

## A panel's take on instruments, connectivity, COVID

July 2020—Has the pandemic changed your thinking or that of your customers? That's one of the questions CAP TODAY publisher Bob McGonnagle put to seven representatives of five companies and two other panelists in a May 13 roundtable on chemistry/immunoassay analyzers and testing. But first up were other topics: scalability, connectivity, standardizing platforms across health systems, consistent sourcing of antibodies, and open automation.

The panelists were Gyorgy Abel, MD, PhD, of Lahey Hospital and Medical Center; David Grenache, PhD, D(ABCC), of TriCore Reference Laboratories; Brittany Greiner of Roche Diagnostics; Denise Pastore of Siemens Healthineers; John Naizer, BSc, MSc, of Randox; Timea Zsiray and Sean Roberts of Beckman Coulter; and Chad Meyers and Jeffrey Watson, MT(ASCP), MBA, of Sunquest Information Systems. Here is what they had to say. ([CAP TODAY's guide to chemistry/immunoassay analyzers](#))

**Dr. Grenache, in past roundtable discussions the topics that have been top of mind and seem to emerge consistently when we talk about instrumentation are matters of menu. We talk about the scalability of analyzers from a given vendor; in other words, can the same analyzer and test method be accommodated to all the various sites, large or small, that the analyzer needs to serve for the hospital or health care system? Connectivity comes quickly into these instrumentation discussions, not only for the laboratory but also result reporting into the EMRs. We have talked about consolidation and about labor shortages in the labs and how instrumentation can help with shortages.**

**Can you comment on whether these topics are top of mind for you as you think about chemistry and immunoassay instrumentation?**



Dr. Grenache

*David Grenache, PhD, D(ABCC), chief scientific officer, TriCore Reference Laboratories; medical director, core laboratory; and clinical professor of pathology, University of New Mexico:* They are critical for TriCore Reference Laboratories. We're a system laboratory. We operate everything from a high-volume reference laboratory in Albuquerque, to large medical center laboratories, to laboratories that are in small critical access hospitals in rural New Mexico. We need to stay on a single platform as much as is practicable because all of our data goes into a central repository and we don't want differences due to different platforms to complicate that data.

Scalability is critical. Our critical access hospitals have very small laboratories, yet we are expected to operate a full-service menu. So we need instruments that can fit the space yet have comprehensive menus, as comprehensive as they need to be for a small hospital. And in the reference lab we need a greater number of instruments to accommodate the volumes, yet consistency with the platform and the menu. So scalability is essential.

If you were to walk into my core laboratory now, you would see instruments from a variety of vendors, with one vendor's platforms predominating. That's not desirable for all of the obvious reasons. It's important that we consolidate to a single platform, as much as possible, to gain economies of scale.

And then there's the personnel issue. New Mexico is not unlike many other states; we are challenged with having access to an appropriately educated and trained workforce. The more we can do with fewer staff because of ease of operating instrumentation or the consolidation that can be enjoyed with some platforms, the better it is for our

operation, which means it's better for our clients and ultimately better for the health of New Mexicans.

**Denise, what are your thoughts on what I mentioned in my opening question and on what Dr. Grenache has put succinctly and eloquently around his needs at TriCore? I assume you're hearing similar things from not only your customers but also your potential customers around the world.**

*Denise Pastore, director of global marketing, laboratory diagnostics, Siemens Healthineers:* Absolutely, and especially in the United States, where diagnostic laboratories combine into networks to thrive. As Dr. Grenache said, the customer needs a range from a low-volume solution all the way to a mega-size solution; many technologists and technicians are retiring now, so the basic skill sets may not be as sophisticated as they were previously.

In answer to that, we need to produce instrumentation and user interfaces that can meet those customer needs, and that's what we're doing at Siemens Healthineers, with a range of instrumentation that will be compatible regardless of the size of the laboratory. Scalability is one of the key metrics of our Atellica Solution because it comes in multiple configurations—greater than 300.

Being able to consolidate all testing is also important, and strong IT can help laboratories accomplish that goal and standardize information across all of our available laboratory diagnostic platforms. The Atellica Data Manager and Atellica Process Manager from Siemens Healthineers help to accomplish that standardization.

