

Health Advisory: False Blood Lead Results

Minnesota Department of Health Thu May 18 09:00 CDT 2017

Action Step:

Local and tribal health departments: Please forward to hospitals, clinics, emergency departments, urgent care centers, and convenience clinics. MDH will be contacting you separately to ask for assistance with contacting individuals who need repeat blood lead testing.

Hospitals, clinics and other facilities: Please distribute to health care providers in these facilities who might conduct blood lead testing.

Health care providers:

- Repeat blood lead testing for children aged < 6 years and women who are pregnant or breastfeeding as of May 17, 2017 if they had a venous test result <10 mcg/dL analyzed on a LeadCare machine. MDH is compiling a list of individuals who meet these criteria.
- Ensure that all venous blood lead tests are analyzed by inductively coupled plasma-mass spectrometry (ICP-MS) or graphite furnace atomic spectrometry (GFAAS).
- Continue to conduct blood lead screening according to normal protocols. Testing of capillary samples is not affected by this notice.

Summary

On May 17, FDA and CDC issued an advisory on LeadCare blood lead testing machines manufactured by Magellan Diagnostics. FDA has advised that LeadCare machines (including the LeadCare II and LeadCare Ultra) should not be used to test venous samples because of falsely low results. Venous samples should instead be analyzed by inductively coupled plasma-mass spectrometry (ICP-MS) or graphite furnace atomic spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]). This advisory does not affect testing of capillary samples.

According to MDH data, around 9,000 people may need to have their blood lead test repeated. This represents less than 5% of people who received blood lead tests. MDH will be coordinating with local public health agencies to reach out to health care providers and their patients who are affected by this advisory.

For more information

- [FDA warns Americans about risk of inaccurate results from certain lead tests](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm558769.htm) (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm558769.htm>)
- [FDA Warns Against Using Magellan Diagnostics LeadCare Testing Systems with Blood Obtained from a Vein: FDA Safety Communication](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm) (<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm>)
- [CDC Lead](https://www.cdc.gov/nceh/lead/default.htm) (<https://www.cdc.gov/nceh/lead/default.htm>)

A copy of this HAN is available in PDF and Word format at www.health.state.mn.us/han. The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.