Purchased for the pandemic? Rethinking instrumentation

October 2022—*Who's doing what with instruments purchased at the peak of the pandemic? That and next-generation sequencing are what* CAP TODAY *publisher Bob McGonnagle asked Compass Group members about when they met virtually on Sept. 6.*

The Compass Group is an organization of not-for-profit IDN system laboratory leaders who collaborate to identify and share best practices and strategies. Here's what they said last month.

John Waugh, COVID testing is winding down. What are you doing with the additional molecular devices purchased during the pandemic?
John Waugh, MS, MLS(ASCP), system VP, pathology and laboratory medicine, Henry Ford Health System, Detroit: The largest devices we had were from a company acquired by Qiagen, and those continue to produce COVID test results daily, although at a lower volume. The most versatile instrumentation we've used since then are Cepheid units, which we're repurposing for *C. difficile* testing at our community hospitals. We're also doing STD panels on the Hologic Panther systems. And we will do more testing for group B strep and MRSA screening for patients headed for surgery. Right now they're giving prophylactic antibiotics if MRSA status is unknown, and we'd like to help get patients off that protocol if we can.

Lauren Anthony, what are you doing with excess COVID devices?
Lauren Anthony, MD, system laboratory medical director, Allina Health, Minneapolis: We try to deploy what we already have in the most effective way. It's been affected by staff shortages because certain methods are more hands-on than others, so the least manual methods are being used preferentially when there is a sudden, unexpected staff shortage and we have to close the more high-throughput station. We've been looking at which instruments to de-implement.

McHale

Linda McHale, what are you doing with your instrumentation in the Atrium system?
Linda McHale, MBA, MT(ASCP), assistant VP, core laboratory and integration, Atrium Health, Charlotte, NC: We're insourcing molecular testing to reduce costs. We invested in a Hamilton for preprocessing and are looking at how we can use it for next-generation sequencing testing.

Are you satisfied with the savings?
Linda McHale (Atrium Health): Yes, and we've had a good stream of molecular technologists and others interested in working in our molecular department. The leadership there has done a great job building a culture of teamwork.

Johan Otter, what are you doing with devices? You've done a lot of reagent rental so you're not stuck with capital goods, is that right?*Johan Otter, DPT, assistant VP, Scripps Health, San Diego:* All are reagent rentals, whether it's the Roche Liat or Abbott ID Now. We still run 100 to 200 tests a day on those platforms. The main platform in the core lab is Hologic, which we use 400 to 800 times a day; our volume hasn't gone down. We're still running a positivity rate of around seven percent.

Clark Day, what's going on at IU with instrumentation bought to deal with the pandemic?
Clark Day, VP of system laboratory services, Indiana University Health: We built a dedicated testing laboratory to

support the NCAA tournament in April 2021, so we're in the process of consolidating molecular testing into our go-forward molecular lab using a couple of Roche 8800 instruments. Throughout the pandemic we deployed Liats and Cepheids to our regional locations, and those remain there. We haven't had to repurpose or get rid of instrumentation; we just continue to add flu and other respiratory and molecular testing to those existing platforms.

We're stable at about 500 tests per day for COVID with less than 10 percent positivity.

Darlene Cloutier at Baystate, are you using the instrumentation you have and repurposing it and perhaps saving on send-outs?
Darlene Cloutier, MSM, MT(ASCP), HP, director of laboratory operations, Baystate Health, Springfield, Mass.: Definitely. We acquired a second Roche 6800 in the midst of the pandemic. We use Hologic Panthers as a secondary platform, and we have Abbott ID Now for point-of-care testing. Most of these platforms use reagent rental agreements, and we've had no trouble exceeding the volume commitments on these agreements. We had Cepheid instrumentation in place across our system for use in prior flu seasons and have expanded it so we could perform more rapid COVID testing onsite at the hospitals themselves.

We are still doing 700 to 1,000 tests a day on the various platforms, with a positivity rate of about seven percent. There is concern about what the next flu season will bring layered on top of a higher baseline percent for COVID positivity.

Karen Brownell at Intermountain, if you have all this repurposed instrumentation and testing, does it change your acquisition plans for new instrumentation next year?
Karen Brownell, AVP, laboratory services, Intermountain Healthcare, Salt Lake City: I don't know that it changes too much for the molecular area. We will bring in more testing that is currently being outsourced. It doesn't impact our instrument planning in other areas of our laboratory.


Brownell

Julie Hess, in hearing about repurposing and bringing tests back in, how do you square that with the labor shortage?
Julie Hess, VP, laboratory services, AdventHealth, Orlando, Fla.: As we think about how we repurpose instruments against a labor shortage, we could deploy the rapid testing we invested in to our smaller campuses, where they may have sufficient labor. Sometimes that is easier than keeping a test centralized. We're planning to do this with STI testing and group B strep. That is potentially a small increase in labor at a given campus versus trying to use large platforms.

