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Health.Alert@nh.gov
July 8, 2021 1530 EDT (3:30 PM EDT)
NH-HAN 20210708

NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs *for all*
Department of Health and Human Services

Recall of LeadCare® Blood Lead Tests Due to Risk of Falsely Low Results

Key Points and Recommendations:

- Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have issued a recall of some LeadCare® blood lead test kits that were distributed between October 27, 2020 and June 15, 2021 because these tests may provide falsely low blood lead level (BLL) results. See the **Table** below, the attached Magellan Diagnostics recall notice, and the FDA recall notice for more information.

- Providers and healthcare organizations should review inventory of point-of-care blood lead test materials to identify and immediately discontinue use of the recalled kits.

- Review the attached CDC Health Advisory with clinical recommendations for retesting children who were tested with the recalled LeadCare test kits, or tested using a LeadCare test kit with an unknown lot number between October 27, 2020 and July 6, 2021.

    - CDC recommends retesting children whose results were less than 5 mcg/dL (the current CDC-recommended blood lead reference value) because children with a BLL of 5 mcg/dL or greater usually have a venous blood confirmation test.

    - Because New Hampshire's BLL "action level" was recently lowered from 7.5 mcg/dL to 5 mcg/dL on July 1, 2021 to align with CDC's reference value (see prior NH HAN), NH DPHS recommends retesting children whose results were less than 7.5 mcg/dL, if they did not already have a confirmatory venous BLL test.

    - CDC recommends retesting be performed with a venous blood sample analyzed with higher complexity testing. If there are barriers to obtaining a venous blood sample, then retesting should at least be conducted with a capillary sample using testing supplies not impacted by the recall.

Table: Magellan Diagnostics, Inc. recalled blood lead tests distributed between October 27, 2020 and June 15, 2021.

Product Name:		LeadCare® II Blood Lead Test Kit	LeadCare® Plus Blood Lead Test Kit	LeadCare® Ultra Blood Lead Test Kit
Catalog Number:		70-6762	82-0004	70-8098
UDI		N/A	N/A	N/A
Recalled Lot Numbers	**Original**	2013M, 2014M 2015M, 2016M, and 2017M	2011MU	
	Expanded	2101M, 2103M, 2105M, 2106M and 2107M	2104MU and 2108MU	
Magellan Reference No.		1218996-05/07/2021-0001R		

Additional Information and Contacts:

LeadCare® test kits which are not part of the recall can continue to be used for blood lead analysis.

The most expedient means of obtaining new test supply kits is to contact your medical supply distributor. Magellan Diagnostics is providing replacement product to healthcare providers impacted by the recall; see instructions in the attached Magellan Diagnostics recall notice. Replacement of recalled testing supply kits may take up to six weeks.

If you have any questions regarding the Magellan Diagnostics recall, please contact Magellan's LeadCare Product Support Team at 1-800-275-0102, or email LeadCareSupport@magellandx.com.

For questions about the contents of this message, please contact the NH DPHS Healthy Homes and Lead Poisoning Prevention Program at 1-800-897-LEAD, or LeadRN@dhhs.nh.gov.

To change your contact information in the NH Health Alert Network, please send an email to DHHS.Health.Alert@dhhs.nh.gov

Status:	Actual
Message Type:	Alert
Severity:	Moderate
Sensitivity:	Not Sensitive
Message Identifier:	NH-HAN 20210708
Delivery Time:	12 hours
Acknowledgement:	No
Distribution Method:	Email, Fax
Distributed to:	Physicians, Physician Assistants, Practice Managers, Infection Control Practitioners, Infectious Disease Specialists, Community Health Centers, Hospitals, Hospital CEOs, Hospital Emergency Departments, EMS, Nurses, NHHA, Pharmacists, Laboratory Response Network, Manchester Health Department, Nashua Health Department, Public Health Networks, DHHS Outbreak Team, DPHS Investigation Team, DPHS Management Team, Northeast State Epidemiologists, Zoonotic Alert Team, Health Officers, Deputy Health Officers, MRC, NH Schools, EWIDS, Dialysis & Transplant Clinics, STD Clinics, Immunization Practices, Travel Centers, Influenza Sentinels, Urgent Care Centers, Ambulatory Surgical Centers, Walk-in Clinics, Poison Center, Alcohol and Other Drug Treatment Centers, Long-Term Care Facilities, Community Mental Health Centers, Health Departments, Internal Medicine, Occupational Health, Gastroenterology, Schools and Daycare Providers, Regional Public Health Networks, Environmental Services, Family Planning Programs, Department of Corrections, Home Care Providers, Local and State Partners, Area Agencies
From:	Benjamin Chan, MD, MPH – State Epidemiologist Jonathan Ballard, MD, MPH, MPhil – Chief Medical Officer, NH DHHS
Originating Agency:	NH Department of Health and Human Services, Division of Public Health Services