**Jeff, at Sunquest you're dealing with all kinds of instruments and instrument vendors. Can you comment on what you've heard so far, in particular the importance of connectivity in the systems and the management of the workflow?**

*Jeffrey Watson, MT(ASCP), MBA, senior director of product management and clinical solutions, Sunquest Information Systems:* It's very much the same set of drivers that we see coming from our clients. They look to have connectivity. It really is around consolidation. A lot of our clients are in the acquisition mode, so they're acquiring new health care facilities, and as they do that, typically they look to standardize the instrumentation.

We also are seeing that even in our clients in the U.K., where they're moving into laboratory networks the NHS Trust hospitals that in the past operated kind of independently. We've got a large client in London that has about seven hospitals where they are just standing up this past year a new centralized automation line to manage the immunochemistry and chemistry testing that doesn't have to be done on a stat basis. So even there they're driving for consolidation and economies of scale.

The ask from our clients is how we can help them from the LIS and connectivity perspective to manage complex rules around autoverification. As they consolidate, they're looking to drive an 80, 90, 95 percent autoverification rate across the organization. We're able to do that with our LIS product proper but also in conjunction with our sister company, Data Innovations.

We've been doing a lot of work, in combination with Data Innovations, where a number of Sunquest customers—TriCore being one of them—have moved to have all of their instrumentation run through Data Innovations and then connect into Sunquest Laboratory. That gives them that combination of a powerful data set that you have in Data Innovations, as well as what you have in the LIS so you can much more fine-tune that autoverification and drive those numbers into the high 90s.

**Timea, what are your thoughts on these topics, and in particular about the need for autoverification solutions not only to foster productivity in labs but also, to some degree, to make up for labor shortages?**

*Timea Zsiray, senior director, global marketing, Beckman Coulter:* There is a lot of similarity with what has been said. We at Beckman Coulter believe that instruments, automation, clinical informatics, and menu should form a comprehensive, harmonized solution that is tailored to the needs and size of the specific laboratory. In our view, the need for automation as a productivity tool is absolute, but we don't believe in one size fits all, and that starts

with instrumentation. Labs of different sizes have different needs, as Dr. Grenache pointed out, so it's important that we bring solutions to fit the operation. An instrument that is best suited for a medium-size laboratory will not optimize the workflow in a high-volume laboratory just by virtue of "multiplication." Therefore, it is important to consider the right instrument specifically designed for the size of the laboratory and then integrate it with the right automation solutions.

At Beckman Coulter we believe that every laboratory should be able to harness the power of automation. Historically, automation was the privilege of the large-volume laboratories, but if you look at the laboratory workflow, 70 percent of the work is happening in the pre- and postanalytical phases and those parts are labor-intensive, so the need for automation is universal—independent of the size of the laboratory. Solutions that will fit in the different size laboratories but help with the physical automation of the processing of the tube will continue to be vital for the industry.

Lastly, we need to rethink automation to be inclusive of not only the physical movement of the tube but, to your point, Bob, of autoverification, automating data flow. Automating the physical movement of the patient sample is only half the solution. There are lots of manual data-processing steps that can be automated with clinical informatics solutions.

**Dr. Abel, we know there is much consensus around these topics. Would you like to add to the consensus or react to what you've heard so far?**



Dr. Abel

*Gyorgy Abel, MD, PhD, medical director of clinical chemistry, molecular diagnostics, immunology, and point-of-care testing, Department of Pathology and Laboratory Medicine, Lahey Hospital and Medical Center, Burlington, Mass., and instructor in pathology (part time), Harvard Medical School:* For the most part I will be in consensus. First, as everyone pointed out, the key change has been the formation of health care systems. Laboratories had to adapt to the health care systems, and some players in the systems with bigger hospitals have large laboratories. Others have smaller laboratories but sometimes with bigger analyzers that could do almost the same menu as was available in the larger hospitals.

This is not sustainable, and as my colleagues pointed out, the manufacturers needed to adapt to this and they did respond well. Most of the manufacturers now have larger and smaller modular instruments so there is scalability. Even if many of the smaller hospitals don't lose the laboratory entirely, they are delivering testing only for their OR, ER, and inpatients, but they still need to maintain a 24/7 laboratory with basic chemistries, hematology, and coagulation testing. The bigger hospitals' labs can do all the specialty and nonurgent chemistry and more complex testing.

