FDA Warns Against Using Magellan Diagnostics LeadCare Testing Systems with Blood Obtained from a Vein: FDA Safety Communication

Date Issued:

May 17, 2017

Audiences:

- 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 blood lead levels (BLL) 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.

Medical Specialties:

Pediatrics, Family Medicine, Internal Medicine, Preventive Medicine, Obstetrics/Gynecology, Emergency Medicine, Clinical Pathology, Hematology/Oncology, Laboratory Medicine, Emergency Medicine, Occupational Health, Safety Specialists

Product:

Magellan Diagnostics Inc. manufactures the following lead testing systems affected by this warning: LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra.

The LeadCare Testing Systems detect the amount of lead in a blood sample obtained from finger or heel prick (capillary) or from a vein (venous). This warning applies to all four Magellan Diagnostics LeadCare Testing Systems when processing **venous blood samples**, in the United States.

Note: Magellan's LeadCare II is a point-of-care (CLIA-waived) blood lead testing system on which users mostly test capillary blood samples. However, some laboratories also process venous blood samples with the LeadCare II system, which is why this safety communication includes all Magellan LeadCare Testing Systems.

The LeadCare Testing Systems are used in clinical laboratories, doctor's offices, clinics, and hospitals throughout the U.S.

Figure: LeadCare Ultra Blood Lead Testing System

Purpose:

The FDA is warning facilities such as laboratories or health clinics that Magellan Diagnostics' LeadCare Testing Systems may underestimate BLLs and give inaccurate results when processing venous blood samples.

The FDA is providing recommendations to help mitigate the risk of inaccurate test results to assure that patients receive accurate information regarding potential lead exposure.

The FDA is also strongly urging parents and at-risk adults to speak with their health care provider about the U.S. Centers for Disease Control's (CDC) recommendations on re-testing.

Summary of Problem and Scope:

Laboratories and health care professionals should follow recommendations in this Safety Communication rather than previous communications from Magellan Diagnostics on their LeadCare Test Systems, including Magellan's most recent Field Safety Correction Notification dated April 28, 2017.

Magellan Diagnostics' LeadCare Testing Systems may underestimate BLLs 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.

At this time, the FDA has no evidence that Magellan's LeadCare Testing Systems have the same problem when processing capillary blood samples.

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 CDC to identify the cause and better characterize the extent of the problem.

The FDA has no reason to believe that other lead tests, such as those using mass spectrometry, are affected by this issue.

Magellan Diagnostics' reports initially recognized possible problems with the performance of their LeadCare Ultra in August 2014 and notified customers by letter on November 24, 2014. The letter instructed facilities to implement a 24-hour incubation step with the blood sample to mitigate and fully resolve what they noted was a low risk of underestimation of BLL.

On November 4, 2016, Magellan notified customers of similar problems when processing venous blood samples via their LeadCare II testing systems and recommended a 4-hour incubation period for blood collection tubes received by laboratories from other facilities.

On November 11, 2016, Magellan notified customers by bulletin that the rubber caps of the Becton Dickinson's (BD) K2-EDTA Vacutainer blood collection tubes may introduce a substance into the blood sample when used with their LeadCare II systems. The bulletin instructed facilities to implement a minimum 4-hour incubation step with the blood sample to mitigate rubber cap exposure.

On April 28, 2017, Magellan notified customers that they should no longer use BD blood collection tubes with lavender- or tan-colored tops with their LeadCare Ultra and Plus systems, and that they should discontinue the 24-hour incubation step.

The FDA's review of the company's data supporting the issues contained in their customer notifications did not confirm a root cause (including the tubes) for the inaccurate results. In fact, the FDA found a lack of reliable data identifying the root cause of the problem, the frequency and extent of inaccurate test results for the LeadCare Testing Systems, and a lack of adequate effectiveness to support the mitigating steps taken by Magellan.