What does next year look like from a budgeting standpoint? We still have PAMA cuts hanging over our heads.
Julie Hess (AdventHealth): We are all feeling that the budget-planning season we're going into might be one of the more challenging ones. We want to be strong with operations, but we will need to be creative.

Eric Carbonneau, what's going on at TriCore?
Eric Carbonneau, MS, MLS(ASCP), chief operating officer, TriCore Reference Laboratories, Albuquerque: Our focus for investment next year is on expanding digital pathology.

We looked at how we can redeploy the Hamiltons that we started using in the laboratory-developed test phase of COVID, so we redeployed those in some of our chemistry and esoteric labs. Now we're looking at investment in

automation in cytogenetics and other prep areas. Where can we automate? Because we don't have labor. We have staff shortages, contract labor is still an issue, and we are rural, and finding staff to go to rural laboratories is difficult.

In vitro diagnostic companies tell me they're grappling with labor and staff shortages and dealing with inflation in components that go into devices and test kits, from plastics to electronics. Dwayne Breining, are those affecting your finances at Northwell?
Dwayne Breining, MD, executive director, Northwell Health Laboratories, New York: It's going to be a tough budget year. The laboratories did great with COVID testing but it looks like it's going away, although we are a bit fearful of what the flu season can bring. For symptomatic patients, you'll have to test for flu and COVID, which might bring volume up. But just about everything else in health care has been hit hard by COVID. In some ways our system's looking to the laboratory to make up some of that gap, so it's going to be challenging.

Do you have acquisition plans for new technologies next year?
Dr. Breining (Northwell): We're bringing up NGS, specifically in the solid and liquid tumor oncology sphere. Just about everything we have on the PCR molecular front is reagent rental, so we have tons of equipment around.

We leveled off at about 3,000 COVID tests a day, and we've been at seven or eight percent positivity for a long time. We've seen COVID spikes occur rapidly in New York, which increases the demand 10 times or even more, so we are happy to have excess capacity because we're not sure what will happen in this flu season.

Dhobie Wong, what are you doing with the equipment you bought for the pandemic? Are you repurposing it?
Dhobie Wong, MBA, MLS(ASCP), CLS, VP of laboratory services, Sutter Health, Sacramento, Calif.: We're trying to identify primary and secondary platforms for our COVID and flu testing and additional molecular testing and consolidate that volume to get better pricing from vendors, as opposed to having a large swath of different instrumentation. We have a centralized reference laboratory with multiple molecular instruments—the Aries system, Roche, Cepheid—and we're trying to identify, by looking at our test menus, which ones we can consolidate to primary platforms. We're doing the same in the acute space, where we have Cepheid, Liat, Abbott.

Schofield

Stan Schofield, I am surprised by how readily people have adapted their COVID instrumentation to do other testing, and even insource some tests as opposed to sending out. What are your thoughts on what you've heard?
Stan Schofield, president, NorDx, and senior VP, MaineHealth: We didn't have to repurpose anything because we were doing laboratory-developed assays. We moved away from Roche as our primary instruments to Hologic for sample-to-answer devices.

People around the country are asking me, "What do you think people are doing with all the equipment?" And I've told them that repurposing, redirecting work, and reagent rentals—extending the menu and extending the term, if necessary—it's all the right stuff.

Budgets, contract labor, continue to be a big issue here, mostly for nursing. The system has cut $125 million out of the health system for capital next year, and we've cut 25 percent, from $4 million to $3 million. Cleveland Clinic reported last quarter the loss of $1 billion. Contract labor is not going away—nurses are not going back for $40 an hour. It's critical financially for every system at every hospital in the country—they can't solve it.

It seems paradoxical to add to test menus on devices at a time of acute laboratory labor shortages. Some say it's not a big deal to add another assay to a machine that's already staffed on shifts. Is that your feeling about it as you've been implementing those solutions?
Stan Schofield (NorDx): Absolutely. When it's a sample-to-answer device, you can get technical support to help set it up from one of the companies. They have the menu and the product. If it is a batch instrument and it's a laboratory-developed test, it's more demanding of staff time for development, validation, correlations, and implementation.

Dan Ingemansen of Sanford Health, are you doing a lot of point-of-care testing as Stan describes, sample in and answer out, and what does your next year look like?
Dan Ingemansen, senior director, Sanford Health, Sioux Falls, SD: Across our 100-plus sites, many of which are small hospitals and clinics, we have point-of-care analyzers. We are standardized across most of our platforms. Standardization requires capital, which remains difficult to obtain, especially for new projects.

