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HOW LONG WILL COVID-19 TESTING LAST?

Three lab CEOs share their predictions!

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab Leaders Say COVID-19 Tests Needed in 2021

How long into the future will clinical laboratories need to offer COVID-19 tests on a large scale? That is the number one question confronting labs in every region of the United States.

Last week, three nationally-known lab CEOs answered that question during the general session of the *Virtual Executive War College*. It was a panel discussion moderated by Robert L. Michel, Publisher of The Dark Report. The three panelists were:

- Rick L. Panning, MBA, MLS(ASCP)CM, retired as of Oct. 2 from the position of Senior Administrative Director of Laboratory Services for **HealthPartners and Park Nicollet** in Minneapolis-St. Paul, Minnesota.
- David Dexter, President and CEO of **Sonora Quest Laboratories**, LLC, a joint venture between **Quest Diagnostics** and **Banner Health** in Tempe, Arizona and President and CEO for **Laboratory Sciences of Arizona, LLC**.
- Stan Schofield, President of **NorDx**, a regional laboratory corporation that supports an integrated delivery system at **MaineHealth** in Portland, Maine.

Panning's Comments: "...our planning points to an ongoing demand for COVID-19 testing. Influenza season is arriving and the pandemic is accelerating. Given that evidence and the guidance from state and federal officials, we expect our clinical laboratory will be providing significant numbers of COVID-19 tests for the balance of this year and probably far into 2021."

Dexter's comments: "We are budgeting to support an increase in COVID-19 PCR testing in both November and December. Arizona state officials believe that COVID-19 cases will peak at the end of January and we'll start seeing the downside in February of 2021. ... if a vaccine becomes available, we think there will be a significant increase in antibody testing, probably starting in second quarter and continuing for the balance of 2021."

Schofield's comments: "Administration of the health system and our clinical laboratory think that the COVID-19 test volume and demand for these tests will be tough on our lab for another 12 months. This will be particularly true for COVID-19 molecular tests."

These three predictions will be invaluable as your lab or pathology group does its budget planning and projections for the balance of 2020 and into 2021. TDR

Medicare to Cut Payment for COVID Tests Jan. 1

Clinical labs with high-throughput analyzers will be paid $75 for tests reported after 48 hours

CEO SUMMARY: Starting Jan. 1, CMS will lower the COVID-19 test payment to $75 when labs with "high-throughput systems" report a COVID-19 test result after 48 hours. This is the federal government working at cross purposes, since other federal agencies are diverting COVID-19 testing supplies from labs. This penalizes a lab that accepts COVID-19 specimens believing it has the supplies needed to report results in less than 48 hours, only to have a federal agency divert those supplies with no advance notice.

News that the Medicare program will reduce payments for molecular coronavirus tests starting Jan. 1 was an unwelcome surprise for clinical laboratories. Responding immediately, several lab associations and groups stated that reduced payment could cripple COVID-19 testing nationwide.

In interviews last week, experts from some of the largest organizations for clinical laboratories and pathologists expressed deep concern about a plan from the federal **Centers for Medicare and Medicaid Services** (CMS) to pay 25% less for what CMS called, "expedited COVID-19 test results." Essentially, this payment policy penalizes clinical laboratories that take longer than two days to report COVID-19 test results.

In April, CMS increased payment to laboratories for high-throughput COVID-19 molecular tests from about $51 to $100 per test. But on Oct. 15, CMS changed that policy, saying that on Jan. 1, the agency would pay only $75 for each COVID-19 molecular test (called clinical diagnostic laboratory tests or CDLTs) when labs do not produce a result in 48 hours.

Only labs that complete high-throughput COVID-19 diagnostic tests within two calendar days of the specimen being collected would be paid $100, CMS said.

In the announcement, CMS said the change in payment is designed to ensure that patients who test positive for SARS-CoV-2 are alerted quickly so they can self-isolate and get medical treatment. Fast turnaround times are more important than ever to allow patients and physicians to make treatment decisions quickly and then to isolate patients and do contact tracing, said CMS Administrator Seema Verma.

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In effect, CMS is amending its Administrative Ruling (CMS 2020-1R2) from April to lower the base payment amount for COVID-19 tests on high-throughput instruments to $75.

The agency made this decision, "... in accordance with CMS' assessment of the resources needed to perform those tests," the announcement said. This statement about "resources needed to perform those tests" contradicts what clinical laboratory directors and molecular pathologists have told THE DARK REPORT since February.

Supply Chain Disruptions

Since then, each lab director and pathologist we've interviewed has said his or her laboratory has run short of collection supplies, viral transport media, COVID-19 test kits, primers, reagents, and other supplies required to perform tests at full capacity.

With few exceptions, every clinical laboratory in the United States has experienced daily supply shortages that hinder clinical laboratories' ability to run all of the incoming SARS-CoV-2 specimens and report the results in a timely manner that would be clinically useful to physicians and patients.

In addition, the cut in payment does not take into consideration the fact that federal agencies and state governments have interceded to redirect lab-testing supplies with little or no notice to the clinical laboratories expecting to receive those supplies. Such disruptions have occurred when government agencies have commandeered supplies to send them elsewhere.

While the base payment rate will be $75 on Jan. 1, CMS also said that it will make a "$25 add-on payment" to laboratories for a COVID-19 diagnostic test run on high-throughput technology if the laboratory hits two benchmarks:

- Completes the test in two calendar days or less, and
- Completes the majority of their COVID-19 diagnostic tests that use high-throughput technology in two calendar days or less for all of their patients (not just Medicare patients) in the previous month.

The new rule defines a "majority of COVID-19 diagnostics tests" as being 51%.

"These actions will be implemented under the amended Administrative Ruling (CMS-2020-1-R2) and coding instructions for the $25 add-on payment (HCPCS code U0005) released today," the agency added.

"In the circumstance that the laboratory has not completed 51% of its CDLTs making use of high-throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (for all patients) in two calendar days from the date the specimen was collected during the applicable month, it may not bill" for the new HCPCS codes in the rule, CMS said.

