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News

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BEST PRACTICE ALERT

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Decreased Antibiotic Days

PAGE 18

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Subscriptions

AACC
900 Seventh St., NW, Suite 400
Washington, DC 20001
Phone: +1 202.857.0717 or +1 800.892.1400
Email: custserv@aacc.org

Editorial Correspondence

Bill Malone, Managing Editor
Phone: +1 202.835.8756 or +1 800.892.1400
Email: bmalone@aacc.org

Clinical Laboratory News is published monthly (10 times per year—Jan./Feb., March, April, May, June, July/Aug., Sept., Oct., Nov., and Dec.) by the American Association for Clinical Chemistry, 900 Seventh St., NW, Suite 400, Washington, DC 20001. Phone: +1 202.835.8756 or +1 800.892.1400 Fax: +1 202.877.5093. Contents copyright © 2020 by the American Association for Clinical Chemistry, Inc., except as noted. Printing in the U.S.A. POSTMASTER: Send address changes to AACC, 900 Seventh St. NW, Suite 400, Washington, DC 20001.

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As supply shortages continued, everyone realized that we would either have to restrict SARS-CoV-2 testing or move forward with pooling.
p64



AACC Joins Groups Pushing Back on Inadequate SARS-CoV-2 Test Payments

AACC joined six other laboratory groups in calling for the Centers for Medicare and Medicaid Services (CMS) to use appropriate codes and payments for SARS-CoV-2 tests in the 2021 Clinical Laboratory Fee Schedule. CMS has proposed using the so-called gapfill process to assign payment for six new SARS-CoV-2 test codes in 2021, four for molecular testing, and two for immunoassays.

AACC and the other laboratory stakeholders however “strongly urge” CMS to adopt rates using a crosswalk rather than gapfill process because already substantially similar tests and rates can be matched to the new codes. Crosswalking matches a new code and payment to an existing one.

The gapfill process is problematic for several reasons. It leads to uncertainty about what the actual payment to laboratories will be part of the year, as CMS does not announce preliminary rates for any gapfilled codes until nearly half-way through the year. And the agency’s gapfill process would also mean different rates across the country.

In a letter to CMS, the stakeholder group recommends specific codes and payments the agency should use for the new test codes. “The specific crosswalks recommended by the stakeholders reflect the significant resources required to develop and furnish COVID-19 tests,” the letter says. “Clinical laboratories

performing these tests continue to incur extraordinary costs in furnishing these tests—costs that are substantially in excess of costs incurred when

performing amplified probe testing for a single type or subtype of influenza. These test developers have been acting under the hope that CMS would establish appropriate and fair reimbursement for this testing.”



PRICE TRANSPARENCY RULE OPENS INSURER'S BOOKS

The Trump administration finalized a price transparency rule for healthcare plans that could have far-reaching implications for how both consumers and providers evaluate the cost of healthcare in the United States. The rule builds upon previous actions by the Centers for Medicare and Medicaid Services (CMS) aimed at increasing price transparency that gave patients access

to hospitals’ standard charges and negotiated rates with third-party payers for all services, including clinical laboratory testing. According to CMS, this new final rule for health plans moves forward the agency’s goal of greater competition in the private healthcare industry.

A star feature of the rule is a requirement for health plans to give consumers real-time, personalized access to cost-sharing information, including an estimate of their cost-sharing liability, through an internet

based self-service tool. Health plans will also be required to disclose on a public website their in-network negotiated rates, billed charges, and allowed amounts paid for out-of-network providers, and the negotiated rate and historical net price for prescription drugs.

“Price transparency puts patients in control and supports competition on the basis of cost and quality which can rein in the high cost of care,” said CMS Administrator Seema Verma. “CMS’ action represents perhaps the

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most consequential healthcare reform in the last several decades.”

Deadlines begin in 2023. Starting on January 1 of that year, health plans must launch the online shopping tool that will allow consumers to see the negotiated rate between their provider and their plan, as well as a personalized estimate of their out-of-pocket cost for 500 of the most shoppable items and services. Then starting on January 1, 2024, these shopping tools must show the costs for the remaining procedures, drugs, durable medical equipment, and any other item or service a patient might need.

In addition, by January 1, 2022 this rule will require plans to make publicly available standardized and regularly updated data files. According to CMS, these data files will open new opportunities for research and innovation. For example, technology companies can create additional price comparison tools and portals, as well as allow for new kinds of research studies and data analysis into how healthcare prices are set.

CMS in the final rule also deals with a particular issue around laboratory testing. Critics of the rule had said that the type of price data insurers will have to disclose would run afoul of a separate law that requires CMS to keep confidential the payer rates reported by laboratories. But CMS says the rule eludes this problem because neither the government nor its contractors will have an active role in publicizing the information.

Insurers have come out against the rule. Matt Eyles, president and CEO of America’s Health Insurance Plans, said the rule would not accomplish the intended goal. “We are committed to making healthcare more affordable for every American, but the approach in the rule is flawed,” Eyles said. “Competition experts, including the bipartisan Federal Trade Commission, agree that disclosing privately negotiated rates will reduce incentives to offer lower rates, creating a floor—not a ceiling—for the prices that drug makers, providers, and device makers would be willing to accept.”

■ HHS CONTRACTS WITH INBIOS, HOLOGIC FOR SARS-COV-2 TESTING

The Department of Health and Human Services (HHS) announced agreements with InBios and Hologic to expand SARS-CoV-2 testing. The first, a \$12.7 million contract with InBios International, expands domestic production capacity for two rapid point-of-care tests for SARS-CoV-2.

One InBios test, called the SCoV-2 Ag Detect Kit, detects current infections by identifying antigens of the virus in a nasal swab sample. The other test, called the SCoV-2 Detect IgM/IgG kit, detects antibodies for the virus in a blood fingerprick sample, indicating whether the person had a previous infection. InBios will use the funds to ramp up production of either or both tests to 400,000 units per week by May 2021.

HHS also awarded Hologic a \$119 million contract to expand production capacity for SARS-CoV-2 tests



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in the company's supplier's facilities in Wisconsin, Maine, and California. The parties expect the agreement to increase the suppliers' production capacity to 13 million tests per month by January 2022.

In a statement, HHS notes that Hologic's systems are in high demand, and currently 1,100 fully automated, high throughput Panther and Panther Fusion systems are installed around the country.

Hologic and InBios are two of many companies that have received ongoing support to develop SARS-CoV-2 tests from the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response. BARDA has so far supported development of 36 COVID-19 related tests. Of these, 16 have received Food and Drug Administration emergency use authorization.



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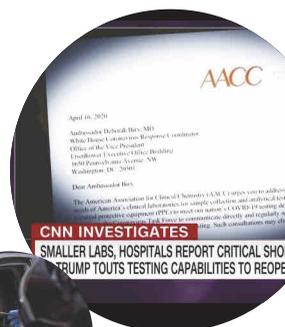
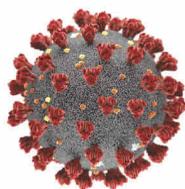
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When word of SARS-CoV-2 emerged in late 2019, AACC acted swiftly, reporting on the tests our community of lab experts would need to detect it. As lawmakers and regulators debated policy throughout 2020, AACC has voiced the needs of frontline lab professionals. And as the public struggled to understand the pandemic, AACC answered their questions with sound science.

AACC has led the way for:

- Lab experts
- Policymakers
- Public



JANUARY



Clinical Chemistry reports on two tests that detect SARS-CoV-2.

21

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ARTICLES

IN AACC'S SCIENTIFIC JOURNALS, *CLINICAL CHEMISTRY* AND *THE JOURNAL OF APPLIED LABORATORY MEDICINE*

FEBRUARY



AACC urges FDA to permit labs to build and use laboratory developed tests (LDTs) to detect SARS-CoV-2.



AACC's letter in *The Washington Post* highlights issues with testing in the U.S.

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POSTS IN OUR LAB EXPERT COMMUNITY, AACC ARTERY

MARCH



AACC launches directory of US and non-US labs performing testing and SARS-CoV-2 Testing forum on AACC Artery.



FDA allows labs seeking EUAs to develop and implement new tests prior to FDA approval.

AACC advocates on FDA regulation and testing coverage. U.S. Senate passes CARES Act, which includes improved coverage for testing.



AACC resources covered in *Forbes*, *Becker's Hospital Review*, NPR and nine other outlets.

AACC President Carmen Wiley discusses testing in *The Washington Post*, ABC News and *South China Morning Post* and speaks at panel hosted by Newswise.

APRIL



AACC creates educational webinar on the unique features of COVID-19 and epidemiology.



AACC informs federal officials on several issues: poorly performing commercial COVID-19 tests, testing and PPE needs for labs, and supply chain challenges.

Congress passes Paycheck Protection Program and Health Care Enhancement Act, which includes \$25 billion to expand testing capacity.



AACC and its COVID-19 resources are covered in *The Washington Post*, *The Wall Street Journal*, *Vanity Fair*, ABC News and other outlets.

Wiley and President-Elect David Grenache discuss testing on CNN.

AACC launches free video series, *Making Sense of Coronavirus Testing*, which earns 1 million views.

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Bench Matters



Alexander B. Leichtle, MD

Total Laboratory Automation— Samples on Track

Industry 4.0 spells minimal user interventions across the analytical spectrum

Industry 4.0—the fourth industrial revolution—denotes an era when many traditional manufacturing processes are becoming ever more automated, and using complex machine-to-machine interactions to introduce more efficiencies, better communications, and self-monitoring and diagnostics. Industry 4.0 has made its way to production of test results in clinical laboratories. Clinical chemistry, with its integrated analyzer systems, always has been a lab automation pioneer, although this mainly was limited to analytical units and standalone devices. Now, solutions that link several analytical platforms are building steam.

While automation doesn't necessarily comprise all parts of the analytical process, total laboratory automation (TLA) combines into an integrated system full automatization of preanalytics, analytics, and postanalytics, such that specimens are processed, tested, and even stored with minimal user intervention. Labs worldwide are exploring or deploying varying degrees of TLA.

In this first of a two-part examination of TLA, I explore the components of TLA, many of which have been implemented in my own lab at Inselspital – Bern University Hospital in Switzerland. TLA has four essential sub-processes: transport of samples to laboratories; preanalytical processing; transport of samples to analytical instruments and intermediate storage; and sample disposal.

FROM BEDSIDE TO LAB

In hospitals, automated sample transport to laboratories offers undeniable opportunities to improve processes and sample quality. Several technical solutions exist, including electrically operated small conveyor





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systems, pneumatic tube systems with collection containers, and transport of individual tubes.

TLA also doesn't require unpacking sample containers. When a laboratory's sample receiving department is operated 24/7 anyway, this might not be a problem, but existing staffing levels combined with incoming emergency samples—especially at night—can delay turnaround times if lab team members are not notified properly. For particularly sensitive samples, ultra-rapid sample transport can be problematic, so carefully evaluating acceleration forces acting on samples is essential.

SAMPLE CHECKS

In TLA, preanalytical modules identify samples, sort out unsuitable or non-processable tubes, and mark specimens "arrived" in the laboratory information management system



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(LIMS). Ideally, the bar code on each sample facilitates this process. If the corresponding analyses have been requested electronically beforehand, a comparison between the LIMS and corresponding requests occurs immediately. This checks whether the material and corresponding patient are both correct, whether the quantity of tubes is sufficient for the planned analyses, and whether the time between blood collection and planned centrifugation is sufficient.

Otherwise, sample tubes can be moved to a waiting position. A further step checks the correct material coding. For example, if the bar code codes serum, the cap color of the tube must match. If necessary, TLA will perform a fill level check using the tube weight.

A SMART PATH FOR SAMPLES

After sample checks, a TLA routing engine assesses the sample path for each tube based on the list of requested analyses. The routing engine uses a comprehensive data table of all analyses that contains

information about analyte, sample material, preanalytical requirements like centrifugation or aliquoting, minimum sample amount, analyzer, and priority ranking. Much of a TLA's efficiency comes from smart sample paths based on this information.

CENTRIFUGATION, DECAPPING, ALIQUOTING

Centrifugation can be a time-limiting step, as centrifuges usually work with batches of samples. With TLA, however, operators can program a maximum waiting time and the centrifuge should start, even if it is not fully loaded. In the meantime, newly arriving samples will be redirected to another centrifuge.

In my experience, aligning centrifugation times for different analyses, such as clinical chemistry and coagulation testing, offers advantages. Whenever this is not practical, it might be reasonable to perform the first preanalytical steps manually and then introduce to the TLA already centrifuged samples. Since many analyzers can't handle

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capped samples (depending on the vendor and system), samples are frequently transported in a decapped state. This is why most TLA systems include decapping stations. Open sample transportation, however, should be reduced to the necessary minimum to avoid sample vaporization, spills, or contamination.

TLA systems usually work sequentially by driving each sample from one analyzer to the next, rendering aliquoting modules optional for most systems. The number of aliquots can and should be reduced, as this supports patient blood management and reduces costs by saving aliquoting vials and storage space. Nevertheless, TLA-driven aliquoting works well when samples need to be transported to another laboratory or stored for biobanking.

SAMPLES TO ANALYZERS AND STORAGE

After preparing samples preanalytically, TLA routing engines guide samples on tracks to attached analyzers that pipette samples directly out of tubes halted on a track. Alternatively, interface modules pick up samples and place them on vendor-specific racks, which are then inserted into analyzers. The latter require space and technical efforts, so labs would need to balance the benefit of automating the loading process against the necessary efforts. For less frequent analyses, specific TLA modules collect and provide the samples in specific racks connected with automated alarms, so staff members know when samples are ready to be picked up.

After the analysis, the TLA collects samples again and depending on their stability stores them in a refrigerated

automated sample storage module. If new tests are requested on a stored sample, the TLA automatically puts the sample back on the track. TLA storage systems are self-organizing, and once fully loaded, the oldest samples can be sequentially discarded. An intermediate storage avoids traffic jams on the track and keeps samples accessible for reflex testing.

Part 2—to be published in the January/February 2021 issue of *CLN*—will explore what TLA can and can't do, and prerequisites for and considerations in installing TLA systems.

Alexander B. Leichtle, MD, is associate professor at the University Institute of Clinical Chemistry and Directorate of Teaching and Research at Inselspital – Bern University Hospital in Bern, Switzerland.

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Elevated cTn Levels Along With Echocardiography Abnormalities Signal Myocardial Injury and Worsening Outcomes in COVID-19

More than 60% of patients hospitalized with COVID-19 who underwent transthoracic echocardiography (TTE) for suspected cardiac involvement had myocardial injury based on cardiac troponin (cTn) levels being greater than the upper reference limit for the assay in use at that institution (J Am Coll Cardiol 2020;76:2043-55).

