

April 2021

# CLIN

Clinical  
Laboratory  
News

SARS-COV-2  
SEROLOGY TIMING



Highest sensitivity in days after RT-PCR positive test

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## Why Test Names Confuse Clinicians



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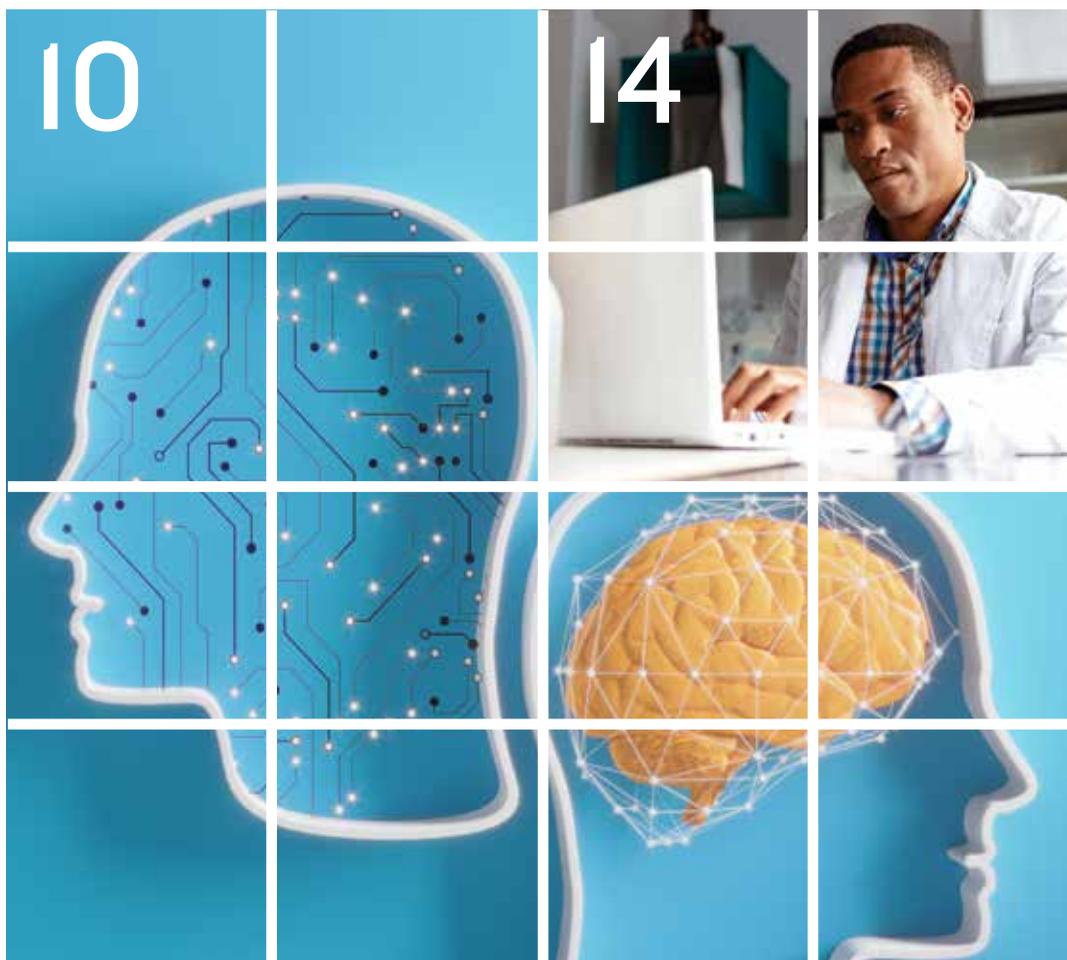
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For more than 30 years, laboratories have used testing in patients with gynecological and germ cell tumors to aid in evaluating therapeutic response and recurrence or metastasis.

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## Federal Insider

## COVID-19 Relief Bill Devotes \$48 Billion to Testing

The \$1.9 trillion American Rescue Plan signed into law by President Biden on March 11 sets aside \$47.8 billion for the Department of Health and Human Services (HHS) to spend on SARS-CoV-2 testing. While HHS has yet to release a full plan for exactly how all the funds will be spent and when, the bill outlines a number of key areas.

A chief problem for clinical laboratories has been a shortage of nearly every kind of supply needed for testing. The bill directs HHS to support the development, manufacturing, procurement, distribution, and administration of SARS-CoV-2 tests and supplies; it also directs HHS to acquire, construct, or renovate facilities to produce diagnostic supplies as necessary to bolster the supply chain.

Congress also tasks HHS with implementing a national, evidence-based strategy for testing, contact tracing, and surveillance. Part of that work must include providing technical assistance or grants to state and local health departments. The law also outlines investment in laboratory capacity for SARS-CoV-2 testing and enhancement of information technology to support data sharing related to public health. HHS also can use the funds to award grants that sustain the public health workforce.

In addition to the \$47.8 billion for diagnostic testing for SARS-CoV-2, the bill appropriates \$1.75 billion specifically for genomic sequencing and surveillance. HHS must use the funds to build capacity through the Centers for Disease Control and Prevention (CDC) and state or local public health departments, with the aim of increasing their capacity to

sequence genomes of circulating strains of “viruses and other organisms,” including SARS-CoV-2. This section of the bill also specifically calls out the need to enhance and expand the informatics capabilities of public health departments.

To further advance informatics capabilities, the bill includes an additional \$500 million for CDC to modernize public health surveillance and analytics so that the agency can track hotspots for SARS-CoV-2 and other biological threats.

### ADVISERS QUESTION KEEPING MEDICARE TELEHEALTH EXPANSION POST-PANDEMIC

A significant and potentially enduring shift during the COVID-19 pandemic has been a rapid expansion of telehealth services. Medicare expanded telehealth benefits in 2020 to encourage greater use of these services. In a new report to policymakers, the Medicare Payment Advisory Commission (MedPAC), an independent advisory panel to Congress, recommends that policymakers “temporarily continue” to pay for certain telehealth services for one to two years after the COVID-19 public health emergency to study clinical benefit.

However, MedPAC recommends that Medicare return after this period to paying the physician fee schedule’s facility rate for telehealth services, which is less than rates for in-person services. The American Hospital Association has called for Medicare to ensure appropriate payment for telehealth services because they require additional technological resources to deliver.

### CMS STRENGTHENS REQUIREMENTS FOR ISSUERS TO COVER SARS-COV-2 TESTS

Following an executive order from President Biden, the Centers for Medicare and Medicaid Services (CMS) issued new guidance

that aims to remove barriers to SARS-CoV-2 testing and ensure that health plans cover diagnostic testing without cost sharing.

According to the guidance, issuers generally cannot use medical screening criteria to deny coverage or require cost sharing for SARS-CoV-2 tests for asymptomatic people, whether performed in a laboratory or at the point of care.

The guidance specifically cites as an example a person wanting to ensure they are SARS-CoV-2 negative prior to visiting a family member. The guidance also includes information for providers on how to get reimbursed for SARS-CoV-2 diagnostic testing or for administering the COVID-19 vaccine to those who are uninsured.



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## Result, Dilute, Comment, or Cancel: How to Handle Icteric Samples

The presence of interferences such as hemolysis, icterus, and lipemia were originally detected by laboratory personnel via subjective visual evaluation of plasma after centrifugation. In contrast, most labs today employ automated tools to detect the presence of these potential interferences using calculations from absorbance measurements, collectively called serum indices. Newer instruments also incorporate cameras to detect these interferences prior to sample analysis, saving time and reagent.

In our core laboratory, all samples processed by our automation system have serum indices measured spectrophotometrically, which include an H-index (hemolysis), I-index (icterus), and L-index (lipemia/turbidity). These serum indices measurements are compared to cutoffs established by the manufacturer and/or validated in our laboratory before deciding if the result is valid. Here, we discuss special considerations for detecting and reporting results on icteric samples that exceed the acceptable I-index cutoff.



By Joe M. El-Khoury, PhD, DABCC, FAACC

### Mechanism of Interference: Conjugated vs. Unconjugated Bilirubin

Icterus, also known as jaundice, is used to describe the yellowish-greenish color observed in the sclera of the eyes or in plasma/serum samples of patients with very high concentrations of bilirubin. Such extreme elevations in bilirubin are most commonly seen in acute and chronic liver disease, biliary cirrhosis, or alcoholism. The form of bilirubin found in patient samples also depends on the patient's disease. For example, conditions affecting

the liver's ability to conjugate bilirubin can lead to an increase in unconjugated bilirubin, while conditions such as cholestasis, which reduces bile flow, can lead to an accumulation of conjugated bilirubin.

Both forms of bilirubin interfere with analytical assays via spectral interference (absorbing strongly in the region of interest) or chemical interference (binding to dyes or acting as a reducing substance with the reagents or products formed in the test system). However, the effect and magnitude of the interference can differ between conjugated and unconjugated bilirubin, which is why it is important that in vitro diagnostic (IVD) manufacturers evaluate the effects of both separately.

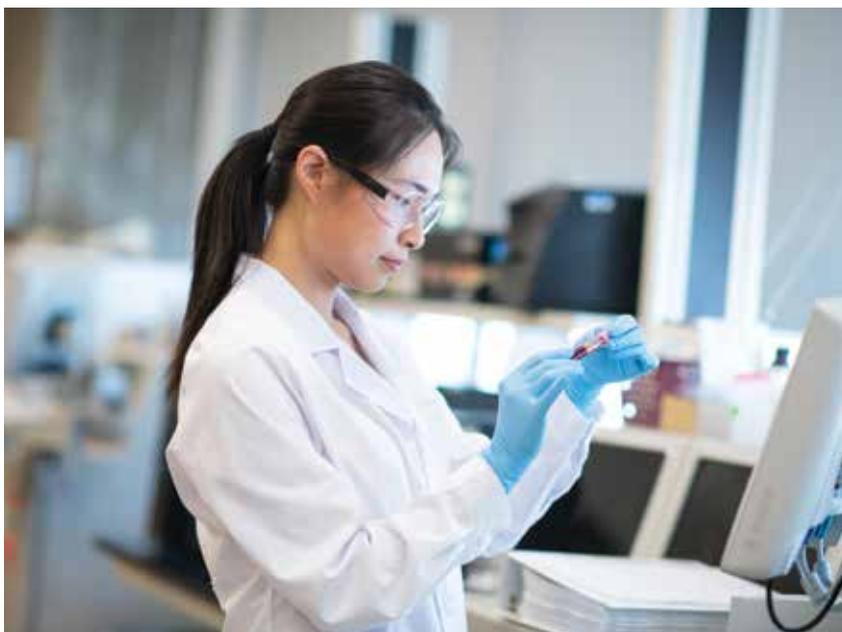
Of course, this means that the manufacturers may list two tolerance cutoffs for I-index—one based on conjugated bilirubin and the other on unconjugated bilirubin spiking experiments. In this case, laboratories are advised to implement the lower I-index as their cutoff for interference because unless total and direct bilirubin are measured, it is impossible to know which form is predominantly found in the sample by I-index alone.

### Automating the Solution

When our laboratory receives a sample with an I-index above the acceptable threshold, we consider three courses of action:

**1. Dilute:** For analytes with a validated or approved dilution matrix, we dilute the sample to lower the I-index within an acceptable range, up to the maximum dilution specified for each assay. Because the lower limit of quantitation (LLOQ) of the assay is affected by dilution, this approach is not recommended for analytes where the LLOQ itself is clinically important, such as troponin.

