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Truvian's blood testing platform provides lab quality results

By Shani Alexander, Staff Writer

News from Truvian Health Inc. that its benchtop blood testing platform can deliver results similar to those generated by central laboratory is promising for the diagnostic sector still coming to terms with fraudulent claims from companies such as Theranos Inc. and Arrayit Corp. that their various technologies were able to run an array of tests with just a few drops of blood.

Truvian conducted a multi-site method comparison study of 237 donor samples on both its platform and central laboratory analyzers. The sample population consisted of donors who were healthy (49%), patients with chronic disease (43%) and contrived samples (8%).

The results of the study, presented at the 2023 American Association for Clinical Chemistry Annual Scientific Meeting (AACC), showed that Truvian benchtop blood testing platforms agreed with central laboratory analyzers in almost all assays in its panel.

Truvian CEO Jay Srinivasan

"The clinical study data has demonstrated the art of the possible in decentralized blood diagnostics – central laboratory quality results that are available in a timely manner at the point-of-action," said Jay Srinivasan, CEO of Truvian.

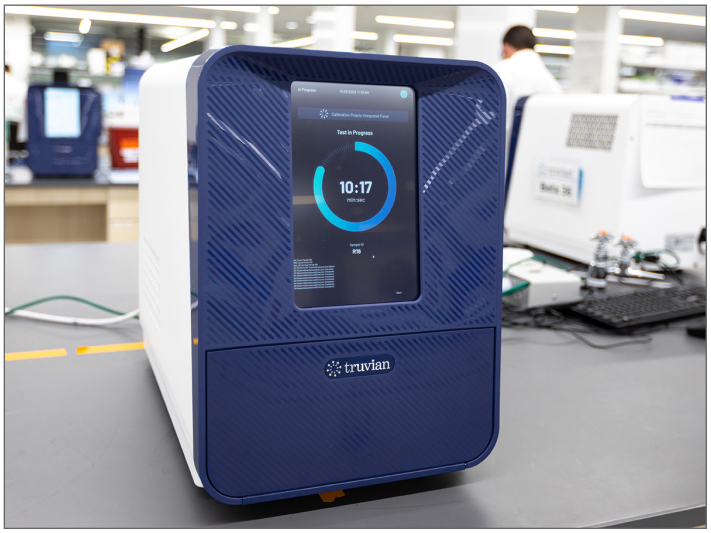
"This multi-site study is also the first-of-its-kind showcasing the field performance of a benchtop platform that has successfully integrated three different testing technologies," he told *BioWorld*.

"These results show that a single platform such as Truvian's has similar performance as incumbent large diagnostic platforms at a central laboratory. Healthcare providers will have the ability to access central lab quality results near the patient and provide medical counsel and intervene in a timely manner."

Patients, likewise, Srinivasan added, will be able to seek an affordable testing option anywhere and be empowered with the insights from their healthcare provider to lead healthier lives.

Results from drops of blood

San Diego-based Truvian's platform is a point-of-care (POC) device. It offers a fully automated solution that leverages three commonly used testing technologies – immunoassay, clinical chemistry, and hematology to simultaneously perform routine blood testing in minutes from a small sample of blood.



Truvian's benchtop blood testing platform can deliver results similar to those generated by central laboratory. Credit: Truvian Health Inc.

With an initial testing panel of more than 30 assays, the Truvian platform can run the most commonly ordered tests that account for greater than 90% of blood test orders, the company said, and its benchtop system will be able to provide lab accurate results in 20 minutes.

Overcoming doubts

Truvian's data and technology is proof that companies have not given up on doing diagnostics on small devices and from small drops of blood. Sentiments towards the sector had certainly turned after Elizabeth Holmes was found to have defrauded investors with claims that Theranos' could run lots of tests on a few drops of blood on a small device. Holmes began an 11-year prison sentence earlier this year.

In addition, a jury last year convicted Mark Schena, the president of Palo Alto-Calif.-based Arrayit Corp., of defrauding investors and causing false claims to be submitted to federal health programs. Schena had claimed to investors that his system could test for a range of diseases "using only a few drops of blood."

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These controversies raise the question of what is feasible in a drop of blood and how much is needed for tests to run.

Srinivasan argued that a single drop of blood is not enough to run tests effectively, but Truvian has sought to reduce the amount of blood required by running all tests in one machine at one time, rather than on three separate machines that each require their own sample. Its platform requires a small blood volume (300µL) in a single tube type (Lithium Heparin) for testing.

"Ultimately, we believe that data from our multi-site clinical study shows that our technology and approach can work in a real-world setting, and we will share these and future results with the scientific and medical community as they become available," said Srinivasan.

Truly unique

But just how unique is the company's testing platform? Several other companies are also looking to advance the blood testing device field with various versions of point-of-care testing technology. For example, Vital Biosciences Inc. introduced the Vitalone at the AACC. Vitalone intends to make blood diagnostics ubiquitous by bringing more than 50 lab-grade test results that cover 95% of routine lab orders to primary care sites in the form of a simple device the size of a desktop computer.

Vital Biosciences said Vitalone will allow doctors to test, diagnose and treat patients in the course of a single visit. Patients receive their results within 20 minutes.

Other companies working on testing services based on small blood volumes include Babson Diagnostics Inc. and Genalyte Inc.

For Srinivasan, Truvian is defining a new category of technologies and tools that will have a significant impact on the healthcare system by bringing accurate, convenient, and transparent blood testing to the point-of-action where patients and healthcare providers engage.

"Historically, the ability to provide central laboratory results at the point-of-action where patients and their providers can review results together and make meaningful and actionable treatment plans has always been the goal for most point-of-care products," said Srinivasan.

"However, the inability to integrate multiple technologies into a small form factor while still providing central lab quality results has remained the issue. The ability to combine three different technologies in a single instrument no bigger than a desktop computer and achieve central lab quality results is a reality with the Truvian platform. "

At AACC, Truvian also presented results from a reproducibility study to evaluate performance of multiple machines over multiple days. The study assessed variance of its technology with multiple replicates of low, normal and high-level controls run on three different machines over a five-day period. Truvian's platform achieved acceptance criteria for 99% of 25 assays evaluated, with just a single outlier observed in 4,500 results from 180 runs.

For now, the company is focused on advancing the product. "We are committed to the journey to bring our product to market when we have refined it to achieve our desired performance," said Srinivasan.

He said the company has more clinical studies in the works at major institutions and will have at least one additional validation study to review changes made to address performance, as well as a pivotal study.

According to an article in *Nature Biotechnology*: "Any new POC device requires extensive testing in large cohorts of patients under varied conditions to ensure the accuracy of measurements. Theranos egregiously failed to do this, but the entire POC field has struggled with reliability, reproducibility and validation. For wide adoption, devices need ease of use, durability (weeks or longer), portability, affordability and preferably self-calibrating capability."