Volume XXVIII, Number 2 Monday, February 8, 2021

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...

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Founder & Publisher

Clinical Labs Have the Opportunity to Deliver Value

FOR DECADES, PATHOLOGISTS AND CLINICAL LABORATORY PROFESSIONALS have called attention to the single most powerful resource possessed by their lab organizations: patient lab test data.

Everyone in lab medicine is familiar with the oft-repeated statement that the cost of lab testing is about 3¢ to 5¢ on the healthcare dollar, but lab test data is involved in 60% to 70% of all critical decisions involving diagnosis and selection of therapies, as well as—in hospital settings—decisions on therapy, and whether to admit or discharge. Ironically, there has never been a paper published in a peer-reviewed journal that uses data collected and analyzed by a team of researchers to prove or disprove this statement! (Hint to all lab professionals: if you conducted such a study, publication of your peer-reviewed finding would immediately become a foundational document that influences payers, healthcare policymakers, and even elected officials tasked with establishing coverage guidelines for federal and state health programs.)

From the onset of the pandemic, the power of lab test data was front and center in the public eye. It is the COVID-19 test result that not only guides clinicians on the diagnosis and treatment of the individual, but informs public health officials about whether the outbreak is spreading or retreating, which communities are experiencing surges, and whether new variants of the SARS-CoV-2 coronavirus are surfacing and where.

Even the news media is learning about lab testing. Journalists are writing stories about genetic testing, rapid molecular SARS-CoV-2 tests, and the complexities of seriological testing, including what differentiates antibody tests from antigen tests and why sensitivity and specificity can change with disease prevalence.

These unique circumstances make the time ripe for Clinical Lab 2.0. The opportunity exists for clinical laboratory professionals to go beyond simply reporting an accurate test result within the target turnaround time. Now is when pathologists can combine lab test data with other clinical, demographic, and geographical data sets to create actionable intelligence that accomplishes two goals: better patient outcomes and reduced cost of care.

Labs that can fulfill the promise of Clinical Lab 2.0 in this way will be rewarded with additional reimbursement, along with new respect for their contribution to improving healthcare. TDR

What's Ahead for Labs? It'll Be Quite Different

Is a 'perfect storm' of unwelcome factors gathering that will confront all laboratories in serious ways?

CEO SUMMARY: In many ways, the nation's clinical laboratories performed magnificently in response to the SARS-CoV-2 outbreak last winter. But that magnificent performance has taken its toll on the infrastructure and personnel within these labs. THE DARK REPORT provides insights into four key factors common to all clinical laboratories, particularly those that curently perform large numbers of COVID-19 tests. The following analysis looks at staffing, finances, equipment, and management in labs today.

IS IT NOW THE BEST OF TIMES OR THE WORST OF TIMES FOR THE CLINICAL LABORATORY INDUSTRY? That converts the famous opening sentence of Charles Dickens' novel, "A Tale of Two Cities" into a question of keen interest to pathologists and lab executives.

The answer is yes to both elements of this question. Yes! It is the best of times for those clinical laboratories performing large volumes of SARS-CoV-2 tests and enjoying the economies of scale that allow them to generate worthwhile profits from that line of testing.

Yes! It is the worst of times for those labs that either do not do COVID-19 testing or do not do enough volume of such tests to generate the cash flow needed to offset the revenue they lost during the March-April collapse of routine test referrals last year.

Some of these clinical laboratories have already closed their doors for good. Others may have been acquired by financially stronger labs that wanted the clients, but closed the acquired lab's facilities and laid off their staffs.

For both classes of clinical labs, 2020 was a year like no other. It brought an unusual "duality" to lab management. Lab administrators and pathologists found themselves confronted with the need to do two major things simultaneously.

The first aspect of this duality was the laboratory management responsibility to react to the pandemic and do so in a crisis mode. That meant bringing up—and sustaining—a robust capability to perform large volumes of COVID-19 tests and support city, county, state, and federal programs to operate drive-in specimen collection sites.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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All of these activities were high stress for the entire lab staff and have lasted for weeks and months with little relief. Supply chain problems only brought more stress and continue to this day.

Second Aspect

The second aspect of this duality occurred during early spring of 2020. As patients returned to hospitals and physician offices, labs had to maintain the expected level of ongoing COVID-19 testing as daily volume of regular specimen referrals climbed back to pre-pandemic levels.

Clinical laboratory executives and pathologists should step back and recognize this duality. They are actually managing two major lab testing operations simultaneously under the same roof, typically using the same lab staff.

Never before have large clinical lab facilities been asked to maintain a "normal" daily volume of routine testing, while at the same time performing a volume of SARS-CoV-2 testing that may equal or double the number of routine tests already performed daily in that facility. Stated differently, labs are cramming double or even triple the number of tests into their existing facilities, compared to pre-pandemic volumes.

Factors for Consideration

The consequences of this situation will be with the entire House of Laboratory Medicine for many years in the future. Strategic planning and operational execution need to consider several factors.

First, across the entire laboratory, staff are experiencing high stress and burnout. Back in March, lab professionals rose to the challenges created by the pandemic with enthusiasm and much success. Lab staff spent long hours manning outdoor, drive-through specimen collection sites—often in inclement weather. Other staff did home collections.

Staff within the laboratory worked long hours to validate SARS-CoV-2 assays and new instruments used to run those tests. The same staff then worked extended hours to keep testing lines going, often on a 24/7 schedule.

New accessioning staff was recruited as fast as feasible to process increased numbers of COVID-19 tests. More medical technologists and clinical laboratory scientists were added to the technical staff to perform each increased wave of SARS-CoV-2 tests.

It should not be overlooked that lab management also is mentally and physically taxed. From the onset of the pandemic, they have been in their labs every day of the week and for long hours each day. Often, it has been the senior lab administrators and managers who invested hours daily fighting an uncertain supply chain. They put much effort into securing necessary clinical laboratory supplies, test kits, and instruments required for the lab to not only meet the demand for COVID-19 tests, but also to handle the daily volume of test referrals for the lab's normal services.

Analyzers Are 'Used Up'

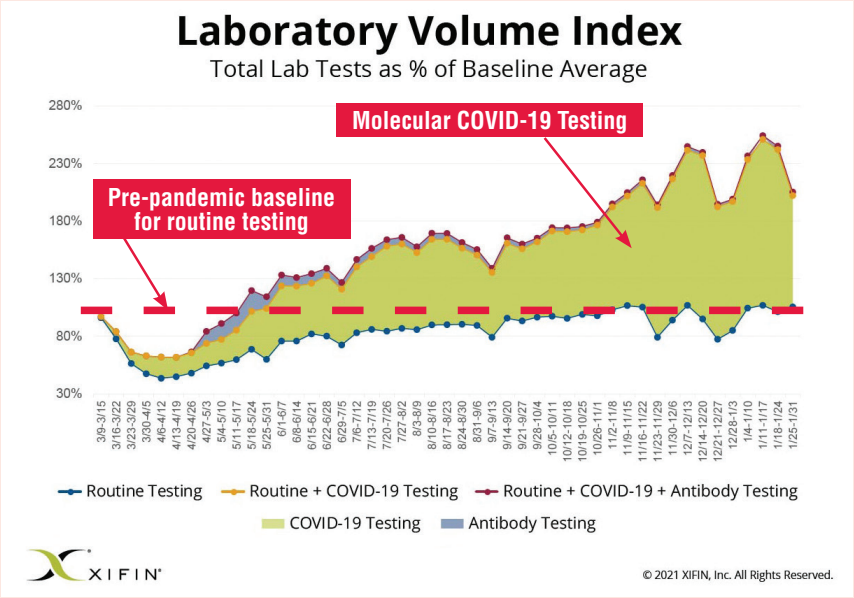
Second, clinical laboratories throughout the United States are using up their analyzers, automation, and testing equipment. This is an unrecognized consequence of the pandemic.

