CHILDHOOD LEAD POISONING PREVENTION BRANCH

CLPPB's Efforts in Response to the Magellan LeadCare Test Kit Recall

Recall Background

- Magellan Diagnostics, Inc, and the U.S. Food and Drug Administration (FDA) have issued notifications about the October 27, 2020 and August 19, 2021 recall and recall expansion of Magellan Diagnostics, Inc. LeadCare® Blood Lead Test kits. The recall now includes the majority of all test kits distributed since October 27, 2020.
- The use of these test kits may cause serious harm because they may underestimate blood lead levels.
- FDA has identified this as a Class I recall, the most serious type of recall.[1]
- The Centers for Disease Control and Prevention (CDC) has issued a Health Alert Network (HAN) Health Update to notify health care providers and state and local health departments and to recommend appropriate follow-up actions in the shortage of LeadCare lead tests.[2]

[1] FDA Magellan Recall

[2] CDC Health Alert

Contact Us

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In response to the recall, the Childhood Lead Poisoning Prevention Branch (CLPPB) has performed the following actions.

Communication with Laboratories

- Notified 500 active blood lead reporting laboratories to inform them of the recall and retesting guidelines.
- CLPPB is engaged in outreach to 500 California LeadCare reporting laboratories to ensure children are being retested if they were tested using the recalled test kits.

Outreach to Health Care Providers

- Developed a Medical Board of California e-blast to notify California physicians of the Magellan recall.
- Magellan recall notification via Continuing Medical Education webinar presentations to medical providers.
- Developed fact sheets for medical providers about the expanded recall and why retesting is needed.[3]

Collaboration with Local, State, and Federal Agencies

- Magellan recall notification sent to Childhood Lead Poisoning Prevention Programs at the local level.
- Contacted FDA, CDC and Magellan for additional information about the recall, retesting, and data on laboratories who have the recalled test kits.

CLPPB continues to review data on blood lead results reported to CDPH during the recall period to determine how many children might be involved with the recall.

[3] CLPPB Magellan Page

[1] Magellan Diagnostics Recalls LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests Due to Risk of Falsely Low Results: www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk

[2] Update: Expansion of Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results: https://emergency.cdc.gov/han/2021/han00457.asp

[3] Information on Magellan LeadCare: 2021 Blood Lead Test Kit Recall and 2017 FDA Safety Communications, and Recommendations: tinyurl.com/CLPPB-MAG

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