

# Magellan Diagnostics LeadCare Analyzers Health Safety Alert FAQs

## **1. Why was this safety alert issued?**

The U.S. Food and Drug Administration (FDA) has issued a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they might result in falsely low test results.

## **2. Who issued the safety alert?**

The safety alert was issued by the US FDA.

## **3. Does this safety alert affect all blood lead tests performed on LeadCare analyzers?**

The safety alert does not apply to capillary blood lead test results collected by fingerstick or heelstick. This safety alert only applies to venous tests that were performed on any of the four Magellan Diagnostics' LeadCare® analyzers noted above. Laboratory tests analyzed by inductively coupled plasma-mass spectrometry (ICP-MS) or graphite furnace atomic spectrometry (GFAAS) are not expected to have resulted in falsely low results.

## **4. What is the recommendation for re-testing?**

CDC recommends that healthcare providers re-test patients who:

- 1) are younger than 6 years (72 months) of age at the time of the safety alert (May 17, 2017) and
- 2) had a venous blood lead test result of less than 10 micrograms per deciliter ( $\mu\text{g}/\text{dL}$ ) analyzed using a Magellan Diagnostics' LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory.

CDC also recommends that healthcare providers re-test currently pregnant or lactating women who had a venous blood lead test performed using a Magellan Diagnostics' LeadCare® analyzer.

See the CDC's flow diagram for additional guidance on re-testing:

[https://www.cdc.gov/nceh/lead/docs/Blood\\_Lead\\_Tests\\_Flowchart.pdf](https://www.cdc.gov/nceh/lead/docs/Blood_Lead_Tests_Flowchart.pdf)

Re-tests are not recommended if the provider is certain that analyzers other than those described by this safety alert were used to analyze the venous blood samples.

## **5. Can my facility or clinic continue to test capillary blood using the point-of-care LeadCare® II analyzer?**

Yes, at this time the FDA does not apply to capillary testing.

**6. What should I do if my facility or clinic was testing venous samples on a point-of-care LeadCare® II analyzer?**

Please notify the Oregon Public Health Division's (OPHD) Lead Poisoning Prevention Program if your facility implemented this practice. See the CDC recommendations above for re-testing those individuals that may have been affected by this safety alert. See the next question for guidance on sending venous samples to offsite reference labs.

**7. If a capillary blood lead test using the point-of-care LeadCare® II analyzer is  $\geq 5 \mu\text{g}/\text{dl}$ , where should my clinic or facility send the venous sample to confirm the capillary test?**

Send venous samples to Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratories using inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]) instruments.

**8. What if my clinic or facility performed split blood tests by testing some of the sample onsite, and sending the remainder to a reference lab?**

Please notify the OPHD Lead Poisoning Prevention Program if your facility implemented this practice. The FDA has expressed interest in receiving these results.

**9. If a capillary blood lead test using the point-of-care LeadCare® II analyzer is less than  $5 \mu\text{g}/\text{dl}$ , does my clinic or facility need to report it?**

Yes, all blood lead tests are required to be reported to either the local health authority or the OPHD Lead Poisoning Prevention Program within 7 working days.

**10. My child recently had his/her blood tested for lead, but I can't remember if it was a venous or capillary (fingerstick) test. What should I do?**

If you have concerns about a recent blood lead test for a child who was six or younger as of May 17<sup>th</sup>, 2017, talk with your pediatrician or healthcare provider to see if another blood test is recommended.

**11. I am currently pregnant or nursing and recently had a blood lead test. Should I get another one?**

If you have concerns about a recent blood lead test and you are currently pregnant or nursing, you may need to be re-tested. Please talk with your healthcare provider to see if your blood test is affected by this safety alert.

**12. If my child or I need to be re-tested, will I have to pay for it?**

If you or your child are on the Oregon Health Plan, re-testing will be covered. Otherwise, call your healthcare provider insurance to see if the cost of a re-test will be covered.

### 13. Where can I find more information about this safety alert?

Please visit the following websites:

Centers for Disease Control and Prevention: <https://emergency.cdc.gov/han/han00403.asp>

U.S. Food and Drug Administration: <https://www.fda.gov/MedicalDevices/Safety/SafetyAlertsandNotices/ucm558733.htm>

#### **Contacts:**

For clinics and healthcare facilities:

#### **Oregon Public Health Division's Lead Poisoning Prevention Program**

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For laboratories:

#### **Oregon Public Health Division's Laboratory Compliance Section**

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