Regarding our COVID testing equipment, we are continuing to use the Cepheid GeneXpert, Abbott Alinity m, and Roche 6800 to internalize new tests and replace aging platforms. We are struggling with a couple of pieces of equipment we purchased because of how niche they are. When we approached COVID, we had to scale and automate our processes—large, high-throughput extractors, liquid handlers, thermal cyclers, et cetera—and we have virtually no use for some of this equipment. The market is saturated with limited buyers. At the same time, they're being decommissioned, so we have dropped service contracts. Looking forward, we will continue to internalize—we opened a reference laboratory in Sioux Falls right before COVID hit. From a labor perspective, we're already touching the sample and preparing it for shipment. We feel there's just as much labor going into preparing the sample to send out and getting results into the system as doing a point-of-care sample-to-answer test.

Tony Bull, what are your plans?
Tony Bull, system administrative officer, Pathology and Laboratory Medicine Integrated Center of Clinical Excellence, Medical University of South Carolina: We are sunsetting our Abbott m2000 RealTime system and transferring to an Alinity m. We have Panthers, but we purchased those with an eye toward what we would do with them at the end of the pandemic, and we'll repurpose those.

We will continue to do point-of-care COVID testing with the ID Now at our clinics. I think a lot of what we'll see in the laboratory will be inpatient driven.

What is at the top of your list for an acquisition or a new testing venture for next year?
Tony Bull (MUSC): The system is always looking at further acquisitions, and we have one that's interesting because it's for a government-owned hospital, and the county commissioners have insisted it be done in the open, so the newspapers are covering the fact that discussions are going on.

In terms of new testing, we're working feverishly on a 500-gene panel as well as adding capacity to do fusion testing. We want those in place by the end of the year.

I'm hearing increasingly about the demand to do NGS in-house, if only for the comfort of the clinicians to have a person to talk to. There also seems to be turnaround issues in NGS. I did a webinar with a pathologist who showed the differential between sending it out and doing it in-house, and it was dramatic. Could you comment on that?
Tony Bull (MUSC): Part of the motivation for bringing NGS testing in-house is the turnaround time, and we are looking closely at how long it's taking us to treat and create care plans for cancer patients. This will help improve that.

Dr. Dysert

Peter Dysert, can you comment on doing NGS in-house versus sending it out?
Peter Dysert, MD, chief, Department of Pathology, Baylor Scott & White Health, Dallas: We've been using NGS for some time to do our human leukocyte antigen testing. Medhat Askar [MD, PhD], who joined us from the Cleveland Clinic, was on the forefront of transitioning many of the historic methods used in HLA laboratories to next-gen sequencers. We used a lot of that equipment as a secondary method for COVID testing. We're ever expanding our NGS capabilities. We just hired someone who is certified by the American Board of Medical Genetics and Genomics, and we have a couple of people working in our cancer center, relative to molecular- and genetic-based diagnosis.

Our percentage of inpatient COVID positives has remained about 24 percent; it represents a more judicious use of the testing because these are people largely presenting to hospitals with symptoms. And in those patients we've broken out those who are surveillance only or don't have signs and symptoms—that positivity rate is about eight percent. We've been able to segregate positivity rates based on clinical presentation.

The only piece of equipment we purchased was the Roche 6800 and we're planning to use it for insourcing.

Tell us about having NGS capability in-house for your cancer patients and oncologists.
Dr. Dysert (Baylor Scott & White): We have site-specific groups of clinicians whom we look to for direction on compliance with NCCN guidelines, for example, under the accreditation processes for cancer centers. We have a couple of molecular genetics pathologists who staff those meetings and listen to and work with clinicians to find the best solution to the clinical issues they're dealing with.

We look for site-specific, clinical experts to partner with us and help make decisions on which types of technology we want to standardize, and then we go through the process and they make a decision clinically whether to make it a standing, delegated medical order so it doesn't have to be individually ordered for one patient at a time. It's done reflexively. We try to standardize on and stick to what appears to have proved worthy of clinical use as a way to control demand.

We also have a popular and growing molecular tumor board. It's an educational investment on our side, run by a clinical oncologist and our two molecular genetics pathologists. We find there's an incredible appetite for these busy clinicians to learn more.

Milt Datta, can you comment too on NGS in-house?
Milton Datta, MD, chair of pathology, Abbott Northwestern Hospital, Allina Health, Minneapolis: We'd love to have more depth on the bench and the ability to put more panels together, but we're focused on using the standardized testing run with automated tests, and we have a committee with the medical oncologists to decide what tests we're going to run and for which tumor types.

One of the discussions we're having is about questions related to molecular test interpretation. Do we send them to our molecular pathologists and risk overwhelming them? Or do we use our subspecialty pathology model and expect our subspecialist pathologists to understand the molecular nuance for the tumors in the organs and areas they serve?