All laboratories have a capital equipment replacement cycle. The analyzers and automated systems have an expected service life that is based, in part, on the number of tests run on the machine from time of purchase until replacement.

Depending on the type of instrument, the replacement cycle is commonly three years, five years, or even seven years. But since the advent of the COVID-19 outbreak in the winter of 2020, normal replacement of testing instruments and automated systems has become difficult.

Additionally, *in vitro* diagnostics manufacturers had to direct their current production of analyzers and automation

How Pandemic Triggered a Divergence in the Financial Fortunes of Different Clinical Labs



SINCE THE OUTBREAK OF COVID-19 IN FEBRUARY AND MARCH, the cash flow of many clinical laboratories has been like a roller coaster ride. As the chart above shows, in the first months of the pandemic, revenue from routine lab testing dropped by as much as 60% per week. It was not until August that revenues from routine testing were consistently back to pre-pandemic levels.

Meanwhile, this chart also shows how revenue from molecular SARS-CoV-2 testing began ramping up in the early months of the pandemic. Currently, weekly revenue from molecular COVID-19 testing is equal to about 130% of revenue from routine testing. For labs doing large volumes of COVID-19 testing, this is welcome cash flow. For labs doing few or no COVID-19 tests, revenue from this line of testing is not enough to offset the diminished cash flow from the early months of the pandemic.

This chart was provided by **XIFIN, Inc.**, of San Diego. It is based on the actual revenue performance of XIFIN's several hundred laboratory clients, most of which are independent commercial lab companies, but also includes a few large hospital lab outreach programs.

This chart is updated weekly on *www.Covid19briefings.com*.

to labs that were capable of expanding the daily volume of SARS-CoV-2 tests they could perform. This was particularly true in the early months of the pandemic.

Because of these developments, there are many clinical laboratories operating today that were forced to delay scheduled replacement of their analyzers, automation, and other systems.

Similarly, many labs are pushing larger numbers of tests through their existing diagnostic machines and lab analyzers than was originally planned. So, even if the scheduled replacement date for these instruments is still a few years away, these machines will have exhausted much of their engineered service life well in advance of the currently scheduled date for replacement.

Third, lab budgets became nearly irrelevant once the pandemic began last winter. Labs spent whatever money was needed to get the job done. Sometimes there was funding from a government agency for things like staffing drive-through specimen collection centers or similar responses to the pandemic.

At the same time, because of stay-at-home directives and patients' reluctance to visit doctors' offices or hospitals, the collapse in routine specimen referrals in March, April, and May blew big financial holes in lab budgets.

Passage of the "Coronavirus Aid, Relief, and Economic Security Act" (CARES Act) by Congress in late March opened the door for financial assistance to all medical providers, including relief for Medicare providers. Of course, the Paycheck Protection Program loans authorized by the CARES Act were an important source of cash for clinical labs and pathology groups as well.

Blowing Up Lab Budgets

The key point with this factor is that few labs were able to stay within their budgets after the onset of the pandemic. Unexpected things kept happening with lab expenditures, the need to fund larger payrolls as more workers and medical technologists were hired, and the uncertainty of reimbursement by payers as labs submitted claims, particularly claims for SARS-CoV-2 tests.

For all these reasons, most labs found it impossible to manage according to their original 2020 budget plan. Instead, lab CFOs and managers scrambled to buy necessary supplies at the lowest prices possible while working to bring in money from any source of funding.

Going forward into 2021 and beyond, the financial fitness of labs can be expected to be an issue. This will be true even after the pandemic subsides and some semblance of pre-pandemic business and social activity is able to return.

The fourth factor to consider involves the managers and administrators of labs, particularly those of hospitals and health systems. It is not only the line staff in the laboratory who have worked long hours and coped with the non-stop stresses of meeting challenge after challenge since the onset of the pandemic. As noted earlier, this is equally true of all the managers and administrators.

Management Burnout

Like their lab teams, these individuals have been on the job for long hours each day, often six to seven days per week. In certain ways, they faced even more intense tension and stress. When cash flow crashed in March and April, it was they who had to decide if workers would need to be laid off or terminated.

It should be recognized that the management and administrative teams at labs have reached deep for the energy and concentration to manage in a crisis mode for nearly a full year.

Collectively, these four factors—unique in the past 100 years of modern laboratory medicine—can be considered a perfect storm. The entire clinical laboratory industry has been stretched to the limit by the duality of managing the response to a global pandemic, while simultaneously managing the full daily flow of routine specimen referrals.

Are Labs Overstretched?

One conclusion to draw from these factors is that the nation's clinical laboratories have performed admirably in response to the pandemic. But they operate today upon a shaky foundation.

For the reasons listed above, it would be prudent for pathologists and clinical laboratory leaders to update the strategic, clinical, and business plans for their labs.

More challenges are ahead, regardless of whether the pandemic ends quickly or continues for months or years into the future. TDR

Academic, Commercial Collaboration for Testing

COVID-19 assay developed by SUNY Upstate now used at 64 campuses statewide to keep them open

CEO SUMMARY: In several important ways, this collaboration involving an academic clinical laboratory and a commercial company has paid big dividends, not just for the two partners, but also the parent university that oversaw the project. The two partners developed a SARS-CoV-2 test, then manufactured it in large quantities. The molecular COVID-19 test, named Clarifi, uses a saliva specimen and has the lowest limit of detection of any saliva test on the market. It is used at 64 SUNY campuses in New York State.

One lesson that academic medical center laboratories are learning during the COVID-19 pandemic is that collaborating with the right commercial diagnostics company can result in development of an effective molecular SARS-CoV-2 test that is then manufactured in large quantities and even used by universities to test their own students, faculty, and employees.

That's exactly the story at **SUNY Upstate Medical University** in Syracuse, N.Y., which partnered with **Quadrant Biosciences**, a molecular diagnostics company embedded at **SUNY Upstate Medical**, to co-develop the **Clarifi** COVID-19 saliva test. The test received emergency use authorization (EUA) from the FDA on September 22, 2020, and **New York State Department of Health** approval in late August.

How a professor within SUNY Syracuse made this all happen provides a road map that will be useful to other pathologists and molecular PhDs as they continue to respond to the pandemic and provide SARS-CoV-2 tests to the communities served by their clinical laboratories.

Moreover, because of the test's performance characteristics, it became the COVID-19 test of choice—not only for the student COVID-19 testing program at the SUNY campus in Syracuse—but for all 64 SUNY campuses throughout the state of New York. The numbers confirm the success of this effort. By the end of January, over 600,000 Clarifi SARS-CoV-2 tests had been performed on students, faculty, and employees at all SUNY campuses statewide.

