

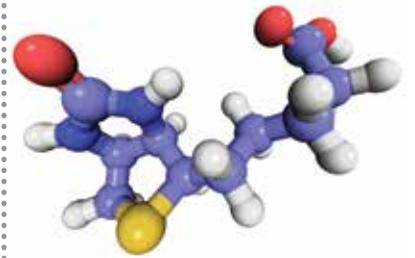
March 2022

C L N

Clinical
Laboratory
News

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TO DEAL
WITH BIOTIN



Assay redesign bests biotin depletion protocol.

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How to
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The hospitalization rate in the 2020–2021 flu season was just 0.7 per 100,000 people, the lowest since the CDC started to collect data in 2005.
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Non-COVID-19 Testing Declined Sharply in 2020

Medicare spent significantly more on clinical laboratory testing in 2020 as the COVID-19 pandemic drove demand for SARS-CoV-2 testing. But the data, released in a report from the Department of Health and Human Services Office of Inspector General (OIG), also reveals a decrease in non-COVID-19-related testing of more than \$1 billion.

Overall spending increased 4%, from \$7.7 billion in 2019 to \$8.0 billion in 2020, with \$1.5 billion in new spending on SARS-CoV-2 tests. Spending on rapid SARS-CoV-2 tests alone reached \$1 billion. The report noted that while routine testing fell dramatically, part of the reduction in spending on other tests was due to reductions in payment rates required by the Protecting Access to Medicare Act of 2014. Since OIG began reporting this data in 2016, total spending increased each year by an average of 4.3% per year.

OIG did find that while non-COVID-19 testing recovered in the second half of 2020, the number of non-COVID-19 tests Medicare paid for during the full year still declined by 12%. Chemistry tests are the largest category by volume and spending, and their decline led the overall slump with a full 12% drop in volume, from 174 million in 2019 to 153 million in 2020.

OIG said that the decline in non-COVID-19 testing “raises questions about the potential impacts on beneficiary health ... If Medicare beneficiaries delayed or avoided preventative healthcare services, they may not have received important tests, such as cancer screenings, that are medically necessary but not urgent. Research suggests that delays of such lab tests could have a long-lasting impact.”

Medicare Spending on Lab Tests



Source: OIG analysis of 2016–2020 spending on lab tests in Medicare Part B, 2021.

NEW STANDARD FOR OPIOID WITHDRAWAL IN INFANTS

The Department of Health and Human Services (HHS) and a group of clinicians and policy experts have published a standard clinical definition for opioid withdrawal in infants (J Pediatr 2021; doi: 10.1016/j.jpeds.2021.12.021). Notably, it also includes principles on bioethical uses for the definition, emphasizing that it is not meant to prove or imply harm and should not be used to assess child social welfare risk or status.

The number of mothers with opioid-related diagnoses documented at delivery increased approximately 130% from 2010 to 2017, HHS said. And infants with opioid exposure and withdrawal lack consistent diagnosis and care.

The new clinical criteria for diagnosis require the presence of two

sets of clinical elements. The first includes in utero exposure to opioids with or without other psychotropic substances. It's recommended this be collected via confidential maternal self-report or through toxicology testing with maternal informed consent. This should be combined with any two clinical signs: excessive crying, fragmented sleep, tremors, increased muscle tone, or gastrointestinal dysfunction.

The lack of a standard definition “has been a historical gap in the care of mothers and infants affected by opioid exposure, and created inconsistencies in diagnosing infants,” the report said.

RECORD NUMBERS SIGN UP AT HEALTHCARE.GOV

The Biden Administration released data showing that a

record-breaking 14.5 million people signed up for healthcare coverage in 2022 through the federal marketplaces, including 5.8 million people who have newly gained coverage. This is about 20% higher than last year.

The American Rescue Plan Act (ARPA) lowered costs for most marketplace consumers: HealthCare.gov consumers saw their average monthly premium fall by 23% compared with the 2021 enrollment period that ended before the law passed.

