Magellan Diagnostics, Inc. RECALL
LeadCare II, LeadCare Plus, and LeadCare Ultra

Magellan Diagnostics, Inc., manufacturer of the point-of-care blood lead testing machines, **recalled** identified lot numbers of their LeadCare II, LeadCare Plus, and LeadCare Ultra units in **May 2021** due to the "risk of falsely low results."

On **September 28, 2021**, the **recall was expanded** to include additional lots. For affected lot codes:

Refer to the Medical Device Recalls database entry for each product.

- LeadCare II
- LeadCare Plus
- LeadCare Ultra

"The EPA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries."

The FDA's September 2021 recall notice can be accessed in its entirety online at: https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk

Customers with questions about this recall should contact Magellan's LeadCare Product Support Team at 1-800-275-0102, or email at LeadCareSupport@magellandx.com.

CDC Recommendation

The CDC strongly recommends that healthcare providers continue on-time lead screenings for patients. If the LeadCare® recall has impacted the ability to offer point-of-care screening, **please pursue traditional capillary and venous testing with laboratory analysis**. For more information about the potential LeadCare® shortage and blood lead testing, please visit: https://www.cdc.gov/nceh/lead/news/potential-shortage-of-test-kits-following-recall.html .