LeadCare® Testing Systems by Magellan Diagnostics: FDA Safety Warning about the Risk of Inaccurate Results and Response by the Michigan Department of Health and Human Services

What was the safety warning issued by the FDA regarding venous blood lead test results?

- On May 17, 2017, the U.S. Food and Drug Administration (FDA) issued a warning that certain lead tests conducted on equipment manufactured by Magellan Diagnostics may underestimate the blood lead levels from venous blood samples. See *www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm*.
- Magellan Diagnostics Inc. manufactures the following lead testing systems affected by this warning: LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra.
- The LeadCare Testing Systems detect the amount of lead in a blood sample obtained from finger or heel prick (capillary) or from a vein (venous).
- This warning applies to tests of venous blood, not capillary blood. At this time, the FDA has no evidence that Magellan's LeadCare Testing Systems have the same problem when processing capillary blood samples.
- The LeadCare Testing Systems are used in clinical laboratories, doctor's offices, clinics, and hospitals throughout the U.S.

Why should health care providers and the public be concerned about this?

- Testing for lead in blood is the most frequently used method to determine if a person has been exposed to lead in the environment.
- Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning.

What actions are being taken by the federal government in response?

- The Centers for Disease Control and Prevention (CDC) issued a health alert accompanying the FDA safety warning on May 17, 2017, which made recommendations for re-testing of children and pregnant/lactating women who had been tested for lead with a venous sample using LeadCare equipment. See *https://emergency.cdc.gov/han/han00403.asp*
- The FDA has been unable to identify the root cause for the inaccurate results, based on data provided by Magellan. The FDA is collaborating with CDC to conduct studies to identify the cause and better characterize the extent of the problem.

What are the recommendations of the MDHHS in response to the FDA safety warning?

- Magellan's LeadCare Testing Systems should not be used with venous blood samples. At this time, all LeadCare systems can be used with capillary blood samples.

- MDHHS recommendations for re-testing of children and pregnant/lactating women closely follow those from the CDC.
- MDHHS recommends that health care providers consider re-testing of their patients who meet the following criteria:
  - Children younger than six years (72 months) of age at the time of the FDA alert (May 17, 2017) if their most recent lead test was conducted using any Magellan LeadCare Testing System, using blood drawn from a vein, and the result was less than 10 micrograms per deciliter; or
  - Women who are currently pregnant or nursing and were tested using blood drawn from a vein using any Magellan LeadCare Testing Systems while pregnant or nursing.

  FURTHERMORE
  - The patient did not have any other valid blood lead test after the venous blood test using a Magellan LeadCare testing system.

How is MDHHS informing health care providers, Local Health Departments, and the public of these recommendations?

- MDHHS issued a health alert and a press release on May 17, 2017 to ensure that the FDA safety warning and CDC recommendations received wide attention in Michigan.
- MDHHS emailed this same information to all Local Health Departments and registered LeadCare laboratories on May 17, 2017, and letter L 17-20 was sent to all Medicaid providers on May 18, 2017.
- MDHHS identified approximately 9,000 children less than age 6 who meet re-testing recommendations, using its database of laboratory reports of blood lead test results.
  - The health care providers of these children will be identified by matching the children's names with Medicaid enrollee data and the Michigan Care Improvement Registry.
  - The health care providers will be mailed a list of their patients, so they can determine whether re-testing is necessary now.
  - This process should be completed by the end of June 2017.
- Each Local Health Department is being provided a list of the children in their jurisdiction who meet these re-testing recommendations, so that they can determine if they want to conduct additional outreach. At this point, however, MDHHS believes that its provider-based outreach is the best strategy to ensure that children be given appropriate consideration for re-testing.

Will insurance cover the costs of re-testing?

- For currently eligible Medicaid beneficiaries, Medicaid will cover the cost of blood lead retesting in response to the FDA warning.
- Affected individuals with private insurance should check with their insurance company to determine whether the cost of blood lead retesting in response to the FDA warning is covered.