Quadrant Bioscience manufactures the test kits and SUNY Upstate performs the Clarifi tests at its clinical laboratory in Syracuse. Along with the high volumes of testing it enables for the SUNY system, Quadrant also sells the Clarifi tests to other clients and customers.

SARS-CoV-2 Assay

This success story begins when Frank Middleton, PhD, Director of the **State University of New York Molecular Analysis Core** (SUNYMAC) facility at SUNY Upstate in Syracuse, knew he had to act quickly to develop an assay that could be used to identify the SARS-CoV-2 virus, which causes COVID-19. Middleton is also Associate Professor in the Department of Neuroscience and

Physiology, Department of Psychiatry and Behavioral Sciences and the Department of Biochemistry and Molecular Biology at SUNY Upstate Medical University.

Middleton was uniquely prepared to take up this challenge. He has worked in saliva-based microbial and RNA biomarker development for the past decade. He had the full support of the university administration and an on-campus partner, Quadrant Biosciences, as well as the assistance of several researchers.

"We were challenged with developing a lab test that could help meet the needs for increased testing capacity, remote self-collection, and use in asymptomatic individuals, while also avoiding as many reagent shortages as possible that so many other labs faced," explained Middleton.

The work on the individual test was initiated in March 2020 with two working prototypes for a saliva-based multiplexed assay by the first week of April, and final data for submission to the federal **Food and Drug Administration** (FDA) by the end of April.

However, changes made by the FDA to its requirements for validation samples forced the team to start over. The team submitted its data to the FDA for approval in early June, received feedback in early July, and resubmitted the request in early August. SUNY's Clarifi COVID-19 test received emergency use authorization from the FDA on September 22, 2020. New York State approved use of the test in late August.

Lowest Limit of Detection

The Clarifi COVID-19 test kit has the lowest limit of detection of any saliva test on the market, at just 600 NDU/mL. In addition, it is engineered to limit false-negative results by integrating an RNA stabilizing solution into the saliva collection kit.

"The Clarifi test is more sensitive than other saliva tests, which likely reflects the fact that the sample collection device stabilizes the RNA in the saliva—including the host and the viral RNA—using a proprietary combination of buffers and enzymes that also completely inactivate the virus and make the samples extremely safe for handling," Middleton noted.

"We worked with the swab collection device manufacturer—**DNA Genotek**—to substantiate all this and even tested the viral and microbial inactivation properties ourselves. This property has the added benefit of allowing the test to be collected remotely—in some cases hundreds of miles away from a lab—and used for both pooled and individual tests after storage or transport at room temperature for several days.

"Of course, we want the results much sooner than that, but there is no substitute for maintaining the quality of the starting material," he added.

Developed with Quadrant

Quadrant Biosciences (Syracuse, N.Y.), a startup that was established on the SUNY Upstate campus about six years ago, began working with Middleton on development of the test early on.

"At the beginning of the pandemic last February and March, Quadrant had a total of about 25 people working on our campus, ranging from programmers, engineers, and data analysts to clinical research associates and bench scientists," Middleton said. "One of those bench scientists was a former PhD student of mine. When our campus went on shutdown mode, I was given the green light by my university to continue working on the saliva test, and Quadrant offered their support in the form of personnel and purchasing power. After a week on my own, I asked my former graduate student to work with me, and we actually co-developed the saliva test. I later added the pooled test component."

SUNY Upstate worked hand-in-hand with Quadrant to get the test through the

SUNY's Clarifi Molecular COVID-19 Assay Uses Saliva Specimen, Supports Pooled Testing

SUNY's COVID-19 POOLED TESTING PROTOCOL allows for collection of saliva that can be tested as part of a pool and also individually if needed. Each pool can test between 10 and 25 people at a time using one assay, although campuses are currently advised to use a maximum of 12 in a pool.

Pooled testing uses the Clarifi COVID-19 test, co-developed by professor Frank Middleton, PhD, his team at SUNY Upstate Medical University, and Quadrant Biosciences. According to SUNY's testing protocols, a local collection team at a school should be able to receive up to 6,000 saliva samples and create 500 pools in a single day.

Each campus typically has a testing area manned by student volunteers along with healthcare professionals. Students or staff swab the inside of their mouths for about 15 seconds and swabs are placed in a collection tube with a stabilizing solution. At the pooling station, a healthcare professional decants the liquid from the tube into a separate common pool tube. The swab remains in the original collection tube so that it can be tested individually if needed.

The samples are sent to the laboratory at SUNY Upstate for testing. A negative test for the pool means that all those in the pool are presumed to be COVID-free. A positive test for the pool requires that each of the individual swabs will then be tested using the Clarifi PCR test.

"The real difference between our pooled methodology and others is that—with a single swab—we can do the pooling and the reflex testing," Middleton noted.

"We average turnaround of under 24 hours from time of receipt for pooled tubes. If we have to test individual samples, that takes a little longer, but no more than one additional day. Each campus gets a report that shows a list of all the students in a pool along with a notification of students who have tested positive for COVID," he added.

FDA authorization process successfully, and they continue to work together on the distribution of the test to the 64 SUNY campuses. Quadrant also helps recruit and hire essential lab workers to staff the laboratory at SUNY Upstate.

"It is an understatement to say that without Quadrant's input, this SARS-CoV-2 test would be just another good idea left on the shelf of an academic scientist, without the ability to reach approximately 150,000 people per week at present and double that number by the end of February," Middleton said.

Test at 64 SUNY Campuses

SUNY is using the Clarifi COVID-19 test to screen students and faculty at the 64 SUNY campuses throughout the state of New York. The system is using pooled surveillance, which allows multiple samples to be run in a single test, along with reflex testing as needed.

As of mid-January 2021, more than 600,000 Clarifi tests had been performed on SUNY's campuses, with 200,000 of them done in the two weeks leading up to the winter break, which began just before Thanksgiving.

"The Clarifi test has served as one of the cornerstones for reopening SUNY campuses, with others being social distancing, preventive hygiene, and personal protective equipment (PPE)," noted Middleton. "During initial development of the test, we thought it was an assay that might be used on our campus [SUNY Upstate] and did not expect that it would eventually be deployed across more than 60 SUNY institutions.

"Since the SUNY-wide surveillance efforts have begun, the test has been used to screen more than half a million samples in pooled fashion, with approximately 2% to 3% of samples being subjected to reflex testing. The cost savings alone from not having to pay for individual testing of those students more than offsets all of the investment made in developing the test," he noted.

Test Performed at Cost

SUNY Upstate, which developed and performs the testing, provides access to the Clarifi test for other SUNY campuses at cost, which is $15.

For other schools outside the SUNY system, the cost is $30 per test. Each campus sets its own testing schedule, but Middleton notes that—as would be expected—campuses that achieve the best overall low positivity rate are those that do the most testing.

"We have some campuses that test all students every week and they have positivity rates of about 0.2%," he said.

Noting this, the SUNY Chancellor in January 2021 directed all SUNY campuses to test 100% of their students each week during the spring 2021 semester.

As of January 29, 2021, a total of 4,261 people tested positive for SARS-CoV-2 out of 778,667 tests administered on SUNY's campuses, according to the SUNY COVID-19 tracker. Each campus sets its own trigger for transition to 100% remote learning.

The trigger at **Buffalo State**, for example, is 100 cases, while the trigger at the **Fashion Institute** in Manhattan is 45.