Information on Lead Exposure

According CDC, at least 4 million households have children living in them that are exposed to high levels of lead. Lead poisoning is particularly dangerous to infants and young children because their bodies may absorb more lead than adults, and their brains and nervous systems are more vulnerable to the damaging effects of lead. Lead poisoning in children typically results from drinking water from corroding plumbing, and inhaling or ingesting dust from deteriorating lead-based paint. Lead can also be transmitted through breast milk. Currently, there is no scientifically accepted safe BLL.

CDC outlines risk assessment and screening guidelines **here (https://www.cdc.gov/nceh/lead/default.htm)**.

Adults may be exposed to lead by working in a job where lead is used, such as paint manufacturers, or construction workers or police officers who are exposed to materials containing lead. They may also inhale or ingest lead dust in areas where deteriorating lead-based paint is present. A pregnant or lactating woman's exposure to lead is concerning because it may not only cause health problems for the mother, but can result in lead exposure to the developing baby.

U.S. Occupational Safety and Health Administration outlines the lead monitoring procedures including the required frequency of blood testing for exposed workers here.

Recommendations for Health Care Professionals and Laboratory Personnel:

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.
- Report any adverse events to the **FDA (/Safety/MedWatch/HowToReport/ucm2007306.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.
- This Safety Communication replaces all previous communication from Magellan Diagnostics on their LeadCare lead testing systems including Magellan's most recent Field Safety Correction Notification dated April 28, 2017.

Recommendations for Patients and Caregivers

- The FDA is encouraging parents and at-risk adults to follow CDC's recommendations listed below regarding any necessary re-testing based on this safety communication.
- The CDC recommends that parents discuss re-testing with their health care provider or health department to determine if their child's blood should be re-tested.
- The CDC recommends that health care professionals re-test currently pregnant or lactating women who had a venous blood lead test performed using a Magellan's LeadCare System Testing System

The CDC recommends that health care professionals re-test patients who:

1. Are younger than 6 years (72 months) of age at the time of this alert (May 17, 2017), and
2. Had a venous blood lead test result of less than 10 (µg/dL) from a test analyzed using a Magellan Diagnostics' LeadCare analyzer.

FDA Actions:

The FDA is aggressively investigating the root cause of this issue with the manufacturers, health care facilities and the CDC, and will update this safety communication as critical information becomes available.

Additional Resources:

- **CDC's Health Advisory – May 17, 2017 (https://emergency.cdc.gov/han/han00403.asp)**
- **CDC - Lead (https://www.cdc.gov/nceh/lead/)**
- **CDC's Lead Exposure in pregnancy and lactating women (https://www.cdc.gov/nceh/lead/publications/leadandpregnancy2010.pdf)**
- **CDC's Adult Blood Lead Epidemiology & Surveillance (ABLES) (https://www.cdc.gov/niosh/topics/ables/)**
- **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)**
- **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)**

- **American Academy of Pediatrics: Lead Screening (https://www.healthychildren.org/English/safety-prevention/all-around/Pages/Where-We-Stand-Lead-Screening.aspx)**
- **2015 Medical Device Report (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM558970.pdf)**
- **2016 Medical Device Report – Received by FDA on May 8, 2017 (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM558973.pdf)**
- **LeadCare Plus and Ultra Testing Systems Recall Notice (/MedicalDevices/Safety/ListofRecalls/ucm560534.htm)**
- **LeadCare 510K Statement (https://www.accessdata.fda.gov/cdrh_docs/pdf/K971640.pdf)**
- **LeadCare II 510K Summary (https://www.accessdata.fda.gov/cdrh_docs/pdf5/K052549.pdf)** & **LeadCare II 510K Decision Summary (https://www.accessdata.fda.gov/cdrh_docs/reviews/K052549.pdf)**
- **LeadCare Ultra 510K Summary (https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123563.pdf)** & **LeadCare Ultra 510K Decision Summary (https://www.accessdata.fda.gov/cdrh_docs/reviews/K123563.pdf)**
- **LeadCare Plus 510K Summary (https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142705.pdf)** & **LeadCare Plus 510K Decision Summary (https://www.accessdata.fda.gov/cdrh_docs/reviews/K142705.pdf)**

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with these devices, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041, or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)

2016 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553855.htm)