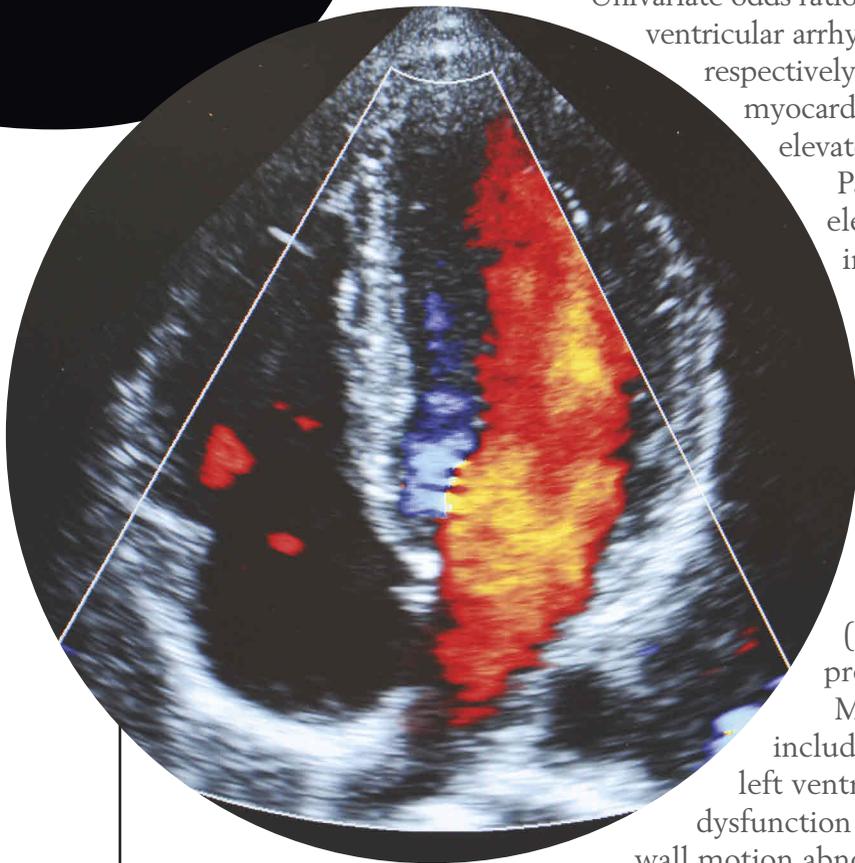
The overall in-hospital mortality rate was 5.2% for all patients who were part of this multicenter cohort study at seven hospitals in New York City and Milan, Italy. Elevated cTn levels alone were associated with an increased mortality rate (18.6%), but patients who had both elevated cTn levels and abnormalities found by TTE fared the worst, with a 31.7% in-hospital mortality rate.

Univariate odds ratios of death, acute kidney injury, shock, or ventricular arrhythmia were 6.67, 6.13, 4.40, and 3.72, respectively for those with cTn levels indicative of myocardial injury in comparison to those without elevated levels.

Patients with myocardial injury also had more electrocardiographic abnormalities, higher inflammatory biomarker levels, and increased prevalence of major echocardiographic abnormalities. Median values of analytes in patients with myocardial injury that were notably elevated in comparison to levels in patients without myocardial injury were interleukin-6 (116 pg/mL versus 58 pg/mL), lactate dehydrogenase (762 U/L versus 445 U/L), ferritin (1,624 ng/mL versus 701 ng/mL), D-dimer (3.7 µg/mL versus 1.5 µg/mL), and procalcitonin (1.3 ng/mL versus 0.2 ng/mL).

Major types of abnormalities detected by TTE included right ventricular dysfunction (26.3%), left ventricular global dysfunction (18.4%), diastolic dysfunction grade II or III (13.2%), and left ventricular wall motion abnormalities (23.7%). In 7.2% of these cases, patients also had pericardial effusion abnormalities.

American College of Cardiology (ACC) guidance recommends measuring cTn levels in patients with SARS-CoV-2 infection who also are being evaluated for acute myocardial infarction. However, this guidance “seems somehow inadequate” in light of this study, according to an accompanying editorial (J Am Coll Cardiol 2020;76:2056-9). The editorialists added that the ACC criteria for assessing cTn would be expanded to include all patients with COVID-19, “not only those with a clinical suspicion of cardiac ischemia.”





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BEST PRACTICE ALERT SUCCESSFULLY CURBS ANTIBIOTIC USAGE FOR LOWER RESPIRATORY TRACT INFECTIONS

An electronic medical record (EMR) best practice alert (BPA) based on procalcitonin (PCT) and polymerase chain reaction (PCR) results reduced inpatient antibiotic days by 2.2 days in patients with lower respiratory tract infections (Clin Infect Dis 2020;71:1684-9). These results demonstrate that “well-constructed EMR provider alerts that integrate PCR, PCT, and antibiotic data can target patients in whom antibiotic therapy can be rapidly narrowed, without need for direct antimicrobial stewardship oversight,” according to the investigators. They went on to suggest that this minimally invasive stewardship practice could be emulated “easily” by other organizations.

The researchers sought to determine whether an automated antimicrobial stewardship provider alert would lower antibiotic use. The BPA alert would be activated for adult patients who met three criteria within 48 hours of each other, including PCT results ≤ 0.25 ng/mL, virus detected via PCR from respiratory specimens,

and active use of systemic antibiotics. The study took place at five hospitals in the Saint Luke’s Health System in Kansas City, Missouri. The primary outcome was inpatient antibiotic days of therapy.

Whenever these criteria were met, the BPA stated “Antimicrobial Stewardship Alert: Your patient has a positive viral PCR + negative procalcitonin + one or more antibiotics ordered. These results suggest viral infection – please reassess necessity of antibiotics as indicated.” Providers in response to the BPA had three choices, including “acknowledge,” “does not meet criteria,” and “not making antimicrobial decisions.” The two former alerts suppressed the alert permanently, while the latter kept firing the alert each time a provider accessed the EMR until he or she chose one of the other options.

The study involved pre-post evaluation of antibiotic use in the proscribed patient population. The authors found that the BPA not only reduced inpatient antibiotic days by a mean of 2.2 days but also the percentage of patients prescribed antibiotics on discharge (20% versus 47%).

MACHINE LEARNING MODELS ACCURATELY PREDICT FAMILIAL HYPERCHOLESTEROLEMIA, BUT CLINICAL UTILITY DIFFERS SUBSTANTIALLY

An analysis of five common machine learning (ML) algorithms found that four show high accuracy in predicting familial hypercholesterolemia (FH) but that the clinical case finding workload to



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yield cases would vary substantially between models (NPJ Digit Med 2020;3:142).

This retrospective cohort study involved routine primary care records of more than 4 million individuals in the U.K. who had a recorded cholesterol measurement. Of these, 7,928 had diagnosed FH. The authors randomly split the study population into a training cohort comprising 75% of patients and a validation cohort of the remaining 25%. They used the training cohort to derive the FH algorithms and the validation cohort to apply and test the algorithms.

The four high-performing ML algorithms were deep learning model (DLM), gradient boosting model, random forest model, and ensemble learning model (ELM). All of these yielded areas under the receiver operating characteristic curve (AUC) >0.89. The logistic regression model

was the poor performer with AUC >0.81.

The models incorporated 45 predictor variables for FH derived from known associations between these features and FH, as detailed in the scientific literature, recommended diagnostic criteria, previously developed algorithms, and expert clinical opinions.

Sensitivity of the models varied considerably, from 30.5% in ELM to 72.6% for DLM. Specificity was more uniform, varying from 90% for DLM to 99.3% for ELM. Positive predictive values ranged from 2.8% for DLM to 15.5% for ELM; negative predictive values were nearly uniform, ranging from 99.7% to 99.9%. Assuming FH prevalence of 1 per 250 population, DLM would identify about 10% of the population as probable FH, whereas ELM would identify just 0.73%.

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BY JEN A. MILLER

Labs, training programs adapt during pandemic as AACC takes steps to better define roles and build up the clinical laboratory workforce



Building a Foundation for the

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LABORATORY FUTURE

At the same time that the COVID-19 pandemic has put a bright spotlight on diagnostic testing, labs are struggling in ways frequently invisible to the public. They have been dealing with not only a persistent shortage of supplies during the public health emergency but also a long-standing workforce issue: lack of a sufficient number of highly qualified clinical laboratory scientists.

As healthcare organizations search for answers, AACC is making the case that stronger support of clinical laboratories and a focus on high standards must be part of the solution—pushing back against plans to undercut the financial and professional bedrock that’s enabled laboratories to respond so quickly to the pandemic.

For one thing, the solution shouldn’t be to substitute other healthcare professionals, like nurses, for laboratory roles; instead, more funding for lab training programs are needed, according to the association. Lab training also needs to be adapted to pandemic conditions, when students might not be able to get practical experience.

A new AACC policy report on the scope of practice for laboratory directors describes for policymakers, healthcare administrators, and the public the qualifications and responsibilities of PhD medical laboratory directors. AACC incorporated this document into a position statement, *Modernization of CLIA: Moderate and High Complexity Testing*.

“My mom doesn’t always know what I do, even though I tell her. Clinical labs tend to be a bit of a black hole,” said Deborah French, PhD, DABCC, FAACC, associate clinical professor, assistant director of chemistry, and director of mass spectrometry at the University of California San Francisco departments of pathology and laboratory medicine. However, during the pandemic, “labs came to the front of everybody’s minds. It’s helped people become more aware that people do this stuff every day.”

French emphasized that it’s crucial for the healthcare field overall to have a clearer picture of what clinical

laboratories do, and who medical laboratory directors are, so that the right people are in place. “You can’t just put any old person in charge of a lab,” French said.

The two complementary AACC reports both solidify the role of laboratory director and push for funding to train more medical laboratory scientists to meet increasingly important—and complex—laboratory needs (See Box).

LABS ARE EVOLVING; REGULATIONS HAVE NOT

Clinical laboratories are fundamentally changing. They are using automation to take over repetitive, manual tasks, while also tackling higher volumes—and more complex tests, like those that involve molecular pathology and mass spectrometry.

Janice Conway-Klaassen, PhD, associate professor and program director of Medical Laboratory Sciences at the University of Minnesota, graduated in 1974 with a B.S. in medical technology. “Things have changed every year. This is just another evolutionary step in the role of laboratories,” she said. Especially now. When her lab switched from ICD-9 to ICD-10 billing codes a few years ago, “we went from 8,000 codes to almost 70,000 codes.”

“Results have to be accurate, and who better to do these procedures, operate these instruments, interpret the results, and consult with doctors than people who have been trained to do that.”

– DAVID KOCH, PHD, DABCC, FAACC

The number of testing sites has also increased in the U.S., from 154,000 in 1993 to 266,000 in 2020. These facilities perform nearly 13 billion tests per year. Advances in technology have also improved the portability of devices, so that tests now can be performed routinely at patients’ bedsides, in ambulances, mobile clinics, doctors’ offices, and sometimes even in patients’ homes. Drive-through testing became the norm during the COVID-19 pandemic.

At the same time, rules governing patient testing have remained largely unchanged since 1995 and haven’t adapted to the way tests are run now. For these reasons, AACC’s CLIA



position statement pushes for more funding to train clinical laboratory scientists to meet testing demand.

“Results have to be accurate, and who better to do these procedures, operate these instruments, interpret the results, and consult with doctors than people who have been trained to do that,” said David Koch, PhD, DABCC, FAACC, professor of pathology and co-director of the

postdoctoral training program in clinical chemistry at Emory University in Atlanta. Koch is a past AACC president and former chair of the AACC Policy and External Affairs Committee. “The assumption that laboratory testing is an easy matter and anybody can do it is not true,” he stressed.

MISUNDERSTOOD ROLES

In a way, the COVID-19 pandemic has boosted the visibility of clinical laboratories, and the constant conversations about and demand for testing have highlighted their crucial role in healthcare delivery. That doesn’t mean the instruments that perform

those tests—or the qualifications of the people who oversee labs—is well understood.

In 2018, the Centers for Medicare and Medicaid Services floated the idea of nurses performing clinical laboratory tests. While that notion was soundly refuted by AACC and other laboratory advocacy groups, the concept still hasn’t gone entirely away.

“Even if you take out of the equation that their training does not involve things like quality control, they’re not trained to do what we do,” French said. Just as no one would expect laboratory scientists to start doing routine nursing tasks, like taking patients’ vital signs, nurses shouldn’t be expected to know how to run tests. “If you are suggesting that nurses become lab people, you’re taking them away from doing important patient care,” she said.

In working on these position statements, Koch said he talked to dozens of nurses, and when he mentioned the idea of nurses taking over lab testing duties, the general response was, “That’s ridiculous; we’re busy all the time,” he said.

Leadership of labs needed to be defined, too. In the new scope of practice statement about board-certified PhD medical laboratory directors, AACC clearly states what these professionals do, their necessary education and experience requirements, and their responsibilities and core competencies.



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“The goal is that medical laboratory directors have the right training, skills, understanding, and responsibility, and fulfill those responsibilities on a daily basis,” Koch said. “It’s important because every patient result is important.”

Koch added that AACC’s practice statement perhaps marks the first time in the clinical laboratory profession that the role has been so defined. “There’s been a hodgepodge of different documents, but it was never put together in one document like we’ve done,” he said.

SHORT STAFFING

The pandemic has also punched a few holes in clinical laboratory training this year. With many hospitals closing labs or imposing strict limits on who was allowed inside, students lost critical opportunities for hands-on training that usually make up the last semester of their education, said Conway-Klaassen.

“Our program was lucky in that we were able to do an adaptive clinical simulation,” she said. Still, students

didn’t do the typical work in real-life situations using actual instruments and facing a real testing load. “It’s been a struggle for programs to finish. Many of us have adapted, but it’s not perfect,” said Conway-Klaassen.

Her program worked with its clinical laboratory partners to discuss what to do and what training would be acceptable to them. The program ended up graduating students even though they weren’t able to complete their capstone clinical training. Laboratories were willing to “accept these students knowing they may need to do additional training,” she said.

All of University of Minnesota’s medical laboratory science spring students graduated with jobs, though more than typical have part-time versus full-time jobs. Many labs are still closed, or under hiring freezes, so that while the program would prefer all students to have full-time jobs, “that they’re employed is huge,” said Conway-Klaassen.

She also said a number of students took deferrals this year. Some are living with elderly parents or grandparents

and didn’t want to risk being exposed to SARS-CoV-2 and bringing it home. Others lost access to childcare or are staying home with their children doing remote learning.

“We’re trying to approach these situations with compassion and treat people with kindness and understanding of the stress we’re all under. We’re all feeling it in all directions,” said Conway-Klaassen.

A bright spot: Even if laboratories are not able to take students on-site, they can help in other ways during the pandemic, Conway-Klaassen said. Already her network of training sites has stepped up to teach and find other means to help students develop. “One of the ways some of the sites helped was by participating in the clinical simulation we did on campus as guest lecturers,” she noted. “They also provided virtual tours of their laboratory facilities. One of them even provided a video of the medical laboratory scientist staff members performing instrument maintenance.” ■

Jen A. Miller is a freelance journalist who lives in Audubon, New Jersey.

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Read the AACC Policy Reports and Position Statements

Both the policy report, “Scope of Practice: Board Certified PhD Medical Laboratory Director,” and the position statement, “Modernization of CLIA: Moderate and High Complexity Testing,” are available on the AACC website, www.aacc.org, under Advocacy and Outreach. Position statements are developed by the AACC Policy and External Affairs Core Committee. A special work group created the scope of practice policy report.

AACC Scope of Practice Document Task Force

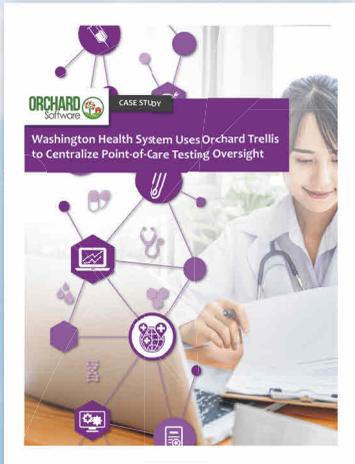
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Understanding the Value of Integrated Point-of-Care Testing in a Pandemic

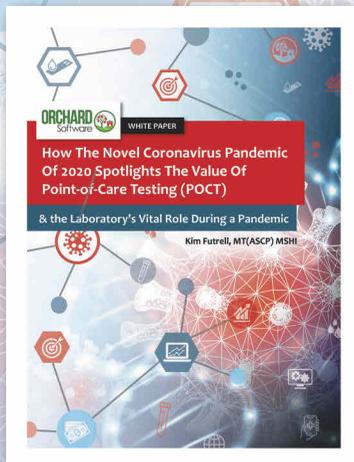
SARS-CoV-2 is a complex virus that can spread from person to person even by people who appear to be asymptomatic, making it much harder to perform contact tracing and manage disease spread.

