Dx Experts See Demand for OTC Self-Tests, Tempered by Lack of Reimbursement

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NEW YORK – In the immediate wake of the COVID-19 pandemic, there was initial enthusiasm that over-the-counter self-administered tests would see an upshot as some believed the widespread use of antigen-based COVID-19 tests would carry over to tests for other indication.

But with the pandemic partly in the rearview mirror, diagnostics industry watchers see promise in the continued growth of OTC testing with answers delivered at home, but some also say the market has been hampered by ongoing hesitancy among government healthcare officials and private payors to trust the answers delivered through self-tests. Payors also balk at reimbursing for such tests.

The widespread adoption of at-home testing during the COVID-19 pandemic, aided by US federal government programs to hasten marketing access for new tests and distribute tens of millions of self-tests directly to homes, has raised confidence among the public and public health authorities that at-home tests can deliver reliable, useful answers. In 2023, the US Food and Drug Administration for the first time gave full marketing clearances to home-use tests for COVID-19, and the National Institutes of Health said recently that it plans to expand its Home Test to Treat pilot project into a national program to provide free home COVID-19 and flu testing along with telemedicine consultations and deliveries of antiviral medications.

Mara Aspinall, a professor of practice at the Arizona State University College of Health Solutions and partner at Illumina Ventures, said self-tests have become an important and growing element of the healthcare system. Though OTC pregnancy and blood sugar tests have been available for decades, antigen-based COVID-19 tests changed the perception that self-tests could be completely performed by individuals at home without the need for a trained expert.

"The idea of testing yourself for an infectious disease sounds good, but you're not fully confident until you've done it at least once," she said. "And what COVID did is push so many Americans to try it at least once."

However, Amy Kelbick, a health policy director for McDermott+ Consulting, said in a recent interview that, in general, self-paid testing isn't a sustainable business. While some people will always be willing to buy tests, test makers and other stakeholders want more some assurances that there will be a consistent demand for the tests and that they will get reimbursed.

"We have also seen a significant decrease in the manufacturing of those tests, and what diagnostic companies will often tell us is it's because there's no certainty," she said. "They have no guaranteed market, and they don't have a lot of faith that there will be folks willing to shell out money."

While the Biden Administration required that insurers cover the costs of at-home OTC tests for COVID-19 during the public health emergency, once the PHE expired last May, the cost of the tests fell on consumers. As a result, overall demand for COVID-19 tests plummeted during 2023, crushing the

bottom lines of firms that were buoyed by pandemic-related revenues and government funding and had bet their futures on the success of their COVID-19 tests.

While the FDA has often been reluctant to give its stamp of approval to direct-to-consumer OTC tests, a limited number of firms have received the agency's imprimatur over the years for such tests, including OraSure, whose oral fluid-based HIV test was approved by the FDA in 2012. The pandemic, however, completely changed the model for OTC infectious disease testing as more than 300 Emergency Use Authorizations have been granted by the agency for molecular- and antigen-based tests for diagnosing COVID-19.

Even as this was happening, some firms sought full FDA authorization for their COVID-19 tests, and last February FDA officials said they were phasing out the EUA program and recommending that test makers seek approval or clearance for tests through the typical *de novo* and 510(k) premarket review pathways.

In June, Cue Health secured *de novo* marketing authorization for its Cue COVID-19 Molecular Test, which received EUA in 2021. Acon Laboratories said in November it gained 510(k) clearance for its Flowflex COVID-19 Antigen Home Test, to which the FDA granted EUA in 2021 and became the second at-home COVID-19 test to pass through traditional premarket review, following the FDA's authorization of Cue's molecular test.

In a statement, the FDA Center for Devices and Radiological Health said that it has been working with COVID-19 test developers who are pursuing marketing authorization through traditional premarket pathways so those tests can remain in use long-term. The agency has not yet set a date for when those authorizations will terminate, and it declined to comment on any other non-respiratory virus OTC self-tests that are currently being evaluated for full marketing evaluation.

Sustainability of COVID-19 OTC testing model

Craig Steger, a director at Outcome Capital, said the rise and fall of home-based COVID-19 testing has forced a realignment of the companies in the OTC testing space and and their offerings. According to him, many of the companies that struggled, filed for bankruptcy, or became acquired probably priced their tests too high for what the self-paid market would sustain. On Amazon, the price for a COVID-19 test currently ranges from less than $10 each for a rapid antigen test to $50 for Lucira by Pfizer's disposable COVID-19 & Flu molecular test. The initial cost can be even higher for tests that require a reusable reader.

However, Steger sees ongoing demand for self-testing in the US by younger generations who want to be involved in their healthcare.

He also noted that Becton Dickinson's 2021 acquisition of Scanwell Health illustrates that BD, at least, sees a future in at-home testing beyond COVID-19 with results read and delivered on personal electronics. BD had collaborated with Scanwell to develop an app used with the BD Veritor At-Home COVID-19 Test, which is an over-the-counter antigen assay.

