Swiss Dx Company Achiko Works Toward Regulatory Approval for Aptamer-Based COVID-19 Test

Mar 04, 2022 | Kelsy Ketchum

Premium

NEW YORK – Like many firms, Swiss shop Achiko hadn't planned on getting into infectious disease testing.

The Zurich-based company was originally a payment platform firm, but two months after it went public on the SIX Swiss stock exchange, the pandemic hit, and Achiko saw a new opportunity.

"Testing had gaps in the early pandemic," Achiko cofounder and CEO Steven Goh said, so the firm pivoted into healthcare solutions and diagnostics development, believing it could help fill those gaps.

The result is its saliva-based test for COVID-19, called AptameX test, which leverages aptamers — artificially synthesized nucleic acid molecules that bind with proteins — and gold nanoparticles to detect the presence of the S1 gene of SARS-CoV-2. The aptamers it relies on were discovered by researchers in China in 2020, who published a paper on them in *Analytical Chemistry* later that year.

A variety of other companies and researchers are using aptamers for both COVID-19 and more general diagnostic applications, including automotive components manufacturer Denso, an international research group with German and Korean scientists, and cancer molecular profiling firm Caris Life Sciences.

To run the AptameX assay, a user first does a mouthwash rinse to remove any food or drink particles, Goh said. The sample is then mixed with gold nanoparticles coated with aptamers, and if the S1 gene is present, the aptamers bind to the surface of the gene and displace the gold nanoparticles, which shift in color from the red spectrum to the blue spectrum. Achiko chose to use the S1 gene for the assay due to the "ease of reactivity" with the aptamers, Goh said.

The test then uses a spectrophotometer to read the color shift and return a result within 15 minutes — although the firm is currently working to optimize the test and get the result below 10 minutes, Goh said. He noted that it would be possible to read the result with the naked eye, but a spectrophotometer provides a more objective result. The company has also created its Teman Sehat, or Health Buddy, app that includes a digital passport to return and certify AptameX test results and help connect users with healthcare facilities offering testing.

Although the company calibrated and validated the test with an industrial spectrophotometer that cost approximately $600, the one that it will sell for use with the assay will be much cheaper, Goh said. Achiko chose the highest quality instrument for its studies to gain regulatory approval but is "currently evaluating" the test with a cheaper instrument, a portable spectrophotometer reader that is the size of a credit card. The company did not respond to a question whether such an instrument would affect the test's performance, saying only it is "evident" that a portable spectrophotometer can be developed, meaning a home system would eventually be possible.

Achiko's data has shown that the test is as sensitive, if not more so, as other rapid antigen tests, Goh said. After evaluating the test on "several thousand" samples in Indonesia and Spain, the company found it to be 100 percent sensitive and specific compared to PCR for patients with cycle threshold, or Ct, values 33 and under, he said, although it lists a sensitivity of 97 percent on the label to account for any potential false results. According to a preprint published by Achiko last month on *MedRxiv,* a Ct value of less than 25 indicates a high viral load, while a Ct value of greater than 25 indicates a low viral load.

In the preprint, the company tested 58 saliva samples from patients in Indonesia and AptameX had greater than 97 percent sensitivity and specificity. Since the calibration study was completed in December, the firm has updated the test's software and algorithms and applied those to 338 samples. Achiko has seen a rise in performance over the preprint's results, the firm said in a statement.

In addition, data has shown its test is "at least as effective" with SARS-CoV-2 variants, Goh added. Achiko is currently in the process of setting up a facility in Barcelona to monitor variants, he noted.

As for regulatory approval, the test was launched in mid-2021 in Indonesia because it was "easiest to get approval" there, and most of Achiko's shareholders are located in there, Goh said. The firm is currently completing its clinical investigation for CE marking and expects to receive the mark this quarter. Achiko is also evaluating the US market where the company is seeing interest in its test from potential partners, according to Goh. He added AptameX could be submitted for breakthrough device designation from the US Food and Drug Administration.

The test itself uses commodity parts, or raw materials, that cost about 30 cents per test, and it's being sold in Indonesia for $2.50, the "cost of lunch" in the country, Goh said. That price will likely stay the same everywhere, he added, although Achiko is working to optimize the test with non-commodity parts. Compared to other antigen tests, which can retail in the US for anywhere between $10 and $25, it's significantly cheaper. "$10 per test is too expensive," he said. "At this price point, we think we're unique."

While COVID-19 is the focus for the company in the first half of 2022, Goh said Achiko is working on using aptamers in other types of assays. A respiratory panel test with "dozens of pathogens" is in the works, with plans to commercialize it later this year. The company is going through its library of biomarkers to see how the technology could further be used — one potential application is a test for dengue fever.

Achiko is also looking at other ways to conduct diagnostic tests, including with electronic sensors, Goh said.

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