MISSISSIPPI STATE DEPARTMENT OF HEALTH

This is an official
MS Health Alert Network (HAN) – Alert

MESSAGE ID:	**MSHAN – 20250505-00602 - ALT (Health Alert)**
RECIPIENTS:	**All Physicians, Hospitals, ERs, ICPs, NPs, PAs, and Healthcare Providers – Statewide**
	Monday, May 5, 2024
SUBJECT:	**Risk of False Positive Results with Certain Capillary Blood Collection Tubes Used with Magellan Diagnostics LeadCare Testing Systems – FDA Safety Communication**

Risk of False Positive Results with Certain Capillary Blood Collection Tubes Used with Magellan Diagnostics LeadCare Testing Systems – FDA Safety Communication

Date Issued: April 24, 2025

The U.S. Food and Drug Administration (FDA) is alerting health care providers and laboratory staff of reports that falsely elevated (false positive) results have occurred when using ASP Global's RAM Scientific SAFE-T-FILL Micro Capillary Blood Collection tubes with the LeadCare Testing Systems. These tests may overestimate blood lead levels and give inaccurate results when processing capillary blood samples collected in these ASP Global's RAM Scientific SAFE-T-FILL tubes. The root cause of these false results is not yet known. The FDA is recommending that ASP Global RAM Scientific SAFE-T-FILL tubes not be used with the LeadCare Testing Systems while this issue is being investigated.

False test results may delay an accurate diagnosis and may lead to improper patient management and unnecessary follow-up tests (with additional risks), increased stress for patients and families, and disruptions in care. Timely and accurate detection of elevated lead levels is essential to prevent the harmful effects of lead poisoning and ensure patients receive the right care without delay.

The FDA is issuing this communication along with the following recommendations to mitigate the potential risk of inaccurate test results to assure that patients receive accurate information regarding potential lead exposure.

Recommendations for Health Care Providers and Facilities, Laboratory Staff, and Patients and Caregivers

- Avoid using ASP Global's RAM Scientific SAFE-T-FILL Micro Capillary Blood Collection tubes with the LeadCare Testing Systems.
- The capillary collection devices that are provided with the LeadCare Test Systems as well as other third-party capillary blood collection tubes, as described in the instructions for use of LeadCare Testing Systems, can still be used.
- If no alternate capillary blood collection devices are available other than the ASP Global's RAM Scientific SAFE-T-FILL Micro Capillary Blood Collection tubes, interpret results with caution and consider retesting with a different method or specimen type.
- Follow CDC's recommendations for confirmatory venous blood testing based on blood lead levels observed in capillary blood lead tests (https://www.cdc.gov/lead-prevention/testing/index.html).

Device Description

The LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests are used to detect lead in a blood sample, which may be obtained from finger or heel prick (capillary). The current reports of inaccurate results are only with capillary samples collected in ASP Global RAM Scientific SAFE-T-FILL tubes. The LeadCare Testing Systems are used in clinical laboratories, doctor's offices, clinics, and hospitals throughout the U.S. The LeadCare Test Kit includes capillary collection devices for use with the test system, and there have not been reports of falsely elevated results with the provided collection devices at this time. Sometimes third-party capillary blood collection tubes, sold separately, are also used for these tests. At this time, falsely elevated results have only been reported when ASP Global RAM Scientific SAFE-T-FILL Micro Capillary Blood Collection devices are used with the LeadCare Test Systems.

FDA Actions

The FDA is investigating the root cause of this issue with the manufacturers of the tests and collection tubes and will provide updates as critical information becomes available.

Reporting Problems with Your Device

Health professionals and patients are encouraged to report adverse events or side effects related to the use of ASP Global's RAM Scientific SAFE-T-FILL Micro Capillary Blood Collection tubes, Magellan Diagnostics LeadCare Testing Systems, or other devices to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.
- You can submit voluntary reports through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations.
- Health care personnel and clinical laboratory staff employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

By promptly reporting adverse events, you can help the FDA identify and better understand the risks associated with medical devices. The FDA regularly monitors the post-authorization use of tests, including reports of problems with test performance or results.

Questions?

If you have questions, contact CDRH's Division of Industry and Consumer Education (DICE).

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Alerting Message Specification Settings

Originating Agency:	Mississippi State Department of Health
Alerting Program:	**MS Health Alert Network (MS HAN)**
Message Identifier:	MSHAN- 20250505-00602-**ALT**
Program (HAN) Type:	**Health Alert Update**
Status (Type):	Actual ()
Message Type:	Update
Reference:	MSHAN-00602
Severity:	Unknown
Acknowledgement:	No
Sensitive:	Not Sensitive
Message Expiration:	Undetermined
Urgency:	Undetermined
Delivery Time:	600 minutes

Definition of Alerting Vocabulary and Message Specification Settings

Originating Agency: A unique identifier for the agency originating the alert.

Alerting Program: The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

Message Identifier: A unique alert identifier that is generated upon alert activation (MSHAN-yyymmdd-hhmm-TTT **(ALT=Health Alert, ADV=Health Advisory, UPD=Health Update, MSG/INFO=Message/Info Service**).

Program (HAN) Type: 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.

Health Info Service: Provides Message / Notification of general public health information; unlikely to require immediate action.

Status (Type):

- Actual: Communication or alert refers to a live event
- Exercise: Designated recipients must respond to the communication or alert
- Test: Communication or alert is related to a technical, system test and should be disregarded

Message Type:

- Alert: Indicates an original Alert
- Update: Indicates prior alert has been Updated and/or superseded
- Cancel: Indicates prior alert has been cancelled

Reference: For a communication or alert with a Message Type of "Update" or "Cancel", this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. "n/a" = Not Applicable.

Severity:

Extreme:	Extraordinary threat to life or property
Severe:	Significant threat to life or property
Moderate:	Possible threat to life or property
Minor:	Minimal threat to life or property
Unknown:	Unknown threat to life or property

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

Sensitive:

Sensitive:	Indicates the alert contains sensitive content
Not Sensitive:	Indicates non-sensitive content

Message Expiration: Undetermined.

Urgency: Undetermined. Responsive action should be taken immediately.

Delivery Time: Indicates the timeframe for delivery of the alert (15, 60, 1440, 4320 minutes (.25, 1, 24, 72 hours)).