When this lower rate is combined with other requirements from CMS, the result of this payment reduction could cause clinical laboratories to struggle still further, crippling their ability to test at full capacity, said Matthew Schulze, Director of the Center for Public Policy at the **American Society for Clinical Pathology**.

Huge Financial Challenge

"Like many medical specialties, clinical laboratories have encountered major economic challenges this year due to the erosion of routine lab test referrals," he commented. "Ordinarily the loss of $25 per test (a decrease of 25%) would pose huge financial challenges for the laboratory community in any year.

"But given all the other financial hits the laboratory community faces right now, this action from CMS could be crippling," he added. "We appreciate the intent of the policy, but this could be a real challenge for some laboratories."

In addition to lower payment, CMS recently imposed new COVID-19 test reporting rules that require labs to provide demographic and other information on those being tested for SARS-CoV-2.

"Those requirements impose a huge financial burden on labs," noted Schulze.

After analyzing the rule requiring more information on patients' demographic information, ASCP reported that the added costs of this rule alone could be significant, Schulze said. *(See sidebar, "Clinical Lab Group Calls for National Testing Strategy," at right.)*

No Solution for Shortages

Mark Birenbaum, PhD, Executive Director of the **National Independent Laboratory Association** (NILA), said reduced payment for COVID-19 tests will do nothing to help labs address the problem of test kit, reagent, and other supply shortages.

"It's not by choice that clinical labs are taking longer to turn around COVID-19 test results," he explained. "The big issue they face is a reduced ability to test at full capacity because of a lack of supplies specifically used for COVID-19 testing. That's what I hear from NILA members.

"They're not getting the supplies they need because test manufacturers limit what they allocate to their lab customers," continued Birenbaum. "Reduced allocations limit the number of COVID-19 tests labs can do in a day. That's the real challenge.

"Adjusting labs' reimbursement for these COVID-19 tests is the wrong incentive mechanism and may boomerang on CMS officials," he added.

On Oct. 1, members of the U.S. House of Representatives sponsored a bill called the "Strictly Pay for Efficient and Expedited Delivery of Your (SPEEDY) COVID-19 Tests" Act, which would change payment for these tests in a way that's similar to what CMS proposed, Birenbaum noted.

"The SPEEDY Act also takes the wrong approach to COVID-19 test turnaround times," explained Erin Will Morton, a Senior Vice President at **CRD Associates** in Washington, D.C., who advises NILA on legislative and regulatory strategy. "While it would offer an increased payment for tests turned around within 24 hours, it would also eliminate payment altogether for any results that take longer than 72 hours.

"This could discourage labs from offering COVID testing and misses the

Clinical Lab Group Calls for National Testing Strategy

ONE PROBLEM THAT CLINICAL LABORATORIES AND MOLECULAR PATHOLOGISTS FACE is a continuing shortage of test kits, reagents, pipettes, and other supplies that labs need to test at full capacity.

Since the spring, many of the nation's groups representing clinical laboratories and pathologists have called on the federal government to address this problem, said Matthew Schulze, Director of the Center for Public Policy at the American Society for Clinical Pathology (ASCP). Those groups also include the **American Clinical Laboratory Association**, the **College of American Pathologists**, and others.

"ASCP has pushed this case for months," Schulze noted. "In early April, ASCP called for the development of a national COVID-19 testing and support strategy.

"We called for direct federal financial support for clinical laboratories to help them provide efficient COVID testing technologies and to get the necessary supplies," he reported. "We also called on the federal government to provide robust payment rates to incentivize the development of our national testing capacity.

"We continue to speak to federal health officials at CMS and HHS to make them aware that shortages of supplies are curtailing the ability of clinical labs to do testing quickly," he added. "Unfortunately, HHS officials told us that many of these supply shortages can't be solved in the short term, particular when the manufacturing site is located outside of the United States. It's really frustrating."

point altogether that labs cannot turn tests around any faster if they don't have the supplies they need to do so," she added. "This is why NILA called for more transparency in laboratory supply distribution in a letter we sent along with five other groups to Vice President Pence."

Neither the CMS policy nor the SPEEDY COVID-19 Act would address the supply-shortage problems that have hampered labs since the pandemic began and continue today, she added.

Assuming that clinical laboratories could produce COVID-19 test results more quickly than they do now, Birenbaum asked how they would report the turnaround times to CMS. "Will labs submit one claim for payment of the test and a separate claim for the extra $25 if the test result is reported in 48 hours?" he asked. "If labs have to submit a second claim, then CMS is creating more work for labs.

Much-Needed Cash Flow

"Then if payments for these COVID-19 tests are delayed, that will just slow down much-needed cash flow to the very labs that other federal agencies are encouraging to increase the number of COVID-19 tests they perform daily," he added.

In addition, would the new CMS rule provide an incentive for labs to report results in 48 hours, and how would CMS know if that reporting is correct, Birenbaum said.

"How will clinical labs prove they've submitted the COVID-19 results in two days?" he asked. "Will Medicare go back to the doctor or other provider to get that information? If so, then Medicare is creating another level of complexity."

Another issue that CMS did not address is that a 25% cut in payment could affect smaller community labs more severely than it would affect larger labs, said Danielle Sloane, a lawyer with **Bass, Berry, and Sims** in Nashville, Tenn.

"This change in payment could be a disadvantage for smaller lab companies that typically have less buying power on the supply side than larger labs," she commented.

"It appears what CMS is trying to discourage labs from committing to do a certain volume of tests that they can't turn around in a timely manner. That's a laudable goal," she added.

Factors Affecting Test TAT

"However, I don't know if CMS appreciated that many factors affect COVID-19 lab test turnaround times," said Sloane. "CMS is likely concerned with laboratories holding onto volume in order to retain revenue, rather than shifting it to a laboratory that has more capacity.

"Ultimately, CMS simply wants faster testing," she added. "Laboratories may have an opportunity here to partner with other labs to help process overflow testing in one region experiencing surges, though certain limitations on referencing out testing would need to be considered."

Given that the implementation date for the new payment rate is less than two months away, groups representing clinical laboratories have called on lab directors and pathologists to contact their members of Congress and send comments about the payment rate to CMS.