It will be up to Congress whether to extend the subsidies from the ARPA past their expiration at the end of 2022. The Congressional Budget Office has estimated that the temporary subsidies under the ARPA would increase federal deficits by \$34.2 billion. Without an extension, the average premium could double, according to analysis by the Kaiser Family Foundation.

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How One Laboratory Navigated a Successful LIS Conversion



By Kacy Peterson, MBA, MLS (ASCP)^{CM}, DLM (ASCP)

Laboratory information systems (LIS) have arguably become the single most critical component of laboratory operations. Common functions of an LIS include storing patient data, receiving test orders, sending orders to laboratory analyzers, tracking and resulting orders, transmitting orders to an electronic health record (EHR), and setting reference ranges and alerts of critical values. Many laboratories also use their LIS for tracking quality control, data mining, and more. An LIS is the brains of the laboratory, and disrupting that flow of data is a large event—even when planned, as in our hospital’s recent LIS conversion.

Early Planning Stages

A successful LIS conversion or implementation starts with planning and assessing risks from an early stage. In our case, the LIS is part of a larger, comprehensive EHR system. It was imperative that our laboratory had a seat at the table from the very beginning of the project. During the early planning stages, the hospital makes many foundational decisions and weighs priorities. It is important that all stakeholders and decision-makers understand that the LIS functionality has as much impact on patient care as those functions directly visible in patient care settings, such as

emergency department tracking, nursing documentation, provider discharge, and more. It was therefore vital to our success that our laboratory was vocal at the time when the hospital was making initial decisions forming the foundation of functionality.

Registration and medical necessity checking were two functions that were not initially considered pertinent to our laboratory but had significant impact on outpatient laboratory operations. Through early planning sessions, we were able to better understand the significance of both. As the registration module was being built, the “registration” or “patient access” team was appropriately the primary stakeholder. However, the registration structure also had to work for patient visits that solely had an outpatient lab draw. Requiring a full and extensive patient registration for those visits was not efficient for high

volume lab service centers, so our laboratory needed to be an involved secondary stakeholder. In addition, stakeholders were discussing new modalities such as cloud-based “hold queues” for all ancillary services order placements—including laboratory—and our laboratory’s early involvement in that conversation resulted in a much more successful outcome.

Identifying the Risks

Identifying risks prior to conversion is imperative for patient safety. Patients may have no history in a new system,

reference ranges, pop-up comments not working correctly, and more minor errors that can easily be overlooked.

We also found it important to make the issue notification process extremely easy at the bench during go-live. For example, asking staff to use sticky notes to identify issues was a simple yet effective way to quickly document problems with functionality. It also provided staff with visibility around which issues had been identified and were actively being worked on. We found it easy to move sticky notes across “identified,”

Deploying small incentives for “good catches” can go a long way toward encouraging staff to speak up during testing.

so automated delta checks will not be present. Looking back at patient history can also be difficult or even impossible. Transfusion services could be impacted, as patients may not have a historical blood type in the system. The American Association of Blood Banks’ guidelines may require a second draw for blood type recheck prior to transfusion if blood bank history is not available, creating operational impact and potential delays for months after the go-live stage. These are just a few examples of why it is important to assess your risk early and throughout your planning and preparation phases and to employ ongoing monitoring for any patient impact post go-live.

Engaging Staff

It is important that laboratory managers encourage staff to identify and bring forward any and all functionality issues during pre-live testing and post go-live. Being as thorough as possible during pre-live testing is essential. Deploying small incentives for “good catches” can go a long way toward encouraging staff to speak up during testing. We used the old standby—chocolate! We gave out candy bars for things such as inverted numbers in

“in process,” and “completed” columns for optimal visibility. Leaders also used these boards to track department-level issues and to monitor and combine issues that were common to all areas.