Test Now Offered to Others

SUNY and Quadrant have begun expanding the Clarifi testing protocol beyond the SUNY system and other private colleges, offering testing for a few elementary and middle schools, including some in Pennsylvania.

"Bandwidth is the problem in terms of expansion," Middleton explained. "We have more people interested in using the services than we alone can accommodate. We expect there to be a continued need for college and pre-college testing for the next six to eight months."

To help meet this demand, SUNY Upstate Medical University and Quadrant are opening a new laboratory at the University of Buffalo to increase testing capacity, Chancellor Jim Malatras announced on January 31.

The new lab, which is expected to be operational by March 1, will be able to process 150,000 tests per week, increasing total COVID-19 testing to 350,000 tests per week across SUNY, with results being returned to campuses within 24 hours.

SUNY is investing $120,000 in the expansion by purchasing the equipment to process the Clarifi test at the new lab. Additional funding will be provided by Quadrant, and the laboratory will be staffed by Quadrant in partnership with SUNY faculty and student medical researcher teams. TDR

Contact Frank Middleton, PhD, at middletf@upstate.edu.

SUNY COVID Test Used to Test Wastewater

SUNY AND OTHER SCHOOLS ARE USING A MODIFIED VERSION of the Clarifi PCR assay to monitor wastewater on campuses to identify community-level transmission.

The SARS-CoV-2 Early Wastewater Surveillance Platform started as a collaboration in mid-March between scientists from **Syracuse University**, SUNY College of Environmental Science and Forestry, and SUNY Upstate. SUNY Upstate provided the space and specialized equipment needed to develop the specifics of the assay.

Although the assay used for wastewater testing is similar to the one used for saliva testing, wastewater is tested in a different laboratory using a different reference gene assay.

Lab Market Update

Critics Say New At-Home Test Is Expensive and Late to Market

They say the first over-the-counter test for COVID-19 to get EUA status from the FDA "is a waste of money"

ONCE AGAIN, THE COMBINATION of the pandemic and the federal government may be creating a credible new competitor in the *in vitro* diagnostics (IVD) industry. This time, the lucky company is **Ellume**, which was just awarded $231.8 million from the Biden administration to scale up production of a home test for SARS-CoV-2.

Ellume was given an emergency-use authorization (EUA) from the federal **Food and Drug Administration** (FDA) in December. This allows the Australian company to market its over-the-counter COVID-19 at-home test to patients. The test will cost $30 and be available online, in pharmacies, and in other retail stores. One big advantage of this test is that it will not require a physician's order, the FDA said in a press release announcing the EUA.

On Dec. 15, the FDA said the Ellume COVID-19 Home Test is a rapid, lateral flow antigen test that detects fragments of proteins of the SARS-CoV-2 virus from a nasal swab sample from any individual age two or older. The at-home test uses an analyzer that connects with a smartphone app. The app helps the user perform the test and interpret results. "Results are delivered in as little as 20 minutes via their smartphone," the FDA said.

Former FDA Commissioner Stephen M. Hahn, MD, characterized the EUA as a significant milestone. "By authorizing a [COVID-19] test for over-the-counter use," he said, "the FDA allows it to be sold in places like drug stores, where a patient can buy it, swab their nose, run the test, and find out their results in as little as 20 minutes."

The test uses a mid-turbinate nasal swab, the FDA said, explaining that the sample is collected further back than a usual nasal swab, but not as far back as nasopharyngeal swabs. The test correctly identified 96% of positive samples and 100% of negative samples in individuals with symptoms, the FDA added. "In people without symptoms, the test correctly identified 91% of positive samples and 96% of negative samples."

Critics: 'a Waste of Money'

But some critics of the test called it a "waste of money," according to *STAT News*. Last week, the Biden administration said it would spend $231.8 million to increase production of the Ellume test and produce 8.5 million versions of the test. The administration also said it would provide funding to build a factory in the U.S. that will eventually make millions of tests every month. But critics said building a factory to boost production will take time when more Americans need access to COVID tests right away, *STAT* reported. Critics also said the test is needed now and at $30 is too expensive and complicated, *STAT* reported without naming those critics.

Nevertheless, Ellume has a quarter billion dollars of American taxpayer money to scale-up production of the SARS-CoV-2 tests. Post-pandemic, this manufacturing capacity can be devoted to other lab tests and make Ellume a serious competitor to existing IVD companies. TDR

Increasing need for local labs to identify, report variants

Variant Sequencing of SARS-CoV-2 Creates Opportunities for Labs

CEO SUMMARY: Variants of the COVID-19 virus are appearing across the world. Recent data show the same variants will infect people in several different countries. Here in the United States, interest is growing in having clinical laboratories sequence specimens from patients who test positive as a way to identify mutations and track their spread. Today, there is no reimbursement for labs that do this sequencing, but a new bill in Congress would establish payment for the genetic sequencing of specimens from patients with positive test results.

TESTING FOR VARIANTS OF SARS-CoV-2 is poised to become the next big thing for many of the nation's clinical laboratories.

Some labs have begun using next-generation sequencing (NGS) to identify mutations in coronavirus strains that may be more lethal or may spread more quickly than the original virus strain. When variants are identified, labs need to report the results to public health officials.

Earlier this month, the **State Serum Institute** in Denmark reported that cases involving variants of the SARS-CoV-2 virus were increasing at 70% a week among the Danish population. The Danes knew that SARS-CoV-2 variants were rising because they had been sequencing positive coronavirus specimens to identify mutations.

Given that Denmark has a population of fewer than six million, it was easier to do SARS-CoV-2-variant sequencing there than it would be in the United States, which has a population of 330 million. At the time, U.S. clinical laboratories were sequencing only 0.3% of positive cases, leaving physicians and public health authorities largely blind to the spread of the various SARS-CoV-2 variants, according to reporting in *The Washington Post*.

Recognizing the pressing need to assess the spread of these variants, some forward-looking pathologists and clinical laboratory directors are already developing methods that use next-generation sequencing specifically to identify variants among patients who test positive. But these nascent efforts face at least three significant hurdles to find ways to run variant-sequencing efforts at scale in the midst of the coronavirus pandemic:

- A lack of payment,
- A shortage of the right equipment in most labs, and
- A shortage of staff.

To understand the hurdles that pathologists and clinical lab directors face when hunting for SARS-CoV-2 variants, THE DARK REPORT interviewed Garret Hampton, PhD, President, Clinical Sequencing and Oncology at **Thermo Fisher Scientific**. Hampton has more than 25 years of experience in precision medicine in oncology, cancer genomics, and companion diagnostics, using next-generation sequencing as a core tool.

Hampton explained how certain hospitals and health systems in the United States and other countries are sequencing COVID positive cases to identify variants. He noted that many observers believe most testing intended to identify variants of SARS-CoV-2 in patients who test positive for the coronavirus is being done almost exclusively in large reference laboratories.

While sequencing in central labs is the dominant approach, pathologists and clinical lab directors have shown strong interest in doing variant sequencing in local and regional laboratories closer to the physicians and patients they serve. Doing so would allow more labs to identify variants and trace their spread quickly.

➤ Testing at the Local Level

"There is a need for SARS-CoV-2 variant testing that can help health officials track and control the outbreak in their communities," commented Hamption. "We've seen the assumption that variant sequencing for COVID-19 is done predominantly in large reference labs and academic medical centers. But that leaves an important element unaddressed. That missing element is the need for local level sequencing for SARS-CoV-2 variants to expand at a faster pace than is currently true. That's the key right now."