Educating Lawmakers

"Everyone concerned about the impact that diminished national testing capacity could have on addressing the COVID-19 pandemic, and everyone working in the laboratory sector—even if they don't work in a facility that does COVID-19 testing—needs to write to their members of Congress and officials at HSS and CMS about supply shortages, reimbursement, and the other issues affecting COVID-19 testing and turnaround times," said Schulze. TDR

Contact Mark Birenbaum at 314-241-1445 or NILA@nila-usa.org; Erin Will Morton at emorton@dc-crd.com; Danielle Sloane at 615-742-7763 or DSloane@bass-berry.com; Matthew Schulze at Matthew.Schulze@ascp.org or 312-735-2285.

New Clinical Lab Opens on March 23 and Prospers

Pathology group's launch of new clinical lab upended by the pandemic, recovers with COVID tests

CEO SUMMARY: Timing is everything when launching a new clinical laboratory business. The March 23 grand opening of Incyte Pathology's clinical lab came in the midst of the collapse of daily routine specimen referrals. But once the lab was operational, Incyte had the capability, the expertise, and the facilities to validate and perform COVID-19 testing. Cash flow from SARS-CoV-2 tests is sustaining the operations of both Incyte's clinical laboratory business and its anatomic pathology group.

In the early weeks of the pandemic, **Incyte Diagnostics of** Spokane, Wash., opened a new clinical laboratory business. It was the worst possible timing for such a venture because, nationally, the inflow of both clinical lab and anatomic pathology specimens was falling by as much as 70%. Thus, when the clinical laboratory began operating on March 23, it opened to a flood of red ink.

About a year earlier, the pathologist partners at Incyte had made a bold strategic decision that is often the subject of rigorous debate among private pathology groups, but seldom implemented: by operating a clinical laboratory, the pathology group would be able to provide referring physicians with the full range of diagnostic testing services.

However, while SARS-CoV-2 infection rates rose in Washington State and throughout the nation, the flow of routine lab specimens collapsed, causing Incyte's new clinical lab venture to operate at a loss. The pathologist-owners had every reason to shut down the new business.

But at the same time, there was an unexpected opportunity to bring up molecular COVID-19 testing to meet the rising demand for these tests. As Louis Pasteur said, "fortune favors the prepared mind" and Incyte's pathologist-partners were prepared to serve this new demand.

Thus, if chapter one in this story is that pathologists opened a clinical laboratory business at the worst possible time, then chapter two is that the savvy business strategy of the pathologists to build a new clinical laboratory created the opportunity to serve the needs of physician clients for molecular SARS-CoV-2 testing.

Cash Flow from COVID Tests

Another positive element to this story came in the form of increased cash flow as the clinical lab operation began processing growing volumes of molecular COVID-19 tests, helping Incyte Diagnostics support its anatomic pathology operations during the months when routine tissue specimen volume had fallen dramatically.

"Our pathology group took what you might call an unusual approach to surviving the COVID-19 pandemic by opening a clinical laboratory in the middle of March," stated Patty Sipes, Incyte's CEO. She explained the strategy during a presentation at The Dark Report's

Executive War College, a virtual event that began this summer and concluded at the end of October.

"Having a grand opening for a new clinical laboratory business on March 23 wasn't the best timing, but we had planned it for over a year," she explained. "Looking back, our pathologists have come to see that the clinical lab was a two-fold opportunity. It builds revenue from routine testing, while it became an important source of COVID-19 testing revenue that helped both the clinical lab and the anatomic pathology (AP) operations survive those early months of the pandemic.

"From an AP perspective, Incyte experienced reductions in case volume that probably were similar to that of other pathology practices," she reported. "We had, for example, a 62% decrease in biopsies in March. That included a 65% reduction in gynecology biopsies that were related to our core business of women's health, and a 45% reduction in biopsies that were not related to gynecology.

Reduced Specimen Referrals

"These reductions all occurred within the first few weeks of the pandemic," she noted. "In March, we had cash projections showing a decrease of about 65% over the next two to three months.

"That projection told us that we needed to move quickly because Incyte is similar to many other pathology groups in that our business model doesn't call for us to carry over a significant amount of cash from one year to the next," she commented. "We needed to ensure the long-term financial viability of the practice. That meant that our number one goal was to keep the company operating.

"Our strategy for April and May was to ensure that the business remained intact," Sipes reported. "We wanted to avoid layoffs and planned to use furloughs instead. We also instituted pay cuts for shareholders and eliminated merit raises for staff.

"At the same time, we decided to pay health insurance and benefit premiums for all employees and made no changes to the 401k match program that we offer," she noted. "As we responded to the deep drop in cash flow, we saw the importance of bringing in new funding. That's when we saw that the clinical lab operation could become a source of revenue."

Clinical Lab's Opening

Coronavirus infections began rising in late February and early March even as the staff at Incyte worked to keep the scheduled March 23 opening date for the new clinical laboratory business. During this time, Sipes and the administrative team noted that the lack of normal AP volume freed up staff who would normally be devoted to reviewing AP cases each day, so that they could work on making the clinical lab operational.

"Having lower than normal AP volume gave us time to work out the kinks we had early on with the clinical lab," she recounted. "Our newly-installed LIS, a new billing system, and the need to interface with EMRs all required time to bring them into smooth operation.

"In addition to fixing problems with our new systems, we assigned a project manager to lead the clinical lab project," she noted. "That's one tip I would suggest to anyone else doing something like this.

"Having a project manager made a big difference because now one person was in charge of every aspect of the venture," Sipes commented. "It sounds basic to assign a project manager, but we didn't have one during the first three weeks. Once we had a project manager, I wished we had done that from day one.

"During those three weeks without a project manager, there were so many items to track every day that the volume of detail became overwhelming," she reported. "Not having someone in charge created a lot of stress for everyone.

"The project manager helped us to add structure, organization, and improved communication among those of who were working on the project," she said. "The

project manager instituted daily huddles, for example, and those made a huge difference in terms of what we needed to do each day.