For example, our enzymatic creatinine assay has a manufacturer-



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GLU BUN Creat  
Hb Hct

### *Blood Gases, Lactate Menu*

pH PCO<sub>2</sub> PO<sub>2</sub> Lac

### *Full Test Menu*

pH PCO<sub>2</sub> PO<sub>2</sub> Hct Na Cl K  
iCa iMg TCO<sub>2</sub> Glu Lac BUN  
Creat tHb SO<sub>2</sub>% CO-Ox Panel

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specified I-index of 15\*, LLOQ of 0.06 mg/dL, and a maximum dilution of 4-fold. For creatinine, performing a 4-fold dilution means we can resolve interferences in samples with an initial I-index up to 60, but our LLOQ is also raised 4-fold to 0.24 mg/dL on a 4-fold dilution. This approach may be applied to resolve other suspected interferences as well, but dilution should not be used to resolve interference from hemolysis. Even though dilution lowers the H-index, the mechanism of interference is typically intracellular release (not spectral or chemical), which is not resolved by dilution.

**2. Result with comment:** For tests where the IVD manufacturer finds no interference up to the maximum bilirubin concentrations tested (for our IVD manufacturer: I-index = 60), we release the result with the comment: "Sample is highly icteric which may affect result. Recommend interpretation within clinical context." In my decade of working in a clinical lab, I have never seen a sample exceed an I-index of 65. So, the likelihood that a result is affected at an I-index of 65 but not 60—and that it is clinically significant—is extremely low. Therefore, the comment advises caution during interpretation because we believe the results are more likely to be accurate than not.

**3. Cancel:** For analytes that have an I-index below the maximum tested (for our IVD manufacturer: I-index <60) and have no acceptable/validated dilution matrix (such as free T4 and total T3), or where dilution does not bring the I-index within the acceptable range (creatinine if I-index > 60), we automatically cancel the result because we know the interference will likely be significant. As mentioned earlier, results are also cancelled when raising the LLOQ due to dilution does not make sense clinically.

Thanks to a few of our savvy middleware superusers, our lab was able to create an automated process by developing rules to trigger the appropriate technique. So, how do we handle icteric samples? Today, we no longer do. After careful consideration of each scenario during initial validation, we now let the instrument do the work. That's the beauty of automation.

\*I-indices vary by manufacturer, with some using a 1–4 scale while others correlate the numbers to concentrations of bilirubin in mg/dL. The numbers provided here are based on Roche cobas 8000 limits.

**Joe M. El-Khoury, PhD, DABCC, FAAC**, is associate professor of laboratory medicine at Yale School of Medicine and co-director of the Clinical Chemistry Laboratory and Clinical Chemistry Fellowship Program at Yale-New Haven Health.

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## The Sample

### Options for Thyroid Testing During Pregnancy Recommended

Indirect free thyroxine (FT4) immunoassay results in pregnancy interpreted in the context of trimester-specific reference intervals may provide a practical and viable alternative to total T4 (TT4) or free thyroxine index (FTI) (Clin Chem 2021; doi.org/10.1093/clinchem/hvab009).

Professional guidelines from the American Thyroid Association and Endocrine Society discourage the use of indirect immunoassays for measuring FT4 in pregnancy when interpreted in the context of the reference interval used outside of pregnancy (NP interval). Instead, the guidelines suggest interpreting TT4 in the context of 1.5-times the NP interval during the second or third trimester or calculating the FTI with a direct method involving measurement of free hormone after a physical separation step. If there is no alternative to a FT4 immunoassay, labs should use trimester-specific reference intervals. These recommendations are based on research that describes the limitations of indirect FT4 immunoassays without using a comparison against a reference method.

To evaluate the recommendations' impact on classifying thyroid status in apparently euthyroid pregnant patients, the researchers evaluated clinical samples from 147 nonpregnant women of childbearing age and a total of 480 pregnant individuals in all trimesters using both indirect immunoassay and direct FT4, thyroid-stimulating hormone (TSH), TT4, and T-uptake. The researchers made split-sample comparisons of FT4 as measured and equilibrium dialysis.

FT4 decreased with advancing gestational age, as measured by both immunoassay and equilibrium dialysis. TSH declined during the first trimester, remained constant in the second, and increased throughout the third, peaking just before delivery. Interpretation of TT4 concentrations using 1.5-times the NP interval classified 13.6% of first trimester specimens below the lower reference limit, despite TSH concentrations within trimester-specific reference intervals. Five FTI results from the 480 pregnant individuals (about 1.0%) fell outside the manufacturer's reference interval.

These findings underscore the need to establish gestational age-specific reference intervals for all assays used to assess thyroid function, the researchers note.

#### TIMING OF SARS-COV-2 SEROLOGY TESTS MAY MATTER

**W**hile antibody response to a SARS-CoV-2 infection is clinically detectable many months after an infection, recent research suggests testing too soon may lead to

an incorrect assessment of immune response (JAMA Network Open 2021; doi:10.1001/jamanetworkopen.2021.0337).

Using clinical data from the University of California Health (UC Health) system, researchers examined three types of clinical

immunoglobulin G (IgG) measurements in patients with real-time reverse transcription-polymerase chain reaction (RT-PCR) confirmation of SARS-CoV-2 infection. The investigators calculated antibody test sensitivity in 7-day increments from the date



of the positive RT-PCR test and used the t-test to compare sensitivity by patient-reported sex and variance analysis to compare sensitivity by assay types and age.

Among the 277,567 UC Health system patients tested via RT-PCR for SARS-CoV-2, 14,290 had antibody tests. Of 10,065 patients with positive RT-PCR results for SARS-CoV-2, 4.8% had subsequent SARS-CoV-2 antibody testing a median of 34 days later.

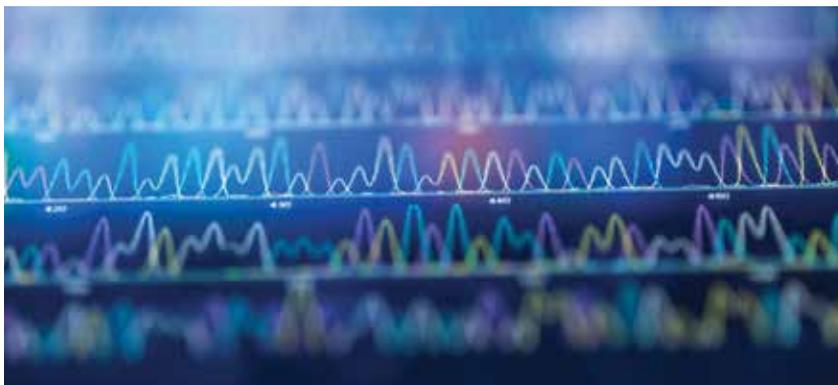
Serology tests were positive in 75.1% of patients, but antibody response varied by test timing. Serology tests conducted closer to a patient's positive RT-PCR results were more likely to have negative results than those done later. The likelihood of positive SARS-CoV-2 antibody test results increased with longer intervals between the positive RT-PCR result and the antibody test, with sensitivity reaching 0.75 at 112 days after the positive RT-PCR result.

Sensitivity varied by test type, sex, and age. Maximum sensitivity for the Beckman Coulter SARS-CoV-2 IgG test, Liaison SARS-CoV-2 S1/S2 IgG test, and DZ-Lite SARS-CoV-2 IgG CLIA kit was 0.84, 0.78, and 0.67, respectively. Serology sensitivity was significantly higher among males than females. It was highest at 126 days after positive RT-PCR results for males, versus 133 days afterwards for females. By age group, sensitivity was highest among patients 50–59 years old. Only pairwise comparisons of antibody test sensitivities between the youngest and oldest groups and patients aged 40–49, versus those aged 50–59, differed significantly.

The researchers suggested a larger study to validate their findings.

### USEFUL BREAST CANCER PANEL GENES SUGGESTED

A recent study defines the genes that are most clinically useful in panels that predict breast cancer risk and provides estimates of risks associated with protein-truncating variants. This information that may guide clinical reporting of panel testing results and genetic counseling (N Engl J Med 2021;384:428-39).



As sequencing becomes more affordable, making the use of larger panels of genes possible, the researchers sought to establish stronger associations of some genes with cancer and more accurate estimates of particular variants' pathogenicity. Using a panel of 34 commonly accepted susceptibility genes, the authors sequenced samples from 60,466 women with breast cancer and 53,461 controls. In separate analyses for protein-truncating variants and rare missense variants in the 34 genes, the authors estimated odds ratios for both breast cancer overall and tumor subtypes. They also evaluated missense-variant associations according to domain and pathogenicity classification.

Protein-truncating variants in 5 genes—*ATM*, *BRCA1*, *BRCA2*, *CHEK2*, and *PALB2*—were associated with a risk of breast cancer overall with a P value of less than 0.0001. Protein-truncating variants in 4 other genes—*BARD1*, *RAD51C*, *RAD51D*, and *TP53*—were associated with a risk of breast cancer overall with a P value of less than 0.05 and a Bayesian false-discovery probability of less than 0.05. For protein-truncating variants in 19 of the remaining 25 genes, the upper limit of the 95% confidence interval of the odds ratio for breast cancer overall was less than 2.0.

For protein-truncating variants in *ATM* and *CHEK2*, odds ratios were higher for estrogen receptor (ER)-positive disease than for ER-negative disease. For protein-truncating variants in *BARD1*, *BRCA1*, *BRCA2*, *PALB2*, *RAD51C*, and *RAD51D*, odds ratios were

higher for ER-negative disease than for ER-positive disease. In aggregate, rare missense variants in *ATM*, *CHEK2*, and *TP53* were associated with a risk of breast cancer overall with a P value of less than 0.001. For *BRCA1*, *BRCA2*, and *TP53*, missense variants in aggregate that standard criteria would deem pathogenic were associated with a risk of breast cancer overall, with the risk being similar to that of protein-truncating variants.



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# Artificial Intelligence

## Is Poised to Transform Point-of-Care Testing

**A**rtificial intelligence (AI) and machine learning (ML) continue to become more prevalent in healthcare. The AI-associated healthcare market is on track to reach \$6.6 billion this year, according to Accenture. AI applications could create opportunities for \$150 billion in healthcare cost savings by 2026. And the use of these technologies has even expanded into the field of point-of-care testing (POCT). As more tests move out of the core laboratory and are performed by nonlaboratory professionals, AI and ML are being used to make POCT cheaper, faster, and easier to check for quality control.

“We generate a lot of data with POCT and in our core laboratories,” said James Nichols, PhD, DABCC, FAACC, professor of pathology, microbiology, and immunology and medical director of clinical chemistry and POCT at the Vanderbilt University Medical Center. “We haven’t even really scratched the surface on what we can do with that data.”

### CHEAPER AND FASTER POCT IN MORE SETTINGS

There’s no lack of enthusiasm for advancing POCT, either among healthcare professionals or even patients, who increasingly expect that most tests will soon be as simple and reliable as home pregnancy tests or blood glucose meters. But translating that ease and price point to other kinds of testing, especially molecular testing, hasn’t been easy. Some new innovations show that AI and ML can help.

Aydogan Ozcan, PhD, Chancellor’s Professor and Volgenau Chair for Engineering Innovation at the University of California (UC), Los Angeles, has been developing disposable vertical flow assays that offer cardiovascular risk stratification using high sensitivity C-reactive protein (NPJ Digit Med 2020;3:66) and an immunoassay for early-stage Lyme disease detection (ACS Nano 2020;14:229-40).

