With Pipeline of Syndromic Tests, Qorvo Eyes Emergence as More Than a COVID Company

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NEW YORK – Qorvo Biotechnologies said it is closing in on the launch of its point-of-care COVID-19 and influenza test as the firm works to expand its menu beyond COVID-19 and into syndromic panels and cardiac disease tests.

The Greensboro, North Carolina-based company is running clinical trials for the combination test, which would be the second diagnostic test to run on its bulk acoustic wave (BAW) Omnia instrument, following its SARS-2-COV antigen test which received US Food and Drug Administration Emergency Use Authorization two years ago. Qorvo is currently trying to move the platform beyond COVID-19 and make the case that its toaster-size, point-of-care instrument will be well-suited to running antigen tests for other diseases in pharmacies, urgent care centers, long-term care facilities, and physicians' offices.

Bryan Bothwell, manager of the Qorvo Biotech said the test achieves near-PCR sensitivity and he predicts the test for COVID-19 and influenza A and B will be one of a handful of highly accurate tests available ahead of the flu season this fall, assuming the firm receives an EUA this quarter and can ramp up manufacturing starting in June. He said the firm is also trying to expand its post-pandemic menu to include multiplex respiratory and sexually transmitted disease panels, cardiac tests, and chronic disease monitoring assays.

Though the FDA has been winding down its EUA program for COVID-19 tests, Bothwell said his firm has gained access to the regulatory pathway through its participation in the Independent Test Assessment (ITAP) Program from the National Institutes of Health Rapid Acceleration of Diagnostics (RADx) initiative.

"We've shown that the Qorvo Omnia BAW-based solution can deliver a molecular-level performance with an immunoassay," he said. "That's pretty groundbreaking and it's hard to do."

Bothwell declined to provide sensitivity and specificity figures for the upcoming COVID-19 and influenza test but said the company will publish data soon.

The most recent instructions for use with Qorvo's COVID-19 test indicate that, in a study of patients with suspected SARS-CoV-2 infection, the Omnia COVID-19 test had about 85 percent sensitivity and 100 percent negative agreement in comparison with RT-PCR results. That clinical study was used in support of the company's EUA application, and the firm said in August 2022 that a separate Omicron variant-specific study showed the Omnia-based antigen test retained that sensitivity and specificity when samples were at or above the limits of detection of the comparator PCR tests.

Bothwell said the COVID-19 part of the upcoming COVID-19 and influenza test improves on that performance. The ITAP program has been helping diagnostic firms accelerate their validation, regulatory authorization, and commercialization of tests. For Qorvo that has meant receiving study protocols agreed upon by the FDA and NIH, contracts with research organizations to conduct

accelerated clinical trials, and support from a team including program managers and regulatory experts tasked with ensuring high-quality tests reach the market quickly and meet US needs.

If the COVID-19/flu test receives EUA, it would serve as the foundation for a submission to the FDA for possible 510(k) clearance that the agency is recommending all firms with EUA'd COVID tests, or developing such a test, apply for.

Lab test in a cartridge

Qorvo Biotech is a subsidiary of publicly traded semiconductor company Qorvo, and the biotech business' Omnia platform leverages technologies sold by the parent company for use in cell phones.

Qorvo Biotech's technology uses radio waves to detect changes in mass on a sensor surface to provide quantitative or qualitative results, depending on the test, and according to Bothwell the firm's combination tests advantages are their high sensitivity, relative to other antigen tests, and lower costs in comparison with molecular tests.

The firm secured its first regulatory authorization for the platform with the April 2021 EUA for its SARS-CoV-2 antigen test, and the same month it announced it had been awarded $24.4 million in funding from RADx to support the production and launch of the diagnostic testing platform.

Bothwell said shortly after the COVID-19 EUA was granted that Qorvo Biotech was "well along" in developing a multiplex test for SARS-CoV-2 and influenza A and B, and the firm announced in January 2022 the firm had been awarded another $4.1 million contract with the RADx program to advance clinical trials and launch its SARS-CoV-2 and influenza test and a separate SARS-CoV-2 antigen pooling application that would allow screening of up to six samples processed together on the Omnia instrument.

For the company's COVID-19 and COVID-19 plus influenza tests, a nasal swab specimen is added to a lysis buffer and that processed specimen is added to a cartridge. Each test cartridge contains a reagent carousel containing enzymes, substrates, and wash buffers to clean the sensor surface of unbound materials and reduce the risk of false positives. As the processed specimen moves over the sensor surface, antibodies attached to that surface capture antigens to the SARS-CoV-2 virus and those now-immobilized antigens also bind to biotinylated detector antibodies and streptavidin coupled to enzyme, which amplify the signal read by the Omnia instrument.

The cartridge is inserted in a high-frequency bulk acoustic wave instrument that measures the change in resonance frequency as the targets become latched to the sensor surface and the increased mass slows its oscillation. Bothwell said the instrument's sensitivity is a product of that high-frequency oscillation.