"Another decision we made during this period was to hire additional staff for the clinical lab operation as we hit certain milestones in terms of rising volume," she said. "At first, we looked for regular clinical lab clients, but the result of our sales and marketing efforts was a growing flow of COVID-19 test orders from physicians and hospitals. This was a welcome development because it meant our clinical lab business was generating revenue.

"Our clinical lab also benefited from the fact that most of the clinical lab companies in our region had not yet geared up for molecular COVID-19 testing, yet the demand was huge and urgent for these tests," added Sipes. "Therefore, a number of those providers sent specimens to us because we were already doing COVID-19 testing. We had a window of opportunity to capture market share as these other labs worked to get their own COVID-19 tests validated and into production.

Staffing to Meet Demand

"For us to handle the growing number of COVID-19 specimens, we eventually hired about 80 new staff members," noted Sipes. "These positions were filled as the demand for testing grew over time.

"Another lesson we learned was that we should have taken more risk with supply orders by not relying on just one or two vendors," recounted Sipes. "We should have identified alternative sources for supplies faster than we did."

Since those early days, Incyte's clinical lab operation has done COVID-19 testing almost exclusively and ran 111,000 COVID-19 tests since March, she reported.

"Our pathologists have watched the progress of the pandemic to identify the point at which we can begin switching over to regular clinical lab testing," commented Sipes. "The result of doing COVID-19 testing is that it strengthened Incyte's cash position. If we compare year-over-year through August, our financial performance was better than at the same time last year. In fact, we had a record month for Incyte in July. By that, I mean we had our highest billed charges and highest level of collected revenue.

"Our pathology group is financially stable today because we have a strong cash position, and our total volume this year has increased over last year," she added. "Things are still not normal, of course. Some client accounts are down over the entire year by about 7%. But overall, our group is in much better shape than we thought we would be last spring." TDR

Contact Patty Sipes at psipes@Incdx.com or 509-892-2700.

One Reason for Success: Getting Bankers' Support

AMONG THE FIRST STEPS THAT INCYTE DIAGNOSTICS TOOK IN FEBRUARY when the coronavirus pandemic hit was to have the administrative team meet with officials at their bank.

"At that time, we were doing what we called 'worst-case-scenario' planning," said Incyte CEO Patty Sipes. "We wanted to know if the bank could be flexible with our credit line. We also wanted to know about our federal funding options and how long it would take for the feds or the bank to process our request for a loan through the federal Paycheck Protection Program.

"For many years, we had worked with that same bank," she noted. "It helped the banking relationship that we were creating a new source of revenue by starting a clinical lab. Having that strong banking relationship was a significant benefit. During these meetings early in the pandemic, our bankers assured us that we didn't need to worry about our credit line and existing debt covenants."

Pathology Update

Joint Pathology Center Goes Digital Signs Deals with Proscia, Huron

Goal is to digitize a repository with 55 million slides and provide a digital pathology workflow solution

It's a major endorsement of digital pathology and whole slide imaging. Last week, the federal government's **Joint Pathology Center** announced agreements with two digital pathology companies. The goal is to digitize incoming slides and archived slides, support a digital pathology workflow, and make the digitized slides searchable to pathologists and researchers.

The first agreement was announced on Oct. 20. The Joint Pathology Center (JPC) will use Philadelphia-based **Proscia's** Concentriq "digital and computational platform" as the foundation for management of images, data, and workflow.

The second agreement was made public on Oct. 22. **Huron Digital Pathology** of St. Jacobs, Ontario, Canada, will provide its Lagotto image search engine "to index and search JPC's growing digital image archive."

World's Largest Repository

Based in Silver Springs, Maryland, the Joint Pathology Center is the world's single biggest repository of anatomic pathology specimens. It is the successor to the **Armed Forces Institute of Pathology** (AFIP), which was founded in 1862. AFIP was closed by the **Department of Defense** as part of a realignment of military bases that happened in 2005.

The Joint Pathology Center received AFIP's archives and has continued to offer anatomic pathology services since its formation. In its repository, the JPC has more than 55 million glass slides, 35 million tissue block samples, and as many as 500,000 to 700,000 wet tissue samples.

A key insight behind these two agreements is that the Joint Pathology Center is taking the first steps to create a fully-digital anatomic pathology laboratory service, while also making tissue specimens that date back as far as 1862 available for research and other purposes.

Adoption of Digital Pathology

One consequence of this—once implementation is complete—is that pathologists in academic and community settings who are themselves using digital pathology (DP) systems will be able to access the digital images in the JPC repository. But that will require community-based pathology groups to adopt and use digital pathology systems.

Another interesting phenomenon may result from the JPC's adoption and use of digital pathology. Given the sheer size of the glass slides in the repository, there will be every incentive for Proscia, Huron Digital, and other digital pathology vendors who may contract with JPC to continuously improve the performance of their scanners, DP systems, digital image analysis tools, and artificial intelligence products.

Surgical pathologists everywhere should understand the significance of these two agreements. They further accelerate the adoption and regular use of whole slide images and digital pathology systems by pathologists in their daily workflow. TDR

Community Lab Ceases after 37 Years of Operation

Medicare's PAMA payment cuts claim another community lab that served Medicare beneficiaries

CEO SUMMARY: In Pennsylvania, one of the state's largest independent clinical laboratories, HNL Lab Medicine in Allentown, acquired a lab competitor last month, Northeastern Laboratory Medicine in Hazelton. The deal is a good strategic move for both labs because HNL will continue to serve NLM's nursing home and at-home patients while adding NLM's 20 clinical laboratory staff members to its employee roster at a time when many labs face a shortage of staff.

MEDICARE FEE CUTS TO CLINICAL LABORATORIES PLAYED A SIGNIFICANT ROLE in the demise of a respected community laboratory in Pennsylvania that served nursing homes and physician offices. **Northeastern Laboratory Medicine** (NLM) ceased business earlier this month when the owners agreed to sell the lab to **HNL Lab Medicine** (HNL) of Allentown, Pa.

