Volume XXVII, Number 11 Monday, August 3, 2020

Introducing

NEW COVERAGE

IVD • Diagnostics • Informatics

Business Intelligence about companies supplying labs and pathology groups in every issue!

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

COVID-19 Changes Lab and Pathology Profession

We are entering the seventh month of the SARS-CoV-2 outbreak and some public health authorities predict that new cases of COVID-19 will continue through the fall and into 2021. If true, this will not be auspicious for the nation's clinical laboratories and anatomic pathology groups.

The current clinical and business model of clinical laboratory and anatomic pathology operations is designed to serve a fee-for-service system where patients generally travel to their local physician's office or hospital for exams and treatment. In this system, lab specimens can easily and quickly be collected while the patient is in the hospital, the doctor's office, or a nearby patient service center.

But as more physicians and patients respond to the COVID-19 outbreak by adopting virtual office visits, labs will need to be inventive and create new ways to obtain lab test specimens from patients who do not physically show up in doctors' offices, but instead are seen via some form of telehealth service.

Similarly, if "hospital in the home" programs become more common as a way to avoid the need for an infected patient to travel to an emergency room or be admitted to a hospital, then labs will need an economical way to collect specimens from those home-bound patients.

The adoption of telehealth and virtual office visits is another element of change. Health systems, such as **Banner Health** in Arizona, are using chat bots to engage patients in novel ways. Because of ongoing technological advances, artificial intelligence solutions are demonstrating value in healthcare in different ways, including the diagnosis of digital pathology images.

These are just a few fundamental ways that the ongoing COVID-19 pandemic is pushing change on this nation's healthcare system. Each month that the pandemic continues, the process of change will continue and become more entrenched. For example, the greater the number of patients and physicians who become comfortable with virtual office visits, the more likely it is that they will continue to utilize this service once the pandemic subsides.

These pandemic-induced changes to current clinical and business models of clinical lab and pathology operations will be a major theme of our virtual *Executive War College*. The first sessions take place this week. You can review details and register by visiting *www.ExecutiveWarCollege.com*. TDR

UHC Ready to Implement New Lab Test Registry

As of Jan. 1, UnitedHealthcare will require every lab and AP test to be registered before it will pay

CEO SUMMARY: UnitedHealthcare announced that its new Test-Registry Protocol will become effective on Jan. 1, 2021, creating a major billing hurdle for labs and pathology groups. By that date, a lab must register each type of test before it can submit claims for these tests to the nation's largest health insurer. In some ways, UHC's test registry resembles the Medicare MolDx program administered by Palmetto GBA. This unwelcome news comes at a time when labs are under intense clinical and financial pressure because of the COVID-19 pandemic.

IT WAS BAD NEWS FOR MANY CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS when, on July 16, **UnitedHealthcare** (UHC) published new guidelines that will require labs to use a new test-registry program in order for their claims to be paid.

UHC's new Test-Registry Protocol will require every in-network laboratory and anatomic pathology group to register almost every type of test before claims can then be submitted to the health insurer for payment.

This policy was initially scheduled for implementation on Oct. 1, 2020. But because of disruptions caused by the COVID-19 pandemic, UnitedHealthcare announced that it would delay implementation of this new policy by three months, until Jan. 1, 2021.

Since UHC first issued statements about the program earlier this year, many clinical labs and anatomic pathology groups have voiced concerns about the administrative burdens required to comply with the program. Lab leaders have also spoken out about the potential for UHC's new program to significantly change the existing system of lab billing and reimbursement in ways that permanently shrink the cash flow of many labs.

Lab managers and pathologists are also troubled by how UHC's new program may affect patient care if claims for medically-necessary tests won't be paid.

UnitedHealthcare's Test Registry Protocol will shake up the status quo in laboratory test coding/billing for two reasons. First, it is the nation's largest health insurer, covering 48.9 million members.

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

Second, if UHC succeeds in implementing this program, other major health insurers will be encouraged to develop similar test-registry requirements for their health plans. From this perspective, UHC's new Test-Registry Protocol is a high-stakes gambit with the potential to radically transform how lab tests are coded, billed, and reimbursed.

Register Each Test Code

In its July 16 announcement, UHC said its new Test-Registry Protocol requires all in-network labs and anatomic pathology groups to register each individual test code they use before they can bill for those codes.

Once the codes are registered, UHC will decide if the labs and pathology groups can use the codes when submitting claims for tests and anatomic pathology (AP) services, according to a notice that UHC posted on its website (at *https://tinyurl.com/y3jfcgpm*).

If the basic description of UHC's new test-registry program has a familiar ring, it is because it seems to contain many of the elements of the Medicare MolDx program first introduced by Medicare Administrative Contractor **Palmetto GBA** in 2012, and which are still required today for certain Medicare regions. *(See TDRs, Nov. 7, 2011, and Nov. 28, 2011.)*

End of Stacking Codes

One goal of the original MolDx program was intended to end the use of stacking codes for the ever-growing numbers of proprietary molecular and genetic tests that were flooding into the market at that time. Another goal was to allow Medicare carriers to understand what the test was intended to do and how it was useful in clinical care.

When MolDx launched in 2012, it used the Z-Code system developed by **McKesson** that has since become the DEX Z-Code Identifier system. Certain payers use this system to supplement non-specific CPT codes.

The DEX Z-Code Identifier uses a five-character alpha-numeric code for certain molecular diagnostic tests. UHC appears to be applying a similar system to identify almost all clinical lab tests and AP services.

What caught the full attention of lab administrators and pathologists is that UHC went "all in" with this program. First, the test-registry program is comprehensive in that it applies to most UnitedHealthcare commercial, Medicare Advantage, and Community Plan networks. Second, the program affects all tests, test panels, and AP services from in-network, freestanding (or independent) laboratories, UHC said. And, it affects most lab testing services from outpatient hospital laboratories, UHC added.

Was MolDx Worth Copying?

One interesting question is how the Medicare MolDx program may have influenced the way UnitedHealthcare assessed current practices in lab test coding, billing, and payment. The Medicare program has the challenge of understanding what biomarker each new proprietary test is measuring, whether it accurately measures that biomarker, and if the results produced by the test change—in positive ways—how the physician treats the patient.

These are the same challenges private health plans face when labs submit claims for new tests that lack adequate clinical studies and data to support their accuracy and clinical utility. Maybe the Medicare MolDx program, now in its eighth year of operation at Palmetto, pioneered a way for other payers to gauge the accuracy and utility of new lab tests.

At the moment, however, the biggest question for labs and pathology groups is whether UHC can administer its new Test-Registry Protocol in a timely and efficient manner. If not, there may be much chaos and financial disruption in how labs submit test claims and UHC settles those claims after Jan. 1. TDR

UHC Issues Details about How Labs Register Tests

Labs, AP groups testing UHC's 45 million members will need to comply with new Test-Registry Protocol

CEO SUMMARY: As of January 1, UnitedHealthcare will require all clinical laboratories and anatomic pathology groups to register every type of test before labs can bill for those tests. Not only is the COVID-19 pandemic disrupting normal activity, but the administrative burden UHC is imposing will be substantial for all of UHC's in-network labs and pathology groups, as well as for the insurer itself. Delays or confusion in getting the payer to review and approve all registration requests could disrupt labs' ability to submit claims and get paid for these tests.

Whenever a private payer with tens of millions of members makes radical changes in how clinical laboratory tests are coded, billed, and paid, it is a major development for the entire clinical laboratory industry. That is certainly true for **UnitedHealthcare's** (UHC) new Test-Registry Protocol.