Clinical chemistry tests, and with no disrespect to any of the manufacturers, are commodities to some extent, because probably 80 to 85 percent of the test menus of the major manufacturers overlap with some specialty tests and with certain innovations. But most of them measure all the cholesterols or enzymes, electrolytes, and so forth and the basic immune assays for liver disease, heart disease, and so on. So it's hard to differentiate between them. It's like selecting between a Honda Accord and Toyota Camry. Both are good but you need to look at your own specific needs. Where they can distinguish themselves is in areas that emerged over the past decade—for example, middleware, connectivity with the LIS and EMR, and the modularity. There are areas where they can make themselves stand out from the others.

On one point I would disagree. Dr. Grenache mentioned that you want to have one system, and in general I agree. But it is good to have a second vendor, at least in the larger laboratories. I say this because if the FDA pulls out one test from one vendor and if everyone is on that same vendor, you have all eggs in the same basket and you will be left without the test and have to scramble to bring on another vendor. It's much more convenient if you already have another vendor, an alternative or supplementary vendor, that provides much the same or a similar test menu, and they can be harmonized. It's quite a bit of work, but at least in the health care system, it's good if at least two vendors are present.

Another situation would be like the COVID-19 situation. One by one the vendors will have a COVID IgG or IgG plus IgM or total antibody test, but over time we will learn that some of these are better than others. If you have a choice between two vendors, you have those systems at least in your health system in one of your hospital laboratories, then you will have a choice. You can choose the better one or you can choose which is first available. So it gives you flexibility and protection against certain disastrous events that may happen with the systems or some tests of one of the vendors.

**Brittany, Dr. Abel has put his finger on one of the challenges we have across the board in a lot of areas of diagnostics, but maybe specifically in the core lab and chemistry and immunochemistry, and that is product and company differentiation. Please give us your thoughts on that.**



Greiner

*Brittany Greiner, marketing manager, systems, Roche Diagnostics:* From a Roche perspective, we're always collecting and gaining feedback from our customers and that's where we put our focus. We have heard a lot already about standardization. We see a lot of consolidation in the market and the need for standardized solutions, and there is benefit to that inside and outside the four walls of the lab. Within the lab, having one system to train your staff, one user interface, one analyzer to maintain, one IT solution—you can quantify the savings as the benefit of having a standardized solution. Outside the lab's four walls, there is benefit in having common reference ranges for interpretive accuracy, in the physician being able to trend the results over time, in one result for the physician, the hospital, the long-term care facility, et cetera.

The second is the menu. Roche takes pride with its R&D in being able to provide and give its customers access to an often first-to-market menu. We invest regularly in new claims for existing tests to put actionable information in the lab and in the physician's hands.

We are also focused on shaping and driving digital diagnostics. We provide a suite of software solutions that will enable laboratories and health care providers to drive the future of care delivery. At the core of every health care decision is diagnostic data, and with Roche Digital Diagnostics, health care professionals are empowered to leverage this data with our broad portfolio of solutions that are designed to work together with our systems.

**John, as a sales manager for Randox, are these the sort of things you hear in the list of asks that potential customers have?**

*John Naizer, regional sales manager, Randox:* A lot of people ask how many tests can be performed on our machine in regard to how large the menu is, because Randox specializes in having a large esoteric clinical chemistry test menu. Often their interest comes down to their being able to run all these tests on one instrument. Maybe there is one specialist in a hospital or clinic who wants to run a highly esoteric test like lipid subfraction, and we're able to offer that type of thing. It can save them time in bringing on a third-party assay. That's the way we have been able

to help and assist customers, along with making sure to be up to date with the most recent software and operating systems.