Attachments:

1. CDC HAN – July 6, 2021
2. Magellan Expanded Urgent Medical Device Recall Notice - June 21, 2021

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

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention, highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##

Magellan
DIAGNOSTICS
A Meridian Bioscience® Company

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N. Billerica, MA 01862 US
www.magellandx.com

EXPANDED URGENT MEDICAL DEVICE RECALL

Dear Valued Customer, June 21, 2021

This is to inform you of a voluntary product removal of specific lots involving the products listed below:

Product Name:		LeadCare® II Blood Lead Test Kit	LeadCare® Plus Blood Lead Test Kit	LeadCare® Ultra Blood Lead Test Kit
Catalog Number:		70-6762	82-0004	70-8098
UDI		N/A	N/A	N/A
Recalled Lot Numbers	**Original**	2013M, 2014M 2015M, 2016M, and 2017M	2011MU	
	Expanded	2101M, 2103M, 2105M, 2106M and 2107M	2104MU and 2108MU	
Magellan Reference No.		1218996-05/07/2021-0001R		

Description of Problem & Associated Health Hazard:

This notice is a follow-up to a notice issued to customers dated May 7, 2021. Magellan has identified and continues to investigate an ongoing issue with testing of the controls included in LeadCare® II Blood Lead Test Kits (Catalog #70-6762) that are in addition to those which you may have already been notified. The additional lots are identified as lots 2101M, 2103M, 2105M, 2106M, and 2107M, and LeadCare® Plus Blood Lead Test Kits (Catalog No. 82-0004) and LeadCare® Ultra Blood Lead Test Kits (Catalog No. 70-8098) identified as lots 2104MU and 2108MU. **You should discontinue use of all lots identified above.**

The original impacted LeadCare® II Blood Lead Test Kits (lots 2013M, 2014M, 2015M, 2016M, and 2017M) were distributed between December 8, 2020 and March 11, 2021; the expanded recall lots (2101M, 2103M, 2105M, 2106M and 2107M) were distributed between March 29, 2021 and June 15, 2021. Lot 2011MU, for use with the LeadCare® Plus and LeadCare® Ultra test systems was distributed between October 27, 2020 and April 29, 2021, while lots 2104MU and 2108MU were distributed between March 25, 2021 and May 28, 2021.

Magellan has received reports that control tests of either the “Low-Control” (e.g., the “Level 1” control at approximately 9 µg/dL ± 3 µg/dL) and/or the “High-Control” (e.g., the “Level 2” control at approximately 28 µg/dL ± 4 µg/dL) generated a “low” result (i.e., “Controls Out of Range – Low” or “COOR-L”). Magellan originally suspected that the issue was isolated to a single lot of plastic caps and tubes by a new supplier As the investigation has progressed, the Company currently believes that the root cause is not limited to that lot of plastic caps and tubes and could be related to other variables associated with the treatment reagent caps and tubes. At this time the root cause has not been identified, however, the combined rate of all complaints received across all lots impacted is approximately 3.2% of all kits distributed; not all kits nor all lots appear to be impacted to the same degree (i.e., there is both intra- and inter- kit variation in occurrence as it relates the COOR-L anomaly).