The COVID-19 pandemic has brought unprecedented challenges to the healthcare industry. Resourceful laboratories are developing strategies to address the need for faster testing turnaround times (TATs).



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- Multiple testing methodologies are being implemented to meet testing demand and enable contact tracing.
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A VIEW FROM GERMANY

on the Preanalytic Phase of Forensic Toxicology Testing

BY HANS-JUERGEN MAURER,
HARALD FREY, NADINE SCHAEFER, PHD,
AND ANDREAS H. EWALD, PHD

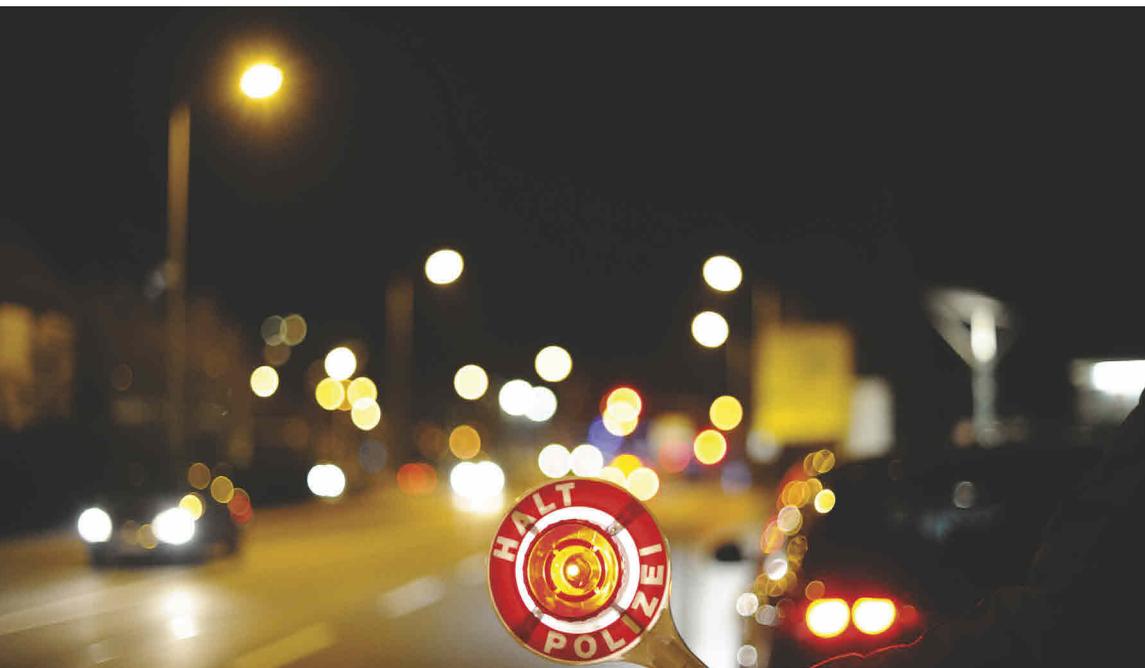




Clinical laboratorians can hone their approaches to drug testing based on unique tactics taken by police around the world.

For police, recognizing people affected by drug or alcohol consumption is complex and requires an ambitious classification process beyond noticing, for example, the odor of alcohol. Police worldwide have distinct methods to identify people under the influence in either traffic stops or after committing a crime.

Beyond asking a person to perform psychophysical tests at a traffic stop, police use drug tests that offer clues about consumption. Depending on the country, police might emphasize one type of test or test medium over another. In Germany, the State Institute for Preventive Action and the Institute of Legal Medicine at Saarland University work on drug use detection strategies independent of drug tests. As a result, our researchers developed the method of unaffected observation (Figure 1) based on an escalating series of communication and recognition processes that police can use to classify a person as affected by a drug.



|||

WHEN A POLICE OFFICER INITIATES UNAFFECTED OBSERVATION, THE GOAL IS TO RECOGNIZE AND ASSEMBLE MOSAIC PARTS OF THE SYMPATHETIC CNS RESPONSE.

Active cooperation with traffic control personnel is voluntary in Germany, and our method is independent of the kind of substance involved. Since this method is based first on behavioral evaluation, no equipment is needed initially, but police need training before they use the method.

CHANGING THE OLD STRATEGY OF DRUG RECOGNITION

A challenge for police is recognizing the effects of drugs so they know when to request testing. While a drug test helps detect affected persons, for police the process

starts with the case background. For example, in individuals suspected of driving under the influence, detecting acute drug actions is important; thus, blood would be the specimen of choice. Police, however, cannot draw blood. This makes saliva a better sample type for on-site testing: Concentrations of drugs in saliva typically correlate well with blood, and the sampling technique is not invasive. Conversely, abstinence programs need to cover longer time periods. This makes urine the better matrix due to the prolonged detectability of drugs and their metabolites.

The convenience and rapid results of on-site testing make police more efficient. But there are disadvantages, too. These include personnel training and hygiene-related aspects of collecting a sample, the possibility that the person suspected of being under the influence might manipulate the specimen, and the potential for false-negative or false-positive results.

False-negative results typically happen when substances or classes of drugs are not covered by on-site tests (for example, new psychoactive substances or pharmaceuticals). Meanwhile, cross reactions of different substances with the screening tests lead to false-positive results.

Psychophysical testing presents another option in recognizing drug

actions during traffic stops and other police interventions. These tests, originally used in Germany, enable police to evaluate shared attention through coordination of motion sequences, and tests of short-term memory, reaction capacity, and fine motor skills.

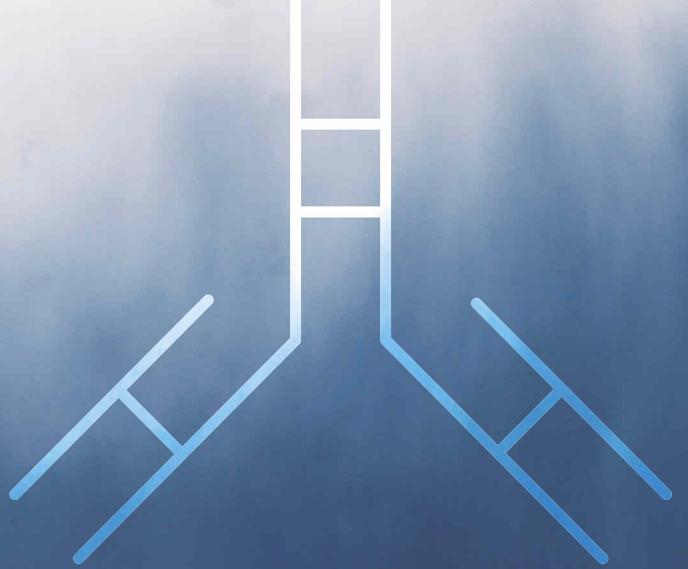
Examples include asking the individual to walk and turn around, stand on one leg, or perform with closed eyes finger-to-finger and finger-to-nose tests. Shared attention tests evaluate a person's ability to capture and process different stimuli at one time and react appropriately. However, police need to be trained thoroughly before using them, as typically these tests would have been conducted by physicians.

A NEW APPROACH: UNAFFECTED OBSERVATION

The method of unaffected observation exploits knowledge about drug actions. The central nervous system (CNS) is a highly complex structure that coordinates the perception, processing, and reaction of body functions. One part of the CNS—the sympathetic nervous system—is independent of a person's will. Consequently, symptoms mediated through this system offer more objective evidence. Activation of the sympathetic nerve system—such as in a dangerous situation that mobilizes the flight response—can result in dilated pupils, dry mouth, restlessness, higher risk readiness, and other observable symptoms.

That said, an otherwise harmless interaction with police can be a reason for excitement. Police must separate natural anxiety from the effects of stimulant drugs like amphetamine, cocaine, or others. Police officers can recognize these basic flight symptoms without performing drug tests or psychophysical tests, which again, are voluntary in Germany after the person has been cautioned. The goal of unaffected observation is to conduct a 3-minute conversation that calms natural stress and allows the police officer to recognize drug symptoms objectively.

When a police officer initiates unaffected observation, the goal is to recognize and assemble mosaic parts of the sympathetic CNS response without the subject's active



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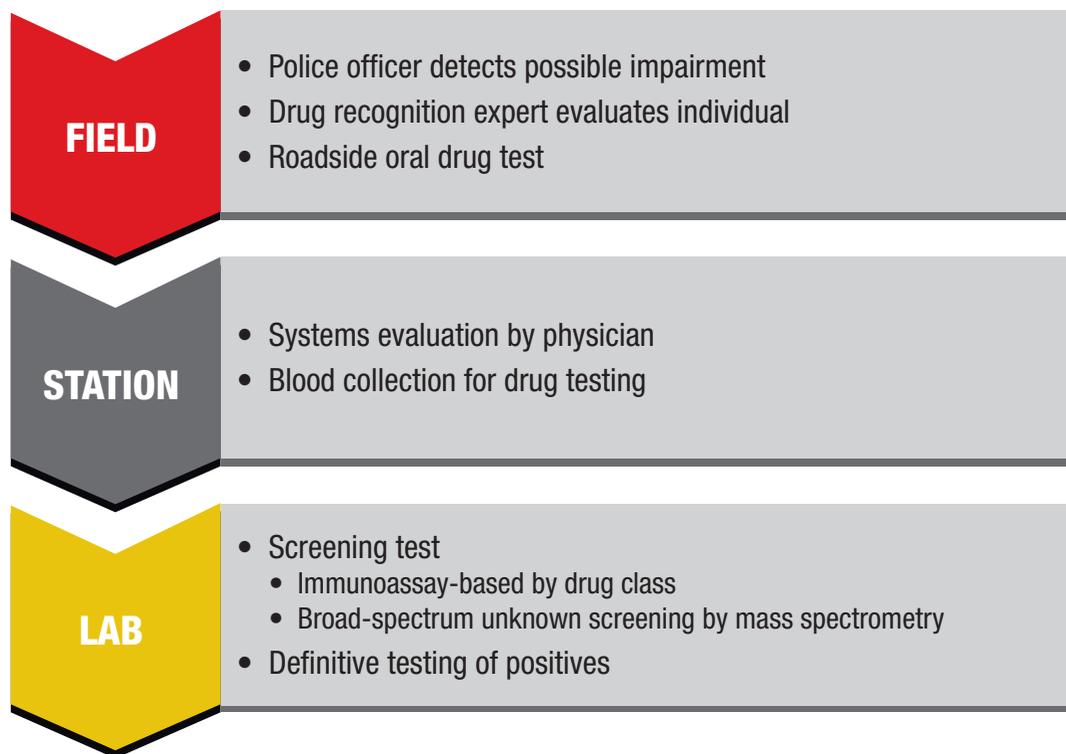
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F1 From Police Observation to Testing



cooperation (Figure 1). When this observation yields enough evidence of impairment, there is no need to perform a drug test. However, when partial evidence of drug effect exists, but the police officer is unsure, he or she can offer a drug test to substantiate drug use and order a blood draw.

The following three case reports show how neither unaffected observation nor drug tests alone can prevent the need for a blood draw, but act as different pieces of the mosaic of drug recognition.

CASE 1: A DISORIENTED WOMAN

A 49-year-old female was stopped by a drug recognition expert (DRE) in a police check. She seemed to be uncoordinated, confused, and disoriented. Her reactions were delayed and her speech was slurred. She staggered and her pupils were constricted. Because the woman appeared to be under the influence of drugs, the DRE offered a saliva drug test for cannabinoids, amphetamines, designer amphetamines, opiates, cocaine, benzodiazepines, and methadone; this test was negative for the included substances.

The DRE then called a physician to draw a blood sample. The physician arrived at the police station 2 hours later and recognized considerable influence of alcohol, drugs, or other medications. Signs included high-frequency nystagmus, disconnected thought, excessive talkativeness, and depressive mood. The blood sample was analyzed for psychoactive substances, starting with immunoassay-based prescreening for classic drugs (i.e., benzodiazepines, opiates, amphetamines, designer amphetamines, cannabinoids, cocaine, methadone, and buprenorphine). All of these were negative, so the specimen was then assessed with a general unknown screening assay using gas chromatography-mass spectrometry (GC-MS). Liquid-liquid extraction in native as well as acetylated extracts was required to screen for at least 10,000 different substances. Diphenhydramine, zopiclone, and trace ibuprofen were ultimately identified in the serum sample, which was then subjected to quantitative measurement in a separate liquid chromatography MS

(LC-MS/MS) test. Quantitative testing revealed concentrations of 0.4 mg/L diphenhydramine and 0.7 mg/L zopiclone. Compared with reference data, these concentrations fall at therapeutic and supra-therapeutic levels, respectively (1).

Diphenhydramine is an antihistamine used for short-term treatment of sleeping disorders. Side effects can be somnolence, drowsiness, concentration disorder extending to the following day after intake, visual disturbances, and paradoxical reactions including arousal and anxiety. Zopiclone is a short-acting sedative, typically used as a hypnotic agent. Expected side effects are similar to benzodiazepines (i.e., delayed reaction, somnolence, dizziness, confusion, affected muscle function, diminished ability to concentrate, visual disturbances, and/or amnesia). In combination with other CNS depressant substances, enhanced interactions are possible. Given these findings, the symptoms could be explained due to the action of the proven medications, which means that the driver committed a traffic offense.



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CASE 2: A MAN WITH AGGRESSIVE BEHAVIOR

A 19-year-old male stopped by the police had the following symptoms: heavy swaying and disturbed equilibrium, extremely delayed reactions, restlessness, babbling speech, drowsiness, confusion, depressed mood, obtrusive and aggressive behavior, dizziness when leaving the car, and requiring support when walking. His pupils were unresponsive to light, and the young man was somnolent and apathetic during the drive to the police station. A saliva drug test was positive for benzodiazepines. A physician came to the police station 2 hours later and recognized a considerable influence of alcohol, drugs, and/or medications with low-frequency nystagmus, unsafe straight walking with staggering, unsafe U-turn with staggering, unsafe standing on one leg, stupor, and disturbed orientation. A blood sample was collected and analyzed in a similar way as described in Case 1, using immunoassay for classic drugs, general unknown screening with GC-MS, and multi-target screening with LC-MS/MS. This testing detected tramadol and flualprazolam; quantitative assessment with LC-MS/MS revealed a concentration of 0.065 mg/L flualprazolam and trace tramadol (i.e., below the limit of quantitation).

Flualprazolam is a derivative of alprazolam, a benzodiazepine used to treat states of arousal, anxiety, and stress. However, flualprazolam is a new psychoactive substance, sold as a legal high via the Internet and not requiring a prescription. Similar to alprazolam, flualprazolam induces strong hypnotic, anxiolytic, and sedative actions. Studies have shown that fluorinated analogs of benzodiazepines are often more potent than unfluorinated analogs (2). Compared with the therapeutic concentration of alprazolam (1), the measured flualprazolam concentration in this case fell in an upper therapeutic level. Thus, the symptoms could be explained due to the action of the proven benzodiazepine detected in the blood sample, which means that the driver committed a traffic offense.