**It used to be that many people in laboratories had a particular liking for one vendor's immunoassay for a given analyte. Perhaps they thought one immunoassay company had a better fertility panel or anemia panel, for example. Sean, do you still see some of this desire to mix and match depending on the feelings about the individual assays?**

*Sean Roberts, senior manager, chemistry/immunoassay business, Beckman Coulter:* What we see with our customers is a balance between two points in terms of consolidation and being able to standardize across a network and those customers that would prefer to keep each of their existing laboratory instruments within their network. We're able to integrate either approach. We can convert laboratories to Beckman Coulter systems, again offering a scalable solution of what I'll call small, medium, and large solutions, offering common reagents across those platforms to provide standardized results, middleware that will integrate all results across the network, and rules writing and control. We can add in an instrument simply for specialty testing. We have open automation systems that allow connectivity of other systems, so we can enable the construction of multi-vendor laboratories if the customer so desires.

**Dr. Grenache, based on what you've heard, is there something you'd like to add or highlight at this point?**

*Dr. Grenache (TriCore):* Open automation—larger laboratories, reference labs, large academic labs really need solutions like that. There are a lot of things I want to add to our automation line but I can't do it. So open automation is like a Christmas gift under my tree.

The other thing I have in mind hasn't been mentioned. We talk about standardization and maintaining consistency, especially with immunoassay. What often goes unrecognized or is unappreciated is the need for consistent sourcing of antibodies. I get the sense that not every company sources its own antibodies or manufactures them or has the ability to do so, so they rely on other parties to do that. And maintaining consistency in immunoassay is something we all recognize as important. When I have the opportunity, I ask, Where do you get your antibodies for your immunoassay? I want to understand that because I need to guarantee, as much as possible, consistency in our immunoassay methods.

**Denise, can you comment on Dr. Grenache's comment about the consistent sourcing of antibodies for immunoassays? We don't have to work too hard to find a considerable literature now on immunoassay performance, and it's not always flattering. So tell us what Siemens is doing to ensure the performance of the Siemens immunoassay products.**



Pastore

*Denise Pastore (Siemens Healthineers):* Yes, we know the criticality of antibody consistency. When you shift antibodies, sometimes you will see that the results have shifted, and this has an impact. It is important at Siemens Healthineers that we make sure to keep antibody pools consistent. And we are making strides in our Walpole [Mass.] facility, which we have just expanded, to do just that. We're making sure we have continuity from lot-to-lot production so that we can provide customers with a product that will drive consistency regardless of a lot change.

**Brittany, what is the Roche Diagnostics perspective on this?**

*Brittany Greiner (Roche):* At Roche we manufacture all of our reagents, but we do allow for third-party vendors or partner channels. Our longtime partner is Hitachi; that is our manufacturer for our instruments and all of our digital portfolio. Everything is designed to work together. That means a better customer experience of our total solution.

And then there is the benefit of our quality. We have our patent in electrochemiluminescence and it's unique to Roche. It provides a broad measuring range, low-end sensitivity, and lot-to-lot consistency, which also comes from our standardization process to deliver a quality reagent from the launch of a test through each subsequent lot release.

**Sean, would you like to comment on the importance of consistent sourcing of antibodies for the immunoassay business?**

*Sean Roberts (Beckman Coulter):* Beckman Coulter has a long history of intellectual property in monoclonal development and production, and in our Chaska [Minn.] facility we grow many of these antibodies in-house, so they are in our control—both antibodies and cell lines for expansion. We can guarantee the consistency of the products we release through those production control processes.

Even though immunoassays have been around for some time, the technologies that go into antibody production, cell culture, molecular biology have all been capitalized upon at Beckman Coulter, such that we're incorporating the latest and greatest technology. So even though it's an immunoassay with an antibody, please don't think that there isn't new technology there. We remain laser focused on reproducibility and quality results.

**John, what can you tell us about antibody sourcing from the Randox perspective?**

*John Naizer (Randox):* Our line of immunoassay testing is specific to more the research side of things and specialty testing and esoteric biochemical markers. We grow a lot of our own monoclonal and polyclonal antibodies in our facilities in Northern Ireland and the Republic of Ireland, so we're able to control what gets released, what gets put on our chips, for testing. We do take pride in making sure our system is foolproof at being able to keep the best antibodies in production.

