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

EXPANDED URGENT MEDICAL DEVICE RECALL

Additional Lots
As of August 30, 2021

Dear Valued Customer,

August 30, 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	**Initial**	2013M, 2014M 2015M, 2016M, and 2017M	2011MU	
	Expanded	2101M, 2103M, 2105M, 2106M and 2107M	2104MU and 2108MU	
	Current Expansion	2012M Sublots: -08, -09, -10, -11, -12, -13, and -14 Full Lots: 2018M, 2102M, 2109M, 2110M, 2111M, 2112M, 2113M, 2114M, 2115M, and 7114M	N/A	
Magellan Reference No.		1218996-05/07/2021-0001R		

Description of Problem & Associated Health Hazard:

This notice is a follow-up to notices issued to customers dated May 17, 2021 and June 21, 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 have been recalled and for which you may have already been notified. The additional lots are identified as LeadCare® II Blood Lead Test Kit Sublots: 2012M-08, 2012M-09, 2012M-10, 2012M-11, 2012M-12, 2012M-13, and 2012M-14; and full lots: 2018M; 2102M; 2109M; 2110M; 2111M; 2112M; 2113M; 2114M; 2115M; and 7114M. **You should discontinue use of all recalled 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.

In the present recall expansion, LeadCare® II Blood Lead Test Kits **Sublots: 2012M-08, 2012M-09, 2012M-10, 2012M-11, 2012M-12, 2012M-13, and 2012M-14; and full lots: 2018M; 2102M; 2109M; 2110M; 2111M; 2112M; 2113M; 2114M; 2115M; and 7114M** were distributed between December 2, 2020 and August 19, 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 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.**

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REQUIRED ACTIONS:

Immediate Actions:

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

Regarding Previous Results:

- Per laboratory policies and procedures, Health Care Providers 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.**
- **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: https://emergency.cdc.gov/han/2021/han00445.asp**

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, Magellan Technical Support will process the form and provide a Return Material Authorization (RMA) 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.

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Magellan Website

– Confirmation of Notification –
Magellan Diagnostics, Inc. ---- Direct Customer

EXPANDED URGENT MEDICAL DEVICE RECALL

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

Please return this form even if you currently have no affected product in inventory.
Please provide full contact information, including email address for delivery of return shipping label.
Incomplete forms will delay the response.

Please **select the products** impacted. **Circle the lot numbers** of current inventory of at your facility and **list the number of boxes** (full and partial) in the space provided of those lots to be returned to Magellan. This information is critical to issuing your return material authorization (RMA):

☐ **LeadCare II Blood Lead Test Kit (Cat No. 70-6762):** **for lots NOT previously reported to Magellan**

2012M: _____ → (Sublots 2012M-08 through 2012M -14)

2013M: _____	2018M: _____	2106M: _____	2112M: _____
2014M: _____	2101M: _____	2107M: _____	2113M: _____
2015M: _____	2102M: _____	2109M: _____	2114M: _____
2016M: _____	2103M: _____	2110M: _____	2115M: _____
2017M: _____	2105M: _____	2111M: _____	7114M: _____

☐ **LeadCare Plus Blood Lead Test Kit (Cat No. 82-0004):** **for lots NOT previously reported to Magellan**

2011MU: _____ 2104MU: _____ 2108MU: _____

☐ **LeadCare Ultra Blood Lead Test Kit (Cat No. 70-8098):** **for lots NOT previously reported to Magellan**

2011MU: _____ 2104MU: _____ 2108MU: _____

☐ **No product remaining in inventory**

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 Website
CRN # if Known: _____
Magellan Diagnostics, Inc.
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Telephone: 1-800-275-0102 FAX: (978) 600-1480
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