In about 15 minutes, the tests show a reaction across immunoreaction spots on a sensing membrane. The user then captures an image

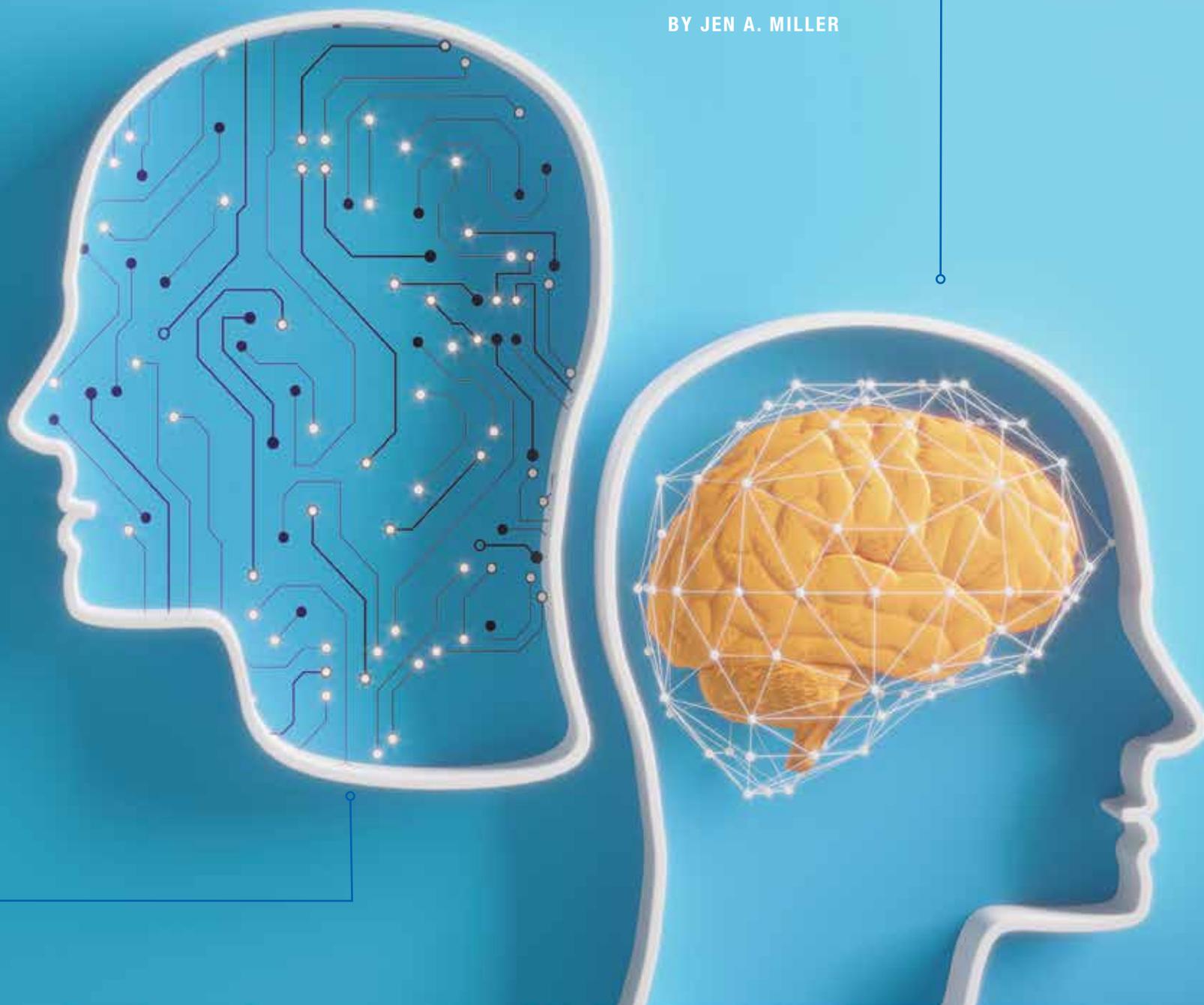
of the spots on a smartphone, and a deep neural net that has been trained to recognize patterns processes the image to indicate the concentration of C-reactive protein, or a positive Lyme test.

Nam K. Tran, PhD, associate clinical professor in the department of pathology and laboratory medicine at UC Davis, recently led a study that looked at a range of variables for predicting acute kidney injury in burn patients and found that AI and ML help make these predictions quickly and accurately. “Humans are typically only able to integrate about six to seven variables at one time, while machines integrate a wide range of variables at once,” he said, adding that tests that automate test interpretation using AI could be more widely distributed, since their users would not need to have in-depth technical backgrounds.

This could bring down costs and make tests easier to use in a variety of settings, including in patients’ homes. “You can imagine lots of tests that need to be administered extremely inexpensively and in field

In both research and practice, advanced software is being deployed to develop new kinds of instruments and help clinical laboratorians monitor quality.

BY JEN A. MILLER



conditions,” said Ozcan. He hopes that within about a decade these tests will be “at the level of a CVS test, where patients will be able to buy it off the shelf and activate it at home, in the same way that today’s glucose monitors are operating.”

### AI/ML MAINTAINS POCT QUALITY CONTROL

Glucose meters are also a good example of where AI started, said Nichols. “They used to be all manual, so you had to apply the blood from the fingerstick to test a strip, wipe it, then insert it into a glucose meter and

have data-management features. We have large amounts of data coming from individual hospitals. Let’s group all that together.”

Clinical laboratorians should also get accustomed to using AI and ML to maintain quality control in devices used outside of the hospital and operated by nurses, emergency medical technicians, and others who don’t have the training that laboratory professionals do. “POC devices are being used in physician offices and clinics, but they’re also being used in helicopters and with visiting nurses,” Nichols said. The

### HURDLES TO NEW POCT TECHNOLOGY

Just because a technology is new and fancy doesn’t mean it’s also worth it—or that it even does what it says it’s supposed to do. In 2012, the University of Texas MD Anderson Cancer Center partnered with IBM Watson on an AI-enabled “Oncology Expert Advisor.” It didn’t work, and cost the healthcare system \$62 million, according to news reports.

That’s why new technology applied to POCT must be validated the same way any other test is and assessed on a continual basis so that bias doesn’t intrude and make POCT less accurate, experts say. Regulations need to keep in step, too. “We have to follow CLIA requirements, but these same regulations must evolve as AI becomes more accepted—AI is not going away,” Tran said.

The evolving technology also needs to be accepted by the clinical laboratory community, which could take time. “In reality, yes, any tech can fail. But it’s going to come to a level of maturity and robustness with checks and balances and eventually work so seamlessly that you won’t notice anything,” Ozcan said. He pointed to mobile and online banking. “Twenty to 30 years ago, people would say, ‘No way, I wouldn’t trust online banking,’” he said. Now Americans routinely deposit checks via their smartphones.

AI and ML in POCT doesn’t need to be a threat to central laboratories either, said Tran. “I see this as less of a central laboratory versus POCT comparison, and more of a look at how the central laboratory and POCT exist together,” he said. “In the end, AI/ML is a tool, and it is here not to replace our most valuable resource—the humans—but to optimize these limited resources.”

Plus, AI and ML can’t do everything. While they analyze data quickly and automatically for things they were trained on, they “may not be able to predict things that fall outside of their training, hence the value of the laboratory professional remains,” Tran said. ■

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



AI could also be applied to the pre-analytic phase of testing, Tran noted, which would be similar to how the automotive industry uses it for vehicle quality control.

read the result,” said Nichols. Then the user had to record the reading.

In the next generation of glucose meters, the result was stored in the meter itself, and uploaded to laptops carried around the hospital. Laboratories could use that data to calculate a hospital-wide group mean, each nursing unit’s group mean, and a group mean for each meter. That could help identify which meters weren’t working correctly.

“That was really the start of AI and utilizing big data to prove competency of operators, to prove that meters were giving results that were close to the other meters in the hospital,” he said. “Jump forward many years and all our POC devices tend to

devices are thrown in the backs of trunks and get tossed around in ambulances. “They’re used in cold and wet conditions, in dust, wind, and sand. How do we ensure quality beyond just the device failing and giving an error message?”

AI also could be applied to the pre-analytic phase of testing, Tran noted, which would be similar to how the automotive industry uses it for vehicle quality control. “AI could be used to evaluate the quality of specimens, including but not limited to examining how specimens are collected and detecting interferences in samples. Machine vision could also be used to watch operators perform a test.”

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# Search "A" for HbA1c

BY KAREN BLUM

Confusing test names are a patient-safety problem, and a special initiative is looking for answers.

I la Singh, MD, PhD, had been troubled for several years about clinicians ordering incorrect or unnecessary tests, in large part because of confusion over test names. One of the last straws was when she heard about clinicians calling a lab to ask if they had a measles test because they couldn't find it listed under "M," completely forgetting to look under "R" for rubella. So Singh, chief of laboratory medicine and pathology informatics at Texas Children's Hospital in Houston, began contacting colleagues at other institutions with the idea of forming a new nonprofit group to tackle the problem.

Thus the Test Renaming for Understanding & Utilization (TRUU)-Lab group was born. The volunteer organization aims to generate a consensus guideline for test naming, generate consensus names for existing lab tests, and promote the adoption and implementation of consensus lab test names and guidance.

Brian Jackson, MD, MS, chief medical information officer at ARUP Laboratories in Salt Lake City, heard about it while eating lunch with colleagues at a laboratory conference in Seattle a couple of years ago and jumped on board.

"The idea is simple, that laboratory test names are often confusing," Jackson said. "When clinicians are selecting tests based just on the 20 to 40 characters that typically display in an electronic medical record, it's hard to figure out how to describe the test accurately and unambiguously enough that they'll always pick the right one."

## A PROBLEM RIPE FOR INNOVATION

Singh has gathered more than 45 stakeholders from clinical pathology and reference labs; societies such as AACC and the College of American Pathologists; instrumentation firms like Siemens; electronic medical record (EMR) companies like Epic and Cerner; government agencies including the Food and Drug Administration, Centers for Disease Control and Prevention (CDC), and Centers for Medicare and Medicaid Services (CMS); and even organizations outside the U.S. to rally around her cause.





“There’s a tremendous amount of interest,” Singh said. “Every organization that I approached said, ‘Oh yes, we need this.’”

There’s a good reason. An estimated 15 billion laboratory tests are performed in the United States each year, Singh said, 10%–30% of which have been found to be either unnecessary or incorrect (PLoS One 2013;8:e78962). Unnecessary laboratory tests cost an average hospital about \$1.7 million a year, according to a National Academy of Medicine (Institute of Medicine) study discussed in the academy’s 2015 publication, “Improving Diagnosis in

### PLANNING FOR A SMALLER WORLD

The reasons for confusion among the 4,000-plus tests to choose from are multifold, Singh said. Frequently, pathology laboratories create their own names with no guidance or discussion with clinicians. In some cases, test names are based upon the disease with which they’re associated, a reagent used, or even the name of a test’s developer (J Gen Intern Med 2013;28:453-8).

Some tests have proprietary names too, Procop noted. A laboratory might list hemoglobin A1C under “H” as its full name, HgbA1C, or HbA1C; under

FRSC, CCRP, medical director of clinical chemistry and point-of-care technology for Texas Children’s Hospital. “If you get a lab test done here, and then go to New York for a second opinion, and they order a test that is not equivalent, then you’re not going to get the right diagnosis,” Devaraj said. TRUU-Lab stakeholders recognize this is an everyday problem in their laboratories, she noted, and they know they have to work together to create the right standards. “That is a win for TRUU-Lab, and for laboratories in general,” she said.

The plethora of mergers and acquisitions among hospitals and

“If you get a lab test done here, and then go to New York for a second opinion, and they order a test that is not equivalent, then you’re not going to get the right diagnosis,” Devaraj said.

Health Care.” A survey of 1,768 primary healthcare providers in the U.S. found that 15% of them were uncertain about which tests to order (J Am Board Fam Med 2014;27:268-74).

Beyond the costs, incorrect ordering presents a significant patient safety issue, said Gary Procop, MD, MS, medical director and former co-chair of the Cleveland Clinic’s Enterprise Laboratory Stewardship Committee. “In diagnosing influenza,” Procop said, “you would order an influenza molecular test, not an influenza antibody test. But those could be sitting right next to each other on the order form. It would be very easy to pick the wrong one.”

Ren Salerno, PhD, agreed. “Physicians often order tests defensively,” said Salerno, director of CDC’s Division of Laboratory Systems. When they’re not really sure what the right test name is, they may order a whole series of tests hoping one of them is correct. “If you’re ordering the wrong test for a particular patient, you may receive a test result that you shouldn’t. And if you get a positive test result, you may believe that’s indicative of a health condition for a patient that is not accurate, because perhaps that test is measuring an analyte that you’re not aware of. It’s been a really complex challenge that the laboratory community has been trying to address for many, many years.”

