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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

Restricted information, see page 3

COMMENTARY & OPINION by...

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Where Does COVID-19 Take Clinical Labs Next?

IT IS EASY TO SAY THAT THE CURRENT COVID-19 PANDEMIC is a global event without precedent in human history. After all, what other event has caused airline travel to drop by 95%, ended all professional and amateur sports events worldwide, shuttered Broadway theaters and movie cinemas, closed all non-essential businesses, and required nearly all citizens to "shelter in place"?

The financial consequences to clinical laboratories and anatomic pathology groups are equally without precedent. As you will read on pages 3-5, in the first 12 weeks after shelter-in-place directives were issued, labs in the U.S. saw as much as a 60% drop in the daily flow of routine lab test specimens and during this time the collective clinical lab industry in the United States lost $6.8 billion in cash flow, compared to pre-pandemic levels in January and February.

THE DARK REPORT has data from multiple lab vendors that indicate the nation's clinical labs collectively lose about $600 million in cash flow each week that the SARS-CoV-2 pandemic continues at its current rate of new infections and deaths. Going forward, there will be some lab organizations, physician groups, and hospitals that finally run out of the financial resources needed to continue operations. It is difficult to predict how quickly that happens and how many healthcare providers close their doors forever.

Whether a billion-dollar lab company or the lab in a community hospital in a small town, every lab organization is now fighting for its financial survival, while at the same time attempting to deliver high quality lab testing services at the very moment when the nation needs them most.

In strategic planning, the key question pathologists and lab leaders need to answer is: "where does COVID-19 take clinical labs next?" This is a question with no simple answer. At the federal level, officials at the CDC, the FDA, HHS, FEMA, and other agencies have taken some actions that proved counterproductive in addressing the challenges of the pandemic. Similarly, every state seems to have a governor with a different idea on how to manage the pandemic.

Will the pandemic subside in coming weeks as summer weather heats up the northern hemisphere? Might SARS-CoV-2 re-emerge when the fall influenza season arrives in October? The financial survival of many labs and pathology groups will depend on savvy strategic analysis and planning for these possibilities. TDR

COVID-19 Pandemic Erodes Cash Flow at Clinical Labs

By week 12 of the COVID-19 outbreak, the nation's clinical lab industry had lost $6.8 billion in revenue

CEO SUMMARY: Every day, national news headlines scream about the shortage of SARS-CoV-2 lab tests needed to manage the COVID-19 pandemic. Recently, national news coverage has begun focusing on concerns about inaccurate or unreliable COVID-19 serology tests. But the story being missed by the national news media is the steady deterioration of the finances of the clinical laboratory organizations that are essential in the nation's management of the COVID-19 pandemic.

Clinical laboratory testing for COVID-19 continues to be a major topic in the daily national news cycle. These news stories seem to emphasize two aspects of lab testing for COVID-19, but ignore a more fundamental consequence of the pandemic on the nation's clinical laboratory industry.

The important and, unreported consequence of the pandemic is the deteriorating financial stability at many of the nation's clinical laboratories, including labs operated by hospitals and health networks. As this pandemic continues, eventually many labs will lack the cash flow and capital required to continue even basic, routine testing operations.

The pandemic has blown a big hole in the daily cash flow of almost every clinical lab organization in the United States. How big is this financial hit? The Dark Report calculates that during the first 12 weeks of the COVID-19 outbreak the nation's labs lost $6.8 billion in revenue, compared to pre-pandemic levels.

The Dark Report's calculation is based on data provided to us by multiple sources, including several vendors that each serve hundreds of lab organizations. At the peak of the pandemic, clinical labs were losing $900 million in cash flow per week, compared to the first two months of 2020. In recent weeks, the lab industry has lost about $600 million weekly in cash flow. (*See sidebar on page 5.)*

Meanwhile, the nation's news media seem oblivious to the cash flow crisis crippling the very clinical lab organizations it regularly castigates for being slow to increase the number of COVID-19 tests needed to manage the pandemic. This is the first aspect of lab testing that gets

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prime coverage by the news media. The gap between the demand for COVID-19 lab tests and the volume of such tests that labs can perform is a daily topic in national news accounts. It was true at the start of the outbreak in February and it is true today, three months later.

The second aspect of lab testing that currently gets daily national news coverage involves COVID-19 serology tests. A flood of these news reports question the accuracy of serological tests for SARS-CoV-2, and they warn the public that serological test results can be inaccurate or unreliable.

Unfortunately, many of the reporters writing these stories do not understand the complexity of testing for antibodies and antigens. Nor are most news reporters aware of the significant challenges involved in creating any antibody assay for a novel infectious agent, especially on the rush basis needed to address the current pandemic.

Shrinking Lab Cash Reserves

Meanwhile, each week that the COVID-19 pandemic continues and patients do not visit doctors for routine care or show up in hospitals for needed elective treatment, the cash flow at many labs is inadequate to sustain ongoing operations. These labs are using their up capital reserves—and even going into debt—to sustain daily testing operations.

If there is a bright spot in this situation, it is that clinical lab organizations performing rapid molecular tests for COVID-19 can submit claims for these tests and be paid by Medicare, Medicaid, and private health insurers. For the nation's largest commercial laboratory companies, this source of revenue has been enough, in some cases, to fully offset the declines in their normal daily volume of routine specimens.

But that is true only for a limited number of independent lab companies. Most academic center labs, hospital labs, health system labs, and community laboratories report that they cannot get the amount of supplies they need to collect COVID-19 specimens, and to test those specimens. On pages 12-20, we report on the experiences of both academic medical center labs and health system labs that are members of the **Joint Venture Hospital Laboratory Network** (JVHL) and the **Great Lakes Laboratory Network** (GLLN).

Supply Chain Failures

The lab directors that were interviewed all stated that, from the earliest days of the SARS-CoV-2 outbreak, their laboratories have been unable to obtain adequate quantities of supplies, test kits, and reagents. That is why these labs have unused COVID-19 testing capacity.

The supply chain problems range from vendors who are unresponsive or who simply allocate supplies and tests to their largest customers, to the **Federal Emergency Management Agency** (FEMA) directing that specimen collection supplies and COVID-19 reagents and tests not go to some labs, but instead be diverted to labs of its choosing.

In both circumstances, smaller labs located in cities, towns, and smaller communities are denied the supplies needed to be contributors on the frontlines of the COVID-19 mitigation effort, despite their ability to perform COVID-19 tests with same-day turnaround.

Irony in Supply Distribution

There is additional irony in this situation. The nation's largest lab companies state publicly that they have huge daily test capacity to perform COVID-19 tests. However, only a portion of this test capacity is used by the daily incoming flow of SARS-CoV-2 specimens.

For example, rumors float throughout the clinical laboratory industry that one national lab company can do between 70,000 and 90,000 COVID-19 molecular tests per day, but that it only gets about 15,000 to 20,000 specimens per day.