CASE 3: A MAN WITH SLURRED SPEECH

An 18-year-old male was stopped with noticeable problems at a police

check and was detained. His thinking routine was delayed, and his speech was slurred. He did not understand questions unless asked repetitively. He was restless, and his legs and fingers showed tremor. His mood was notably depressed, and his gait was unsafe and wobbly. Also, his eyelids fluttered, and he swayed while standing with closed eyes. His face was pale, he had dry mouth, and his pupils showed a delayed reaction to light.

A saliva drug test performed in the presence of the police revealed negative results for classic drugs. An hour later, a physician determined as minor the influence of alcohol, drugs, or medication. Nevertheless, he observed unsteady walking, unsafe finger-finger and finger-nose tests, delayed thinking, as well as depressed mood. A blood sample analyzed as described in cases 1 and 2 identified the synthetic cannabinoid JWH-210, and quantitative LC-MS/MS testing revealed a concentration of about 0.17 ng/mL.

As a synthetic cannabinoid, JWH-210 theoretically has the same effects as cannabis—particularly, tetrahydrocannabinol (THC) and other bioactive intermediates. These effects include disturbances in judgment and the ability to take criticism, altered mood and actuation, and thought disorder. Lack of interest and general slowdown are further effects to be expected from cannabinoids, as well as diminished attention and concentration. Also, perception and spatial orientation can be affected. Overdose can lead to tachycardia, hallucinations, and panic attacks. Due to the stronger binding of JWH-210 to the cannabinoid receptor compared with THC, JWH-210 has a higher potential for toxic effects. In this case, the symptoms were consistent with a lower-level exposure to JWH-210, which means that the young man committed an offense.

CONCLUSION

The foundation for the police to order blood samples from drivers in Saarland, Germany, rests on them recognizing sympathetic CNS symptoms that might be explained by the action of psychoactive substances. On-site drug testing is just one piece

of the puzzle to prove a drug action, but it is limited to certain drug classes. Thus, even negative pretests cannot prevent a blood draw when a police officer recognizes symptoms of drug action in a detained individual. Labs should use comprehensive screening and quantitative confirmation methods to cover as many psychoactive substances as possible and should enable a forensic toxicologist to examine each case. ■

Hans-Juergen Maurer is a police officer retiree at the State Institute for Preventive Action in Saarland, Germany.

Harald Frey is a police officer at the State Institute for Preventive Action in Saarland, Germany.

Nadine Schaefer, PhD, is deputy head of forensic toxicology at the Institute of Legal Medicine at Saarland University in Germany.

Andreas H. Ewald, PhD, is a forensic toxicologist (GTFCh) and head of forensic toxicology at the Institute of Legal Medicine at Saarland University in Germany.

+EMAIL: andreas.ewald@uks.eu

REFERENCES

- Schulz M, Iwersen-Bergmann S, Andresen H, et al. Therapeutic and toxic blood concentrations of nearly 1000 drugs and other xenobiotics. *Crit Care* 2012;26:16:R136.
- Hester JB Jr, Rudzik AD, Kamdar BV. 6-phenyl-4H-s-triazol[4,3-a][1,4]benzodiazepines which have central nervous system depressant activity. *J Med Chem* 1971;14:1078-8

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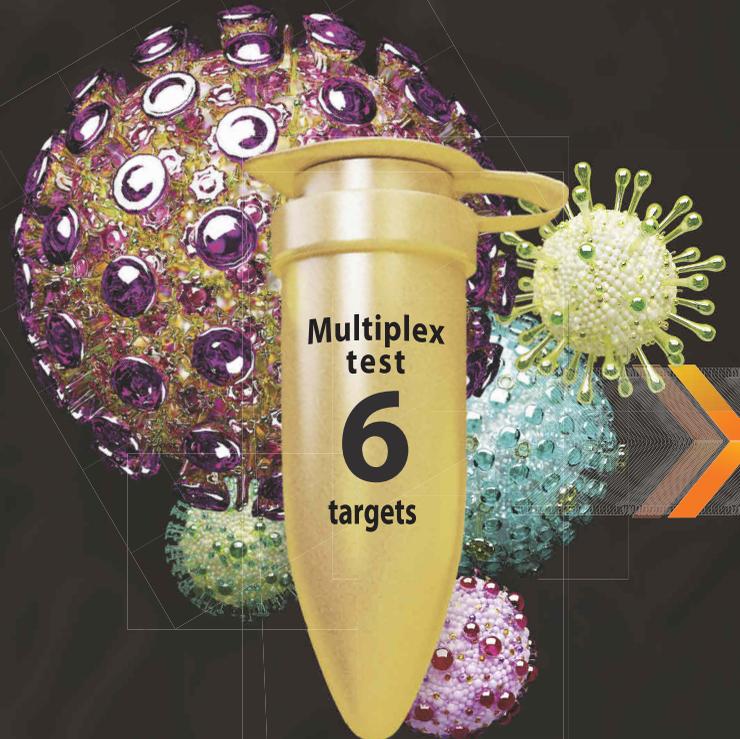
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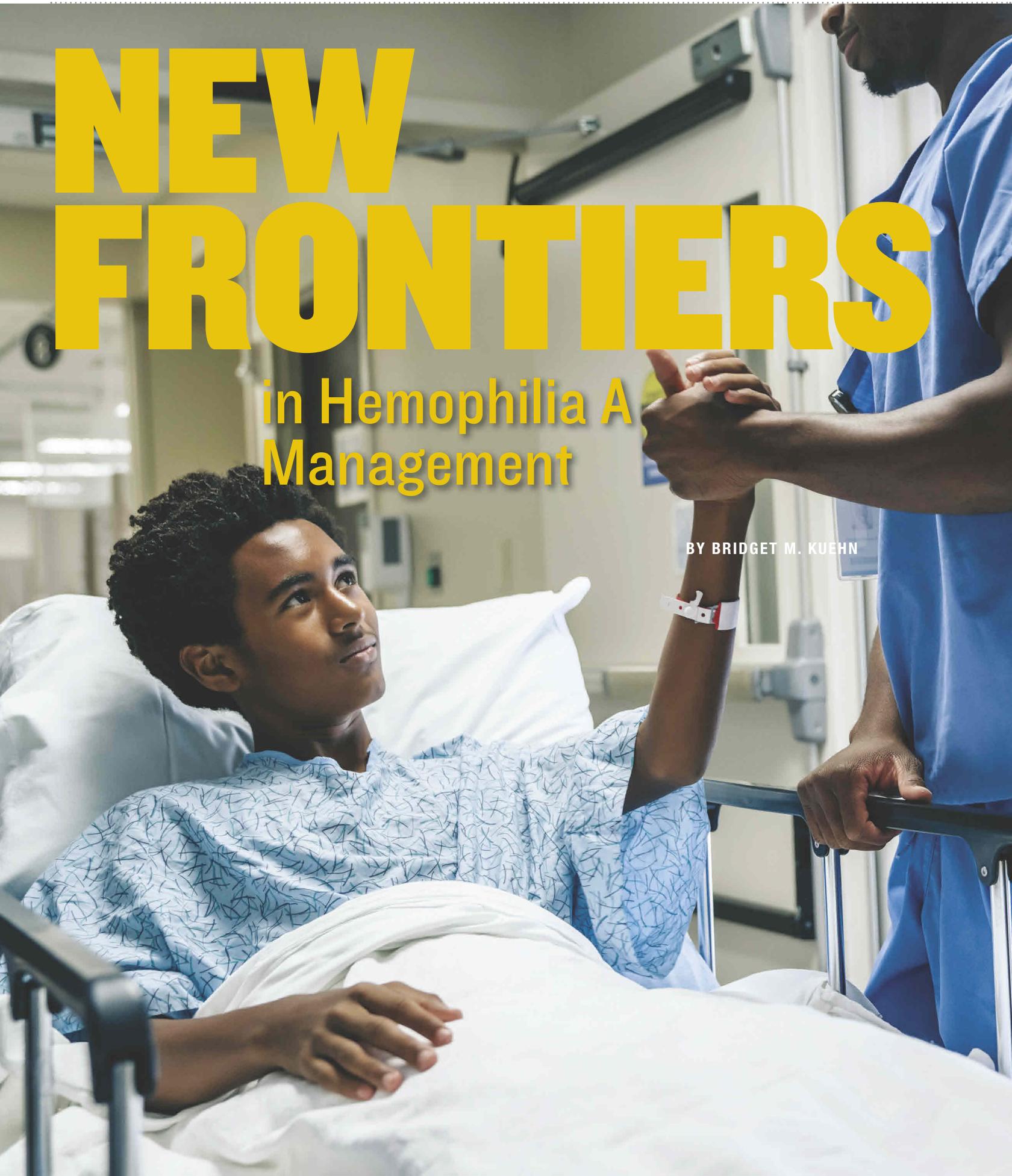
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Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay is intended for in vitro diagnostic use in Europe. Not available in all countries

NEW FRONTIERS

in Hemophilia A Management

BY BRIDGET M. KUEHN





A novel treatment requires updated testing approaches

The emergence of emicizumab (Hemlibra) has marked a sea change in both the clinical management and laboratory monitoring of many individuals with hemophilia A.

This drug—first introduced in 2017 as an alternative to bypass agents for patients who have developed inhibitors to and can no longer take standard Factor VIII (FVIII) replacement therapy—also is increasingly being used in patients without FVIII inhibitors. Several considerations are driving this uptick: emicizumab's ease of use and less frequent dosing, as well as data supporting its efficacy.

Instead of replacing the clotting agent FVIII, emicizumab mimics its activity using a bispecific monoclonal antibody, said Michael Spannagl, MD, PhD, professor in the department of hemostasis at Ludwig Maximilian University of Munich in Germany. This creates a steady level of the drug for weeks, eliminating the need for frequent dosing and monitoring associated with FVIII replacement, which has a short half-life resulting in between-dose peaks and troughs in blood levels.

"It's a completely new concept and completely different pharmacology," added Spannagl.

To support the clinical management of patients taking emicizumab, the National Hemophilia Foundation (NHF) and the United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) have each created a guideline. Both guidelines and the drug's manufacturer, Genentech, recommend against using traditional laboratory tests based on activated partial thromboplastin time (aPTT) because they will give aberrant results. Instead, all three recommend using specific chromogenic assays as well as other adjustments in testing protocols.

EXPANDING USE AND INDICATIONS

Impressive results from the HAVEN 2 trial published in late 2019 showed that emicizumab dramatically reduced bleeds in children with hemophilia A who have developed inhibitors to FVIII replacement therapy (*Blood* 2019;134:2127–38). These results further established the role of emicizumab, which was first approved by the Food and Drug Administration (FDA) in 2017 for adults and children with hemophilia A with FVIII inhibitors, said Steven Pipe, MD, pediatric medical director of the Hemophilia and Coagulation Disorders Program at the University of Michigan in Ann Arbor.

"It's really a slam dunk as far as patients with inhibitors go," added Pipe, who is also director of the university's special coagulation laboratory. "[Emicizumab] has changed the standard approach for patients with FVIII inhibitors. In my own practice there are no patients with inhibitors who are not on emicizumab for their regular prophylaxis."

Before emicizumab became available, Pipe explained, the only prophylaxis options for patients with inhibitors to FVIII were bypassing agents, such as recombinant factor VIIa or activated prothrombin complex concentrate. These products have inconsistent results for treating bleeds and don't prevent bleeds as effectively as FVIII, he said. Emicizumab, however, has "phenomenal results with patients getting their bleed rates essentially down to zero," Pipe said.

Spannagl agreed that emicizumab represents a great improvement for patients, noting that bypassing agents are very expensive and pose safety concerns.

Pipe expects that up to 90% of individuals with inhibitors eventually

will use emicizumab. A growing number of patients without inhibitors also have started taking the drug since FDA approved this indication in 2018. However, Pipe noted, not all are eager to switch from FVIII therapy, which has been the standard-of-care for decades.

“This patient population is generally conservative, particularly with respect to safety issues with new

for prophylaxis at this point, and that number is growing,” Pipe noted.

LESS MONITORING, DIFFERENT ASSAYS

As growing numbers of individuals with hemophilia A take emicizumab, all laboratorians should be aware that traditional, clot-based FVIII assays will overestimate factor FVIII activity. For example, one of these tests used

not rely on standard clot-based assays.

Routine prophylactic dosing of emicizumab doesn’t require monitoring because the drug’s levels remain stable, Spannagl said, but a different set of tests and reagents is needed perioperatively and in emergency situations.

“You have to develop a completely different laboratory management system for patients with hemophilia on emicizumab,” he said. For example, Vince Jenkins, PhD, laboratory head of specialized hemostasis diagnosis and research at University Hospital of Wales in Cardiff, said he and his colleagues set up an electronic health record notification, accessible to any clinician in Wales, that will alert laboratorians that a patient has hemophilia and is being treated with emicizumab, which will interfere with

“You have to develop a completely different laboratory management system for patients with hemophilia on emicizumab.”

– MICHAEL SPANNAGL, MD, PHD

products,” he explained. “So, if a patient is well-managed with regular prophylactic therapy with FVIII, they might not have embraced a transition to emicizumab.”

Still, Pipe has seen benefits in patients who have made the switch. For example, he noted that emicizumab’s subcutaneous administration weekly, every 2 weeks, or every 4 weeks, improves adherence. The drug’s very long half-life means patients who forget a dose can take it as soon as they remember without fear of a breakthrough bleed beforehand, he added.

“What I appreciate most about emicizumab prophylaxis is that it provides steady state hemostatic protection, as opposed to the peaks and troughs of traditional FVIII replacement therapy,” he said. Additionally, he said it might benefit individuals who have bleeding in their joints even just once or twice a year, which can lead to damage over time.

Despite these advantages, emicizumab does not completely normalize clotting, Pipe noted, and some patients will have breakthrough bleeds that require FVIII replacement, though often just a single dose. In addition, FVIII replacement lends itself better for customizing to patients’ needs.

“Overall, at least half of our non-inhibitor patients use emicizumab



on a patient taking emicizumab might yield FVIII concentrations in the 500% to 900% range above normal, said Neil Harris, MD, core laboratory director at the University of Florida in Gainesville.

This can be a serious problem if someone with hemophilia A who is taking emicizumab presents at emergency and a clinician concludes the patient doesn’t need FVIII based on such an aberrantly high reading on a standard clot-based assay, said Pipe, who chairs the NHF Medical and Scientific Advisory Council that drafted the guideline. To prevent this, he educates his patients and their parents to tell emergency physicians to

aPTT test results.

“The important thing is that the shortened aPTT in patients treated with emicizumab does not reflect the hemostatic state,” said Jenkins, who was also the lead author of the UKHCDO guideline.

Instead of one-stage clot-based aPTT assays, both NHF and UKHCDO recommend chromogenic assays using bovine reagents to measure FVIII activity. This might be necessary when a patient requires FVIII replacement because of a bleed or surgery. Harris explained that the chromogenic substrate assay test uses an enzymatic reaction rather than the one-stage clot-based aPTT assay.

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With bovine reagents, the reaction won't recognize the endogenous human clotting factors, the activity of which is driven by the presence of emicizumab, thus providing a more accurate reading of true FVIII activity.

However, these tests aren't widely available in the U.S., said Olajumoke Oladipo, MD, DABCC, director of coagulation and hematology and associate director of the automated testing laboratory at Penn State Health Milton S. Hershey Medical Center in Hershey, Pennsylvania.