Early indications are that this will be a comprehensive effort to fundamentally change how the health insurer works with both clinical laboratories and anatomic pathology groups to manage claims for diagnostic tests.

90-Day Implementation Delay

When UnitedHealthcare announced the details of its Test-Registry Protocol on March 9, it said implementation of the program would begin on Oct. 1, 2020. On July 20, however, UHC said that it would delay the start 90 days, until Jan. 1, 2021.

The program will be all-encompassing. First, most of UnitedHealthcare's commercial, Medicare Advantage, and Community Plan networks will need to participate. Second, the in-network clinical laboratories and anatomic pathology (AP) groups will be required to register each type of test they perform, said UHC.

In the announcement July 20, UHC said its new Test-Registry Protocol requires all in-network labs (including some hospital laboratory outreach services) and AP groups to register each individual test they use before they can bill for those tests.

The program also affects all claims using the place-of-service code 81, UHC added. Also affected are outpatient hospital labs using place-of-service codes 19 and 22, and all testing services using revenue codes 300 through 319 and 971.

"We may deny claim submissions for [included] laboratory services that aren't registered and don't include a test code on the laboratory services claim," warned UHC, the nation's largest health insurer with 45 million members.

The deadline to register tests is Dec. 1, meaning all labs and AP groups must register every type of test (including AP services) that a freestanding or outpatient lab would bill by that date, UHC said.

"For each test, every lab would need to register its own unique identifiers (or test codes) by Dec. 1," explained Ann Lambrix, VP of Client Services at **Vachette Practice Management**, consultants in Sylvania, Ohio. "Once registered, the test code will need to be submitted on claims labs and AP groups send to UHC, starting on Jan. 1. UHC will deny claims that lack the new test codes."

UHC will deny payment requests from all in-network labs that do not follow the new procedure for any test claims included in the program, the insurer added. UHC provides guidance on how the claim submission should incorporate the test code.

List of Excluded Tests

Clinical lab directors and anatomic pathologists should note that some tests are excluded, including the following laboratory test services:

- Those requiring notification or prior authorization through UHC's Genetic and Molecular Lab Testing Notification/ Prior Authorization process;
- Those requiring placement of the **National Institutes of Health** Genetic Testing Registry ID under UHC's molecular pathology reimbursement policy;
- Those test services that outpatient physician office laboratories submit, such as place-of-service billing code 11; and
- Those test services for which UHC is not the primary payer.

Some Exceptions Allowed

Also, some exceptions are allowed. Test codes will not be required for capitated laboratory services when a capitated lab provider does the test for a member in a capitated plan. Nor for laboratory testing done on a hospital inpatient or for patients treated on an emergency or urgent-care basis, UHC said.

Lambrix recommended that labs begin working to comply with the test-registry requirements. "Lab managers will want to leave themselves some time so that if the lab or UHC has questions about their tests, they'll be able to work through those questions to ensure the lab can comply with the appropriate deadlines for registering the test codes.

Denial of Claims

"If claims do not include the new test codes, UHC will start denying claims (as of January 1, 2021)," she added.

For UHC, the Test-Registry Protocol allows the insurer to fill a gap in how lab tests are identified throughout the industry, the company said.

To identify each test on a claim today, every lab and AP group must use Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes. But UHC wants more information on each test from every lab and AP group in its networks.

"In the absence of industry-standard ways to identify the specific test being performed, requiring test registration is a reasonable alternative that achieves needed test transparency," UHC explained. "Often, a procedure (CPT or HCPCS) code alone on the claim does not sufficiently describe the actual testing being ordered and performed. Rather, it describes procedures for which the lab bills."

Transparency is lacking, UHC explained, when a physician orders a test using a single corresponding procedure code, such as 80061 for a lipid panel and other times the same code is used when a physician orders a panel when doing a broader assessment for a patient, said UnitedHealthcare. "One lab offers a 'diabetes comorbidity assessment' that contains 80061 plus three other CPT codes," UHC noted.

As of Jan. 1, test claims, "must contain your laboratory's unique test code," and "each test code on a claim must match a corresponding laboratory test registration provided in advance to

UnitedHealthcare," the insurer said. Labs will need to add the new test codes to four types of claim forms:

- CMS-1500,
- UB-04 or CMS 1450,
- HIPAA 5010 837 Professional, and
- HIPAA 5010 837 Institutional.

"When a laboratory test CPT code or HCPCS code is billed, a corresponding test code with a matching test registration will be required for each claim line submitted, or we'll deny the claim," UHC said in its most recent UHC announcement about the program, dated July 16.

Included in the UHC announcement is a list of frequently-asked questions (FAQs). In one answer, UHC defines the term "laboratory test code" as a "laboratory's unique identifier that a physician would use to order a test (either independently or as a part of their EMR's integration with the lab or the lab's LIS implementation)."

Certain AP Services

One problem for UnitedHealthcare's in-network AP groups is that applying test codes to certain AP services—such as biopsies—could be troublesome because pathologists do not always know how many samples they may collect. "Also, each patient's case is different, whether a pathologist is collecting a breast biopsy or a prostate biopsy or any other sample," noted Lambrix.

For these reasons, there is some confusion about how outpatient pathology labs would follow the new Test-Registry Protocol requirements. "There's still a question about how UHC will recognize the test codes for surgical or cytology specimens," Lambrix explained. "The question applies when an outpatient pathology lab has a separate pathology group directing the hospital laboratory and performing the professional interpretation of the pathology or cytology specimens for hospital outpatients.

UHC Review Will Result in Multiple Actions

ONCE CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS apply for a unique test identifier under UnitedHealthcare's test-registry program, the insurer can accept or reject the test for claim filing or require the lab to answer questions about the test. UHC also can deny payment by deciding that a test has expired.

Here are the categories UHC will use when reviewing test identification requests. UHC said that its Test-Registry tool will list the status of a lab's test as "Draft, Lab Action Required, Pending Review, Released, Denied, or Expired." UHC explained those terms as follows:

- **Draft test registrations** are incomplete and require more information from the requesting lab.
- **Lab Action Required** means UHC needs further information.
- **Pending Review** means UHC is reviewing the application.
- **Released** means no further information is required and the lab can submit claims.
- **Denied** means the test cannot be billed, but that UHC may include a reason for denial.
- **Expired** means a test registration has reached its "available-through date" or otherwise expired while under review.

"UHC has confirmed that place-of-service (POS) 22 (outpatient laboratory) is included in this program," she added. "Also, UnitedHealthcare has confirmed that those anatomic pathology groups only billing the professional component must register their 'test/order code' and include that code when submitting claims. The question for these types of laboratories is how UHC will recognize the test/order code for a surgical or cytology specimen, and how UHC will want these test/order codes registered.

"My concern is that some pathology groups may not know that this program affects them," Lambrix warned. "But, if they are participating with UHC and bill POS 19, 22, or 81, then this protocol definitely affects them.

"Therefore, if you are a hospital-based pathology group billing PC only, then I highly recommend that you work directly with UHC on your test/order code registry process," she noted. "That means you should not wait until January to resolve these questions with UHC."

Test Identifier

UHC explained that the test identifier "should uniquely identify the test offered by the laboratory and correspond to what the physician ordered, whether it was a single test that is ultimately billed as a single procedure code, or a test 'panel' that ultimately bills as multiple procedure codes." Most labs define a 'test code,' 'order code,' or 'test identifier' to identify each test being ordered, and that code or identifier is distinct from the procedure codes, UHC noted.