That means a large volume of collection supplies, kits, and reagents are going

Decline in Daily Routine Specimen Volume Cuts Lab's Cash Flow by $600 to $900 Million Per Week

COVID-19 Pandemic Cuts Deeply into Routine Specimen Volume, Revenue at Nation's Clinical Labs; Cash Flow Down by $6.8 Billion in Past 12 Weeks

Dollars in Millions	Routine Weekly $	% Gain or Decline for Week	Cumulative % Gain or Decline	Actual Routine $ Collected for Week	Actual Cumulative Routine $ Collected	Routine $ Lost for Week	Cumulative Routine $ Lost
Week March 15	$1,500	-4.5%	-4.5%	$1,432.5	$1,432.5	$67.5	$67.5
Week March 22	$1,500	14.0%	-19.5%	$1,207.5	$2,640.0	$292.5	$360.0
Week March 29	$1,500	21.0%	-40.5%	$892.5	$3,532.5	$607.5	$967.5
Week April 5	$1,500	14.5%	-55.0%	$675.0	$4,207.5	$825.0	$1,792.5
Week April 12	$1,500	5.0%	-60.0%	$600.0	$4,807.5	$900.0	$2,692.5
Week April 19	$1,500	2.0%	-58.0%	$630.0	$5,437.5	$870.0	$3,562.5
Week April 26	$1,500	2.0%	-52.0%	$720.0	$6,097.5	$780.0	$4,342.5
Week May 3	$1,500	2.0%	-44.0%	$840.0	$6,787.5	$660.0	$5,002.5
Week May 10	$1,500	2.0%	-42.0%	$870.0	$7,447.5	$630.0	$5,632.5
Week May 17	$1,500	2.0%	-40.0%	$900.0	$8,077.5	$600.0	$6,232.5
Week May 24	$1,500	10.0%	-38.0%	$930.0	$8,707.5	$570.0	$6,802.5
TOTAL *(in millions)*	**$16,500**			**$8,707.5**		**$6,802.5**	

Notes:
1) Assumption: for 2019, total lab revenues in United States were $80 billion.
2) Assumption: divided by 52 weeks, average weekly routine testing revenue would be $1.5 billion.
3) Weekly lost lab revenue estimate calculated by $1.5 billion/week divided by cumulative % decline for week.
4) Cumulative lost lab revenue calculated by adding each week's lost revenue.

CASH FLOW AT THE NATION'S CLINICAL LABS FIRST TOOK A HIT DURING THE WEEK ENDING MARCH 15. The previous week is when most states issued shelter-in-place orders and restricted business to essential services. By April 12, cash flow from routine specimen referrals at clinical labs was down by $900 million per week, compared to the levels of January and February. As the table above shows, from mid-April to the present, there have been modest, but steady increases in routine specimen referrals. Yet, despite those improvements, clinical labs continue to lose almost $600 million in cash flow per week, compared to pre-pandemic levels. THE DARK REPORT used the data provided by multiple lab vendors, each of which serves hundreds of clinical lab clients, to develop this cash flow analysis. THE DARK REPORT thanks all the vendors who contributed to this project.

unused at this lab—even as hospital, academic medical center, and independent labs are complaining that they have doctors ready to submit large volumes of specimens, but that they lack the supplies to perform those tests for local providers.

This is one reason why—even as governors and public health officials report that there is not enough COVID-19 test capacity to meet the demands of their states and communities—many of the local labs in these same states sit idle because large volumes of supplies, test kits, and reagents are prioritized to be shipped to very large national labs.

Here's another other important consequence to the prioritization and allocation of limited tests and supplies to certain lab companies. Clinical laboratories in communities across the nation cannot generate desperately-needed revenue from large volumes of COVID-19 test claims to help offset the lost cash flow from the collapse in the daily flow of routine lab specimens. **TDR**

—Robert L. Michel

COVID-19 Serology Test Claims 98.8% Accuracy

Two clinical lab experts discuss the challenges when developing a new test for a novel disease

CEO SUMMARY: When it announced its new antibody test for the novel coronavirus SARS-CoV-2 on May 3, Roche Holdings explained that its sensitivity level after 14 days was 100%, which is an important point to understand about the test. When assessing Roche's claims, two experts agreed that the test performs exceptionally well. Abbott Laboratories also reported high performance levels for its COVID-19 antibody test in its April 27 press release announcing the FDA's EUA for the test.

Clinical laboratory directors and pathologists may have wondered about the validity of the claims **Roche Holdings AG** made on Sunday, May 3, about its new serological test to identify the presence of antibodies for SARS-CoV-2.

When Roche announced that the **Food and Drug Administration** (FDA) granted the Swiss biotech giant an emergency use authorization (EUA) for its Elecsys Anti-SARS-CoV-2 antibody test, the company stated that the test has a specificity greater than 99.8% and sensitivity of 100% 14 days after confirmation with polymerase chain reaction (PCR). This sensitivity level after 14 days is an important caveat.

Sensitivity and Specificity

That same day, *The Wall Street Journal* reported, "Roche says its serological test has proven 100% accurate at detecting COVID-19 antibodies in the blood, and 99.8% accurate at ruling out the presence of those antibodies. In other words, only two in every 1,000 samples lacking the antibodies would produce a 'false positive' result."

When assessing the company's claim, two experts in clinical lab testing pushed back slightly on the news coverage, but overall they agreed that Roche's serological test performs exceptionally well.

"What you are seeing is a newspaper description of sensitivity and specificity," explained Roger D. Klein, MD, JD, a former adviser to the FDA and a Faculty Fellow at the **Center for Law, Science and Innovation** at the **Sandra Day O'Connor School of Law**. "That said, the Roche assay looks like a good test. It is an electrochemiluminescence assay that uses what's called a sandwich principle.

"It employs a recombinant version of the virus' nucleocapsid protein as a detecting antigen," he added. "Two differentially-labeled antigens bind to the antibody, where one allows for isolation and the other for detection.

"To validate the assay, Roche used about 5,476 specimens, which, by itself, is a large number," he added. "It specifically looked at cross reactivity for a number of viruses, such as HIV, hepatitis B, hepatitis C, including 40 specimens from individuals with commonly-circulating coronavi-

ruses, and 40 specimens from people with colds for a total of 130 specimens in this phase, and found no cross reactivity.

Varying Time Points

"Roche also assessed sensitivity by testing a total 204 PCR-positive specimens from 69 infected people at varying time points after the PCR diagnosis," Klein explained. "The 100% sensitivity was based on 29 specimens taken at 14 or more days after the PCR test. Therefore, it can claim 100% sensitivity—on a reasonable, but relatively small number of specimens.

"We should note, however, that the sensitivity drops off considerably to 88.1% at seven to 13 days after the diagnostic PCR test, and to only 65.5% at zero to six days after the diagnostic test," he added.

"The point is that it takes time for an infected person to generate antibodies, and that's why Roche's COVID-19 test is most accurate at least two weeks after PCR diagnosis," commented Klein. "The test is not sensitive early in the course of infection, presumably because infected individuals have not yet developed antibodies."

This finding in Roche's analysis is similar to the findings that other researchers have uncovered in their work analyzing serological tests.

Determining Specificity

Looking at specificity, Klein noted excellent results in this area as well. "Specificity—which is of great concern because it reflects false positive results—is very high based on tests of 5,476 presumably negative specimens," he explained. "These specimens were of different types and appeared to include the cross-reactivity specimens above, such as 40 coronavirus and 40 cold specimens. The largest numbers of specimens were from 'routine diagnostic' and blood donor patients.

"There were only 10 false positive results in these presumably negative specimens—seven in the routine diagnostic group and three among the blood donors, yielding 99.8% specificity," he added.

"It's important to note that the positive predictive value (PPV) is the number of true positives divided by true positives plus false positives," Klein explained. "PPV depends on the prevalence of antibodies in the population, which means that this test will perform much better for identifying antibody positive people in New York, for example, than it will perform in central Montana.

"If 25% of people in New York City are positive, then among every 5,000 people tested there would be 1,250 true positives and 10 false positives, yielding a PPV of 99.2%," he calculated. "That percentage comes from dividing 1,250 by 1,260. This means almost all individuals in New York City who test positive would have antibodies to the virus.

