



**For Immediate Release**

**Magellan Diagnostics, Inc. Expands Voluntary Recall of LeadCare® Test Kits**

CINCINNATI, September 1, 2021 (ACCESSWIRE) -- Meridian Bioscience, Inc. (NASDAQ: VIVO), a provider of diagnostic testing solutions and life science raw materials, today announced its wholly owned subsidiary, Magellan Diagnostics, Inc. (“Magellan”), expanded the Class I recall of its LeadCare® II Blood Lead Test Kits, LeadCare Plus® Blood Lead Test Kits, and LeadCare Ultra® Blood Lead Test Kits (the “LeadCare Test Kits”) for the detection of lead in whole blood.

Magellan provides two controls in the test kits which are designed to mimic blood and are spiked with lead to specific target values with an associated acceptable range. Results of the control tests within the acceptable range indicate that the system is operating properly before testing patient samples. In May 2021, Magellan initiated this voluntary recall after identifying an ongoing issue with testing of the controls included in the LeadCare Test Kits. Magellan continues to investigate this issue and has conducted extensive testing to evaluate potential root causes.

**Scope of Recall**

Magellan 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., “Control Out of Range-Low” [“COOR-L”]). Magellan initiated the recall because the impacted LeadCare Test Kits lots could potentially underestimate blood lead levels when processing patient blood samples.

As part of the recall to the user level, Magellan is notifying customers and distributors affected by the recall. Magellan's customer recall notification provides instructions for the return and replacement of the impacted LeadCare Test Kits (see list of affected lot numbers below).

Catalog No.	Product	Lot Number	Expiration Date
70-6762	LeadCare® II Blood Lead Test Kit	2012M sub-lots***	Apr 8, 2022
		2013M*	Apr 22, 2022
		2014M*	Apr 29, 2022
		2015M*	May 12, 2022
		2016M*	May 19, 2022
		2017M*	Jun 10, 2022
		2018M	Jun 6, 2022
		2101M**	Jul 28, 2022
		2102M	Sept 30, 2021
		2103M**	Aug 18, 2022
		2105M**	Sep 11, 2022
		2106M**	Jan 21, 2022
		2107M**	Sept 30, 2022
		2109M	Oct 15, 2022
		2110M	Oct 29, 2022
		2111M	May 31, 2022
		2112M	Nov 13, 2022
		2113M	Jun 30, 2022
2114M	Dec 17, 2022		
7114M	Dec 17, 2022		
2115M	Dec 29, 2022		

82-0004 70-8098	LeadCare Plus® Blood Lead Test Kit LeadCare Ultra® Blood Lead Test Kit	2011MU*	Mar 25, 2022
		2104MU**	Aug 25, 2022
		2108MU**	Mar 31, 2022

\* Lots previously included in the recall initiated on May 7, 2021

\*\* Lots previously included in the recall initiated on June 11, 2021

\*\*\* Only the following sub-lots of lot 2012M are included in the recall: -08, -09, -10, -11, -12, -13, and -14

### Magellan recommends the following:

- Customers should discontinue use of all LeadCare Test Kits lots identified as part of the recall and quarantine remaining inventory.
- Distributors should stop distribution of all LeadCare Test Kits lots identified as part of the recall, review current inventory and quarantine any remaining stock.
- Health Care Providers should evaluate patient test results that were generated with all recalled lots.
  - 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.
  - See CDC's recommended actions based on blood lead level:  
<https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm>
- Promptly complete and return the Customer Notification Form in the Urgent Medical Device Recall letter to [LeadCareSupport@magellandx.com](mailto:LeadCareSupport@magellandx.com) or FAX to (978) 600-1480. Complete this form even if you have no remaining inventory. These forms are also available on Magellan's COOR-L recall webpage: <https://www.magellandx.com/resources/leadcare-test-kit-controls-out-of-range-low-coor-lo-recall/>
- After the form has been submitted, contact Magellan Technical Support 1-800-275-0102 to obtain a FedEx label to return any remaining inventory to Magellan and receive replacement product when available.

Product distribution has been paused until further notice and replacement product is currently unavailable. 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. If you have questions about this recall, please contact Magellan's LeadCare® Product Support Team at 1-800-275-0102, or email at [LeadCareSupport@magellandx.com](mailto:LeadCareSupport@magellandx.com).

The U.S. Food and Drug Administration ("FDA") has been notified of this recall.

### FDA MedWatch Reporting

Adverse reactions/events or product concerns may also be reported to FDA's MedWatch online voluntary reporting system.

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

### About Meridian Bioscience, Inc.

Meridian is a fully integrated life science company that develops, manufactures, markets, and distributes a broad range of innovative diagnostic products. We are dedicated to developing and delivering better solutions that give answers with speed, accuracy and simplicity that are redefining the possibilities of life from discovery to diagnosis. Through discovery and development, we provide critical life science raw materials used in immunological and molecular tests for human, animal, plant, and environmental applications. Through diagnosis, we provide diagnostic solutions in areas including gastrointestinal and upper respiratory infections and blood lead level testing. We build relationships and provide solutions to hospitals, reference laboratories, research centers, veterinary testing centers, physician offices, diagnostics manufacturers, and biotech companies in more than 70 countries around the world.

Meridian's shares are traded on the NASDAQ Global Select Market, symbol VIVO. Meridian's website address is [www.meridianbioscience.com](http://www.meridianbioscience.com).

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