# A lab world embroiled in pandemic

## Karen Titus

May 2020—Along with SARS-CoV-2, clinical laboratory testing has been hiding in plain sight far longer than many people realize. But it took the novel coronavirus (which, frankly, hardly feels novel anymore) to make that clear to the rest of the world.

As the COVID-19 pandemic spread across the globe, laboratory testing crashed the news cycle. National leaders sought to reassure citizens by promising millions of test kits. Economies shattered—and have since sought to return to life—based on testing availability. Ordinary people woke before dawn to wait in lines at drive-through testing sites—often to be turned away when supplies ran out. Emergency use authorization became a common phrase. And behind every heartbreaking photo from an emergency department or ICU lingered an unnerving thought: *We don't have tests.*

"There are a lot of eyes on the lab right now," says Tabetha Sundin, PhD, scientific director, molecular diagnostics and serology, Sentara Healthcare, a 12-hospital system based in Norfolk, Va. Like the 1968 Democratic Convention in Chicago, the whole world is watching.

Labs found themselves crisscrossing a no man's land between "Anybody that wants a test can get a test" and "The tests are all perfect" to "It is a failing, let's admit it." How did their stories—the warnings, the scramble for tests and collection kits, the pleas from colleagues and politicians—unfold? And what lies ahead?

The international scope of the diagnostics business is hardly new to John Waugh. But the scarcity of the supply chain took him by surprise. "We're as good as our next delivery," he said of the testing in early April. (Photo: Dwight Cendrowski)

**Distant thunder**

John Waugh, system vice president, Pathology and Laboratory Medicine, Henry Ford Health System, spoke with CAP TODAY on April 3.

Or, as he puts it, "It's about March 34th for me."

Waugh and his colleagues at the Detroit-based system had been watching news reports about a novel coronavirus spreading elsewhere in the world, leading to lockdowns and health care crises. “But for a long time it was ‘over there,’” says Waugh. “It was China. It was Italy.”

Then cases started popping up in the Pacific Northwest. That’s when “a lot of people really dug in very, very hard on planning,” he says. Work had already been underway in various departments. But now it became a concerted effort to develop surge beds and double inpatient capacity.

The magnitude and speed of events was “absolutely unprecedented,” says Waugh. By April 2, Henry Ford hospitals were caring for 624 patients with COVID-19.

At Washington Kaiser Permanente, Dina Greene, PhD, also recalls that people weren’t all that alarmed initially. “At first we really weren’t sure this was going to be a big deal,” says Dr. Greene, technical director, Kaiser Washington Laboratories, who spoke with CAP TODAY on April 6. No one dismissed the threat, but many also carried memories of preparing for earlier viral threats that never materialized in the United States. “We had SARS fears, but nothing ever took off like this. With Ebola, we were worried about having containment areas and having safe places to test blood,” Dr. Greene says. But that didn’t extend to setting up internal testing capabilities.

We’ve always used lab testing to change behaviors, but this is on a global scale. It’s unprecedented.
**— Dina Greene, PhD**

“It’s like a hurricane, right?” she continues. “You know that the hurricane has demolished the Bahamas. You can see it coming, and it’s definitely raining, but that doesn’t necessarily mean it’s going to hit Florida.”

Dr. Sundin, who spoke with CAP TODAY April 7, recalls watching the numbers slowly tick up in the United States—about a dozen cases had been confirmed by mid-February—but not realizing until near the end of that month “that we were going to see a surge. Which may have been a little later than my colleagues,” she adds, noting she’d not experienced a pandemic before in her career.

Early on, she continues, “I thought, *Oh, it’s not going to be a big deal, and our reference lab will support us, and the public health lab will support us.*” As she and her colleagues realized “that those two sources would not be sufficient to handle the testing volume, we started reaching out to our vendors.”

**Who has tests?**

At the same time, vendors had started reaching back. “We were seeing vendors’ email, saying, *We see this coming*, or, *We’re seeking an EUA,*” recalls Dr. Sundin. “So at first, again, we thought what we had would be sufficient. In hindsight, we were not correct.” Her local site already had a small, low-throughput instrument in place, and they pursued in-sourcing a few additional instruments across the system. Contracting was assigned; reagents were expected. The lab could exhale.