“G” as glycosylated hemoglobin or glycosylated hemoglobin; or even under “A” as A1C, Singh said. And some EMR platforms only allow a maximum of 20–40 characters to list and describe tests.

TRUU-Lab’s efforts are not the first to examine laboratory test naming. CDC began gathering experts on the clinical laboratory’s role in providing quality testing to improve patient outcomes as far back as 1984, Salerno said. Then, from 2008–2016, the agency’s Clinical Laboratory Integration into Healthcare Collaborative actively worked to optimize use of laboratory services and deal with diagnostic errors caused by misordering or misinterpreting laboratory results, he said. Those efforts wrapped in 2018 after issuing several publications. Logical Observation Identifier Names and Codes, developed by the Regenstrief Institute in the 1990s, is an ongoing effort to establish common language for health measurements including laboratory tests, although its target is computing systems, not clinicians.

But TRUU-Lab members are optimistic that between the timing and the wide net of committed participants, they will slowly be able to effect change.

The world has become smaller over the past few years, said Sridevi Devaraj, PhD, DABCC, FAACC,

laboratories presents another reason why time is of the essence, Singh added, noting that two merging hospitals may have different naming conventions for their tests. “I can’t tell you how many people have contacted me asking if we have a standard list. I would like to be able to give them a list and say, ‘Build this one,’” she said. “How do you choose between two sets of suboptimal names?”

### THE ROADMAP TO IMPLEMENTATION

TRUU-Lab members have already conducted surveys to learn the most common problematic test names. Some 274 responses yielded about 100 unique laboratory tests that respondents felt were confusing, and included substantial diversity between institutions. The top 10 most commonly cited tests had at least three unique names, and the top two tests (for vitamin D and anti-factor Xa) had at least 10 unique names (Am J Clin Path 2020;154:S18-9).

Now, with a grant from CDC, TRUU-Lab is working with the Brand Institute—known for its expertise in pharmaceutical naming—to tackle these top 10. Surveys of primary care providers this year will assess name preferences given short prompts. In a second phase, a simulated EMR environment will present mock clinical

scenarios in which physicians will select tests. Survey results will inform TRUU-Lab's naming guidelines (Am J Clin Path 2020;154:S1-2).

"When we finally end up with the name, it will be the right name for the right test at the right time," she said.

Singh acknowledges the long road ahead. There are a lot of test names to go through, so the scope of the work is tremendous, she noted. Even when new names are identified and agreed upon, change is hard. It's going to take endorsements from EMR companies and professional societies, or even guidelines from groups like CMS or CLIA, for new naming conventions to take hold. "I think we have a plan, but I'm not going to say that it's going to be easy," she said.

While it could take years for TRUU-Lab to slowly chip away at naming conventions, the organization has a lot going for it, according to Salerno. Some previous attempts were government-led, top-down approaches, while TRUU-Lab is "a true collaborative effort among experts who are on the front line," he said. "They've put

## TRUU-Lab is working to create better naming for these 10 popular tests:

1. Vitamin D
2. Anti-Xa
3. Testosterone
4. C-Reactive Protein
5. HIV
6. Epstein-Barr Virus
7. Parathyroid hormone
8. Human Chorionic Gonadotropin
9. Thyroid hormones
10. SARS-CoV-2

together a very impressive group with excellent leadership that represents the complexity of the problem and the diversity of the stakeholders. For those reasons, I'm extremely optimistic that it will be successful."

Meanwhile, laboratory professionals can help by being aware of the issue, and understanding that laboratory abbreviations can be confusing to clinicians, according to Jackson. "Be very careful about how you use them, and seek feedback from clinicians on whether your test names make sense," he said.

Monitoring utilization patterns also can alert laboratories to potential naming problems. Jackson's laboratory created its own style guide that relies on a number of rules for test names that a human can subjectively interpret. For example, the name of the analyte is the first element in the test name. Trade names are used only in parentheses where necessary. It's also critical for laboratory professionals to be part of hospital informatics committees or other subcommittees that build order sets, Procop said. ■

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BY RYAN S. NELSON, PharmD,  
AND HOWARD L. MCLEOD, FASCO, FCCP

## How Precision Medicine Combats Underused Genomic Testing

**M**edical oncologists strive daily to provide the best cancer care for each of their patients. However, the rapid rate of practice-changing developments makes keeping up to date a significant challenge.

Furthermore, a recent report from the American Society of Clinical Oncology outlines trends that could worsen the caseload burden for practicing medical oncologists. These include lengthened cancer patient survival and a decreased number of medical oncologists entering the United States workforce between 2009 and 2018 (1).

### Understanding the Problem

The dueling issues of high medical oncologist caseload and the expanding complexity of practical cancer care provide an impetus to avoid compromising patient care. This includes meeting success metrics, such as achieving National Comprehensive Cancer Network (NCCN) guidelines

or similar evidence-based consensus strategies. A recent retrospective study of 1,497 patients with metastatic colorectal cancer from 23 practices across the U.S. (2013–2017) assessed how often the molecular tumor testing that patients received met NCCN guideline recommendations (2). Surprisingly, testing rates for guideline-aligned *RAS*, *BRAF*, and microsatellite instability/mismatch repair deficiency were 41%, 43%, and 51%, respectively.

Patients were more likely to have guideline-aligned testing if they were female, treated at an academic center, and diagnosed with de novo metastatic disease (2). Of the 177 patients (12% of the cohort) who received anti-EGFR therapy (primarily panitumumab or cetuximab), only 50 (28%) had undergone guideline-aligned biomarker testing (2). This is especially concerning because it means that the patient could be exposed to the systemic toxicity risk from anti-EGFR therapy without benefiting from the

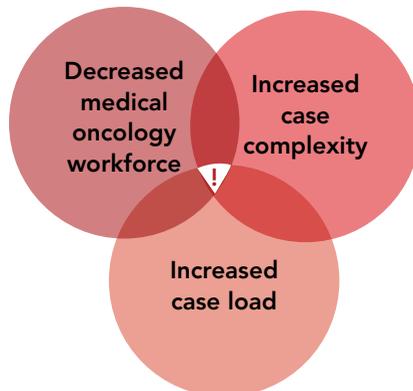
effect of anti-EGFR therapy in the presence of a *KRAS* or *NRAS* driver mutation. These results illustrate one example, in a common single cancer type, where underutilized genetic testing led to missed opportunities for guideline-supported therapies based on absent biomarker-directed therapeutic considerations.

Precision medicine stratifies patients according to predictive biomarkers associated with sensitivity to targeted cancer therapies. The impact of this approach on cancer treatment outcomes continues to grow annually. The “2020 Personalized Medicine Report” released by the Personalized Medicine Coalition reported that between 2016 and 2020, the number of personalized medicines grew from 132 to 286 (a 113% increase) (3). As of 2018, 39% of cancer therapy clinical trials employed biomarker-based inclusion criteria to stratify patients likely to respond to therapy (up from 25% in 2010). Targeted biologic therapies now represent over 90% of the total oncology development pipeline (4).

A recent study by the University of Texas MD Anderson Cancer Center's Precision Oncology Decision Support (PODS) team compared their genomic interpretations of actionability and related therapeutic options against those made by the physicians of treated patients (5). The authors found that while physicians were often able to detect hallmark hotspot alterations in their patient's molecular results, physicians frequently interpreted alterations as nonactionable when the PODS genomic annotators classified them as actionable or potentially actionable. Discordant alteration interpretations and determined actionability in some cases represented missed therapeutic opportunities for patients (5).

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### F1 Compounding Challenges in Personalized Cancer Medicine



Medical oncologists face challenges in clinical practice that compound into a scenario that reduces the amount of time they can spend per patient. As Food and Drug Administration indications continue to expand, guideline recommendations rapidly evolve, and clinical trials support expanded associations between molecular biomarkers and therapeutic options, the complexity of patient cases increases. This—combined with increased caseloads and a decreasing medical oncology workforce—has led to medical oncologists' bandwidth being more constrained than ever.

## Outlining the Need

Medical oncologists need reliable and concise strategies to clarify therapeutic recommendations that consider patient-specific characteristics. Correlating somatic alterations to a patient's clinical scenario is a time-consuming endeavor that requires continual updating to reflect the rapidly evolving information in the field of oncology. Contextualizing and sequencing somatic alteration interpretations with potential treatment options is prohibitively time-intensive for medical oncologists, a trend that will intensify even more as caseloads increase.

High patient volumes, limited time per patient, and the complexity of using somatic molecular reports are all likely contributors to why less than half of metastatic colorectal cancer patients received NCCN guideline-recommended testing and may have missed potentially beneficial targeted therapy (2). In cases in which a patient harbors potentially actionable alterations or variants of unknown but possible significance, molecular tumor boards and thorough literature searches for supporting data on the function of the alteration and related therapy options are required. Precision medicine experts can support medical oncologists by performing such interpretations and therapy considerations in a distilled consult for individual patients.

Medical oncologists often depend on a specialized pathologist to interpret and report relevant diagnostic findings. Similarly, medical oncologists with imaging needs can rely on a specialized radiologist. Conversely, in most cases, when a medical oncologist orders a molecular cancer panel, they are left to review and interpret the therapeutic application of results, often with no formal training on interpreting genomic alterations of lesser-known or unknown significance into a clinical context.

## Finding the Solution

The presence of a medically focused precision medicine consultative service has shown proven value in the context of the current complexity and time constraints that medical oncologists face. This can take the form of an in-house molecular tumor board-style service (often a mix of pathology,

medical oncology, and pharmacy) or partnership opportunities with clinical consultative companies.

This approach will help medical oncologists reduce the amount of time spent interpreting somatic alterations and ensuring that interpretations are up to date with the most recent data relevant to individual cases. In turn, this will standardize and improve clinical care. The reporting from such a consultative service is also of high impact in letter of medical necessity discussions, where the goal is insurance company support for precision oncology options. By reducing the time burden spent per patient on result interpretation and therapeutic considerations, improved time efficiency may also strengthen revenue.

## Conclusion

Utilizing a precision medicine consultative service to contextualize somatic test results relevant to individual cases, medical oncologists can combat the underutilization of guideline-aligned genomic testing and ensure a clear strategy for therapy options and the best available care for patients. ■

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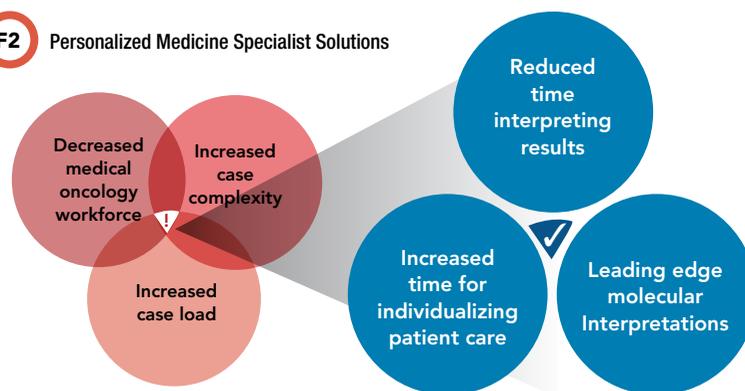
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### F2 Personalized Medicine Specialist Solutions



The challenges medical oncologists face when implementing precision medicine in clinical practice can be addressed by using personalized medicine specialists, who interpret molecular results and then individualize them to specific clinical scenarios. This streamlines and standardizes precision medicine deployment in medical oncology clinics, which in turn reduces the time needed to provide the best possible care for patients and increases the number of patients a medical oncologist can effectively treat per unit time. This approach provides clinical and financial opportunities for clinics while also providing greater value to payers.

