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Quanterix Launches RUO Simoa Platform with 18 Initial Assays and Homebrew Kit

By Molika Ashford

Quanterix said this week that response to the launch last week of its research-use-only automated Single Molecule Array, or Simoa, platform has been enthusiastic – particularly among developers of laboratory-developed tests – and that it will ship the first of its systems to customers in about 10 to 12 weeks.

Along with the release of the RUO system, which it says can measure proteins at concentrations 1,000 times lower than the best current immunoassays, the company has also made available 18 initial single-plex assays that customers will be able to purchase for systems being shipped in the next few months.

Julien Bradley, Quanterix's senior director of marketing, told *ProteoMonitor* this week that the company plans to expand this assay menu starting early next year with both additional single-plex assays and multiplex assays based on customer interest.

Bradley said the initial 18 assays cover a variety of therapeutic areas, including neurology markers, which he said are in very high demand, as well as a number of cytokines, cardiology markers, and a number of others covering oncology and other areas.

"We might add a little bit to it [that menu] this year," he said. "But we will definitely continue to add to it at a pretty rapid clip starting early next year."

Another important step in terms of RUO assay development, he said, will be expanding the company's offerings to multiplex assays. "We made the decision to start with single-plex assays, but to then develop multiplex assays as soon as we have a clear sense of which ones are most important to our customers," he explained.

In addition to the initial 18 markers available to early customers, Bradley said the company has also released a homebrew kit to allow researchers to interrogate their own markers of interest.

"We decided, frankly, to put more energy into [the homebrew kit] because we recognize that there are so many potential markers out there, and we know we can't have assays for all them immediately," he said. "We want our customers to be able to develop their own assays cost effectively, and use their own antibodies for a wide range of markers including things that are common, but not on our menu yet, or also esoteric markers that not a lot of people are looking at."

In a statement this week, Quanterix also credited its collaborator Sony DADC BioSciences for aiding in development of the new automated platform.

Quanterix's Simoa analysis relies on arrays of reaction chambers designed to isolate single molecules, enabling each well to serve effectively as an independent assay for a single molecule. According to the release this week, the new RUO Analyzer uses a "smart consumable" designed and manufactured by Sony DADC, which it is calling the Simoa Disc, for these arrays.

"We wanted to emphasize that [this disc] really empowers the automated analyzer to provide the sensitivity that Simoa science allows," Bradley said.

According to Bradley, the company plans to ship the first Simoa instruments in about 10 weeks.

Though Bradley declined to detail how many customers Quanterix has had for the system so far, he did say that the company is targeting customers across the research market.

"One segment is clearly the pharmaceutical and biopharmaceutical companies doing drug discovery and research," he said. "A second is [contract research organizations] which do a lot of the clinical work on behalf of pharma."

"Academia also, of course, which is doing a lot of the upfront and early work in exploring new applications for these markers. And, finally, providers of laboratory developed tests, who see the platform as a way to offer a better test in a shorter timeframe than going through a full FDA approval process," he added.

Last year Quanterix inked an agreement with French diagnostics firm BioMérieux, giving the company worldwide exclusive rights to the Simoa technology for development of *in vitro* diagnostics and industrial applications. Researchers or firms seeking to bring to market as IVDs any of the protein markers they identify or develop on the RUO device must take their commercialization efforts through BioMérieux.

But that does not preclude labs from using the RUO system to develop LDTs in-house for clinical use, Bradley said this week.

According to Bradley, while the first customers for the new RUO device are spread across the research market, the company has observed a "surprisingly large amount of interest from LDT providers."

"They see a fully automated analyzer that offers this incredible increase in sensitivity as a really significant differentiator in a space that is otherwise competing mostly on costs," Bradley said.

"I think LDTs, for one thing, will seed the market a little earlier, and will also allow more esoteric tests that might not be the first ones BioMérieux would be interested in, but have a specific need in a particular market, to become available," he added.

Meanwhile, Bradley said, the relationship with BioMérieux also offers research customers a path to the clinic though the IVD development process.

Bradley said the IVD-ready version of the platform that BioMérieux is working with is "almost identical" to the RUO platform.

"We designed the instrument with the idea that it had to meet both RUO and IVD requirements, so that really allows us to speed up the process and begin the initial work for regulatory filings," he explained.

"I think the fact that we are launching this research use platform at the same time as working on developing IVD assays with BioMérieux is a unique approach," Bradley said.

"This way, customers in research who obtain and start working with the platform know that there is going to be an outlet, if you will, for whatever discovery comes out of that into the clinical diagnostic space," he said. "That's often a gap [with other technologies] where customers in research might want to explore a new technology, but they have no idea whether it will actually be available in hospitals or labs for clinical work."

"Now that we are building up an RUO customer base, we are going to be able to introduce research customers to BioMérieux, who are working on something that could be of interest [for diagnostics,]" he said.