**I want to move to the next issue on the IT side—how we are getting these results into the EMR. We continue to see, in large systems, domination by Epic. There are a lot of Cerner EMRs out there. And yet we hear about the problems in populating the EMR lab data that the physicians have to access to make decisions. Chad, could you give us a bit of discussion about this?**



Meyers

*Chad Meyers, vice president of product management and strategy, Sunquest Information Systems:* Historically there had been the ability to view that data in the EMR in a more textual format. But as the technologies improve and there is more digitization, images, quantitative data, and other types of complementary information included on the report by the clinicians and the laboratory staff, we're finding that the need to be able to display rich and formatted content in the EMR, such as hyperlinks or images, has grown.

We continue to collaborate across instrument and LIS vendors and EMRs to allow for as much rich content as possible on the report, using PDF attachments, so the clinicians can get the information they need. We continue to see evolution there, but there are still times when clinicians are frustrated because they're not getting the fully rich content in the EMR or have trouble finding it.

**Dr. Abel, from your experience at your institution, can you comment on that?**

*Dr. Abel (Lahey):* It's critical that the entire health care system is on the same EMR/LIS, and every health care system should focus on achieving that. It takes time to achieve that, so which EMR it should be is a big decision. No matter which EMR/LIS is used, a lot of work is required to get everyone under the same umbrella, but it's critical to have easy access to the patient records from all parts of the health care system.

Communication between the analyzers and the LIS or the EMR can be achieved through innovative middleware solutions. Reliability is important for all of these analyzers, as is test menu, speed, easy operation, and low maintenance. But one of the competitive areas is the innovative middleware solutions to make these communications easy.

Standardizing across the system with the same one or two vendors is also difficult because when the health care system starts up there are various vendors, and it takes a lot of time and negotiation and looking at all the proposals to decide which is the right fit for a system.

These immunochemistry analyzers are big systems on which the majority of the tests are run. It takes a lot of money, full-time employee work and commitment, and even space to switch because you still need to maintain the operation with your old system. Most vendors come up with a new system every 10 years or so, and I would say much of the chemistry technology is settled. Every 10, 15 years, one might want to think about whether the system is still the right system to use. But switching from one vendor to another is difficult, so most laboratories do it only if they see something innovative or are unhappy.

**I'd like to talk further about the display of chemistry and immunoassay results in the EMR. Dr. Grenache, are you satisfied at TriCore, as a reference lab serving many clinicians and nurses, that that is going smoothly and satisfactorily from your perspective? Or is there still room for improvement in the display of results?**

*Dr. Grenache (TriCore):* There is still room for improvement and that's not to say that what we're currently doing—the collective all of us—is poor. It's just that there are inherent limitations in HL7 messages. Chad was talking about how we have started to move beyond just providing discrete data. It's no longer just a numerical result in a reference interval. Many times we're asked to provide graphics, images, or tables. It's not always easy, particularly in immunoassay for some steroid hormones, to provide adequate reference intervals for all the different partitions in terms of sex and age. That can be a challenge depending on the EMR that laboratory is connecting to.

How many PDFs do I get sent to me each day as an email attachment, yet I can't send a PDF of an enhanced report of lab results—electrophoresis results, say, that have an image of the gel or the electropherogram. I can't push that across an interface easily into an EMR. Or if I can, many times what we hear from our customer end is, "No, no, no. I don't want your PDF because it's just going to take up space." Which I don't understand because PDFs don't appear to be that big.

So to answer your question, yes, there is still more to be done and I look forward to getting there. We still have, in some cases, to print out an enhanced report and put it in the mail to get to the client the information that certain clients want. Yet we have this amazing technology where we should be able to push it across a network and have it end up in the EMR. But there are challenges that are still difficult to solve. We'll get there eventually, but we're not there yet.

**When we talk about chemistry being sort of routine and easily commoditized, is that in part because the clinicians themselves have routinized and commoditized the data they're looking at? How often are you asked for an interpretive comment on the results you're presenting to these clinicians?**

*Dr. Grenache (TriCore):* I hate to think of lab tests as a commodity and we have to push back against that, because when something is a commodity you buy it at the lowest possible price. And there's tremendous value in our

laboratory data that we—again, the collective we—have to do a better job communicating and demonstrating. This is something that TriCore has been passionate about and has been working diligently toward. And I think it's starting, slowly, to get recognized—the inherent value of these huge data warehouses.