Establishing Partnerships

One unexpected benefit of our work on the LIS conversion in the early stages was building relationships with our IT partners and other stakeholders. Our close collaboration on planning created trusted partnerships that made navigating any go-live or post go-live issues easier. By starting these conversations early, we were able to educate our IT partners on reasons for any pushback and change requests. During the beginning of the project, we gave tours of our lab to our IT partners, helping them connect our conversations with real-world, day-to-day operations. Early on, we also identified a few individuals within the IT team that would be the laboratory advocates and developed those relationships further. When crunch time came on go-live day and after, we communicated and resolved problems more efficiently with those foundational relationships already in place.

Documenting Lessons Learned

As in any large-scale IT implementation or conversion, there will always be lessons learned. Having a debriefing post go-live with all stakeholders is another important step in the total process. While it may be a decade or more before another total LIS conversion or implementation is needed, this blueprint can help you navigate any future changes or developments within your current LIS or larger EHR system.

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The Sample

An Alternative to Biotin Depletion Methods

If manufacturers redesign their immunoassays to include preincubation of biotinylated capture antibody to streptavidin, they could make them more accurate and robust against biotin interference (J Appl Lab Med 2022; doi: 10.1093/jalm/jfab169).

Streptavidin-to-biotin binding, among nature's strongest noncovalent interactions, is incorporated into many immunoassays. It makes them susceptible to interference from free biotin in patient specimens and can produce inaccurate results.

Biotin interference has been particularly problematic in thyroid hormone assays in cases involving multiple sclerosis patients on 300 mg/day of biotin therapy. Some of these patients have been misdiagnosed with Graves' disease because of falsely elevated thyroid hormones. Interference also has been a problem with parathyroid hormone and testosterone immunoassays, leading to misdiagnosed hypoparathyroidism and testosterone-secreting tumor, respectively, in patients taking 5–10 mg of biotin/day for hair and nail growth.

To prevent biotin interference, researchers developed a method to preincubate biotinylated antibodies to the assay's streptavidin solid surface before adding patient specimens. The researchers compared this technique to a biotin depletion protocol. The researchers established biotin interference in three manual ELISA assays and two automated immunoassays and evaluated mitigation of biotin interference by preincubation in each. The evaluation involved adding biotinylated antibody to the streptavidin-coated surface before adding biotin- or PBS-spiked serum.

In the presence of 400 µg/L biotin, the researchers found analyte detection reduced to 10%–15% of total in the ELISA assays. In the automated sandwich (thyroglobulin) immunoassay, analyte detection was reduced to 15.2% of total. In the automated competitive (free thyroxine) immunoassay, biotin caused increased detection of 551.6%. Preincubation of the biotinylated capture antibody to the streptavidin surface in the ELISA assay resulted in 84%–99% activity recovery, compared to 84%–97% by a biotin depletion protocol. Automatic sandwich and competitive immunoassays got 97.1%–116.5% recovery by preincubation, compared with 95.6% and 100.3% via the depletion method, respectively.

RNA PROFILES DURING PREGNANCY REVEAL SIGNATURES OF DISEASE

mRNA molecules in plasma cell-free RNA (cfRNA) sequenced from a single blood sample could predict preeclampsia—a major driver of maternal morbidity and mortality—months before symptoms appear (Nature 2022; doi: 10.1038/s41586-021-04249-w).

Researchers' results came from comprehensive transcriptome data from eight independent prospectively collected cohorts comprising 1,840 racially diverse pregnancies and retrospective analysis of 2,539 banked plasma samples. The preeclampsia data included 524 samples (72 cases and 452 non-cases) from two diverse independent cohorts collected 14.5 weeks before delivery.

The researchers showed that cfRNA signatures from a single blood draw can track pregnancy progression at the placental, maternal, and fetal levels and can robustly predict preeclampsia, with a sensitivity of 75% and a positive predictive value (PPV) of 32.3%, compared with state-of-the-art methods that depend on clinical factors and have a PPV of 4.4%.





