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Alert from the U.S. Food and Drug Administration (FDA) Regarding LeadCare® Analyzers

Dear Health Care Providers,

This alert only affects providers and laboratories who use Lead Care® analyzers for blood lead testing of **venous** blood samples.

The FDA has issued a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus). Lead Care analyzers should no longer be used with **venous** blood samples because of the potential for falsely low BLL results. The safety alert does **not** apply to capillary blood lead test results collected by fingerstick or heelstick at this time.

Recommendations:

- 1) Health care providers should retest children who were younger than 6 years (72 months) of age at the time of the alert (May 17, 2017) and who had a venous blood lead test result of less than 10 micrograms per deciliter (blood lead levels in the range of 9.5 mcg/dL to 9.9 mcg/dL are considered 10 mcg/dL) analyzed using a Magellan Diagnostics' LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory.
- 2) Health care providers should retest currently pregnant or lactating women who had a venous blood test performed using a Magellan Diagnostics' LeadCare® analyzer.
- 3) For future blood testing, venous samples should be sent to and performed by Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratories using inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]) instruments.
- 4) There is no change in the recommendations regarding testing capillary blood samples using a Magellan Diagnostics' LeadCare® analyzer.

Attached is the official alert from the Centers for Disease Control and Prevention (CDC) and the flow diagram to help you more quickly determine potentially affected blood lead tests and the need for retesting. Please contact our Childhood Lead Poisoning Prevention Program at 714-567-6220 if you have questions.

Enclosures