Prevalence of the Infection

"But then consider what would happen in central Montana if 0.1% are positive," he said. "In this situation, because the prevalence of the infection is so low, the PPV would also be much lower. With 5,000 tests there would be only five true positives, but there would still also be 10 false positives.

"Dividing the five true positives by all 15 positive results yields only 33% of the positive results actually having antibodies," he added. "In that case, two thirds of the tests would be false positives!

"Now consider what it means to have a negative predictive value (NPV) based on the sensitivity of 100% at 14 days or more," Klein said. "The NPV would be very high wherever the test is used, which means that if the result is negative, that person probably doesn't have antibodies."

A second expert offers a slightly different analysis and cautioned that, as with many tests, it's important to look closely at the validation data. Michael A. Noble, MD, a professor in the Department of Pathology and Laboratory Medicine at the **University of British Columbia**, in Vancouver said, "The devil is in the details." At UBC, Noble is also the Chair of the

Clinical Microbiology Proficiency Testing Program and Chair of the Program Office for Laboratory Quality Management.

Unique SARS-CoV-2 Protein

"It sounds like what the company is saying is that it isolated a protein that's unique to SARS-CoV-2, but which is not found on SARS or MERS or the other Alpha or Beta coronaviruses generally," he explained. "I would take Roche's word (with caution). It has done a broad and extensive study of all the variations found within those general human coronaviruses. That said, I am usually very skeptical of laboratory work done in a hurry.

"For any lab, sensitivity testing is challenging," emphasized Noble. "Therefore, I suspect that within the roughly 6,000 patient samples, more than 5,500 were symptomatic and were of a variety of ages," he explained. "Also, it could be that the company's study had 500 mild or asymptomatic patients.

"If we assume that all of the 5,500 should be positive, and all the 500 should be negative, then we can do some arithmetic," he said. "Roche says it has 100% sensitivity, which means that the 5,500 all have the antibody. Then, if only one of the 500 did have antibodies, that would give them a specificity of 99.8%.

Size of Asymptomatic Group

"But, if there are not 500 people without symptoms of COVID-19, but 5,000, and instead of picking up only the expected 10, the test picks up 25 positives, then the specificity goes down to 99.5%," he added. "That reflects the fact that the bigger the size of the asymptomatic group gets—included the 'worried well,' the more the specificity of the test will drop."

From there, Noble recounted what happened during the spread of novel infectious pathogens in the past. "In these earlier outbreaks, both the United States and Canada, we limited the number of people being tested without symptoms to as close to zero as possible," he said. "I think that may be done specifically to make the specificity of the reverse transcription PCR test results look good, at least relatively speaking.

"That's what was done in the early days of HIV to prevent people from being falsely reported as positive," he noted. "I suspect that when the United States opens up COVID-19 testing to everyone, we will find that the number of asymptomatic people will be five to 10 times the number of symptomatic people. At that point, all sorts of confusion will reign." TDR

—Joseph Burns

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Abbott's Antibody Test Also Performs Well

When the federal Food and Drug Administration approved Abbott Laboratory's serological test for the novel coronavirus SARS-CoV-2, it reported high numbers for sensitivity and specificity. The scores were not quite as high as those of the Roche test, but were impressive, nonetheless.

Both tests have emergency use authorizations (EUAs) from the FDA and the CE Mark. The FDA granted the Abbott test—called Architect SARS-CoV-2 IgG—an EUA on April 27 for the enzyme-linked immunosorbent assay (ELISA). The agency said the high-throughput assay's ability to detect IgG antibodies had a sensitivity level of 100% (88/88), and a specificity of 99.6% (1,066/1,070).

Late in April, Abbott was scaling up its manufacturing for antibody testing. At that time, the company said it expected to ship about one million tests to U.S. customers that week and ship four million antibody tests during April.

Roche said that in May it would provide "high double-digit millions of tests" in Europe and in the United States and ship more tests thereafter.

Coronavirus Tests Boost Immunology Lab's Volume

Physicians can assess immunocompromised patients for higher risk of severe COVID-19 illness

CEO SUMMARY: Physicians treating patients with compromised immune systems who contract the new coronavirus need immunology tests to guide risk-assessment decisions for these patients. At a Virginia lab that specializes in such testing, specimen volume has tripled since the SARS-CoV-2 pandemic began. The lab does immunology testing for patients needing transplants, as well as for patients who have AIDS, cancer, diabetes, heart disease, and certain genetic disorders.

Since the start of the novel coronavirus pandemic, a small immunology lab in Fairfax, Va., that tests patients with compromised immune systems has seen its test volume soar by about 300%.

The increased demand for testing led Oral Alpan, MD, founder and Lab Director of **Amerimmune**, a private diagnostic immunology flow cytometry in-office lab, to add three members to the lab team. Founded in 2011 with two employees, Amerimmune now has eight staff members caring for COVID patients.

Targeting High-Risk Patients

For any clinical lab, adding immunology testing could be a winning strategy for physicians treating patients who have the COVID-19 illness. These doctors need to identify patients who have compromised immune systems from a known or unknown deficiency or illness that could place these patients in a high-risk category for serious disease, Alpan said.

"With the onset of the pandemic there has been an increasing demand to work up COVID patients immunologically in addition to identifying those who are at risk for serious disease," said Alpan, an allergist and clinical immunologist who is also the Director of the clinic's immunopathogenesis section.

More Lab Test Referrals

In an interview with The Dark Report, Alpan stated that lab test referrals rose significantly due to demand from physicians and hospitals caring for patients diagnosed with the COVID-19 illness, both locally and from cities and states—such as New York—where the rate of infections and hospitalizations were high.

"This increased demand for testing came because of the need for complex flow cytometry assays that are validated to be used in clinical settings," noted Alpan, who is an Associate Professor of Pediatrics at the **Virginia Commonwealth University** Inova Campus in Falls Church.

"The demand for these specialized assays put Amerimmune in a unique position to do the work-up on these patients," he added. The laboratory normally runs about 300 tests each month.

"Patients who have compromised immune systems may have AIDS, cancer, diabetes, heart disease, some genetic

disorders, or be obese or malnourished," he explained. "Also, certain treatments can suppress the immune system, such as anticancer drugs, radiation therapy, or treatment with stem cells or in preparation for an organ transplant. All of those patients would be immunosuppressed."

From Fellow to Entrepreneur

Board-certified in allergy and immunology, Alpan had a fellowship early in his career in allergy and immunology at the **National Institute of Allergy and Infectious Diseases**, a division of the **National Institutes of Health in Bethesda**, Md. At NIH, he worked with Anthony S. Fauci, MD, the Director of the NIAID and a member of President Trump's Coronavirus Task Force.

Seeing a need for immunology testing, Alpan founded Amerimmune in 2011. "Our initial requests for testing came from a wide variety of doctors who were taking care of transplant patients with possible immune disorders," he said.

Now, many of those same physicians are caring for hospitalized COVID patients and are using Amerimmune's flow cytometry tests to determine how the virus attacks patients' immune systems.

"At this time, for example, there is no literature on how the COVID infection affects transplant patients," continued Alpan. "Yet, it's critical for physicians taking care of these patients to understand how COVID affects transplant patients' immune systems. Once they know that, they can prescribe the medications their patients need.

Laboratory-Developed Tests

"Almost all flow cytometry tests are classified as laboratory-developed tests (LDTs), and we plan to submit for FDA review certain of our LDTs that have predictive value in response to drugs or would be diagnostic for certain disease states," he added.