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BY JENNIFER EICHMEYER, MS, CGC,  
AND CHRISTINE MUNRO, MS, MPH, CGC

## The Building Blocks of a Pharmacogenomic Program

From stakeholders to services, get the basics for crafting a program in this rising field of personalized medicine.

In this era of personalized medicine, the field of pharmacogenomics is experiencing significant growth and growing interest.

Pharmacogenomic (or pharmacogenetic) testing analyzes specific genetic variants to better understand how a person may respond to medications (1).

Because medication use is pervasive for treating a variety of conditions, pharmacogenomics offers a type of genetic information that could impact many of us. Current medical practice often relies on a trial-and-error approach to prescribing medications. The initial choice and dose of medications may be based on population data, but individuals vary significantly in the way they respond. Only about 50%–75% of individuals taking a medication will have the intended response (2). The goals of pharmacogenomic testing are to shorten the trial-and-error period, optimize medication dosage, and reduce the risk of side effects.

It's important to note that pharmacogenomic information is still relatively new and somewhat limited. Genetics are not the only factor that influences a person's response to medications. Other factors include sex, age, race, other medications, other medical conditions, and diet. In addition, not all medications have enough—or any—data to support changing prescribing guidelines based on genetic test results. Clinical guidelines, such as those from the Clinical Pharmacogenetics Implementation Consortium (CPIC) and PharmGKB,

can help clinicians sort out the utility of pharmacogenomic testing for their patients (3, 4, 5, 6).

### Service Delivery and Stakeholders

The delivery of pharmacogenomic testing involves numerous factors, such as assessment of the utility or appropriateness of testing, test choice, interpretation of complex results, and informed consent. Patients increasingly seek a high level of personalized care—including pharmacogenomics—so it is important to model best practices for testing and service delivery, which should include multiple stakeholders. In addition to the patients themselves, these stakeholders include laboratories, insurance companies, providers, pharmacists, and genetic counselors.

When weighing lab and test options, keep in mind that each lab has its own unique list of medication-genes covered by their test. If clinicians are interested in a specific medication, they need to make sure the lab and test includes it. Some labs offer smaller, disease-specific panels, while others offer broader panels covering many diseases, genes, and medicines. Although reference labs commonly offer gene panels, third-party payers may not cover them, which can leave the patient or billing institution with uncovered charges. The recent trends in coverage policies have been positive, but it's important to consider each patient's

coverage as well as affordable self-pay options.

There are many healthcare providers who should be involved in developing institutional practices for pharmacogenomic testing. For example, genetic counselors and pharmacists can serve as excellent resources. Genetic counselors have expertise in genetic test selection, paired with unique training in communicating complex genetic information and risk. They are trained to empower patients with information so that patients can make an informed decision.

Additionally, genetic counselors are an important patient resource when it comes to incidental findings, such as implications around the inclusion of the *APOE* gene on many pharmacogenomic panels, and implications for family members, such as the dominant inheritance of malignant hyperthermia genes.

Pharmacists have specialized training in pharmacodynamics and application of pharmacogenomic data, such as for medication adjustment. Pharmacists also are able to assess past medication history and appropriateness of such testing for a given patient. In both instances, pharmacogenomic testing is a natural extension of the services these professionals provide, and their complementary training makes them an excellent choice when considering collaborative working relationships for service delivery.

Ideally, a clinical pharmacogenomic program would integrate

several disciplines, including medical genetics, genetic counseling, health informatics, pharmacy, pharmacology, clinical pathology, and laboratories. However, it may not be realistic for all institutions, particularly those in rural or community centers, to have access to these specialty providers. At a minimum, the genetic counselor and pharmacist partnership can be quite effective, especially when working with specialties such as oncology, cardiology, pain management, psychology, neurology, and infectious disease, which all have established drug and gene pairs and could benefit from pharmacogenomic services.

In our own practice, we started with evaluating frequency of medication use and associated toxicity in our clinic, researching CPIC guidelines, and assessing test availability and costs. We then developed a multidisciplinary process in which the patient is identified as a candidate for testing via the electronic medical record system, counseling is provided by the pharmacist and genetic counselor, testing is ordered by the provider, and results with recommendations are communicated to the patient and ordering provider by the genetic counselor and pharmacist. This allows for the patient to receive necessary pretest counseling that covers benefits and, more importantly, limitations with pharmacogenomic testing. This kind of informed consent process sets the patient up with reasonable expectations and an evidence-based plan of care.

### Pharmacogenomics in Action: A Case Example

A 19-year-old female presented to a primary care clinic for evaluation with pharmacogenomic testing. The patient had an uncontrolled pain experience during a recent spinal surgery and was nervous about undergoing a second surgery for hardware removal. The patient met with a multidisciplinary team that included a pharmacist, genetic counselor, and physician.

The pharmacist reviewed the patient's medication history and initially determined she may benefit from *CYP2D6*-guided pain control. The pharmacist and genetic

counselor were able to address the utility of pharmacogenomic testing in the context of pain and the limitations of this testing. The genetic counselor also was able to provide supportive counseling around the patient's anxiety, manage expectations, and provide informed consent.

After the pretest counseling session, the patient chose to move forward with testing and was found to be a *CYP2D6*\*2/\*4 intermediate metabolizer, which is associated with reduced formation of active metabolites for opioids metabolized by *CYP2D6*. In the case of intermediate metabolizers, CPIC guidelines recommend initiating standard therapy and monitoring for adequate analgesic response before selecting an alternative agent. However, the patient was worried about having insufficient pain relief from medications such as codeine, and her primary care physician was able to recommend alternatives to *CYP2D6* substrates for her upcoming surgery.

This case example demonstrates the clinical utility of pharmacogenomic testing and highlights the benefits of a collaborative multidisciplinary pharmacogenomic service delivery model. ■

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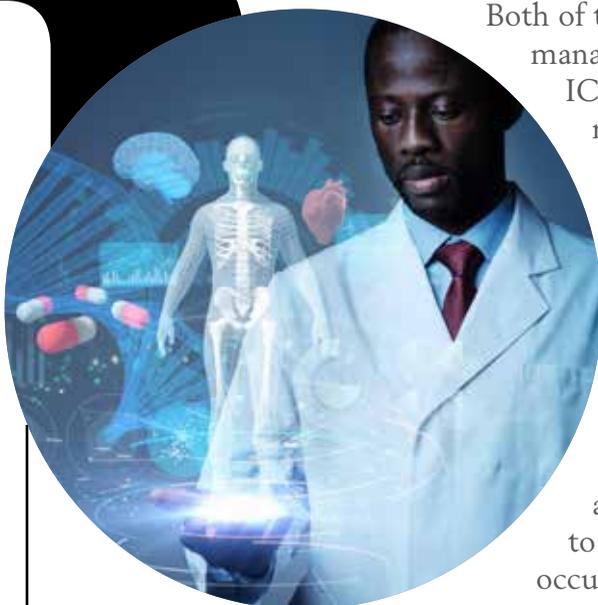
## Regulatory Roundup

### FDA Clears AI-Based Software That Predicts Hemodynamic Instability in ICU Patients

CLEW Medical, a company that specializes in artificial intelligence (AI)-powered predictive analytics, has received Food and Drug Administration 510(k) clearance for CLEWICU, the company's AI-based intensive care unit (ICU) software that predicts hemodynamic instability in adult patients. CLEWICU continuously monitors and categorizes a patient's risk of clinical deterioration and enables early intervention by providing notification that a patient is developing hemodynamic instability up to 8 hours in advance. The system also identifies low-risk patients who are unlikely to deteriorate.

Both of these functions could enable better ICU resource management and optimization, which is critical now that ICUs are dealing with unprecedented volume levels as a result of the COVID-19 pandemic.

CLEWICU bases its predictions on a broad range of patient data, including the patient's laboratory test results, vital signs, and history of medications, medical procedures, and prior hospitalizations. The system ingests this data either through periodic direct querying of the SQL database of the electronic health record or by receiving real-time HL7 messages from the hospital's interface engine. CLEWICU then analyzes the data in near real-time using AI-based algorithms and machine-learning models that are trained to identify the likelihood of significant clinical events occurring for patients in the ICU.



#### FDA GRANTS EUAS FOR SARS-COV-2/FLU COMBO TESTS

The Food and Drug Administration (FDA) has granted emergency use authorizations (EUA) to three new tests that detect SARS-CoV-2, influenza A, and influenza B. These tests are BD's SARS-CoV-2/Flu assay, Bio-Rad's Reliance SARS-CoV-2/FluA/FluB RT-PCR assay kit, and Thermo Fisher's Applied Biosystems TaqPath COVID-19, Flu A, Flu B Combo kit. The EUA for BD's test in particular includes information in the test's instructions for use that addresses testing for SARS-CoV-2 variants, including those that originated in the U.K. and South Africa. A computer analysis has shown that 99.9% of the genetic sequences of these variants are an identical match to at least one of the two molecular targets for BD's

test, which means that it can identify these variants specifically. It shares this capability with BD's standalone SARS-CoV-2 test for the BD Max system, which already has an FDA EUA. The BD SARS-CoV-2/Flu assay also runs on the BD Max system, returns results in 2 to 3 hours, and has received the CE mark as well.

#### ROCHE GETS FDA NOD FOR BK VIRUS TEST

The Food and Drug Administration (FDA) has cleared Roche's cobas BKV test for use with urine samples stabilized in cobas polymerase chain reaction (PCR) media. This test, which FDA previously cleared for use with EDTA plasma samples, aids in the management of BK virus (BKV) in transplant patients and is designed to run on the cobas 6800/8800 systems. Because

BKV DNA levels often increase in urine before they increase in plasma, healthcare professionals can now use this test for early prediction of impending infection. The test uses real-time PCR with dual-target technology, which guards against the risk of sequence variations in the virus impacting the test's accuracy. It has a limit of detection of 21.5 IU/mL and an expanded linear range of 21.5 IU/mL to  $1 \times 10^8$  IU/mL in EDTA plasma, while in stabilized urine samples, it has a limit of detection of 12.2 IU/mL and a linear range from 200 IU/mL to  $1 \times 10^8$  IU/mL.

#### CE MARK GRANTED TO QIAGEN FOR AUTOMATED MOLECULAR SAMPLE PROCESSING PLATFORM

Qiagen has received the CE mark for the QIAcube Connect MDx, a flexible platform for

automated DNA, RNA, and protein sample processing. The system fully automates the lysis, binding, washing, and elution steps of the Qiagen spin columns used to process molecular samples, and standardizes the purification of these samples as well. With features such as fully automated worktable decontamination, the system is designed to increase lab process safety, making it suitable for preparation of SARS-CoV-2 and other viral samples for diagnostic testing. The QIAcube Connect MDx comes with diagnostic and research protocols that can be used in combination with Qiagen's QIAamp DSP kits and PAXgene Blood RNA extraction kits, meaning that overall, labs can use this system with more than 80 Qiagen kits and more than 140 standard protocols.

#### HEALTH CANADA AUTHORIZES SALIVA COLLECTION DEVICE FOR SARS-COV-2 TESTING

**O**raSure Technologies has earned an Interim Order authorization

from Health Canada for the Omnigene Oral (OME-505) saliva collection device, which is a product of OraSure's Ottawa, Ontario-based subsidiary DNA Genotek. This device is intended for the collection, stabilization, and transport of saliva specimens suspected of containing SARS-CoV-2 RNA that will be analyzed with molecular diagnostic tests for the virus. With this Interim Order, patients in Canada can now use the Omnigene Oral for specimen self-collection, either at home or while supervised by a healthcare worker in a healthcare setting, and healthcare workers can also use the device for specimen collection. However, clinical laboratories adding saliva testing to their workflow must still validate the use of the Omnigene Oral with their assays prior to SARS-CoV-2 testing in accordance with applicable regulations.

Omnigene Oral also has emergency use authorization from the Food and Drug Administration, as well as the CE mark for in vitro diagnostic use in the European Union.

