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Frequently Asked Questions about the Recall of LeadCare Blood Lead Tests

Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have issued notifications about the expansion of Magellan Diagnostics' recall of LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests, which were distributed from October 27, 2020 to August 19, 2021. Additional LeadCare II product lots, including lots previously reported to be unaffected, were recalled due to a significant risk of falsely low results. The use of these devices may cause serious injuries because they might underestimate blood lead levels. FDA has identified this as a Class I recall, the most serious type of recall.

What is being recalled?

- LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests
- Lot codes: Refer to the Medical Device Recalls database entry for each product
  - LeadCare II
  - LeadCare Plus
  - LeadCare Ultra
- Manufacturing Dates: October 26, 2020 to August 12, 2021
- Distribution Dates: October 27, 2020 to August 19, 2021

Why are these lead tests being recalled?

The FDA is concerned that the falsely low results may contribute to health risks in special populations such as young children and pregnant individuals. A pregnant or lactating individual's exposure to lead is concerning because it may cause health problems for the parent and the developing baby. Obtaining falsely low blood lead level results may lead to patients not receiving appropriate follow-up assessments, which may result in patient harm, including delayed puberty, reduced postnatal growth, decreased IQ, and attention and behavior problems in children.

What should clinicians do?

- Continue to schedule and perform required blood lead tests for patients. Delaying or reducing blood lead testing for children due to the unavailability of LeadCare lead test kits could lead to children with elevated blood lead levels not being identified and receiving the necessary treatment and services.
- A venous or capillary blood sample analyzed using higher complexity methods such as inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectroscopy (GFAAS) from a CLIA compliant laboratory should be used if LeadCare test kits are unavailable.
- Discontinue using all test kit lots identified as part of the recall.

- Follow recommendations for best practices when collecting a capillary blood sample for lead testing.

Who should be retested?

- Retest children who were tested with the recalled LeadCare test kits whose results were less than the CDC's blood lead reference value. Retesting should be done with higher complexity testing (i.e., inductively coupled plasma mass spectrometry or graphite furnace atomic absorption spectroscopy) with either a venous or a capillary sample. Capillary screening results above the blood lead reference value should be confirmed with blood drawn by venipuncture. Please note that effective October 28, 2021, CDC has updated its blood lead reference value (BLRV) from 5 µg/dL to 3.5 µg/dL in response to the Lead Exposure Prevention and Advisory Committee recommendation made on May 14, 2021.
- Retest children who were previously tested with a LeadCare test kit if the lot number of the initial test kit is unknown and the test was done after October 27, 2020.
- Prioritize testing for:
    - Children where there is clinical concern that symptoms or developmental problems may be related to lead exposure,
    - Populations at higher risk of elevated blood lead levels, such as children tested due to Medicaid-required screening or due to other state or local requirements,
    - Individuals who are pregnant or breastfeeding, and
    - Children who are immigrants, refugees, or recently adopted from outside of the United States.
- Discuss the recall and retesting recommendations with a parent and/or caregiver of children who meet the retesting criteria.

What if my clinic does not have the resources to retest everyone impacted by the recall?
Priority for retesting should follow the guidelines listed above. Clinics without appropriate resources to retest should refer affected patients to a local lab that is able to conduct the testing or contact the Section of Epidemiology at (907) 269-8000 for additional guidance.

Who is responsible for paying for the test if a patient needs to be retested as part of this recall?
For Medicaid enrolled children, Medicaid will pay for re-testing because blood lead screening tests are mandatory services. For non-Medicaid enrolled children, payment should be determined by the provider in consultation with the patient's insurance.

How can my clinic continue lead testing without LeadCare test kits?
Clinics should work with their regular labs to continue lead testing. Labs can provide information on supplies needed to continue both capillary testing and venous draws. Both capillary and venous tests can be sent to the lab for analysis. Please contact the Section of Epidemiology at (907) 269-8000 if you need additional guidance.

Does a capillary sample that is analyzed at a lab with a high complexity method still need to be confirmed with a venous draw?
Yes. Capillary tests are used for screening. A venous sample is required to confirm an elevated blood lead level.

What should health care providers do if they used the recalled kits and/or have remaining inventory?

- Discontinue use of all test kits identified as part of the recall and quarantine remaining inventory.
- Providers impacted by this recall should have received a letter from Magellan Diagnostics with instructions on what to do with remaining inventory and how to receive replacement kits.
- If recalled test kits were used, please see the FDA webpage pertaining to this recall for more detailed instructions on what to do next.

Is it OK to continue to use a LeadCare machine with test kits that were not part of this recall?
Yes, if non-recalled LeadCare test kits are still available and have not reached their expiration date.

When will I be able to order new LeadCare test kits?
Product distribution has been paused until further notice, and replacement product is currently unavailable. It is unknown when replacement product will be available.

Who can I contact if I have further questions about this recall?
Those who have further questions can contact the Section of Epidemiology at (907) 269-8000 or eph@alaska.gov. Specific questions related to recalled products can also be sent to Magellan's LeadCare Product Support Team at 1-800-275-0102 or LeadCareSupport@magellandx.com.