Given the complexity of the program, labs should welcome UHC's decision to move the start date to Jan. 1, 2021, because it gives labs more time to understand how to comply with the new protocol.

"Pushing the start of this program further out gives labs an additional 90 days to comply with UHC's new protocol," noted Lambrix. "That time will allow labs to register their tests, and it gives UHC time to review each test. Then, if UHC has questions when it reviews a lab's tests, there still may be time for UHC to answer those questions before it starts to process claims using the new protocols."

The fact that UnitedHealthcare's new Test-Registry Protocol is intended to cover every test a lab performs could result in rejected claims or delayed settlement of claims if UHC has not completed its review of every code a lab submits for review. THE DARK REPORT sent questions to UHC asking for clarifications on some of the issues reported here. As of our press deadline, UHC had not responded. TDR

Contact Ann Lambrix at 517-486-4262 or alambrix@vachettepathology.com.

UHC's Test Registry Has Earlier Antecedents

WHEN UNITEDHEALTHCARE ANNOUNCED ITS NEW TEST-REGISTRY PROTOCOL IN MARCH, the description UHC offered made it seem similar to a molecular diagnostics identification system that Medicare Administrative Contractor **Palmetto GBA** introduced in 2012. That Medicare effort resulted in nonpayment for certain molecular diagnostic codes under what Palmetto call the MolDx program.

MolDx is similar to a program **McKesson** developed earlier that has since become the DEX Z-Code Identifier system, which certain payers use to supplement non-specific CPT codes. The DEX Z-Code Identifier uses a five-character alpha-numeric code for certain molecular diagnostic tests. UHC appears to be applying a similar system to identify almost all clinical lab tests and anatomic pathology (AP) services.

In addition, UHC's new test registry is similar to a program UHC launched in Florida in 2015 with **Beacon Laboratory Benefit Solutions**, a subsidiary of **Laboratory Corporation of America**. Under that program, clinical labs and AP groups had to apply for approval before they could submit claims for any one of more than 100 molecular tests. Once labs and AP groups received the pre-approval to submit claims for these tests, they could bill as usual if BeaconLBS approved the test for the patient involved.

UHC's new test registry is different, however, in two significant ways. First, it affects all clinical laboratory and AP services and, second, it is not a pre-authorization review because test claims can still be denied.

Amazon Building Labs to Do COVID-19 Testing

Internet retailer will test its own employees, but it could use these labs to disrupt clinical lab industry

CEO SUMMARY: For pathologists and clinical lab directors, Amazon's nascent lab-testing venture for employees could be a significant concern given that the e-commerce company could disrupt the clinical lab business nationwide. The online retail giant has long had an interest in medical diagnostics and has a reputation for disrupting other industries by acquiring or starting companies in such diverse fields as cloud computing, artificial intelligence, consumer electronics, and retail grocery stores.

One under-reported aspect of the COVID-19 pandemic is the significant number of companies now building new clinical laboratories in response to the skyrocketing demand for SARS-CoV-2 testing.

One of the biggest corporations building clinical laboratory facilities is internet retailer **Amazon**, which announced in April that it would begin regular clinical laboratory testing of all employees for the COVID-19 coronavirus, including those showing no symptoms.

Amazon has a history of entering an industry and successfully disrupting it. Thus, its willingness to build lab testing facilities to do its own COVID-19 testing may be the first step in a multi-year strategy to enter the clinical laboratory industry and disrupt it by offering better quality lab testing services at a cheaper price.

One reason why this could be a credible prediction is that Amazon is currently building a network of lab testing facilities with the capacity to do needed COVID-19 testing for its 840,000 employees. Earlier public statements by Amazon support the conclusion that, once the pandemic subsides, the company intends to use this substantial infrastructure—including lab analyzers and skilled lab scientists—for ongoing testing of Amazon employees participating in its health benefits plan.

Amazon's foray into clinical lab testing was precipitated by the onset of the COVID-19 outbreak that took hold in this country in late January. Since then, Amazon's challenges with keeping its fulfillment centers staffed and disease-free made national news on multiple occasions.

In April, in a letter to shareholders, Amazon CEO Jeff Bezos disclosed plans to develop COVID-19 testing capabilities. He next stated that this was a first step in a program intended to perform regular checks on its employees globally. Another statement indicates that Amazon is looking at a permanent capability do its own clinical lab testing.

In that shareholder letter, Bezos wrote, "Regular testing on a global scale, across all industries, would both help keep people safe and help get the economy back up and running. For this to work, we as a society would need vastly more [COVID-19] testing capacity than is currently available."

In a later corporate blog post, titled, "Scalable Testing for Coronavirus," the company reported that it had started building incremental COVID-19 testing capacity.

SARS-CoV-2 Test Services

Early in June, *CNBC* reported more details on the progress Amazon has made to provide SARS-CoV-2 testing for workers at its fulfillment centers. It is doing so, "after several [Covid-19] outbreaks at its warehouses" in at least five states: Colorado, New Jersey, New York, Pennsylvania, and Oregon, the network added.

After these COVID-19 outbreaks among its 840,000 employees, the employer may be worried about the legal liabilities inherent in having workers in close proximity. "By ramping up COVID-19 testing, it is hoping to stem the spread of the virus before it gets out of control," *CNBC* explained.

That Amazon is building a clinical lab testing infrastructure indicates it has an economic incentive to offer testing to physicians, hospitals, and other providers.

In addition, *CNBC* reported that medical diagnostics has long been an area of interest for the e-commerce behemoth, which has earned a reputation for disrupting other industries since it was founded in 1994.

Originally a book seller known as **Cadabra**, Amazon has since acquired or started companies in cloud computing, artificial intelligence, consumer electronics, and digital distribution. In 2017, Amazon acquired the national grocery store chain **Whole Foods**.

If Amazon builds clinical laboratories at only some of its 75 warehouse and fulfillment centers in the United States, what is to stop the online retailer from offering clinical laboratory testing to physicians and hospitals in those areas, or to serve healthcare providers nationwide?

Testing for Other Employers?

For that matter, Amazon easily could serve other employers of all sizes, particularly for those companies that share Amazon's concern about the legal liabilities involved in having workers return to offices and jobsites as state and local officials lift shutdown orders while COVID-19 infection rates decline. *(See sidebar, "Concern about COVID Infections Among Workers Causes Employers to Take Steps to Limit Liability," on next page.)*

All these actions would be consistent with an ongoing business initiative at Amazon, which is to disrupt the delivery of healthcare and health insurance. In January 2018, Amazon got involved in a joint venture called **Haven** with **Berkshire Hathaway** and **JP Morgan Chase** to cut healthcare costs and improve health services for their workers.

"The giant companies, which together employ more than 1.1 million workers, will launch an independent operation that's intended to be free from profit-making incentives," *CNBC* reported at the time. "The new company's goal at first will be to target technology solutions to simplify the healthcare system."

Building a New Clinical Lab

In April, Amazon said on its blog that it has shifted workers from their jobs as program managers, procurement specialists, software engineers, and research scientists to assemble the equipment needed to build the first company-owned and operated clinical laboratory.

The initial intent was to start testing small numbers of front-line employees, the company said. In one of the photos that accompanied that blog post, Amazon showed workers installing a QuantStudio analyzer from **Thermo Fisher**.

Based on information from three sources familiar with Amazon's plans to

Concern about COVID Infections Among Workers Causes Employers to Take Steps to Limit Liability

MANY EMPLOYERS HAVE EXPRESSED CONCERNS about the legal liability risks involved with having workers return to work as stay-at-home orders end and states allow businesses to reopen.

