR with an unaffected LeadCare II product (if available).
- Retest individuals 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 for whom 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 recommendations (linked below), and
    - Individuals who are pregnant or breastfeeding.
- If retesting indicates blood lead levels in excess of the current CDC Blood Level Reference Values (BLRV, linked below) or Colorado state action level of ≥5 µg/dL, the health care provider or public health official should refer to CDC guidelines (linked below) or state/local guidelines for appropriate follow-up action.
    - Blood Level Reference Values (BLRV): https://www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fnceh%2Flead%2Facclpp%2Fblood_lead_levels.htm
    - CDC Guidelines for Lead: https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm
    - Colorado Lead Testing Recommendations: https://drive.google.com/file/d/1qcJ8C5dPvGBI8tA1yJVvrFctQNjevq9E/view
- Discuss the recall and retesting recommendations with a parent and/or caregiver of children who meet the retesting criteria.

More information

- 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
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