



HEALTH ADVISORY #136

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

TO: West Virginia Local Health Departments, West Virginia Health Care Providers, Laboratories

FROM: Rahul Gupta, MD, MPH, FACP, Commissioner and State Health Officer
WVDHHR, Bureau for Public Health

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LOCAL HEALTH DEPARTMENTS: PLEASE DISTRIBUTE TO COMMUNITY HEALTH PROVIDERS AND HOSPITAL-BASED PHYSICIANS INCLUDING FAMILY CARE PROVIDERS AND PEDIATRICIANS, LABORATORY DIRECTORS, AND OTHER APPLICABLE PARTNERS

Children are particularly vulnerable to lead exposure due to the effect on their developing brains and organ systems. The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are warning Americans that certain lead tests manufactured by Magellan Diagnostics may provide inaccurate results for some children and adults in the United States. FDA is now warning that Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) 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. This safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick. The majority of tests performed on LeadCare® analyzers use capillary samples and are performed at the point of care, in provider offices and clinics. Laboratory tests on both venous blood and capillary blood samples 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.

The purpose of this Health Advisory is to notify local health departments, healthcare providers, and laboratories about CDC's re-testing guidance in light of the safety alert. The CDC is recommending that healthcare providers retest children younger than six years (72 months) of age at the time of this alert (May 2017) if their test was conducted using blood drawn from a vein using any Magellan Diagnostics' LeadCare® analyzer and received a result of less than 10 micrograms per deciliter (µg/dL). The CDC recommends healthcare providers re-test pregnant or lactating women who have had a venous blood test performed using LeadCare® analyzers. Adults with potential occupational exposure to lead tested in this manner should also be re-tested. Healthcare providers should discuss re-testing with their patients. 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.

For more information, visit CDC's Lead Poisoning Prevention Program website at www.cdc.gov/nceh/lead/ and the BPH, Office of Maternal and Child and Family Health's childhood lead poisoning prevention and blood lead screening guidelines at www.wvdhhr.org/mcfh/lead/

This message was directly distributed by the West Virginia Bureau for Public Health to local health departments and professional associations. Receiving entities are responsible for further disseminating the information as appropriate to the target audience.

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.

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