Clinical labs in the United States would already have identified more SARS-CoV-2 variants except that few—if any—sources of payment exist for labs that sequence COVID-positive specimens for the purpose of identifying variants of SARS-CoV-2.

On Feb. 4, members of the U.S. House and Senate introduced legislation to boost U.S. efforts to track coronavirus variants, and the Biden administration has proposed funding to pay for that work. *(See sidebar, "Federal*

Legislation Would Fund Sequencing of COVID Variants," page 15.)

Further, many local and regional labs may lack the equipment and staff n eeded to do such sequencing at scale. Therefore, there is a growing need to encourage health insurers and the federal government to pay for such testing, Hampton said. The following is an edited presentation of Hampton's interview with Joseph Burns, Senior Editor for THE DARK REPORT.

EDITOR: Can you describe the work that Thermo Fisher's laboratory clients are doing to identify variants to the SARS-CoV-2 coronavirus?

HAMPTON: Yes, certainly. But first, I'd like to step back just a bit to explain that currently almost all the genomes of the positive infections from the SARS-CoV-2 virus are being sequenced in two different lab settings in the United States, Europe, and in other countries.

EDITOR: How do the settings differ?

Garret Hampton

➤"These labs know that if they see an altered result via the SARS-CoV-2 PCR result for certain patients, that result indicates something is different from this specimen, compared to the original strain. Those are the specimens that they will sequence to identify any variants that may be present."

HAMPTON: One setting is comprised of the large reference labs, such as **LabCorp** and **Helix Diagnostics**. The other setting is made up of academic medical centers (AMCs). To a lesser extent, some hospital networks are doing this work too. In one program, the CDC has contracted with large reference labs and with other labs, such as those in AMCs, to sequence genomes. That's important to know because the goal of some of these efforts is to sequence coronavirus genomes at scale.

EDITOR: How is Thermo Fisher tracking these developments?

HAMPTON: We've heard from our customers that those efforts are important because they give us a way to track and trace the various viral strains. And tracking and tracing viral strains is what they tell us they want to do at the local level.

EDITOR: We have seen that many labs are interested in tracking and tracing viral strains in the areas they serve. What is the goal of those efforts?

HAMPTON: From what we've seen, our customer labs want to perform surveillance at a local level so that they can identify variants that are known, or new strains that may be more impactful than the original strain. Once they have that data, they can alert local public health agencies and provide accurate and actionable information to those authorities.

EDITOR: How might labs flag specimens that would be candidates for sequencing?

HAMPTON: Several of our customers do this work now. For example, these labs know that—if they see an altered result via the SARS-CoV-2 PCR result for certain patients—that result indicates something is different from this specimen, compared to the original strain. Those are the specimens that they will sequence to identify any variants that may be present.

EDITOR: Are any of your lab customers doing this sequencing currently?

HAMPTON: One of our lab customers is pathologist Timothy Triche, MD, PhD, the Co-Director of the Center for Personalized Medicine Program at the **Children's Hospital Los Angeles** (CHLA). At his lab, they sequence 100% of their COVID-19 PCR positive cases. As you know, Los Angeles County has had—and continues to have—high COVID-19 infection rates. They're looking for variants and, not surprisingly, they're finding that some of them are the same variants that labs in the United Kingdom have reported. We don't yet know whether

those variants tend to spread COVID-19 infections faster than other strains.

EDITOR: Are there other interesting findings from labs doing this gene sequencing?

HAMPTON: Another of our customers is the **Cedars-Sinai Medical Center**, which is also in Los Angeles. In that lab, they've identified a new strain called the California Strain, abbreviated as Cal.20C. This strain is thought to be more infectious than other strains and it's actually been found in about a third of Cedar-Sinai's positive patients. There's speculation that this strain is contributing to the surge in cases there.

EDITOR: Have any labs that regularly do next-generation sequencing (NGS) for cancer testing started to use those capabilities to do variant sequencing of the SARS-CoV-2 coronavirus?

HAMPTON: Yes. We have labs that typically use NGS for tumor sequencing and are using some of those capabilities for COVID-19 sequencing. One of those labs is the **Kabara Cancer Research Institute** which is part of the **Gundersen Medical Foundation** in La Crosse, Wisc. They recently pivoted from doing cancer research to sequencing known SARS-CoV-2 positive samples from that region in Wisconsin. That work is interesting because they traced a single infection in a meatpacking plant in Northeast Iowa across three states over six weeks. Following the migration of the individuals who had that strain into different states is important for anyone identifying a variant and then trying to understand the epidemiology of how that infection spreads.

EDITOR: Each of those cases are fascinating and worthy of further study. Have you had any customers identifying SARS-CoV-2 variants in other countries?

HAMPTON: Yes, we have two customers in Italy and one was among the first to tell us that they were able to find new strains with our technology and assays.

Federal Law to Fund Sequencing of Variants

SOME MEMBERS OF CONGRESS RECOGNIZED THE NEED TO ESTABLISH PAYMENT to clinical laboratories that are gene sequencing SARS-CoV-2 to identify variants. On Feb. 4, U.S. Senator Tammy Baldwin (D-Wisc.) and U.S. representatives Ami Bera (D-Calif.) and Scott Peters (D-Calif.) introduced a bill to boost efforts in clinical laboratories to identify and track variants to the SARS-CoV-2 coronavirus.

In announcing the bill, the members of Congress said the United States was conducting sequence-based surveillance of only about 0.3% of COVID-19 cases, and that our nation's efforts lagged behind that of other nations. "It is critical that the United States scale up its efforts to survey at least 15% of cases to better grasp new and emerging variants, understand their origins, and develop mitigation strategies," the lawmakers said. "The virus has changed, and it will continue to change as more Americans are vaccinated."

In the same announcement, the members of Congress said the Biden Administration's proposal, called the American Rescue Plan, addresses the need to identify emerging strains of SARS-CoV-2. Further, the plan includes funding to increase sequencing, surveillance, and outbreak analytics.

Also, they added, the Tracking COVID-19 Variants Act would provide $2 billion for the **Centers for Disease Control and Prevention** to support a national sequence-based surveillance program.

Another customer was in Sao Paulo, Brazil, where the lab identified the first case of a COVID-19 reinfection in Sao Paulo. From these examples, you can see that there are a variety of different uses for variant sequencing among our customers.

EDITOR: As your lab customers seek to identify SARS-CoV-2 variants, have you seen a theme in the work they are doing?

HAMPTON: The central tenet that I see in these examples is that labs are looking for variants so that they can alert their public health authorities, and so that they can understand the prevalence of the variants in their areas. We see stories in the news that are similar to what we hear from our customers. Many of our lab customers want to know if they can do this sequencing at the local level and they want to know if they can do it quickly.

EDITOR: Is that evidence that interest in variant sequencing among labs is growing?

HAMPTON: Yes, and that's the state of SARS-CoV-2 variant testing right now. We hear about large reference centers doing most of the variant sequencing for SARS-CoV-2, but the key right now is that there is definitely increased interest in doing more sequencing for SARS-CoV-2 variants at the local level.

