



SAN BENITO COUNTY

HEALTH & HUMAN SERVICES AGENCY

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Healthy People in Healthy Communities

June 6, 2017

Dear Healthcare Colleagues:

San Benito Public Health Services received the following advisory from the California Department of Public Health describing recent investigation into Magellan Diagnostics' LeadCare® analyzers. These analyzers can give falsely low results with venous samples. If you have any further questions, please send them to the email address at the end of the health advisory.

Sincerely yours,

A handwritten signature in cursive script that reads "Melissa Schilling".

Melissa Schilling, RN
Community Health Nurse II

The U.S. Food and Drug Administration (FDA) has issued a warning about the use of Magellan Diagnostics' LeadCare® analyzers (Lead Care, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples, because they might result in falsely low test results. The information provided by the FDA and the Centers for Disease Control and Prevention (CDC) follows an investigation into the performance of Magellan LeadCare® analyzers when using venous blood.

At this time, the warning does not apply to capillary blood lead test results collected by fingerstick or heelstick using Magellan Diagnostics' LeadCare® analyzers. This health advisory does not apply to laboratory tests analyzed by inductively coupled plasma-mass spectrometry (ICP-MS) or graphite furnace atomic spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]). This alert applies to venous blood lead tests conducted using Magellan Diagnostic's LeadCare® analyzers, whether the patient is a child or an adult.

The CDC recommends that health care providers re-test patients who:

- 1) are younger than 6 years (72 months) of age at the time of the alert (May 17, 2017); and
- 2) had a venous blood lead test result of less than 10 micrograms per deciliter (mcg/dL) analyzed using a Magellan Diagnostics' LeadCare® analyzer at an onsite (e.g., health care facility) or at an offsite laboratory.

CDC also recommends that health care providers re-test currently pregnant or lactating women who had a venous blood lead test performed using a Magellan Diagnostics' LeadCare® analyzer.

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CDC recommends parents discuss re-testing with their health care provider or health department to determine if their child's blood should be re-tested.

The Childhood Lead Poisoning Prevention Program is looking into the advisory, actions are being taken, and we are working with other programs and entities, regarding further information and recommendations.

For additional information, please see:

<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm>

<https://emergency.cdc.gov/han/han00403.asp>

<http://www.leadcare2.com/getmedia/2fd8a90f-5c64-4058-b6ab-5db13512f0fe/Letter-to-our-customers-5-17-17.pdf.aspx>

<http://www.lcultra.com/getmedia/931f603d-37ab-47cf-b8ee-a63f2fa8fec4/Letter-to-our-customers-5-17-17.pdf.aspx>

There is also an informational webinar available at 1-888-562-6109.

If you have questions, please send them via email to CLPPBPHN (CLPPBPHN@cdph.ca.gov).

Valerie Charlton, MD, MPH, Chief
Childhood Lead Poisoning Prevention Branch

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