Public Health Update
06/09/2025

Urgent FDA Alert: Risk of False Positive Lead Results associated with Specific Capillary Blood Collection Tubes with LeadCare Systems

Situation:

- The U.S. Food and Drug Administration (FDA) has issued an update to its April 24, 2025, safety communication regarding reports of falsely elevated (false positive) blood lead test results when using **ASP Global's RAM Scientific SAFE-T-FILL Micro Capillary Blood Collection tubes** with **Magellan Diagnostics LeadCare Testing Systems**.
- These tubes may result in overestimated blood lead levels, potentially leading to:
- a) unnecessary follow-up testing, b) increased stress for patients and families and c) delays in accurate diagnosis and care.
- This issue does not affect the blood collection devices included with LeadCare kits or other third-party tubes listed in the test instructions.
- On May 9, 2025, the FDA issued a Warning Letter to Kabe Labortechnik GmbH, the tube manufacturer of the implicated collection tubes, citing significant violations of the Quality System Regulation and Medical Device Reporting. As a result, the FDA placed an import alert on devices from this manufacturer, preventing their entry into the U.S.
- This alert is directed to healthcare providers, public health professionals, and laboratory personnel.

Impacted Devices

Applies only to capillary blood samples collected using the affected tubes with the following systems:

- LeadCare
- LeadCare II
- LeadCare Plus
- LeadCare Ultra

Recommendations:

- **Immediately discontinue** using SAFE-T-FILL Micro Capillary Blood Collection tubes with any LeadCare system.
- **Use only** tubes provided with the LeadCare Test Kit or those explicitly approved in the test system's instructions for use.
- If SAFE-T-FILL tubes must be used, interpret results with caution and consider retesting using a different method or venous specimen.
- Follow CDC guidance on confirmatory venous blood testing when capillary blood lead levels are elevated: CDC Testing Recommendations.
- Report any adverse events or suspected false results to the FDA MedWatch Program: FDA MedWatch.

More Information:

- FDA Safety Communication - Updated May 27, 2025

For questions regarding laboratory testing procedures, clinical concerns, or reporting, contact the FDA's Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov.

Cassius Lockett, PhD
District Health Officer
Southern Nevada Health District

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