Magellan
DIAGNOSTICS
A Meridian Bioscience® Company

May 26, 2017

On May 25, 2017, the FDA released a communication with information inconsistent with the actual FDA recommendations about a recall of Magellan Diagnostics LeadCare testing systems. Magellan is working with the FDA to quickly correct this information. Accurate information is summarized below:

- The FDA Safety Communication confirms that **all Magellan LeadCare systems can be used with capillary blood samples**.
- Laboratories and healthcare professionals should **discontinue using venous blood samples** with the LeadCare testing systems.
- The **testing systems (equipment) and kits are not being removed from the market, only the use of venous samples.** There is no evidence of problems when processing **capillary blood samples**.

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.

If your facility uses **venous** blood collection tubes, please use an alternative method for blood lead testing until further notice. At this time, the FDA noted that all LeadCare Blood Lead testing systems can be used with capillary blood samples.

Contact Magellan at **800-275-0102** for all questions. When calling, please have your serial number as well as the following contact information available.

- Contact name, title, email address, return phone number
- Institution name, city, state and zip code
- LeadCare serial number(s)

Magellan will continue to work closely with the FDA to address the concerns identified with the venous blood samples as quickly as possible.

101 Billerica Ave, Building 4, North Billerica, Massachusetts 01862 • Telephone: 978.856.2345 • Fax: 978.856.2335 • www.Magellandx.com