A recent College of American Pathologists' (CAP) survey found that only 25 laboratories were participating in CAP's chromogenic FVIII

Jenkins suggested that laboratorians familiarize themselves with emicizumab's mechanism of action and collaborate closely with clinicians who prescribe the drug. "There needs to be good communication between the treating physician, the hemophilia physician, and the laboratory," he stressed.

The NHF guideline notes that in rare circumstances individuals develop anti-drug antibodies to emicizumab. In the HAVEN 2 trial, two of 88 children taking emicizumab developed antibodies, and the drug lost efficacy in one of them.

"The incidence [of anti-drug antibodies] appears to be less than 1%

preliminary warning of drug failure, the guideline notes. "Routine assays available in any hospital laboratory are able to provide that initial assessment," Pipe said.

The UKHCDO recommends against using aPTT as a surrogate to measure emicizumab efficacy, because even low levels of emicizumab might interfere with the result, Jenkins explained. "You might get a normal aPTT even with low levels of the drug," he explained. Instead, this guideline recommends a one-stage clotting assay with emicizumab-specific calibrators to measure emicizumab levels. The emicizumab-specific calibrators available in the U.K., however, are only available in the U.S. for research use, according to Narayanan Ramamurthy, director of research and development at r² Diagnostics, the company that makes them.

Oladipo agreed that the aPTT assay is sensitive enough to detect rare cases of loss of emicizumab efficacy. "Prolongation of the aPTT really is an indication that the drug is not effective, especially if you know the baseline for the patient," she said. "The aPTT is a test that is readily available, it's affordable, and it's in almost every lab."

As laboratories adapt to the challenge of monitoring patients taking emicizumab, they should also be aware that other non-FVIII replacement therapies are in the pipeline, Pipe said. For example, he noted drugs that target the coagulation inhibitor antithrombin, tissue factor pathway inhibitor, and activated protein C. He added, "this is going to continue to challenge laboratories that support patients taking these nontraditional hemophilia therapies." ■

Disclosures:

Pipe has received consulting fees from ApcinteX, Bayer, BioMarin, Catalyst Biosciences, CSL Behring, HEMA Biologics, Freeline, Novo Nordisk, Pfizer, Roche/Genentech, Sangamo Therapeutics, Sanofi, Takeda, Spark Therapeutics, and uniQure. Jenkins has received a consultancy fee from Roche/Chugai. Oladipo, Harris, and Spannagl report no disclosures.

Bridget M. Kuehn is a science writer in Chicago, Illinois.

+EMAIL: bridgetmkuehn@gmail.com

"Shortened aPTT in patients treated with emicizumab does not reflect the hemostatic state."

— VINCE JENKINS, PHD

activity proficiency testing, she noted, compared with more than 300 that perform traditional, one-stage clot-based FVIII assays.

Jenkins stressed that the former require a high level of technical capacity and are unlikely to be done outside of specialty centers. The chromogenic Bethesda assay for measuring inhibitors is also not widely available in the U.S., added Oladipo.

"It's absolutely critical that people are aware that they need to send inhibitor patient assays to a lab that is capable of evaluating patients taking emicizumab," Pipe said. In the U.S., both hemophilia treatment centers and the Centers for Disease Control and Prevention have this capability.

Oladipo said that at her institution, emergencies or other circumstances calling for STAT chromogenic FVIII activity levels are uncommon. "We do send our samples out to reference labs when needed, which is very rare," she said. "There's really no urgent push to have all these tests in-house because the drugs have a long half-life of about 4 weeks and maintain a steady level in the system for a long time."

of patients who are treated, but it is possible that they would have neutralizing potential and then wipe out the protective effect of emicizumab," said Pipe.

Spannagl noted that anti-drug antibodies have been identified as a concern in the fields of rheumatology and oncology, which use dozens of therapeutic antibodies. However, he believes there is less risk of anti-drug antibodies with fully humanized antibodies like those used in emicizumab.

"We are hopeful that they will not develop in many patients, but we have to be aware that one patient or another might develop antibodies against emicizumab," he said.

If loss of efficacy is suspected because of breakthrough bleeding, a chromogenic assay with human reagents or a widely available conventional aPTT assay could be used, the NHF guideline notes. The aPTT test should be in the normal range for a patient taking emicizumab and clot-based assays will be well above normal, so a prolonged aPTT assay result or low FVIII concentration on a clot-based test might provide a

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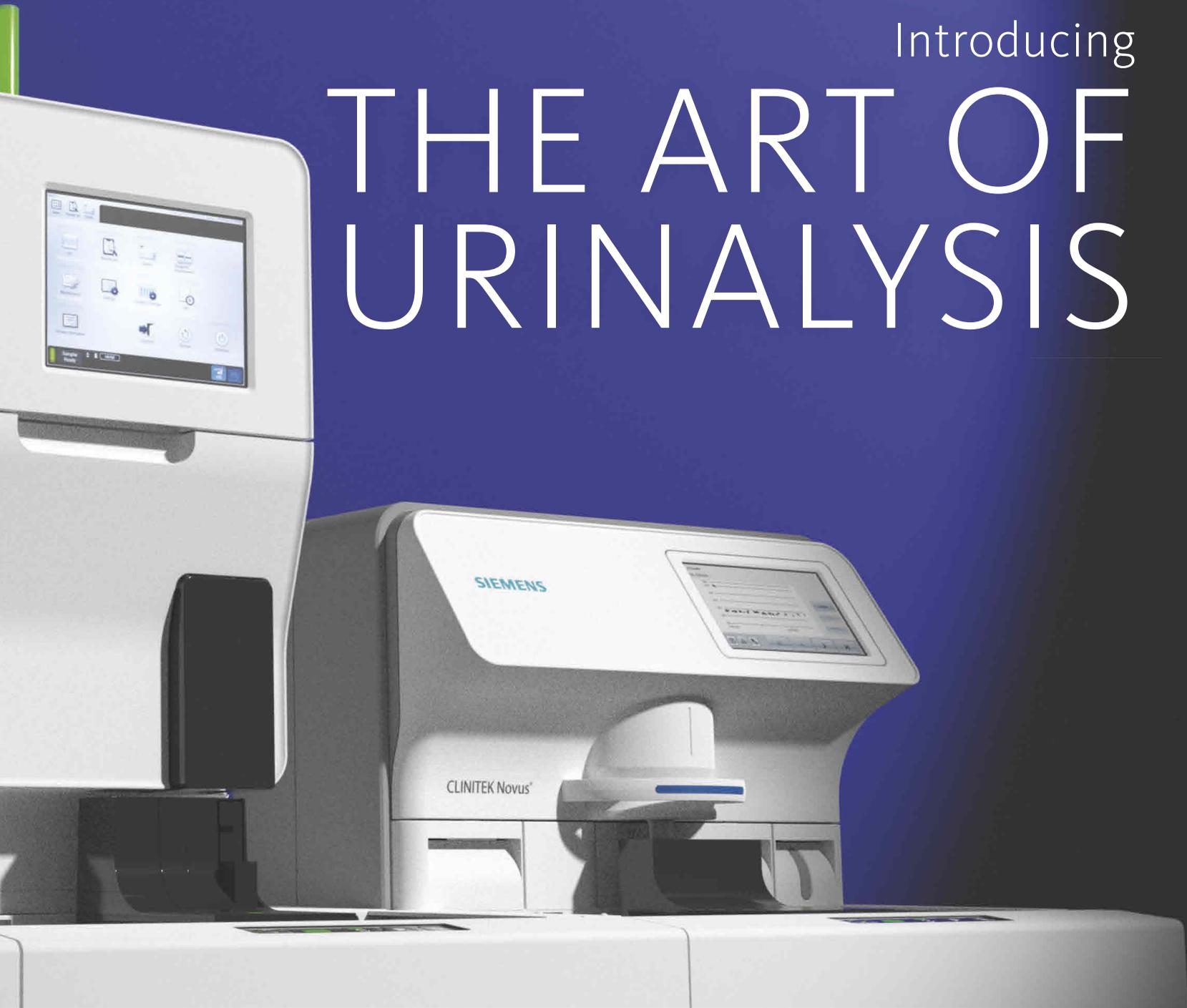
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With the 2020 AACC Annual Scientific Meeting & Clinical Lab Expo, attendees will find that the exhibiting companies are harnessing their full creativity to offer novel and engaging experiences on this all-digital platform. Exhibitors will not only be on hand to showcase products and services but also to offer flexible, one-on-one scheduled meeting appointments, live Q&A chat with experts, exclusive product resources, valuable custom downloads, and more.

The virtual meeting platform also boasts unique matchmaking technology, powered by self-learning, artificial intelligence software that streamlines networking and business discussions. Each attendee is prompted to set up a profile in the meeting platform, and a smart algorithm then recommends exhibitors and other attendees to connect with based on the attendee's self-identified professional goals and interests.

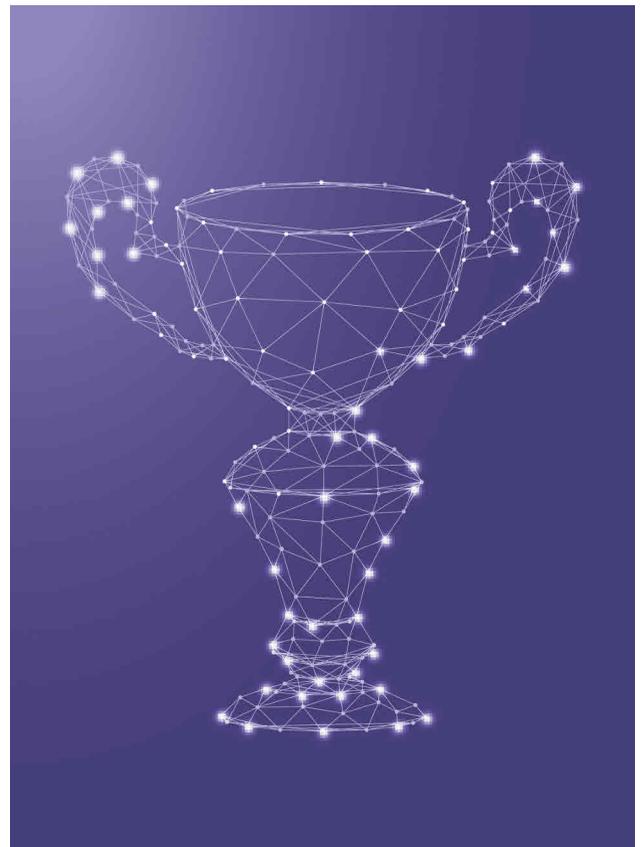
Meanwhile AACC is making sure that the number and scale of exhibits doesn't overwhelm. The virtual exhibit hall features a robust online directory that will allow attendees to search for booths by category, making it easier to pinpoint exactly those exhibitors they want to visit.

Attendees will also rack up points based on their level of engagement with exhibitors, toward a chance at winning daily Amazon gift cards. Conference and Expo only attendees will automatically earn points for dropping their virtual business cards, attending industry workshops, requesting a chat in a booth, and watching videos and other activities in exhibitors' booths.

Preview the exhibitors who will be online in the pages that follow, or use advanced search options before the event starts at meeting.aacc.org/clinical-lab-expo.

Virtual 2020 AACC Clinical Lab Expo Hours

Exhibits open at 8:30 a.m. U.S. Central Time on Sunday, December 13, for exhibit viewing and remain accessible 24/7 through January 18, 2021. Exhibitors will have live booth staff available for appointments with attendees and to answer questions from 10 a.m.–2 p.m. Central Time each day, Monday, December 14, through Thursday, December 17. Exhibitors can also set up special appointments or chat online with attendees outside of these hours.



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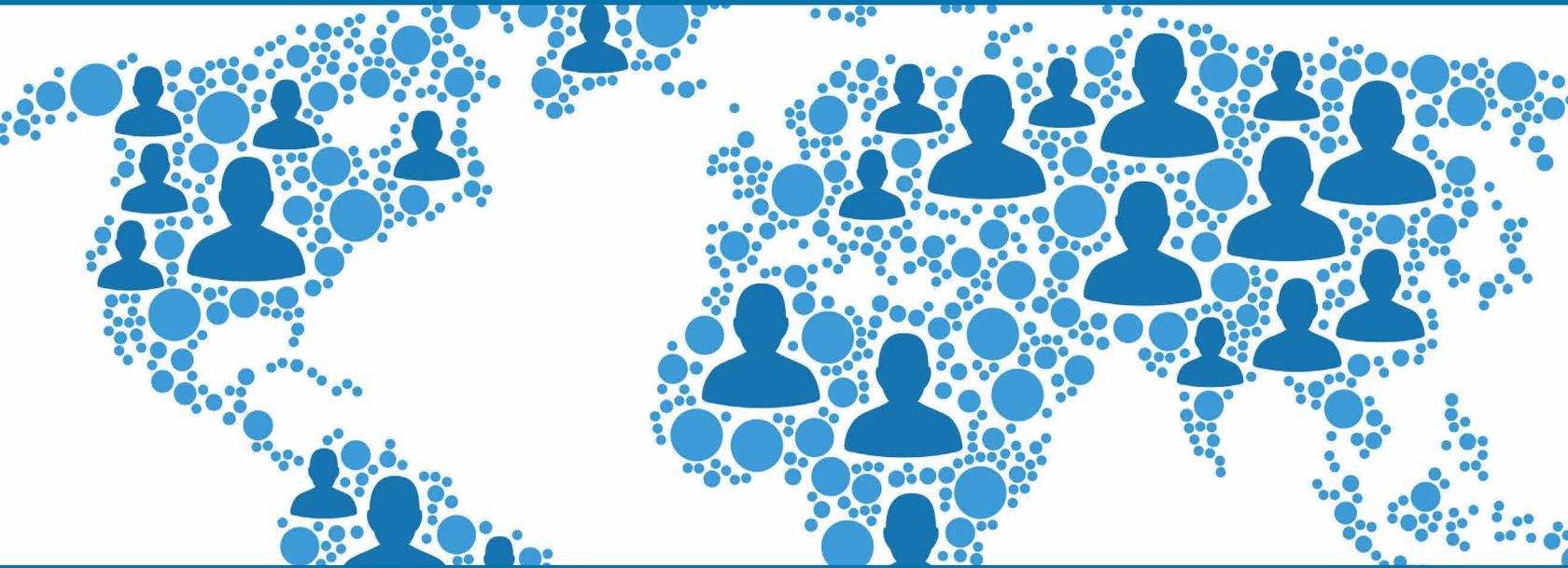
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Regulatory Roundup

FDA Grants EUA for UCLA Health's Sequencing-Based SARS-CoV-2 Test

Scientists at UCLA Health have received Food and Drug Administration emergency use authorization to begin using a new method for SARS-CoV-2 detection based on the sequencing technology SwabSeq. This method is capable of testing thousands of SARS-CoV-2 samples at the same time, providing individual results in 12 to 24 hours. This could enable the expansion of SARS-CoV-2 testing particularly for asymptomatic patients, not only because this technology is highly scalable, but also because it won't be limited by the same supply chain bottlenecks that have constrained polymerase chain reaction testing. SwabSeq works by adding a unique molecular bar code to each sample in the first step of its processing. The samples are then combined in a sequencer, and the bar codes enable labs to identify which specific sample(s) is positive for the

virus. Labs can use this method with any sample type, including nasopharyngeal and oropharyngeal swabs and saliva.