At this time, Magellan is not aware of any complaints or reports from the field of false suppression involving patient blood samples tested with the impacted LeadCare lots. However, Magellan has conducted numerous studies and experiments to understand the root cause of this phenomenon and we currently believe that this issue has the potential to affect patient blood samples and could potentially underestimate blood lead levels when processing patient samples. **Therefore, patient testing should not be performed (using any of the impacted lots) until resolution of the issue.**

Magellan Diagnostics, Inc.
101 Billerica Avenue, Bldg. 4
N. Billerica, MA 01862 US
www.magellandx.com

REQUIRED ACTIONS:

Immediate Actions:

- **Review current inventory and segregate any remaining stock.**
- **Discontinue use of any remaining stock.**

Regarding Previous Results:

- Per laboratory policies and procedures, laboratories should evaluate patient test results that were generated with the impacted lots.
- **Confirm suspect results with a high complexity testing method at a reference laboratory.**

Regarding this Notification:

- Promptly complete and return the Customer Notification Form below to LeadCareSupport@magellandx.com or FAX to (978) 600-1480 (this will indicate receipt of this field correction notice).
  - Complete this form even if you have no remaining inventory.
- Once the form has been submitted, please contact Magellan Technical Support 1-800-275-0102 to obtain a FedEx label to return any remaining inventory to Magellan Diagnostics, Inc. and receive replacement product.
  - Product will be replaced based on availability; replacement product is NOT currently available.

Actions to Be Taken by Magellan:

Magellan intends to continue the root cause investigation into the COOR-L failure mode and replace product for those users that have any remaining inventory of impacted product (replacement product is currently NOT available).

Contact Information:

If you have any questions, please call Magellan's LeadCare Product Support Team at 1-800-275-0102, or email at LeadCareSupport@magellandx.com.

Supply of safe, effective, and reliable product is our highest priority. We apologize for any inconvenience or concern this action may cause and we thank you for your continued support of Magellan Diagnostics, Inc.

Sincerely,

Mike West
Product Support Manager

Please promptly complete and return the Customer Notification Form on the next page.

This will indicate receipt of this field correction notice.

Complete this form even if you have no remaining inventory.

Magellan Diagnostics, Inc.
101 Billerica Avenue, Bldg. 4
N. Billerica, MA 01862 US
www.magellandx.com

– Confirmation of Notification –
Magellan Diagnostics, Inc. Direct Customer
URGENT MEDICAL DEVICE RECALL

LeadCare Blood Lead Test Kits
Catalog Numbers: 70-6762, 82-0004, and 70-8098
Magellan Reference Number: 1218996-05/07/2021-0001R

Please return this form even if you currently have none of the affected product in inventory

Please select the current inventory of impacted product at your facility:

- ☐ LeadCare II Blood Lead Test Kit (Cat No. 70-6762: lots 2013M, 2014M, 2015M, 2016M, 2017M, or lots 2101M, 2103M, 2105M, 2106M and 2107M)
- ☐ LeadCare Plus Blood Lead Test Kit (Cat No. 82-0004: Lot 2011MU, or lots 2104MU, 2108MU)
- ☐ LeadCare Ultra Blood Lead Test Kit (Cat No. 70-8098: Lot 2011MU, or 2104MU, 2108MU)
- ☐ No product remaining in inventory

Confirm that impacted product has been returned to Magellan and indicate quantity shipped:

- ☐ No product to return
- ☐ LeadCare II Test Kit (Cat No. 70-6762) Impacted Quantity Returned: _____
- ☐ LeadCare Plus Test Kit (Cat No. 82-0004) Impacted Quantity Returned: _____
- ☐ LeadCare Ultra Test Kit (Cat No. 70-8098) Impacted Quantity Returned: _____

Please answer the following questions if you used any impacted lots of these products:

☐ YES	☐ NO	Did you test the controls for these lots before use?
☐ YES	☐ NO	If so, did the controls pass the testing?
☐ YES	☐ NO	Have you seen any unexpected patient results?
☐ YES	☐ NO	If so, were they lower than expected?

I have read and understood this notification and will keep this notification on file.

☐ Yes ☐ No

Contact Name	Date
Signature	Phone Number
Institution Name	Email
Address	

For more information, please contact **Magellan Diagnostics, Inc. Technical Services at 1-800-275-0102.**

Please return this Response Form to: **Mike West, Product Support Manager**
Magellan Diagnostics, Inc.
101 Billerica Avenue, Bldg. 4, N. Billerica, MA 01862 USA
Telephone: 1-800-275-0102
FAX: (978) 600-1480
Email: LeadCareSupport@magellandx.com