NAPA-SOLANO-YOLO-MARIN-MENDOCINO COUNTY PUBLIC HEALTH LABORATORY
2201 COURAGE DRIVE, MS 9-200
FAIRFIELD, CA 94533
(707) 784-4410 FAX (707) 423-1979

July 6, 2021

To: Blood Lead Sample Submitters

Our laboratory was recently notified by our blood lead kit test manufacturer, Magellan Diagnostics, about an expanded recall of test kit lots that could potentially underestimate blood lead levels. Per the recall, the manufacturer has suspended all use of affected test kit lots and has recommended that suspect results be confirmed with a high complexity testing method at a reference laboratory. We reviewed blood lead level test results obtained with the additional affected kit lot and did not find abnormalities with the test based on the performance of the controls. However, if a sample was collected by your facility between February 1, 2021 and July 2, 2021 and the result is suspect or the patient is demonstrating symptoms of blood lead poisoning, venous testing should be considered using a commercial laboratory, such as Quest Diagnostics or LabCorp.

Unfortunately, our laboratory will not be able to perform capillary blood lead level testing until replacement kits have been received. At present, there is no estimate on when manufacturer can provide these supplies, and we anticipate that it could be several weeks before replacement kits are received. We will communicate about when testing will resume once we obtain a firm estimate. We apologize for any inconvenience this recall may cause.

Please let us know if you have any questions or concerns about this notification.

Sincerely,

Beatrix Kapusinszky, Ph.D., PHLD(ABB)
Public Health Laboratory Director
Napa-Solano-Yolo-Marin-Mendocino County Public Health Laboratory
2201 Courage Drive, MS 9-200
Fairfield, CA 94533
(707) 784-4410
https://www.solanocounty.com/depts/ph/bureaus/laboratory/default.asp

Magellan
DIAGNOSTICS
A Meridian Bioscience® Company

Magellan Diagnostics, Inc.
101 Billerica Avenue, Bldg. 4
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.