Next moves for core labs—panel takes stock

June 2021—*Pause and restart, or rethink and reorient? That's the question CAP TODAY publisher Bob McGonnagle put to instrument vendors and James Faix, MD, and David Grenache, PhD, D(ABCC), about COVID and core labs and the instruments in those labs.*

What impact the pandemic had on them and their customers was a topic of discussion when they met on an April 27 call during which they talked, too, about antibody testing and the proliferation of SARS-CoV-2 testing labs during the pandemic. What follows is part of their conversation. The rest, on IT and the staffing shortage, will be published in July, as will our guide to chemistry and immunoassay analyzers for mid- to high-volume labs.

See CAP TODAY's guide to chemistry and immunoassay analyzers for point-of-care and low-volume laboratories here.

David Grenache, we had a call like this about a year ago and we didn't talk about COVID-19 until the end of our discussion. This year I'd like to begin with COVID-related issues and I will repeat what we said a lot of last year: What's going on in chemistry and immunoassay? We have consolidation of lab sites, a real need for connectivity and scalability and platforms that are all in one family and can fit in the various sizes of testing sites that a given system may have. No one would disagree that these are still prime matters of interest on the part of companies and laboratorians. In your experience with COVID, running a core laboratory, how has that changed your outlook, if at all, about your core laboratory and the instruments we're discussing?

Dr. Grenache

David G. Grenache, PhD, D(ABCC), chief scientific officer and medical director, core laboratory, TriCore Reference Laboratories, and clinical professor of pathology, University of New Mexico: When I look at our core laboratory processes in the past year through the lens of the COVID pandemic, I see what I'm sure many labs saw: an abrupt decline in the volume of testing we were receiving, as patients, particularly outpatients, were not seeking the care they normally would. But there was a quick rebound. The effect that had on our core laboratory operations was minimal except for the decline in volume and therefore the decline in revenue. But the way our core laboratory functioned was still largely unaffected by the pandemic.

'We happened to be replacing our main automation line last April at a time when the volume of our routine testing had declined. That made that job easier.

We know that volumes dropped for a while and then largely caught up. Mike Massei, from Abbott's perspective, do you think we've had a pause and then will resume with consolidation, connectivity, and scalability concerns? Or do you see signs that some people may reorient some of their testing strategies, including those of the core lab? I'm thinking in particular of labor and supply chain, both of which have been under pressure and scrutiny this past year.

Mike Massei, senior director, global marketing, core diagnostics portfolio innovation and strategy, Abbott: A couple of interesting things happened as a result of COVID. One is that the value of the clinical laboratory and in particular the core lab was in the spotlight. As a result, some elements of the health care ecosystem will take a look at how to spur innovation and focus on how to increase operational productivity.

The volumes have come back up—not quite to 100 percent but close to that in most regions. As a result, for future

solutions and business continuity, laboratorians will be looking for solutions that continue to evolve the value proposition for the core laboratory.

Some of the attributes that the core laboratory, or any laboratory in the various volume segments, has been looking at in the past decade will continue to be important. But there is an opportunity now for greater innovation when we look at systems, quality of results, and efficiency from a workflow perspective and then the sharing of commodities, consumables, and commonality of results across the different system solutions, from the very low segments through the ultra-high segments.

Sean Roberts, would you like to add your own perspective?
Sean Roberts, senior product manager, chemistry/immunoassay business, Beckman Coulter: We experienced a slowdown in reagent sales and have now recovered in all geographies. We did see some deferral of new instrument installations as well. What the COVID crisis gave us is an opportunity to have a more intimate provider-customer relationship in terms of supporting clinical research. COVID raised many questions that we had to answer around immunology, and specifically about immunoassay being well suited to serology testing, antigen detection, and all the technologies that were put into play in a crisis mode. All of us had to address this on a scale we had likely not seen in our lifetimes. The stresses of COVID drove an intimacy between the customer and provider and research support that was escalated and compressed.

Did you find it difficult given your lack of direct access to laboratories?
Sean Roberts (Beckman Coulter): No, not at all. We have direct access to laboratories and great research partners, and we just redirected a number of areas of focus into COVID research, particularly around those aspects that lend themselves to the immunoassay and nucleic acid testing technologies.