Like most community laboratories, NLM operated on razor-thin profit margins before the deep, multi-year cuts in Medicare payments that the federal **Centers for Medicare and Medicaid Services** (CMS) imposed starting in 2018. Lower payment for Medicare tests—which made up the majority of patients NLM served—left the lab company struggling financially.

"Before the end of the first quarter this year, the coronavirus pandemic started to spread nationwide and this caused our lab's client physicians and hospitals in Northeastern Pennsylvania to cut back on routine lab testing," said Joseph Shiskowski, Principal and a co-founder of NLM. "The reductions in routine lab testing exacerbated the financial problems many community laboratories were facing, including NLM."

When HNL approached Shiskowski and his co-founder John Lazo about consolidating the two labs, Shiskowski was open to the idea. "We've experienced Medicare cuts for the past three years or more," he said. "In addition, if competitive bidding for lab work ever goes through, that would be financially devastating for smaller independent laboratories like ours.

Retaining Loyal Lab Staff

"We were also concerned about losing some of the clinical lab scientists, pathologists, and support staff in our lab," explained Shiskowski. "Many are approaching retirement age, and they were concerned about becoming infected.

"The fact is that small community clinical laboratories like ours don't have the volume and economies of scale," he continued. "With smaller volumes of tests, our cost structure is so much higher than that of a much larger laboratory, such as HNL Lab Medicine. Those facts persuaded us that it was time to sell the business.

"I don't think that laboratories are where the fee cuts should come from, but Medicare officials will continue to cut what they pay labs," he commented. "That seems almost inevitable because of the political climate we're in."

Given this list of concerns, Shiskowski and the management team at NLM agreed to let HNL acquire the business. When the deal was announced on Sept. 30, financial terms were not disclosed.

Waiting for the 'Right Fit'

"Over 37 years of running NLM, we've been approached numerous times by different entities and I never got the feeling that any of them would be the right fit," Shiskowski said in an interview with The Dark Report.

"Some of those entities that approached us wanted to break up our lab or to divide up the assets in a piecemeal fashion, which we didn't want to do," he noted. "But after HNL approached us—and with the healthcare environment being what it is—it was the right opportunity for us to leave the business."

First, however, Shiskowski wanted to know that HNL would be a good fit for NLM, its 20 employees, along with the physicians, nursing facilities, and patients it had served since its founding in 1983.

"Once we started talking with HNL, and I dealt with Dean Hoppes and the other executives there, I had a strong feeling that the acquisition would be for the best," he commented. "It would be best not only for Northeastern Lab Medicine, but it would also benefit both parties and our client physicians, patients, and nursing facilities." Hoppes is the Chief Financial and Administrative Officer for HNL, a much larger lab that has more than 1,000 employees and does some 60 million tests per year in nearby Allentown, Pa.

"Also, the two companies seem to be a good fit and we hope HNL can take what we started and expand the services we offer," he added. "If our lab was to totally disappear, that would reduce the

HNL to Provide Services to NLM's Existing Clients

When HNL Lab Medicine reviewed the financial statements of Northeastern Laboratory Medicine, HNL saw that the smaller lab with 20 employees had been gaining new clients even as three years of deep Medicare payment cuts eroded the lab's financial stability.

"During our due diligence review, we could see that NLM had a significant reduction in revenue related to Medicare cuts due to PAMA," said Dean Hoppes, the Chief Financial and Administrative Office for HNL, in Allentown, Pa. PAMA is the Protecting Access to Medicare Act that called for Medicare to cut what it paid labs 10% per year starting in 2018.

"Because of the high proportion of Medicare beneficiaries that NLM served, the PAMA price reductions caused its revenue to decline by about 4% to 5% each year," recalled Hoppes.

"But the quality service this local lab provided was bringing it new clients," Hoppes said. "That's because NLM has a great reputation for excellent customer service in Northeastern Pennsylvania."

By combining the employees from both labs in the Allentown facility and continuing to serve patients in Hazelton with blood draws and other patient services, HNL will support what NLM has done since it was founded in 1983, Hoppes said.

The two labs have a combined 1,100 employees. including 35 board-certified pathologists and scientific directors and more than 400 certified lab scientists and phlebotomists. Also, the labs have more than 60 patient service centers throughout Pennsylvania and New Jersey.

HNL will do house calls for patients who need that service and will continue to provide phlebotomists for specimen collection services at long-term-care facilities, he said.

Medicare beneficiaries' access to local, high-quality lab testing in these towns and rural areas.

"HNL and NLM share a common vision focused on serving healthcare professionals and their patients with comprehensive lab testing services, timely diagnostic insight, and convenient access for patients. This acquisition expands access to full-service laboratory diagnostics, while maintaining convenience and improving service for healthcare professionals and patients in Northern Pennsylvania," Hoppes said.

HNL Will Retain Employees

Shiskowski will continue to have a role with HNL, while his partner and co-founder, John Lazo, decided to retire. HNL will retain all of NLM's employees, he added.

NLM specializes in serving patients in nursing homes and other long-term care facilities, and those needing at-home specimen collections. It also provides a daily nursing home phlebotomy service and a house-call service for patients who need blood or other specimen collections at home. Among the roughly one million clinical lab tests NLM runs each year are genetic and molecular testing. This year, NLM has done as many as 2,000 molecular tests per day for COVID-19.

"About 40% of our patients are outpatients who simply walk into our lab here in Hazelton," he reported. "That's easy for our patients because we're centrally located in the city. Another 40% of our work is for nursing homes and other long-term-care facilities. About 10% of our volume is for house calls. The remaining 10% is lab testing we do for home health agencies.

"Home health agencies in this area use us almost exclusively because we are local, we are very efficient, and we can report test results in just a few hours, if necessary," he added. "Since they can drop off their samples at the laboratory, we can do the tests without sending the specimens out of town."

Community laboratories that serve patients at home and collect specimens in nursing facilities have suffered the most under the cuts the federal **Centers for Medicare and Medicaid Services** (CMS) imposed under PAMA.

Even before PAMA went into effect in 2018, the business of collecting specimens from patients who were home-bound or in nursing facilities and running those tests was only barely profitable. The cuts from PAMA that NLM absorbed equaled about 4% to 5% of total revenue and were compounded each year.

