

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. 2018M, 2102M, 2109M, 2110M, 2111M, 2112M, 2113M, 2114M and 2115M	N/A	
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.

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.