EDITOR: One question many labs will ask is how do they get paid for sequencing SARS-CoV-2 variants? As you may know, many health insurers do not pay for COVID-19 testing for asymptomatic patients. Does that suggest that insurers will balk at paying to sequence variants?

HAMPTON: I think that's one of the biggest hurdles to doing large-scale genome sequencing of the virus. It's different outside the United States. In Europe, for instance, government-run health systems in France and Germany are paying for variant sequencing at a specific rate. But here in the United States, insurers are not paying, because the value of variant sequencing is not immediately obvious to them. Once the need for more variant sequencing is widely known, and variants become more visible, there will be heightened awareness about the need. Also, I'm hopeful that the government will step in at some point in part because I don't think anybody expected to see the numbers of strains we're seeing.

EDITOR: One researcher estimated that the SARS-CoV-2 coronavirus was mutating at a rate of about two variants per month. If correct, does that mean that, after 12 months, the world now has about 24 extant variants, or is it more or less than that number?

HAMPTON: That number is probably not too far off. Today, we know of a variety of strains. There's what is being referred to as the Brazilian Strain, the South African Strain, the UK Strain, and the Los Angeles Strain to name just a few. The sheer number of infected people in the world leads to that kind of a detectable mutation rate. When you have numbers like we've seen worldwide, then you start to see a wider variety of variant strains.

EDITOR: The other challenge for pathologists and clinical labs is that they need the right equipment and staff to identify SARS-CoV-2 variants. How do labs solve those problems?

HAMPTON: Here at Thermo Fisher, we have been working to make sequencing easier for clinical labs working with the Ion Torrent Genexus System that we introduced in November 2019. The Genexus is the first fully integrated NGS platform that includes an automated specimen-to-report workflow that delivers results in a day.

Garret Hampton

➤"We hear about large reference centers doing most of the variant sequencing for SARS-CoV-2, but the key right now is that there is definitely increased interest in doing more sequencing for COVID-19 variants at the local level."

EDITOR: What do clinical labs need to know about developing this capability?

HAMPTON: At the time we developed our Genexus System, and continuing today, we saw a need in oncology for the decentralization of testing to make testing easier, faster, and simpler. Because most labs taking on this work may not

be sophisticated users of NGS, we had to develop something that's fully integrated and has a short hands-on time. We did that on purpose because laboratories want results, and that means it's not about the machine necessarily. It's about getting results from your lab quickly.

EDITOR: So, the Genexus System solves some of the problems pathologists and clinical labs face when they prepare to sequence for SARS-CoV-2 variants. But where do they find the clinical laboratory scientists to run these machines?

HAMPTON: Up until now, most NGS has been done in bigger, sophisticated labs, such as those in academic medical centers or in large hospital systems. In those labs, the staff has done sequencing before and the senior staff fully understands sequencing. The senior staff have also hired the technicians or trained their lab techs to do NGS for cancer or for other testing. We saw that pattern clearly and wanted to get NGS beyond those settings alone, to make gene sequencing available to smaller labs and smaller local hospitals. NGS can't be and shouldn't be just in the realm of the AMCs or the larger hospital systems. It has to be done in more local and regional lab settings.

EDITOR: How has Thermo Fisher addressed this need for smaller clinical labs?

HAMPTON: Our premise is that we offer equipment for NGS that does not require a lab to hire highly trained technicians. That's a huge cost for most labs. We want labs that can take an immunohistochemistry technician, for example, and have that person also do genetic sequencing. That's how we view it, and we're approaching that level in terms of the value proposition and ease-of-use of our NGS equipment. Labs want to do this sequencing for more patients. They just need the equipment to do it with a certain level of ease of use.

EDITOR: Assuming that more clinical laboratories will be able to start sequencing for SARS-CoV-2 variants, what do they do with that data? First, they would report it to local or state health authorities, but where else would they report that data?

HAMPTON: There are repositories for this data. One of them is GISAID [Global Initiative on Sharing Avian Influenza Database] at www.GISAID.org. This initiative promotes the rapid sharing of data from the SARS-CoV-2 and influenza viruses. This includes genetic sequences and related clinical and epidemiological data associated with human viruses and geographical and species-specific data associated with avian and other animal viruses. That data is designed to help researchers understand how viruses evolve and spread during epidemics and pandemics.

Garret Hampton

"We saw that pattern clearly and wanted to get NGS beyond those settings alone, to make gene sequencing available to smaller labs and smaller local hospitals. NGS can't be and shouldn't be just in the realm of the AMCs or the larger hospital systems. It has to be done in more local and regional lab settings."

EDITOR: Besides GISAID, are there other places that clinical laboratories doing SARS-CoV-2 variant sequencing can report their data?

HAMPTON: That's a more difficult question to answer. It could be that state public health labs will need to develop the ability to collect and publish local SARS-CoV-2 variant sequencing data.

EDITOR: Thank you for taking the time to update our clients and regular readers about the latest developments in variant sequencing of SARS-CoV-2.

HAMPTON: The identification of variants is an important new development that affects how clinical labs respond to the pandemic. Thanks for the opportunity to share this information. TDR

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IVD Update

Proscia Lands Major Deals as Digital Pathology Demand Grows

Just weeks apart, Proscia lands big contracts with the Joint Pathology Center and LabPON

Even as the worldwide COVID-19 pandemic derailed some industries, it gave a major boost to digital pathology. That has meant an expanding market for **Proscia**, a seven-year-old provider of digital and computational pathology solutions.

Established in 2014, Proscia recently won what may be the world's most important contract involving digital pathology and computational pathology solutions. On Oct. 20, 2020, it was announced that the federal government's **Joint Pathology Center** (JPC) in Silver Springs, Md., would use Proscia's Concentriq platform for management of images and data, as well as collaboration among researchers. *(See TDR, Oct. 26, 2020.)*

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. The pathology specimens date back to 1862.

Similarly, Proscia inked another significant agreement when, on Jan. 11, it announced that **LabPON** (Laboratory Pathology East Netherlands) of Hengelo, The Netherlands, would use Proscia's Concentriq Dx, which carries the CE mark. LabPON is recognized as the world's first lab to reach 100% digital pathology diagnosis.

"Our Concentriq software enables diagnostic labs and research organizations to view, manage, and analyze whole-slide images," explained Nathan Buchbinder, Proscia Chief Product Officer and one of the company's three founders. "Concentriq makes possible connection to applications such as whole-slide scanners and laboratory information systems, and launch of computational pathology and AI solutions. Currently thousands of pathologists and scientists use it."

During 2020, despite the pandemic—or because of it—the steady increase in demand for digital pathology (DP) solutions and whole-slide imaging (WSI) was so robust that Proscia was able to raise $23 million in Series B funding last December. **Scale Venture Partners** was the lead investor, with participation from **Hitachi Ventures**.

Conjunction of Factors

Philadelphia-based Proscia appears to be benefitting from the conjunction of several factors behind the increased demand for digital pathology:

- Stay-at-home orders in the early months of the pandemic caused many pathologists to recognize how use of digital pathology and WSI could allow them to diagnose cases from their home offices.
- Research and pharma organizations are increasing their adoption and use of DP, WSI, and computational pathology solutions.
- Advances in image analysis and computational pathology are giving pathologists new tools to diagnose cancer and guide the selection of appropriate therapies.