"When the pandemic started, we saw an opportunity to help COVID patients because their immune systems are compromised," Alpan noted. "Physicians want to understand how their patients' immune systems are suppressed. We also realized that we could help not only physicians and their patients, but also society and the business as well.

"For several years, we've worked with the **Medstar Georgetown Transplant Institute** in Washington D.C. because those patients who need transplants are on immunosuppressants," he said. "We also have collaborated with the **State University of New York (SUNY) Downstate Health Sciences University** Division of Transplantation in Brooklyn.

"Since the start of the pandemic, we've done testing for physicians treating patients in the transplant institute and for physicians at SUNY Downstate who are referring testing to us for their patients," Alpan reported. "Our tests help to identify the immunophenotype in those patients to understand what the COVID-19 disease is doing to them.

Immunophenotyping Tests

"Any patient with the coronavirus is vulnerable, but those with a compromised immune system are among the most vulnerable of COVID patients," he said. "For these patients, we do flow immunophenotyping and may also run some of the traditional standard flow cytometry assays."

Amerimmune also works with its referring physicians to develop novel assays to identify the specific clinical needs of coronavirus patients. As a principal investigator in immunology, asthma, and allergic disorders, Alpan has published articles and abstracts in peer-reviewed journals.

"Since the end of March, we've developed and validated about 10 new assays for this population, so that we could offer these tests for clinical purposes," he explained. To understand how to treat these patients, Alpan and his colleagues reviewed the research published about treating HIV patients and applied what physicians treating those patients learned.

"These tests are not available in kits that a lab can buy," Alpan commented.

"That's why we read the clinical literature to understand what kinds of tests would work for these patients. From there, we perform assay development in a clinically relevant way. Once we determine that an assay works, then we validate it."

The Role of Immunodeficiency

In the immune system, no single cell is responsible for immunodeficiency, explained Alpan. "Some people are compromised in different parts of their immune systems," he commented.

"If a patient's antibody-producing B-cells are immunocompromised, that patient may not be a good candidate to respond to a coronavirus vaccine," he said. "Or, if a patient has a problem with NK-cells—which are the initial defense against viruses—he or she may not do well during the acute phase of a viral infection. Those with T-cell problems are probably at the highest risk for severe disease.

"First, we need to understand what parts of the immune system are affected," he added. "When we know that, we have a different thought process about how to care for that patient moving forward.

From Bench to Bedside

"We also have to understand how a patient's immune system works as a whole, and we can do that by analyzing the data wholistically," he said.

Amerimmune's client physicians were already familiar with Alpan's work. Thus, when the coronavirus started to spread, those physicians turned to Amerimmune to learn more about how the virus affected their immuno-compromised patients.

"That's when we started getting calls from physicians who had used us in the past," he explained. Some of those physicians were treating transplant patients and some had new positions in other practices but were treating high-risk patients who had compromised immune systems.

"Certain patients are easy to identify, such as those who are obese, diabetic, or have heart disease," Alpan commented. "Other patients might be compromised, but their conditions are invisible. For those patients, laboratory testing is required to define the condition.

"Patients are compromised if they have rheumatoid arthritis, multiple sclerosis, or inflammatory bowel disease," added Alpan, the co-director of the clinic's Eosinophilic Gastrointestinal Disorders unit. "But others are just people who don't know they have problems.

"A person doesn't need to have a long-standing problem to be immunodeficient," he said. "Sometimes he or she could be immunocompromised and parts of their immune system make up for that deficiency. Then one day, the individual gets hit by a virus and that's when things go south. This is often the case when you hear in the news that an otherwise healthy teenage boy got COVID and died."

An Unusual View

From his position as an expert in the the diagnosis of high-risk coronavirus patients, Alpan has an unusual view of the effect of the SARS-CoV-2 outbreak.

"The COVID-19 pandemic has been tough on our communities, on the country, and on the world as a whole," he commented. "For those of us in healthcare, it has brought different challenges. Physicians on the frontlines have been dealing with the dying and critically ill in a heartbreaking way.

"Others, such as those of us in diagnostic testing, are innovating by identifying new diagnostics and therapeutics," he added. "That's a real test for us: to deliver for the larger good after years of training and practice.

"The pandemic and the challenge to find cures and diagnostics will continue for months and perhaps longer. For laboratories like ours, it means there will continue to be challenges and moments to shine," he concluded. TDR

—Joseph Burnsl

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JVHL labs say lack of supplies limits COVID-19 testing to just 40% of capacity

In Michigan, Short Supplies Constrain COVID Test Capacity

CEO SUMMARY: Because of a severe shortage of supplies, members of Michigan's two hospital laboratory networks have been stymied in their ability to respond to the pandemic and operate their SARS-CoV-2 analyzers at full capacity. The lack of primers, reagents, specimen-collection swabs, test kits, and viral transport media resulted from directives federal officials imposed in the supply chain in favor of unnamed preferred laboratories, unusually strong demand for testing after years of payment cuts, and disruption in traditional relationships with vendors, lab directors reported.

Testing supplies such as reagents, swabs, and transport media have been so scarce that members of two hospital laboratory networks in Michigan have been running tests for the novel coronavirus at only about 40% of full capacity.

If the members of the **Joint-Venture Hospital Laboratory** (JVHL) and the **Great Lakes Laboratory Network** (GLLN) could get all of the supplies they need to perform coronavirus testing at full capacity, they could run more than 20,000 tests per day for the SARS-CoV-2 virus that causes the COVID-19 illness, said JVHL CEO John Kolozsvary. But a shortage of specimen-collection swabs, viral-transport media (VTM), and reagents limited the daily number of tests the labs could run to 6,500 per day, or about 40% of full volume.

What's more, the hospital labs have been extremely cautious in their use of supplies by limiting the average number of virus tests performed to about 5,000 per day, Kolozsvary said. "Hospital labs do not want to take the chance of running out of reagents, swabs, or VTM in anticipation of a delivery that might turn out to be a 50% cut of their supplies or a complete diversion of supplies from the hospital," he added.

To understand the scope of the problems now choking the clinical laboratory virus-testing supply chain in the United States, The Dark Report interviewed seven Michigan lab directors on April 23. Those lab directors represent more than 30 hospitals in the Detroit metropolitan area and statewide. Other lab executives, including Kolozsvary of JVHL and Mike Hiltunen MBA, MT(ASCP), CLC(AMT), Executive Director of GLLN, were on the call as well. Since then, the lab directors provided data on the number of tests they were running as of the last week in May.

This article includes comments from lab directors at **Beaumont Hospital, McLaren Health, Memorial Health Care, Michigan Medicine Labs**, and the **Saint Joseph Mercy Health System**. In a coming issue, our coverage will include comments from other JVHL-member lab directors.

Three Supply Choke Points

During the call with hospital and health system lab directors, the participants explained that a variety of factors cut into their normal supply sources, limiting test volume. Among the most important of the factors were these three:

1) **Federal redistribution of the supply chain contributed to an unequal distribution of supplies** that favored unnamed commercial and other preferred labs over hospital laboratories. One lab director on the call reported that her lab ran short because the **Federal Emergency Management Agency** (FEMA) had requisitioned substantial volumes of reagents, swabs, and transport media, taking about half of all the supplies from the lab's regular supply vendor. That vendor has been unable to fulfill her lab's normal supply orders, she said.
2) **Choke points in the supply chain.** Traditionally, labs acquire all the materials and supplies they need through their relationships with a variety of vendors, including the manufacturers of their installed analyzers. But during the pandemic, those traditional vendors ran short, forcing one lab to acquire a new analyzer from **Thermo Fisher,** and then get the machine installed and validated so that the lab could run at least some of the tests needed to meet the rising patient demand while the other analyzers ran routine assays.
3) **Strong demand for testing after years of lab payment cuts.** Over several years, commercial and federal payers have made deep reductions in payment for lab testing. That now hampers the ability of all labs to prepare for a huge surge in testing during the pandemic, said Hiltunen.