“And then that vendor was not able to meet that supply—the instrumentation or the reagent,” Dr. Sundin says. “We also, at about that time, realized this is a huge deal.” At least 400 specimens a day were coursing through the system. A glimmer of hope appeared when their reference lab committed to a five-day turnaround time. That quickly ballooned to 10 days, though Dr. Sundin makes clear the lab was obviously doing its best to cope with unanticipated volume.

That’s when Dr. Sundin and her microbiology clinical specialist embarked on a divide-and-conquer strategy, as she puts it. Her colleague began working to source collection devices, including VTM, nasopharyngeal swabs, ESwabs—“everything at this point”—and Dr. Sundin began trying to source different reagents from different vendors, knowing that every vendor would be facing a supply chain disruption. They added assays to an instrument already in the lab; they also in-sourced a new instrument, setting up an entire COVID lab to accommodate its large size. By the first week in April, the lab had four live assays, with two more in the works. They also validated a second extraction for one of the methods—“so seven different validations, just to make sure we could supply the demand,” Dr. Sundin says.

Sentara wasn’t the only one embarking on an unorthodox scavenger hunt. As Henry Ford braced itself for the onslaught, “It became kind of a race here,” says Waugh. “The hospitals had to very quickly pivot and turn into acute care medical facilities. That’s hard to do. The whole hospital is starting to look like an ICU.”

Waugh points to a head-turning moment on March 17, at a Compass Group conference call on COVID-19, which he moderated. During the Q&A session, Waugh asked the VP of a major diagnostics company about reagent availability for labs with test systems already in place. The answer: Federal authorities were advising the company to redirect its instrumentation and consumable supplies to the largest commercial laboratories.

“That was shocking news to a lot of people on the phone,” Waugh says. “They had made investments in these test systems, and then they found out they weren’t going to be able to use them.” It also signaled to him that he’d need to start scouring elsewhere for supplies.

Early on, Henry Ford set up the testing system used by the CDC, which required consumable supplies from four different companies. This felt untenable to him. “If one of them doesn’t deliver, we’re dead in the water.”

Deliveries were indeed becoming doubtful. As so often happens, “Companies get very enthused about their offerings,” Waugh says. It’s a little like starting to sing in the shower before the water starts flowing. He received a stream of messages about what was available—“and then you find out they haven’t even started production yet, and they only made enough to get their approvals. And now they have an infinite number of requests coming from all over the world,” including hard-hit countries in Europe.

The international scope of the diagnostics business is hardly new to Waugh. Nevertheless, “It even took me by surprise how scarce the supply chain was.”

‘It has been tough to comprehend that raw materials to make kits and reagents aren’t available.’

**—Beverly Rogers, MD**

Even vendors sounded nonplussed. When Beverly Rogers, MD, chief of pathology, Children's Healthcare of Atlanta, reached out to one longtime, high-ranking vendor colleague to ask about the possibility of getting tests, he said he didn't know, given that the federal government was directing where kits were being sent. "I wish I could tell you more—everything changes hour to hour," he told Dr. Rogers.

Waugh reports similar encounters. "Many suppliers—very senior executives within these companies—were worried," he says. One supplier told him, "John, we have dealt with surges before, but we have never been backordered for flu testing supplies, even when we had something huge like H1N1. This is unprecedented."

Waugh continues: "All of them, you could tell they were carrying big burdens. They weren't looking at this as a sales bonanza. They were looking at this and saying, *I don't want to let anybody down.*"

Waugh also had to beware of fraudulent offers for supplies that hadn't been cleared by the FDA. Many came from China, he says, or from groups that were importing them. Some offers came through Henry Ford's supply chain groups; others were forwarded by well-intentioned colleagues. "We had a lot of distractions," he says. "We had to respond, politely, to nearly all those requests."

**LDT purgatory**

The most obvious, pressing need was testing, Waugh says, to cohort and triage patients. "But we were prohibited from developing an LDT." Instead, labs waited for the CDC to develop a test—later shown to be flawed—and to push it out to public health departments. Says Waugh: "Those tests that could be performed at public health departments would be recorded as presumptive positive until they were sent to the CDC, where they were retested. It was a glacial pace."