"As U.S. stores, restaurants, and offices reopen in some parts of the country following coronavirus shutdowns, many businesses are worried they'll see an uptick in lawsuits from sick workers and customers," according to a report on Friday, June 19, from *CNBC*.

Business owners and managers fear that if employees or customers are not careful about how to prevent the spread of the highly-contagious SARS-CoV-2 coronavirus, an employee could contract the disease and later allege in a lawsuit that his or her employer did not do enough to keep workers safe from the virus.

Members of the U.S. Congress have heard about concerns among employers, who are asking lawmakers to pass another COVID-19 stimulus package that could include liability protections for businesses. Senate Majority Leader Mitch McConnell (R-Kentucky) has said he would seek to include such liability protections for businesses in new legislation, *CNBC* added. "The litigation epidemic has already begun," McConnell said, according to the network.

"The move has garnered broad support from Republicans in Congress, who argue businesses need greater protection from lawsuits by customers or workers who catch the virus and then claim the business was the source of the infection," *CNBC* noted. "Without these protections, they say businesses will be hampered by lawsuits, which could slow down their efforts to reopen."

Business groups that support such liability protections include the **U.S. Chamber of Commerce** and the **National Association of Manufacturers** (NAM).

Several states, including Arizona, Massachusetts, New Jersey, and New York have passed laws that offer immunity from coronavirus-related lawsuits for certain healthcare facilities, *CNBC* noted.

Laws in Iowa, North Carolina, and Utah protect a broad range of businesses. Also, at least six states have passed bills that allow businesses to require that customers sign waivers, saying they won't sue if they catch the coronavirus.

roll out millions of COVID-19 tests this summer, *CNBC* added important details about this effort.

Amazon's goal is to test most warehouse workers every two weeks by having employees collect their own specimens via nasal swabs, while a clinical professional supervises and guides the employees' collection efforts via video, the network reported.

In addition to having workers collect their own biological samples, the company plans to open stand-alone diagnostic laboratories in several locations, *CNBC* added. The first of these labs would be in Sunnyvale, Calif., and Kentucky, sources told the network.

"These labs would analyze some of the samples to see if they're positive or negative," *CNBC* said.

Spend $1 Billion on Testing

Earlier, the company said it would spend $1 billion on testing this year, and that it planned to spend its second-quarter profit of $4 billion on its response to COVID-19. In addition to testing, the company has taken other steps to keep workers safe, *CNBC* reported.

According to *CNBC*, an Amazon spokesperson said the company has started a pilot testing program at some of the fulfillment centers, but declined to name those facilities.

"We don't yet know exactly how it's going to shape up, but we continue to believe it's worth trying," the spokesperson added, *CNBC* reported.

Hiring Diagnostics Scientists

To develop the testing program, Amazon is adding to the team of professionals working on the project. "Amazon's hardware group Lab126, based in Sunnyvale, Calif., is hiring three additional research scientists in diagnostics to help scale its testing efforts, according to recent job postings," *CNBC* reported. "Lab126 is also hiring several lab assistants, engineers, and scientists in Hebron, Ky."

In addition to clinical lab testing, Amazon is considering using temperature checks and pulse oximetry to screen workers for the COVID-19 illness. Pulse oximetry measures oxygen levels in serum, which some scientists suspect could identify patients who have respiratory symptoms.

Any Amazon workers who test positive for the COVID-19 coronavirus, or who have flu-like symptoms, would be referred to **Grand Rounds**, a company that provides online medical consultations for workers at its employer clients, *CNBC* reported.

"During those consultations, a medical professional walks the worker through the risks and tells them to stay home or seek follow-up care," *CNBC* explained. "Those who test negative don't typically hear from a Grand Rounds representative, but the company has told fulfillment center workers that its service is available to answer questions about the virus."

Online Medical Consults

Collectively, these developments, and the fact that Amazon is building a clinical laboratory testing infrastructure to do large volumes of COVID-19 tests for more than 800,000 employees, indicates the company has an economic incentive to explore how it could also offer clinical laboratory testing services to physicians, hospitals, nursing homes, and other healthcare providers.

Others Think Amazon May Enter Lab Business

OTHER MARKET-WATCHERS SHARE THE DARK REPORT'S VIEW that Amazon could use the new COVID-19 laboratories it is building for in-house testing as a springboard to disrupt the clinical laboratory industry. That includes one observer at the ***Motley Fool***.

On July 4, *Motley Fool* contributor Jeremy Bowman wrote the following:

> *Amazon has not provided an update on the [COVID-19] testing project since April and has declared no intentions to offer tests to non-employees, but the company has a history of developing new projects in-house, like **Amazon Web Services** and logistics, before deploying them to the general public. If the company can reach the scale necessary to make enough [clinical lab] tests, offering them to the public would be a logical next step. Amazon already has a burgeoning healthcare business and a clear appetite for the industry based on the launch of pilot program **Amazon Care**, its acquisition of online pharmacy **Pillpack**, and its Haven joint venture with JPMorgan Chase and Berkshire Hathaway.*
>
> *If the company can reach the scale necessary to test non-employees, doing so would help burnish its reputation as an innovation powerhouse and establish it as a force in healthcare, serving as a launchpad to a growing business in that industry. Additionally, it would engender goodwill among the general public at a time when antitrust regulators have been eyeing it closely.*

Because of its track record of successfully disrupting several other industries, clinical laboratory leaders and pathologists may want to keep close watch on how Amazon uses its clinical laboratories as the COVID-19 pandemic recedes. TDR

Employers, Others Looking to Build New Clinical Labs

Existing labs may see competition from a range of unlikely entrants into COVID-19 test marketplace

CEO SUMMARY: Employers, universities, municipalities, and other large organizations are interested in building their own clinical laboratories. In addition, entrepreneurs—many with no prior experience in laboratory medicine—want to make money providing COVID-19 testing. Many of these entities seek to provide a safe work environment and limit their legal liability associated with COVID-19, and they want their own clinical laboratories to ensure adequate supplies of timely and low-cost COVID-19 tests for their workers and students.

If the COVID-19 pandemic continues into 2021, then clinical laboratories can expect many new competitors for SARS-CoV-2 testing. A significant and growing number of organizations are building new lab facilities specifically to provide COVID-19 tests.

Two dynamics are fueling this trend. First, entrepreneurs see that the demand for COVID-19 testing exceeds the current capacity of the nation's labs. Therefore, they may be able to profit from building new labs to serve that demand.

Second, many employers and larger organizations recognize the need to test their employees and others in their organizations for COVID-19 as a way to ensure a safe workplace and limit their liability risks.

Amazon is an example of a large employer building multiple clinical laboratories to provide COVID-19 testing for its 840,000 employees in its warehouses and distribution centers. *(See "Amazon Building Labs to Do COVID-19 Testing," pages 9-12.)*

Organizations wanting to build their own clinical labs to provide COVID-19 testing for their employees generally have three goals.

One is to access ample COVID-19 testing capacity. A second is to ensure fast turnaround time for test results—thus avoiding the lengthy delays reported widely in the news. Third, by operating their own clinical labs, these organizations might pay less than if they bought the same number of COVID-19 tests from existing clinical laboratories.

Ground Zero

One person at ground level in the trend to build new clinical laboratories is Jon Harol, President and founder of **Lighthouse Lab Services** in Apex, N.C. Lighthouse consults with clinical laboratories and provides recruiting and staffing services for labs.

