Magellan Diagnostics Recalls LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests Due to Risk of Falsely Low Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries.

Recalled Product

- **LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests**
- **Lot codes:**
    - LeadCare II: 2013M, 2014M, 2015M, 2016M, 2017M, 2101M, 2103M, 2105M, 2106M, and 2107M
    - LeadCare Plus and LeadCare Ultra: 2011MU, 2104MU, and 2108MU
- **Manufacturing Dates:** October 26, 2020 to May 20, 2021
- **Distribution Dates:** October 27, 2020 to June 15, 2021
- **Date Initiated by Firm:** May 28, 2021

Device Use

The LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests are used to find out a person's blood lead level. The test uses a finger or heel stick whole blood (capillary) sample. After the sample is mixed with treatment reagent, a LeadCare analyzer measures the amount of lead collected on a sensor.

Magellan's LeadCare II is a point-of-care (CLIA-waived) blood lead testing system. The LeadCare systems are used in clinical laboratories, doctor's offices, clinics, and hospitals throughout the United States.

Reason for Recall

Magellan Diagnostics, Inc., is recalling its LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests due to a significant risk of falsely low results. The FDA has significant concerns that the performance of the test may provide falsely low results and may lead to health risks in special populations such as young children and pregnant individuals. A pregnant or lactating individual's exposure to lead is concerning because it not only may cause health

problems for the parent but can result in lead exposure to the developing baby. Obtaining falsely low results may lead to patient harm including delayed puberty, reduced postnatal growth, decreased IQ, and inattention and behavior problems in children.

Who May Be Affected

- Health care providers and laboratories who may have access to these tests
- People who were tested using these devices

What to Do

On May 28, 2021, Magellan notified distributors through phone calls and on June 7, 2021 sent customers an Urgent Medical Device Recall letter requesting product removal of specific lots. On June 23, 2021, Magellan notified customers by phone the recall has been expanded to include additional lots.

At this time, Magellan has reported that three lots of test kits which were previously distributed to customers are not impacted by this recall. Laboratories or health care providers who currently have LeadCare II lots 2012M, 2018M, and 2102M in their inventory may continue to use these tests. Report any failed Quality Control or suspected test results to Magellan Diagnostics.

Customers and distributors are instructed to also take the following actions:

Customers:

- Discontinue use of all test kit lots identified as part of the recall and quarantine remaining inventory.
- Laboratories should evaluate patient test results that were generated with the impacted lots.
- Confirm suspect results with an alternative lead testing option, such as those using inductively coupled mass spectrometry or graphite furnace atomic absorption spectrometry at a high complexity, CLIA-certified, reference laboratory.
- 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 (this will indicate receipt of this field correction notice). Complete this form even if you have no remaining inventory.
- 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.

- Be aware, product will be replaced based on availability; replacement product is NOT currently available.

Distributors:

- Stop distribution of LeadCare blood lead test kits identified as part of the recall; review current inventory and quarantine any remaining stock.
- Promptly complete and return the Customer Notification Form provided in the Urgent Medical Device Recall to LeadCareSupport@magellandx.com (mailto: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.
- 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.
- Be aware, the product will be replaced based on availability; replacement product is NOT currently available.
- Provide to Magellan a distribution list of customers that have received the impacted product.

Contact Information

Customers with questions about this recall should contact Magellan's LeadCare Product Support Team at 1-800-275-0102, or email at LeadCareSupport@magellandx.com (mailto:LeadCareSupport@magellandx.com).

How Do I Report a Problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.