#### FDA CLEARS INOVA TEST FOR SYSTEMIC LUPUS ERYTHEMATOSUS

**I**nova Diagnostics has received 510(k) clearance from the Food and Drug Administration for the Nova Lite DAPI dsDNA *Crihidia luciliae* kit. This kit aids in the qualitative and/or semiquantitative determination of anti-double stranded DNA (dsDNA) IgG antibodies using the Nova View Automated Fluorescence Microscope or manual fluorescence microscopy. The presence of anti-dsDNA antibodies can be used in conjunction with other serological and clinical findings to aid in the diagnosis of systemic lupus erythematosus. When used together, the Nova Lite kit and the Nova View are designed to reduce laboratory turnaround time and technician hands-on time for the detection and titering of these antibodies.

## AACC ANNOUNCES 2021 CANDIDATES

Paul J. Jannetto, PhD, DABCC, FAACC, AACC Secretary, has announced the slate of candidates selected by the nominating committee for the 2021 AACC elections. The nominating committee identifies a single candidate for each open officer and board position and more candidates than open positions for the nominating committee. The online election process will run May 1-31, 2021, and the membership will have the opportunity to vote for or against each candidate on the single-candidate slate and to elect three members to the nominating committee through a plurality vote.

The candidates and positions are:

#### PRESIDENT-ELECT

Shannon Haymond, PhD, DABCC, FAACC; Vice Chair, Computational Pathology; Director, Clinical Mass Spectrometry Laboratory; Director of Laboratory Research Services; Co-director, Biorepository; Department of Pathology and Laboratory Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago.

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Joe M. El-Khoury, PhD, DABCC, FAACC; Director of Clinical Chemistry at Yale-New Haven Health; Associate Professor of Laboratory Medicine at Yale University, New Haven, Connecticut.

Bonny L. Van, PhD, FAACC, HCLD(ABB); Sr. Consultant, J Michael Consulting, Roswell, Georgia.

#### NOMINATING COMMITTEE

Linnea M. Baudhuin, PhD, FACMG, DABMGG; Professor of Laboratory Medicine and Pathology, Division of Laboratory Genetics and Genomics, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota.

Roger L. Bertholf, PhD, DABCC, FAACC, MASCP; Medical Director of Clinical Chemistry; Houston Methodist Hospital, Houston, Texas; Professor of Clinical Pathology and Laboratory Medicine, Weill Cornell Medicine.

Mark Cervinski, PhD, DABCC; Associate Professor of Pathology and Laboratory Medicine, The Geisel School of Medicine at Dartmouth; Director of Clinical Chemistry, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire.

Dennis J. Dietzen, PhD, DABCC, FAACC; Professor of Pathology and Immunology; Washington University School of Medicine; Medical Director, Laboratory Services; St. Louis Children's Hospital, St. Louis, Missouri.

Robert Fitzgerald, PhD, DABCC (CC and CT), FAACB, NRCC; Professor of Pathology; Director of Clinical Toxicology Laboratory; Associate Director of Clinical Chemistry Laboratory; University of California, San Diego.

Khushbu Patel, PhD, DABCC; Director of Clinical Chemistry and POC; Children's Hospital of Philadelphia; Assistant Professor of Pathology and Laboratory Medicine; Perelman School of Medicine at the University of Pennsylvania, Philadelphia.

## Industry Playbook

### Veracyte Acquires Decipher for \$600 Million

Veracyte and Decipher Biosciences have entered into an agreement under which Veracyte will acquire Decipher Biosciences for \$600 million. Through the acquisition, Decipher's expertise in urological cancers will assist Veracyte in expanding its current genomic cancer diagnostics market. The companies aim to accelerate commercialization of tests to physicians and patients across the globe.

Decipher's current test menu includes whole transcriptome analysis and machine learning algorithms to advance clinical care and cancer therapies for patients. The company has marketed its tests to all 28 National Comprehensive Cancer Network (NCCN) centers in the United States with both the Decipher Prostate Biopsy and Decipher Prostate RP test recommended in the NCCN guidelines. The company has also developed a bladder test to launch this

year and is currently working on a test for kidney cancer.

Veracyte currently focuses on diagnoses of lung, breast, and thyroid cancer as well as interstitial lung diseases. With Decipher's portfolio of prostate, bladder, and kidney cancer tests, Veracyte will not only expand its test menu but also increase distribution of its nCounter Diagnostics platform in laboratories and hospitals across the world. In addition, Veracyte will obtain Decipher's Genomics Resource for Intelligent Discovery artificial intelligence database, which holds more than 85,000 urologic cancer samples.

Under the terms of the agreement, Decipher employees, including its president and CEO, will join the Veracyte team. The companies expect the deal to be finalized in May of 2021.



#### ■ BECKMAN, GENEDRIVE ANNOUNCE SARS-COV-2 KIT SHIPMENT TO U.S.

**B**eckman Coulter and Genedrive have announced the first shipment of Genedrive's 96 SARS-CoV-2 kits to the United States after teaming up in a distribution agreement. Under the terms of the agreement, Beckman agreed to sell and distribute the kits across the U.S. and Europe.

Genedrive's 96 SARS-CoV-2 test utilizes a polymerase chain reaction (PCR) bead format that eliminates the need for the reagent preparation, including fluid dispensing steps, that is typically required by other test

kits. Patient samples are first mixed with the PCR beads, then analyzed on PCR platforms. The companies plan to utilize the test on Beckman's Biomek i7 system, which processes about 1,000 samples per day with a focus on upper respiratory samples for SARS-CoV-2.

"This is an important milestone for Genedrive as the first shipments of our Genedrive 96 SARS-CoV-2 kit are exported to the U.S.," said David Budd, CEO of Genedrive. "We are very optimistic about the U.S. market for COVID-19 PCR testing and it has market drivers that are favorable to the adoption of the Genedrive assay: efficiency, ease of use, automation-friendly, and scalability."

#### ■ HOLOGIC AND GOOGLE CLOUD PARTNER FOR ADVANCED CANCER SCREENING

**H**ologic and Google Cloud have announced a collaboration to integrate Google Cloud's machine learning technologies with Hologic's Genius Digital Diagnostics platform. The newly formed partnership aims to advance Hologic's current work in screening, diagnosing, and treating cervical cancer in women.

Hologic's Genius Digital Diagnostics system combines artificial intelligence (AI) with imaging technology to identify precancerous tissue and cancer cells. By digitizing images of patient cells, the



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AACC members who purchase the sample sets for academic research purposes will receive a significant discount.

International shipping now available.

For more information visit [www.aacc.org/samplebank](http://www.aacc.org/samplebank).

Disclaimer: AACC collected 60 mL of blood from volunteer donors attending the AACC Annual Meeting in Atlanta, GA in order to establish the 99th percentile for cardiac troponin in a healthy population. After collection, the blood was processed on site, divided into equal sample sizes and then transported to CDC for storage at -80°C. Samples were de-identified and no test results will be provided to donors. Sets of donor samples are being offered to IVD manufacturers of cardiac troponin assays for purchase. AACC has undertaken this activity as part of its mission to further scientific research. THE DONOR SAMPLES ARE PROVIDED "AS IS". AACC DISCLAIMS ALL WARRANTIES INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

system has the ability to provide clear visuals of up to 400 test slides at once for thorough screening. The companies hope to integrate Google Cloud's machine learning expertise to gain greater insights into the screening process for cytotechnologists and pathologists. According to the partners, Google Cloud will complement the cytology platform by providing a secure data cloud for patient information.

Both Hologic and Google Cloud hope to further explore the combination of AI and machine learning in diagnostics to improve patient healthcare. Hologic's Genius Digital Diagnostics platform is currently CE-marked for use in Europe.

#### BRUKER TO ASSESS AVACTA SARS-COV-2 ASSAY

**A**vacta Group is collaborating with Bruker Corporation to allow Bruker to assess its bead-assisted mass spectrometry (BAMS) SARS-CoV-2



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assay, which was developed from a previous partnership between Avacta and Adeptrix in 2020.

Under the partnership between Avacta and Adeptrix, the companies developed the antigen test that combined Avacta's Affirmer-based reagents, which bind SARS-CoV-2 protein to capture virus particles from a patient sample, and Adeptrix's BAMS platform, which utilizes mass spectrometry to monitor existing and emerging viral strains. According to Avacta, the BAMS SARS-CoV-2 assay allows analysis of up to 1,000 samples a day by a single technician.

Through the agreement with Bruker, Avacta hopes to further development of the test as an in vitro diagnostic product for SARS-CoV-2 and make it available for clinical microbiology laboratory use. The companies plan to run the test on Bruker's MALDI-TOF instruments currently commercialized in the U.K. and Europe.

#### LIGHTDECK RECEIVES \$5.65 MILLION FROM BARDA

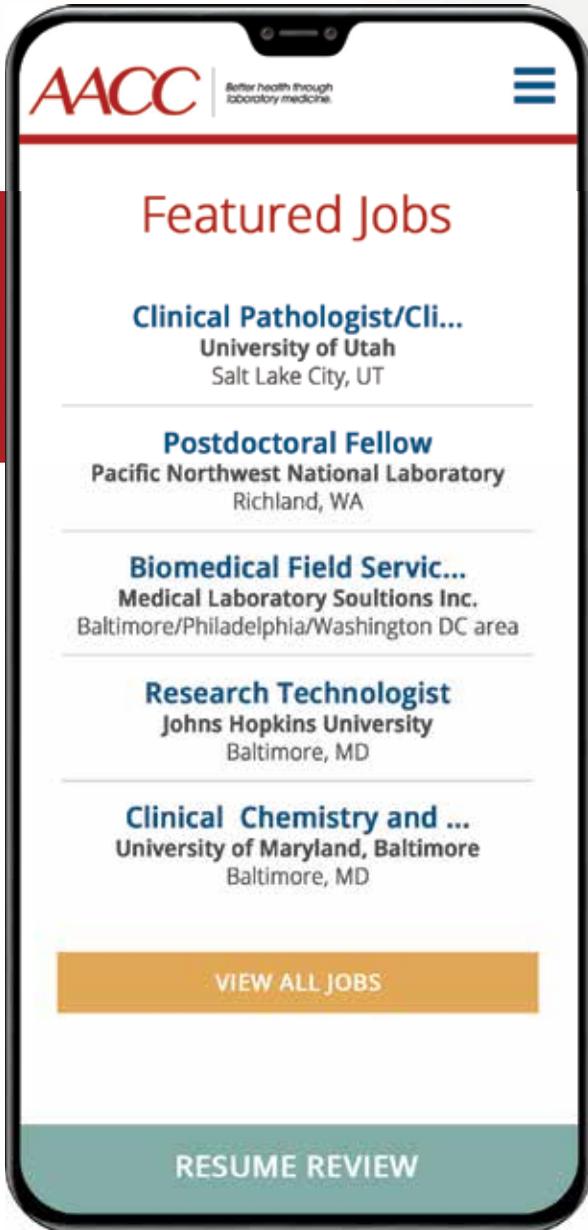
**T**he Biomedical Advanced Research and Development Authority (BARDA) has granted LightDeck Diagnostics \$5.65 million in funding to further development of a rapid antigen test to detect SARS-CoV-2.

LightDeck's COVID-19 antigen test will build on its pre-existing platform that combines laser waveguide technology with cost-effective manufacturing techniques for highly sensitive and simple testing processes that can deliver results at any time and place. According to the company, the antigen test has the ability to deliver accurate and scalable patient results in less than 6 minutes.

The company previously received \$11 million in funding from Series B to support its portfolio of in vitro diagnostic tests. The company plans to combine funding from both Series B and BARDA to advance its COVID-19 testing strategy.



