



**COUNTY OF SAN LUIS OBISPO HEALTH AGENCY
PUBLIC HEALTH DEPARTMENT**

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Recall of Certain LeadCare® Blood Lead Test Products

Magellan Diagnostics, Inc. and the FDA issued a recall notice concerning certain LeadCare® blood lead test kit lots. These lots were distributed between October 27, 2020 and June 15, 2021. These lots might have underestimated blood lead levels.

The affected test kit lots are

- LeadCare II: 2013M, 2014M, 2015M, 2016M, 2017M, 2101M, 2103M, 2105M, 2106M, and 2107M
- LeadCare Plus and LeadCare Ultra: 2011MU, 2104MU, and 2108MU

The CDC has issued the following recommendations related to this recall:

- Discontinue use of all affected test kit lots identified as part of the recall.
- Retest children who were tested with the recalled LeadCare test kits whose results were less than 5 µg/dL, the current CDC-recommended blood lead reference value. Retesting should be done with a venous blood sample analyzed with higher complexity testing.
- 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 between October 27, 2020, and June 15, 2021.
- Priority for retesting should be given to—
 - o Children where there is clinical concern that symptoms or developmental problems may be related to lead exposure,
 - o 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, and
 - o Individuals who are pregnant or breastfeeding.
- If retesting indicates blood lead levels in excess of the current CDC Blood Level Reference Values (BLRV) or state or local action level, the healthcare provider or public health official should refer to CDC guidelines or state/local guidelines for appropriate follow-up action.
- Discuss the recall and retesting recommendations with a parent and/or caregiver of children who meet the retesting criteria

For more information regarding this recall, see [CDC-HAN-00445.pdf](https://emergency.cdc.gov/han/2021/pdf/CDC-HAN-00445.pdf) (<https://emergency.cdc.gov/han/2021/pdf/CDC-HAN-00445.pdf>).

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