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

Clinician Outreach and Communication Activity (COCA) Webinar

May 24, 2017

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CDC HEALTH ADVISORY

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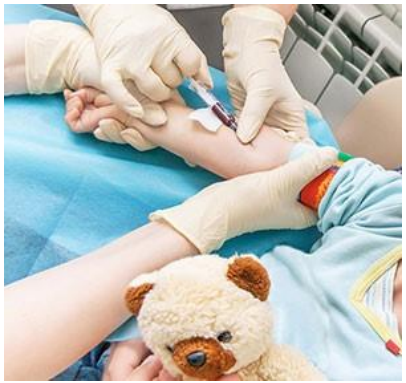


Objectives

At the conclusion of the session, the participant will be able to:

1. Describe the importance of lead testing among children and pregnant or lactating women.
2. List the patients who are most at risk for falsely low blood lead level test results.
3. Determine which of their patients need to be retested.
4. Understand and discuss the safety alert and need for retesting with their patients.

Target Audience

- Health care professionals who perform blood lead tests using Magellan Diagnostic's LeadCare® Testing Systems
- Laboratories that use Magellan's LeadCare® Testing Systems as part of diagnostic applications
- Laboratory personnel who interpret the results of Magellan's LeadCare® Testing Systems

FDA Safety Communication

- On May 17, 2017, the U.S. FDA issued a safety communication that involved a Class I recall for LeadCare® (all versions). Available at: https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm
- FDA is warning that Magellan Diagnostics' LeadCare® Testing Systems should **no longer be used with venous blood samples** due to the potential for falsely low test results
- FDA is aggressively investigating the root cause of the problem
- Not all blood lead tests are affected

Potential Public Health Risk

- CDC was contacted by FDA requesting assistance in assessing the potential public health risk of a **negative bias** associated with Magellan's LeadCare® Testing Systems that could **underestimate** blood lead test 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
- However, children (and pregnant and breastfeeding women) are particularly vulnerable to lead exposure due to the effect on children's developing brains and organ systems

Lead Exposure

- Lead exposure can affect nearly every system in the body. Because low level exposure often occurs with no obvious symptoms, it frequently goes unrecognized
- A **blood lead test** is the best way to identify lead exposure
  - No safe blood lead level has been identified
- Approximately half a million U.S. children ages 1-5 years have blood lead levels above 5 micrograms per deciliter (µg/dL), the reference level at which CDC recommends public health actions be initiated

Blood Lead Testing

The three main methods to measure blood lead are:

ICP-MS – Inductively coupled plasma mass spectrometry (ICP-MS)

GFAAS – Graphite furnace atomic absorption spectroscopy (GFAAS)

Leadcare® – Point-of-care (POC) and Laboratory-based Anodic Stripping Voltammetry (ASV)

- All blood lead measurements must be CLIA Compliant (waived or not-waived)
- Non-waived testing laboratories must participate in a CLIA approved Proficiency Testing (PT) Program; many waived facilities also participate
- Current CLIA performance criteria is ±4 µg/dL or 10% which ever is greater

Magellan Diagnostics' LeadCare® Products

LeadCare II®

Point-of-care Analyzer (FDA 510(k) cleared device, CLIA waived)

LeadCarePlus™

LeadCare Ultra®

FDA 510(k) cleared devices for quantification of lead in whole blood in a moderately or highly complex CLIA compliant laboratory

Recommendations for Re-testing

CDC recommends that healthcare providers re-test patients who:

