

# Magellan

D I A G N O S T I C S

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## **Magellan Diagnostics Announces Voluntary Resolution of Federal Investigation *Underlying Product Issues Were Remediated in 2018***

**BILLERICA, MA,** – Magellan Diagnostics, Inc. (Magellan), a Meridian Bioscience, Inc. (Meridian) company, today announced that it has finalized an agreement with the U.S. Department of Justice (DOJ) that resolves the DOJ’s investigation of Magellan. The investigation commenced in 2018 and primarily involved conduct by former Magellan employees that occurred between 2013 and 2017 concerning the use of venous blood samples with Magellan’s LeadCare® line of products. The use of venous blood samples was discontinued in 2018, and the product-related issues involved in the investigation were fully remediated at that time. As part of the resolution, Magellan will pay \$42 million over time in accordance with the negotiated terms of the settlement.

“We are pleased to have reached an amicable resolution concerning issues that happened nearly a decade ago with Magellan,” said Tony Serafini-Lamanna, president of Magellan Diagnostics. “Magellan and Meridian engaged constructively with the DOJ to develop a mutually acceptable resolution, including fully cooperating with the DOJ and providing resources to support victims that were impacted. Magellan takes seriously our responsibility to provide reliable, FDA-cleared products to support some of our most vulnerable populations. The underlying issues that affected the results of some of Magellan’s products from 2013 to 2018 have been fully and effectively remediated. Today, the devices and tests sold by Magellan are safe, FDA-cleared and are performing as intended.”

This settlement does not affect the DOJ’s ongoing prosecution of three former Magellan employees who no longer work for the company.

The key terms of the settlement include:

- Magellan will continue to fully cooperate with the DOJ until all related investigations and prosecutions are concluded
- Payment of a fine of \$21.8 million
- Forfeiture of \$10.9 million of revenue from the sale of affected products
- Creation of a Victim Compensation Fund, initially funded with \$9.3 million
- Engagement of a compliance monitor for the next two years
- Admission to two misdemeanor violations of the Federal Food, Drug, and Cosmetic Act
- Entering into a deferred prosecution agreement with the DOJ

Copies of the settlement documents and information regarding the victim compensation fund will soon be available on [Magellan's website](#).

Magellan is the leading provider of point of care pediatric lead testing solutions. All three of Magellan's medical devices (LeadCare Ultra, LeadCare II and LeadCare Plus) and their testing kits have been fully remediated and cleared by the FDA.

### **About Magellan Diagnostics, Inc.**

Magellan is a fully integrated diagnostics company that develops, manufactures, markets, and distributes innovative blood lead level testing solutions across the globe. Magellan has been a pioneer in the analysis of blood lead for over 50 years. Since the late 1960s, our company (then called ESA, Inc.) was founded by four PhD graduates from the Massachusetts Institute of Technology (MIT). Applying a novel technique called Anodic Stripping Voltammetry (ASV), they designed and built a bench top analyzer for the measurement of lead in blood. The company then adapted this technology to create smaller, portable instruments that can be used outside of traditional laboratory settings. This major achievement broadened the accessibility of lead testing by bringing it to the point of care.

In 2016, Magellan Diagnostics was acquired by Meridian Bioscience, Inc., an established diagnostics and life science industry leader. Magellan's website address is <https://www.magellandx.com/about-us/>.

### **About Meridian Bioscience, Inc.**

Meridian is a fully integrated life science company that develops, manufactures, markets, and distributes a broad range of innovative diagnostic and life science products. We are dedicated to developing and delivering better solutions that give answers with speed, accuracy, and simplicity that are redefining the possibilities of life from discovery to diagnosis. Through discovery and development, we provide critical life science raw materials used in immunological and molecular tests for human, animal, plant, and environmental applications. Through diagnosis, we provide diagnostic solutions in areas including gastrointestinal and upper respiratory infections and blood lead level testing. We build relationships and provide solutions to hospitals, reference laboratories, research centers, veterinary testing centers, physician offices, diagnostics manufacturers, and biotech companies in more than 70 countries around the world. Meridian is a privately held company headquartered in Cincinnati, Ohio. Meridian's website address is [www.meridianbioscience.com](http://www.meridianbioscience.com).

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