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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
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Coming Soon: a Different Clinical Lab Industry

"KEEP YOUR EYE ON THE BALL" is an idiom that originated with baseball. The idea is that every player on the field should, at all times, know where the ball is so that they can be ready to do their job when the ball comes their way.

This is excellent advice for clinical lab administrators and pathologists during the current pandemic. That's because all lab managers should be responding to the unique and pressing demands of the SARS-CoV-2 outbreak while continuing to position the core routine testing activities of their labs to serve the needs of proactive care, value-based payments, and other healthcare trends.

All the major forces of change in healthcare and the clinical lab marketplace that were visible before the pandemic continue to reshape healthcare today. Take reimbursement as an example. In recent years, government and private payers steadily forged ahead with the introduction of different, value-based forms of reimbursement. The best example of that is Medicare Advantage, which pays health plans a set fee per Medicare beneficiary. In turn, a health plan then contracts with a hospital or a physician to provide services for a per-member, per-month payment. Of 60 million Medicare beneficiaries, 21 million currently are enrolled in Medicare Advantage plans.

What's changed with how payers contract and settle lab test claims since the advent of the pandemic? Not much. THE DARK REPORT has regularly briefed clients and readers on the efforts of some major private payers to deny COVID-19 test claims and to continue excluding labs as providers by narrowing networks and by instituting new requirements for lab claims to be paid. For example, **UnitedHealthcare** is requiring labs to register every test and panel under its Laboratory Test Registry Program, which goes into effect on Jan. 1, 2021. *(See TDR, Aug. 3, 2020.)*

The pre-pandemic trend of altering reimbursement to be value-based and discouraging fee-for-service arrangements is an important example, because the fastest way to change the behavior of people and organizations is to change how they are paid. This illustrates why pre-pandemic trends in healthcare and the clinical lab marketplace are still active today. Even as the COVID-19 pandemic interrupted many things in healthcare, all the major drivers of change before the pandemic continue to reshape our profession, today and into the future. That is why we should all "keep our eyes on the ball!" TDR

Understanding COVID-19's Changes to Lab Industry

Having survived the cash flow collapse this winter, many lab professionals want to know: 'What's next?'

CEO SUMMARY: With the SARS-CoV-2 pandemic about to enter its eighth month in the United States, it remains difficult to predict whether the pandemic will strengthen with the fall influenza season or steadily diminish. What is clear to most pathologists and clinical laboratory executives is that the COVID-19 pandemic has already changed several aspects of how laboratories select suppliers, purchase supplies, interact with physicians and patients, and utilize digital pathology.

By Robert L. Michel

WHENEVER THE COVID-19 PANDEMIC ENDS, what comes next for the clinical laboratory industry? This important question is being asked in board rooms across the country, as pathologists and clinical lab managers review clinical and business plans for their labs and pathology groups.

The SARS-CoV-2 outbreak washed across all medical laboratories in the United States like the 2004 Indonesian Tsunami devastated coastlines from Indonesia to Thailand and India. This tsunami killed an estimated 230,000 people.

Similarly, the onset of the COVID-19 tsunami hit the nation's clinical laboratories and pathology groups with a comparably devastating blow. This blow was the near-total collapse in the daily volume of routine lab specimen referrals and the cash flow associated with these specimens. Routine test referrals fell by 70% or more during the months of March, April, and May as shelter-in-place directives took effect in nearly all states.

Concurrently, and in response to the pandemic, every medical laboratory in this country went into a crisis response mode. During those months, a large number of the nation's independent clinical laboratories used furloughs, lay-offs, and terminations to reduce staff. As the daily volume of routine lab test specimens began recovering in late spring, many labs began returning these employees to work.

It was a different story at the clinical labs of hospitals and health networks. These institutions saw a deep drop in emergency room visits for routine conditions at the same time that they ceased admitting patients for elective services. But the need to

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admit and treat COVID-19 patients meant that hospital labs found themselves on the front lines as the earliest waves of COVID-19 patients began flooding into hospitals, particularly in states such as New York, California, Florida, and Louisiana.

The urgent need for accurate, timely molecular COVID-19 tests at hospitals meant their labs were truly the essential clinical service. Hospital labs immediately put all existing staff into that effort. Hospital labs provided significant numbers of staff to collect COVID-19 specimens at drive-through sites in their communities, for example.

Those hospital and health system labs that had molecular testing capabilities typically were developing SARS-CoV-2 test in late February and began performing these tests early in March.

Yet the pandemic proved relentless. As the winter gave way to spring and spring yielded to summer, both independent labs and hospital labs continued to perform increasing numbers of molecular COVID-19 tests as the number of newly-diagnosed cases in this country pushed over 70,000 per day in mid-July.

Patients Again Visiting Docs

If there was some good news during this time, it was how the easing of shelter-in-place directives in May and June encouraged patients to again visit their physicians and allowed hospitals to begin scheduling elective services.

THE DARK REPORT has data from multiple companies that—because of these two developments—show the daily volume of routine specimen referrals originating in the outpatient/outreach sector is back to between 80% and 90% of pre-pandemic levels.

However, that three-month collapse in cash flow from routine testing left many labs with a financial deficit that these labs will never make up from other sources (such as COVID-19 molecular testing). By its calculations, THE DARK REPORT estimates that in the first 10 weeks of the pandemic (from March 14 through May 15), the collapse in cash flow from reduced routine lab testing totaled $6.8 billion.

$6.8 Billion in Lost Cash Flow

To give perspective to this collective loss of $6.8 billion in cash flow, the **Office of the Inspector General** reported that Medicare Part B clinical lab test reimbursement totaled $7.1 billion during 2017. In the first 10 weeks of the pandemic, the nation's labs were starved of cash flow that nearly equaled what they are paid by Medicare during a full year! *(See "From Mid-March, Labs Saw Big Drop in Revenue," TDR, April 20, 2020.)*

Simultaneous with this crash in routine test referrals and associated cash flow was the immediate need for large volumes of molecular COVID-19 tests. Any independent lab company or hospital lab with existing instruments and staff trained in molecular and genetic testing rushed to bring up COVID-19 tests. The CDC's SARS-CoV-2 test was the first authorized test that labs were allowed to perform.