Inadequate Lab Supplies

"Due to declining reimbursements over the last several years, the laboratories have gotten very good at just-in-time ordering and other Lean activities that keep supplies at what we might consider to be 'normal' testing levels," he explained. "Manufacturers are in the same boat, in that demand for reagents and

consumables far exceeded 'normal' testing patterns because the novel coronavirus has been anything but normal. In other words, the system totally failed."

Among the labs' biggest need is for reagents to run their high-speed reverse-transcription polymerase chain reaction (RT-PCR) analyzers. After reagents, the labs also need specimen-collection swabs and VTM.

On May 25, the **Association for Molecular Pathology** (AMP) released results of a survey of lab professionals from academic medical centers, commercial reference laboratories, and community hospitals, all based in the United States, that offer SARS-CoV-2 tests. The survey confirmed what the Michigan lab directors reported to TDR.

The lab directors explained the problems they faced in obtaining the requisite supplies to increase virus testing volume in their laboratories, and outlined the plans they have to collect specimens in the state's nursing homes and other congregate facilities and to serve other high-risk populations.

Beaumont Hospital

Barbara S. Ducatman, MD, Lab Director at Beaumont Hospital, Royal Oak, said the lab introduced its first COVID-19 test on March 17, but since then has yet to run at full testing capacity due to supply contraints. Beaumont has 1,109 beds and serves Detroit and its suburbs as a level 1 trauma center and as a major teaching hospital. The Beaumont system has nine clinical labs.

"When we went live with testing for COVID-19 we were one of the first health systems to do so in Michigan," said Ducatman, Professor and Chair of Pathology at **Oakland University** at the **William Beaumont School of Medicine**. "We are testing in three different ways. We have the CDC's assay and tests from **Luminex** and **Cepheid**. But on all platforms, we've been severely limited."

As of April 23, the Beaumont Hospital lab was running about 500 tests per day. "At that time, we were extremely limited by the number of extraction reagents we could get for the Cepheid machines," she explained. "The people at Cepheid told me they've been constrained by FEMA in how many reagents they could send out because they had to give FEMA about half of their supply.

FEMA's Directives, Control

"Since FEMA began directing where those supplies go, we were unable to get those reagents, even though Michigan was a hotspot at that time and still is to some extent," Ducatman said.

At that time, Michigan had 2,812 deaths (third highest among the 50 states behind only New York and New Jersey) and 33,929 cases (seventh highest among states in the number of cases per 100,000 residents), according to data from the **American Heart Association Health Metrics and Evaluation**. On May 29, Michigan ranked eighth in the number of cases, and fifth in number of deaths, AHA data show.

"In late April, we were doing only about 500 tests a day, and into May we still do 500 tests a day because we are unable to obtain the supplies needed to support our total capacity of 3,000 tests," Ducatman reported. "Therefore, we have limited COVID-19 testing to only our emergency room patients, hospital inpatients, and labor and delivery.

"Sometimes we would give second tests to people who have a strong pretest probability of having COVID-19, but who tested negative," she added. "Also, we were sending some tests out, but those tests were mostly for our employees who were returning to work."

By the end of April, the lab started serology testing for all 38,000 employees of Beaumont Health. "That testing is voluntary," noted Ducatman. "For the employee testing, we're using **Perkin Elmer** and the **EUROIMMUN** system,

Local Health Systems Contribute to Detroit's Effort to Operate a Drive-Up Specimen-Collection Site

IN LATE MARCH, Detroit Mayor Mike Duggan called on multiple health systems to develop a drive-up site to collect specimens from patients concerned they had the novel coronavirus.

Following that request, Duggan and Public Safety Health Director Robert Dunne, MD, announced a partnership with **Henry Ford Health System**, the **Detroit Medical Center**, and **Trinity Health** in Detroit to establish the site at the **Joe Dumars Fieldhouse** at the former Michigan State Fairgrounds.

"At the site, we collected almost 9,000 tests," said Isabel Gauss, MT (ASCP), Regional Lab Operations Director for **Saint Joseph Mercy Health System**, an affiliate of Trinity Health, one of the nation's largest Catholic health systems. "By doing that, we helped to decompress a lot of the patient testing volume that was coming in through the emergency rooms in hospitals and health systems," she explained.

The program began at the end of March and a closing date has yet to be set. At the drive-up site, the health systems collected more than 400 specimens per day for Detroit residents. Each patient needed an appointment and a doctor's requisition for testing. One lesson Gauss learned was the importance of explaining to hospital administrators that using the term "drive-up testing sites" was misleading.

"We had to be very specific with our medical leadership about drive-up and curbside collections," noted Gauss. "Many of our patients thought they would drive up, get a specimen collected with a nose swab, and have a moment of pain. But then they expected to get a COVID-19 test result. That's not the case, because those tests are not designed to produce rapid results."

To increase testing for the novel coronavirus, the health system's labs have run Cepheid and Abbott instruments and recently acquired one of the new **BioFire** platforms, Gauss said.

"Our allocation of the reagents we need for COVID-19 testing has been quite limited," she commented. "So, we do what we can to preserve reagents. We also work with multiple different vendors to get the supplies we need," she noted.

"In addition, we have multiple different collection sites—such as curbside and drive-through collections. We transport those samples to our community hospital labs and also use our primary reference lab, **Warde Medical Laboratory**.

"Currently, we are working on developing plans to open up our operating rooms and to do COVID-19 testing in our nursing homes," she commented. "Our mission is to facilitate COVID-19 testing in both settings."

but that's only if we can get the reagents for those tests.

"Obtaining supplies has been a continual problem," Ducatman commented. "Every day is like the Wild West—not only in our attempts to get reagents but to get other essential lab supplies as well."

During the pandemic, Ducatman has filled two jobs: Chief Medical Officer for Beaumont Hospital, the largest facility in the Beaumont system, and the system's Lab Director. "There are nine labs in our eight hospitals and one in our free-standing emergency center," she noted.

"Every day there is a shortage of something our laboratory desperately needs for testing," she added. "Nothing we do seems to get us the reagents we need. We would love to run 3,000 tests per day and it's very frustrating not to do so.

"Our purchasing department has been told that our vendors have allocated

reagents for us, but they also said that the federal government is directing our vendors where to send those reagents," Ducatman explained. "Early in April I was on the phone with FEMA, and their comment to me was to send the tests that we couldn't do to **LabCorp** and to **Quest Diagnostics** because they had the reagents that we didn't have.

"At that time, Beaumont Health had the largest share of COVID-positive patients in Michigan," she said. "Therefore, sending those tests to other labs didn't make a whole lot of sense."

Michigan Medicine Labs

The **Michigan Medicine Laboratories**, known as **MLabs**, went live with its first COVID-19 tests on March 20. Based in Ann Arbor, the labs are part of the **University of Michigan Health System**, said Julia Dahl, MD, Associate Director of MLabs.

