Greek Researchers Developing Point-of-Care COVID-19 LAMP Assay

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NEW YORK – A team led by investigators at the Foundation for Research and Technology Hellas (FORTH) in Greece is moving ahead with plans to develop and validate a new point-of-care test for SARS-CoV-2, the virus that causes COVID-19, as well as other diseases.

The scientists received backing in the form of a €2.4 million ($2.8 million) EU grant this month and have founded a company, called Biopix-T, to commercialize the platform.

Electra Gizeli, a professor of biology at the University of Crete in Heraklion and a group leader at the Institute of Molecular Biology and Biotechnology at FORTH, co-led the development of the technology. She said the team's approach relies on a portable, 3D-printed device that allows LAMP isothermal amplification to be carried out in real time, while the quantitative colorimetric detection of target analytes takes place via a tablet or smartphone. The researchers and their commercial partners are positioning the platform and the single-step quantitative assay, which has an analysis time of about 30 minutes, for point-of-care use in diverse settings.

"It's a point-of-care system, so it doesn't need a lab," said Gizeli. "[Users] would be the local health center, mobile medical units, doctor's offices, airports, or anywhere where you need a rapid answer," she said. "The most important thing is that the technology is suitable for global diagnostics. It is affordable while maintaining the high performance of a quantitative molecular diagnostic test," Gizeli added. "Everyone can use it, meaning the same system can go to North America, Europe, to Africa, wherever."

The EU funding, part of a new, €128 million EU package to combat COVID-19, will support the certification of the platform, called Iris, as well as a validation study of a panel for SARS-CoV-2 and influenza A. Partners on the project, called IRIS-COV, include Heraklion-based startup Biopix-T, University College London Hospital; Inserm, the French National Institute of Health and Medical Research; and the University of Leuven in Belgium.

Other members of the project are PKNM Solutions, a Swiss company that will assist with the certification process; EnzyQuest, a Greek reagents company also based in Heraklion; and Kiara Health, a Johannesburg, South Africa-based pharmaceuticals and diagnostics company, which will offer the test in the South African market.

As Gizeli noted, IRIS-COV's partners at UCLH, Inserm, and ULB will validate the test, while the others will provide a fast track to CE-IVD certification. Biopix-T will also prepare for large-scale production of the device.

One reason why the effort is moving quickly toward commercialization is that the team behind Iris was preparing to commercialize the platform even before the pandemic began. Last month, the researchers described the approach in a *BioRxiv* preprint, detailing its real-time, quantitative,

colorimetric, loop-mediated isothermal amplification assay, which is able to work with both saliva and tissue samples, along with the smartphone-based operation and the use of 3D printing to produce the devices.

The test is one of several LAMP-based tests for SARS-CoV-2 in development.

The team provided results from two validation studies in the paper. Using 38 positive and 51 negative samples from patients previously tested for COVID-19 by PCR, they showed 97.4 sensitivity and 100 percent specificity for their test. They also demonstrated BRAF V600E mutation testing from tissue biopsy samples for the platform, as well as concordance with digital droplet PCR and Sanger sequencing.

Gizeli noted that the approach combines colorimetric detection, often used for naked-eye detection in simple tests and resource-limited areas, with precise quantitative measurements, normally obtained through the use of fluorescent labels and optical detectors. The replacement of microfluidic technology with a static plastic reaction tube was also an improvement, she said.

"We had a lot of experience with integrated platforms and lab-on-chip devices," notes Gizeli. "These were sophisticated, nice systems developed with partners, but whenever we took these devices to end users, it was not easy for them to adopt them straight away and the implementation was slow," she said. "That is when we decided to move to something where the philosophy would be simplicity but smart design and good performance."

According to Gizeli, it took about a year to design the Iris system and to 3D-print the device. "3D printing is the beauty of this technology," she said. "It allows us to make several prototypes in a week."

Biopix-T is now working to commercialize the technology. The company was incorporated by Gizeli, as well as fellow scientists George Papadakis, Alexandros Pantazis, and Nikolaos Fikas as Biopix DNA in December 2019, with an objective to debut an assay for influenza testing. Papadakis is serving as CEO of the firm.

"Our main market was influenza," said Sergios Katsaros, who is responsible for commercial operations and finance for Biopix-T. "The reason for that is, it was a known market with a known size, needs, everything," he said. "Then COVID-19 came along and we switched to COVID-19 to help the national effort."

Biopix-T is in the process of raising about €1.2 million in seed funding from a variety of Greek investors to support the commercialization of the platform, and the new EU funding will give the effort an added push into the market, Katsaros said.

"Our next step is to quickly finalize the industrial design concerning the manufacturing process, and to go to industrial scale from a prototype in the lab, then complete certification," he said. Iris will be certified under the existing *In Vitro* Diagnostic Directive, he noted, which remains in force, though companies are expected to eventually receive clearance for their devices under the new *In Vitro* Diagnostic Regulation by May 2022. Katsaros said the company will seek clearance for the test under the IVDR "for the period after the pandemic."

While scores of companies are developing tests for SARS-CoV-2, including new point-of-care platforms for use in similar settings, the team behind Iris believes its 3D printing approach will enable it to offer a platform at a lower cost than rivals in the market. "We can offer [the Iris platform] for much less than $1,000," he said, without elaborating further. "That is a commercial strategy issue."

And while COVID-19 is Biopix-T's current target, the published work on cancer mutation testing shows another potential market for Iris, outside of infectious disease testing.

"Our main business plan foresaw entering the market for [respiratory and] infectious diseases to begin with," said Katsaros, noting that it is an underserved market, followed by pharmacogenomics two years later. There are also plans to support the use of Iris for at-home testing. "You would go to the pharmacy, pick up a test, and run it [at] home," Katsaros said.

Gizeli agreed that the technology is "certainly suitable" for eventual use in pharmacogenomics and personalized medicine. She also noted that despite the competition from other test platforms being developed thanks to COVID-19 emergency funding, she expects the system to be adopted once it becomes available.

"There is a lot of room for many devices," said Gizeli. "The market is not saturated. But of course the competition is high."

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