



HEALTH ALERT NETWORK | HEALTH ADVISORY | SEPTEMBER 10, 2021

Magellan Diagnostics, Inc LeadCare® Blood Lead Test Recall Expansion

The Blood Lead Program with the North Dakota Department of Environmental Quality is notifying health care providers and medical laboratories about an expansion to the recent recall of certain Magellan Diagnostics, Inc. blood lead test kit lots. The recalled test kits may yield falsely low blood lead levels which may further increase health risks to people with high blood lead levels. If you have questions about testing or reporting please feel free to contact Justin Otto at 701-328-5166 or jotto@nd.gov.



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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; 2115M; and 7114M. (“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. 2018M, 2102M, 2109M, 2110M, 2111M, 2112M, 2113M, 2114M, 2115M, and 7114M | N/A | |
| Magellan Reference No. | | 1218996-05/07/2021-0001R | | |

Magellan recommends the following:

- Discontinue use of all recalled test kits noted above 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.

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.

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

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