I'm asked for an interpretive comment with some frequency. Usually it's related to a confounding result, something that doesn't make sense to them, and almost immediately they call me or they call TriCore and they find their way to me, but usually it's around some sort of interference and they're concerned about a result being compromised because of x factor. So it does happen, though maybe not as often as it should. I don't think clinicians largely recognize that there are laboratory professionals they can turn to for help and consults. That's been an age-old problem in our profession.

**Dr. Abel, how often are you asked to add interpretive comments and field questions and consults on results, particularly from chemistry and immunoassay?**

*Dr. Abel (Lahey):* I would like to first say that by no means did I mean that lab tests are commodities. I meant only that the most common high-volume tests are widely available on all of the systems and largely at the same quality. So it's hard to find distinguishing qualities—which system measures better potassium or better sodium?

I am asked questions or to provide interpretive comments quite often. It is actually our main job now, in addition to, of course, safeguarding the patient's safety and the high-quality testing in the laboratory. Our main job is to be available for questions and to look for opportunities where we can provide interpretation, advise the clinicians, participate in all of the committees in which order sets are made, and help clinicians optimize laboratory testing.

We want to have improved quality at lower cost and that's possible if we decrease the use of tests that are outdated or over-ordered. We monitor that. We also have to increase the use of tests that are highly valuable and develop algorithms, order sets. I spend much of my time receiving and answering emails or pager calls about what to order or how to interpret critical tests, particularly in immunology and molecular testing but also in coagulation or just when they see an unusual result. They ask us what might be the reason for that unusual result. This is a big part of our job these days, and this is how it should be. It's not about volume anymore; it's about value, and we can provide it.

We are heading into an era that is more like managed care, where we want to provide optimal care and decrease health care costs. The laboratory can play a huge role, not just by lowering laboratory costs but overall by finding the more optimal management of patients.

**Dr. Abel, to some degree, is alluding to the famous Dr. Michael Laposata, who is the chair at UTMB Galveston and who in many ways led the charge for optimizing test ordering and interpretation. And Dr. Grenache is involved at TriCore in the Clinical Laboratory 2.0 initiative. These are two important lines of thinking as we address the future. And of course there is a lot of discussion about what the proper test menu is, eliminating unnecessary tests, having testing algorithms to optimize care. Brittany, can you tell us briefly about Roche's participation in this? And I'd like the others at companies to do the same.**

*Brittany Greiner (Roche):* Viewics is part of our diagnostics and digital portfolio, and that is for test optimization and utilization. It is providing a broad portfolio of solutions to meet the needs of our customers.



Zsiray

*Timea Zsiray (Beckman Coulter):* I'm going to borrow from the Lab 2.0 initiative, where it was said that the lab is the first to know. The laboratory has tremendous insight and plays a critical role in patient care. It is important that we—industry partners—provide solutions that free up the time of the scientists, the medical technologists, and give them time back to collaborate with the physicians and to become part of the care team.

This is how we view it at Beckman Coulter: How can the various disciplines, the various parts of the organization—i.e. instruments, automation, and clinical informatics—be integrated and add to each other in terms of making the whole system more intelligent? We have a tremendous opportunity to expand the power of automation to the various sizes of the laboratories, to remove the mundane, non-value-added tasks from the daily routine, which will free up medical technologists' time and ultimately translate into operational efficiency.

*John Naizer (Randox):* We always speak with customers and use the newest software and technologies to aim for the quickest and best results with all the supporting documentation.

*Denise Pastore (Siemens Healthineers):* In our existing middleware we have a lot of flexibility in our coding and algorithms that can be customized at the customer level so laboratories can avoid unnecessary testing and put in proper reflex testing.

In Clinical Lab 2.0, labs establish the value they bring not only to the institution but to the community at large. One of the ways we are trying to do that is by helping with data support software to help guide the physician when they get a set of results. What is my next step? Where do I take this from here?

*Jeff Watson (Sunquest):* We're working on a module for Sunquest Laboratory called Clinical Validation, focused on the interpretation workflow. It automates the process of moving those noninterpreted results from the bench into a platform on which a pathologist, medical director, or supervisor can make that interpretation and get that information quickly to the clinician. It goes out not only with a numeric result but also with that interpretation attached.