Almost every day, Harol's firm gets calls from interested parties wanting to build clinical laboratories or seeking advice and assistance designing and accrediting proposed labs.

"The daily pace of incoming calls has increased over the past five months,"

stated Harol. "We've been contacted by entrepreneurs, companies, and others who want to build new clinical laboratory facilities."

In some cases, the goal is simply to build a lab to perform only COVID-19 tests. But other callers intend to build labs to do both COVID-19 and other clinical lab tests.

Build New Clinical Labs

"We get about one or two inquiries a day and average around 60 leads a month," noted Harol. "Not all of those inquiries turn into actual contracts to build new clinical labs, but many do.

"About half of the inquiries are COVID-related, meaning they want to test exclusively for the new coronavirus," explained Harol. "The other inquiries are for standard clinical lab testing, including testing for COVID-19.

"About one third of these inquiries are from companies that have not been in this industry before," he added. "That's good and bad. It's good because they bring fresh eyes to the clinical laboratory industry and want to do innovative things.

"But it's bad because it's about half the time. I need to explain that—even though their ideas about lab testing make good common sense—federal and state regulations govern clinical lab operations," he added. "I have to tell them, 'You can't do that.'

Unaware of CLIA

"Much of the time, I have to explain that clinical labs need CLIA certificates and that Medicare has rules governing the operation of a CLIA-certified lab," he commented.

"It is surprising how many business people and entities preparing to build clinical laboratories are unaware of CLIA and state laws governing the operation of clinical laboratories.

"People who contact us from outside of the clinical lab industry are interested almost exclusively in COVID-19 testing for asymptomatic populations," he said. "For example, employers want to test their employees. In some cases, the employers themselves want to build their own labs to do COVID-19 testing.

"We've had interest from companies that run sporting events or other big gatherings and want to test participants and possibly fans too," Harol reported.

"Another category of inquiries comes from clinical trial groups that want to test potential participants in their clinical trials," he explained. "They don't want the symptoms of COVID-19 to show up as side effects of their drugs or therapeutics.

> ***"People who contact us from outside of the lab industry are interested almost exclusively in COVID-19 testing for asymptomatic populations."***

"Those people are already in the healthcare business in some fashion but have little or no experience with clinical diagnostic labs," noted Harol. "They are involved in the research and development side of healthcare and now they're looking for guidance on how they can get a CLIA certificate for the clinical lab they want to perform COVID-19 tests.

"Another group of callers are individuals representing colleges and universities that want to do COVID-19 testing for students, faculty, and staff," he said. "They want to know how they can reopen safely. To reopen safely, they want to avoid the legal liability that could come from infections that spread among students.

"In addition, municipalities have asked us about starting their own clinical labs because their workers have to go back to work," Harol commented. "Many of those workers need to interact with the public.

"One way that municipalities can keep their employees safe is to conduct

COVID-19 coronavirus testing," he noted. "Therefore, these cities want their own clinical laboratories."

One city making such inquiries is in a Mid-Atlantic state. Harol could not be more specific. Under non-disclosure agreements Lighthouse has with its clients, Harol cannot name the companies or other entities making these inquiries.

"We've had federal agencies inquire about how we could build labs for them," he offered. "One government agency wants us to give them a proposal to build a lab to do mobile COVID-19 testing for federal employees."

Lab Industry Interest

Some clinical lab companies also are asking about adding their own new facilities, Harol noted. "Clinical lab companies working with employers, cities, or universities have asked about building labs so that they can test employees and students for COVID-19.

"Our biggest lab project involves a company building a clinical laboratory in the San Francisco Bay Area. They want to test 200,000 COVID-19 samples a day," he said. "This new lab company will specialize in COVID-19 testing and will build what could be the biggest COVID-testing lab in the world.

"Often, we get calls from people within the clinical laboratory industry," stated Harol. "They may want to add additional lines of testing into their existing labs, or they may want to start new lab companies and need to build new labs," Harol explained.

"They already know the industry because they may have been lab executives, or they were sales reps who want to start their own labs, or lab managers who want to break out on their own. These people are focused on all forms of clinical laboratory testing, including testing for the COVID-19 coronavirus," he noted. TDR

Contact Jon Harol at 860-833-0489 or jon@lighthouselabservices.com.

Lab Developer Offers Subscription Model

WHILE INTEREST IS HIGH AMONG EMPLOYERS, UNIVERSITIES, AND MUNICIPALITIES for building new clinical laboratories, many of these organizations are not committing to doing so, said Jon Harol, CEO and Founder of Lighthouse Lab Services.

"One issue that causes many of them to reconsider plans to build their own clinical labs is that they consider the price of COVID-19 tests to be too high," explained Harol.

"To serve this market for COVID-19 testing, our team put together subscription models," he noted. "For example, we offer to test all employees every month for $100 per employee. Or, we'll test all employees twice a month for $150 a month per employee. Employers are interested, but most have not yet committed to those rates.

"From what I've heard, our subscription model would be competitive with the prices charged by larger clinical labs, which is in the range of $75 per COVID-19 test or more," he said. "The market's response has been that this is not reasonable for large scale asymptomatic testing.

"Sample pooling for COVID-19 testing could lower that price to a more attractive level, say below $50 per test per employee each month," he observed. "If we can get to that level, then we may see a lot more companies testing their employees. I believe under $50 could be an amount they might be more willing to pay.

"At that price point, COVID-19 testing is more like an employee or workplace safety benefit," he commented. "Employers don't want the loss of productivity that results when workers are out sick with COVID-19. They also don't want the liability either. These are among the reasons why employers are exploring their COVID-19 testing options, at least for now."

In Just 13 Days, Lab Buys, Validates & Uses Analyzer

Swift purchase was achieved despite demand by labs for COVID-19 analyzers, kits, and supplies

CEO SUMMARY: In response to the nationwide outbreak of SARS-CoV-2, clinical labs are introducing new analyzers whenever possible to boost testing capacity. Pre-pandemic, buying and installing new instruments could take at least two months, and that timeline can go longer now. But because of advance planning, working closely with its instrument vendor, and adjusting on the fly when needed, a 161-bed community hospital lab in Michigan cut that time to under two weeks!

In the midst of the supply chain chaos caused by the COVID-19 pandemic, one hospital lab and a major IVD company pulled off a true "mission impossible." In just 13 days from signing a contract for a new molecular analyzer, the instrument was delivered, installed, validated, and put into service to perform SARS-CoV-2 tests.

What makes this a remarkable accomplishment is the fact that *in vitro* diagnostics (IVD) manufacturers and other lab vendors are overwhelmed with demand for their instruments, test kits, reagents, and collection supplies because of the soaring demand for more COVID-19 test capacity. Thus, the story of how a community hospital lab contacted a new vendor and was able to get delivery of a new analyzer and bring it into service in just 13 days proves that it is still possible for labs to get instruments and kits from new vendors.

The lab at 161-bed **Memorial Healthcare Hospital** in Owosso, Mich., obtained funding for the new lab instrument on March 9. This story then commences on March 12, when the order was placed with **Thermo Fisher Scientific** for a QuantStudio 7. The instrument was installed on March 18, with validation and training completed by March 20. On March 23, the lab used the analyzer to run the first SARS-CoV-2 molecular tests.

Before the pandemic, these steps might take four weeks or more. "Once the instrument was delivered, it typically takes another month to get it installed and validated," commented Nicholas Decker, MLS (ASCP), Lab Director at Memorial Healthcare, the only hospital serving rural Shiawassee County. "In an ideal environment, that's about two months."

