

Magellan

D I A G N O S T I C S

A Meridian Bioscience® Company

January 16, 2018

On January 10, 2018, and January 15, 2018, related news organizations reported that the FDA had recalled over 7 million Magellan Diagnostics blood lead tests.

We would like to clarify for our customers that the recall referred to in these news articles is part of the earlier FDA Safety Notification dated May 17, 2017. The recall did not remove the LeadCare Systems from the market, rather customers were asked to discontinue the use of venous blood samples with LeadCare Blood Lead Testing Systems. Capillary testing can be used with all LeadCare Systems.

The FDA Safety Communication states that all Magellan LeadCare Systems can be used with CAPILLARY BLOOD SAMPLES.

Magellan's LeadCare II is a point-of-care (CLIA waived) blood lead testing system which is primarily used with capillary blood samples. A highly effective way to screen children and pregnant/lactating women is to use a fingerstick at the point of care providing the health care provider and the patient with an immediate result. Capillary point-of-care testing is a critical tool for addressing the risks associated with undiagnosed lead exposure.

Because symptoms for lead poisoning are usually not present, or if there are symptoms they are nonspecific and easily attributed to other childhood illnesses physicians are able to order a lead test whenever lead exposure is suspected or the risk is unknown. The only way to know for sure is to conduct a blood test. Delivering the message to the parent that there is no need for concern is equally valuable information.

We understand that our customers conduct blood lead testing in diverse environments and that quick, reliable results are imperative to their ability to deliver the best health care possible. Magellan continues to work diligently to address the FDA's concerns with Magellan LeadCare Systems when used with venous blood samples.

For product support questions, please contact Magellan at:
leadcaresupport@magellandx.com or 800-275-0102.

For media inquiries, please contact Catherine Lufkin at:
Catherine.Lufkin@magellandx.com.

For investor inquiries, please contact Meridian Bioscience at:
mbi@meridianbioscience.com.