Large national laboratories have absorbed those cuts and have continued to grow through acquisitions. But the large labs typically decline to serve nursing homes and patients at home because the high costs make this work unprofitable to them.

Since public labs left the nursing home sector in the 1990s, smaller community labs, such as NLM and HNL, have filled that void. *(See TDR, June 2, 1997.)*

"We're confident that NLM's sale to HNL Lab Medicine is a good fit and they will maintain the local lab testing services we've provided in this community with house calls and to nursing homes," Shiskowski explained. "Serving the very elderly population in this area is part of our business model.

Deep Cuts to Medicare Fees

"Despite the deep cuts in Medicare payment that make it tougher for community laboratories—with their higher costs—to keep serving these suburban and rural areas, the team at HNL Lab Medicine is supporting us and we've not missed a beat service-wise.

"I hope that, in the long run, our nursing homes, physicians, and patients will continue to have access to high-quality, local lab testing," he added. TDR

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IVD Update

$481 Mil Federal COVID Contract Awarded to Young IVD Company

HHS had relationship since 2018 with Cue Health; wants to quickly scale up made-in-USA portable tests.

In their fight against the pandemic, federal officials are boosting the fortunes of some little-known or emerging *in vitro* diagnostics (IVD) companies. One example is the recent award of a $481 million COVID-19 test contract to **Cue Health Inc.**, of San Diego.

Earlier this month, the federal **Department of Health and Human Services** (HHS) and the **Department of Defense** (DoD) announced a contract that calls for Cue Health to produce six million rapid molecular COVID-19 tests by March 2021.

Feds May Be Fueling IVD Trend

This development could signal an important trend in the IVD industry that could have long-term consequences. According to statements by HHS and DoD officials, the nation's billion-dollar IVD corporations are unable to fulfill this and similar contracts for COVID-19 instruments and tests because their manufacturing capacity is already stretched to the limit.

This is why federal agencies are willing to issue sizeable contracts for COVID-19 testing products to young IVD companies and new entrants such as Cue, which reportedly has capacity to immediately launch production of tests exclusively at its San Diego facilities. The contract terms provide Cue with up-front capital so it can increase its manufacturing capacity.

The total contract—worth $481 million—will help Cue Health achieve manufacturing economies of scale that could allow it to compete more effectively against the major IVD corporations as the SARS-CoV-2 pandemic eventually winds down.

Another interesting element in this story is that Cue Health is a known factor to HHS. The Cue Health platform, HHS said, was funded starting in 2018 for development of a molecular influenza test by the **Biomedical Advanced Research and Development Authority** (BARDA). As the pandemic surged in March, BARDA expanded the collaboration and Cue had adopted its platform to the coronavirus.

BARDA is part of the HHS Office of the Assistant Secretary for Preparedness and Response.

"This award exemplifies the importance of agencies like BARDA, which invest in platform technologies that can be applied to diverse health security needs," said Admiral Brett Giroir, M.D., U.S. Assistant Secretary for Health, in an HHS statement. "This investment will allow Cue Health to expand its footprint and significantly scale up production, and by doing so enable this technology to be deployed throughout our testing ecosystem to benefit all Americans."

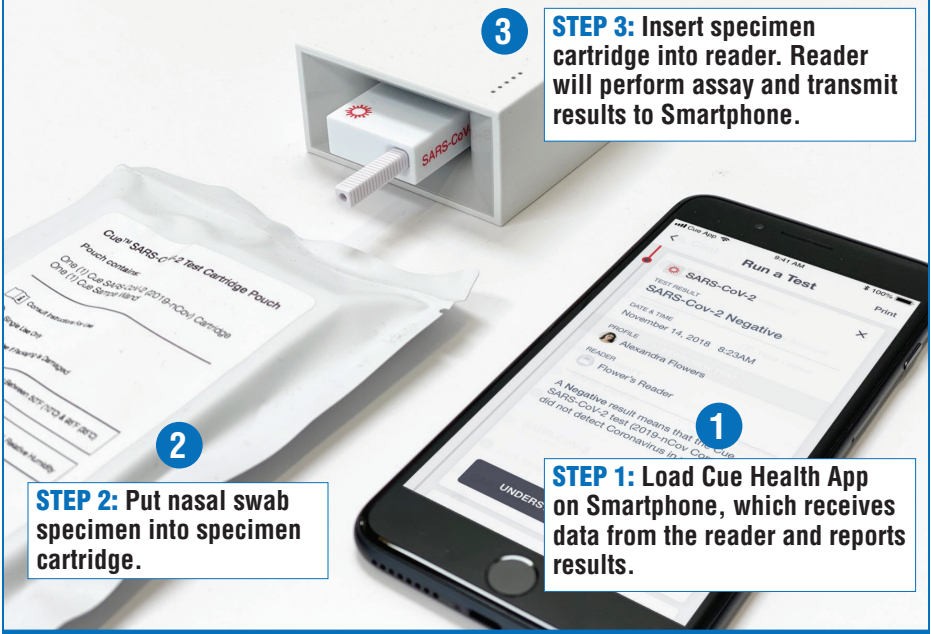
In an interview with *Bloomberg News*, Giroir added, "Companies need money up front, particularly small companies. This is not Abbott or BD (**Becton Dickinson**)."

However, **Abbott Laboratories**, Abbott Park, Ill., does have a $750-million contract with HHS and DoD for 150 million rapid tests. Abbott has "invested hundreds of millions in two manufactur-

CUE Health's COVID-19 Test Uses Nasal Swab, the Reader Reports Results to a Smartphone

NOT ONLY IS IT NOTEWORTHY THAT TWO FEDERAL AGENCIES AWARDED A $481 MILLION CONTRACT for six million COVID-19 tests to an emerging *in vitro* diagnostics (IVD) company in San Diego, but it is equally noteworthy that the company's technology is built around a small reader and smartphones for collecting and reporting data from the reader. Cue Health's system is designed to perform "in-home and in-clinic diagnostics" and was used by the National Basketball Association (NBA) this summer and fall to do COVID-19 testing on the players and staff.