Steger said that OTC COVID-19 and influenza tests are likely here-to-stay, even if the number of cases are past their peak. With a test for group B streptococcus, Steger said, patients can present the results to their doctors by phone or video conference and potentially get prescriptions for antibiotics. Meanwhile, the market for OTC tests for sexually transmitted infections is becoming increasingly crowded as new entrants enter the space amid a surge in the number of new cases of syphilis, gonorrhea, chlamydia, and other STDs.

Last year, the Centers for Disease Control and Prevention called for healthcare and public health sectors to help address a rising numbers of confirmed STIs, especially a sharp rise in syphilis cases. In surveillance from 2020 and 2021, the agency identified a 4 percent rise each gonorrhea and chlamydia cases. But the agency saw syphilis cases surge 32 percent, and that included an alarming rise of congenital syphilis cases that resulted in 220 stillbirths and infant deaths.

While people still tend to want to see a doctor to get treatment for an STI, they don't necessarily want to get tested at the physician's office, Steger said. At-home STI tests have largely involved home-based sample collection with lab-based analysis, such as LetsGetChecked's recently cleared Simple 2 multiplex test for chlamydia and gonorrhea. Other firms are developing STI tests that can deliver results at home.

Jeremy Schubert, CEO of 3EO Health, said that, while the demand for COVID-19 tests has declined from its peak, hundreds of millions of tests continue being sold and a strong market remains for the detection of not only respiratory diseases but also sexually transmitted infections. He said optimizing healthcare will require a massive shift in testing closer to patients through diagnostics that can be decentralized in a cost-effective way.

"If you want to fix the health system, the health challenges in the US, you're going to have to figure out how you locate the care of individuals as close to the individual, including their home," he said.

3EO received in September Emergency Use Authorization from the FDA for the firm's over-the-counter 3EO Health COVID-19 Test, a reverse transcription loop-mediated isothermal DNA amplification test that is performed with anterior nasal swab samples and cartridges on the 3EO Cube instrument. It also announced in October it had received $773,700 from the National Institutes of Health Rapid Acceleration of Diagnostics (RADx) program to develop a multiplex test for COVID-19 and influenza A/B and the phased award could provide up to $6 million through milestones and additional work packages.

Shubert said that while 3EO has been focused on the firm's molecular tests for respiratory diseases, it has been developing a *Streptococcus* assay as well as eyeing the market for STI testing. People generally want easier methods to manage their own health with the option to see a healthcare provider when needed, but otherwise they prefer to stay out of doctors' offices.

Cue Health declined to make its executives available for comment but it provided a list of molecular diagnostics that were in the company's pipeline for at-home testing, including three respiratory tests that are under review by the FDA. The company is also conducting clinical studies on a multiplex test for chlamydia and gonorrhea, preparing for clinical studies for a strep throat test, and using federal grant money from the BARDA program to develop a multiplex test for the over-the-counter and point-of-care detection of COVID-19, flu A/B, and RSV.

Nikos Pavlidis, acting president for BD's Diagnostic Solutions business, said self-testing for infectious diseases helps patients avoid crowded medical offices, reducing the risk of disease spread, while pairing the results with telehealth gives patients access to treatments. Tests that use self-collected samples, too, improve access among underserved populations to STI diagnosis and cervical cancer screening, in addition to offering increased comfort and privacy compared to sample collection in healthcare settings.

The FDA provided a framework during the pandemic that accelerated consumer adoption of self-tests, "creating lasting changes to consumer behavior" and opening the door for non-COVID OTC tests to gain adoption, he said.

"These regulatory and behavioral changes create opportunities for additional IVD products, including non-COVID tests, to enter and gain adoption in the OTC market, although we envision a more traditionally regulated environment moving forward in non-public-health emergencies," Pavlidis said.

Performance concerns

But developing tests for the OTC market requires more clinical validation, useability studies, and performance evidence compared to lab-based and point-of-care tests, Pavlidis said. Those tests need to be simple, safe, and effective in the hands of untrained users, and they generally need to hit higher sensitivity and specificity thresholds compared to tests performed under the supervision of a healthcare provider, he said.

McDermott+ Consulting's Kelbick said some of the at-home tests that have already entered the market are too expensive for most consumers, and she suspects that some upcoming OTC multiplex respiratory and STI tests may encounter the same resistance among consumers and payors who may not want to pay for them. She said it's hard to envision a strong consumer base for use of more advanced testing technologies at home without insurance coverage.

"Are you really going to pay $40 out-of-pocket to make sure that your kid doesn't have flu A, flu B, or COVID, or are you probably just going to go to the doctor and pay your copay for your visit?" she said.

Jeffrey Jones, managing partner for the Deerborne Group, said the reimbursement for OTC tests also must be convenient, he said. He doubts the average person finds it worthwhile to write a letter to their health insurer to request reimbursement for a diagnostic test even if it is an eligible expense.

Several private insurers contacted for comment did not respond. AHIP, a trade organization representing the health insurance industry, did not respond to emailed questions.