He pauses, then adds, "It was a lost month."

The public health system excels at tracking food poisoning outbreaks or outbreaks of certain focal points of disease, Waugh says. But it's hardly a modernized system. Routing samples to state labs meant, among other things, filling out required forms. "When you're in a worldwide pandemic, and a tsunami's coming toward you, it's not the time to reach for pen and paper." The system also required calling the state health department and obtaining a tracking number for each sample.

"It's a lot of waiting on hold, and that process quickly broke down," Waugh says. Eventually the requirements for the forms and tracking numbers were waived. "It soon became apparent that the state public health laboratories were overwhelmed and backlogged."

'I'm so impressed by the collaboration between diagnostic companies. I've never seen

anything like it.'
**—Tabetha Sundin, PhD**

Labs also dealt with conflicting information from the CDC and the WHO, as well as shifting sample requirements. Early on, Waugh says, labs were told they needed to send an oropharyngeal sample and a nasopharyngeal sample to state labs; submissions that didn't include both types would not be tested.

Directing testing to commercial labs was a good-faith attempt to catch up, but may have backfired as these entities were swamped, Waugh says. Some of his own send-outs to a commercial lab had 10-day TATs, plus transit time. "And then what comes back is a paper report," he says, "instead of an electronically interfaced report to your information system," since the lab didn't do business with them on a regular basis.

Another eye-opener occurred Feb. 29. That's when the FDA issued a new policy that allowed certain labs that had validated LDTs for COVID-19 to begin using them prior to FDA review; EUA requests then needed to be submitted within 15 days.

"That was momentous," says Isabella Martin, MD, medical director of microbiology at Dartmouth-Hitchcock Medical Center, who spoke with CAP TODAY a week after the FDA's announcement. "I think it's the first time FDA has ever put something out on a Saturday."

That whole week, every lab was focused on capacity, says Dr. Martin, who is also assistant professor of pathology, Geisel School of Medicine, Dartmouth College. "And how quickly can we develop these tests?" While the limits on developing LDTs are rooted in safety concerns, "That's a huge problem when you've got this novel pathogen. High-complexity laboratories are used to thoughtfully validating LDTs, but once a public health emergency and EUA are invoked, all of a sudden you have to get through a lot of federal bureaucracy to start using a test."

Waugh speaks more bluntly. "We actually had handcuffs on us at the federal level."

Nevertheless, labs were prepared to move quickly, given the enormity of what they saw coming. "We were looking a pandemic straight in the eye," Waugh says. "You have to make what-if plans." If labs were eventually allowed to develop LDTs, how would they do so? What pieces would they put in play? How would they train staff, change IT systems, move consumable supplies? What could they reasonably promise to deliver?

Waugh reports that Henry Ford had its LDT ready by March 16. Its EUA was approved, and the system began testing. And again, there was worldwide competition for scarce testing supplies. "We've never had a situation like this before," Waugh says. "Everybody's competing for things like RNA probes."

While he's managed to acquire what the lab needs, Waugh notes the precariousness of the situation. "We're as good as our next delivery."

Dr. Greene, in Washington, reports a rapid rollout once the green light was given. When the state reported its first death on Feb. 29, she texted her colleague Alex Greninger, MD, PhD, assistant director, Virology Division, University of Washington Medical Center, and asked, *When are we going to have a test?* His answer came quickly: *Text me tomorrow.* "That's how quickly he was planning on having his analysis completed," says Dr. Greene. The test went live about a week later.

That eased some of her fears but created others. "It felt daunting to think that I was going to bring something online that hadn't been properly vetted by the FDA and start giving these results to people immediately." That's not to say the new tests were necessarily bad, but there's a reason laboratory directors and regulations exist, she says.

Initially she waited to bring testing in-house, preferring to send samples to UW "until we got our feet grounded and could make a less impulsive decision on which testing we wanted to bring in," given that EUA options were starting to expand.

