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Leinenkugel, Kathy <kathy.leinenkugel@idph.iowa.gov>

Support at FDA/DICE Re:Current status regarding venous specimen testing on Magellan analyzers

4 messages

"DICE" <dice@fda.hhs.gov> <dice@fda.hhs.gov> Thu, Jan 31, 2019 at 9:11 AM
To: "kathy.leinenkugel@idph.iowa.gov" <kathy.leinenkugel@idph.iowa.gov>

Dear Ms. Leinenkugel,

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account. It is our pleasure to assist

Our current 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 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.

The webpage has a lot of information about this safety communication.

If we can be of further assistance, please don't hesitate to contact us (Division of Industry and Consumer Education, DICE). We are available via email at DICE@fda.hhs.gov and also by phone at (800) 638-2041 (please refer to our webpage for our hours of operation). Please direct all new email inquiries to the main email address provided. Thank you.

Sincerely,

Industry Team

Division of Industry and Consumer Education
Office of Communication and Education

Center for Devices and Radiological Health

U.S. Food and Drug Administration