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DHHS.Health.Alert@dhhs.nh.gov
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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, Update #1: Expanded Recall to Include all LeadCare® II Testing Supply Kits

Key Points and Recommendations:

- Magellan Diagnostics, Inc. has expanded their product recall involving the LeadCare ® blood test kits. This expanded COOR-LO recall includes LeadCare® II Blood Test Kits lots: 2012M (Sublots -08, -09, -10, -11, -12, -13, and -14); 2018M; 2102M; 2109M, 2110M; 2111M; 2112M; 2113M; 2114M; and 2115M and is outlined below. These lots are **in addition** to previously recalled lots.

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	**Initial**	2013M, 2014M 2015M, 2016M, and 2017M	2011MU	
	Expansion	2101M, 2103M, 2105M, 2106M and 2107M	2104MU and 2108MU	
	Current Expansion	2012M Sublots: -08, -09, -10, -11, -12, -13, and -14.	N/A	
		2018M, 2102M, 2109M, 2110M, 2111M, 2112M, 2113M, 2114M and 2115M		
Magellan Reference No.		1218996-05/07/2021-0001R		

- Providers and healthcare organizations should discontinue use of **all** LeadCare® II testing supply kits and quarantine remaining inventory.
- Providers and healthcare organizations should identify and contact patients tested with recalled test kit lots.
    - All results tested on impacted lots should be confirmed with an alternative lead testing option analyzed using a high complexity testing method, such as Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or Graphite Furnace Atomic Absorption Spectroscopy (GFAAS) and depending on availability may include:
        - Venous sampling
        - Capillary Microtainer (EDTA) tube
- The CDC has an instruction poster Steps for Collecting Finger Stick Capillary Blood Using a Microtainer® available.

- LeadCare analyzers are not impacted by the recall.
- Magellan Diagnostics has temporarily stopped shipments of LeadCare® test kits and has not issued a definitive date to resume shipments.

Additional Information and Contacts:

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 20210831 Recall of LeadCare® Blood Lead - Update
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:	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. Magellan Notice of Impending Recall Expansion

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

Dear Valued Partner,

The purpose of this communication is to update you on the COOR-LO product recall involving the LeadCare® Blood Test Kits. At this time, Magellan Diagnostics has decided to expand the COOR-LO recall to include LeadCare® II Blood Lead Test Kit lots: 2012M Sublots: Sublots: -08, -09, -10, -11, -12, -13, and -14; 2018M; 2102M; 2109M; 2110M; 2111M; 2112M; 2113M; 2114M; and 2115M. ("3rd Expansion").

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	**Initial**	2013M, 2014M 2015M, 2016M, and 2017M	2011MU	
	Expansion	2101M, 2103M, 2105M, 2106M and 2107M	2104MU and 2108MU	
	Current Expansion	2012M Sublots: -08, -09, -10, -11, -12, -13, and -14.	N/A	
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Magellan Reference No.		1218996-05/07/2021-0001R		

Magellan recommends the following:

- **Discontinue use of all test kits and quarantine remaining inventory.**
- **Health Care Providers should evaluate patient test results that were generated with all recalled lots.**
  - **See CDC's Recommended Actions Based on Blood Lead Level**
- **Suspect results should be confirmed with an alternative lead testing option, such as those using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or Graphite Furnace Atomic Absorption Spectroscopy (GFAAS) at a high complexity, CLIA-certified, reference laboratory.**

Refer to previously issued retesting recommendations from CDC: Magellan Diagnostics has temporarily stopped shipments of the LeadCare II®, LeadCare Plus® and LeadCare Ultra® Test Kits.

- **The CDC alert can be found here: CDC Health Alert Network**
- **Magellan has not yet set a definitive date to resuming shipments.**
- **LeadCare Analyzers are not impacted.**

Magellan continues to investigate the root cause of the COOR-LO failure mode and is working diligently to find a solution to resume shipments/replacements as quickly as possible.

We are currently on backorder but intend to fulfill orders once product becomes available. We are continuing to accept orders at this time. Please note, there will be significant delays. Magellan will ensure order fulfillment as quickly as possible once shipments resume.

Supply of safe, effective, and reliable product to you, our valued customers, and your patients is our highest priority. We sincerely apologize for the inconvenience or concern this action may cause.

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

Notification letters with Confirmation Notification Form ("Response Form") will be sent via USPS certified mail; please be sure to respond to any notification. If you have any questions or concerns, please do not hesitate to contact our Product Support team at leadcaresupport@magellandx.com or via telephone by dialing 1.800.275.0102.

Thank you,

Magellan Diagnostics, Inc.