**Who gets tested?**

Like many other providers, Sentara set up drive-through collection sites. But when their reference lab was unable to tamp down TATs for those samples—10 days soon became 15—they shut it down. Dr. Sundin speaks with no trace of frustration in her voice. "Again, I firmly believe they were doing their best. We're doing our best. So are all the diagnostic companies. We're all trying to move very quickly to meet demand."

The demand has been huge. "Everybody and their brother wanted to be tested," says Waugh. But self-selection is not a good strategy, particularly when, as Waugh puts it, "a third of the United States decides they all want to be tested at the same time."

Like other institutions, Henry Ford settled on a strategy that prioritized inpatients, followed by patients in the EDs—there are nine in the system. The third category covered health care workers, primarily those who exhibited symptoms of COVID-19 and took themselves offline for 14 days. After that, "We needed to be able to test them, clear them as negative, and then bring them back to work."

The strategy worked well for a while, Waugh says. "Then we discovered other populations of patients," such as people brought to the ED from a skilled nursing or long-term care facility because they had COVID-19 symptoms.

"Ultimately everyone got tested, but we did have to make choices," he says. "Everybody could not be first in line."

Kaiser Washington was running 200 to 300 tests daily in early April, for the most part limiting testing to patients with symptoms of COVID-19. Dr. Greene acknowledges that waiting to test asymptomatic but clearly exposed patients is controversial. "Should we be trying to adopt more universal screening?" she asks. "Or should we be saving resources? I don't know. It's a very interesting ethical problem. We know we have a limited amount of swabs and transport media. And then there's some amount of bottleneck in the analytical capabilities."

In Atlanta, Dr. Rogers, who is also adjunct professor of pathology and pediatrics, Emory University School of Medicine, says she faced tremendous pressure from colleagues to have an in-house test. "We weren't going to bring up our own LDT. We have a great molecular diagnostics lab, but it's small and does a large volume of clinical testing." In the meantime, she sent samples to a commercial lab, which went from a two- to three-day turnaround to what she calls an I-don't-know-what TAT. Finally she was able to send samples to another institution in town, which gave her 24-hour TAT—and some much-needed if short-lived breathing room. "People were relaxing a little bit at that point." Dr. Rogers spoke to CAP TODAY on April 7, the day testing was brought in-house. "But soon the doctors are back, saying, 'We need more testing than what we are getting.'"

"The surgeons are anxious," she says—"understandably so." To conserve testing for symptomatic patients, the surgical services were given an allotment of collection kits to test asymptomatic patients before surgery. Then a surgical director thought to ask: *If we use them at this pace, we're going to be out in April—can we have more?*

"It has been tough to comprehend that raw materials to make kits and reagents aren't available," she says.

One surgeon asked her, "Bev, what can I do to make this happen?" she says. "And I said, 'Not a thing. Allocation is allocation, and children's hospitals aren't high on the list to get test kits.'"

While necessity is the mother of invention, a pandemic can be the parent of possibility. "We've seen a lot of great things," says Dr. Sundin. Early assays were able to go live quickly, with manufacturers then "going back to update their EUA to allow more sources, or to validate saline—one vendor is allowing you to use pool chlorine to clean their hardware after a run. So we're all getting creative about what's going to affect test performance." (Dr. Rogers reports a lab colleague who was trying to validate urethral swabs.)

Dr. Sundin heaps praise on vendors in the midst of the madness. "I'm so impressed by the collaboration between diagnostic companies. I've never seen anything like it." No one is demanding she use their instrument solely or commit to volume. "We've been really open with them that they're supporting a portion of our volume and not all of it. The only thing they've asked for is standing POs," which she can adjust in ensuing months. It boosts confidence on both sides, she says: Vendors know their assay will be used, and she feels more sure-footed of her

future supply chain. “We also don’t want to hoard supplies,” she says.

**Your first time in a lab?**

At Kaiser Washington, deciding who would be tested fell to leaders “way above me,” Dr. Greene says, which she suspects has been the case throughout the country. “This is not a lab director decision.”