"We've validated four different platforms: Abbott, Cepheid, **DiaSorin**, and Thermo Fisher,"she said. Dahl, who is the Associate Director for MLabs' outreach and reference testing programs, also serves as Assistant Professor, Gastrointestinal and Hepatobiliary Pathology at Michigan Medicine. "We use the DiaSorin as a rapid test for emergency room patients. That rapid test is useful for making admitting decisions for emergency room patients because it has the fastest turnaround time," she noted.

On April 23, MLabs, a reference laboratory, was running 500 to 600 daily coronavirus tests, but it had the capacity to do about 2,000 tests per day. "Our lab is eager to test more patients, but we couldn't run that many tests because we didn't have enough reagents, swabs, or viral transport media," explained Dahl. "We have tested dry swabs, but those are not ideal. We've been negotiating for swabs from our supply chain, but doing that through our normal channels has been challenging.

"The supplies we need most are swabs. Less so reagents because we have four platforms, which allows us to spread out which platforms are meeting our demand for these tests," she added. "It appears that we have more capacity to test COVID-19 patients than we have demand for testing because we've restricted who can get tested—at least for the moment. We expect that to change in the coming weeks.

"We are working with four nursing homes because those facilities are of strategic interest to Michigan Medicine and because state officials made it a priority to provide testing in those facilities," she explained. "In early April, we reached out to them to discuss how we could develop a plan for COVID-19 testing in those congregate environments.

"Then, we rolled out that testing over the next few weeks to provide services to those four nursing homes and to several skilled nursing facilities," she said. "We are developing a COVID-19 testing strategy in those facilities to determine universal versus symptomatic and how frequently we will test patients in these facilities given changing census and risks of new exposures.

Lower Threshold of Detection

"In an ideal world, we may eventually have an effective point-of-care test for COVID-19, but we don't have that now, at least not one we can use in a lot of different settings," said Dahl. "Personally, I would not place point-of-care serologic testing in a nursing home, because the immunologic response to infections of people over age 60 leaves them on the lower threshold of detection. Therefore, I would be cautious about putting point-of-care testing for serologic assays in a nursing home.

"There may be a use-case scenario to consider for point-of-care PCR testing or point-of-care rapid-result testing for the SARS-CoV-2 virus," she added. The BioFire assay is an example of a rapid-result test. These COVID-19 tests could be used in nursing homes to guide which patients should be isolated.

"Also, rapid detection COVID-19 tests can be used for employees who become febrile at work," said Dahl. "Then, they

could be sent home if they test positive so as to protect the vulnerable population in those facilities who have a much higher rate of death from COVID-19."

At **McLaren Health**, the lab has been doing molecular testing for the SARS-CoV-2 virus since April, "despite not having enough reagents," said Barton P. Buxton, EdD, McLaren's President and CEO of **McLaren Health Management Group**. MHMG provides home health, palliative, and hospice care, as well as home infusion, pharmacy, and laboratory services in more than 30 counties throughout Michigan.

Testing for Area Hospitals

"In our corporate laboratory, we have the **Roche** 6800 platform and the Cepheid Infinity GeneXpert analyzer," he reported. "All of our hospitals are outfitted with the **Abbott** IDNow platforms. In about mid-April, we started testing for hospitals outside of the McLaren system, and we are now testing specimens for several nursing homes in our service area. We have ample capacity, both within our lab and if we need to pivot. We also have the ability to send out COVID-19 tests.

"Our goal is to do as many tests as we can in-house, and we could do so in up to six runs each day if needed," he added. "Our COVID-19 testing is limited only by supplies we can acquire; meaning swabs and VTM. If we can't get the supplies we need, we have validated our equipment to run on specimens transported in saline if necessary."

In late April, McLaren was running about 400 to 500 tests per day on the Roche machines and 300 per day on the Cepheid equipment in the core laboratory. McLaren's hospital labs have been running about 50 tests per day.

"But our total systemwide capacity is 2,500 tests a day, meaning we're below total capacity," said Buxton. "We have a shortage of swabs and viral-transport media, and those are probably the two most-limiting factors. We can use dry swabs, but we don't like to do that because the specimens collected with those swabs are not ideal for running tests on our high- or medium-throughput machines. The Abbott machines take the dry swabs, which has been helpful.

CAP Survey Shows Supply Shortage

On May 6, the College of American Pathologists (CAP) reported that pathologists continued to face shortages of critical testing supplies for COVID-19.

A CAP survey of accredited laboratories showed that more than 60% of laboratory directors who responded report difficulties getting test kits (69%), nasopharyngeal swabs (66%), and viral or universal transport media (62%).

Nearly 80% of the laboratories providing COVID-19 tests reported that they had the capacity to do more COVID-19 testing than they were doing when the survey was conducted from April 23 to 30. And, laboratory directors expected their COVID-19 testing volume to increase by about 40% by the middle of May.

Nearly all labs surveyed reported substantial losses in revenues and the need to furlough employees in some cases.

Testing in Nursing Homes

"When our laboratory started testing, we tested for the coronavirus in acute patients who were in our hospitals," he explained. "As we tested more of those patients, we started seeing cases in nursing homes. Where we can get into nursing homes, we are offering them COVID-19 testing.

"In the hospital, we take the position that we treat the patient, not the test result," he commented. "But in the nursing homes, once we test, then they want to separate those patients as best they can.

"Some nursing homes in our area were hit hard by COVID-19, because people there are closely located," he said.

"This is also true in prisons," Buxton added, "where social distancing isn't always possible unless prisoners are independent in their cells."

Nicholas Decker, MLS (ASCP), Lab Director for **Memorial Healthcare** in Owosso, Mich., said his lab was prepared to test for COVID-19 since March 25. "But for our Cepheid and Abbott machines, we've had no reagents," he noted. "So, I bought a Thermo Fisher RT-PCR platform and had it installed, validated, and got an emergency use authorization from the FDA. We did all that before either of those other two companies would return a call from us or give us any indication about when we would get reagents."

Need to Do Extractions

As of April 23, Memorial was testing 270 patients a day problem-free on the Thermo Fisher equipment. "One of our limiting factors is a labor issue, because we have to do the extractions before we load the tests onto the Thermo Fisher platform," he explained. "While that process cuts into the number of tests our laboratory can do, we can still perform about 500 tests a day without any issues."

Memorial may be able to provide COVID-19 PCR tests for some of the **Ascension** hospitals in Michigan, he reported. "Ascension has had a challenge using the commercial labs, and so some of its smaller outlying hospitals have sent COVID-19 specimens to us since about the beginning of April. That turned out to be a short-term need."

Decker also contacted nursing homes in Memorial's service area between Flint and Lansing, offering to test their residents for the novel coronavirus. "They were sending tests to LabCorp and Quest, but those labs had a 10-day turnaround time," he said.

"It doesn't do those nursing homes any good to test all their residents and then wait almost two weeks to get the results," he commented. "That kind of delay means those nursing homes would have to test everybody all over again. That's why some lab directors say that testing individuals with a PCR test that takes 10 days to two weeks for results causes more problems than it solves."

Next-Gen Testing Labs

One way to address the problems of testing shortages in Michigan is to use the capacity in next-generation sequencing labs. "State officials have suggested sending COVID-19 tests to **NxGen MDx** in Grand Rapids, a private, next-generation sequencing lab that has reagents and some idle equipment," said Decker. "That idea is interesting because that lab normally does genetics testing."

In its report on supply shortages issued last Thursday, the **Association for Molecular Pathology** (AMP) confirmed what the Michigan lab directors were experiencing. The supply shortages affected RNA extraction kits, primers, probes, enzymes, specimen collection swabs, and VTM, reported the AMP.