Looking Ahead in Fall 2019

One factor that helped speed up acquisition of the new analyzer was Decker's foresight in November 2019. Well before the novel coronavirus was identified in China, Decker discussed with Thermo Fisher's sales staff the possibility of purchasing a molecular analyzer. But those conversations ended quickly.

"That discussion was a long-term game plan for the future," recalled Holly Senter, the Genetic Analysis Solutions Representative in Thermo Fisher's Life Sciences business. "By no means was a purchase authorized at this point."

In the fall of 2019, Decker outlined the need for more molecular testing to hospital administrators. "Our lab normally runs 600,000 to 700,000 clinical lab tests each year, and we've had two molecular testing instruments—one from **Cepheid** and one from **Abbott Laboratories**," he said. "But—in a normal year—if one or both of those machines runs short of supplies or goes down for any reason, the lab would need to send out its molecular tests. That would increase the turnaround time and could affect patient care."

Discussions Paid Dividends

These efforts to educate health system administrators about the need to expand their lab's molecular testing capacity while adding redundancy paid big dividends sooner than anyone imagined.

In February, Memorial Healthcare and Thermo Fisher were still discussing molecular instruments, but not for the SARS-CoV-2 coronavirus.

"On February 28, we had our first in-person meeting at Memorial Healthcare to discuss bringing on non-COVID-19 molecular testing," Senter reported. "Within a week of that meeting, we provided the first quote—for regular, non-COVID-19, molecular testing."

On March 6, Decker presented the numbers to hospital administrators. That same week, coronavirus infections were spreading worldwide, and Decker was one of many clinical lab directors in Michigan considering whether to add SARS-CoV-2 molecular assays.

"We knew we were going to do a ton of lab work servicing nursing homes, group homes, and other high-risk groups that can be underserved during an emergency," said Decker "Our lab had to gain access to more molecular testing by any means necessary."

That's when Decker and hospital administrators shifted focus to molecular assays for COVID-19. For that testing, Memorial Healthcare considered the high-throughput QuantStudio 7 to run the company's TaqPath COVID-19 Combo Kit for the qualitative detection of nucleic acid from SARS-CoV-2.

"For that instrument, we were asking the administration to step into uncharted waters to spend an initial amount of $60,000 to $70,000," recalled Decker. "In addition to the analyzer itself, we needed equipment to do RNA extraction, which costs about $25,000. Altogether, we've invested about $100,000.

"At the beginning of the year, this amount wasn't even budgeted," he commented. "We had only discussed adding this instrument sometime in 2020. So, for our administration, that was a big ask. And they said, yes."

On March 9, state health officials reported 373 coronavirus cases and Memorial Healthcare's administrators approved funding to add more COVID-19

13-Day Timeline to Buy, Install, Validate, & Test

AFTER NOVEMBER 2019, when Thermo Fisher Scientific (TF) began early discussions with Memorial Healthcare about a new molecular instrument, progress was slow for four months. But then in March, both sides began working in earnest.

- **March 12:** Memorial Healthcare placed the order for a QuantStudio 7.
- **March 17:** Instrument manufactured and shipped overnight to Owosso.
- **March 19:** Thermo Fisher's Don VanBuskirk begins to install the instrument.
- **March 20:** Jessica Eichmiller, PhD, trains with lab staff via remote web connection.
- **March 24:** TF's Holly Senter drives to Sparrow Hospital in Lansing to get calibration plates needed to prepare the instrument for COVID testing.
- **March 25:** Memorial Health's lab staff runs its first live patient COVID-19 test on the QuantStudio.

testing as soon as possible. Decker placed the order on March 12. The next day the FDA allowed the TaqPath COVID-19 Combo Kit under an emergency use authorization.

In the first two weeks of March, Thermo Fisher was flooded with orders and had no QuantStudio analyzers in stock. Therefore, its factory floor staff shifted production into high gear. "That's when they started providing daily updates about all the steps in their process until the analyzer was physically here and installed," recalled Decker.

Pieces Fit into Place

"At the same time, we also had to coordinate the ordering and shipment of testing supplies because we had to sprint through calibration and validation," he commented.

On Tuesday, March 17, Thermo Fisher (TF) confirmed the instrument would go out for overnight shipping. It arrived the next day. On Thursday morning, Thermo Fisher's Field Service Engineer Don VanBuskirk was on site in Owosso to work with the lab team for the instrument's shakedown runs.

On Friday, Thermo Fisher's Field Applications Scientist Jessica Eichmiller, PhD, conducted training over an interactive web-connection, while Senter worked onsite with the lab staff.

"There was no idle time," Decker reported. "If you wrote an ideal project management script for the installation of this equipment, you'd see that it went just as you would want it go."

Overcoming Hurdles

Set-up proceeded with few problems. However, the Memorial lab was missing a key piece of equipment—calibration plates—on Tuesday, March 24. To solve that problem, TF's Senter drove to Sparrow Hospital in Lansing, borrowed the calibration plates, and drove back to Owosso. The lab ran the first patient test on Wednesday, March 25.

Even as the QuantStudio was running, the lab needed to further boost COVID-19 testing volume. "We're capable of doing about 240 tests a day, but that's mostly because of our staffing model," he noted. "For each SARS-CoV-2 test, it takes time to extract the RNA. Currently, our lab can do only about 12 extractions every 30 minutes.

"In theory, we could do more than that," he added. "But, as it stands now, we try to batch the samples so that we can get all the extractions done in the morning, and then report all of our PCR plates in the afternoon."

Still, those 240 tests each day have made a significant difference for Memorial Healthcare's physicians, because the QuantStudio fills the gap when supplies run short on the lab's other molecular instruments. "Often, we wait days for a response from some vendors," said Decker.

"It turned out that, as a vendor, Thermo Fisher really came through in the clutch," Decker commented. "In addition, our administration was extremely supportive as well. I fully appreciate their confidence."

Several Lessons Learned

For Decker, there were several lessons learned from this experience:

- First, look ahead to anticipate what testing capacity the hospital might need in the coming year or two.
- Second, engage lab team and the vendor's support staff to identify resources required to meet increased demand for tests.
- Third, present to administration the plan to increase testing capabilities, how it improves patient care, capital requirements, and a return-on-investment (ROI) analysis. TDR

Contact Nicholas Decker at ndecker@memorialhealthcare.org or 800-206-8706; Holly Senter at holly.senter@thermofisher.com or 248-345-4140.

IVD Update

IVD Firms Report Boom in Sales of COVID-19 Instruments, Tests

Fall-off in routine lab testing in second quarter was offset by robust sales of COVID-19 tests

Because of the COVID-19 pandemic, second quarter earnings reports were a good news/bad news situation for most of the nation's major *in vitro* diagnostic (IVD) companies.

The good news was that demand for COVID-19 tests meant increased sales and revenues for IVD firms selling those products. But the collapse in routine lab testing that happened in March, April, May, and June was bad news for companies providing those products.

However, despite the dramatic decline in routine testing by clinical labs in the months following the onset of the pandemic, on balance, most of the major IVD companies saw positive revenue growth during the second quarter of 2020. At the same time, demand for lab analyzers and tests for COVID-19 exceeded the ability of the manufacturers to supply enough product to clinical laboratories here in the United States and abroad.

For IVD manufacturers, a second-quarter financial decline in one side of the business—routine clinical laboratory testing—was generally offset by skyrocketing sales of molecular tests. In fact, **Roche** even reported molecular test sales at record levels, and **Hologic** said molecular testing there is "on a roll."