"The number of pathology groups, labs and research organizations going digital has absolutely skyrocketed. I don't anticipate that is going to stop when the pandemic does," said Buchbinder in an exclusive interview with THE DARK REPORT.

"Prior to the pandemic, there was growth in the DP market," he continued. "Since the pandemic, the discussion has changed from one of 'When should we do this?' to 'How do we make digital pathology happen for our lab?' Not only are there more buyers, but there is urgency in their decision to implement a digital pathology system."

Digital Pathology Systems

Clinical laboratories, as well as life science and pharmaceutical companies, are using digital pathology systems that include these elements:

- Whole-slide scanners for capturing digital images from glass slides;
- Software platforms for case review and viewing digital images; and,
- Computational pathology and artificial intelligence (AI) to generate insights from data.

Another development favorable to adoption of digital pathology was the federal **Food and Drug Administration's** (FDA) "Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency" issued last April. The agency relaxed requirements for use of digital pathology during the pandemic, giving pathologists the go-ahead to remotely review scanned images. Now, an FDA federal notice (86FR4088) filed in January, aims to make permanent the regulatory flexibility.

Also, the federal **Centers for Medicare and Medicaid Services** (CMS) waived requirements for remote locations doing pathology case sign-outs to have separate CLIA licenses during the pandemic. *(See CMS memorandum QSO-20-21-CLIA: CLIA Labs Given Guidance During COVID-19 Public Health Emergency).*

Buchbinder shared these additional insights with TDR during the interview.

EDITOR: From Proscia's perspective, what are key healthcare trends in diagnosis and cancer care that benefit pathology groups?

BUCHBINDER: The biggest transformational trend is the broad adoption of digital pathology brought on by the recognition that there is an urgency to digitize. And the other trend is the ability to finally realize the potential of applications that use artificial intelligence (AI) or computational pathology to help the pathologist interpret the whole-slide images.

EDITOR: What is fueling demand for digital pathology?

BUCHBINDER: I see two factors driving adoption. One is the global pandemic and the other is growing enthusiasm around AI. We and a handful of other companies are at a stage now where we have lab clients deploying AI in practice and showing value creation from these products. This is on a trajectory to becoming routine in pathology practice. It is an exciting time for the DP industry and the anatomic pathology profession. We are excited to be in both realms and driving both trends.

Product Development

EDITOR: What niche and segment of cancer is Proscia concentrating on with its product development?

BUCHBINDER: Our core digital pathology platform Concentriq can be used to view, manage, and analyze images of any type of tissue. It is meant to be a platform that can be used across any of the work a routine pathology lab performs. As a focus area in AI we have announced skin cancer, and we are focusing on a handful of other sub-specialties too. Broadly speaking, we see other companies working on high impact sub-specialties, which are either difficult to diagnose or time-consuming.

EDITOR: You mentioned other companies offering digital pathology solutions. What are Proscia's strengths?

BUCHBINDER: We are strong in three key things. First, our DP platform is designed for use in multi-site enterprises, whereas other products are designed for single labs with single workflows. Our product is designed to accommodate labs with multiple sites and many pathologists working together. Second, we are extremely pathologist centric. We have pathologists on our team who are involved in the day-to-day development of our systems and digital tools. Digital pathology systems need to complement the existing workflows of pathologists, even as use of the system makes those pathologists more productive. Third, we believe we are the only company sitting at the intersection of digital and computational pathology.

Support of Routine Workflow

EDITOR: Could you explain this?

BUCHBINDER: Yes. If someone builds an AI application, it is innovative technology that still needs to be put into practice. We built a platform designed to integrate with *any* third-party AI application—including those we are building—into routine workflows. Our goal is that the pathologist feels the AI is a natural extension of his or her digital pathology environment.

EDITOR: How do you develop AI?

BUCHBINDER: The first application we built is called DermAI. It serves the dermatopathologist by classifying images of skin biopsies into more than 200 unique diagnoses. We are deploying it for research use only today, but as we generate evidence of this product at laboratories, we are finding more and more value. It is kind of a harbinger of where the market stands today and where it is going.

Building applications requires a lot of diverse data and validation work. We partner with leading academic and commercial laboratories: **Johns Hopkins**, **University of California San Francisco**, **Thomas Jefferson University Hospital**, and the **University of Florida**.

EDITOR: Please share examples of customers using Concentriq in clinical care.

BUCHBINDER: LabPON, which has already gone digital, is in the process of adopting our solution. They use digital pathology for every pathologist's day-to-day work. When pathologists come in, rather than pulling out the microscope, they log in on the computer and look at their digital pathology system and their list of cases. They see whole slide image views and the diagnoses of their cases in that platform. So, their work has largely shifted from the microscope to monitor; from analog to digital.

EDITOR: When a lab or pathology group uses a digital pathology solution like Proscia's on a case, how do Medicare and private insurers reimburse?

BUCHBINDER: In general, cases read using digital pathology are reimbursed the same way as cases read under the microscope. In fact, at the start of the pandemic, CMS expanded reimbursement to cover cases read digitally at home.

EDITOR: What factors would speed up adoption of digital pathology?

BUCHBINDER: There is a need for all the players in digital pathology to provide evidence of the value of digital pathology in patient care, along with DP's potential to improve pathologist productivity and improve diagnostic accuracy. To show how digital pathology creates value for the lab, we collaborated with THE DARK REPORT on a white paper, titled, "Pathology at the Tipping Point? The Economic Case for Adopting Digital Technology and AI Applications Now." The white paper demonstrates how adoption of digital pathology can improve lab productivity and efficiency by 13% to 21%. Evidence that demonstrates value can accelerate adoption of digital pathology. In the near future, we believe that pathology groups using digital pathology and related digital tools will have competitive advantage in the marketplace. TDR

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hc1, Visiun, and Viewics: Analytics Market Evolves

In last 36 months, three billion-dollar firms purchased or partnered with analytics companies

CEO SUMMARY: To understand any development in the marketplace, it is best to follow the money. That Roche, Quest Diagnostics, and LabCorp spent money either to purchase or partner with a lab analytics company in the past 36 months indicates that these enterprises believe acquiring or working with lab analytics systems can deliver competitive advantage. Labs began showing interest in real-time analytics solutions during the 2000s as a way to improve productivity and cut costs.

Middleware that provides clinical laboratories with real-time analytics is getting serious attention from a growing number of the nation's largest laboratory companies. One sign that an era of real-time lab analytics may be dawning is that, over the past 18 months, three of the nation's billion-dollar lab companies inked significant deals with a lab analytics company.

Just weeks ago, in December, **LabCorp** acquired **Visiun**, a company in Ann Arbor, Mich., that analyzes lab-performance data for hospital and health system laboratories.

Analytics Collaboration

That deal came just 14 months after **Quest Diagnostics** formed a strategic partnership in September 2019 with **hc1**, another lab data and analytics company. In this partnership, Quest and hc1 said they would work to enhance test-ordering stewardship by identifying inappropriate and inefficient testing to improve lab test utilization.

In an earlier deal involving a lab analytics company, **Roche** purchased **Viewics** in November 2017, a company founded in 2010 in Sunnyvale, Calif. Rebranded as Viewics Analytics, **Roche Digital Diagnostics** offers this company's services as a part of Roche Diagnostics.