Point of Care Creatinine/eGFR Method is More Accurate than Laboratory Method: Large Medical Center Study

In a 670 patient study funded by the International Society of Nephrology, the South Africa Medical Research Council and the University of Witwatersrand, Johannesburg, South Africa, the Nova Point of Care StatSensor Creatinine/eGFR meter was more accurate than the central laboratory IDMS-traceable Jaffe methodology in estimating GFR when both methods were compared to MEASURED GFR (iohexol).¹

- StatSensor measurements showed less proportional and constant error than respective IDMS Jaffe measurements when compared to iohexol measured GFR (mGFR).¹
- StatSensor showed better accuracy than the IDMS Jaffe methodology at identifying patients with mGFR's <90 mL/min/1.73 m².¹
- Of particular interest in the study, StatSensor showed better accuracy than the laboratory Jaffe methodology in the 60-89 mL min/1.73 m² range, where individuals with early disease may benefit from renal protective measures.¹



Nova Biomedical StatSensor Creatinine Meter

1. George J et al. Evaluating chronic kidney disease in rural South Africa: comparing estimated glomerular filtration rate using point of care to iohexol measured GFR. CCLM 2021.

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The cfRNA signatures of normal pregnancy progression and preeclampsia are independent of clinical factors, such as maternal age, body mass index, and race, which cumulatively account for less than 1% of model variance. Additionally, the cfRNA signature for preeclampsia contains gene features linked to biological processes implicated in the underlying pathophysiology of preeclampsia.

The researchers emphasized that given the study's large sample size and diversity, it shows that race has a negligible effect on the expression patterns of gestational age estimates and preeclampsia risk evaluation. These findings allow for the development of personalized assessments for pregnancy, they added.

The researchers called for further research to identify drivers of the identified pathophysiological pathways and effective stratification of risk without the need for enrichment of pretest probabilities based on maternal sociodemographic characteristics. Understanding of the maternal-fetal-placental transcriptome may provide novel insights into maternal and neonatal morbidity and mortality, they wrote.

EQUATION PREDICTS END-STAGE KIDNEY DISEASE

The Kidney Failure Risk Equation (KFRE) score better predicts 2-year end-stage kidney disease (ESKD) risk than estimated glomerular filtration rate (eGFR) alone, regardless of adjustment for race (Ann Intern Med 2022; doi:10.7326/M21-2928).

New eGFR equations from the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) do not include a race adjustment, but little is known about the impact of removing race.

The researchers compared ESKD prediction performance of five different CKD-EPI eGFR equations in an observational prospective cohort study conducted at seven U.S. clinical centers involving 3,873 participants with CKD. The equations are based on serum creatinine and/or cystatin C, with or without adjustment for race. The researchers used KFRE to predict the 2-year risk for ESKD. KFRE includes age, sex, eGFR, and urinary albumin-creatinine ratio. The researchers evaluated the prediction performance of eGFR equations and the KFRE score using discrimination and calibration analyses.

During a maximum of 16 years of follow-up, 865 participants developed ESKD. Across all eGFR equations, the KFRE score worked better at predicting 2-year incidence of ESKD, compared with eGFR alone, based on area under the curve ranges from 0.945 to 0.954, versus 0.900 to 0.927. Prediction performance of KFRE scores using different eGFR equations was similar, but the creatinine equation without race adjustment improved calibration among Black participants. Among all participants, compared with an eGFR less than 20 mL/min/1.73 m², a KFRE score greater than 20% had similar specificity for predicting 2-year ESKD risk, with a range of 0.94 to 0.97 versus 0.95 to 0.98. However, KFRE's sensitivity was higher, with ranges of 0.68 to 0.78 versus 0.42 to 0.66.

Because a KFRE score greater than 20% showed similar specificity (approximately 95%) but higher sensitivity compared with an eGFR less than 20 mL/min/1.73 m², a KFRE score greater than 20% could be used for preparing kidney replacement therapy, the researchers noted. "The four-variable KFRE showed better sensitivity and specificity in our study compared with eGFR alone, is easy to implement in routine clinical settings, and does not consider a patient's race," the researchers wrote.

