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Theranos Results Could Throw Off Medical Decisions, Study Finds

Researchers find that lab-testing company's results on cholesterol tests were lower by an average of 9.3% than Quest and LabCorp



Elizabeth Holmes, founder and CEO of Theranos, at the WSJLive conference in Laguna Beach, Calif., in October.

PHOTO: NIKKI RITCHER FOR THE WALL STREET JOURNAL

By **JOHN CARREYROU**

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A study by researchers at the Icahn School of Medicine at Mount Sinai showed that results for cholesterol tests done by Theranos Inc. differed enough from the two largest laboratory companies in the U.S. that they could throw off doctors' medical decisions.

The Mount Sinai study was published online Monday in the peer-reviewed *Journal of Clinical Investigation*. The authors recruited 60 healthy adults in the Phoenix area and sent them for 22 commonly prescribed blood tests over a five-day period in July 2015.

The tests were performed by Theranos, which operates blood-drawing sites in

Walgreens drugstores, Quest Diagnostics Inc. and Laboratory Corp. of America Holdings, according to the study. The researchers at Mount Sinai in New York said they did the blood-testing comparison without the companies' knowledge or participation.

The study concluded that Theranos's results for total cholesterol were lower by an average of 9.3% than those produced by Quest and LabCorp. Doctors often use cholesterol-test results to determine whether to prescribe statins, a class of drugs that can help ward off heart disease.

The Mount Sinai researchers wrote that the average gap on the cholesterol test between Theranos and the other labs was large enough that it could lead doctors to "either inappropriately initiate or fail to appropriately initiate statin therapy" in some patients.

A Theranos spokeswoman didn't respond to requests for comment. In a letter Theranos sent to JCI last week, it called the study "flawed and inaccurate" and criticized two of its authors for an alleged conflict of interest because of their affiliation with a pharmaceutical company. The authors denied any conflict.

LabCorp said the study shows that its tests "are well within established guidelines and meet performance expectations," according to a spokeswoman for the Burlington, N.C., company.

A spokesman for Quest, of Madison, N.J., said the Mount Sinai researchers found "a concerning lack of agreement between the reference labs and the 'low-volume-specimen' lab, especially for heart health."

Eric Schadt, chairman of the department of genetics and genomics at Mount Sinai and one of the study's lead authors, said in an interview that executives at Theranos, based in Palo Alto, Calif., didn't respond to his attempts last fall to discuss the findings.

The Mount Sinai study is the first peer-reviewed comparison of Theranos test results with those of other labs.

Some scientists have called on Theranos to publish data in a peer-reviewed medical journal to support the accuracy of its fingerprick blood-testing technology. Theranos founder and Chief Executive Elizabeth Holmes said in October that the company would publish peer-reviewed data but it hasn't done so yet.

One key question that wasn't addressed in the Mount Sinai study is whether Theranos used its proprietary devices to run those tests.

Test reports provided to patients show that the tests were run at the company's lab in Newark, Calif. That lab has Theranos's proprietary Edison devices and traditional lab machines bought from diagnostic-equipment makers such as Siemens AG, according to former Theranos employees.

One former Theranos employee said the company wasn't performing the 22 tests in question on Edison devices as recently as June 2015, or the month before the Mount Sinai tests.

Instead, Theranos was diluting small blood samples collected from fingers to increase the volume of those samples and then running them through traditional lab machines, according to the former employee.

Dr. Schadt said the Theranos tests assessed in the study were run on small blood samples drawn from patients' fingers. Quest and LabCorp ran their tests on larger blood samples drawn with needles from patients' arms.

If Theranos diluted blood samples from patients in the Mount Sinai study, that might help explain the average difference in cholesterol-test results, because dilution introduces more potential for error, said Stephen Master, associate professor of pathology at Weill Cornell Medical College in New York.

Timothy Hamill, professor emeritus at the University of California, San Francisco's department of laboratory medicine, said Theranos's results also might have been affected "by the differences between capillary and venous samples." He said capillary blood pricked from a fingertip often mixes with fluids from tissue and cells, making it less pure than blood drawn from an arm vein.

Drs. Hamill and Master weren't involved in the Mount Sinai study.

Ms. Holmes denied in October that Theranos diluted blood samples before running them on traditional machines. Since then, the company has declined to comment on the matter. Theranos has stood by the accuracy of tests run from finger-pricked blood.

The Mount Sinai study also concluded that Theranos was more likely than Quest and LabCorp to reject samples as inadequate for testing.

In addition, the researchers found that Theranos flagged test results as being outside the normal range 60% more often than the two other lab companies.

"This increase in abnormal test results can have negative consequences for medicine in

the form of extra testing, additional patient visits to clinics/hospitals, and added doctor services, all of which result in additional costs and burdens to patients or to the healthcare system and are potentially harmful, if the abnormal tests were misdiagnoses,” the Mount Sinai researchers wrote.

A federal inspection of the same Theranos lab in Newark, Calif., last fall found “deficient practices” in five categories. The lab is at risk of losing its federal certification if the problems aren’t resolved.

Theranos has said the inspection report “does not reflect the current state of the lab.” Theranos has said it has fixed many of the problems and has submitted a correction plan to regulators to remedy the remaining problems.

Write to John Carreyrou at john.carreyrou@wsj.com

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