DIAGNOSTIC LABORATORY SERVICES, INC.

DATE: Revised June 13, 2017

TO: Our Valued Clients

FROM: Wesley Kim, MD, Medical Director

SUBJECT: LEAD BLOOD TESTING (742)

In light of the FDA's recent Safety Notice, published May 17, 2017, we received notification from Magellan, our LeadCare Ultra analyzer vendor, that we should not be using venous blood samples for lead testing until additional data is submitted and reviewed by the FDA. Prior instructions for use included both capillary and venous blood samples (BD Royal Blue Top EDTA vacutainer) as acceptable samples. However, as the FDA has determined that venous blood samples should not be used with any LeadCare Blood Lead Testing System at present, which includes our LeadCare Ultra platform, DLS will no longer be accepting this sample type for testing for blood lead levels.

Effective **Monday 5/22/2017**, **DLS will only accept EDTA Microtainer Tubes (BD), by capillary collection for Lead testing**. Samples collected in BD Royal Blue Top EDTA (Trace Metal) vacutainer tubes will be sent out for Lead testing by test method (Mass Spectrometry), not currently affected by the FDA advisory. All other venous collected samples for Lead testing, to include Lavender EDTA vacutainer tubes will be rejected, until further notice, and a call will be made to the client and/or patient to schedule recollection in the proper tubes if indicated.

For those patients that go to one of the DLS draw sites, our satellite phlebotomists have been educated and trained to draw the correct sample. If you are a physician that has their patient's blood drawn by your own office staff, please note the change stated above and ensure the correct tube is drawn and submitted to avoid any issues with sample rejection and repeat phlebotomy procedures on your patients to recollect samples.

For recommended guideline on repeat testing of LEAD performed on Megellan LeadCare Analyzer from venous collected blood. See CDC Health Advisory, below.

If there are questions or concerns please contact DLS client services at 589-5101 or Dr. Wesley J Kim at 589-5131.

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
May 17, 2017, 0900 ET (9:00 AM ET)
CDCHAN-00403

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 (µg/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.

If re-testing indicates blood lead levels in excess of the CDC reference level (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).

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

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

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##