

Startup BioFlyte Detects Airborne SARS-CoV-2 Using BioFire FilmArray

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NEW YORK – A longtime developer of environmental air testing technology has spun off a startup focused on commercializing systems for detecting COVID-19 and other dangerous pathogens. Called BioFlyte, the startup is collaborating with BioFire Defense using FilmArray multiplex panels to detect SARS-CoV-2 and other infectious disease agents in enclosed spaces, such as schools, offices, and ships.

The firm launched its field-deployable Sentinel 720 Airborne Coronavirus Detection System earlier this summer.

BioFlyte was spun out of a company called Zeteo Tech last year, a firm that was in turn founded by Chuck Call and Wayne Bryden eight years ago. Bryden is a physical chemist with expertise in miniaturizing mass spec, while Call has a background in the sampling, concentration, and optical detection of bioaerosols.

The two had been collaborating to use mass spec to detect microbes in aerosols since 9/11, when Bryden led the development of the core technology — including miniaturized MALDI-TOF — at the Johns Hopkins University Applied Physics Lab and School of Medicine.

Unfortunately, "the technology never made it over the hump and into the market," Call said in a recent interview. Bryden subsequently worked as a program manager at DARPA, but he and Call were reunited at a firm called FLIR Systems.

"About eight years ago we decided, let's go pick up the JHU technology and push it over the hump this time," Call said.

BioFlyte and Zeteo's mission is to bring the detection technology and associated optical bioaerosol sampling and collection technologies to the market, he said.

The pair had been working on the [aerobiology](#) and respiratory transmission of tuberculosis in South Africa for many years, as part of a project funded by the Bill and Melinda Gates Foundation and the US National Institutes of Health.

"We were kind of dialed in to respiratory transmission when COVID came along," Call said.

The firm is currently manufacturing mass spec units for testing and validation by end users. "What we are trying to do is show we can detect the occurrence of a new bioaerosol in an indoor environment, and identify it at the species level very rapidly, in five minutes or less," Call said.

This rapid time would allow users to take mitigation steps to protect occupants of a building from exposure, for example.

"Proving that you can do that in the real world means putting units in buildings for extended periods of time, in different kinds of environments, and showing that the system works in all of those environments," Call said.

A bioterror attack would presumably result in much higher concentrations of pathogens than an infectious person with SARS-CoV-2 walking through the lobby of an office building, so the technology had to be adapted, including by considering how the virus is diluted by the air in the enclosed space and the ventilation system.

BioFire collaboration

"When COVID came along we asked the question, 'Can we use what we currently have to detect if a person who is shedding the virus comes into a building?'" Call said.

There are challenges to using mass spec to detect the SARS-CoV-2 virus, he said, and also major advantages of using PCR, so the team decided that genetic-based testing was the best way to go to find low concentrations of virus in indoor air.

"PCR is more sensitive, and very specific, and able to handle a very cluttered sample," Call said. "Mass spec is not as good at that — it has the advantage that it is very fast, and it doesn't require expensive reagents, but it is not particularly good at finding a needle in a haystack," he added.

That said, the difference in sensitivity between the two technologies is only about one order of magnitude, Call noted.

"The Delta variant may cause people to put out as much as an order of magnitude more copies of virus per liter of air, so if variants evolve in such a way that people are shedding more virus, mass spec may become a reliable tool for detection," he said.

The BioFire FilmArray was an obvious choice for PCR-based detection for the BioFlyte team, and the two firms have signed OEM, pricing, and distribution agreements.

"We have known the people behind the FilmArray for 20 years, and we've known that product to be an incredibly robust, proven, and tested platform," Call said.

The team collaborates specifically with BioFire Defense, a subsidiary that split off from BioFire when the firm was acquired by BioMerieux.

Matt Scullion, VP of sales and marketing at BioFire Defense, said in an email that his crew supplies BioFlyte with testing platforms and test panels, and has assisted BioFlyte with data analysis in their initial system development effort.

From Scullion's perspective, the FilmArray has definite advantages for environmental testing.

"It is easy to use, has a small footprint, and provides highly sensitive and specific PCR results for a variety of applications," Scullion said.

The FilmArray system also has robust, integrated sample preparation "which makes it well suited for a variety of challenging sample types," and it can be made portable with a rolling carrying case, "allowing it to be used in settings outside of a traditional laboratory."

The regulatory system is geared toward patient samples, so things like CLIA waiver don't necessarily apply to BioFlyte's use scenario. But, the ease of use of the FilmArray could enable easy uptake. BioFlyte also has a training program for indoor air quality professionals, such as industrial hygienists,

and Call said the team has also trained school nurses to run the system in order to test environmental air samples.

The overall workflow involves the BioFlyte biocapture system — called the z750 — which passes ambient air through a collection filter. The filter is then collected from the instrument and placed in an extraction buffer, then a sample is transferred to the [Emergency Use Authorized](#) BioFire Defense SARS-CoV-2 test.

"In addition, we've been doing some work with the FilmArray respiratory panel," Call said.

BioFlyte is collaborating with a firm called [OnSite](#) to detect pathogens in air from the entire FDA-cleared BioFire [RP 2.1 panel](#) in critical sites such as surgery suites, but also in schools and workplaces, he said.

Another current BioFlyte customer is a firm called Critical Environmental Remediation Industries in Manistee, Michigan.

Scott Fisher, founder and VP at [CERI](#), said in an interview that his firm is using the BioFlyte system in the maritime industry, to clear ships for crew and passengers. It has also been brought in to surveil schools, as well as large indoor spaces for events like parties and galas.

While CERI is using the BioFlyte system for SARS-CoV-2, Fisher said the firm can also use it for other pathogens by using the full respiratory panel, and it has the capability to process separate [assays](#) to monitor for things like Legionnaire's disease that aren't currently part of the RP 2.1.

Going forward, the BioFlyte team will continue to target potential customers in schools and workplaces, Call said. It has seen growing interest from the meat processing industry, for example, where the high death toll among workers in the early stages of the pandemic may have made some employees reluctant to return to work.

"Our solution brings an additional tool to the table to help companies and schools reopen and get back to full operational capability as safely and quickly as possible," Call said.

Future directions

BioFlyte has recently established a [scientific advisory board](#) with experts from industry, government, and academia, which Call said should help accelerate commercialization.

There are not yet any competing products that Call is aware of, and he believes BioFlyte's solution to be fairly differentiated. But, he expects there will soon be plenty of competition as the pandemic continues.

Meantime, BioFlyte will focus on commercializing the firm's most advanced technologies, while Zeteo Tech will continue to be the R&D-oriented company, led by Bryden. BioFlyte also [raised](#) \$1.25 million in seed funding last year to support commercialization efforts.

BioFire Defense, meanwhile, has numerous projects focused on SARS-CoV-2 testing in collaboration with the US Department of Defense, Scullion said.

"Most of these efforts are focused on expanding the utility of the FilmArray and increasing current testing standards," he said.

The firm also recently launched the FilmArray [Global Fever Panel](#) "which has been a multi-year effort with the US Department of Defense and the National Institutes of Health." The FDA-cleared panel can

detect and identify *Leptospira*, chikungunya virus, dengue virus, and *Plasmodium* from whole blood samples.

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