ABBOTT, BECKMAN COULTER EARN FDA EUAS FOR SARS-COV-2 IGM ANTIBODY TESTS

The Food and Drug Administration (FDA) has issued emergency use authorizations to both Abbott and Beckman Coulter for their new SARS-CoV-2 immunoglobulin M (IgM) antibody tests. Both companies already have FDA-authorized tests on the market for SARS-CoV-2 IgG

antibodies, which are the antibodies that typically persist the longest in the body after infection. In comparison, IgM antibodies are most useful for identifying a recent infection, as these antibodies become undetectable weeks to months following infection. Studies have demonstrated that Abbott's test, the AdviseDx SARS-CoV-2 IgM, has 99.56% specificity and 95% sensitivity for patients tested 15 days after symptom onset. The test is

available for use on the company's Architect and Alinity platforms. Beckman Coulter's assay, on the other hand, specifically detects IgM antibodies to the receptor binding domain of the SARS-CoV-2 spike protein. The test has a specificity of 99.9% and a sensitivity of 98.3%.

FDA AUTHORIZES TWO NEW SALIVA COLLECTION DEVICES FOR SARS-COV-2 TESTING

Spectrum Solutions and DNA Genotek, a subsidiary of OraSure Technologies, have both received Food and Drug Administration emergency use authorizations (EUA) for their respective saliva collection devices for SARS-CoV-2 testing: the SDNA-100 and the Omnigene Oral (OM-505, OME-505). Both devices are designed for the self-collection and transport of samples for polymerase chain reaction testing, and both stabilize and neutralize viral RNA transcripts. The two collection kits can be used either in a healthcare setting or unsupervised

at home when used as part of an approved or validated at-home test kit.

Spectrum's SDNA-100 first received an EUA in March that authorized Rutgers Clinical Genomics Laboratory to use this kit for saliva SARS-CoV-2 testing. With this new EUA, other laboratories will now also be able to use this kit with a broad range of platforms and assays, including those from PerkinElmer, Thermo Fisher, Roche, and Qiagen.

FOUNDATION ONE CDX GETS FDA APPROVAL FOR USE AS A CO-DIAGNOSTIC FOR LAROTRECTINIB

The Food and Drug Administration (FDA) has approved Foundation Medicine's next-generation sequencing (NGS)-based FoundationOne CDx test as a companion diagnostic for patients with solid tumors who are eligible for treatment with larotrectinib



ADVERTORIAL

TECH TALK

The role of **Syndromic Testing** in the era of COVID-19

Dr. Christine C. Ginocchio, PhD MT (ASCP)
VP, Global Medical Affairs, bioMérieux/BioFire

COVID-19 has changed our world. Millions of cases globally have caused hundreds of thousands of deaths. Researchers, health officials, and diagnostic companies have come together to better understand the SARS-CoV-2 virus, protect communities, and produce robust diagnostic testing. Out of the many SARS-CoV-2 diagnostic tests, syndromic testing is of particular significance as we combat the pandemic. The BioFire® Respiratory 2.1 (RP2.1) Panel (EUA)* uses syndromic testing to simultaneously target and detect multiple pathogens that cause overlapping signs and symptoms – detecting SARS-CoV-2 as well as 21 other common respiratory pathogens in about 45 minutes. Syndromic respiratory testing has been key in allowing healthcare professionals to make informed decisions about personal protective equipment, isolation precautions and quarantine plans, as well as deciding on admissions, infection control, treatment, or identifying co-infections. Outside of the COVID-19 pandemic, the benefits of syndromic respiratory testing abound, oftentimes leading to improved antimicrobial stewardship, reductions in hospital length of stay, and

more appropriate, cost effective use of infection control measures and ancillary services¹⁻⁴. As we move into subsequent phases of the pandemic, being able to detect whether an individual has COVID-19, or something else, will be key in maintaining the progress that we have made during this pandemic. While the future course of the COVID-19 pandemic and its full impact are uncertain, we can be certain that syndromic respiratory testing will continue to provide rapid, comprehensive results that will arm healthcare workers with the information they need to make smart, effective decisions to continue the fight against respiratory illness.

*This test has not been FDA cleared or approved; This test has been authorized by FDA under an EUA for use by authorized laboratories; This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

1. Brendish NJ, et al. *Lancet Respir Med*. 2017;5(5):401-411.
2. Brendish NJ, et al. *Eur Respir J*. 2018;52(2):1800555. Published 2018 Aug 9.
3. Echavarría M, et al. *J Clin Virol*. 2018;108:90-95.
4. Shengchen D, et al. *Clin Microbiol Infect*. 2019;25(11):1415-1421.

(Vitrakvi). Larotrectinib received FDA approval in 2018 for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment. To identify patients who might benefit from larotrectinib, the test detects fusions in the *NTRK1*, *NTRK2*, and *NTRK3* genes in DNA isolated from tumor tissue specimens. FDA based this approval on a study that used the FoundationOne CDx assay to retrospectively test available tumor tissue samples from patients enrolled in the clinical trials that supported the approval of larotrectinib.

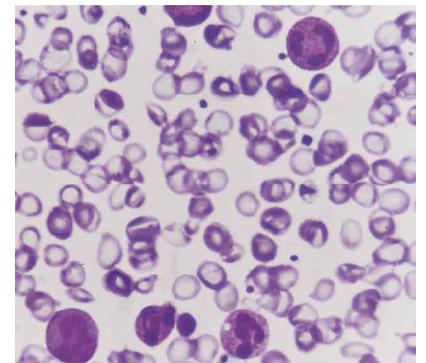
FDA OKS CLONOSEQ ASSAY FOR CHRONIC LYMPHOCYTIC LEUKEMIA PATIENTS

The Food and Drug Administration (FDA) has cleared Adaptive Biotechnologies' clonoSEQ assay to detect and monitor minimal residual disease (MRD) in blood or bone marrow from patients with chronic lymphocytic leukemia (CLL). This clearance expands on the existing FDA-authorized uses of clonoSEQ, which include the detection and monitoring of MRD in bone marrow from multiple myeloma and B-cell acute lymphoblastic leukemia patients.

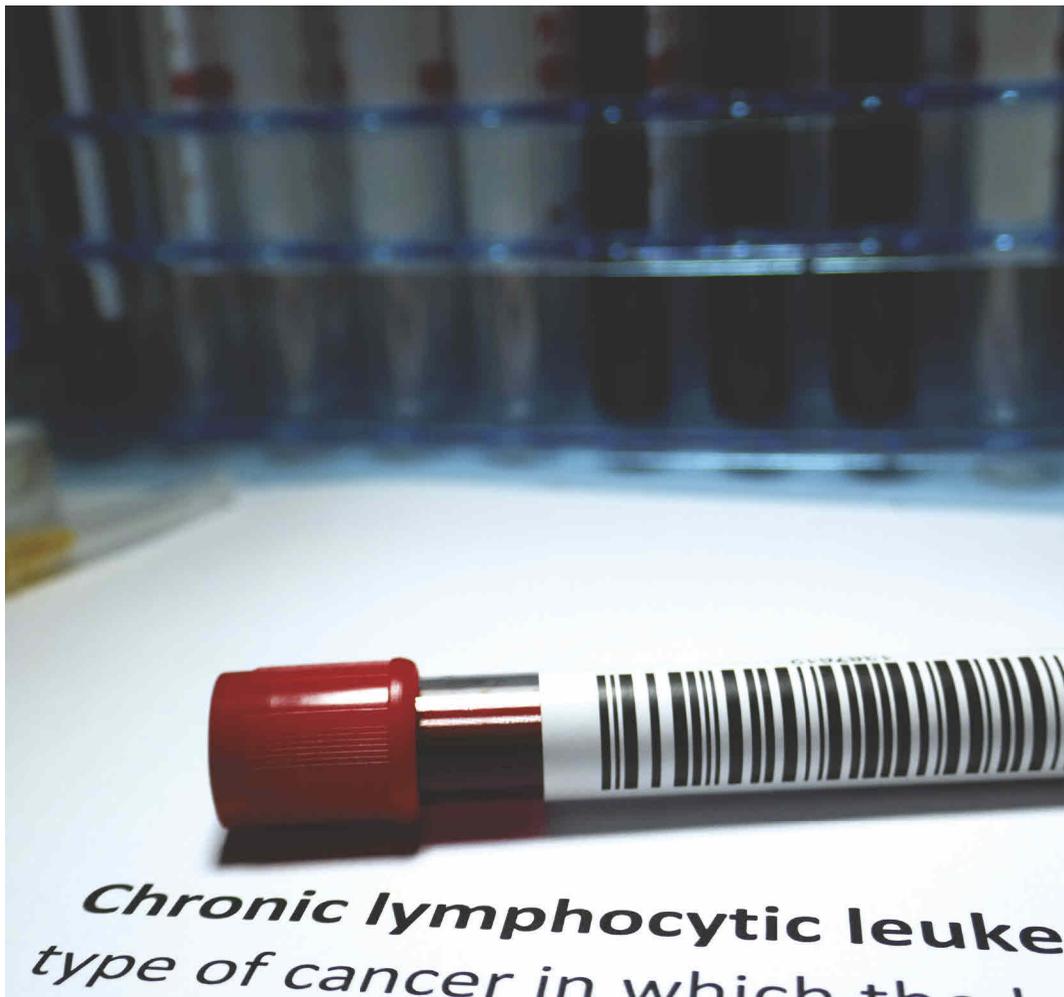
FDA based its clearance of clonoSEQ in CLL on clinical validation data from two clinical trials. The first trial enrolled 337 patients and found that those with undetectable MRD

in blood by clonoSEQ at 3 months post-treatment had a nearly seven-fold reduced risk of disease progression compared with patients who did not reach undetectable MRD. At 30 months post-treatment, the probability of disease for patients with undetectable MRD dropped to 5%, compared to a 36% probability for patients with detectable disease. The second clinical trial supported these findings.

FDA CLEARS SCOPIO LABS' AI-POWERED FULL FIELD PERIPHERAL BLOOD SMEAR APPLICATION



Scopio Labs, a provider of full field morphology, has received Food and Drug Administration clearance for Full Field PBS, the company's X100 with full field peripheral blood smear (PBS) application. This application also received the CE mark in Europe earlier this year. Scopio designed this instrument to improve upon current digital hematology solutions, most of which do not showcase all required regions of interest in a PBS slide and only capture snapshots of cells. Using advanced computational photography imaging and tailored artificial intelligence tools, Full Field PBS gives clinical laboratories the ability to capture digital scans with full field view of the monolayer and feathered edge at 100X oil immersion resolution level. Additionally, the Full Field PBS uses adaptive monolayer identification in support of long and short smears, and automates the analysis process by pre-classifying 200 white blood cells, providing platelet pre-estimate, and enabling red blood cell morphology evaluation.



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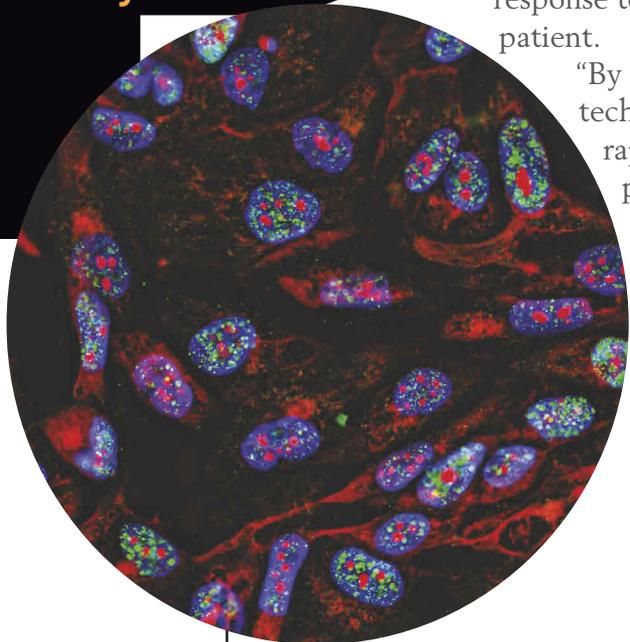
Companies Advance Therapeutic Response Monitoring for Cancer

Molecular diagnostics company Oncocyte and Chronix Biomedical have entered an agreement under which Oncocyte will license Chronix's patented CNI Monitor technology for the TheraSure-CNI Monitor clinical assay. The partnership aims to advance Oncocyte's work in cancer care by adding Chronix's blood-based test to Oncocyte's existing portfolio of tests.

The TheraSure-CNI Monitor assay will utilize copy number instability (CNI) to analyze a cancer patient's blood sample for DNA sequences associated with cancer. The CNI score will allow healthcare professionals to assess patients' response to therapy and then determine the best treatment options for each patient.

"By identifying early resistance of a tumor to immune therapy drugs, this technology could provide useful information that may allow physicians to rapidly adjust patients' therapies to optimize the immune system's power to fight cancer. The rapid expansion of immune therapy options presents many choices for physicians. Thus, quickly assessing the effectiveness of therapies can be a game-changer for patients," said Ron Andrews, president and CEO of Oncocyte.

Through the partnership, Oncocyte will join the market of therapeutic response monitoring in cancer care and use Chronix's network in Germany to commercialize its current chemotherapy treatment selection test, DetermaRX.



ABINGDON SUPPLIES SARS-COV-2 RAPID ANTIBODY TEST TO U.K. GOVERNMENT

The United Kingdom government has placed an order for 1 million SARS-CoV-2 rapid antibody tests as part of its newly formed contract with Abingdon Health.

Abingdon Health's recently developed AbC-19 Rapid test enables patients to test themselves with results returned in just 20 minutes. The testing kit provides patients with supplies to collect a blood sample via fingerprick and apply it to a test card to show positive or negative results without leaving home. The test has already received the CE mark in the U.K. and European Union and is being mass-produced.

"Our test will help give a picture of how many people in the U.K. have

antibodies. This will be a crucial part of the understanding of immunity to COVID-19," said Chris Yates, CEO of Abingdon Health. "Mass testing will also help understand what the longevity of immunity is and, in time, help assess the efficiency of any vaccine on the market. In this respect, high-quality mass antibody testing has never been more important, and it will be critical for future public health responses."

The AbC-19 Rapid test was developed from Abingdon Health's U.K.-Rapid Test Consortium, supported by the U.K. government as a way for scientists and medical manufacturers to deliver mass testing kits as quickly as possible.

LABCORP AND GENFIT TEAM FOR NASH DIAGNOSIS

LabCorp and the biopharmaceutical company Genfit have signed a 5-year contract to integrate

Genfit's NIS4 technology with a blood-based molecular diagnostic test developed by LabCorp. The two companies aim to better identify patients at risk for nonalcoholic steatohepatitis (NASH).

NASH is defined as nonalcoholic fatty liver disease (NAFLD) activity score (NAS) ≥ 4 and fibrosis stage ≥ 2 . The NIS4 technology is specifically designed to diagnose patients at risk for NASH through a multi-biomarker-based algorithm. Clinical laboratories will be able to detect the condition by a single test score generated from four biomarkers, miR-34a-5p, alpha-2-macroglobulin, YKL-40, and HbA1c.

Research shows that NASH remains one of the fastest growing medical conditions in the U.S. Currently, the standard diagnosis method for NASH is a highly invasive liver biopsy procedure.

The partners have begun using the NIS4 technology for clinical

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studies and plan to commercialize the test across the U.S. and Canada.

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STOOL TEST PROVIDES ACCURATE GUT MICROBIOME ANALYSIS

CosmosID and Microbiome Labs have collaborated to further develop BiomeFx, a stool test that evaluates the gut microbiome.