Throughout March, April, May, and into June, government officials and the news media closely tracked the increase in the number of molecular COVID-19 tests that labs in this country could perform. Throughout these same months, local, state, and federal governments took a big role in organizing drive-through COVID-19 specimen collection sites.

Testing at Nursing Homes

The next major effort took shape in May and June. It involved nursing homes and long-term care (LTC) facilities. Particularly at the state level, governments organized programs designed to regularly test all nursing home patients and their staffs. Much of the funding for this SARS-CoV-2 testing came from the federal government.

It was in May-June that the clinical lab industry split into two groups. One group of labs was capable of performing

molecular COVID-19 testing that also generated much-needed revenue to offset the decline in cash flow from routine testing. The other group of labs were not performing molecular COVID-tests. Thus, that source of revenue was denied to them.

These are the labs with the most desperate finances. Having lost more than half their cash flow in March, April, and May—and with outpatient/outreach testing still at just 80% to 90% of pre-pandemic levels—they face an uncertain future, particularly if the pandemic continues for months into the future.

COVID-19 Changes

The COVID-19 pandemic of 2020 has caused fundamental changes across almost every aspect of our society. Who imagined, at the start of 2020, that movie theaters would be closed, amateur and professional sports would be canceled, concerts of all types and church services would be forbidden, and that restaurant, bars, and nightclubs would be closed for months at a time?

Healthcare and the profession of laboratory medicine were similarly impacted. The COVID-19 pandemic continues to reshape the delivery of medical services and how clinical lab testing is provided. With clinical labs and pathology groups preparing their clinical and financial plans for 2020, it is timely to offer insights as to the more obvious ways that the clinical laboratory marketplace will be different going forward.

The easy predictions involve how labs buy instruments, tests, and consumables. That's because supply chain problems became the number one management issue at every lab in the U.S., as well as globally.

Several things will probably be true for the laboratory supply chain of the future. First, pre-pandemic, it was common for many labs to select one *in vitro* diagnostics (IVD) company to be their major source for instruments and tests. But from the onset of the pandemic, most labs could not get additional instruments and adequate volumes of supplies from their major IVD source. In the future, labs can be expected to spread their purchases of instruments, tests, and consumables across multiple IVD firms. *(see pages 14-16.)*

Bring Manufacturing to U.S.

Second, IVD companies and lab vendors will be rethinking their own manufacturing and supply chain. The days of manufacturing in a least-cost country, then importing either parts or finished product into this country for final assembly and delivery to lab customers, may be over.

This will probably be true for the United States. It is the world's largest single market for healthcare, spending almost $4.0 trillion in 2018. Thus, the global IVD giants have a motive to manufacture here. That shortens and simplifies the supply chain for U.S. labs and still allows the IVD firms to send products manufactured here to overseas lab customers.

More Use of Telehealth

Third, the pandemic has caused both consumers and healthcare providers to rethink the value of telehealth and virtual doctor's visits. News stories throughout the pandemic have trumpeted the increased use of telehealth. At the same time, federal and state regulation of telehealth services was temporarily eased and many expect authorities to make those changes permanent.

Telehealth is an issue for clinical laboratories because, if the patient never visits a traditional physician's office, where and how will the lab access the patient to collect the specimens to perform the lab tests that were ordered by the patient's physician?

Fourth, use of digital pathology, whole-slide images, and telepathology will increase and probably become the norm. Many pathologists required to work from home during the pandemic now recognize the benefits of a digital pathology system that can allow them to read images and diagnose from any location away from the pathology laboratory. TDR

Texas Company Operates 400 COVID-Collection Sites

Under a federal HHS contract, eTrueNorth manages SARS-CoV-2 specimen collection sites in 44 states

CEO SUMMARY: In April, the federal Department of Health and Human Services contracted with eTrueNorth to operate COVID drive-through specimen-collection sites under the Community-Based Testing Sites program. The drive-through sites are an extension of non-COVID testing the company has done since 2016 in partnership with some of the nation's largest retail pharmacy and grocery chains. Under the HHS contract, eTrueNorth collects COVID specimens from as many as 5,000 patients each day.

What started as one drive-through COVID specimen-collection site in Joliet, Ill., has grown to more than 400 sites and more than $90 million in federal contracts for **eTrueNorth**, a wellness company that coordinates testing at those sites.

By interceding between clinical laboratories and patients who need SARS-CoV-2 testing, this small company in Mansfield, Texas, has become the latest example of an innovative company rethinking the traditional way clinical laboratory test services are delivered, and then introducing more efficient and cost-effective production methods.

Beginnings in Drug Stores

In this case, eTrueNorth developed a way to interpose itself into the specimen-collection step of the clinical lab testing process. Yet any clinical lab organization with an entrepreneurial nature and out-of-the box thinking could have provided the same service that eTrueNorth delivers under contract with the federal **Department of Health and Human Services** (HHS).

eTrueNorth does not do any testing for COVID patients. Pre-pandemic, its primary business was to arrange CLIA-waived testing sites in retail stores under contracts with large pharmacy and retail operators such as **Walmart**, **Kroger**, **Hy-Vee** stores, **Health Mart** pharmacies (a division of **McKesson**), and other independent pharmacies. Those pharmacy chains are part of eTrueNorth's eLabNetwork, which does wellness testing (such as hemoglobin A1c, lipids, PT/INR, and pharmacogenetic testing) and onsite tests for medication management.

CLIA-Waived Labs

Until this year, eTrueNorth's largest client was Walmart, one of the nation's largest retailers. Since 2016, eTrueNorth has developed CLIA-waived labs in Walmart's 4,300 stores nationwide, eTrueNorth's President and CEO Coral May said in an interview with The Dark Report.

