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MEMORANDUM

To: Medical Practices That Use a LeadCare II Instrument

From: Nirav Shah, MD, JD, Director, Maine Center for Disease Control and Prevention

Date: July 19, 2021

Re: LeadCare II Blood Lead Test Kit Recall – Information on Patient Re-Testing

This memorandum provides guidance to medical practices approved to conduct in-office blood lead testing in connection with the recall of certain test kits for the LeadCare II point of care blood lead testing device. Recently, Magellan Diagnostics, the manufacturer, initiated a recall of 10 lots of test kits used with the LeadCare II instrument because of the potential to underestimate blood lead test results. Magellan Diagnostics, the U.S. Food and Drug Administration (FDA), and the U.S. Centers for Disease Control and Prevention (CDC) advise providers to re-test patients who were tested with the affected kits with a result of less than 5 micrograms per deciliter (<5 mcg/dL) in order to ensure patients receive an accurate blood lead test and appropriate follow up.

Who should be re-tested?

- Any patient who was tested with one of the recalled test kits and the result was less than 5 micrograms per deciliter (<5 mcg/dL)
- Any patient tested with the LeadCare II device if the lot number of the test kit is unknown and was used between October 27, 2020, and July 6, 2021, and the result was <5 mcg/dL
- For patients tested with one of the recalled kits with blood lead levels of 5 mcg/dL or greater, obtain a confirmatory venous blood lead test as soon as possible if the patient has not already had a confirmatory venous test

How should children be re-tested?

Maine CDC recommends re-testing patients with either a capillary or venous blood sample analyzed at the Maine Health and Environmental Testing Laboratory. This approach is consistent with U.S. CDC and FDA recommendations that re-testing be performed with a high complexity method at a CLIA-certified reference laboratory. To obtain capillary samples in the office you may need to order the appropriate capillary testing tubes for use. For free blood collection supplies and mailers, call the Maine Health and Environmental Testing Lab at (207) 287-2727. To prevent false positive capillary samples, wash and scrub the finger or toe with soap using a surgical brush or soft toothbrush before collecting the sample.

When should patients be re-tested?

Maine CDC recommends providers re-test all patients within three (3) months from the date of this guidance. Providers should also consider Maine CDC's guidelines to perform required blood lead tests for 1-year-olds between the ages of 9 and less than 18 months and for 2-year-olds between the ages of 18 and less than 36 months. Maine law requires that all children receive a blood lead test at ages 1 and 2 years, and providers should view patients in these age groups in need of re-testing as having missed a required test.

If we have many patients who need to be re-tested, how should we prioritize them?
All children affected by this recall should be re-tested. However, consider prioritizing patients for re-testing by risk. Children in the following groups may be at higher risk for lead poisoning:

- Children who were tested with a recalled kit with a result of 3.3 to <5 mcg/dL
- A child whose parent answers "yes" or "don't know" to any of the four questions in Maine CDC's Risk Assessment Questionnaire

What about the cost of re-testing?
MaineCare will cover the cost of re-testing patients. If there are uninsured or under-insured patients for whom the cost of re-testing is a barrier, please reach out to us with the contact information below.

Why should children be re-tested?
Think of these patients as having missed a required or recommended blood lead test. Maine law requires that all children receive a blood lead test at ages 1 and 2 years. Maine CDC recommends testing children ages 3-5 years based on risk and prior history. Some children tested with the recalled test kits may have elevated lead levels and may require public health services to identify and remove the source of their lead exposure. Timely re-testing will help ensure children in need of intervention receive it. Maine CDC provides free, comprehensive lead investigations of the home environment for all children with a confirmed, venous blood lead level of 5 mcg/dL or greater.

What should we do if a patient who was re-tested has an elevated result?
Following re-testing, confirm all capillary blood lead levels of 5 mcg/dL or greater with venous samples. Maine CDC recommends obtaining this confirmatory venous sample as soon as possible so that public health services can be initiated.

What should I do for routine lead testing if I have no LeadCare II test kits because of the recall?
For routine blood lead testing of children not affected by the recall, submit capillary or venous specimens for analysis to the Maine Health and Environmental Testing Laboratory as required by Maine law. It is important to continue to follow blood lead testing requirements and recommendations even if you are not able to perform in-office testing with the LeadCare II device. For free blood collection supplies and mailers, call the Maine Health and Environmental Testing Lab at (207) 287-2727.

Where can I find more information about the recall, affected test kit lots, and re-testing?

- U.S. FDA: https://www.fda.gov/medical-devices/medical-device-recalls/magellan-diagnostics-recalls-leadcare-ii-leadcare-plus-and-leadcare-ultra-blood-lead-tests-due-risk
- U.S. CDC: https://emergency.cdc.gov/han/2021/pdf/CDC-HAN-00445.pdf
- American Academy of Pediatrics: https://www.aappublications.org/news/2021/07/07/retest-blood-lead-070721

Who can I contact if I have questions?

- Maine CDC Childhood Lead Poisoning Prevention Section: (207) 287-4311; or email Maggie Bordeau, DO, MPH, Public Health Physician, Margaret.bordeau@maine.gov, or Emily Brown, RN, Child Health Coordinator, Emily.brown@maine.gov
- Maine Health and Environmental Testing Lab: (207) 287-2727
- Magellan Diagnostics: (800) 275-0102 or LeadCareSupport@magellandx.com