**How has the COVID-19 pandemic altered your thinking about the issues we've spoken about? When labs adopted Lean in the laboratory, they made supply chains skinny in the interest of efficiency, trying to consolidate on one system vendor. This has left some laboratories a bit short because they simply didn't have a platform on which to run available tests. Has COVID altered your thinking or that of your customers?**



Naizer

*John Naizer (Randox):* It has changed the thinking of Randox customers in terms of what tests are the most important to run and the volume the lab is running. They're thinking: We're not seeing all these patients anymore, so how can we change our day-to-day operations to save money and be more efficient? Many customers we are talking to are looking at smaller kits. They say, "We used to buy this kit that does 1,000 tests but now we're running only 100 tests before it expires." So we are asking: How can we find ways to keep products as long as possible to be up and running? We are aiming to find them kits that have a longer shelf life. Or: "Once we have COVID-19 patients and they're being treated, what requests are going to be increased for testing?" We're trying to work with them to find out what's the best way to get results to people and still run the lab efficiently and save time and money with limited staff.

*Timea Zsiray (Beckman Coulter):* It reinforces the need for thoughtful development of high-quality assays that provide meaningful insight clinicians can use, and the importance of strong partnerships with our customers and

with strategic partners in terms of the supply chain. The pandemic has reinforced fundamental core values.

*Sean Roberts (Beckman Coulter):* I agree, and I would add that the pandemic is presenting the laboratory with an opportunity to prove itself at how it can be effective in managing patients and patient care and outcome.

It's rewarding to see a company like Beckman Coulter, and Danaher, put their full weight behind this pandemic. It brings great pride that we can have that impact on patient care.

*Denise Pastore (Siemens Healthineers):* It was a pleasure to see all the vendors working side by side and talking with the administration to the public about the testing they're providing. From a Siemens Healthineers perspective, one thing we were able to do is provide a pocket guide for physicians and nurses on what other tests you want to conduct once a patient tests positive for COVID-19, to help in furthering their therapy.

Because of the limitations in getting into the laboratory, we capitalized—both customer and Siemens Healthineers—on the remote support. Reliance on remote and virtual health has increased.

*Brittany Greiner (Roche):* The pandemic has been at the forefront of our thinking and our decision-making. We want to be there to support our clinicians, laboratories, and patients in the best way we can. That is where our focus is. We introduced two new tests quickly to the market, one molecular and one serologic. And we have worked with the government to develop an allocation strategy that prioritizes labs with the broadest geographic reach and highest patient impact. We also recognize that addressing a pandemic requires the contributions of all members of our health care community, so we are pleased that the FDA granted emergency use authorization to other companies' tests as well to increase the testing capacity for our country's health care system.

#### **Dr. Abel, how has COVID changed your thinking in a big perspective sense?**

*Dr. Abel (Lahey):* It gave us and everyone else a major challenge to deal with, but as a system we were able to resolve the initial supply chain and testing demand problems, and we have been doing well. COVID is a unique opportunity because it brought laboratory medicine and the diagnostic profession into focus. We are in the news much more than before and it is a momentum we should take advantage of by showing the impact of laboratory diagnostics, not only in COVID but also in all other diseases and conditions.

Many patients missed or postponed appointments and others just didn't see doctors. Patients are waiting and at the end might be coming in sicker. On the other hand, some patients are not getting tests that they perhaps shouldn't be getting because of overuse, and they may be doing fine without those tests. So in time we can mine the data on the general health situation of patients who were without health care because of COVID, partly or entirely. Are there more abnormal results, in proportion to all the results? In microbiology, is there a higher percentage of abnormal results or unusual cultures, and extreme numbers in chemistry? It may help us sort out what is necessary and what is not necessary. What did we do right and what didn't we do right?

Telemedicine has been a phenomenal success during COVID-19, and it will not go away once the pandemic is over. And self-testing too—the use of continuous glucose monitors in the wards, for example, which the FDA permitted. The pandemic will bring into focus central laboratory testing versus point of care, and this new, COVID-driven dynamic will likely influence the manufacturers' focus and efforts.□