Magellan
DIAGNOSTICS
A Meridian Bioscience® Company

June 6, 2017

On June 5, 2017, the FDA posted a notice on their medical device recall website stating that Magellan Diagnostics is *expanding* a recall to include LeadCare and LeadCare II Systems.

We would like to clarify for our customers that this recall is part of the earlier FDA Safety Notification dated May 17, 2017, which included all four LeadCare Blood Lead Testing Systems when used with venous blood, and is not a new recall.

As in our prior communications, we would like to clarify that product is not being removed from the field, but rather customers are being asked to discontinue use of venous blood with LeadCare Testing Systems.

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

Note: Magellan's LeadCare II is a point-of-care (CLIA waived) blood lead testing system which is primarily used with 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.

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

For product support questions, please contact Magellan at:
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