Through sequencing technology, BiomeFx analyzes pathogens and species for a closer look into gut microbiota composition, which the companies say could help physicians ensure their patients have proper gut microbiome functionality. The firms also expect the test will speed up detection of disorders involving the gut microbiome.

“We see a growing demand for gut microbiome tests that are sufficiently accurate and functionally informative to enable healthcare professionals to deliver on the promise of personalized healthcare and nutrition. Conventional stool tests rely on methods that are either limited to only detecting a small part of the gut microbiome or that fail to identify gut microbes correctly and with species and subspecies level resolution,” said Manoj Dadlani, CEO of CosmosID.

BiomeFx was first launched in March and has been widely distributed to healthcare professionals across the U.S.

DARPA AWARDS \$1.1 MILLION FOR COVID-19 SEVERITY TEST

The Defense Advanced Research Projects Agency (DARPA) has awarded molecular diagnostics company Inflammatrix with \$1.1 million to further develop its host-response diagnostics, which predict severity of COVID-19 in patients.

Through a machine learning approach and multiple mRNA biomarkers, Inflammatrix’s CoVerity COVID-19 Severity test quickly reads a patient’s immune system to determine the risk of respiratory failure. According to the company, this testing approach has proven highly accurate in comparison to other clinical biomarkers.

Inflammatrix—winner of the 2019 AACC Disruptive Technology

Award—expects the test to help healthcare workers make better decisions about which patients should be hospitalized.

“While major progress has been made in developing rapid platforms to diagnose SARS-CoV-2 infection, predicting severity in COVID-19 patients remains an unmet medical need,” said Evangelos J. Giamarellos-Bourboulis, MD, professor of Internal Medicine and Infectious Diseases at Attikon University General Hospital, chairman of the European Sepsis Alliance, and president of the European Shock Society. “Existing tools have shown limited accuracy in enabling us to confidently identify high-risk patients early who need close monitoring or discharge non-severe patients to recover at home.”

QUANTERIX AND ABBOTT ENTER \$10 MILLION LICENSE AGREEMENT

Quanterix, a company centered around digitizing biomarker analysis, has entered a license agreement with Abbott Laboratories. Under the agreement, Abbott will gain access to Quanterix’s bead-based technology patents for use in in vitro diagnostics applications.

Though the companies have not disclosed many details regarding what the agreement would center around, Quanterix’s technology has been used previously in therapeutic areas such as oncology, neurology, cardiology, inflammatory, and infectious diseases. “The agreement is an important step forward for Quanterix,” said Doug Schenkel, research analyst at Cowen. “The partnership with Abbott validates Quanterix’s technology potential in the diagnostics market and should continue to help build investor confidence that the opportunity is real.”

The agreement provides Quanterix with an initial \$10 million license fee, milestone fees subject to Abbott achieving development, regulatory, and launch milestones, and royalties on the sales of licensed products.

Experts believe the partnership will also provide an opportunity to explore COVID-19 applications of Quanterix’s technology.



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Ask The Expert

One Lab's Experience With Pooled SARS-CoV-2 Testing



EXPERT

Nanette West, MBA, MT (ASCP)

Why did your lab start pooling SARS-CoV-2 specimens?

A: Like all other laboratories, when SARS-CoV-2 first reached the U.S. we found ourselves needing to ramp up testing faster than the supply chain for reagent and ancillary supplies could support. Every week was a struggle to ensure that we did not run out of reagent, and we were forced to

make difficult decisions about which patient samples we would run and which ones we would save until our next reagent shipment. This was what led us to consider pooled testing.

When we initially presented the pooling concept to our medical directors, they rejected the idea. As supply shortages continued, though, everyone realized that we would either have to restrict SARS-CoV-2 testing or move forward with pooling.

How does your pooling process work?

First, we create a mock accession number and label the pooled test tube, then we manually pipette four 400 µL patient samples into the accession tube and vortex to ensure adequate mixing. We use a 10 x 5 rack so that we can rack the individual specimens directly behind the mock/pooled accession tube, and specimens remain in the rack until we have verified all results. After we pool the specimens, we then load the pooled accession specimens onto the polymerase chain reaction (PCR) platform, where they are treated as individual specimens.

What challenges have you experienced with pooled testing?

Implementing and sustaining pooled testing has presented our staff with numerous challenges. For starters, we are a mid-volume lab with automation and very few processes offline from our laboratory information system (LIS) or middleware. To implement pooling, we therefore had to create a process that gives each pool specimen a unique barcode identifier so that the PCR analyzer can associate results with individual patients within the pool. This enables us to break apart the pool and rerun individual samples in the event of a positive pool, or to result negative pools as individual patients.

Pooling has increased our handling of SARS-CoV-2 specimens, which in turn has increased the staff's exposure risk. Instead of processing specimens once and loading them onto the analyzer, we are now processing and handling specimens multiple times. Storage has also become an issue as all

pools are stored along with individual specimens until the test results are cleared.

Resulting pools is an offline process and requires the laboratory to manually enter all results. This has added to our turnaround time as it requires intervention instead of our LIS releasing results once each run is validated.

Unanticipated delays occur because we have to hold off on testing until we have the 94 specimens needed to run a full plate. This is particularly problematic on weekends, as our collection station is open on Saturdays but closed on Sundays.

Additionally, as the positivity rate continues to increase in our community, pooling is becoming less efficient, and it's becoming more difficult for laboratory staff to ensure that known positive samples aren't included in pools.

What is the clinical impact of pooling?

Our validation of pooled testing did not show a significant loss of sensitivity or specificity. Pooled cycle counts were also within acceptable limits compared to individual cycle counts, which indicates that it is unlikely that pooling is generating false negatives.

Most of the clinical impact we've seen is due to the extended turnaround times caused by having to retest individual samples from positive pools. With that said, we've saved more than 40% of our reagents by pooling, and it continues to be worth the extra effort to test as many patients as we can.

Nanette West, MBA, MT (ASCP), is the system director of laboratory operations at TMC in Kansas City, Missouri.

+EMAIL: nan.west@tmcmcd.org

The author wishes to acknowledge and thank her Truman Medical Center (TMC) colleagues Kamani Lankachandra, MD, medical director of laboratory operations; Jeffrey Kelleher, MBA, MLT (ASCP), core laboratory supervisor; and Debra Engblom, MT (ASCP), quality assurance manager, for their support with developing responses to these questions.



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Clinical
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News

An AACC Publication | Special Supplement

EARLIER DETECTION
OF KIDNEY DISEASE

90%

Patients identified as
high risk for CKD referred
to nephrologist

PAGE 3



A NEW WAVE OF Global Efforts to Improve Patient Outcomes



A NEW WAVE OF Global Efforts to Improve Patient Outcomes

BY KIMBERLY SCOTT

Clinical laboratory professionals are collaborating inside and outside their institutions like never before to make a difference in improving patient outcomes worldwide, from significantly shortening the time a chest pain patient spends in the emergency department (ED) during the COVID-19 pandemic, to identifying kidney disease in indigenous communities early enough to slow the progression of disease, to reducing catastrophic adverse events in patients with hemorrhagic shock.

AACC, Abbott, and other leading healthcare organizations this year continued special recognition for a number of interdisciplinary teams through the UNIVANTS Healthcare of Excellence program. Teams are judged on initiatives that achieve measurable, innovative impact within healthcare systems. Approximately 180 applications were initiated and three top-performing teams were selected as the top global winners in 2020 based on key performance indicators, unity of the team, and process attributes of the initiative. Several other finalist teams were recognized with distinction or achievement, with the highest award scores within a region designated a classification of “best in area.” Below *CLN* highlights the five global and two best-in-region winners for 2020. AACC will keep the spotlight on these unique award-winning achievements with special supplements on other exceptional teams in 2021.

Reducing Risk in the COVID-19 Era Through a New Chest Pain Pathway

Patients with chest pain and other symptoms of a possible heart attack have historically represented the most common cause of hospital admissions in New Zealand – about 10% -15%. In preparing for the impact of the COVID-19 pandemic early in 2020, clinicians and laboratorians at Christchurch Hospital in Canterbury, part of Canterbury District Health Board, aimed to minimize the number of tests performed and consequently the amount of time spent in the ED. A secondary goal was to reduce the number of patients admitted to the hospital.

To tackle the challenge, a multidisciplinary project team formed that incorporated the ED, cardiology, the hospital laboratory, a separate community laboratory, primary care, community nursing, and health management. The team analyzed laboratory cardiac troponin results, clinical risk, and final patient outcomes to determine if it was possible to design and subsequently implement a new pathway for patient care that could reduce the number of patients requiring two cardiac troponin tests while in the ED. They projected that reducing the number of patients needing two troponin tests could also cut the amount of time spent in the ED and, importantly, minimize the potential exposure to SARS-CoV-2, the virus that causes COVID-19.

The team, co-led by Martin Than, MD, an emergency medicine specialist, developed and implemented a new chest pain pathway through which approximately 70% of low risk chest pain patients in the ED received one troponin test while at the hospital and then were discharged home, usually with orders for a follow-up troponin test done in the community the next day. The team also created a patient streaming process so that patients determined to be at high clinical risk were assessed directly by the cardiology team without an extensive emergency medicine physician evaluation, thus reducing duplication of care.

“In the past, a patient with chest pain would be in the ED for up to six hours,” explained Than. “Waiting for and then actioning the results of the second cardiac troponin test really takes time, and they often are moved somewhere else in the hospital, which potentially increases their risk of exposure to the [SARS-CoV-2] virus. If they are admitted overnight, they can have physical contact with up to 30 staff members, but with one troponin test, we can get that number down to three people.”

The clinical laboratory played a crucial role in developing and implementing the chest pain protocol along with other departments in the hospital, explained Christopher Florkowski, MD, a consultant in chemical pathology.



Detecting Kidney Disease Earlier

SEVEN OAKS GENERAL HOSPITAL, WINNIPEG, CANADA

30 MINS

Time at clinic for screening
test, education, and treatment
plan per patient

22%

Number of First Nations
children with at least one
CKD risk factor

“The relationships that we’ve built over the years between the clinical laboratory, physicians in the ED, cardiology, and other services have been absolutely pivotal to this initiative,” Florkowski said. “Chest pain is a very common admission, and with the advent of troponin tests, we needed to best define how to interpret test results in full clinical context and in relation to clinical outcomes. There was an increased incentive to develop accelerated diagnostic pathways to facilitate safe early discharge from the ED. We started working on accelerated pathways more than 10 years ago, and with the passage of time, we have been able to define and constantly refine better pre-test probability scores for the ED environment. With newer and better troponin assays, we have also been able to identify more chest pain patients at lower risk for adverse outcomes.”

Following implementation of the chest pain pathway early in the pandemic, there was a 45% increase in the total number of patients presenting with chest pain who were safely sent home within 2 hours and a 35% increase in the number of patients sent home within 3 hours of presentation. Overall, there was a 55% increase in patients being assessed using only a single troponin result in the ED, and, consequently, fewer patients required multiple troponin results to rule out heart attacks. This streamlined diagnosis (ruling in and ruling out heart attacks) was achieved without any clinically significant increase in major adverse cardiac events post implementation, reinforcing overall quality – paired speed with safety – of the clinical pathways. For these reasons and more, the chest pain pathway and team were selected as one of the three global winners in the 2020 UNIVANTS Healthcare of Excellence program.

Than and Florkowski hope to share the chest pain pathway with other hospitals throughout the world so that it can be adopted even in a post-pandemic environment. In addition, they plan to use the collaborative model to streamline other patient care pathways.

“This is not a single event,” Florkowski said. “This is a work in progress – COVID-19 just gave an extra emphasis. We want to share this as widely as possible.”

Early Identification of Kidney Disease in Indigenous Communities

Indigenous groups in Canada endure disproportionately high rates of chronic kidney disease (CKD), diabetes, and hypertension. Often marginalized from mainstream healthcare services geographically, economically, or culturally, many of these individuals lack the preventive health benefits associated with continuity of care. This barrier can result in delayed detection

and treatment of disease, which then leads to an increase risk of adverse outcomes.

A team of professionals in Winnipeg got creative to search for progress in this unique situation. The Chronic Disease Innovation Centre at Seven Oaks General Hospital and University of Manitoba developed a comprehensive screening, triage, and treatment initiative designed to bring preventive kidney care to rural and remote indigenous communities across Canada. The initiative, dubbed Kidney Check, employs point-of-care testing (POCT) to identify CKD, diabetes, and hypertension in individuals ages 10 and up regardless of pre-existing risk factors.

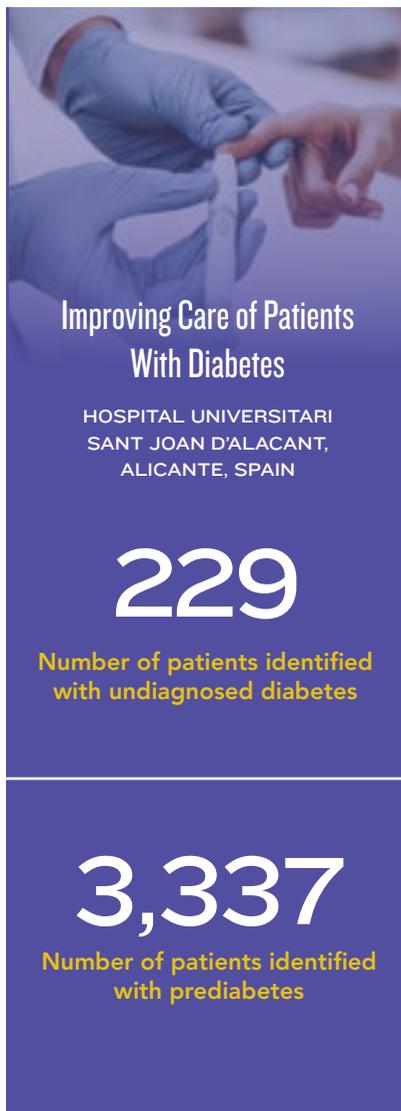
Using portable diagnostic equipment, a Kidney Check health team travels to remote communities to screen for cardiovascular disease, diabetes, and CKD. Screening is performed at community sites, such as nursing centers or schools. Immediately following screening, clients are triaged according to their individualized kidney failure risk prediction scores calculated by an iPad application and offered additional resources accordingly.

The Kidney Check initiative uses a locally developed algorithm that predicts the risk of kidney failure in 2 to 5 years.

“Many indigenous people in Canada live in northern or very remote locations... there is also a lot of poverty. We linked up with laboratory and indigenous clinicians to develop a better way to screen these communities for kidney disease.”

–PAUL KOMENDA, MD

This team crafted a strategy in which they added HbA1c testing to all eligible requests from general practitioners for patients without known diabetes. To improve monitoring of known diabetes, HbA1c and other key biomarkers – such as lipid markers and urinary albumin – were added to GP requests in accordance with guideline recommendations.



“Many indigenous people in Canada live in northern or very remote locations,” explained Paul Komenda, MD, a nephrologist, professor of medicine at the University of Manitoba, and research director at the Chronic Disease Innovation Centre. “In some cases, they live in fly-in only communities, without access to roads, so they have reduced access to ongoing preventive care. There is also a lot of poverty in those communities. We linked up with laboratory physicians and indigenous clinicians to develop a better way to screen these communities for kidney disease.”

Since launching, the Kidney Check initiative has reached 5,891 indigenous adults in 11 communities, of which 1,700 (22.4%) opted in for screening and became more aware of their kidney disease risk. All patients screened and identified at risk for cardiovascular disease, diabetes, or CKD were provided education and counseling and subsequently linked to appropriate care.

