



## This is an official **CDC Health Advisory**

Distributed via Health Alert Network  
May 17, 2017; 4:30 PM  
10395-CHA-05-17-2017-LEAD

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

#### **Summary**

The U.S. Food and Drug Administration (FDA) has issued a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they might result in falsely low test results. FDA is now advising that Magellan Diagnostics' LeadCare® analyzers 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. The purpose of this Health Advisory is to notify state and local health departments, healthcare providers, and laboratories about CDC's re-testing guidance in light of the safety alert.

#### **Background**

CDC was contacted on April 24, 2017 by FDA requesting assistance in assessing the potential public health risk of a negative bias associated with Magellan's lead testing systems. FDA is now warning that Magellan Diagnostics' LeadCare® analyzers should no longer be used with venous blood samples due to the potential for falsely low test results. Not all blood lead tests are affected. 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]) are not expected to have resulted in falsely low results. This safety alert applies to venous blood lead tests conducted using Magellan Diagnostics' LeadCare® analyzers whether the patient is a child or an adult. At this time, the safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick using Magellan Diagnostics' LeadCare® analyzers. Children are particularly vulnerable to lead exposure due to the effect on their developing brains and organ systems. CDC is working with public health officials throughout the United States to determine where the analyzers were used and which blood lead test results might be affected.

## Recommendations

CDC recommends that healthcare 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 ( $\mu\text{g}/\text{dL}$ ) analyzed using a Magellan Diagnostics' LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory. CDC also recommends that healthcare providers re-test currently pregnant or lactating women who had a venous blood lead test performed using a Magellan Diagnostics' LeadCare® analyzer. CDC recommends parents discuss re-testing with their healthcare provider or health department to determine if their child's blood should be re-tested.

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

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

If re-testing indicates blood lead levels in excess of the CDC reference level ([www.cdc.gov/nceh/lead/acclpp/blood\\_lead\\_levels.htm](http://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm)), or the state or local action level, the healthcare provider or public health official should refer to CDC and/or local guidelines for appropriate follow-up action ([www.cdc.gov/nceh/lead/acclpp/actions\\_blls.html](http://www.cdc.gov/nceh/lead/acclpp/actions_blls.html)).

Re-tests are not recommended if the provider is certain that analyzers other than those described by this Health Advisory were used to analyze the venous blood samples.

For future blood lead testing, healthcare providers and public health officials should:

- Send venous samples to 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.
- Send capillary samples to CLIA-compliant laboratories using any CLIA compliant analyzer including ICP-MS, GFAAS, or LeadCare® analyzers.
- Report results of retests and all other lead test results to DHEC. See the July 2016 DHEC Health Update: Blood Lead Screening & Reporting (<http://www.scdhec.gov/Health/docs/HAN/10383-DHU-07-11-2016-LEAD.pdf>) for reporting guidelines.

**For More Information**

CDC’s Lead Poisoning Prevention Program: <https://www.cdc.gov/nceh/lead/>

CDC’s Lead and Multi-element Proficiency Program: <https://www.cdc.gov/labstandards/lamp.html>

**Reference**

FDA safety communication warning, May 17, 2017. Available at: <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm>

**DHEC contact information for reportable diseases and reporting requirements**

Reporting of **blood lead test results** is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2017 List of Reportable Conditions available at: <http://www.scdhec.gov/Library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

<b>Regional Public Health Offices – 2017</b>			
Mail or call reports to the Epidemiology Office in each Public Health Region			
<b>MAIL TO:</b>			
<u>Lowcountry</u>	<u>Midlands</u>	<u>Pee Dee</u>	<u>Upstate</u>
4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051	2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993	145 E. Cheves Street Florence, SC 29506 Fax: (843) 661-4859	200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373
<b>CALL TO:</b>			
<u>Lowcountry</u>	<u>Midlands</u>	<u>Pee Dee</u>	<u>Upstate</u>
<b>Berkeley, Charleston, Dorchester</b> Phone: (843) 953-0043 Nights/Weekends: (843) 441-1091  <b>Beaufort, Colleton, Hampton, Jasper</b> Phone: (843) 322-2453 Nights/Weekends: (843) 441-1091  <b>Allendale, Bamberg, Calhoun, Orangeburg</b> Phone: (803) 268-5833 Nights/Weekends: (843) 441-1091	<b>Kershaw, Lexington, Newberry, Richland</b> Phone: (803) 576-2749 Nights/Weekends: (888) 801-1046  <b>Chester, Fairfield, Lancaster, York</b> Phone: (803) 286-9948 Nights/Weekends: (888) 801-1046  <b>Aiken, Barnwell, Edgefield, Saluda</b> Phone: (803) 642-1618 Nights/Weekends: (888) 801-1046	<b>Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion</b> Phone: (843) 661-4830 Nights/Weekends: (843) 915-8845  <b>Clarendon, Lee, Sumter</b> Phone: (803) 773-5511 Nights/Weekends: (843) 915-8845  <b>Georgetown, Horry, Williamsburg</b> Phone: (843) 915-8804 Nights/Weekends: (843) 915-8845	<b>Anderson, Oconee</b> Phone: (864) 260-5581 Nights/Weekends: (866) 298-4442  <b>Abbeville, Greenwood, McCormick</b> Phone: (864) 260-5581 Nights/Weekends: (866) 298-4442  <b>Cherokee, Greenville, Laurens Pickens, Spartanburg, Union</b> Phone: (864) 372-3133 Nights/Weekends: (866) 298-4442
<b>For information on reportable conditions, see</b> <a href="http://www.scdhec.gov/Health/FHPF/ReportDiseasesAdverseEvents/ReportableConditionsInSC/">http://www.scdhec.gov/Health/FHPF/ReportDiseasesAdverseEvents/ReportableConditionsInSC/</a>		<b>DHEC Bureau of Disease Control</b> <b>Division of Acute Disease Epidemiology</b> 2100 Bull St • Columbia, SC 29201 Phone: (803) 898-0861 • Fax: (803) 898-0897 Nights / Weekends: 1-888-847-0902	

Categories of Health Alert messages:

- Health Alert** Conveys the highest level of importance; warrants immediate action or attention.
- Health Advisory** Provides important information for a specific incident or situation; may not require immediate action.
- Health Update** Provides updated information regarding an incident or situation; unlikely to require immediate action.
- Info Service** Provides general information that is not necessarily considered to be of an emergent nature.