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BACK TO THE FUT

A recent shift in the Department of Health and Human Services' (HHS) approach to regulation of laboratory developed tests (LDTs) has left the waters surrounding these tests murkier than ever and has many in the laboratory community concerned about duplicative oversight.

Department of Health and Human Services (HHS) Secretary Xavier Becerra said in November that the agency was withdrawing a policy established under the Trump Administration that limited the Food and Drug Administration's (FDA) review of LDTs. The Trump Administration's move was designed to speed up access to

newly developed tests for SARS-CoV-2. Prior to the Trump Administration policy, FDA had used "enforcement discretion" in its regulatory approach to LDTs. Essentially, this meant that FDA employed a hands-off approach to LDTs unless there was a specific need to regulate them.

Jeff Shuren, MD, director of FDA's Center for Devices and Radiological Health, said in a statement in November that the latest actions were aimed at increasing access to "accurate and reliable" SARS-CoV-2 tests. But what exactly does this action mean for other LDTs? Will FDA start cracking down on tests

The Biden Administration has reversed a controversial decision to circumscribe FDA's role in regulating these tests, yet the more likely threat of new regulation comes from Congress. **BY KIMBERLY SCOTT**

URE ON LABORATORY DEVELOPED TESTS

developed by labs for use in-house? Probably not, according to experts, who note that FDA has not pursued oversight of LDTs unless there are known problems with them or in the case of a public health emergency.

"FDA has generally not enforced premarket review and other applicable FDA requirements for most LDTs, except in certain situations such as declared public health emergencies or when a test or tests pose a significant public health concern," said an FDA spokesperson in an email.

But even if FDA maintains a laissez-faire approach to most LDTs, dueling bills in Congress have the potential to shake up the field.

LONG-TIME DEBATE

The recent action by HHS does nothing to deal with the long-time debate over whether FDA should have oversight authority over LDTs. Many in the lab community, including AACC, emphasize that these tests are already regulated under CLIA. All LDTs are classified as high-complexity tests, and labs performing them must comply with rigorous quality control, proficiency testing, and personnel requirements—and must demonstrate the test's analytical validity. Although CLIA does not require clinical laboratories to establish clinical validity, the major private sector accrediting organizations, such as the

College of American Pathologists and the Joint Commission, do require that labs document clinical validation.

Manufacturers of diagnostic test kits, however, have long argued that LDTs should be required to go through the same review process as the IVD industry.

Figuring out how to protect the need for testing for rare disorders while also ensuring the safety of patients subject to tests that have not gone through an extensive outside review process is difficult and

has fueled debate for years.

Patricia Jones, PhD, clinical director of the Chemistry and Metabolic Disease Lab at Children's Medical Center in Dallas, and chair of AACC's Policy & External Affairs Core Committee, acknowledges that FDA oversight of COVID-19 testing is a difficult balancing act, especially with the number of "pop-up" laboratories established to offer SARS-CoV-2 tests. But she believes that the vast majority of LDTs—tests that are developed in-house and run only in that particular laboratory—are already sufficiently regulated under CLIA and should not be regulated by FDA.

"We don't need double regulation," Jones said. "We need better definitions. The tests I develop in my laboratory, I use for my patients. I don't sell them for others to perform, and I don't market them." Jones added that most LDTs are developed because there is not already an FDA-approved test available, and in her lab, they are mostly used to diagnose rare conditions, such as genetic abnormalities in newborns.

"We're talking about [phenylketonuria] or maple syrup urine disease—these are not simple tests, they require 20-step extractions," she said. "If we had to file with FDA and go through premarket review for all of these tests, we probably would stop doing them altogether."