What the team found was significant. Almost 22% of First Nations children had at least one risk factor for CKD. More than 10% of those children had an albumin-to-creatinine ratio of more than 3 mg/mmol, and 6.2% had an estimated glomerular filtration rate less than 90 ml/min/1.72 m², suggestive of early kidney disease.

Based on the calculated risk for each individual (low, medium, and high), the program developed personalized kidney health plans for 343 patients. A year and a half since the initial screening, 90% of

patients identified as high risk have been seen by a nephrologist, and a number of them continue to be regularly monitored.

In addition to improving patient outcomes, the initiative is expected to have a significant impact on healthcare costs through the reduced need for dialysis. In Manitoba, the cost of dialysis runs \$60,000 to \$80,000 per year. In remote Northern Manitoba, the cost is as high as \$200,000 per year. Identifying kidney disease at an earlier stage when lifestyle factors can have an impact on progression ultimately saves the healthcare system money.

“We had a lot of partners on this project,” Komenda emphasized. “There was a close collaboration of indigenous health specialists, nephrology clinical specialists, lab medicine specialists to run the point-of-care testing, app developers, patient partners, and funding through CANSOLVE CKD, a pan-Canadian patient-oriented kidney research network. All of those ingredients go into the fact that we can go into these rural and remote underserved populations and mass screen in a very easy and efficient way, provide them instant results on their risk of kidney disease, and give them educational materials and a treatment plan, all within a 30-minute window.”

Building on the success of the initial Kidney Check screening, the initiative has since expanded to four additional provinces across Canada. Komenda expects the initiative to be scaled up in underserved communities in other countries as well. “We are all very excited about the possibilities that this can be used in vulnerable communities around the world,” he said.

Early Diagnosis and Improved Management of Patients With Diabetes

Diabetes mellitus is a significant global health problem and a leading cause of mortality worldwide. Direct healthcare costs and the loss of labor productivity are extremely high, in part due to complications related to delayed diagnosis and inadequate monitoring and treatment. Recognizing that significant opportunities exist for earlier detection, targeted treatment, and improved monitoring to minimize costs of diabetes-related

complications and improve quality of life, the Hospital Universitari Sant Joan d'Alacant in Alicante, Spain, in 2016 developed an automated strategy for improving detection of undiagnosed diabetes and prediabetes while also ensuring routine monitoring of patients with known diabetes.

This team crafted a strategy in which they added HbA1c testing to all eligible requests from general practitioners (GP) for patients without known diabetes. To improve monitoring of known diabetes, HbA1c and other key biomarkers—such as lipid markers and urinary albumin—were added to GP requests in accordance with guideline recommendations, explained Maria Salinas, PhD, head of the hospital laboratory.

In patients between 45 and 75 years of age, HbA1c was added to every GP request for complete blood count (CBC) when predefined inclusion criteria were met (no known diabetes, glucose between 5.6 and 6.9 mmol/L, no HbA1c requests in last 3 years). Patients 25 to 45 years of age had HbA1c tests with every GP request for CBC when lipids and fasting glucose were elevated.

Controlling and monitoring lipid and urinary albumin levels is also critical for optimizing treatment plans, Salinas noted. Of tests from patients with diabetes, 14.4% had these biomarkers automatically added to order sets; 21% had lipid tests with pathological values, and 17.6% had urine albumin values above 30 mg/G. In these cases, GPs were alerted to re-review their patients' care plans and take the appropriate steps.

Through this initiative, which is a global winner, the hospital laboratory was able to identify 229 patients with undiagnosed diabetes. In addition, 3,337 patients were diagnosed with prediabetes. Collectively, the total test costs were €2,730 over 84 months for patients 45-75 and €309 for patients 25-45 over 36 months.

"The cost of doing an HbA1c is very low in Spain, so this is a cost-effective way of identifying people with diabetes," Salinas said. "We know the prognosis of the disease improves when cases are diagnosed earlier. We are improving the quality of life of these patients by identifying them early and getting them on treatment plans."

Between 2016 and 2019, the number of patients with HbA1c under 8% improved significantly, thus reflecting improved diabetic control in patients treated at the institution, Salinas said. Diabetes guidelines recommend that for diabetic patients HbA1c levels should stay below 8%. In addition, appropriate monitoring of patients with diabetes helps avoid unnecessary repetition of hospital resources, including laboratory testing requests and associated phlebotomies, she noted. In this case, additional testing was avoided in 14.4% of cases (4,355 out of 30,216) between July 2016 and July 2020.

Salinas believes this initiative is highly scalable and could easily be implemented by other hospitals. "The use of algorithms and HbA1c in clinical care is not unique," she said. "However, the strategic implementation of our automated test algorithms into clinical care is unique. Our algorithm was developed to automatically add HbA1c testing to primary care requests in patients at risk for diabetes and to ensure monitoring of glycemic control in patients twice a year."

Reducing Catastrophic Adverse Events in Patients With Hemorrhagic Shock

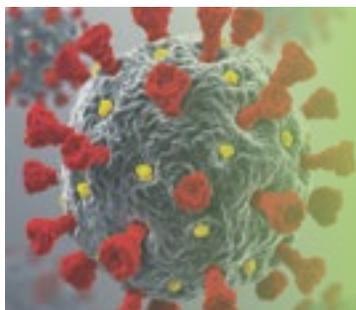
Between 2013 and 2015, 29.1% of all catastrophic adverse events reported at the Hospital Israelita Albert Einstein in São Paulo, Brazil, were related to bleeding management failure and hemorrhagic shock. It is estimated that the median time from the onset of hemorrhagic shock to death is 2 hours. The ability to provide lifesaving treatment is heavily dependent on the ability to recognize risk early, but challenges often exist in the identification of hemorrhagic shock, especially when the source of bleeding is unknown. There are subtle clinical indicators of shock, but they must be acted on rapidly to be effective.

The integrated clinical care team at Hospital Israelita Albert Einstein set out to reduce the number of catastrophic adverse events related to hemorrhagic shock by reducing barriers for risk identification, as well as enhancing the management of patients with severe bleeding, according to João Guerra, MD, PhD, medical head of hematology at the clinical



laboratory. Among the challenges that had to be addressed were logistical and procedural changes, activation of dedicated resources, systematic multidisciplinary alerts, and accelerated turnaround for critical tests and faster decision-making.

The team made strategic changes to enable comprehensive, patient-centric protocols for urgent patients, including establishing a new "code yellow" that enables identification of patients whose vital signs indicate risk of decompensating, Guerra said. When code yellows are activated, a rapid response team is triggered for enhanced vital sign monitoring. If a patient continues to decompensate, a "code H" alert is called. Code H alerts are based on validated criteria for



Optimizing Care for Patients With COVID-19

DUBAI HEALTH AUTHORITY, UNITED ARAB EMIRATES

98.6%

Number of SARS-CoV-2 tests reported within 48 hours of collection

83%

Reduction in rate of COVID-19 mortality in the United Arab Emirates

hemodynamic instability, triggering a cascade of actions across multidisciplinary health professionals through automated alerts. This includes immediate ordering of blood and blood components through a massive transfusion protocol with a 15-minute response time.

The laboratory completes the testing panel for code H within 30 minutes, enabling activation of imaging teams within 1 hour of the exam. Vascular intervention occurs within 30 minutes, and the ICU and operating room are put on stand-by. All procedures and tests are overseen by an on-call code H team that is in operation 24 hours a day, 7 days a week.

The clinical laboratory played a critical role both in developing and carrying out the code H protocol, Guerra emphasized. “The clinical laboratory team introduced concepts of precision medicine and value-based medicine for rapid and accurate diagnosis through point-of-care testing and hemostatic and therapeutic drugs for efficient treatment,” Guerra said. “In addition, we created a code H application, which guides the protocol step-by-step with algorithms and flowcharts developed with the help of artificial intelligence. The lab team was directly involved with both the coordination and validation of the point-of-care testing and with the development of the app.”

The project was implemented in May 2016, and after 2 years, there was not only a significant improvement in indicators, but also a reduced length of stay in the ICU, reduction in use of blood components, and better cost-effectiveness when compared to a control group. Moreover, the development and implementation of a rapid response team enabled the hospital to mitigate catastrophic adverse events in 88.5% of code yellow patients, Guerra said. In addition, the average time to transfusion for

decompensating critical patients with active bleeding (code H patients) was reduced by 1.25 hours (from 1.30 hours to 15 minutes).

Perhaps most significantly, mortality related to bleeding management failure dropped from 29.3% the 3 years prior to implementation of code H to 4.3% in the 4 years post-implementation.

Although clinicians initially were skeptical of the initiative, once the results started coming, they got on board. In the first 6 months of the project, the team trained more than 150 emergency room doctors, intensive care specialists, and anesthesiologists, as well as some 400 nurses and 50 clinical pharmacists.

“The results speak for themselves,” Guerra said. “Patients are receiving better and safer care; clinicians are more confident with better training and work with the adequate coordination of efforts and actions; health administrators do not have to deal with catastrophic adverse events related to failure in the management of patients with severe hemorrhagic diseases; and payers are, at the end of the day, happy.”

The Code H initiative placed as a UNIVANTS finalist with distinction and received the highest award scores for the Latin America and Caribbean region.

Optimizing Patient Care Through COVID-19 Public-Private Partnership

To combat the COVID-19 pandemic, the Dubai Health Authority (DHA), the government healthcare provider, engaged private laboratories to increase testing capacity and boost access to SARS-CoV-2 testing. Once DHA began partnering with private laboratories, competition between the public and private laboratories disappeared, the price of testing dropped, and individuals had greater access to testing,

according to Rana Nabulsi, MD, a consultant in healthcare quality for DHA.

“This collaboration is unusual,” Nabulsi explained. “During the early days of the COVID-19 pandemic, there was huge competition between the public and private sectors on obtaining COVID-19 testing supplies. The DHA public laboratory was not able to procure adequate extraction and [polymerase chain reaction] kits as the process of purchasing in the public sector takes much longer. Private laboratories were more efficient in obtaining COVID-19 supplies. The partnership allowed us to unify logistics and the supply chain and facilitate data sharing.”

DHA initially contracted with eight private laboratories to handle testing that exceeded the public lab’s capacity; that number is now up to 17 private laboratories. The contracts with the private labs were conditioned on 24- to 48-hour result turnaround. In addition, the DHA team ensured that the laboratory information systems (LIS) of the private labs were interfaced with the DHA LIS, which in turn was integrated with the public health system. This offered the public health system the data it needed for prompt contact tracing and isolation of infected individuals.

According to Nabulsi, 98.6% of all SARS-CoV-2 test results were provided back to physicians and patients within 48 hours of collection, enabling actionable next steps for infected patients while mitigating risk for transmission to others. At its highest level, the COVID-19 mortality rate in the United Arab Emirates (UAE) was 1 death per million people; that rate subsequently dropped to 0.17 deaths per million, a reduction of approximately 83%. Nabulsi credits the public-private partnership with this reduction in mortality.

“The partnership enabled increased testing capacity and facilitated access to COVID-19 testing for symptomatic patients and their contacts,” she said. “In addition, providing rapid polymerase chain reaction (PCR) within two hours at all hospital emergency departments had a great impact on early triage of patients. By using both routine PCR and rapid PCR, the transmission of the virus, the hospitalization rate, and mortality rate all were reduced.

The pathology department at DHA played a crucial role in improving quality of testing, regulating private laboratories with DHA’s rigorous testing guidelines, mandating rapid turnaround time, conducting inspections, and mandating monthly interlaboratory comparison programs. In addition, the DHA pathology department was able to negotiate with private laboratories for reduced prices for SARS-CoV-2 testing. All these efforts reduced healthcare costs, and those saved resources were put toward mass screening programs.

While DHA initially covered the testing and treatment costs for the pandemic, insurance companies eventually begin covering clients and beneficiaries with the same negotiated testing prices. The UAE’s streamlined SARS-CoV-2 testing initiative placed as a finalist with distinction and received the highest award scores for the Middle East and Africa.

Optimizing Patient Care

Whether helping identify CKD early enough to effect substantive change or improving diagnosis and treatment of patients with diabetes, clinical laboratories around the world are making a real difference in improving quality of life and patient outcomes.

The initiatives highlighted herein are just a few of the many projects in which laboratories are playing a critical role in transforming healthcare delivery. To learn about other UNIVANTS winners, go to www.univantshce.com.

Kimberly Scott is a freelance writer who lives in Lewes, Delaware.

+EMAIL: kmscott2@verizon.net

UNIVANTS 2020 TEAMS RECOGNIZED IN THIS ISSUE

The UNIVANTS of Healthcare Excellence Award recognizes teams who collaborate across disciplines to transform healthcare delivery and patient care. Now in its second year, the program is recognizing teams from all regions of the globe.

For more details on these and other teams recognized this year, visit www.univantshce.com.

TOP GLOBAL AND AREA WINNERS

Reducing Patient Risk and Enhancing Care Through the Development and Implementation of a New Chest Pain Pathway, Expedited by and for the COVID-19 Era

Canterbury District Health Board, New Zealand | Best of Asia Pacific

- › Martin Than
- › Jacques Loubser
- › John Pickering
- › Chris Florkowski
- › Sally Aldous

Kidney Check: The Next Generation of Surveillance for Hypertension, Diabetes, and Chronic Kidney Disease

Chronic Disease Innovation Centre, Seven Oaks General Hospital, Winnipeg, Canada | Best of North America

- › Paul Komenda
- › Barry Lavallee
- › Abdul Razaq Sokoro
- › Binh Nguyen
- › Adeera Levin

Early Diagnosis and Improved Management of Patients With Diabetes Through Strategic and Automated Test Algorithms via Primary Care

Hospital Universitari Sant Joan d’Alacant, Alicante, Spain | Best of Europe

- › Maria Salinas
- › Emilio Flores
- › Beatriz Massa
- › Maite López-Garrigós
- › Francisco J. Pomares-Gómez

RECOGNITION OF DISTINCTION – BEST IN AREA WINNERS

Reducing Catastrophic Adverse Events in Patients With Hemorrhagic Shock Through Early Recognition of Risk and System-Wide Automatic Alerts

Hospital Israelita Albert Einstein, São Paulo, Brazil | Best of Latin America and Caribbean

- › João Carlos de Campos Guerra
- › Priscilla Bento Matos Cruz Derogis
- › Michele Jaures
- › Roseny dos Reis Rodrigues
- › Carlos Eduardo dos Santos Ferreira

Novel Collaborative Approach Among Public and Private Sectors for Streamlined SARS-CoV-2 Testing Towards Optimized Patient Outcome During Covid-19 Pandemic

Dubai Health Authority, Dubai, United Arab Emirates | Best of Middle East and Africa

- › Rana Nabulsi
- › Hussain Al Samt
- › Mohammed Daoud
- › Hanan Al Suwaidi
- › Laila Al Dabal

The Next Generation of Kidney Surveillance for Improved Population Wellness

CHRONIC DISEASE INNOVATION CENTRE,
SEVEN OAKS GENERAL HOSPITAL

Automated Test Algorithms for Early Diagnosis of Diabetes

HOSPITAL UNIVERSITARI SANT JOAN D'ALACANT

New Chest Pain Pathway Reducing Patient Risk and Enhancing Care

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BEST PRACTICES**

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**Chronic Disease Innovation Centre,
Seven Oaks General Hospital**

NORTH AMERICA

★
Hospital Israelita Albert Einstein

LATIN AMERICA

★
Dubai Health Authority

MIDDLE EAST

★
Canterbury District Health Board

ASIA PACIFIC

★
**Hospital Universitari
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