That’s led to other novel scenes, she suggests. “This is a time where everybody thinks they know how to run the lab,” she says with a laugh. Indeed, it bears a resemblance to the exuberant lead-up to the stock market crash of 2008, when everyone seemed to be a whiz at investing and mutual fund managers were media darlings. “I’m not saying I should be the one who decides who gets tested, but in many cases, the lab and the people with lab expertise are probably being consulted less than they should be.”

She casts her gaze cross country. Has a laboratory expert been named to prominent task forces? Spoken at White House press conferences? She answers her own questions. “There has not.”

“There have been very smart physicians who are part of our federal government response,” Dr. Greene continues. “But none of them have been laboratory people to explain what’s going on.”

Dr. Rogers saw a similar problem locally. “People are so anxious in this environment that well-meaning conversations about capacity occur among administrators and physicians outside the lab with other organizations. This happened with a promise to help made by someone at another institution, but when I called the lab director myself, he said, ‘Bev, I wish we could do your testing, but we don’t have any capacity.’ Multitudes of suggestions come into the lab about how to increase our lab’s testing capability. We have to investigate and bring things back to reality about what is and isn’t possible.”

Dr. Sundin has been encouraged as she watches lab testing become part of the conversation. Sentara’s senior leaders have walked through the labs on a handful of tours (as have local news organizations). “We actually had the COO ask, ‘What do you all do on a normal day?’” The answer—virology, genetics, and oncology-related testing for the entire system—may not have previously been apparent, she says. She’s also used the opportunity to explain sensitivity and specificity on the analytic side versus the clinical side. “Now that they’re in here they understand that we are central—no more for COVID than anything else—and they actually get it. And they’ve all said, *This is your time to shine.*”

“I would actually call it a silver lining of this whole process,” Dr. Sundin adds.

Dr. Rogers also finds herself explaining lab medicine to other colleagues. In response to the nonstop questions she was getting, in fact, she put together what she calls tip sheets—sort of a field guide to COVID testing basics, including major vendors. She was spurred to do this by a seemingly small incident: As she sat in on endless rounds of meetings, she realized leaders were trying to make decisions about tests whose names they couldn’t pronounce.

The tip sheets, simple and low-tech, helped with that and more. “People felt better simply because they had facts,” Dr. Rogers says. She followed this with a one-page brief on the assay Children’s started using—sensitivity, specificity, how it’s validated, how it’s done. She even included pictures of the instrument. “You know what? People became calmer.”

**Everyone in**

As Waugh watches the surge beds fill up, he marvels at the response from colleagues. “Exceptional—just exceptional—work has been done by our entire team. I have never encountered a situation where people step up, and cross over into other areas and backfill, and continue to come to work. I’ve just never, ever seen that kind of thing happen before.” This included those from the transplant immunology lab who began working in the microbiology lab. “They helped extend our staff, who at that point had been working nearly 28 days straight.”

He also commends the work done by the transfusion medicine division head. “I was initially concerned about our blood supply,” given that collection sites closed under stay-at-home orders. The supply has been skillfully managed, he says, and the division has worked to harvest plasma from convalescing patients who tested positive.

He applauds the work of the pathology informatics group as well, who brought order to the intricate daily testing reports, surge beds, and new order codes.

In trying to keep laboratory personnel working, members of the lab outreach team—no longer engaged with private offices that had closed—were deployed to the lab customer service center, Waugh says. “We were getting hammered with telephone calls from people who wanted to know, *Where is my result*?” That was especially difficult to untangle early on, when samples were being sent to five different locations: in-house, the state public health lab, and a reference lab that referred it in turn to another reference lab, which then passed it along to yet another site. “It took a lot of detective work,” Waugh says.

Sometimes the samples were much closer, but untested. “At one point we had a queue of 900 health care [worker] samples in our refrigerator waiting to be tested because we did not have testing supplies.” The alternative? Send them to a commercial lab and wait two weeks.

Ultimately all those were tested. “There was a lot of heavy lifting by our staff,” Waugh says. “I’m extraordinarily grateful.”

Dr. Sundin, too, lauds her colleagues inside and outside the lab. “I have a team I can’t thank enough,” says Dr. Sundin. “But I’m also seeing that with my other colleagues—our teams are all stepping up and managing the pandemic from the front line. I think that is really true for most lab professionals.”