Brittany Greiner, what was Roche's experience with its customers and systems, and will there be a rethinking of things? Or is it more "We had a pause, we recognized how serious it was, we have addressed it as best we can, and now we're moving back to normal in core labs in the instrumentation we're discussing in chemistry and immunoassay"?
Brittany Greiner, U.S. marketing manager, Roche Diagnostics: Everybody has had a similar experience. At Roche we are seeing an uptick not only in the core lab but also in decision-making. Customers are off the pause button and now making decisions because they might have systems that are old and breaking down and have to be replaced. Customers are asking how they can maximize their purchase with the vendors. For example, what are we doing to help with staff shortages? They also want to maximize their purchase with a vendor that is continuing to bring new tests to the market. In terms of COVID, customers want to know how manufacturers are continuing to expand menus and offerings for their patients.

Denise Pastore, what is the Siemens Healthineers perspective? How did COVID impact the core lab and the instrumentation in it? Is it a pause and now things will resume, or is there rethinking and reorienting?
Denise Pastore, director of global marketing, laboratory diagnostics, Siemens Healthineers: We are resuming like everyone else in terms of the volume of testing performed on our analyzers. What we all had to do is work on a couple of different levels, not only in the core lab with the antigen and antibody testing but also for the point of care because of the rapid tests and the demand for them. We had to expand in all of those directions. The core lab has rebounded well. Assays were added that will remain with us for the next couple of years. The biggest difference is the surge in point of care for the rapid SARS-CoV-2 tests.

James Faix, what was your experience in coping with COVID, particularly with your being in New York?
James D. Faix, MD, medical director, clinical chemistry and immunology, Montefiore Medical Center: It was a bad time, depressing and scary. Even though the number of cases nationwide wasn't as large as during the second wave, New York seemed to be the epicenter. A lot of people worked from home and I too could have done a lot of work from home, but I felt it was important for me and for other leaders to be there, to be on site to support the people who couldn't work from home—the technologists and phlebotomists. The phlebotomists bore the brunt of the psychological problems because they had to draw blood from patients who were dying day in, day out, and it

was important for all of us to be there to support them.

Dr. Faix

As far as the core lab was concerned, the impact was that we had less work to do because of the shutdown of the outpatient areas and elective surgery. Our virology section was the hero. Our virology lab director got every possible platform available for RT-PCR implemented early on. She saw this coming in February and they stepped up and were remarkable in terms of the way they handled the testing.

David Grenache, were you surprised at what might seem like the low level of demand for antibody testing in the past year?
Dr. Grenache (TriCore): I was surprised initially but only because when we were bringing up that antibody test, which we started doing in April, we were so focused on getting it done that I made a cardinal sin in laboratory medicine: not stopping to think how the test would be used. It quickly became apparent that we weren't likely to use the test in the way we might have earlier briefly considered it would be used. And then we pushed out messaging about what the appropriate use of an antibody test was and how it should not be used. So when the large volume of antibody testing failed to materialize, I was relieved and somewhat satisfied because, although we figured it out a little later in the game, our messaging seemed to have been effective.

One would think the demand for antibody tests would be much greater post-vaccination, that it may even be the niche for antibody tests, at least for now. Sean Roberts, is that what you're seeing at Beckman?
Sean Roberts (Beckman Coulter): Yes, that's what we're seeing, and it's keying off of Dr. Grenache's comment that what people were looking for with antibody tests has evolved over time. We ramped up for a broad variety of potential applications and then people found various niches for themselves. This ranged from thinking about convalescent plasma screening to monitoring immune response post-natural infection, to the highlight of our current research—post-vaccine immune response monitoring. A common question today is, how long am I going to be immune after getting my COVID shots?

Dr. Faix, do you have a comment on antibody testing?
Dr. Faix (Montefiore): I don't have much to add except that it's a good example of people requesting a test for which there is no known indication or clear purpose, and wanting information they don't know how to use. It's not uncommon in laboratory medicine: People want test results, sometimes whether they can use them or not. This is a good example.

Jeff Watson, tell us about Sunquest's experience, particularly in this area of the core lab and the chemistry and immunoassay instruments.
Jeff Watson, MT(ASCP), MBA, senior director, product management for clinical solutions, Sunquest Information Systems: The experience we had in the past year was similar to the experience of the IVD companies. We saw a decline in the typical upgrades and new purchases. But we saw a big uptake in new instrumentation being deployed, and we worked with clients to stand up temporary units and beds and then later with the demand for testing.

In the area of chemistry and immunology, we're beginning to see people deploy or start to deploy new instrumentation, after the pause in 2020. The numbers of new lines coming on is increasing. We haven't seen a tremendous amount of change in what they want to do from an interfacing perspective, at least in these areas.

Curt Johnson, what are your views on the past year and what has it meant to Orchard and for your customers?