Dennis Dietzen, PhD, professor of pathology and immunology at Washington University in St. Louis, agrees. "LDTs fill a void where there is no FDA-approved test," he said. "We need to be able to build these things with a healthy amount of regulation, but not a burdensome amount of regulation. We don't make any money running LDTs. If labs had to go through premarket review for all their LDTs, it would make the assays more expensive to run, and I think a

lot of laboratories would just throw in the towel."

Both Jones and Dietzen believe that LDTs developed by large reference laboratories that sell these tests for profit should be treated differently than LDTs that are used only in a single laboratory. "That's a different ball game," noted Dietzen. "When you start to market them broadly, the tests look less like traditional LDTs, and the regulatory bar might need to be a bit different."

RISK-BASED OVERSIGHT

Over the years, many have argued that FDA oversight of LDTs should be based on risk. Most recently, an October 2021 report by the PEW Research Center, "The Role of Lab Developed Tests in the In Vitro Diagnostics Market," made the case for such an approach. The report maintained that while the LDT regulatory process offers labs significant flexibility and enables a more rapid response to public health needs when no FDA-cleared or -approved test exists, the relative lack of oversight for LDTs puts the health of patients at risk.

The current diagnostic testing regulatory system—in which tests are regulated according to where they are developed and used, rather than the risk they pose if they are inaccurate—creates double standards and potential loopholes that undermine public health objectives, the report said. The authors argued that while labs that develop LDTs are subject to Centers for Medicare and Medicaid Services regulation under CLIA, they are not required to demonstrate clinical validity or report cases of patient harm from their products, requirements that FDA applies to manufacturers that develop, distribute, or sell IVDs for use in multiple facilities.

"Although regulatory harmonization has been discussed for decades, the current dual system—and the public health vulnerabilities that

AACC's Position on Modernization of CLIA and Laboratory Developed Tests

In a position statement issued in December 2021, AACC argues that CLIA, under the Centers for Medicare and Medicaid Services (CMS), should remain the primary mechanism for overseeing clinical laboratories and laboratory-developed tests (LDTs). AACC also issues recommendations for modernizing CLIA to ensure it meets the healthcare community's needs. Core recommendations of the document include:

- CLIA should be updated to require laboratories to demonstrate that LDTs are clinically valid for use in medical decisions.
- AACC encourages CMS to credential third-party organizations to review a laboratory's clinical validation data for LDTs.
- Additional guidance from CMS to laboratories performing LDTs is recommended to help ensure that the results consistently meet clinical needs and expectations.
- AACC urges CMS and its deemed accrediting organizations to ensure that CLIA inspection teams include individuals with specialized method expertise to evaluate LDTs.
- CMS should update CLIA proficiency testing (PT) requirements to allow for the addition or deletion of required analytes subject to PT and to reevaluate the number of challenges and scoring criteria.
- AACC urges policymakers to define LDTs as "new" or significantly modified tests for which the modification alters the clinical claims.



it perpetuates—remains in force,” the report said. “The COVID-19 pandemic only underscores the need to establish a unified regulatory framework that ensures the safe and effective use of all tests.”

Two pieces of legislation are pending in Congress to tackle the thorny issue of LDT regulation. The Verified Innovative Testing in American Laboratories (VITAL) Act would place LDTs solely under the oversight of CLIA regulations and would exclude FDA from any oversight over LDTs, even during a public health emergency. AACC endorsed the bill in 2020.

The Verifying Accurate Leading-Edge IVCT Development (VALID) Act would explicitly grant FDA the authority to regulate LDTs through a risk-based format that categorizes LDTs as high-risk or low-risk, with high-risk tests facing approval requirements that are comparable to existing medical device regulations. The legislative proposal would unify the separate paradigms of traditional IVDs and LDTs into a common regulatory framework for in vitro clinical tests (IVCTs).

Notably, the measure would employ “technology certification” for LDTs that are not high risk. The developer of the test would submit FDA information on a representative test, along with an assessment of the developer’s methods and procedures for test development, validation, and maintenance. If FDA granted approval, the test developer would be able to modify the test or develop related versions of the test within the scope of that approval.

