Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Meridian Bioscience, Inc.

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 g/dL ± 3g/dL) and/or the "High-Control" (e.g., the "Level 2" control at approximately 28 g/dL ± 4g/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.
1. 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.
2. 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 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.

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

FDA MedWatch Reporting

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

. Complete and submit the report Online
. Regular Mail or Fax: Download form 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

Contact:
Charlie Wood
Vice President - Investor Relations Meridian Bioscience, Inc.
Phone: +1 513.271.3700
Email: mbi@meridianbioscience.com

Company Contact Information
Consumers:
Magellan's LeadCare® Product Support Team
1-800-275-0102
LeadCareSupport@magellandx.com

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No action is required of local health departments at this time for either of these recalls. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

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For all recalls - http://www.recalls.gov/recent.html