Curt Johnson, chief commercial officer, Orchard Software: At the same time that core labs may have taken a pause, independent small reference labs sprung up across the country focused on COVID testing. Those labs started with one test in mind, but many of them have since grown and are taking on additional testing. Whether that growth will continue will be interesting to watch.

Laboratory testing and diagnostics and laboratory information are gaining more of the spotlight they have always deserved based on how critical they are in the continuum of care, to not only better serve patients but to reduce costs. The other thing COVID is doing is changing the dynamics of how information gets transmitted to patients. For example, college students had more laboratory testing done in the past year than they've had in their whole lives, and they want the data to go directly to them. They want it on their phones, they want a patient portal, they want to be able to access that information in ways we haven't seen in the traditional markets. So not only is interoperability and exchanging of data going to be important, but also the testing is moving closer to the consumer. Information needs to go directly to the consumer as well as to their physicians and other care providers. That will continue to evolve over the next several years.

Greiner

Brittany Greiner, do you predict that this proliferation of new labs will be short term? Or will it shift the testing landscape in some way—in particular, some of the offerings from Roche and other test manufacturers?

Brittany Greiner (Roche): I don't think we have a good enough pulse on that to make a long-term prediction. Overall, yes, the testing dynamic has changed, it's evolved, and manufacturers are evolving with it, whether it's asking ourselves things like how can we train our customers in a different way or how can we support our customers virtually? These are small dynamics outside of the norm we've talked about already aside from expanding our menu, not just by bringing new testing to market but also expanded claims within the same menu.

David Grenache, what's your perspective? TriCore serves an entire state. What do you make of so many new labs springing up? Did you see that in New Mexico?

Dr. Grenache (TriCore): Yes, we saw a version of it. We didn't see a lot of new labs pop up; we saw an expansion of services in some existing smaller labs that have carved out a niche for themselves. It is difficult to be an independent laboratory in 2021, and TriCore is a big lab for the state of New Mexico but we are an independent lab and times are tough with declining reimbursements and expectations of faster turnaround times and greater quality. In a state like New Mexico where we have a lot of rural areas, getting qualified technologists and laboratory personnel to come here to work is a challenge. I know I'm singing a song that's familiar to the folks on this call; everyone is struggling with that. So some of the new labs that popped up are probably going to find a way to stay alive, but I don't think many of them will have a long lifespan.

Curt Johnson (Orchard): There's a parallel to be seen with the toxicology labs that sprung up in the past five years or so. When toxicology and pain management first hit, labs sprung up across the country and they didn't all survive. I think we will see the same thing for the COVID labs. Labs that get into the business with a focus on the patient and have a true understanding of the benefit they can bring have a better chance of survival than the ones who say, "Hey, I have a chance to make a lot of money. There is an opportunity here. I should jump in."

Now, there are many toxicology labs that probably shouldn't have survived, but they adapted and added COVID testing to their portfolio and that kept them around longer. Many of the COVID labs will go by the wayside. Those

who can adapt and understand the molecular technology they have in hand and understand how to use it for patients and how to move their offerings closer to the patients will be the ones that are successful. Most of them, I believe, will fade away over the next three to four years.

Mike Massei, let me ask you to comment on this same question. I do so in part because Abbott has wonderful technology for the core lab and for point-of-care testing. The latter was featured heavily on the lawn of the White House several times last year. What do you make of this current situation as you see it?

Mike Massei (Abbott): The past year was a remarkable time in terms of innovation not only from Abbott but also from many players in the market, spanning molecular, core lab, and point of care, in addition to telehealth and telemedicine and that change in dynamic in terms of the ordering and where the laboratory testing is going to. That's normalized a little now, but that market has changed and that business model will change for certain types of laboratories, possibly the core laboratory and likely the commercial reference laboratory. We've already seen examples of that.

One of the other opportunities is that it could refocus some of the testing or some of the development for testing toward population health and preventive medicine. It also presents an opportunity to get greater access for people who need testing in more rural areas if they don't have the same access to health care institutions, professionals, and laboratories. So there's a lot of opportunity that will be evaluated in the future.

Denise Pastore, do you also see some of these new labs remaining, as important players and almost a new source of new blood and innovative thinking?

Denise Pastore (Siemens Healthineers): Some may, but I tend to think not because in the United States more than 60 percent of labs are within some cohort of an integrated delivery network or a buying group and things like that—they have to be in order to thrive. These smaller labs may thrive for a period. This is a pandemic; when that starts to decrease, they don't have everything that, for example, the major reference labs can provide: patient service centers, couriers, the LIS, the EHR connection. They don't have that infrastructure to support them, and if they want to grow, it is going to mean investment. I tend to think they may not remain very long.