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## Ask The Expert

# Using Human Chorionic Gonadotropin as a Tumor Marker



EXPERT

By Kevin F. Foley, PhD, MT, DABCC

**Which tumor types produce human chorionic gonadotropin (hCG)?**

**A:** For more than 30 years, laboratories have used serum hCG testing in patients with gynecological and germ cell tumors to aid in evaluating therapeutic response and recurrence or metastasis. The use of hCG as a tumor marker is most common in

seminomatous and nonseminomatous testicular tumors, ovarian germ cell tumors, the gestational trophoblastic diseases (GTDs) hydatidiform mole and choriocarcinoma, and nontesticular teratomas. Other tumor types that are more rarely associated with hCG elevations include hepatic, neuroendocrine, breast, ovarian, pancreatic, cervical, and gastric cancers.

**Can laboratories use hCG pregnancy assays for tumor marker testing?**

Interestingly, there are currently no Food and Drug Administration-approved hCG assays specifically intended for use in cancer patients. This means that the only hCG tests available are pregnancy assays and that their use for tumor monitoring is considered off-label. However, published reviews have shown that several of these assays have sufficiently broad specificity and sensitivity to justify their use in oncology settings. These include assays such as the Immulite 2000, Elecsys 2010, Advia Centaur Total hCG, and the Architect Total hCG.

Like most serum hCG immunoassays, the tests above are designed to pick up as many hCG isoforms as possible. They recognize the holo-hormone (an alpha-subunit bound to a beta-subunit), “nicked” or unglycosylated forms of hCG, as well as hyperglycosylated forms, beta-core fragments, and free beta-subunits. There are also assays that specifically measure free alpha- and beta-subunits. This is noteworthy because, in malignant cells, the balanced ratio of alpha- and beta-subunits can be altered, leading to the secretion of excess free alpha- and beta-subunits. Some laboratories offer these independent alpha and beta measurements, but they are less commonly used than total hCG assays.

**When is hCG monitoring specifically recommended?**

According to clinical practice guidelines from numerous medical associations, the use of hCG as a tumor marker is limited to a few specific settings. These guidelines recommend it in the workup and monitoring of

patients with suspected or known germ cell tumors of the testes and patients with GTD.

However, there is less consensus about using hCG in patients with germ cell tumors of the ovary, as ovarian cancer monitoring is more commonly performed using the tumor marker CA-125. The European Group on Tumor Markers as well as AACC Academy do not recommend routine use of hCG for ovarian tumors, while the National Comprehensive Cancer Network states that hCG can be measured to assess less common ovarian histopathologies.

**How frequently should hCG be measured in cancer patients?**

AACC Academy has made recommendations concerning the frequency of tumor marker measurements in the follow-up of testicular cancer. They recommend four to six tests per year for the first 2 years post-treatment and two tests per year thereafter. They specifically note that up to 12 tests may be useful during the first year in germ cell tumors of advanced stage. Importantly, since individuals serve as their own baseline, increases in hCG within a specific patient are more important than the absolute concentration and a single increasing value should be confirmed with repeat testing.

In GTD, hCG monitoring is typically performed over a shorter period of time with a higher frequency in an effort to monitor short-term chemotherapy (such as methotrexate). Post-molar gestational trophoblastic neoplasia is indicated if hCG values plateau over a period of at least 3 weeks or increase over a 2 week period. AACC Academy also recommends that hCG values be checked 6 months after evacuation to confirm treatment. Other associations recommend that hCG testing in GTD be done every 14 days, following 14-day methotrexate or dactinomycin treatment, until hCG levels return to normal.

**Kevin F. Foley, PhD, MT, DABCC**, is the director of clinical pathology for Kaiser Permanente Northwest, Oregon.  
+EMAIL: Kevin.F.Foley@kp.org

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# CLN

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SCALING UP  
SARS-COV-2  
TESTING



Number of tests performed  
at North West London Pathology  
in 24 hours

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## Rising To Meet The COVID-19 Challenge





# Stepping Up During a Global Pandemic

Five award winners show how clinical laboratories reacted to COVID-19 with speed and innovation.

BY KIMBERLY SCOTT

At the beginning of the COVID-19 global pandemic in 2020, clinical laboratories around the world were called on to ramp up diagnostic testing for the SARS-CoV-2 virus to help mitigate spread of the infectious disease. From North America to Europe to the Middle East and beyond, labs moved quickly to validate new systems, enact new protocols and deliver test results in a timely manner. These actions were essential for healthcare organizations to continue providing much-needed patient care.

AACC, Abbott and other leading healthcare organizations have recognized a number of these clinical laboratories through the UNIVANTS of Healthcare Excellence Program, a prestigious global award program designed to celebrate innovative efforts that have improved patient

care. Interdisciplinary teams, which either include laboratories or are led by laboratory professionals, are scored on development of integrated care initiatives that achieve measurable impact within healthcare systems. Below, we highlight five COVID-19-related initiatives that were recognized with “distinction” or with “achievement” in 2020. (A sixth initiative, “Novel Collaborative Approach among Public and Private Sectors for Streamlined SARS-CoV-2 Testing Toward Optimized Patient Outcome During COVID-19 Pandemic,” was highlighted in the December 2020 issue of *Clinical Laboratory News*).

### MAXIMIZING RESOURCES FOR TIMELY COMMUNICATION

When the COVID-19 pandemic began to affect the province of Nova Scotia in spring 2020, leaders recognized that contacting patients with their test results would be a challenge. As testing ramped up, more than 60 Nova Scotia Public Health staff members were responsible for delivering test results to more than 40,000 Nova Scotians by phone. Most results were given within a 48-to-72-hour timeframe — a pace that threatened to overwhelm the staff.

Leaders at Nova Scotia Health began considering ways to notify patients with negative results via email to save the staff time. Patients whose test results came back positive would get a phone call from the Public Health Department. The organization developed a fully automated and secure in-house application that combines data from two systems (the registration systems and lab information system) and identifies which patients the email notifications should go to. The notification includes a link to a webpage managed by Nova Scotia Health, where patients can view their results.

The solution went live in June 2020. Between June and December 2020, 85,849 emails were sent, with 71,776 people accessing their online information via a unique link, said Lauren MacDougall, senior communication adviser for Nova Scotia Health. By clicking on the link and entering the last four digits of their provincial health card number, individuals are

able to access their results. There is no personal information in the email itself.

“Patients are now receiving negative test results within a day, whereas prior to this technology it would have taken two to three business days,” said MacDougall. “A decrease in wait times provides patients and their families peace of mind sooner, reducing overall stress and anxiety.”

Given that each phone call or voicemail to deliver a negative test result takes two to three minutes, the solution is estimated to have saved staff 3,577 hours between June and December 2020, for an approximate savings of \$107,310 CDN. Staff that otherwise would be calling patients are now able to spend their time supporting schools and community partners.

The initiative, which was recognized by the UNIVANTS of Healthcare Excellence program with achievement, is being scaled up within the province, noted MacDougall. “Nova Scotia Health has adapted the application to be used for mandatory postsecondary student testing, and we continue to work with our partners and other testing scenarios that the application could be used for to deliver negative test results,” she says.

### STRATEGIC SARS-COV-2 TESTING FOR WORKERS AND PATIENTS

The ability to track, trace and quarantine individuals infected with SARS-CoV-2 is essential to minimizing transmission and maximizing the health of the population. Protective measures are especially crucial in hospitals, where risk of transmission is high and potentially lethal. A team at Marienhospital in Stuttgart, Germany, early in the pandemic developed and implemented new policies and procedures to maximize the health and safety of patients and healthcare workers. These policies and procedures have resulted in low transmission of the virus to healthcare workers and patients and have allowed the hospital to return to almost normal operations.

Under the new procedures, all inpatients are tested upon admission. Nasopharyngeal swabs are collected from high-risk patients one day prior to admission; for low-risk patients, the swabs are collected on

day of admission. High-risk patients are quarantined until test results are available, while low-risk patients are treated with normal precautions, such as wearing face masks and social distancing. High-risk healthcare workers, such as those working on COVID-19 wards, are tested every other day. Low-risk healthcare workers and outpatients with risk of transmission (e.g., dental patients) are tested every four weeks, according to Matthias Orth, MD, PhD, head of the Institute of Laboratory Medicine.

Average turnaround time on the tests is 10 hours, and more than 95% of the test results are reported on the same day. Not only does the quick turnaround time allow for rapid quarantining of infected patients, it also reduces avoidable anxiety among those waiting for results, Orth noted.

In total, the hospital has had about 200 healthcare workers believe to have contracted COVID-19 outside of the hospital. Until the fall, when the region began experiencing a second wave of infection, there were no cases of healthcare workers being infected on the job, or iatrogenic infection. However, during the second wave, there were two small outbreaks that started with patients who tested negative on admission and became positive afterward. In one case, the patient contracted COVID when dialyzed in her dialysis center (not within the hospital). In the other case, a patient became infectious five days after admission and transmitted the virus to healthcare workers and other patients.

“Both outbreaks were detected by our sentinel screening scheme, but it took quite some time and effort to stop the outbreak — the second infected patient was on three different wards with lots of contacts,” said Orth. “Our patients are admitted with bacterial pneumonia or a rather bad health status, and it is difficult to detect the beginning of a COVID-19 infection in these sick patients.”

**85,849**

The number of SARS-CoV-2 results sent by email between June and December 2020

**3,577**

The estimated staff hours saved, for an approximate savings of \$107,310 CDN

In 2020, the hospital treated 372 patients with COVID-19, with 52 fatalities. In January of 2021, the hospital treated about 100 patients, with 15 fatalities. The hospital also transformed three wards to COVID-19 wards, and one of its two intensive care units was treating only COVID-19 patients.

Implementation of strategic SARS-CoV-2 testing and COVID-19 protective measures has enabled Marienhospital to resume operations at 95% capacity, a more than 50% increase since the start of the pandemic. Despite some federal compensation for strategic distancing, the resumed capacity has enabled

hospital revenue comparable to the services rendered pre-COVID, said Orth.

Healthcare workers who require a two-week quarantine incur at least 2,500 euros in direct-labor costs to the healthcare system, along with additional lost labor costs.

Because of its sentinel testing system the hospital estimates potential cost avoidance as high as 1.5 million euros in direct labor costs for healthcare workers alone in a three-month period.

With limited outbreaks tied to patients within the hospital, the testing initiative, which was recognized by UNIVANTS with achievement, is a success, noted Orth. “The concept gave a very high level of safety for patients and personnel,” he said. “We had the chance to introduce the sentinel testing system in late spring when the prevalence was low. With the second wave coming last fall, we were very well prepared and were able to solve our challenges very smoothly.”

#### SUPPORTING BETTER OUTCOMES THROUGH DATA, INNOVATION, COLLABORATION

At the beginning of the COVID-19 pandemic, Public Health England (PHE) laboratories had a considerable backlog of tests for SARS-CoV-2, and National Health Service (NHS) laboratories were asked to provide additional support to hospitals. In March 2020, North West London Pathology (NWLP), an

NHS pathology partnership serving three major London hospital trusts (Imperial College Healthcare NHS Trust, The Hillingdon Hospitals NHS Foundation Trust and Chelsea and Westminster NHS Foundation Trust) began providing in-house testing for COVID-19, which enabled the three trusts to stop sending their SARS-CoV-2 tests to the PHE labs.

NWLP introduced multiple SARS-CoV-2 assays to ensure that the testing service was flexible, resilient and could cope with any challenges, such as supply shortages, explained Saghar Missaghian-Cully, managing director of NWLP and pathology incident director for the network. Teams within NWLP worked closely together to ensure there was enough staff to cope with the increased demand to process tests. Staff within NWLP were deployed from other teams to work in the Infection and Immunity Division to support and assist colleagues. For example, staff within the renal transplant service were deployed into a new laboratory set up solely for SARS-CoV-2 testing.

“We collaborated with colleagues from Imperial College London and the Dementia Research Institute to set up a dedicated COVID-19 laboratory using a novel diagnostic solution,” said Missaghian-Cully. “The solution repurposed high-throughput robotic technology first used in our laboratories in April 2020 with more testing modules purchased a few months later to increase capacity. Unlike the vast majority of testing equipment worldwide, the new platform was not reliant on specific reagent suppliers. This means our service was more resilient, as different kinds of kits could be used on the same platform.”

