Magellan
DIAGNOSTICS
A Meridian Bioscience® Company

Safety Communication
LeadCare® Blood Lead Testing Systems

05/17/2017

Following the FDA's Safety Notice, published May 17, 2017, this notification is to advise your facility regarding a change to existing LeadCare product usage and labeling. Prior instructions for use included capillary and venous blood samples. However, because the LeadCare Testing Systems may underestimate blood lead levels and give inaccurate results when processing venous blood samples, the FDA recommends discontinuing the use of any LeadCare Blood Lead Testing System (LeadCare, LeadCare II, LeadCare Ultra, LeadCare Plus) with venous blood samples.

At this time, the FDA noted that **all LeadCare Blood Lead Testing Systems can be used with capillary blood samples**.

If your facility uses venous blood collection tubes, please use an alternative method for blood lead testing until further notice.

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
- Institution Name, City, State & Zip Code
- LeadCare Serial Number(s)

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

The vast majority of tests performed on LeadCare Systems use capillary samples and are performed at the point of care, in physician offices and clinics. The LeadCare II System was designed to help ensure broad-based blood lead screening is available by providing a quick, easy and accurate way to identify children, pregnant women and adults at risk for lead exposure. We remain committed to the importance of providing results at the point of care, as this creates the best opportunity to facilitate patient education and intervention.

We sincerely apologize for this interruption in your venous blood lead testing.

For more information, see the FDA's safety notice at:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm558769.htm

Sincerely,

Reba Daoust

Reba Daoust
Director of Quality & Regulatory Affairs