The lab professionals who responded to the survey reported needing to validate at least three diagnostic testing methods in case reagents or other materials for one method ran short. Also, survey results showed that 60% to 70% of labs responding from academic medical centers and hospitals had serious supply shortages, while only 13% of commercial labs surveyed reported supply shortages.

Supply Allocations

In its report, AMP recommended that federal, state, and local governments set priorities for supply allocations based on clinical testing needs, and that they should recognize these needs could change over time.

"The need for testing supplies designed for acute care, surveillance, high-throughput, and other clinical needs should be monitored widely to provide real-time feedback to agencies to support data-driven supply allocations," said the AMP. TDR

—Joseph Burns

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Testing Strategy Update

Lab Directors Develop Plans for Return of Routine Hospital Care

In Michigan, clinical lab directors are preparing strategies to allow hospitals to reopen safely

CLINICAL LABORATORY DIRECTORS IN MICHIGAN are developing plans to test patients who will return when hospitals reopen for routine care.

Included in those plans are strategies to do testing for the novel coronavirus on patients who will return for everyday care and elective procedures, said Barton P. Buxton, EdD, President and CEO of **McLaren Health Management Group**. MHMG provides laboratory and other services in 30 Michigan counties.

After Buxton and clinical lab scientists at McLaren developed coronavirus testing for patients in hospitals and in congregate settings, Buxton recognized that the health system needed to develop two other testing strategies.

A Need for Two Strategies

"Once our hospitals reopen for elective procedures, we need a twofold-testing strategy," Buxton explained. "That's because of the differences in the testing done at our hospitals and health systems for the coronavirus, and the virus testing done within our health system for contact tracing and for the purposes of epidemiology.

"We also need to develop a COVID-19 testing strategy for public health," he added. "Each kind of testing is different, and I don't think we've found a good way to do both yet.

"When our lab team talks about building up its COVID-19 molecular test strategy, we must keep in mind that those patients who test positive with a molecular test will have a viral load and will have virus shedding," he explained. "However, if a lab doesn't have enough tests or supplies to test everyone, then testing people who have no symptoms creates a unique set of problems. Plus, tests done on people who are asymptomatic are valid only for the time when the specimen was collected.

Contact Tracing Required

"If someone is tested for COVID-19 on a Monday, and that person comes in contact with an infected person shortly thereafter, the first person may no longer be negative on Wednesday or later," added Buxton. "That person may have symptoms or have symptoms coming. That's one of the most difficult challenges hospitals must address as they reopen, in cases where patients are tested for COVID-19 two to three days in advance of their admission. Our first priority has to be to take care of patients, of course.

"We don't know that any COVID-19 test is a panacea," he added, "or if any COVID-19 testing strategy will give us every answer we need.

"Take the example of patients who've tested negative but who have full-blown symptoms of COVID-19," stated Buxton. "Our lab cannot say if that result is from a false negative; if those patients were tested too early; or, if they have a DNA structure that confounds the molecular test in some way. Our lab has had all of those patients and lots of them.

"Even if our lab could run 3,000 COVID-19 tests per day, I wouldn't recommend testing asymptomatic patients

unless like they've been exposed and there's a reason to think they should be tested," Buxton concluded.

At **Michigan Medicine Laboratories** (**MLabs**), Julia Dahl, MD, the Associate Director at MLabs, is wrestling with some of the same issues related to hospitals doing routine surgical care. MLabs is part of the **University of Michigan Health System**, in Ann Arbor.

Keeping Patients Isolated

"When hospitals open up, we'll want to test patients coming in for care that's not COVID-related—meaning surgical and other patients," she noted.

"Since it's difficult to ensure that patients remain isolated after a COVID-19 test unless they are already admitted, it makes little sense to test these patients for the virus well before the day of surgery," she explained. "Testing several days or more than a week prior to surgery requires that patients—and all of their at-home contacts—must stay at home and not go out before their admission for surgery or treatment.

"We know this to be true because we've had instances of patients who arrived sick at our hospital, had a nasal swab specimen drawn, and a negative result for COVID-19, or they had a different coronavirus," Dahl reported. "But when we tested these patients three days later, they had a new exposure to COVID-19 and the SARS-CoV-2 was positive at that time.

Questions about Quarantines

"Re-opening medical facilities for non-COVID care while providing a safe environment for patients, providers, and staff will require expansion of testing to asymptomatic people with results available as quickly as possible," she added. "When planning for pre-procedure or pre-admission testing, consider the requirement that the result of this COVID-19 test is valid only as long as those patients are quarantined and everyone else in their quarantine environment also is quarantined.

"If patients and their contacts cannot be assured of complete quarantine between the test collection and arriving for the procedure, then our lab's testing plan can shift to providing testing immediately prior to the procedure," she advised.

"Many facilities are requesting COVID-19 testing days in advance of procedures. That tells us it is absolutely essential to work with our facilities to provide accurate information about COVID-19 test results," she explained. "And we have to explain that if hospital staff are relying on the RT-PCR assay to be a true positive about the exposure and infection risk of COVID 19, then that test must be done on the day those patients arrive at the facility."

50,000 Students This Fall

At the end of April, MLabs was finishing the validation steps for serologic tests for the new coronavirus. "Being in Ann Arbor, we've got possibly 50,000 students coming back in the fall to the **University of Michigan**. We have to plan for and prepare to test those returning students," Dahl noted. "Right now, the university has not made that decision, but it could do so at any time.

"Plus, we're not far from Detroit and employers there will be interested in testing their employees returning to work. Those employers want their workers to return into a safe environment," she said.

"For those reasons, we're looking at how to do serologic tests for the SARS-CoV-2 virus on a large scale and the utility of giving every patient an RNA test," observed Dahl. "To do all that testing, we have a very limited timeframe before students return in the fall. That means if we are not prepared to do so by July, there will be some very tough decisions to make in the coming months." **TDR**

—Joseph Burns

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Physician Office Lab Update

March, April Patient Visits Drop at Virginia Physician Group and Lab

At gastroenterology practice, specimen volume fell by 90% in April before patient visits rose in May.

During the coronavirus pandemic, gastroenterology and other physician groups with in-house medical laboratories—like most medical practices and clinical laboratories in the United States—have seen a sharp drop in patient visits and specimen volume.

That drop occurred at the same time gastroenterologists experienced strong growth in patient visits and in the specimen volume they sent to anatomic pathologists, said Kenneth N. Josovitz, MD, MPH, President of **Associates in Gastroenterology** (AIG) and **Endoscopy Associates** in Woodbridge, Va.

"Let's put it this way: gastroenterology is a field that was flourishing, at least pre-COVID," he commented. "Then almost overnight, work at our practice went from 100% to 10% of normal volume. It was a devastating drop."

Normal Volume in January

AIG has a staff of 60 employees in five offices, including 11 physicians, nine of whom are co-owners of the specialty group. Three of the offices have in-office endoscopy centers and the other two do ambulatory surgery.

Josovitz and his AIG co-owners also own **Maya Laboratories**, a high-complexity lab in Manassas, Va. The 5,000-square-foot, lab is CAP-accredited and CLIA-certified and has 15 employees, including three part-time pathologists.

"In January, patient visits and specimen volume ran at normal levels," Josovitz said in an interview with The Dark Report. "Each month, our gastroenterologists send an average of about 5,000 jars to Maya Lab. So, if a routine month was 5,000 specimens, that's 1,250 specimens per week. Our group was on track to send about 60,000 jars or more by the end of the year."