In April, eTrueNorth acquired a large new client when HHS contracted with the company to operate COVID drive-through specimen-collection sites under the federal Community-Based Testing Sites (CBTS) program. The drive-through sites became an extension of the non-COVID testing the company has done for years, she said.

"In April, we opened our first drive-through COVID-19 collection site," she noted. "Today, we coordinate collections at about 400 sites, including very-high volume surge sites in 12 hotspot cities where we have multiple sites in place.

"Those 400 sites are located throughout the United States," May said. "Some are in geographies that simply don't have a lot of other COVID-19 testing options. The actual number of sites changes almost daily, depending on what the federal or state governments need."

At most of those sites, pharmacy staff from its retail partners collect COVID-19 specimens. For surge sites, eTrueNorth provides staff to observe specimen collection. Over the past four months, May estimated that eTrueNorth has collected specimens from more than 500,000 patients. The company cannot disclose the cost per test or what it pays labs for those tests, May said.

Filling a Need

Under the CBTS program, HHS has set up more than 700 federally-backed drive-through specimen-collection sites and has spent $230 million to pay for the tests run at those sites, according to *Stat News*.

In its role as the coordinator of more than half of the CBTS collection sites, eTrueNorth ships specimens to eight labs, one of which is **HealthQuest Esoterics**, in Irvine, Calif. Recently, *Stat News* reported the company was working with **Gravity Diagnostics** in Covington, Ky., and **Reditus Laboratories** in Pekin, Ill.

Last week, eTrueNorth said it stopped working with those two labs and added seven more labs to meet a rising demand for testing. It did not disclose the names of the seven new labs. Gravity Diagnostics, HealthQuest Esoterics, and Reditus Labs did not return requests for comment.

All eight labs are CLIA-certified and have the capacity to run the polymerase chain reaction (PCR) tests for SARS-CoV-2, the virus that causes the COVID-19 illness. In addition, Michael McEntee, co-founder of eTrueNorth, has been developing a network of clinical labs that can handle 80,000 tests per day, May said. "This capability is expected to expand to

Wellness Protocol Used for Covid-19 Testing

WHEN WORKING WITH RETAIL PHARMACIES TO DO NON-COVID TESTING, eTrueNorth developed a system for patients to register for CLIA-waived tests and then adapted that model for its drive-through specimen-collection operation for COVID patients, according to eTrueNorth's President and CEO Coral May.

"The way our model works is we have our non-COVID platform that allows individuals to visit one of the retail pharmacy sites and select their test location," she reported. "Then, they create an appointment within a 10-minute time block." eTrueNorth has contracts with Walmart, Kroger, and other independent pharmacies.

"We already had the technology so that we could pivot to make it support COVID-19 testing," she added. "Those patients register on our site, select their preferred pharmacy and then complete the risk assessment from the CDC to determine if they're eligible for COVID-19 testing." The federal **Centers for Disease Control and Prevention** risk assessment asks patients about their symptoms and medical conditions.

"We have appointment scheduling throughout the day, which means we've had a maximum of about 20 to 25 cars in line at any one time," May noted. "The goal is to get people in and out as close to their allotted 10-minute timeframe as we can.

"With the proper planning, and appointment scheduling and if people come at their appointed times, we can significantly reduce the wait time," she said.

more than 100,000 tests per day with the eight laboratories we have now," he said.

When choosing labs to do COVID tests, eTrueNorth prefers to contract with independent laboratory companies that have the capacity to do such testing, May said.

Hospital labs have other priorities because they need to serve their own inpatients and outpatients first, she explained.

Sites to Meet Surge Demand

The clinical laboratory companies working with eTrueNorth do not need to be near the collection sites, because specimens are shipped overnight for delivery the next morning, and the sites change regularly depending on the need in states where surge testing is required, May said.

"We just finished testing in two Florida sites—one in Jacksonville and the other in Miami," she noted.

"We have sites in Phoenix, and in New Orleans and Baton Rouge in Louisiana. We also have sites in Bakersfield, Calif.; at the Atlanta airport; and in Edinburg, Texas, in the Rio Grande Valley. We have two sites in Houston and two in the surrounding Harris Country area.

"Recently, we began participating in surge sites that can collect specimens from as many as 5,000 patients daily, but that number varies depending on many factors," May commented.

Volume, TAT Management

Effective coordination at each specimen-collection site helps eTrueNorth manage the demand for testing to ensure that the clinical laboratory companies running the SARS-CoV-2 tests do not get more specimens than they can run in a day or so, she said.

"We know the daily throughput capacity of our laboratory partners, and so we make sure we don't overwhelm any laboratory beyond that level," she explained. "Doing that helps to keep our turnaround times predictable, in the range of three to five business days," May continued.

"From every collection site, we send our COVID-19 specimens for overnight delivery via **UPS** or **FedEx** so they arrive the next morning," explained May. "We monitor turnaround times continuously at each lab facility doing the COVID-19 testing and want to know about any slowdowns. If there are slowdowns, we can take steps during specimen-collection to fix those problems."

No physician requisitions are needed. All testing is done with a standing order. "Every person who registers at our site gets a one-page voucher that's essentially a lab requisition," stated May. "It contains a unique identification number, which becomes the identifier for that patient's specimen.

"Then, the patient prints the voucher and takes it to the test site," she continued. "If the patient doesn't have a printer, he or she can register on their smartphone to get an identification number. That voucher number is part of the identifier that goes onto the specimen tube.

Accessioning at the Lab

"When the tube arrives at the clinical laboratory, the lab will have the ID number, the patient's date of birth, and the patient's first and last name. All of that information is similar to what a lab gets on its own requisitions, but it's different because we adapted the normal test requisition to our needs. The COVID-19 test results go directly to the patients by email or phone," she added.

