

# Thousands of children got tested for lead with faulty devices: What parents should know

June 13 2024, by Julie Appleby, KFF Health News

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A company that makes tests for lead poisoning has agreed to resolve

criminal charges that it concealed for years a malfunction that resulted in inaccurately low results.

It's the latest in a long-running saga involving Massachusetts-based Magellan Diagnostics, which will pay \$42 million in penalties, according to the Department of Justice.

While many of the fault-prone devices were used from 2013 to 2017, some were being recalled as late as 2021. The Justice Department said the malfunction produced inaccurate results for "potentially tens of thousands" of children and other patients.

Doctors don't consider any level of lead in the blood to be safe, especially for children. Several U.S. cities, including Washington, D.C., and Flint, Michigan, have struggled with widespread lead contamination of their water supplies in the last two decades, making accurate tests critical for public health.

It's possible faulty Magellan kits were used to test children for [lead exposure](#) into the early 2020s, based on the recall in 2021. Here's what parents should know.

## **What tests were affected?**

The inaccurate results came from three Magellan devices: LeadCare Ultra, LeadCare II, and LeadCare Plus. One, the LeadCare II, uses finger-stick samples primarily and accounted for more than half of all blood lead tests conducted in the U.S. from 2013 to 2017, according to the Justice Department. It was often used in physician offices to check children's lead levels.

The other two could also be used with blood drawn from a vein and may have been more common in labs than doctor's offices. The company

"first learned that a malfunction in its LeadCare Ultra [device](#) could cause inaccurate lead test results—specifically, lead test results that were falsely low" in June 2013 while seeking regulatory clearance to sell the product, the DOJ said. But it did not disclose that information and went on to market the tests, according to the settlement.

The agency said 2013 testing indicated the same flaw affected the LeadCare II device. A 2021 recall included most of all three types of test kits distributed since October 27, 2020.

The company said in a [press release](#) announcing the resolution that "the underlying issues that affected the results of some of Magellan's products from 2013 to 2018 have been fully and effectively remediated," and that the tests it currently sells are safe.

## **What does a falsely low result mean?**

Children are often tested during pediatrician visits at age 1 and again at age 2. Elevated lead levels can put kids at risk of developmental delay, lower IQ, and other problems. And symptoms, such as stomachache, poor appetite, or irritability, may not appear until high levels are reached.

Falsely low test results could mean parents and physicians were unaware of the problem.

That's a concern because treatment for [lead poisoning](#) is, initially, mainly preventive. Results showing elevated levels should prompt parents and [health officials](#) to determine the sources of lead and take steps to prevent continued lead intake, said Janine Kerr, health educator with the Virginia Department of Health's Childhood Lead Poisoning Prevention Program.

Children can be exposed to lead in a variety of ways, including by

drinking water contaminated with lead from old pipes, such as in Flint and Washington; ingesting lead-based paint flakes often found in older homes; or, as reported recently, eating some brands of cinnamon-flavored applesauce.

## **What should parents do now?**

"Parents can contact their child's pediatrician to determine if their child had a blood lead test with a LeadCare device" and discuss whether a repeat blood lead [test](#) is needed, said Maida Galvez, a pediatrician and professor at the Icahn School of Medicine at Mount Sinai in New York.

During an earlier recall of some Magellan devices, in 2017, the Centers for Disease Control and Prevention recommended that patients be retested if they were pregnant, nursing, or children younger than 6 years and had a blood lead level of less than 10 micrograms per deciliter as determined by a Magellan device from a venous blood draw.

The 2021 recall of Magellan devices recommended retesting children whose results were less than the current CDC reference level of 3.5 micrograms per deciliter. Many of those tests were of the finger-stick variety.

Kerr, at the Virginia health department, said her agency has not had many calls about that recall.

The finger-stick tests "are not that widely used in Virginia," said Kerr, adding that "we did get a lot of questions about the applesauce recall."

In any case, she said, the "best course of action for parents is to talk with a health care provider."

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Citation: Thousands of children got tested for lead with faulty devices: What parents should know (2024, June 13) retrieved 27 June 2024 from <https://medicalxpress.com/news/2024-06-thousands-children-faulty-devices-parents.html>

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