

 [Print](#)

Theranos CEO **Elizabeth Holmes** Banned from Operating a Lab for Two Years

7/8/2016 6:21:09 AM



July 8, 2016

By [Alex Keown](#), BioSpace.com Breaking News Staff

PALO ALTO, Calif. – The hammer has fallen. **Elizabeth Holmes**, the embattled chief executive officer of blood testing company **Theranos**, **will not be allowed** to own or operate a blood testing laboratory for two years, the company announced on its website Thursday afternoon.

The **U.S. Center for Medicare and Medicaid Services** handed down a ruling Thursday banning Holmes as well as revoking the company's maligned Newark, Calif. blood-testing laboratory's CLIA (Clinical Laboratory Improvement Amendments) certificate. In a **lightly redacted 45-page letter** dated March 18 laying out its concerns about the laboratory, the CMMS repeatedly used the bold-texted phrase "The laboratory's allegation of compliance is not credible and the evidence of correction is not acceptable."

In addition to the Holmes' two-year ban, the company also faces an undisclosed civil fine and will be the subject of a mandatory directed plan of correction for the lab. Other penalties include a "suspension of the laboratory's approval to receive Medicare and Medicaid payments for any services performed for the specialty of hematology" and the "cancellation of the laboratory's approval to receive Medicare and Medicaid payments for all laboratory services."

The CMMS revocation will not take place for 60 days, but Theranos said it will not conduct any patient testing in the Newark lab until further notice. Over the two-month period, Theranos said it will continue to work with the federal regulators to resolve and remediate outstanding issues in the Newark lab. While the Newark lab will be closed, Theranos said it will continue to support blood testing through its Arizona lab, which the company has maintained handles more than 90 percent of all its testing services.

In a statement on the company website, Holmes said she was disappointed in the CMMS ruling, but said she and the company are "committed to fully resolving all outstanding issues with CMMS and to demonstrating our dedication to the highest standards of quality and compliance."

"We accept full responsibility for the issues at our laboratory in Newark, California, and have already worked to undertake comprehensive remedial actions. Those actions include shutting down and subsequently rebuilding the Newark lab from the ground up, rebuilding quality systems, adding highly experienced leadership, personnel and experts, and implementing enhanced quality and training procedures," Holmes said.

The decision by the CMMS has been looming over the beleaguered company for some time, particularly since Theranos announced it was voiding two years' worth of blood-testing data that invalidated test results for an estimated tens of thousands of patients. The voiding of test results, plus the intense scrutiny on Theranos' blood-testing claims, led its partner

Related Jobs
Analytical Chemist – PrimaPharma
QC Scientist - Stemcentrx
Production Manager - Neos Therapeutics
Cell Culture Scientist - Vaxart
Clinical Research Associate - Puma Biotech
Scientific Study Manager - Atreca

Walgreens to terminate its contract for 40 Theranos wellness centers in 40 of its Arizona stores—a critical blow to the company as the drugstore chain was its largest source of revenue.

[View More Jobs](#)

Last week, a congressional committee issued a letter to Holmes and the company seeking information on the company's failure to comply with federal clinical laboratory testing standards as well as the company's decision to [void two years' worth of data](#) sent to customers. Several lawsuits have been filed as a result of the test results being voided.

"Given Theranos' disregard for patient safety and its failure to immediately address concerns by federal regulators, we write to request more information about how company policies permitted systematic violations of federal law and how Theranos is working with regulators to address these failures," the lawmakers said in the letter.

Theranos is also the subject of a criminal investigation by the **U.S. Department of Justice** centering on whether Theranos and its executives [misled investors](#) as to the efficacy of its blood-testing products.

What the latest ruling against Holmes and Theranos means for the long-term health of Theranos is not known, but the company has reportedly sustained a major financial blow. At one point Theranos was valued at \$9 billion. However, Forbes recently valued the company at closer to \$800 million. Forbes also speculated that Holmes herself is now worth "nothing."

//-->