Pathologists and clinical lab executive should recognize that eTrueNorth is an example of a new class of entrepreneurial companies that recognize new opportunities to deliver diagnostic testing solutions in unconventional ways. One common attribute of these companies is that they do not perform the tests. Rather, like **Uber** or **eBay**, eTrueNorth and similar firms function as a platform that connects consumers with sources of lab tests. **TDR**

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Lab Acquisitions Update

Franciscan Missionaries Sells Lab Outreach Business to LabCorp

Only second sale of a hospital lab outreach program since the onset of COVID-19 pandemic in February

Since the onset of the pandemic in late February, the nation's two largest clinical lab companies have announced only two acquisitions of hospital laboratory outreach programs, one in June and one this month.

Last week, **LabCorp** announced its acquisition of the clinical ambulatory laboratory business of **Franciscan Missionaries of Our Lady Health System** (FMOLHS) in Baton Rouge, La. Earlier, on June 23, **Quest Diagnostics** announced an agreement to buy out the hospital partners' share of **Mid America Clinical Laboratories** (MACL), a joint venture of Quest and two hospital systems with operations in Indianapolis. *(See sidebar, "Quest Buys Out Hospital Partners of Mid-America Clinical Labs," page 10.)*

Only one other major hospital lab/commercial lab transaction happened this year. On Jan. 27, Quest Diagnostics announced a deal with 1,014-bed **Memorial Hermann Health System Hospital** in Houston. Quest bought the outreach laboratory division and certain lab assets. It will manage the inpatient labs in 17 Memorial Hermann hospitals. *(See, "Memorial Hermann Sells Outreach Lab to Quest," TDR, Feb. 17, 2020.)*

In recent years, executives of the nation's two largest public laboratory companies have regularly told Wall Street analysts and investors that CEOs of hospitals and health systems have strong interest in selling their laboratory outreach businesses to generate capital that can be invested in other priorities. Hospital CEOs also are described as having an interest in lowering the cost of their inpatient laboratory testing by outsourcing.

Yet, the fact that only two sales of hospital lab outreach business have been announced in the almost eight months since the SARS-CoV-2 outbreak—and just three for all of 2020—may be a sign that hospital and health system CEOs are recognizing the true clinical and financial value of a strong inpatient laboratory and a robust lab outreach program. If this proves to be true during the next 12 to 24 months, then the COVID-19 pandemic will have had an important role in demonstrating the essential value that hospital labs deliver to their parent organizations.

Sizeable Lab Acquisitions

In both of the deals since June, Quest Diagnostics and LabCorp have come away with sizeable new partners. As noted earlier, this month LabCorp acquired the clinical ambulatory laboratory business of Franciscan Missionaries of Our Lady Health System (FMOLHS) in Baton Rouge, La. The relationship expands LabCorp's reach in Louisiana and Mississippi.

LabCorp will take over the ambulatory laboratory services for patients, physicians, and other providers that FMOLHS had been doing in both states. LabCorp will also provide specialty reference testing services for FMOLHS' hospitals in Louisiana and Mississippi. Terms of the transaction were not disclosed, and LabCorp said it was unable to

Quest Diagnostics Buys Out Two Hospital Partners of Mid-America Clinical Laboratory Joint Venture

IN AUGUST, QUEST DIAGNOSTICS COMPLETED THE ACQUISITION of its joint venture partners' interests in Mid America Clinical Laboratories (MACL), marking the end of a hospital lab/commercial lab joint venture that had lasted for almost 18 years.

It was on June 23 when Quest Diagnostics announced the agreement to do the multi-part deal that was completed on Aug. 3. In one part of the deal, Quest would buy out the hospital partners' share of MACL.

Formed as a joint venture in 1997, MACL was a partnership of Quest and two Indianapolis hospital systems: **Ascension St. Vincent** and **Community Health Network** (CHN).

In another part of the deal, Quest said it would provide professional hospital lab services under long-term service agreements for about 30 hospital labs owned and operated by Ascension St. Vincent and CHN. CHN is a nine-hospital system in Indianapolis serving patients in nine counties in central Indiana. Ascension St. Vincent is part of **Ascension Health**, a 150-hospital system with facilities in 11 states and the District of Columbia. There are seven Ascension St. Vincent hospitals in Indiana.

In its announcement, Quest also said that its pathology unit—**AmeriPath Indiana**—would continue to provide specialized pathology services to CHN and Ascension St. Vincent and to other providers in Indiana. Financial terms were not disclosed except that Quest said it was an all-cash transaction.

The deal is a significant one for both MACL and for Quest Diagnostics, according to one healthcare executive familiar with the Indiana market who asked not to be named.

"Since MACL was founded, it has grown significantly so that it is now a substantial clinical lab company in Indiana," the executive said. "In that way, it's an important acquisition for Quest, in part because MACL has had such strong growth in test volume in recent years."

Outreach Sale to Raise Cash

Frequently, hospitals and health systems are motivated to sell their clinical laboratory outreach businesses because they need or want substantial capital for other purposes. These sales can generate tens of millions of dollars in capital for the seller.

In the case of Community Health Network, the *Indiana Business Journal* reported that CHN lost $13.7 million on operations during the first three months of this year due to the fall-off in patients because of the pandemic. It also reported that CHN lost $201.2 million on investments during the first quarter of 2020 when the economy and financial markets tanked.

Ascension St. Vincent's parent, **Ascension Health** based in St. Louis, has experienced significant swings in profit and losses in recent years. *Fierce Healthcare* reported that Ascension posted losses of $2.7 billion in the first quarter 2020 compared with $1.1 billion in earnings in the first quarter of 2019.

accommodate a press interview at this time.

Hospital lab administrators will want to continue watching to see if any other major hospitals or health networks enter into deals that allow any of the billion-dollar public lab companies to acquire a lab outreach business and possibly also include a contract to manage the inpatient laboratories. As long as the pandemic continues, hospital CEOs would have a motive to retain their inpatient laboratories and keep control of the COVID-19 testing in their institutions. **TDR.**

NY Firm to Build CLIA Labs in Shipping Containers

'Pop-up' clinical labs will test for SARS-CoV-2 and can perform other types of diagnostic tests

CEO SUMMARY: In many respects, the COVID-19 pandemic is like a gold rush for entrepreneurs. Federal and state governments, colleges, employers, school districts, and other entities need COVID-19 tests and tens of billions of dollars are available to pay for such tests. This modern gold rush has encouraged companies such as Amazon and Alphabet/Google to build their own clinical labs. Now two companies are teaming up to design, build, and install CLIA-certified labs in shipping containers that can be located almost anywhere.

