# COVID-19 Testing Is Not an Automatic Choice for Pharmacists

## Preparation taking place in some pharmacies, but clarification is still needed.

By **Fred Gebhart**

Are you testing for coronavirus disease 2019 (COVID-19)? A recent National Community Pharmacists Association (NCPA) survey found that most pharmacists want to be part of the testing process, but few pharmacies offer sample collection or onsite testing.[1]

"There are so many different barriers. One thing gets cleared, and then there's another step and then another," said pharmacy owner and California Pharmacists Association President Ken Thai, PharmD. "Especially if you are an independent pharmacy wanting to do testing, you have to find your own channels to get it going. And then it comes down to economics. Billing mechanisms seem to be in place, but they aren't necessarily functional. There are still a lot of questions before we can start widespread testing in pharmacies."


Ken Thai, PharmD

Some pharmacists have opted not to test. In the Atlanta suburb of Johns Creek, Good Neighbor Pharmacy affiliate Lily's Pharmacy focused on existing patients and the flood of discharge patients as Emory Johns Creek Hospital cleared its wards.

"The pandemic hit hard and fast," said co-owner Jennifer Shannon, PharmD, BCPS. "Our volume went sky-high for the first 6 weeks of [COVID-19]—really sick patients who needed a lot of pharmacist attention. We started curbside pickup, ramped up delivery, and set up new protocols as hospitals and doctors closed. Relationships with our providers have been strengthened, and we are caring for patients at a higher level than just a few months ago. I'm amazed at how many people are coming by to say they never realized how much they needed a local pharmacy."

Other pharmacists built their own testing programs. In rural Surgoinsville, Tennessee, Beth Bryan, PharmD, was the first pharmacist in the state and one of the first in the country to offer COVID-19 testing. Her Surgoinsville Pharmacy began offering appointment-only, drive-up testing in mid-April 2020. Pharmacy staff collected nasopharyngeal swabs and sent them to a lab for processing. Bryan said there are clear public health, community service, and professional advancement arguments for providing COVID-19 testing. And she didn't have to worry about the business case. Her pharmacy partnered with the state health department to obtain sample collection kits, the local fire department to acquire hazmat suits, and a local welder for face masks. Community members donated N95 masks.

"Without community support, we would not have been able to obtain test kits or PPE [personal protective equipment]," Bryan said. "There is no good pathway to reimbursement. We're working on it, [the US Department of Health & Human Services (HHS)] is working on it. There is a learning curve for all of us, just like there was with immunizations. But if somebody is looking for a big moneymaker, COVID-19 testing isn't it."

In West Sacramento, California, Capitol Pharmacy is building relationships, not profits. The Health Mart pharmacy has yet to be reimbursed for testing. Health Mart, part of McKesson, was part of an HHS pilot program to test community pharmacies as sample collection sites for molecular testing. The test manufacturer provided sample collection kits, McKesson provided PPE and supplies, and pharmacies provided space and personnel.


Richard Dang, PharmD, RPh BCACP

"We're not paying for testing supplies," said Capitol Pharmacy owner Thomas Bui, PharmD. "When we agreed to be a testing site, we got supplies overnight, but we didn't have time to prepare, to communicate to the community that we would be offering COVID-19 testing. We're just trying to give back to the community. It's the right thing to do."

Economics made a huge difference at the University of Southern California (USC), said Richard Dang, PharmD, RPh, BCACP, assistant professor of clinical pharmacy. Plans to test the entire

USC community—students, faculty, and staff—went on hold when the university saw cost estimates for test kits, PPE, and supplies. "They were not expecting the budgetary impact of testing," said Dang, a California Pharmacists Association COVID-19 Taskforce chair and speaker. "They had sticker shock."

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JENNIFER SHANNON, PHARMD, BCPS

And then there is the murky question of regulatory authority.

On April 8, HHS authorized licensed pharmacists to order and administer FDA-authorized COVID-19 tests, including serology tests.[2] By mid-May, about two-thirds of states were allowing pharmacists to play a role in testing.

On May 19, the agency issued an advisory opinion (20-02) declaring that states and localities may not establish, enforce, or continue in effect any legal requirements that prohibit licensed pharmacists from ordering and administering FDA-authorized COVID-19 tests. HHS cited the Public Readiness and Emergency Preparedness Act as preempting state licensing laws that restrict pharmacists from ordering and administering COVID-19 tests.[3]

By early June, some 40 states had cleared the way for pharmacists to test. California, New York, and Pennsylvania were notable exceptions. New York had announced plans for a pilot program with independent pharmacies to provide COVID-19 testing. However, the rollout was delayed.

## CLIA Waivers Present Barriers

In California, lawmakers thought they had the testing problem solved. The state conferred provider status on pharmacists in 2014 and allowed pharmacists to provide point-of-care testing. But point-of-care serology testing is limited to blood glucose, glycated hemoglobin $A_{1c}$, and cholesterol, Dang noted. The FDA has issued Emergency Use Authorizations for 4 point-of-care COVID-19 tests, but the state is not allowing pharmacists to use them without first getting a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver from the state health department.

"We are seeing disagreement with HHS from the state," Dang said. "Our department of health is indicating there are no changes to their requirements regarding CLIA certificates of waiver. The ultimate issue is that pharmacists are unable to obtain a waiver without having a qualified laboratory direction, whose definition does not include a pharmacist."

CLIA waivers are also a barrier in Pennsylvania, said Patricia A. Epple, CAE, CEO of the Pennsylvania Pharmacists Association. The state's Bureau of Laboratories, part of the health department, requires a lab director with a doctorate in science and at least 2 years of hands-on experience that is acceptable to the bureau.

Patricia A. Epple, CAE

"A PharmD would qualify, but the bureau is requiring experience in a clinical lab, which excludes most pharmacists," Epple said. "Pennsylvania has the lowest percentage of pharmacies with CLIA waivers in the country, around 2.8% of our pharmacists. We have been working for 10 years trying to get changes and have not gotten any result."

## Reliable Testing Remains in Question

The reliability of existing tests is another consideration. The FDA released independent evaluations of 5 COVID-19 serological tests in early June, including 1 that had been voluntarily withdrawn from the market. Among the marketed tests, positive predictive values ranged from 100% to 63.7%. Negative predictive values ranged from 100% to 99.5%.

Rich Tremonte

AmerisourceBergen is not distributing any of them.

"We just haven't been comfortable with the accuracy of tests that have been FDA approved, so we are not distributing them," said Rich Tremonte, executive vice president and president of community and specialty pharmacy at AmerisourceBergen. "We know that some of our independent pharmacy customers are administering tests and some of our chain customers are doing testing. They are focusing on molecular tests where you collect samples and send them to a lab for processing. Many independent pharmacies just don't have the resources to do that."

Hannah Fish, PharmD, CPHQ

The need for pharmacy testing is clear, especially as flu season approaches. Influenza and COVID-19 share multiple signs and symptoms. Pharmacists cannot practically identify one for treatment without ruling out the other. Respiratory syncytial virus is another potential confounder.

"The diseases are so similar in presentation that you want to be able to test for all 3 to advise the best course of action," said Hannah Fish, PharmD, CPHQ, associate director for strategic initiatives at the NCPA. "We are seeing some of that preparation already taking place in pharmacies. We need clarification on pharmacists' ability to offer testing and to bill for tests." ■

For references, visit drugtopics.com.