Cue Health's Smartphone-based diagnostic system



Business Milestones for Cue Health

- **2010:** Cue Health, a healthcare technology company manufacturing medical diagnostic products for clinical and at-home use, is founded by Ayub Khattak and Clint Sever in San Diego, Calif.
- **2018:** Cue partners with the Biomedical Advance Research Development Authority (BARDA) to develop a molecular Influenza test.
- **March 2020:** BARDA announces acceleration of collaboration with Cue to manufacture Cue's COVID-19 test. Cue adapts its platform to respond to the pandemic.
- **June 2020:** Cue raises $100 million in a Series C funding round for developing Influenza and COVID-19 tests. The Cue Health Monitoring System and Cue COVID-19 test receive Food and Drug Administration Emergency Use Authorization.
- **October 2020:** Cue Health announces $418 million award by Department of Health and Human Services and Department of Defense to produce six million molecular point-of-care COVID-19 tests using the Cue Health System.

ing facilities," to produce its BinaxNOW COVID-19 Ag Card test.

Cue acknowledged that the federal government's award will help the company access supplies and speed-up production of the molecular point-of-care tests to 100,000 COVID-19 tests kits per day by March, 2021.

"Our vision in designing the Cue Health Monitoring System was to enable individuals to have more control over their health and lives by providing access to actionable, accurate health data in real time. The U.S. government's support has and will allow us to fulfill this vision in this particularly critical moment," said Ayub Khattak, Cue Founder and CEO, in a news release. THE DARK REPORT contacted Cue Health for its comments and had received no response as of press time.

Test Has EUA, Used in NBA Bubble

Cue's COVID-19 test is already being used in healthcare, education, and business settings. In fact, Cue COVID-19 tests were deployed by the **National Basketball Association** (NBA) during the 2019-2020 season. Before players or staff entered the "NBA bubble," they were required to have two negative COVID-19 tests, *MedCity News* reported.

"So, if it's good enough for LeBron (LeBron James of the Los Angeles Lakers), we want to democratize it and make sure it's available to the American people," Giroir said in *Bloomberg News*, where he explained the government will use these SARS-CoV-2 tests in geographic areas that have COVID-19 outbreaks and at healthcare locations such as skilled nursing facilities.

The U.S. **Food and Drug Administration** announced Emergency Use Authorization in June for the Cue Health Monitoring System and the Cue COVID-19 test. Also important to HHS and DoD was a prospective study by **Mayo Clinic** suggesting accuracy of the test. (The study data was requested by THE DARK REPORT and have not yet been released to the public.)

"The Cue testing system is highly sensitive and specific and nearly equivalent to the best large referral laboratory systems," Giroir said. Across four clinical studies, the test has 98.7% sensitivity and 97.6% specificity, Cue said. In a Limit-of-Detection (LoD) study, the Cue COVID-19 cartridge confirmed LoD of 20 SARS-CoV-2 RNA genomic copies per sample.

Compact COVID-19 Test System

Cue's COVID-19 test is performed on the Cue Health Monitoring System, which is small enough to fit in the palm of a hand. Included is a Cue Test Cartridge (operated by a reusable battery-operated Cue Cartridge Reader) and single-use test kit with a Cue Sample Wand (a nasal swab).

The test works after the swab is inserted into the cartridge, which detects the genetic material of the SARS-CoV-2 using a molecular amplification reaction, according to the Cue website. Results are sent to the Cue Health App and the user's smartphone in about 20 minutes.

The sample reader, which can be reused, costs a "few hundred dollars" and the cartridge "tens of dollars," according to a statement by Khattak in the *San Diego Union-Tribune*.

New IVD Opportunities

The need by federal agencies to respond to the SARS-CoV-2 pandemic is the reason why regulators are revising regulations governing clinical laboratory testing and how the lab analyzers and tests used for COVID-19 testing are reviewed and cleared for market.

In normal times, a federal agency would not be granting a contract worth almost half a billion dollars to an emerging IVD company. But these are extraordinary times and the longer the pandemic continues the greater the likelihood that smaller IVD companies can win big contracts from different federal agencies. TDR

Lab Regulatory Update

Labs, AP Groups Confused about UnitedHealthcare's Test Registry

UHC plans webinars to explain steps it requires for labs, path groups to register their tests before Jan. 1

Confusion continues among clinical laboratories and anatomic pathology groups about how they should comply with **UnitedHealthcare's** new Laboratory Test Registry Program. The program goes into effect on Jan. 1, 2021, but labs and pathology groups must register all tests and testing procedures with UHC by Dec. 1, 2020.

Since UHC announced the test registry in June, labs and anatomic pathology (AP) groups have struggled to understand how they should register their tests, according to experts who consult with labs and AP practices.

The level of confusion varies widely among labs and AP groups and is so widespread that UHC decided in September to conduct webinars to help labs and AP practices understand the nuances of registering all clinical lab tests and AP procedures, which is required for labs to be paid for their test claims when UHC's program becomes effective in January.

In an interview with The Dark Report, Leigh Polk, PathLab Marketing Specialist at **Change Healthcare**, said UHC's webinars will run through March, raising questions about whether UHC will push back the implementation date of the new test registry program. Last summer, UHC moved the start date from Oct. 1 to Jan. 1, 2021.

UHC's Laboratory Test Registry Program requires freestanding clinical or outpatient hospital labs to register all unique test codes and corresponding CPT codes by Dec. 1. The unique test code may be billed under single or multiple procedure codes effective Jan. 1, and all claims submitted must include the unique test code. UHC will deny claims if the test code does not match the corresponding test registration. *(See "UHC Ready to Implement New Lab Test Registry" and "UHC Issues Details about How Labs Register Tests," TDR, Aug. 3, 2020.)*

"For the past few weeks, there was confusion about which labs and which places of services were affected," Polk said. "All AP groups and clinical laboratories billing place of service 19, 22, or 81 are affected."