Demand for COVID-19 testing continues to outstrip supply, as the nation's clinical laboratories struggle to increase the number of SARS-CoV-2 tests they perform daily. This gap between supply and demand has caught the attention of employers, universities, and school systems that need COVID-19 tests and are willing to build their own clinical laboratories.

To meet this demand for more clinical laboratories, two companies joined forces and announced they will build CLIA-compliant laboratories in shipping containers. This development is the latest example of entrepreneurs offering a product that new competitors to existing clinical labs can use to perform both COVID-19 tests and routine medical laboratory tests.

The idea behind the plan is that two companies—**SG Blocks Inc.** in New York and **Clarity Lab Solutions** in Boca Raton, Fla.—will build, deliver, and install pop-up, scalable clinical laboratories in parking lots, lawns, fields, or other open space outside hospitals, big companies, universities, and other entities needing onsite testing and fast results, said Dan Leger, president of Clarity Lab Solutions and president of **Clarity Diagnostics Solutions**, a division of the lab that formed the joint venture with SG Blocks under the name **Clarity Mobile Venture LLC** (CMV).

'Clinical Lab-in-a-Box'

In a joint news release Sept. 1, the companies said these labs-in-a-box initially will do testing for the coronavirus for employers, universities, and hospitals nationwide. Later, the pop-up labs will be used to test for other conditions, such as influenza, other upper respiratory illnesses, cancer, opioids, and urinary tract infections, the companies said.

For independent lab companies and hospital-based clinical laboratories, these shipping container CLIA-compliant lab facilities could become a serious competitor. First, they can fill the niche that drive-through COVID-19 specimen collection sites are providing now. Second, they are scalable, meaning one, two, or more ship-

CLIA-Compliant Clinical Labs Built from Shipping Containers

Here is the concept of a CLIA-compliant clinical laboratory facility built from shipping containers. It was developed by SG Blocks and its partner, Clarity Lab Solutions. The companies say they will deliver their first such lab facilities within 12 months. They describe these as "pop-up" clinical labs that can be quickly delivered and brought into service in localities where the need for lab testing is urgent and having fast turnaround time for lab test results is important. The companies hope to sell these CLIA-compliant shipping container labs to employers, universities, and schools that need COVID-19 testing to protect their staffs, students, and customers.

ping containers could be added to each site to increase lab test capacity as needed.

"The CMV labs will contain the molecular testing instruments, information systems, plumbing, lighting, electrical, heating, and air-conditioning equipment used to run molecular tests 24 hours a day, seven days a week if needed," stated Paul Galvin, CEO of SG Blocks. Galvin's company describes itself as a fabricator of container-based structures and builds homes, retail shops, and healthcare facilities for a variety of clients.

First Container Lab Delivery

The first such container-based lab is scheduled for delivery in about 12 months and will be near Clarity Diagnostics' lab in Boca Raton, said Leger. At this site, Clarity will run the GeneFinder COVID-19 Plus RealAmp Kit from **Osang Healthcare**, a South Korean company.

On April 18, under an emergency use authorization, the FDA allowed Osang to sell its reverse-transcription polymerase chain reaction test kit in the United States to CLIA-certified, high-complexity labs. *Korea Biomedical Review* reported that the test kit detects three gene types: E gene, RdRP gene, and N Gene. In May, SG Blocks signed a one-year, non-exclusive agreement to market, sell, and distribute the Osang test kit in the United States.

In an interview with The Dark Report, Galvin said the pop-up labs are expected to be placed in high risk, densely populated, or rural areas. SG Blocks has had interest from employers, universities, hospitals, clinical laboratories, and other entities for these container-based labs to provide on-site testing, he added.

Therefore, the container labs could supplement independent and hospital-based labs needing to add testing capacity. *(See "Employers, Others Looking to Build New Clinical Labs," and "Amazon Targets COVID-19 Testing in Its New Lab-Building Venture," TDR, Aug. 3, 2020.)*

SG Blocks recently launched prefabricated healthcare facilities it calls the D-Tec suite, which offers five sizes of structures. **Grimshaw**, an international architectural firm, designed each one, SG Blocks said.

The shipping container-based clinical labs would be 20-feet long, eight feet wide, and eight and a half feet high. Smaller units would contain two such shipping containers and larger units would have five containers or more. In the larger containers, Leger said, Clarity Lab Solutions could run 5,000 tests in nine hours or almost 15,000 tests in just over 24 hours.

"With SG Blocks, we're designing different configurations of shipping container laboratories that will be scalable and that will allow medical lab testing at whatever volume a facility needs," said Leger.

Supply Chain Shortages

For its clients in Florida and throughout the United States, Clarity now runs thousands of COVID-19 tests, he said. Like other labs, Clarity has found that reagents, plastics for transport media, and test kits often are in short supply. Since SG Blocks has the distribution agreement with Osang Healthcare, Leger expects to be able to deliver enough COVID-19 test kits to support high-capacity testing without shortages, he said.

"The concept behind our joint venture with SG Blocks is to break the barriers of capacity issues around the country with reagents, plastics, and test kits used for SARS-CoV-2 testing," he commented. "Having this relationship will give us an immense amount of scalability."

First Container Lab

By about this time next year, the two companies plan to have the first container lab placed near Clarity's lab in Boca Raton, said Galvin. "Clarity Diagnostics has engaged us to do a design and build for a redundant facility outside of their Florida lab to provide them with a backup facility," he added. "Because Florida has unique weather conditions, it will be made from a heavy-gauge steel shipping container and be hurricane resistant. Right now, we're doing a market analysis to see where to put this lab facility."