But going forward into the second half of 2020, uncertainty about the pandemic's duration and when a SARS-CoV-2 vaccine might be ready for clinical use, pose questions about what quantities of COVID-19 tests will be needed and where the global companies should market them.

During the earnings calls, there was recognition by IVD executives that healthcare providers and clinical laboratories are facing tough challenges meeting operating and financial goals. Thus, lab customers may put off capital investments, such as in laboratory analyzers.

Similarly, IVD firms' access to labs became an issue during the second quarter. A **Danaher Beckman Coulter** executive told investors it has been difficult to do laboratory equipment installs (for technology that was planned pre-COVID-19) as their service people could not access healthcare campuses and labs during the pandemic.

The recaps of the second quarter earnings reports of several of the larger IVD companies that follow will provide lab administrators and pathologists with a basic overview of financials, testing, and relevant comments from the key manufacturers serving and supplying clinical labs.

Roche

ROCHE: COVID-19 Tests 'Soaring,' Overall U.S. Sales Dropped in Q2, Global Sales Up 3%

During the second quarter, the pandemic impacted Switzerland-based Roche in different ways. In the diagnostics division, Roche reported sales growth of 3% due to COVID-19 testing.

Further, requests for Roche equipment for processing COVID-19 tests are soaring, *Reuters* reported. "The orders we've gotten

are as high as what we would normally sell in four to five years," Thomas Schinecker, Diagnostics Head, said in the *Reuters* story. "We even had governments that flew in with military planes to pick up instruments, because they were in such need."

Indeed, Roche's global sales of molecular diagnostics grew by 61% during Q2-20 and totaled US$6.6 billion even as U.S. sales declined by 4% overall, Roche reported. The company said sales of it cobas SARS-CoV-2 PCR tests offset much of the pandemic's negative affect on the sales of other routine diagnostic tests.

Strong Demand for COVID-19 Test

"We have seen very strong demand for our molecular COVID-19 test, and that has been compensating for the decline in the routine testing," Severin Schwan, Roche CEO, noted during an earnings call with investors on July 23.

Roche executives see healthcare providers "adapting" to the pandemic. "The ultimate impact will depend on the length and severity of the pandemic," Bill Anderson, Roche CEO Pharmaceuticals, told investors during the call. "But we also see the healthcare system adapting.

"We see hospitals, doctors, and clinics figuring out how to make sure patients do get treated," he continued.

"We're confident we won't see another month like May, and that makes us optimistic for the rest of this year and going forward."

Other data and news reported by Roche for the period were:

- Sales expected to grow in the low-to-mid-single digit range.
- Launches of new COVID-19 diagnostic tools: Elecys IL-6 Anti-SARS-CoV-2 test, Roche v-TAC digital algorithm, and the Elecys Il-6 test.
- Six medicines for COVID-19 in 28 clinical trials.
- Sales expected to grow in the low to mid single-digit range.

DANAHER–BECKMAN COULTER, CEPHEID: Revenue Up, Four-in-One COVID-19 Test Planned

Danaher Corporation, headquartered in Washington, D.C., has a diagnostics division that includes several well-known diagnostics companies, including **Beckman Coulter**, **Cepheid**, **Leica Biosystems**, and **Radiometer**. In its Q2-20 earnings report, Danaher disclosed that the diagnostics business had revenue of $1.66 billion, a gain of 2.5% over Q2-19.

Danaher, which has Beckman Coulter Diagnostics as one of its core clinical laboratory and pathology businesses, had sales of $5.3 billion during the second quarter, Tom Joyce, Danaher President and CEO, told investors in a July 23 earnings call.

"We are very pleased with our second quarter results, especially in such a challenging environment. We are tackling the challenges and opportunities presented by the COVID-19 pandemic head-on and are fortunate to do so from a position of strength," Joyce said.

"Moving to Diagnostics, reported revenue was up 2.5%, with 5% core revenue growth led by continued strength at our point-of-care businesses Cepheid and Radiometer," he continued. "Global demand for Cepheid COVID-19 tests and GeneXpert instruments helped drive more than 100% core revenue growth at Cepheid in the quarter."

Other data and news reported by Danaher about its diagnostics division for the period were:

- Declines at Beckman Coulter Diagnostics and Leica Biosystems due to the severe slowdown in elective procedures and wellness visits in the U.S. as well as in Europe.
- "Record number" of Cepheid instruments delivered to customers.
- Development of a rapid four-in-one combination test for COVID-19, Influenza A, Influenza B, and RSV from

a single patient sample with expected launch in third quarter.

During the call's Q&A period, an analyst inquired about the company's take on hardware purchases relative to Beckman Diagnostics and Leica Biosystems.

Joyce's response described the challenges company representatives experienced getting access to labs. "In this COVID-19 environment, access to hospitals in any area—whether it's the reference lab area, anatomical pathology, microbiology—access to those labs' hardware installations has been limited, if not in certain cases, zero," he said.

"We are starting to see hospitals opening up a bit relative to elective procedures and overall utilization, and we are now starting to see our ability to get in and install equipment that's in the order book. So, we will see some improvement ... [but] hospitals are still highly restricted in their access [for lab equipment installs]. But as we go into later this year and early next year, we'll start to see that return to a more normal growth rate," explained Joyce.

Abbott
A Promise for Life

ABBOTT LABORATORIES: Rebounding in Q2, Global Growth of 7%

Abbott Laboratories, based in Abbott Park, Ill., reported sales of $7.3 billion during Q2, which included $615 million of COVID-19 diagnostic testing, the company said in a news release.

In diagnostics worldwide, Abbott boosted sales 7% during the period (Abbott uses an organic measure that excludes "foreign exchange" effects). The company noted less conventional testing during Q2 that picked up near quarter-end and were also "partially offset" by demand for Abbott's antibody testing.

"The diagnostics business—excluding COVID-19 tests—rebounded to 90% of pre-COVID-19 levels by the end of the second quarter," Robert Ford, Abbott's President and CEO, said during the company's July earnings call with investors and financial analysts. "Over the first half of the year, we've developed and launched several COVID-19 tests across our testing platform for both laboratory and rapid point-of-care settings."

But sales for the second quarter overall declined 5.4%, according to Bob Funck, Executive Vice President of Finance and CFO, who spoke during the earnings call.

Other data and news reported by Abbott for the period were:

- Revenue from IgG antibody testing on Abbott's Architect and Alinity platforms was $152 million.
- Molecular diagnostics revenue increased 241%, driven by $283 million in sales of COVID-19 molecular testing on Abbott's m2000 and Alinity platforms.
- Rapid diagnostics revenue increased 11%, with noteworthy sales of $180 million in Abbott's COVID-19 Rapid Diagnostics division.

A question surfaced during the earnings call about "durability" of COVID-19 testing going forward in the second half of the year and during 2021. Ford acknowledged a possible "vaccine phase" and an opportunity for Abbott in testing for surveillance purposes.

"That's probably where I also think that we'll see an increase in serology and antibody testing [for COVID-19]. That's going to be an opportunity for us and for other companies," Ford said.

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Imaging Sales Make up for Sales Decline in Diagnostics Division

Siemens Healthineers, with headquarters in Erlanger, Germany, has two primary multi-billion dollar businesses. One is imaging and the other is diagnostics. In its second quarter earnings report, Siemens Healthineers stated that there was a "slight decline" in its diagnostics business that was offset by revenue growth in imaging and advanced therapies.

