Magellan Diagnostics Inc. Recalls LeadCare Plus and Ultra Testing Systems Due to Inaccurate Test 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 or death.

Recalled Product

- Product Name: LeadCare Plus and LeadCare Ultra Blood Lead Testing Systems
- Serial Numbers: All serial numbers
- Kit Lot Numbers: All Kit Lot Numbers
- Manufacturing Dates: September 2013, to Present
- Distribution Dates: September 2014, to Present
- Devices Recalled in the U.S.: 1,089,984 systems nationwide

Device Use

The LeadCare Plus and the LeadCare Ultra Testing Systems detect the amount of lead in a blood sample obtained from finger or heel prick (capillary) or from a vein (venous).

Figure: LeadCare Ultra Testing System (Left) LeadCare Plus Testing System (Right)

Reason for Recall

Magellan Diagnostics is recalling the LeadCare Plus and the LeadCare Ultra Testing Systems because they may underestimate the blood lead levels (BLL) and give inaccurate results when processing venous blood samples. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning. The use of affected product may cause serious adverse health consequences.

This recall accompanies **FDA's safety communication (/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm)** from May 17, 2017. Magellan's LeadCare Plus and Ultra Testing Systems are two of four blood lead testing systems affected by the recommendations in FDA's safety communication.

The FDA is unable to identify the root cause for the inaccurate results, based on data provided by Magellan. We are conducting studies with the Center for Disease Control and Prevention (CDC) to identify the cause and better characterize the extent of the problem.

Who May be Affected

- Laboratories that use Magellan's LeadCare Testing Systems as part of diagnostic applications.
- Laboratory personnel who interpret the results of Magellan's LeadCare Testing Systems.
- Health care professionals who perform lead tests using Magellan's LeadCare Testing Systems.
- Patients being tested for elevated BLLs with Magellan's LeadCare Testing Systems, in particular children in high-risk environments with BLL in the 5 to14 micrograms per deciliter (µg/dl) range.

What to Do

On May 24, Magellan Diagnostics Inc. sent a "Customer Safety Communication" letter to all affected customers. The letter provided the following information:

- Do NOT use venous blood samples with any LeadCare Blood Lead Testing Systems.
- Capillary blood samples are permitted for use with the LeadCare Blood Lead Testing Systems, for example:
  - Capillary tubes shipped in LeadCare II test kits
  - RAM Scientific SAFE-T-FILL capillary collection tubes
- Complete the "Fax Form Record: Notification on LeadCare Systems" and return it by fax 978-600-1480 or 888-789-8040. Or, fill out the online version of the form, available at **www.leadcare2.com/recall (http://www.leadcare2.com/recall)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- Share this safety information with appropriate personnel and retain a copy of the letter.

The FDA recommends laboratories and health care professionals take the following actions:

- Discontinue using Magellan's' LeadCare System Testing Systems with venous blood samples. At this time, all LeadCare systems can be used with capillary blood samples.
- Laboratories and health care professionals should follow recommendations in the **FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm)** issued on May 17, 2017 rather than previous communications from Magellan Diagnostics on their LeadCare Test Systems, including Magellan's Field Safety Correction Notification dated April 28, 2017.
- Report any adverse events to the **FDA (/Safety/MedWatch/HowToReport/default.htm)** and to Magellan Diagnostics.
- If laboratories or health care professionals are concerned about using the LeadCare Test Systems, the alternative options are mass spectrometry or atomic absorption methods. These are not point-of-care tests, and may be available only from larger-capacity laboratories such as reference labs.

The FDA is also encouraging parents and at-risk adults to follow CDC's recommendations listed in their **Health Advisory issued on May, 17 2017 (https://emergency.cdc.gov/han/han00403.asp)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** regarding any necessary re-testing based on this recall.

Contact Information

Customers with questions are instructed to contact Magellan Diagnostics' Product Support by telephone at

800-275-0102 with any questions related to this recall.

Date Recall Initiated

April 12, 2017

Additional Resources

- FDA Warns Against Using Magellan Diagnostics LeadCare Testing Systems with Blood Obtained from a Vein: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm)
- CDC's Health Advisory - May 17, 2017 (https://emergency.cdc.gov/han/han00403.asp) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- CDC - Lead (https://www.cdc.gov/nceh/lead/) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- CDC's Lead Exposure in pregnancy and lactating women (https://www.cdc.gov/nceh/lead/publications/leadandpregnancy2010.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- CDC's Adult Blood Lead Epidemiology & Surveillance (ABLES) (https://www.cdc.gov/niosh/topics/ables/) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- American Congress of Obstetricians and Gynecologists Opinion on Lead Screening During Pregnancy and Lactation (http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Lead-Screening-During-Pregnancy-and-Lactation) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- U.S. Occupational Safety and Health Administration—Medical Surveillance Guidelines (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10033) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- American Academy of Pediatrics: Lead Screening (https://www.healthychildren.org/English/safety-prevention/all-around/Pages/Where-We-Stand-Lead-Screening.aspx) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)