NWLP was able to ramp up testing quickly while also reducing turnaround time. The practice went from having no COVID-19 testing to having the ability to process more than 2,400 tests in a 24-hour period. NWLP currently has the capacity to process 3,000 tests per day and is able to meet the demand for testing. The current average turnaround time is nine hours from receipt within the laboratory, and 100% of samples are processed in 24 hours.

According to Missaghian-Cully, NWLP expanded its testing capacity

**95%**  
of test results  
reported on the  
same day

**10 hrs**  
average turnaround time  
for SARS-CoV-2  
tests

**50%**  
increase in hospital  
capacity since phase I of  
the pandemic



by introducing new assays and different platforms, including rapid testing options. It is an ongoing process, she says, noting that NWLP continuously reviews its service to see how it can improve and utilize its labs and staff as effectively as possible.

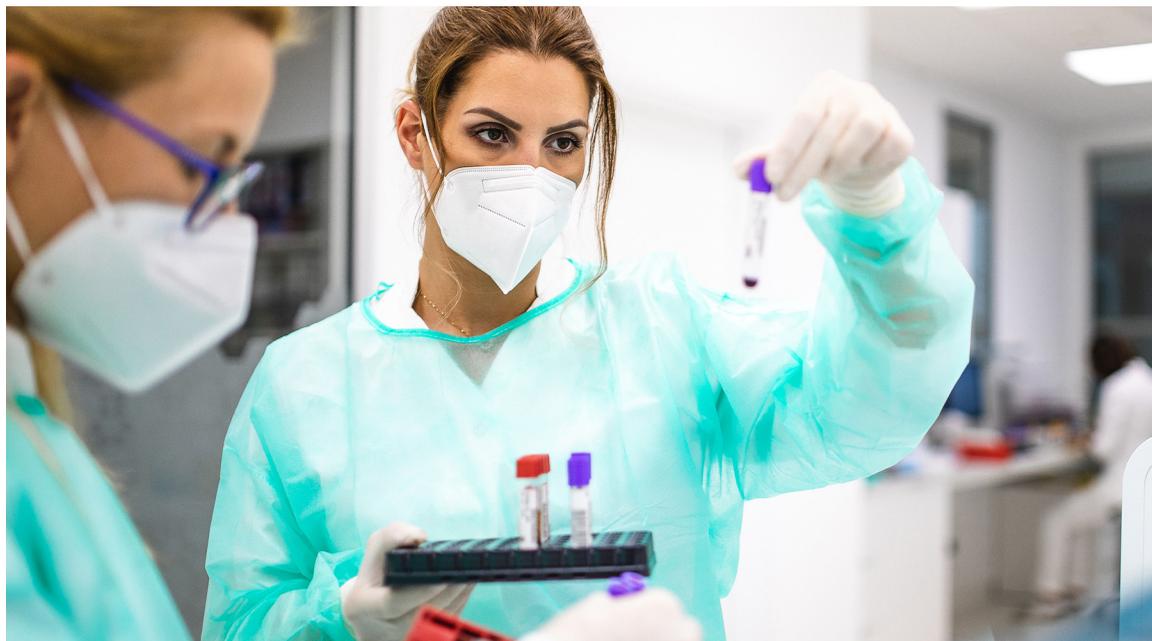
“Using data has been incredibly important — it has enabled us to monitor the situation in real time,” she explained. “We are able to use the data to monitor and review our performance on a daily basis, such as turnaround times, staffing levels, number of tests processed each day, patient epidemiology and to identify hospital-acquired infections. We produce daily reports to share relevant data with our key stakeholders in each of the hospital trusts we serve.”

The data was used to drive decisions to ensure the service was operating as efficiently and effectively as possible, noted Missaghian-Cully. NWLP’s senior management team was able to use the data during its daily operational updates to determine such things as staff sickness rates, which could have affected the service’s capacity to deal with the pandemic.

The clinical care initiative, which was recognized with achievement, is highly scalable, said Missaghian-Cully. She notes the way the teams worked together and across disciplines was exemplary. “We could implement the same or similar structures for any project bringing expertise from across our organization to achieve success,” she said.

### LABORATORY-LED SCREENING FOR BACK-TO-WORK PROGRAMS

In an effort to help businesses reopen safely in the midst of the COVID-19 pandemic, a multidisciplinary team within Dr. Suliman Al Habib Medical Group (HMG) Hospital in Riyadh, Saudi Arabia, identified an opportunity to leverage insights and services from the clinical laboratory to develop a COVID-19 screening program for employees returning to work. The initiative involved offering both PCR diagnostic testing to identify active viral replication as well as antibody testing to identify past viral exposure and potential transient immunity. The group offered screening services to diverse companies,



institutions and sports centers, according to Faisal Abdullah Al Owaidi, laboratory director at the hospital.

“Our care team focused on risk mitigation through strategic collaborations with industrial business owners via employee-wide screening programs in support of their returning back to work business strategies and timelines,” said Al Owaidi. “The goal was to maximize productivity and employee safety while minimizing virus transmission and loss of work due to new infection and quarantines.”

Early results from a screening of 267 employees at one company showed that 79% of them (210) had no active virus, but that 56% of those (118) were positive for the SARS-CoV-2 IgG antibodies, indicating a past infection. Identifying active infection is critical for quarantining infected individuals and reducing transmission, but identifying those with antibodies is also important, noted Al Owaidi.

“During pandemics, fear can prevent many individuals from seeking care when they need it while triggering other individuals to seek care when they don’t,” he said. “Patients with known antibody presence are more likely to seek care without fear of infection, and patients who now know that they do not have the disease aren’t coming to my facility for fear that they might.”

The PCR and antibody testing allowed the company to quarantine only those employees with active infection, while those with no infection or past infection could continue to work using safety protection and social distancing. With an average salary of 6000 Saudi Riyal (SAR) per employee, the company avoided lost labor as well as paid sick leave in up to 79% of the company employees, according to the hospital’s data.

The new screening initiative, which was recognized with achievement, has created a new revenue stream for the clinical laboratory and is helping offset some of the revenue that was lost during the early days of the pandemic.

The creation of algorithms and consultation on test interpretation were important first steps in support of the return-to-work program, noted Al Owaidi. While companies must pay for the testing and services provided, the value of risk mitigation and the health and financial benefits far outweigh the cost of testing.

### MAINTAINING HIGH QUALITY CARE DURING THE PANDEMIC

Early in the pandemic, the Österreichische Gesundheitskasse (ÖGK), the largest social health

**2,400**  
Number of tests North West  
London Pathology can perform in  
24 hours

**9 hrs**  
Average turnaround time  
for SARS-CoV-2 tests

insurance fund in Austria serving more than 7.2 million people, established strict safety measures to protect both patients and employees. In Vienna, the ÖGK Hanusch Hospital (HKH) and four ÖGK healthcare centers tightly controlled hospital and ambulatory patients to minimize infection rates until treatment or vaccinations became available.

The Hanusch Hospital is a third-priority hospital in Vienna, taking in COVID-19 patients only when priority one and two hospitals reach capacity. In the first stage of the pandemic, a multidisciplinary team — including laboratory, hygiene, infection control, and clinicians — prepared a safety protocol for the HKH and the four

ÖGK healthcare centers. This protocol consisted of PCR testing for SARS-CoV-2 with results within eight hours, a separate entrance for patients and healthcare workers, patient entrance control and use of protective masks, according to Johann Bartko, MD, PhD, a specialist for medical and chemical laboratory diagnostics.

All patients admitted to the hospital were tested prior to admission. Ambulatory patients and ÖGK healthcare workers were tested if there was any suspicion of infection. During

lockdown from mid-March to the end of April 2020, patient care, including elective surgeries in the HKH and the healthcare centers, was reduced by up to 70%. The safety protocols allowed the healthcare centers to reopen access to care, which reached almost 90% of prepandemic levels by the end of July with no uncontrolled transmission seen among patients and healthcare workers.

In June 2020, the ÖGK offered all their employees antibody testing so they could find out their immunity status. Overall seroprevalence in ÖGK employees in Vienna was 2.67% (66 out of 2470). Asymptomatic infections were seen in 34% (23 out of 66) of healthcare workers. No uncontrolled transmission was seen in the slow reopening that began in mid-April, said Bartko.

From the end of March to the end of July, 8,304 tests were performed with a confirmation rate of 0.41% (nine confirmed healthcare workers, eight hospital patients and 16 patients in ambulatory care). These results are an indication that the safety protocols were successful in reducing the spread of the virus, which allowed the

healthcare centers to continue serving patients, including those in need of emergency care

who may have put off coming to the hospital, said Bartko.

“Between mid-March 2020 and mid-April 2020, the lab was running at only 50% capacity, compared with the same time period in 2019,”

he said. “This was partially due to shift work, which was established in the lab to avoid the spread of COVID-19 among employees. Reduction in testing also included troponin, the key biomarker in the diagnosis of myocardial infarction. There were only 110 elevated troponin results during the lockdown period, in contrast to the 213 positive results in the year before. Notably, the number of patients with elevated troponin results are now approximating the prelockdown rates.”

Given the low number of patient and healthcare worker infections that occurred after implementation of the safety protocols, the initiative is considered a success, said Bartko. He notes that patient care can be maintained even when community spread of the virus is increasing.

**90%**  
level of ambulatory care possible by July 2020 after 70% reduction during lockdown

**2.67%**  
Overall seroprevalence in ÖGK employees in Vienna in June 2020

**56%**

of employees at one company tested positive for the SARS-CoV-2 IgG antibodies, indicating past infection

## Teams Recognized In This Issue

Strategic SARS-CoV-2 Testing for Risk Mitigation and Optimal Health of Healthcare Workers and Patients | Marienhospital  
Matthias Orth, Markus Bauer, Stefan Reinecke, Sr., Karin Johanna Haase

Maintain High Quality Patient Care During the COVID-19 Pandemic | Institut für Medizinische und Chemische Labordiagnostik, Mein Hanusch Krankenhaus  
Nazanin Sédille-Mostafaie, Johann Bartko, Andreas Krauter, Elisabeth Zwettler, Felix Keil, Andrea Schlögl

Maximizing Delivery Method and Clinical Resources for Timely Patient Communication of COVID-19 Status | Nova Scotia Health  
Lauren MacDougall, Jamey Martell, Amy MacDonald, Pam Butler, Don Doiron, Linda Plummer, Mark Ralph, Karen Drakes, Andrew Smith

Laboratory-Led Company-Wide Screening Programs for Safe, Back to Work Strategies during COVID-19 Pandemic in Saudi Arabia  
Dr. Suliman Al Habib Medical Group  
Faisal Abdullah Al-Owaidi, Abdullah Nasser Al-Jurayyan, Tarif Imadeddin Bizrah, Nasser Mohammed Al-Huqbani

COVID-19: Using Data, Innovation, and Collaboration to Support Better Patient Outcomes (1372) | North West London Pathology  
Saghar Missaghian-Cully, Paul Nacmanson, Paul Randell, Gabriel Roberts, Panos Pantelidis, Leanne Hughes, Helen Hobson

### QUICK RESPONSE TO PANDEMIC IMPROVES PATIENT CARE

The initiatives highlighted above are just a few of the many projects across the world in which clinical laboratories reacted quickly to the COVID-19 global pandemic. Beyond simply providing test results, clinical laboratories take an active role in improving patient care and enabling healthcare institutions to continue serving their communities, even as they confront an infectious disease. To learn more about these initiatives, as well as others recognized by the UNIVANTS of Healthcare Excellence awards, go to [www.diagnosticsabbott/us/en/univants-healthcare-excellence](http://www.diagnosticsabbott/us/en/univants-healthcare-excellence) or [www.univantshce.com](http://www.univantshce.com). ■

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