"In Q2, the impact from the pandemic took roughly low to mid single-digit percentage points off the comparable growth at Diagnostics," Jochen Schmitz, Siemens CFO, said during an earnings call in May. "Consequently, Diagnostics posted declining revenues of minus 2.2% driven by declining reagent sales, which represents 90% of our diagnostic business. As the reagent sales usually carry most of the gross margin in that business, a drop in regent sales also dropped through to the bottom line to a large degree."

Other data and news reported by Siemans Healthineers for the period were:

- Revenue of €14.2 billion, on par with Q2 2019.
- Orders fell 8% to €15.1 billion.
- Net income was €0.7 billion compared to €1.9 billion in Q2 2019.
- Original fiscal 2020 guidance cannot be confirmed "given the current situation."

"Bear in mind that Diagnostics is still in transition, and we said previously that fiscal year 2020 will be tough. But we also said that Q2 will be better than Q1, which is the case, admittedly on a low level," Schmitz added.

HOLOGIC®
The Science of Sure

HOLOGIC: Molecular Testing 'On a Roll', Women's Health Sales Fall During Second Quarter

Hologic of Marlborough, Mass, is the developer of the Panther instrument (used at more than 1,800 clinical labs worldwide) and the Panther Fusion Platform for SARS-CoV-2 testing.

The company performed well in its Diagnostics and Surgical areas through most of the quarter, according to a news release. Still, Hologic, which focuses on women's health technology, also experienced a negative impact on sales as patient visits to doctors dropped during second quarter and customers put off mammogram appointments.

"As COVID-19 spread and threatened global economies, we moved quickly to mitigate the risk with a focus on cash, so that our healthy fundamentals would be intact on the other side of this pandemic," Stephen MacMillan, Hologic's Chairman, President and CEO, said during an earnings call about fiscal Q2, ending March 28.

"As one of the world's leading molecular diagnostics firms, this is a unique moment for us to live into our purpose.

"Global molecular revenue increased 14.2%, the highest growth rate since 2012," he continued. "This included only about $3.4 million of assay revenue related to our COVID test.

"Excluding this, the business still grew more than 12%, as we continued to layer additional tests—including our COVID assays—onto our Panther installed base," MacMillan explained. "Make no mistake about it: our Molecular Diagnostics business is on a roll on a global basis," he said.

Hologic announced plans for a second SARS-CoV-2 assay for the Panther Fusion, and the milestone of manufacturing one million tests weekly.

Other data and news reported by Hologic for the period were:

- Revenues of $756.1 million, a decrease of 7.6% compared to same time last year.
- Molecular diagnostic revenue of $190.6 million (an increase of 13.6%, the highest rate since 2012), which included $3.4 million of sales from SARS-CoV-2 testing.
- About 600,000 Panther Fusion SARS-CoV-2 tests are performed monthly, actually 12-times more than comparable tests done on the Panther Fusion system.

➤ Routine Test Volume Recovery

What was not discussed in much detail during the second quarter earnings calls these companies had with investors was the companies' expectations for the recovery of routine clinical laboratory testing.

The nation's labs saw declines of about 60% in routine testing during March, April, and May. Routine test volumes are recovering, but are still at least 20%, collectively, below pre-pandemic levels. TDR

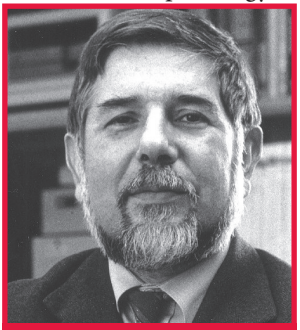
Notable People

Globally-Respected Pathologist Juan Rosai, MD, Dies at 79

In a career spanning five decades, he innovated and contributed many advances in pathology

Internationally-respected pathologist Juan Rosai, MD, died on July 7, at the age of 79, in Milan, Italy. Although born in Italy, his distinguished career in surgical pathology started in the United States in the early 1970s, where he practiced until moving to Italy in 1999.

Among many accomplishments, he is known for his textbook, "Rosai and Ackerman's Surgical Pathology," now in its 10th edition. He published more than 400 papers and his website "Juan Rosai Collection of Surgical Pathology Seminars" is an important resource for pathologists around the world.



Juan Rosai, MD
1940-2020

Born in Poppi, Italy, a town in Tuscany, Rosai's parents moved to Argentina when he was eight years old. Here is where his original first name of Giovanni was changed to the equivalent Spanish name Juan. He was just 15 when he enrolled in the **University of Buenos Aires**' School of Medicine. By the age of 21, he had been awarded his MD and started an anatomic pathology residency at the same school.

Soon after, at a conference in Argentina, Rosai met pathologist Lauren Ackerman, MD, who invited him to train with him at **Washington University School of Medicine** and **Barnes Hospital** in St. Louis, Mo. Rosai completed his residency and fellowship and joined the faculty there.

In 1974, Rosai became Professor and Director of Anatomic Pathology at the **University of Minnesota School of Medicine**. In 1985, he accepted a similar position at **Yale University School of Medicine** in New Haven, Conn. He next accepted the position of Chairman of pathology at **Memorial Sloan-Kettering Cancer Center** in New York City in 1999. It was 2000 when Rosai moved permanently back to Italy to become Chairman of the Department of Anatomic Pathology at Milan's **Instituto Nazionale dei Tumori** (National Cancer Institute).

For the next 20 years, Rosai kept active both in the United States and in Italy. For example, during these years he had professorships at **Weill Cornell Medical College**, **Harvard University,** and **Massachusetts General Hospital**. In the commercial sector, Rosai was a senior consulting pathologist at **Genzyme Genetics** (**LabCorp**). He also was consultant pathologist for the Department of Pathology at the **University of Utah** and **ARUP Laboratories**. He provided surgical pathology consultations through telepathology while still working in Milan.

Rosai developed Parkinson's disease in his late 60s. Sources say it was well-controlled over the years, but recent complications led to his death on July 7. TDR

25 YEARS JOIN US EXECUTIVE WAR COLLEGE

It's Now a Virtual Event!


Robert L. Michel

COVID-19 IS CHANGING EVERYTHING IN HEALTHCARE AND LAB TESTING, which is why our virtual *Executive War College on Lab and Pathology Management* is ready to deliver all that you need to keep your lab at the leading edge of clinical excellence during the SARS-CoV-2 outbreak.

Equally important is how to restore your lab's cash flow to prepandemic levels, and we have speakers and experts to show you ways to achieve that.

Beginning August 4 and running over the following 12 weeks, we'll present several hour-long live sessions each week which will be recorded so you can have on-demand access 24/7. You'll also have the opportunity to network at virtual receptions; meet the major vendors of COVID-19 instruments, tests, and supplies; and work with consultants in billing and collections to help you collect more revenue. Here's your opportunity to meet, interact, and learn from your peers the proven ways to deal with COVID-19 and get paid for all your lab's tests and services.

For program details and to register, visit www.executivewarcollege.com

UPCOMING...

- ***First report from the Virtual Executive War College's keynote speakers: Robert Michel of THE DARK REPORT and Lâle White, CEO of XIFIN.***
- ***Hospital owners sell Mid-American Clinical Labs to joint venture partner Quest Diagnostics: Is COVID-19 pandemic triggering clinical lab sales?***

For more information, visit:

www.darkreport.com

Publisher: Robert L. Michel *rmichel@darkreport.com*

Executive Publisher: Bob Croce *bcroce@darkreport.com*

Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*

Managing Editor: Michael McBride *me@michaelmcbride.com*

Senior Editor: Joseph Burns *joeburns@capecod.net*

IVD Reporter: Donna Pocius *donna11019@att.net*