Patient visits rose sharply in February, when the seven care centers sent 7,065 jars to Maya Lab, Josovitz said. Of that total, AIG accounted for 912 jars, and another care center collected 1,980 jars.

Workload Drops by 90%

Then, routine GI patient visits and AP volume dropped in March, as coronavirus infections spread in Virginia and the mid-Atlantic states, and after Virginia Gov. Ralph Northam implemented a stay-at-home order on March 23. Under that order, Northam ordered the closing of non-essential businesses and public schools and banned public gatherings of more than 10 people.

"On March 18, we were still at 100% of normal patient volume," Josovitz said. "At AIG, we have two endoscopy rooms in Woodbridge and everyone was fully busy. We have other care centers that have one room each and they were all going strong five days a week.

"But then our patient workload started to drop slightly, and then more until we were down to 10% of our normal volume by the end of the month," he added. "For all of March, we were down about 20% off our normal volume. In April, workload was down by about 90%."

Since May 1, when state officials allowed routine screening colonoscopies and other care services to return with restrictions, the number of patient visits started to rise slowly.

50% of January's Volume

"For the next few weeks, I expect we'll be at 50% of where we were in January," Josovitz predicted. "I hope that over the next couple of months, we'll be fully back to where we were in February.

"We still have to be careful, and we can't use all of our capacity yet," commented Josevitch. "Plus, we can't fill up the waiting rooms at our clinics and endoscopy centers due to social distancing and the need for heavy cleaning of the endo rooms."

To boost revenue and add another level of patient care, Josovitz plans to have Maya Lab add immunology testing. "We're trying to expand services in our lab, and immunology testing will be useful because patients can see if they've been at risk of contracting the virus," he explained.

New Testing Considered

"Our in-office laboratory primarily does anatomic pathology testing," he reported. "We could easily expand by adding some clinical lab testing and recently added molecular testing for stool samples for infections. Also, immunology testing could be useful for our practice."

The drop-off in patient volume and lab test referrals at Associates in Gastroenterology and Endoscopy Associates is similar to what other labs have seen.

As Josovitz noted, patients continue to defer chronic care and preventive screening. This is an inauspicious trend for lab directors trying to predict when patient volume and routine lab test referrals will return to pre-pandemic levels. TDR

—Joseph Burns

Contact Kenneth N. Josovitz, MD, at 703-580-0181 or kjosovitz@hotmail.com.

When Will Patients Want Preventive Care?

"IN OUR FIVE CARE CENTERS, WE GENERATE MORE TISSUE SPECIMENS compared to some hospitals," said Kenneth N. Josovitz, MD, MPH, President of both Associates in Gastroenterology (AIG) and Endoscopy Associates (EA). "But almost all of our work is preventive screening. That's the nature of gastroenterology.

"We do certain life-saving procedures—such as bowel obstructions and gastrointestinal bleeding—but those cases represent only about 1% of our patient volume," he explained. "The other 99% is chronic and preventive care, such as screening colonoscopies.

Preventive Care Deferred

"In the age of COVID, a patient wants to defer his or her screening colonoscopy and similar preventive care," said Josovitz.

"Recently, I was concerned about a patient's condition, and even he decided to wait until June for his screening procedure. Because of the pandemic, our patient visits and lab test volume have gone down and there aren't many ways to make that up."

When the number of patient visits dropped in March and April at AIG and EA, so did the number of specimen jars and revenue. "Our revenue went down in March to about 80% of what it was in January," noted Josevitz.

To cut costs and retain all 60 employees in the care centers, the nine physician owners took no salary since March, he noted. The groups also applied for and received federal stimulus funds from the Paycheck Protection Program (PPP) and from the Medicare Advance Payment Initiative, as authorized by the CARES Act.

The PPP funds came in the form of a loan that Josovitz hopes the federal government will forgive.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Daily, national news headlines call attention to the lack of adequate testing for COVID-19. News reporters question why clinical labs are unable to meet the demand for SARS-CoV-2 tests. One major reason is the lack of adequate supplies labs need to collect specimens, transport them, and perform COVID-19 tests in large numbers. This is one finding of a study conducted by the **Association for Molecular Pathology** (AMP). In a press release issued last Thursday, it reported that supply chain issues are one major reason why clinical labs are unable to perform large numbers of COVID-19 tests.

MORE ON: *COVID-19 Tests and Supply Chain*

AMP said its survey generated 118 complete responses, of which 95 labs were AMP members and 23 labs were non-members. It wrote, "the types of supply chain interruptions that laboratories experienced were vast and include testing platforms, testing kits, reagents, swabs, viral transport media (VTM), laboratory consumables, and PPE, with swabs being the biggest limitation across laboratories." For labs which complain that when shipping supplies vendors favor some labs over others, the AMP survey offers evidence that this may be true. In response to questions about the restrictions and allocation of testing kits and reagents, 70% of hospital and health system labs and 64% of academic medical center labs said they were unable to get adequate quantities due to either government restrictions or how vendors were allocating kits. By contrast, only 13% of commercial reference laboratories said they could not get adequate supplies.

COVID-19 BRIEFINGS WEBSITE FOR LABS

In recent weeks, THE DARK REPORT initiated a free daily service that provides real-time news, information, and alerts to help clinical labs and pathology groups respond to the COVID-19 pandemic. The COVID-19 STAT Intelligence Briefings website is: *https://covid19briefings.com*. COVID-19 Live! calls lasting 30 minutes take place every Tuesday and Thursday at 1:00 PM EDT. All lab professionals are invited to participate.

TRANSITIONS

• **Progenity, Inc.**, of Austin, Texas, announced that Damon Silvestry is now its new Chief Operating Officer. He previously held executive positions at **Natera**, **Miraca Life Sciences**, **Recy-Kleen**, and **Dell**.

Tony Serafini-Lamanna was promoted to Executive Vice President, Diagnostics, at **Meridian Bioscience Inc.**, of Cincinati, Ohio. Prior to Meridian, he was with **Siemens Healthcare Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 22, 2020.

Special Free Webinar!

Thursday, June 11
at 1:00 PM EDT

James O. Westgard, PhD, & Sten Westgard

Achieving High Confidence Levels in Quality, Accuracy of Your Lab's COVID-19 Serology Tests

Your lab's next big challenge is to develop a top-flight COVID-19 serology testing program using new assays that only recently obtained an FDA emergency use authorization. The challenge is to validate your chosen assay, then have high confidence that the clinical results are accurate and high quality.

Who better to guide your lab team through this process than James O. Westgard, PhD, and Sten Westgard, the principals of Westgard QC who are internationally recognized for their expertise in helping labs achieve and sustain quality in their testing programs. Topics will include:

- Confirm assay accuracy from the clinical agreement study,
- Verify claims for sensitivity and specificity with confidence (limits),
- Characterize precision or uncertainty of classification from limit of detection and/or cutoff interval,
- Utilize positivity rate to estimate limit of detection or cutoff interval,
- Build a COVID-19 reflex strategy—repeating positive tests to optimize correctness in surveillance.

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https://covid19briefings.com

UPCOMING...

- ***How Labs Can Renegotiate Reagent Rental Deals in Response to the Decline in Daily Test Volume.***
- ***COVID-19 Serology Tests May Be a Much-Needed Financial Bonanza, but Labs Face Many Risks.***
- ***Forward-Looking Labs Prepare for Much Different Healthcare System Once Pandemic Eases.***