Jochen Lennerz, MD, PhD, medical director of the Massachusetts General Center for Integrated Diagnostics, believes that the concept of technology certification could bridge the gap between FDA review of all LDTs and no FDA review of any LDTs. In a September 2021 study that examined how FDA regulated SARS-CoV-2 LDTs and what

this might mean for the broader universe of LDTs, Lennerz suggested that technology certification, which was used to validate SARS-CoV-2 tests, could serve as a blueprint for regulation of LDTs (*Journal of Molecular Diagnostics* 2021; doi: 10.1016/j.jmoldx.2021.07.011).

However, both Jones and Dietzen maintain that technology certification is not the answer. “For one thing, it’s still far from clear how it would actually work,” Jones said. “More importantly, though, it’s still duplicate regulation, and it appears to be almost as onerous as the usual premarket approval process.”

Many in the laboratory community, including AACC, warn that a new regulatory framework could disrupt innovation and limit patient access if clinical laboratories face new requirements, such as FDA registration, quality requirements, investigational studies, premarket review and approval, adverse event reporting, and product corrections and removals.

AACC supports modernizing CLIA to ensure that it continues to meet the changing needs of the healthcare community and recommends that revisions to the regulations deal with the laboratory inspection process, quality control recommendations, proficiency testing requirements, and the definition of what constitutes an LDT.

“Much of the discussion pertaining to laboratory developed tests focuses on how the tests should be regulated rather than what constitutes an LDT,” AACC said in a December 2021 position statement, “Modernization of CLIA: Laboratory Developed Tests.”

“It is clear that a new test developed and used in one laboratory without FDA clearance or approval is an LDT. However, there is considerable uncertainty around when a modification to an approved or cleared test warrants the label of LDT.” AACC recommends a definition of LDTs that is based on the

clinical claims of the laboratory and that would restrict the application of the term for modified tests to those with new clinical claims.

Lennerz agrees that it is important to note the distinction between tests based on novel biomarkers versus tests based on biomarkers that have already been established. “In this case, there should be two separate regulatory pathways,” he said, adding that there should also be two separate pathways for true novel LDTs that are used solely in a single lab and novel tests that are distributed outside the lab.

The VALID Act continues to be refined to address some of these concerns, Lennerz said, and he believes that the VITAL Act is unlikely to move forward. He believes those who oppose VALID have provided few concrete suggestions on just how CLIA would be reformed. To truly improve diagnostics regulation, Lennerz believes stakeholders either need to provide a detailed proposal on how to modernize CLIA or work to optimize the proposals in the VALID Act.

Those who oppose the VALID Act still maintain that FDA oversight of LDTs would be duplicative and that the regulatory framework proposed under VALID is misguided. In addition, AACC’s position statement lays out seven proposals for how clinical validity, third-party review, updated proficiency testing, and other measures can strengthen existing regulation under CLIA (See Sidebar page 12).

“In an ideal world, FDA reform would be independent of reform of LDTs,” Dietzen noted. “We believe that oversight of diagnostics does need some reform, but the VALID Act is not the right way to do it. Our preference would be to redo some of this regulation in terms of CLIA modernization.” ■

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Expert Advice on a

Lab Design

or

Remodel

BY JEN A. MILLER

Aging infrastructure is a growing problem for clinical laboratories, and the path to new automation often leads to complex, yet rewarding changes to a lab's space.

W

hen the UCSF Medical Center set out to combine three of their laboratories into one, Reid Rosehill, MS, MLS(ASCP)^{CM}, lab manager of clinical laboratories, didn't quite know what he and the rest of the clinical laboratory were in for. Not only did the lab still need to operate during the renovations, but the design changed for reasons that he couldn't fathom—like the weight of the refrigerated storage module. The construction team couldn't just put it anywhere. It had to go where the building could support such a heavy item, and that placement determined key elements of the lab design. "You'd never think about how something is too heavy for the floor," he said.