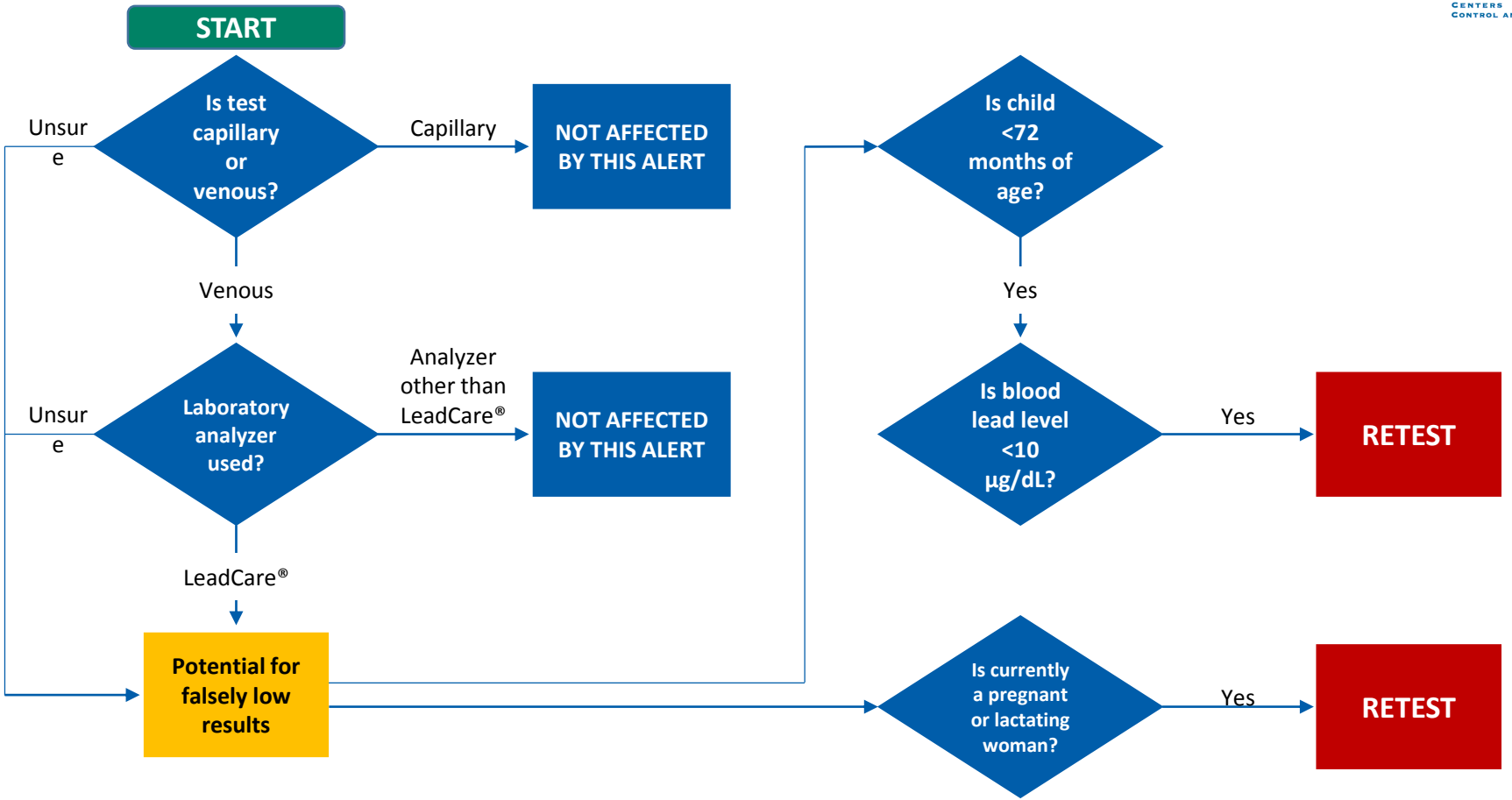
1) are **younger than 6 years (72 months) of age** at the time of the alert (May 17, 2017)

and

2) had a **venous blood lead test** result of **less than 10 micrograms per deciliter (µg/dL)** analyzed using a Magellan Diagnostics' LeadCare® Testing System 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® Testing System

Flow Diagram for Determining Potentially Affected Blood Lead Tests and the Need for Re-testing



Future Blood Lead Testing

- 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® Testing Systems

GFAAS

ICP-MS

Follow-up of Re-testing Results

- 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

Summary

- The U.S. Food and Drug Administration (FDA) has issued a safety communication warning advising that Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) should no longer be used with venous blood samples because they might result in falsely low test results
- The FDA safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick
- CDC is recommending re-testing of potentially affected tests for certain groups of children and pregnant or breastfeeding women
- For future blood lead testing, venous samples should be analyzed only by CLIA-compliant laboratories using ICP-MS, GFAAS, or ETAAS

Next Steps

- 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

- FDA is leading the investigation to determine the root cause of the LeadCare® issue. CDC is in communication with FDA on the issue.

References

FDA Warns Against Using Magellan Diagnostics LeadCare Testing Systems with Blood Obtained from a Vein: FDA Safety Communication, May 17, 2017.

Available at:
https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm

CDC Health Alert Network. Potential for Falsely Low Blood Lead Test Results from LeadCare® Analyzers, May 17, 2017.

Available at:
https://emergency.cdc.gov/han/han00403.asp

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

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