Labs Have Many Questions

Diana Richard, Director of the Anatomic Pathology Program at **XIFIN**, a revenue practice management company for labs, said AP clients working with XIFIN also have questions. "We've been communicating with our 30 or so AP customers, who, combined, submit more than 100 million diagnostic claims each year," she added. "Early on, there was much confusion, but now they understand what UHC expects, and we're working with them to ensure the requirements are implemented cohesively for each party."

Both Polk and Richard advise labs and AP groups to focus on registering their tests and to work closely with their billing companies when doing so.

Polk said, "We recommend that all AP practices and clinical labs focus first on developing their test registration lists, and we will work with our lab and AP clients to ensure that the information in UHC's test registration database matches what

the labs will submit on their test claims." Change Healthcare has about 280 clinical lab and AP group clients.

In addition to concern about which labs are affected, labs and AP groups also are worried about the increased administrative burden to register tests and then bill for those tests, added Polk.

Administrative Burden

"Not only does UHC's lab test registry program increase the administrative burden on labs, but it also creates chaos for labs and AP groups as they prepare to comply with the program's requirements," she commented.

Richard agreed, saying, "This requirement has created a massive administrative burden for all diagnostic providers and circumvents the AMA's CPT coding process." The new identifiers that UHC requests were designed to be used for more discrete identification of proprietary and complex genetic testing services, she added.

"The new codes don't really make sense anymore since Medicare introduced PLA (Proprietary Laboratory Analyses) codes in 2016," Richard commented. "These codes certainly don't make sense for all lab testing because a portion of all testing is routine and straight-forward—meaning there's no need for additional identifiers."

UHC Requires PLA Codes

PLA codes are an addition to the AMA's CPT codes and already include a corresponding descriptor for clinical laboratories that want to identify tests with more specificity. On this point, Polk agreed with Richard. "I have yet to find someone who understands what UnitedHealthcare hopes to accomplish with this program," she remarked.

"We do know that UHC finally confirmed that all freestanding labs that use place-of-service code 81, and all outpatient hospital laboratories that use POS codes 19 and 22, and that use revenue codes 300 to 319 and 971, are required to register for the test registry protocol," said Polk. "This information came from a provider relations advocate for UHC." Place-of-service 19 is for an off-campus outpatient hospital; 22 is for an on-campus outpatient hospital, and 81 is an independent laboratory.

Along with the need to resolve the confusing aspects of UHC's test registry program, clinical labs and AP groups have the added administrative burden of registering tests using billing modifiers and the associated number of units, said Polk.

"For example, a lab can register an 88305 with 10 units as long as it has never billed for more than 10 units," she explained. "But should the lab later have a big case of more than 10 units, then UHC will not pay for that claim unless the lab first registered that test with more than 10 units.

List Every Test in a Panel

"In addition, there are numerous clinical lab tests that are ordered as a panel, and labs will need to list each test in those panels," noted Polk. "Further, when a lab adds a CPT code or when an AP practice adds any new tests, UHC requires that lab or practice to register those tests.

"We tell our clients to compile the test list first before registering that list with UHC," she continued. "We want to fully understand the registration process before a lab client then registers the tests with UHC, because if a clinical laboratory's code billed doesn't match what UHC has in its registry, it will create chaos when claims are submitted.

"We are working with each of our lab and pathology clients to make sure all of their tests get registered correctly with UHC," she said. "That's a huge administrative burden for labs, AP groups, and billing companies." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Houston, an 18-year-old high school student started a mobile laboratory company to provide COVID-19 tests to home-bound patients. As the youngest emergency medical technician in Texas, Taft Foley, III, saw the need for this service. **Texas Mobile Medical Labs** is the name of his company and it is emblazoned on his van. It is a CLIA-certified lab offering both molecular and rapid antigen tests for COVID-19. Foley's lab company has a relationship with **Baylor Genetics Laboratories** for PCR tests.

MORE ON: *Taft Foley, III*

His company has done 500 COVID-19 tests to date and has earned local and national news coverage. Foley, an honor student and Eagle Scout, says the colleges on his radar screen include **Harvard**, **Stanford**, **Princeton**, and **Yale**. Pathology programs at these universities might want to reach out to Foley and encourage him to follow a path into laboratory medicine and pathology.

KALORAMA SAYS $12 BILLION SPENT YEARLY ON LDTS

Government and private health plans are struggling to manage the explosion in the number of claims submitted for laboratory-developed tests (LDTs). In a just-issued report from **Kalorama Information** of Arlington, Va., the company says the market for LDTs "is currently valued at $12 billion and this figure will grow to $17 billion by 2025." It further notes that "the COVID-19 pandemic is driving demand for new LDTs even as regulatory agencies fight over how to regulate the tests." As published in the Oct. 4 issue of THE DARK REPORT, California-based **Bruce Quinn Associates LLC**, did an analysis of 2019 Medicare payment data and determined that from 2018 to 2019 (pre-pandemic) spending on genetic tests, including LDTs, increased by as much as 700% during that period for four Medicare Administrative Contractors (MACs). Pathologists and lab executives should expect payers to take aggressive actions to manage the dramatic rise in the number of LDT claims, such as cutting fees paid for LDTs in coming years.

TRANSITIONS

• **Proscia, Inc.,** of Philadelphia, named pathologist Monica Santamaria-Fries Cambridge, MD, as its first Digital Transformation Officer. She previously worked at **Kaiser Permanente** in California for 32 years.

• **Becton Dickinson** of Franklin Lakes, N.J., promoted Dave Hickey to the position of Executive Vice President and President of Life Sciences, effective Jan. 1, 2021. Hickey currently is BD's Worldwide President of Integrated Diagnostics Solutions and prior to BD, he held executive positions with **Siemens Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 16, 2020.

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Resources and Help for Labs During SARS-CoV-2 Pandemic

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UPCOMING...

- ***HHS sends legal advisory to FDA challenging its attempts to regulate LDTs: an analysis of what this means for labs.***
- ***Batched testing and pooled testing for COVID-19: What's working and secrets labs must know to succeed.***
- ***COVID-19 lab testing fraud is targeted by federal agencies, including enforcement of CLIA violations.***

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