One risk in the SG Blocks–Clarity strategy is whether the COVID-19 pandemic is still a significant concern 12 months from now, when it delivers its first CLIA-compliant clinical laboratory in a shipping container. If the pandemic diminishes in coming months, there may not be enough demand for COVID-19 tests to justify this lab facility. However, the more important fact of this development is that the two companies are ready to sell CLIA-compliant clinical laboratory facilities built in shipping containers to any interested party for any type of clinical lab testing. TDR

Contact Dan Leger at 941-917-1173 or info@claritylabsolutions.com.

Why Not Open Labs Near Drive-Through Sites?

ANY PLAN TO ADD CLINICAL LABS IN SHIPPING CONTAINERS raises the question: Why not set up drive-through specimen-collection sites for COVID-19 testing, as many cities and states have done? In this arrangement, specimens collected at drive-through sites are sent overnight to clinical labs that run the tests and provide results within 24 hours.

For Dan Leger, president of Clarity Lab Solutions, the answer is that the entities most interested in container-based clinical laboratories are employers and universities that want turnaround times for COVID-19 test results within 24 hours or less.

"Businesses, schools, and other organizations require certain turnaround times—meaning faster results than what they currently get from hospital labs or independent labs," Leger explained. "Our container-based clinical labs can provide faster results because we're putting additional capacity onsite. This speeds up time to result because the labs in shipping containers will have the capacity to run 5,000 molecular tests for COVID-19 in nine hours.

"We have a local presence here in Boca Raton, and we believe that having a local presence is the key to delivering faster COVID-19 test results," he said. "While we do a lot of local samples, some of our samples come from all over United States. Our goal is to provide the turnaround times that our clients need."

IVD Update

Is Covid-19 Pandemic Creating New IVD Winners and Losers?

Clinical labs are scrambling to buy analyzers and SARS-CoV-2 tests from multiple firms

With the pandemic now in its ninth month, *in vitro* diagnostics (IVD) company executives and industry consultants recognize the market for clinical laboratory instruments, tests, and products is changing in fundamental ways.

"Evidence accumulates that the pandemic is helping create new winners and new losers among big and little IVD companies," stated Peter van Overwalle, who is Head of Marketing and Partner at **LiquidSMARTS** and previously served in marketing and product management positions at **Thermo Fisher Scientific** and **Roche Diagnostics**.

Shortage of Instruments, Tests

"Pre-pandemic, it was common for a clinical laboratory to work with one IVD company as its primary source for instruments, automation, and tests," he continued. "The pandemic and the shortage of instruments and tests for SARS-CoV-2 has caused many labs to go to multiple vendors to buy analyzers, test kits, primers, and reagents as a strategy to increase their daily COVID-19 test capacity. Since the onset of the pandemic, this created opportunities for certain IVD companies to win market share from their competitors."

Recently, The Dark Report brought together three IVD executives to offer observations and insights about how the COVID-19 pandemic is changing the IVD marketplace. Joining van Overwalle on the conference call were Gunter Wessels, PhD, and John Hardesky.

Wessels is the General Manager and co-founder of **LiquidSMARTS**, a global professional services and technology company. Wessels has 25 years of experience in healthcare, including 16 years as a consultant to marketing and sales teams. Until recently, Hardesky was Vice President of Customer Laboratory Solutions at **McKesson Corporation** and has 20 years of IVD experience.

During the interview, the three professionals noted that the widespread supply shortages caused by the pandemic will probably be the single biggest reason why the post-pandemic IVD marketplace can be expected to look much different than the pre-pandemic market.

In fact, while he was still at McKesson, Hardesky was tasked with studying how the pandemic would alter the status quo among lab suppliers. "At McKesson, I wrote a COVID-19 positioning document that reflected my work with key opinion leaders and interviews with numerous customers in different care settings over the last several months," he said.

"Unequivocally, the number one problem identified were challenges related to supply chain," continued Hardesky. "There have been donations of supplies and funds from many different sources to hospitals. As a result, most labs have money to buy instrumentation for testing, but they continue to struggle in obtaining it. In addition to equipment, labs reported concerns about obtaining personal protective equipment to keep testing staff safe."

"Because clinical labs of all sizes and settings have been under extreme pressure to increase the volume of COVID-19 tests they perform, the inability of many of the largest IVD companies to meet the quantity needs of their long-time lab customers caused these same customers to open their doors to IVD firms that could supply additional instruments, tests, and other supplies," observed van Overwalle.

Major Weakness Exposed

"This is a key insight," interjected Wessels. "The pandemic has exposed a major weakness in the common practice of a clinical lab working with one major IVD company for the majority of its automation, instrumentation, and tests.

"Before the SARS-CoV-2 outbreak, labs working with a primary IVD supplier could negotiate lower price because of a larger volume of purchases," added Wessels. "Standardization of instruments and tests across the different lab sites in a health system also helped improve productivity and quality while lowering costs.

"It is now tougher for a large manufacturer to dominate a laboratory's inventory because the pandemic has shown how that strategy concentrates the risk of a single source in the supply chain," he said. "That alone is a pretty big incentive for laboratory customers to diversify their suppliers of instruments, tests, collection supplies, and other consumables.

More Workstation Options

"I agree," noted van Overwalle. "The dominance of an IVD firm as a featured or preferred provider is significantly strained. On one hand, labs are going to need to consolidate some significant workflow onto a consolidated platform. On the other hand, workstation options are going to multiply and the ability to do more specialized testing from newer products—and not the same brand—is enhanced by this trend. The IVD industry has forced labs to shop for alternate sources and shopping now doesn't seem as scary."

COVID Changes Lab Access and More

BECAUSE OF THE PANDEMIC, IN VITRO DIAGNOSTICS (IVD) COMPANIES and their clinical lab customers are interacting in different ways. For example, it is now more difficult for IVD firms' service engineers, trainers, and sales reps to gain access to the lab facilities of their customers.

