

TO: Vermont Health Care Providers

FROM: Mark Levine, MD, Health Commissioner

Expanded Recall of LeadCare® II Testing Supply Kits Due to Risk of Falsely Low Results

Magellan Diagnostics, Inc has expanded their product recall of LeadCare II Blood Lead Test Kits. This expanded COOR-LO recall includes LeadCare® II Blood Test Kits lots: 2012M (Sublots -08, -09, -10, -11, -12, -13, and -14); 2018M; 2102M; 2109M, 2110M; 2111M; 2112M; 2113M; 2114M; and 2115M. These lots are in addition to [previously recalled lots](#). Magellan Diagnostics has temporarily stopped shipments of LeadCare® test kits and has not issued a definitive date to resume shipments.

Recommendations

- Discontinue use of **all** Lead Care® II test kits and quarantine remaining inventory.
- Retest children who were tested with the recalled LeadCare test kits whose results were less than 5 µg/dL. Retesting should be done with an alternative lead testing option, such as those using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or Graphite Furnace Atomic Absorption Spectroscopy (GFAAS) at a high complexity, CLIA-certified, reference laboratory. 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, but if they did not, confirm with a venous blood sample.

Until this issue is resolved, provider practices affiliated with UVMMC can use the UVMMC Laboratory in accordance with the recent guidance provided. Please contact Judy Schwenn (Judy.Schwenn@uvmhealth.org) or Jocelyn Stocker (Jocelyn.stocker@uvmhealth.org).

All other practices can use the Vermont Department of Health Laboratory for blood lead testing. The Health Department Lab's testing supplies are free and results can be sent via email. For practices who collect more than 10 blood lead samples per day, the Health Department Lab may also be able to send a courier to pick up samples.

- To order free supplies, use this form www.healthvermont.gov/sites/default/files/documents/pdf/PHL_InorgTox501-BloodLead-Order.pdf or contact Cheryl Brinkman (802-338-4708 Cheryl.brinkman@vermont.gov).
- To request a blood lead test, use this form www.healthvermont.gov/sites/default/files/documents/pdf/PHL_InorgTox200-BloodLead-Req.pdf and submit it with the blood sample.

- Call the Health Department Lab's customer service team with any questions at 802-338-4724 or 800-660-9997 and find more information at www.healthvermont.gov/public-health-laboratory/clinical-testing/blood-lead-testing.

Additional Information and Contacts:

If you have any questions regarding the Magellan Diagnostics recall, please contact Magellan's LeadCare Product Support Team at 1-800-275-0102, or email LeadCareSupport@magellandx.com.

For questions about the contents of this message, please contact the Healthy Homes and Lead Poisoning Prevention Program at 800-439-8550 or AHS.HealthyHomes@vermont.gov.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.