To: CAHAN San Diego Participants
Date: May 23, 2017
From: San Diego County Childhood Lead Poisoning Prevention Program

Potential for Falsely Low Blood Lead Test Results from LeadCare® Analyzers

On May 17, 2017, the U.S. Food and Drug Administration (FDA) issued a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers with venous blood samples because they might result in falsely low test results. FDA is now advising that Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) should no longer be used with venous blood samples. The safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick.

In conjunction with the FDA warning, Centers for Disease Control and Prevention (CDC) issued the attached health advisory about these analyzers with the following recommendations:

- Health care providers should retest children who are younger than 6 years (72 months) of age at the time of the alert (May 17, 2017), and had a venous blood lead test result of less than 10 mcg/dL analyzed using a Magellan Diagnostics' LeadCare® analyzer at an onsite (e.g. healthcare facility) or at an offsite laboratory.
- Health care providers should retest currently pregnant or lactating women who had a venous blood test performed using a Magellan Diagnostics' LeadCare ® analyzer.

The CDC advisory contains a flow diagram for determining potentially affected blood lead tests and the need for retesting. **A CDC Clinician Outreach and Communication Activity (COCA) call is planned on Wednesday, May 24, 2017 from 11 AM to noon Pacific Standard Time** to inform clinicians about the importance of lead testing for children and pregnant or lactating women, which patients may be impacted by this analyzer issue, and CDC's recommendations for re-testing. Call details may be found here.

Providers who have general questions about lead screening should contact the San Diego County Childhood Lead Poisoning Prevention Program at 619-692-8487.

Providers who are uncertain about what type of equipment is used by the laboratory that supports their lead screening should direct those questions to that laboratory.

Any questions specifically about the LeadCare® analyzers should be directed to the manufacturer, Magellan Diagnostics at 800-275-0102.

Thank you for your continued participation.

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