"I know of many examples of IVD company representatives having challenges getting into hospitals and labs now," said Peter van Overwalle, Head of Marketing at LiquidSMARTS. "In our practice, we've reached out to help the IVD companies' representatives develop communication skills to do their work from afar because the loss of a face-to-face connection really changes the dynamic and nature of the business relations between a lab and its IVD supplier.

"I also hear some of the big players are heavily investing in virtual training whereby they can—without having to bring the customer to their campus for a three-and-a-half or five-day event—do a virtual reality technology training to create a hands-on experience," he added.

"The pandemic has changed IVD sales in a similar way," noted Gunter Wessels, PhD, General Manager of LiquidSMARTS. "Physical sales visits to labs have been extinguished. It's all Web meetings—if it's happening. Moreover, these meetings are usually about service issues and getting more supplies, such as, 'This is broke. Fix this. Fix that. My lab can't get this. Can you get me that?' There are fewer discussions about how to help the lab move forward."

"The simple fact is that, for IVD sales reps, it may be more difficult to show up and visit the laboratory," explained John Hardesky, Commercialization Consultant for LiquidSMARTS. "Sales visits won't be as frequent as before the pandemic."

"Scarcity drives a lot of purchasing decisions, which we know is more emotionally-rooted," stated Wessels. "What I find concerning is the erosion of standardization because it affects what these larger IVD companies could offer via the same platform for multi-site labs.

"Take mass spectrometry as an example. For an open system, a lab gets seven different versions of the truth from operating open systems, which is unfortunate, but true," Wessels added.

"I think standardization in a lab takes a back seat during the pandemic because if the lab is to provide serology results, and it must do it on multiple vendor platforms for the same patient, that's not going to hold out very well," declared van Overwalle. "Not all serology tests are created equal. Lab managers must answer this question for the longer term: Does their lab do best-in-class testing by disease state or not?"

New IVD Companies

"Another change we see in the IVD market is how the pandemic is opening doors for new technology companies and the different solutions they are developing," stated Hardesky. "It is surprising how many companies have pivoted because of COVID-19 and developed useful solutions for labs.

"Today, the traditional lab customer that utilizes multiple technologies from one major IVD company is forced to go out and look around," he said. "Lab leaders have opened their eyes and are looking at innovative technologies from smaller companies that they may not have considered prior to the outbreak. I think we'll continue to see some market changes coming from that as well."

"Not only is that happening, but I see the direct relationship between IVD manufacturers, and the labs of hospitals and health systems being augmented by indirect relationships and with more focus on having distributor partners," noted Wessels. "This helps clinical labs because distributors can offer instruments and tests from different IVD companies. They also know and understand the supply chain capabilities of the IVD firms they represent. That's a big help to labs during this supply chain crisis."

Opportunities to Add Value

Based on interactions with IVD organizations through the course of the pandemic, Wessels believes IVD companies have three opportunities to add value and be relevant to their clinical lab customers.

"First, every close-to-the-customer company will want to work with its lab customers to help them respond to uncertainty," said Wessels. "That includes showing the lab team to be better and faster at recognizing change. It is a characteristic of many labs to be slow to react to important changes in technology and the clinical market.

"The second thing IVD firms and distributors can do to assist their clinical lab clients is to help them understand how to be better with employee engagement, maintenance, and retention," he noted. "The lab industry entered this pandemic with a shortage of laboratory technicians. Yes, there is plenty of automation. But the complexity of the COVID-19 assays, the multiple instruments, and tests in the lab requires med techs to have more knowledge and skills to maintain quality test results.

Helping Labs Innovate

"Third, most labs are using multiple platforms and assays for COVID-19 testing," concluded Wessels. "This gives suppliers the opportunity to add value by helping their clinical lab customers develop new and innovative reconfigurations of workflow and the physical lab space to improve productivity and reduce costs. TDR

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Lab Regulatory Update

Is HHS Ruling on COVID-19 LDTs Negative for Reimbursement?

While some labs celebrate the perceived flexibility that comes from not having to get an emergency use authorization (EUA) for COVID-19 laboratory-developed tests (LDTs), there is a potential downside—difficulty getting reimbursed for the test.

On Aug. 19, the **Department of Health and Human Services** (HHS) issued a new directive that said clinical laboratories are no longer required to obtain an EUA from the **Food and Drug Administration** (FDA) for their LDTs. The announcement initially was met with relief by many in the lab community, which has long believed that the FDA does not have regulatory oversight over tests that labs develop themselves and use in their own laboratories.

To Get an EUA or Not?

But Danielle Sloane, an attorney with Nashville-based **Bass, Berry and Sims PLC**, says that not seeking an EUA from the FDA is likely to have a cascading effect on clinical lab reimbursement for COVID-19 LDTs. "This is because certain pieces of legislation have tied coverage expectations for COVID-19 tests to those that are provided pursuant to an FDA approval or an actual or pending EUA," she explained.

"The Family First Coronavirus Response Act (FFCRA), as amended by the Coronavirus Aid, Relief and Economic Security (CARES) Act, requires most commercial payers to cover medically appropriate COVID-19 diagnostic tests, without requiring cost-sharing, prior-authorization, or medical-management limitations," continued Sloane. "Effectively, FFCRA requires a commercial payer to reimburse laboratories even if the labs are not in-network with that payer. This is a big advantage, since it is often nearly impossible for some labs to obtain provider status with health plans."

To Qualify for Reimbursement

There is a catch, though, noted Sloane. To qualify for FFCRA reimbursement protections, she said, a COVID-19 test must meet one of the following criteria:

1) Is approved, cleared, or authorized under section 510(k), 513m, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (FDCA).
2) The developer has requested or intends to request an EUA under section 564 of the FDCA, unless and until the EUA has been denied or the developer does not submit a request within a reasonable timeframe [i.e., 15 days based on FDA guidance].
3) Is developed in and authorized by a state that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19.
4) Another test that the HHS Secretary determines appropriate in guidance.