Henry Ford has its own LDT but also turned to four other EUA procedures. “We bounce back and forth between different ones, depending on when the consumable supplies are coming in,” Waugh explains. The replication—of workstations, training, IT, supply and delivery orders, and payment—has added levels of complexity. It also was an opportunity for others to shine, he notes. He says he’s “exceptionally proud” of colleagues who work in supply chain and in finance, “who helped speed things along that we needed desperately. It didn’t matter the hour of the day or the day of the week.

“I said to people, ‘Every day is Monday. That’s just the way it’s going to be. Pandemics do not take time off. Pandemics do not have weekends or holidays.’”

Dr. Greene applauds the work of colleagues throughout her state. “We’ve done a really good job getting lab tests out, which is partly the work of Alex Greninger. We aren’t actually being recognized for the speed at which we’re doing this, and for the positive predictive value of the test.” By late April, Washington, along with California and Oregon, had begun shipping ventilators to East Coast hot spots, reported The New York Times. Until mid-March, Washington had the highest number of confirmed cases in the country.

Says Dr. Greene, “We’ve been able to calm down a little because we’ve seen what we’re doing is working.” Early on, one of her colleagues at UW said he wanted Washington to be the South Korea, so to speak, of the United States. “I thought that was a great goal,” Dr. Greene says. “That’s not to say we’re not having an increase in cases, but it is to say our strategy has mitigated risk. And that includes testing people.”

**Facts versus wishful thinking**

The pandemic has pushed the importance of lab testing into the national conversation. It hasn’t always been a pretty sight.

The challenges of testing have crashed head-on with perceptions at a fundamental level, says Dr. Rogers. “We live in America. We have our comforts; we have our freedoms. We have every test we want, when we want, how much we want. And that’s just not life right now,” she says.

“Part of the issue that we’re seeing with the national news is setting up an expectation that anybody can be tested before we were really capable,” Dr. Sundin acknowledges. She sighs heavily.

Those promises popped up around the time labs were pushing ahead with their LDTs. “Millions and millions—everybody’s going to get tested,” echoes Waugh. “And the reality is no.” The backlog was at least three

weeks, he says, when leaders were making those promises.

That optimism trickled down to clinicians. “We’re all being cautious,” Dr. Sundin says, “and our physicians want more data rather than less. But we have to manage their expectations about what a proper turnaround time looks like. Most of these tests are not point-of-care, even though they’re being marketed as such.” That has translated into national news reports saying that POC tests can provide results in five minutes. “We can’t fulfill that promise,” she says. That was also a frustration with the drive-through testing sites—not testing sites at all but rather collection sites. “But the local and national news presented this as ‘testing’ and talked about the limited supply of ‘testing kits.’ There was a lot of confusion.”

That confusion was being perpetuated from a high level outside the lab, Dr. Sundin says. “It almost sets the lab up not to meet the expectation that’s been given.”

Dr. Rogers marvels at the leaders who are talking about testing. “And so inaccurately,” she adds.

That made it more difficult to manage her colleagues’ expectations. “When we didn’t have this test in-house, there was such anxiety. Because we’re a lab that delivers. And we couldn’t deliver. It’s the first time that anything has been this extreme, where I said, *Sorry, I can’t do it.*” She did what she could to meet the needs but it often wasn’t enough. “I felt helpless and like I was personally failing.”

“Part of my job as a laboratory medical director is just to be an anxiety sink,” she continues. That’s why her fact sheets worked so well, she says—they tamped down the anxiety colleagues felt when everything felt chaotic and in constant flux. “I think just giving them facts is useful,” she says.

Of course, she adds, “To some degree, that’s all I could do.”

But it’s valuable, she says. “It’s so important to give a clear message at a time of crisis and chaos. If I could share one thing with the federal government, it’s that clarity of message, and basing every comment on fact rather than emotion, is extremely important in times of crisis.”

