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Nanodx, IBM partner on cost-effective diagnostics platform for various diseases

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Nanodx Inc. entered into a license agreement with IBM Research ([https://www.cortellis.com/intelligence/qsearch/"IBM Research"](https://www.cortellis.com/intelligence/qsearch/)) to use IBM's nanoscale sensor technology and develop diagnostic platforms for rapid and cost-effective detection of various diseases, including COVID-19 and traumatic brain injury, among others. This marks IBM's first collaboration to allow a medical device company to use its nanoscale technology.

The COVID-19 pandemic drove the unique collaboration between Southborough, Mass.-based Nanodx and Armonk, N.Y.-based IBM, with the increased awareness and demand for rapid point-of-care (POC) testing. It was largely what made Nanodx reach back out to IBM to close the deal after the two companies had had initial discussions – and did some coding – around licensing IBM's metal-oxide semi-conductive (CMOS)-compatible nano biosensors a few years ago. This technology has been known to enable cost-effective, rapid, and high-volume production.

Sufi Zafar, an IBM researcher who participated in the development, said, "This collaboration is significant because it offers a health care use case for IBM's CMOS hardware technology."

In addition to COVID-19 and TBI, other medical conditions for which Nanodx plans to use IBM's CMOS technology include different forms of influenza, sepsis and stroke, as well as to develop biosensors.

Nanodx had reached out to IBM when it saw a study Zafar and others published in 2018 with interest in collaborating in the field of diagnostics and biosensors on the company's TBI detector. It had obtained (<https://nanodiagnosics.com/2019/02/11/biodirection-receives-breakthrough-device-designation-from-fda-for-tbit-system/>) breakthrough device designation from the FDA for this use indication on its diagnostics platform in 2019.

Diagnostics and the COVID-19 catalyst

The emerging research on the organic semiconductor interface, integrated biosensors with CMOS-compatible, metal-organic frameworks, has accelerated the practical application of biosensors. Nanodx was developing a MEMS sensor, or micro electro-mechanical system. IBM was separately but concurrently developing biosensors to address the need for mass production.

But it wasn't until the pandemic hit that Nanodx approached IBM again, this time with an interest in modifying their device for rapid COVID-19 testing. The interest stemmed from IBM's expertise with CMOS. Integrating this technology into the medical device company's existing process would allow it to achieve its goals of mass-producing the tens of millions of units needed to meet the projected demand.

"When we were working with them many years ago, we did some preliminary testing and as we started to make plans for significant scaling for a wide variety of testing, including COVID-19, we went back to them and suggested that we reconnect, given how important POC had become in the world," Nanodx President and CEO Sharad Joshi told *BioWorld* about working in collaboration with IBM Research.

Nanodx's real-time, nanowire-based POC diagnostics platform can detect almost any analyte with a small sample, including blood, saliva, nasal and urine, in less than two minutes with high levels of accuracy that will be enhanced. Its levels of sensitivity and specificity are projected to be in the high 90s.

And the device's low limit of detection – or the smallest amount limit of detection – is projected to be between 100x and 400x smaller than any of the competing devices that are currently on the marketplace.

"That's just for COVID-19 and if those levels of accuracy and the mechanism of action remain the same for other areas, it's very likely that we could put a big dent in the POC market," Joshi said.

The company's technology shines where there are "very good signs of biomarkers" that will tell whether a person has a disease combined with the strong need for rapidly detecting and identifying these biomarkers at the POC or point of injury and the need to have high levels of accuracy, Joshi argued.

IBM's first move into diagnostics

IBM has not entered any other collaboration anywhere like the one with Nanodx before.

"That's what makes it even that much more special," Joshi added. The appeal in Nanodx relates to the extensive intellectual property portfolio that the company has built around its nanosensor design as well as its manufacturing processes that encompasses the entire field of in vitro diagnostics, and biosensors.

IBM's initial goal of developing its nanosensor technology to advance sensor CMOS technology can now come to fruition. "Though Nanodx, IBM Research's innovative nanoscale technology may now play a crucial part in rapid tests for COVID-19 and other health conditions," Zafar said. Yet IBM has licensed its nanosensor technology "without warrantee of success for it to solely develop a diagnostic product."

The terms of the agreement were not disclosed because of a confidentiality agreement between Nanodx and IBM, though there is an ongoing arrangement between the two in terms of royalties.

“To be able to combine Nanodx’s technology and biosensing with that of the CMOS technology from IBM is really a massive gamechanger,” said Joshi. “It’s extremely rare for two companies of very different sizes to collaborate on something like this that could really transform a major marketplace,” he added.

The collaboration was also made possible thanks to the \$18 million in financing Nanodx recently raised (<https://www.bioworld.com/articles/436237-nanodx-gets-18m-to-pursue-fast-easy-covid-19-tbi-tests-aims-for-market-shortly>).

A full panel in less than 2 minutes

Nanodx aims to provide a platform that can perform a full panel in less than two minutes. It is currently conducting its final validation studies to be able to support an FDA emergency use authorization (EUA).

The company will likely achieve EUA status for its platform within the next two months, said Joshi.

There are other companies that have attempted POC testing. Abbott, for example, acquired Alere Inc. in 2016 with the goal of becoming the leader in POC testing. It has had some success with that business, but its process requires a lengthy preparation time and there were several things that cannot be measured.

Joshi said that Nanodx’s approach, on the other hand, is “a simple, digital lab on a chip. It takes a whole lab, puts it on a chip the size of an eraser head, and allows patients to measure samples rapidly at POC.

Moving forward, Nanodx plans to work closely with IBM and a third-party vendor that is responsible for the manufacturing of Nanodx’s device to be able to optimize its process prior to device validation.