



Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

October 22, 2021

RE: Expanded Recall of Test Kits Due to Risk of Falsely Low Results

Dear Colleague,

On September 28, 2021 The U.S. Food and Drug Administration (FDA) [announced](#) an expansion of its Class I recall for blood lead testing kits manufactured by Magellan Diagnostics, Inc., including the LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests. The reason for the recall (and the expansion) is a significant risk of falsely low results when measuring blood lead levels. Continued use of these tests may lead to significant health risks, especially among young children and pregnant individuals.

Maryland Department of Health and the Maryland Department of the Environment (MDE) advise that providers using Magellan Diagnostics blood lead testing devices follow these [CDC recommendations](#):

- 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 after October 27, 2020 and July 6, 2021, the date of this health advisory.
- 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 Medicaid-required screening or due to other state or local requirements, and
 - 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.

Per [CDC guidance](#), children with blood lead levels at or greater than 5 µg/dL should have had a subsequent test with a venous blood sample for confirmation. LeadCare instruments are currently approved for use only with capillary or finger/heel stick samples. Venous blood confirmation levels are performed with higher complexity testing such as inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectroscopy (GFAAS) and are generally considered more accurate.

If providers need MDE's assistance with identifying a child tested that had a blood lead level <5 µg/dL, please contact Dr. Rena Boss-Victoria at (410) 537-3880 (rena.boss-victoria@maryland.gov).

If you have questions related to this recall, please contact the EHB Environmental Helpline at 866-703-3266 or mdh.envhealth@maryland.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Clifford S. Mitchell". The signature is fluid and cursive, with a large initial "C" and "M".

Clifford S. Mitchell, MS, MD, MPH
Director, Environmental Health Bureau