The conversation continued when the first antibody kits came on the scene, Waugh says. And it persists as governors publicly discuss the merits and meaning of antibody testing. Such scenes, which at the start of 2020 would have seemed astonishing if not downright disorienting, are now the norm. Once again, those with no laboratory experience are placing enormous demands on it. Will antibody tests be used to reopen economies? Will there be similarities to HIV testing, when patients who are positive but have undetectable viral loads are unable to transmit the virus? “We’ve always used lab testing to change behaviors,” Dr. Greene says, “but this is on a global scale. It’s unprecedented.”

At the same time, those who worried about the slow rollouts of LDTs are simultaneously asking the pendulum not to swing too far in the other direction with antibody testing. “My fear,” says Dr. Greene, “is that things are oscillating to the other side. There is a lack of regulation that’s a little bit unnerving.” Then again: “We are in a high state of emergency.”

**What’s ahead?**

In between managing diagnostic testing and antibody testing, labs are also considering the next wave of the pandemic, which many deem inevitable. Preparations might be different, or they may not be.

A member of Children’s leadership asked Dr. Rogers if anything could have been done differently. She responded that it’s likely nothing would have made a difference, because of the scarcity of raw materials. “And pediatrics is not where the greatest problems are.” (Even so, the virus looms large at Children’s. “While we are the least affected by all this, it feels like we’re extremely affected because COVID is what we do all day,” says Dr. Rogers. On the day she spoke with CAP TODAY, she had five scheduled COVID meetings, with additional COVID meetings squeezed in between.)

She told him she could plead with an adult hospital to take on her admittedly low volume of cases—“but that

means there's an adult they can't test. And they're sending tests out themselves."

Dr. Sundin, who oversees molecular diagnostics as well as serology ("It's not like I'll get past RNA testing of COVID and then get to hand it off," she says with a laugh), had sourced rapid IgG/IgM kits. "We're not exactly sure where the testing will move," she says, "but we want to have the option to move in that direction." She was also fielding questions about employee health screening, as well as hearing from vendors that plan to offer serological boxes with an EUA. "So we will probably transition quickly to an automated method for that—hopefully on a chemistry line, which I could hand off to the chemistry clinical specialist." As with the RNA testing, she'll likely diversify the supply chain.

She sees the need for more data from serological assays to understand how they'll pair with both PCR assays and patient management. "I've seen the data on serological conversion for IgM; with IgG, we need more data to know when they're going to convert, and is it specific to COVID versus other coronaviruses." In addition to such data, she hopes the WHO or CDC will suggest an algorithm that combines serological and PCR testing. Without that, Dr. Sundin predicts widespread confusion as physicians try to interpret both results. "We want to make sure we're giving guideline-driven care despite the fact that this is moving fast."

Large-scale data will be hard to get, and no one has the luxury of time. But Dr. Sundin says her institution will be able to perform smaller studies using their own samples—"discarded serum from patients who we know are positive or negative, and actually challenge the assay."

Looking back and looking forward, Dr. Sundin says she's hard-pressed to figure out if the lab should have reacted differently, or will in the future. Since it's based in the hospital, there's little storage space to accommodate larger supply stocks. Off-site storage might be an option, but that would lead to worries about expiration dates and test performance, given that a warehouse is not temperature controlled.

The larger issue is that, "although I would love to be prepared with enough reagent, we don't know what testing is going to be required" in a future pandemic. "Is it going to be an antibody test? A chemistry test? A PCR test?"

Dr. Rogers agrees. "You don't know what test you might need. Storage space is limited. And specimen collection kits don't last forever." Ironically, she says, clinicians might actually use fewer collection kits in the future, perhaps having been spooked by the lack of supplies this go-round.

The changes she would like to see would be ones outside the lab. "One thing that would have gone much better is if we had had testing capability earlier. I think the U.S. let down its guard. I hope this will be a reminder about scaling up fast to do the testing, define the protocols, et cetera. That's really the area that let the country down. And I don't think it's the manufacturers at all."

"I would hope," Dr. Rogers continues, "that this is an opportunity for us as a nation to learn something. If you don't learn from a crisis, then it's wasted. And I would hope that those who can effect national changes will do so, so we can be prepared when, not if, this hits again."

*Karen Titus is CAP TODAY contributing editor and co-managing editor.*