"Within something the size of a credit card, we're able to run central lab-like immunoassay chemistry in 20 minutes," he said.

Though Bothwell declined to provide an approximate price per test, he said it will fall somewhere between the $10 of some competing rapid antigen tests and the price of a point-of-care PCR assay. He also declined to give an approximate price per Omnia instrument.

Bothwell's main concern during the clinical trials is whether the company can secure sufficient influenza samples while the infection rate is low. FDA officials have said diagnostic companies have had difficulties securing sufficient influenza B samples, and Bothwell credits the agency with flexibility in how it evaluates flu B testing. If Qorvo secures an EUA for the combination test, Bothwell said the

firm will need to later finish gathering additional performance data in its subsequent pursuit of 510(k) clearance.

If it is successful in bringing the test to market, it will compete against a mix of already authorized point-of-care, laboratory use, direct-to-consumer and over-the-counter combo tests for COVID-19 and influenza respiratory ailments, as well as for respiratory syncytial virus.

According to Craig Steger, a director at investment bank Outcome Capital, one challenge to Qorvo is it is trying to expand into a highly competitive point-of-care market, and while the company appears to have good technology and the potential to deliver on its promised sensitivity and specificity, he predicts the firm will struggle because it will be competing against established point-of-care diagnostic firms, some of whom have lower costs per test. Steger further noted he does not think Qorvo's tests are highly differentiated from the competition.

While Qorvo believes one potential market for its technologies are pharmacies and urgent care centers, Steger said he thinks those settings remain wary about newcomers in testing since the collapse of Theranos and the money lost from investments into those machines. Large scale retailers are more likely to buy from diagnostic firms with a proven track record, he added.

Bothwell said the crowding and competition seen among test providers in the early years of COVID-19 has dwindled as COVID-19 has become endemic and testing demand is shifting in favor of high-quality multiplex tests and point-of-care testing. Qorvo's advantage is in its ability to deliver quick results, its lower cost than molecular diagnostics, the small size of the instrument, and the instrument's fit with existing workflows. In particular, he noted the test automatically delivers results to medical records once each test is completed rather than requiring manual interpretation and transcription during certain time windows.

"In a nutshell, we believe this is a first-in-class product platform that has broken the paradigm between antigen and molecular tests," Bothwell said. "This goes far beyond a COVID/flu test because, now, instead of being limited in antigen or molecular markets, Qorvo can cover both."

He added pharmacies are an especially nice fit for Qorvo's tests. Even before the pandemic, pharmacies had started offering on-site testing for limited indications, a move that some expect to accelerate as the pandemic has provided a boost for point-of-care testing.

"With the COVID pandemic increasing access to point-of-care testing, the pharmacy chains are actively looking at how they can build out revenue streams of more testing" that can deliver better access to prescriptions, according to Bothwell.

While Qorvo Biotech wasn't founded until 2019, its parent firm had established *in vitro* diagnostics as part of its pipeline several years earlier following an evaluation how the company could leverage its BAW technology. The company initially focused on tests for high-sensitivity quantitative cardiac troponin and *Clostridioides difficile*. The company also developed an interleukin-6 assay, for use as an indicator of inflammation.

Diagnostics startups that emerged during COVID-19 and reaped the benefits of widespread testing at the height of the pandemic have struggled to maintain stable footing as COVID-related revenues have plummeted. Qorvo's parent company has not broken out revenues for its biotech business, but, in general the firms that have leveraged COVID-19 revenues into diversifying their product lines have tended to fare better since testing fell off.

Bothwell said that beyond the COVID-19 and influenza panel in clinical testing, the firm's immediate plans include a syndromic respiratory panel that would incorporate SARS-CoV-2, influenzas A and B,

and RSV and *Streptococcus*. It also plans to begin clinical trials by late this year on a combination chlamydia and gonorrhea test that will form the foundation of an STI panel to include trichomonas, HIV, and syphilis.

Bothwell said the instrument can deliver quantitative results on all assays and plans for certain upcoming assays to have that capability. That will come into play through plans for a high-sensitivity cardiac troponin assay that could be used to rule out heart attack, as well as other cardiac tests. The firm also is developing a portfolio of tests that could aid management of chronic conditions such as a thyroid-stimulating hormone panel that Qorvo Biotech already has in-development and that could be used to monitor treatment response. The firm plans to seek 510(k) clearance for all of those tests.

Beyond securing an FDA EUA, Qorvo has an eye on gaining the approvals needed to distribute the COVID-19 and influenza tests in Europe and Asia, as well as Australia and other Southern Hemisphere countries that can help offset some of the seasonal fluctuations in sales.

Bothwell said that, as testing shifts away from workplaces, cruise lines, and sporting events during the endemic phase of COVID-19, the traditional reimbursement-based test providers will take ownership of point-of-care testing. Qorvo plans to work within those channels to fill that shifting demand.

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