

# Important Recall of Several Magellan LeadCare® Test Kits and CDC Recommendations for Healthcare Providers

On August 31, 2021, Magellan Diagnostics, Inc. began customer notification of an expansion of its May 2021 recall of its LeadCare® Blood Lead Test Kits due to a significant risk of falsely low results, which may lead to health risks especially in special populations such as young children and pregnant and lactating individuals. The recall now includes the majority of all test kits distributed since October 27, 2020. The US Food and Drug Administration (FDA) has identified this as a Class I recall, the most serious type of recall. Obtaining falsely low results may lead to patient harm.

[FDA Magellan recall](https://www.fda.gov/oc/press-releases/2021/s092821), updated September 28, 2021 ([tinyurl.com/FDA-M21-928](https://www.tinyurl.com/FDA-M21-928))

**Customers should discontinue use of all LeadCare® Test Kits lots identified as part of the recall and quarantine remaining inventory.**

## Recalled Test Kit Lot Codes:

- **LeadCare II:** 2013M, 2014M, 2015M, 2016M, 2017M, 2101M, 2103M, 2105M, *Expansion:* 2012M Sublots: -08, -09, -10, -11, -12, -13, and -14, 2018M, 2102M, 2106M, 2107M, 2109M, 2110M, 2111M, 2112M, 2113M, 2114M, 2115M and 7114M
- **LeadCare Plus and LeadCare Ultra:** 2011MU, *Expansion:* 2104MU, 2108MU

## US Centers for Disease Control (CDC) Recommendations

- **Retesting** ([tinyurl.com/CDC-HAN-457](https://www.tinyurl.com/CDC-HAN-457))
  - Retest children who were:
    - Tested with the recalled LeadCare® test kits whose results were less than the current [CDC blood lead reference value \(BLRV\)](https://www.tinyurl.com/CDC-BLRV-21). ([tinyurl.com/CDC-BLRV-21](https://www.tinyurl.com/CDC-BLRV-21))
    - 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.
  - Retesting should be done with a venous or capillary blood sample analyzed with high complexity testing:
    - Inductively coupled plasma mass spectrometry (ICP-MS)
    - Graphite furnace atomic absorption spectroscopy (GFAAS).
  - Capillary screening results above the BLRV should be confirmed with a venous blood draw.
  - Priority for retesting should be given to:
    - 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 Medi-Cal-required screening or due to other state or local requirements.
    - Individuals who are pregnant or breastfeeding.
    - Children who are immigrants, refugees, or recently adopted from outside of the United States.
  - Discuss the recall and retesting recommendations with the parents or guardians of children who meet the retesting criteria.
- **Test Kit Shortages for Blood Lead Screening** ([tinyurl.com/CDC-M21-KITS](https://www.tinyurl.com/CDC-M21-KITS))
  - If LeadCare® test kits are unavailable, CDC strongly recommends clinicians continue to schedule and perform required blood lead tests for patients.
  - Blood lead tests can be done with either a venous or capillary blood sample, submitted to a laboratory for analysis with higher complexity methods. Contact your lab for acceptable minimum sample size and recommended blood collection supplies.
  - Follow [best practices](https://www.tinyurl.com/CDC-LAB-821) ([tinyurl.com/CDC-LAB-821](https://www.tinyurl.com/CDC-LAB-821)) when [collecting a capillary blood sample](https://www.tinyurl.com/CDC-FSP-621) ([tinyurl.com/CDC-FSP-621](https://www.tinyurl.com/CDC-FSP-621)) for lead testing.
  - Contact [California Laboratory Field Services](https://www.tinyurl.com/DPH-LFS-CLIA) ([tinyurl.com/DPH-LFS-CLIA](https://www.tinyurl.com/DPH-LFS-CLIA)) for a list of higher complexity laboratories.

# 2017 FDA Warning about Magellan LeadCare® Analyzers Producing Falsely Low Results with Venous Blood Samples

**Some children have not received appropriate retesting related to this 2017 FDA warning. These children should be retested with a capillary or venous sample analyzed using a high complexity device.**

On May 17 2017, FDA issued a [safety communication warning](http://tinyurl.com/FDA-M17-517) (tinyurl.com/FDA-M17-517) about the use of Magellan Diagnostics, Inc.'s LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they might result in falsely low test results. FDA advised that Magellan's LeadCare® analyzers should no longer be used with venous blood samples.

- This safety alert applied to venous blood lead tests conducted using Magellan's LeadCare® analyzers whether the patient was a child or an adult.
- The safety alert did not apply to capillary blood lead test results from samples collected by fingerstick or heelstick and analyzed using Magellan's LeadCare® analyzers.
- Further [FDA safety issue report](http://tinyurl.com/FDA-M17-918), September 27, 2018. (tinyurl.com/FDA-M17-918)

## **CDC HAN notification (tinyurl.com/CDC-HAN-403) recommended:**

- Healthcare providers retest:
  - Children who were younger than 6 years (72 months) of age at the time of the alert (May 17, 2017) **AND**
  - Had a venous blood lead test result of less than 10 mcg/dL analyzed using a Magellan LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory.
  - Pregnant or lactating individuals who had a venous blood lead test performed using a Magellan LeadCare® analyzer.

For retesting, providers should send capillary or venous samples to laboratories using ICP-MS or GFAAS (also known as electrothermal atomic absorption spectrometry [ETAAS]) instruments.

If you have questions, contact Magellan's LeadCare® Product Support Team at 1-800-275-0102 or email: [LeadCareSupport@magellandx.com](mailto:LeadCareSupport@magellandx.com).

## **Additional Information and Resources**

[Childhood Lead Poisoning Prevention Branch Magellan LeadCare® Recall Information](http://tinyurl.com/CLPPB-MAG)

(tinyurl.com/CLPPB-MAG)

[Information for Health Care Providers](http://tinyurl.com/CLPPB-Prov) on the CLPPB web site (tinyurl.com/CLPPB-Prov)