Reimbursement isn't the only hurdle for new entrants to the at-home diagnostics market. Jones said he recently consulted with the operator of a large-scale CLIA-certified laboratory, that he declined to identify, that ultimately decided against entering the OTC testing market after analyzing the barriers to entry, including regulatory requirements and the relationships needed with few distributors who can deliver the products nationwide.

One of the distributors he contacted during that consultation indicated a preference for firms that have the capacity to produce at least 1 million tests per month. The firm decided the operations needed to bring tests to market were too far removed from its core laboratory operations, he said.

"There's opportunity, but there are so many barriers," he said.

Harry Glorikian, general partner at Scientia Ventures, said whether a home-based test succeeds depends on a complicated mix of factors including the indication, the patient, the ability to act on the results, the equipment requirements, where the test will be performed, the size of the market to produce a viable at-home test, and how often the tests will be performed. Whether people can pick up the tests at a nearby pharmacy, rather than ordering them for delivery, will also make a difference for companies in this space.

"If the market is growing, there's going to be incumbents out there with new tests that would probably grow because they've got the infrastructure to produce them," he said.

Before those tests even hit the market, the FDA will also consider what information those tests convey and whether a physician needs to interpret them. Patients with diabetes need blood glucose tests to help them manage their health, but Glorikian thinks regulators will have questions about how patients could use tests to potentially diagnose something significantly more complex, such as cancer.

CDRH officials said in a statement that the agency is interested in increasing access to tests, including at-home tests, and they encourage test developers to talk with them about their devices. In March 2023, the CDRH also called for public input on what the agency should do to increase at-home access to medical technologies and what evidence or design features the agency should consider in decisions whether to approve or grant clearance for those technologies.

In comparison to a point-of-care test that can be used in a healthcare setting, OTC tests have additional design and validation considerations that need to be met to gain market clearance. Test makers need to show the FDA that their OTC tests are safe and effective in the hands of lay users, and that the tests function in various environmental conditions. The instructions and results also need to be easy-to-interpret. The agency determines which regulatory controls and marketing pathways should apply to a test based on risks connected with its use.

Steger also said the cost of good sold is key in the self-paid diagnostic testing market, where the pricing pressure is always downward. Companies that start at prices the public finds reasonable are more likely to take off.

Arizona State University's Aspinall expects to see more influenza tests and potentially *Streptococcus* tests to enter the market. In addition to the firms that have announced efforts focused on creating STI tests, she also sees potential for home-based testing to aid the monitoring of patients with serious conditions, including cancer and organ transplant patients.

Aspinall, who is chair of the board of directors for OraSure Technologies, said that while the cost of OTC tests may be prohibitive for some patients, "it's not as if going to the doctor is free" in the US when you factor in copayments, loss of hourly wages, and transportation costs. Tests performed at home offer privacy, and they can help address shortages of doctors and space in healthcare facilities.

But she said OTC tests are also subject to human error both in the test performance and interpretation of results, despite efforts by test makers to simplify the process. The lack of reporting for at-home test results also hampers efforts by public health officials to track infectious disease cases.

Medical record systems also need to be updated to include results of home-based tests, Aspinall said, although she noted that a minority of US states forbid inclusion in charts of patient-reported results from OTC tests. When the results of tests used for patient monitoring are excluded from medical records, insurers may decline reimbursement for treatment related to those results, hospitals may make inappropriate decisions on patient treatment, or doctors may order redundant tests.

"In the short term, trust is a big issue because we'll probably go through an awkward stage where every test of an important nature is repeated" in a doctor's office or hospital, she said.

Increasing that comfort and trust in diagnostic testing requires education, including more lessons for medical school students, physicians, and the public about the constraints of home-based testing.

Starting in April 2022, CMS implemented a demonstration project to cover the costs of up to eight OTC COVID-19 tests per month during the public health emergency for people with Medicare Part B. The program was intended to determine whether Medicare payments improved access to the tests and reduced overall Medicare spending on testing and healthcare services. CMS documents indicate that by March 2023, the program had spent $1.1 billion for about 101 million OTC tests.

Under that program, eligible Medicare beneficiaries could show their Medicare cards at pharmacy counters and receive tests at no charge, provided they were under their limit, and the pharmacies could file standardized claims for reimbursement.

Because the CMS started that demonstration project under its existing authority, rather than any temporary powers that were enacted in response to the pandemic, Kelbick had hoped the CMS would use the same authority to continue coverage of OTC COVID-19 tests beyond the public health emergency or extend coverage of a wide range of OTC diagnostic tests.

"The diagnostics community would really need to invest in advocacy efforts because CMS is not going to be easily persuaded on this," she said. "I think there's a hesitancy to do anything precedent-setting, and coverage for any kind of OTC item is new and different."

The tests that have secured FDA marketing authorizations have been shown through clinical data to be worthwhile, she said, and she thinks the lack of reimbursement leads to missed opportunities for innovation and development.

"I do think that there just needs to be a greater awareness both on behalf of payors and providers as to the benefits of at-home tests and also the cost-saving potential," she said.

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