Hundreds of labs in the United States use one of the major lab analytics solutions to manage the operations in their labs. This trend is one that The Dark Report identified more than a decade ago. *(See "New Study Demonstrates How Lean Labs Outperform Peers." TDR, Dec. 31, 2007.)*

Since then, some of the most innovative lab clients of hc1, Visiun, and Viewics have made presentations at The Dark Report's conferences, the *Executive War College* and *Lab Quality Confab*.

It was not an accident that third-party middleware analytics products emerged during the 2000s. Following the huge wave of hospital acquisitions and mergers in the 1990s (which was a reaction to the managed care contracting tactics of health maintenance organizations [HMOs]), from 2000 forward, multi-hospital health systems spent much capital and time to consolidate, standardize, and regionalize their clinical laboratory services across all testing sites.

The larger the core laboratory of a multi-hospital health system, the greater the opportunity to cut costs, raise productivity, and improve quality.

But waiting for the month-end reports that legacy laboratory information systems (LIS) provide was inadequate for labs that need real-time or near-real-time data to meet the challenges they face in today's market. To solve problems and to identify opportunities to improve lab operations, lab managers need detailed data and management reports on operations by the hour, by the shift, day, week, and month.

Another early trend from years past reinforced the need for real-time operations and performance reports: the adoption of Lean and Six Sigma methods.

That trend started in 2003, when three major hospital laboratory organizations became the first in the nation to use Lean to reorganize the workflow of their high-volume core chemistry, hematology, and immunoassay operations. Lean and Six Sigma methods deliver the greatest results when lab management can monitor workflow and individual work processes in real time. *(See TDR, "How 'Lean' is Benefiting Early-Adopter Laboratories," Sept. 8, 2003.)*

What Comes Next?

It is significant that both Roche and LabCorp decided to acquire lab analytics companies and bring them in-house. Both Viewics and Visiun are pure lab analytics plays. In contrast, hc1 launched as a customer relationship management (CRM) tool that targeted clinical labs. In subsequent years, hc1 has expanded into additional healthcare sectors.

It is also interesting that none of the major companies selling laboratory information systems were acquirers of these middleware analytics companies, since those features would complement their LIS services. **Sunquest Information Systems** did acquire **Data Innovations** (DI) in 2015, but DI is known more for its interconnectivity solutions than for its analytics capabilities. TDR

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Using Lab Analytics to Respond to New Needs

ACCESS TO REAL-TIME OR NEAR-REAL-TIME ANALYTICS IS HELPING LABS in significant ways during the COVID-19 pandemic, particularly for reporting SARS-CoV-2 test data to federal and state governments.

Last year, for example, the federal **Centers for Medicare and Medicaid Services** (CMS) required labs to report demographic data on patients tested for COVID-19, said **Visiun's** Founder and CEO Thomas Joseph. Also, when CMS announced in October that it would change how it pays labs for COVID-19 testing, labs needed to report results in two new ways, he added.

On Oct. 15, CMS said it would cut what it pays on Jan. 1 from $100 to $75 for each COVID-19 molecular test (called a clinical diagnostic laboratory test or CDLT) when labs do not produce such results in 48 hours. *(See "Medicare to Cut Payment for COVID Tests Starting Jan. 1," TDR, Oct. 26, 2020.)*

CMS also said it would add a $25 payment for COVID-19 CDLTs run on high-throughput analyzers if the laboratory completes each test in two calendar days or less and completes most COVID-19 diagnostic tests on high-throughput technology in two calendar days or less for all patients (not just Medicare members) in the previous month.

To comply with these two requirements, labs running COVID-19 CDLTs needed to develop new reporting systems, Joseph noted. "This two-tier reimbursement structure is difficult for labs because getting the extra payment depends on how quickly results can get returned to the lab's clients and ordering physicians," he said.

"For us, that required that we develop reports to help labs understand where they are in terms of their ability to recover that higher-tier payment for COVID-19 tests."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pathologists and clinical lab managers with an entrepreneurial yen will be interested to know that **Anthem, Inc.**, which serves 43 million beneficiaries, has launched a digital incubator. The new initiative was announced last month. *Fierce Healthcare* reported that the Anthem Digital Incubator (ADI) will "pair financial backing with with mentorship and opportunities for partnerships with universities and others."

MORE ON: *Anthem DI*

News reports say that ADI is accepting applications for community health challenges and specifically mentions medication adherence. Given the significant role clinical labs play in supporting medication adherence, particularly for prescription drugs that can be abused, the Anthem Digital Incubator might be a useful path forward for lab professionals with business concepts to serve that need.

TRANSITIONS

• Viresh Patel, PhD, is now Senior Director of Global Marketing, Genomics, for **Agilent Technologies** of Santa Clara, Calif. Patel formerly served at **Bio-Rad Laboratories**, **MJ Research**, and **Ingenuity Systems**.

• **Gravity Diagnostics** of Covington, Ky., appointed Michael Tarwater as Vice President of Information Technology. Tarwater previously held positions at **Progenity**, **Atherotech**, **John Muir Health Laboratories**, and **DSI Laboratories**.

• **Mammogen, Inc.**, of Aliso Viejo, Calif., announced that Elizabeth Cormier-May is its new CEO. Prior executive positions include **Persona Health**, **Exosome Diagnostics**, **Definiens**, **HTG Molecular Diagnostics**, **Biodesix**, **Predictive Biosciences**, **Myriad Genetics,** and **Novartis**.

• **Roche Diagnostics**, appointed Cindy Perettie to head its Molecular Lab Solutions business that is located in Pleasanton, Calif. Perettie was CEO of **Foundation Medicine**, another division of **Roche Holdings**. She previously held positions at **Genentech**, **Ivax Pharmaceuticals**, **Sarah Cannon Research Institute**, and **Élan Corporation**.

• John Spinosa, MD, PhD, is the new Chief Medical Officer at **Murrieta Genomics**. Spinosa previously served at **Agilent Technologies**, **San Diego Blood Bank**. **Lexent Bio**, **Scripps Memorial Hospital**, **Trovagene**, and **Verinata Health**.

• Pathologist Francisco Velázquez, MD, was appointed as Interim Health Director of the **Spokane Regional Health District** in Spokane, Wash. Previous positions were at **PAML**, **Quest Diagnostics Nichols Institute**, **Focus Diagnostics**, **University of Texas Southwestern Medical Center**, **Boston Medical Center**, **Boston University Medical Center**, **Wayne State School of Medicine**, **Detroit Medical Center**, **SUNY at Buffalo**, and **Kaleida Health**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 1, 2021.

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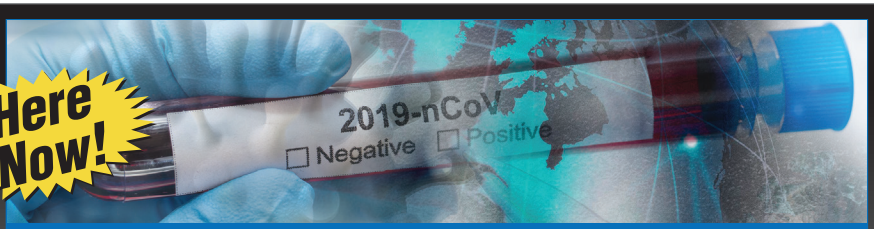

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- ***Why Silicon Valley wants access to healthcare data and how this is both a threat and an opportunity for labs.***

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