Sloane said she is not aware of any COVID-19 LDTs that would fall under categories 1 (FDA approved), 3 (state authorized), or 4 (other HHS authorized), with one potential exception—tests reviewed by New York, which runs its own version of the CLIA program, and which the FDA authorized to validate tests back in May.

"As a result, absent an EUA—at least until HHS develops a list of qualifying tests or the state applies to review tests—clinical labs that use LDTs for COVID-19 detection have no guarantee that their

services will be reimbursed by commercial payers," she commented.

"In-network laboratories might be able to negotiate rates for COVID-19 LDTs, but they still could be subject to cost-sharing, prior-authorization, and medical management measures," continued Sloane. "Out-of-network clinical laboratories may struggle to get their claims paid on an out-of-network basis. From a reimbursement standpoint, the easiest path to ensuring payment from commercial payors for COVID-19 LDTs is still to obtain an EUA."

Uninsured Individuals

Sloane also emphasized that this is not simply a commercial payer issue. That's because the Health Resources and Services Administration (HRSA) Uninsured Program provides reimbursement to clinical labs performing COVID-19 tests on uninsured individuals. "Coverage for COVID-19 testing under the HRSA Uninsured Program uses the same definition discussed above," she stated. "This suggests a lab submitting a claim for a COVID-19 LDT, absent an active or pending EUA, would run afoul of the terms and conditions of the HRSA Uninsured Program, at least until further guidance suggests unapproved COVID-19 LDTs qualify for one of the categories above.

"Given these restrictions, a laboratory could not submit a claim for a COVID-19 LDT for an uninsured person even if it wanted to take that step," added Sloane. "Were a lab to submit a claim for a COVID-19 LDT test that did not have an active or pending EUA, there is a litany of potential penalties, including False Claims Act liability and exclusion from federal healthcare programs."

Labs wanting to move forward with a COVID-19 LDT that lacks an EUA have another issue to consider. While the Public Readiness and Emergency Preparedness (PREP) Act typically provides immunity protection in cases of a public health emergency, clinical laboratories cannot qualify for such protection for COVID-19 LDTs if they are not approved by the FDA. This means clinical labs need to weigh the advantages of increased flexibility for their COVID-19 LDTs with the potential for being sued over an inaccurate test result.

Costly Ramifications

"Considering the potential for LDTs—by their very nature—to produce inaccurate results, such as false negatives, which could lead an infected individual to infect others, being ineligible for PREP Act protection could have costly ramifications to the lab that performed such tests," observed Sloane.

However, there are other ways to limit liability, such as through contractual indemnification, notes Gail Javitt, an attorney with **Hyman, Phelps and McNamara**, based in Washington, D.C. "How important the PREP Act protection is depends on the entity offering the COVID-19 LDT and what other means it might have to protect itself. That's one consideration, as is market perception.

"For some customers," she continued, "having the EUA gives them reassurance that a third party has evaluated the COVID-19 LDT. Also, the FDA can provide useful feedback. If a lab doesn't go through the process, it might not have the opportunity to hear that feedback on the test," she added.

Pros and Cons of an EUA

"Ultimately, each lab will have to weigh the pros and cons of seeking an EUA for its COVID-19 tests," says Javitt. "There is no one answer that will work for all."

Sloane agrees. "Ultimately, it is simply important for clinical laboratories to know and understand the implications of not obtaining an EUA for COVID-19 LDTs, so they can make an informed choice," she concluded. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Alphabet, Inc., the parent of **Google**, is expanding its COVID-19 testing activities. In recent months, **Verily Life Sciences**—a division of Alphabet devoted to research into life sciences—organized a clinical laboratory for COVID-19 testing. It obtained CLIA certification and is licensed with the State of California. In a blog, Verily's Head of Pathology, Deb Hanks, MD, wrote that the lab had "verified the performance of the SARS-CoV-2 RT-PCR test via **ThermoFisher Scientific's** TaqPath test kit," which has an Emergency Use Authorization (EUA) from the federal **Food and Drug Administration** (FDA).

MORE ON: *COVID Tests at Google's Verily*

Hanks also wrote that Verily submitted an EUA application to adapt the TaqPath test for use in pooled testing as a way to expand the number of COVID-19 tests the lab can perform. These moves by Alphabet/Google to enter the clinical laboratory market mirror similar steps taken by **Amazon**, which is building multiple clinical labs to provide COVID-19 tests for its 1,000,000 employees. *(See TDR, Aug. 3, 2020.)* The fact that both Alphabet/Google and Amazon are gearing up sizeable clinical laboratory operations could mean that they intend to compete against established clinical labs in coming years.

TRANSITIONS

• **ARUP Laboratories** of Salt Lake City announced the appointment of Tracy George, MD, as Chief Medical Officer. George's prior positions were with **University of Utah**, **University of New Mexico**, **TriCore Reference Laboratoires**, and **Stanford University**.

• **Biocept** of San Diego selected pathologist Michael Dugan, MD, to be Senior Vice President, Chief Medical Officer, and Medical Director. Dugan previously held positions at **Clinical Genomics**, **Exact Sciences**, **Quest Diagnostics**, **Roche Molecular Systems**, and **Genzyme Genetics**.

• **Sherlock Biosciences** of Cambridge, Mass., announced that Martin Madeus is its new Chief Operating Officer. Prior to joining Sherlock, Madeus held executive positions at **Ortho-Clinical Diagnostics**, **Millipore**, and **Roche Diagnostics**.

• Ryan Phan, PhD, was appointed Vice President, Lab Operations and Medical Director by **CareDx** of Brisbane, Calif. He previously was with **Kaiser Permanente**, **UCLA**, and the **U.S. Department of Veterans Affairs**.

• Carmen Wiley, PhD, joined **Incyte Diagnostics** of Spokane, Wash., in the role of Clinical Medical Director. Prior positions were with **Veravas**, **Roche Diagnostics**, **PAML**, and the **Marshfield Clinic**. She is also a past president of the **American Association of Clinical Chemistry**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 5, 2020.

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