Remodeling a lab can be a frustrating, tedious, and at times surprising process, but one that's becoming increasingly common as small, cramped spaces for each kind of laboratory have fallen out of fashion, and as automation of clinical

laboratory processes have become more common.

If change hasn't come for your laboratory yet, it may soon. According to a report from research firm MarketsandMarkets, the global lab automation market size is expected to grow from \$4.3 billion in 2020 to \$5.5 billion by 2025.

"It's daunting when you're faced with an older facility. You have HVAC issues or mechanical, electrical, and plumbing issues, or you know that your pure water isn't pure anymore, and you have a series of small rooms for all your activities and you want to put a new line in there," said Marilee Lloyd, AIA, senior laboratory architect/planner at HED, who has been working on laboratory designs and remodels for more than 30 years. "It can be mind-numbing and overwhelming."

Communication between stakeholders—from bench laboratorians to construction project managers to hospital administrators—can help ease the process. "People just want to

know what's going on," said Rosehill. "If the team is aware of what's coming and they understand that there are benefits at the end of the tunnel, including a nice, new automated lab they get to work in, they'll have more patience with the process."

WORK TOGETHER FROM THE START

When Stanford Healthcare set out to remodel a 11,400-square-foot space into a new clinical laboratory, everyone had to be at the table from the start of design, said Raffick Bowen, PhD, MHA, MLT(CSMLS), DCLCHEM, FCACB, DABCC, FAACC, codirector of the clinical chemistry and immunology laboratory at Stanford Healthcare. "We made sure to have all key stakeholders involved. That meant not just electricians and the architect, but lab staff—and not just higher-ups." That included clinical lab scientists and "key personnel who would be working at the benches." The team continued to have stakeholder meetings once a week, which allowed the plans to be scrutinized from both the construction feasibility and the lab functionality points of view.

Bowen said they also used mock simulations "where we pretended you're a tube going through the lab," he said. They helped because "sometimes those computer simulation models don't really reflect what's going on in the lab."

Rosehill also made sure to share the initial design drawings with the team and asked for their input, telling them "there's no guarantee I can give you everything you want, but what are your thoughts?" He kept getting their input throughout the process, especially as things shifted and changed.

While lab directors might feel out of place when speaking to construction and design professionals, especially if they don't know some of the lingo, it is an important step for the finished product to be the best possible solution for their needs, Lloyd said. Talking up front about a potential issue or needed shift early in the process can also avoid costly changes later.

"We try to ask a lot of questions about equipment and try to



understand all of the lab's services," Lloyd said. "It's not just the weight and size of items or their intended location but also how they're going to get into the building."

Laboratory professionals won't need to suddenly become construction experts either. Most hospitals and healthcare systems will provide a construction manager or an "owner's representative," who comes to the job from a construction or design background but works for the parent company. That person represents the interests of the laboratory and also the hospital administration, and is the go-to person when solving surprises—like finding pipes in a wall when they aren't on a drawing—and dealing with design changes and potential cost overruns. This role also will help coordinate utility shutdowns (things like power, water, and air conditioning) which can affect multiple floors and multiple departments.

EXPECT CHANGES, AND BE FLEXIBLE

If your lab is located inside an older building, expect the unexpected, Rosehill said. Their 3,000 square foot laboratory is located in a building first constructed in the 1950s. "Everybody tries to do their homework in the beginning and look at the ceiling and behind walls, but until you start demolition, you don't know what's there," he said.

Their design changed multiple times, and the placement of automated lines had to move according to what the building allowed. The project budget wasn't big enough to strengthen the foundations of the building, so the refrigerated storage module and HVAC unit could only be positioned in limited spots based on what the building could support. "We had to work with our engineers to identify where we could place it and then redo our entire line configuration," he said. He also made sure to keep a project journal with key decisions and discussions documented in case he needed to reference them in the future.

Bracing for the complexity of a remodel, and focusing on the benefits of the temporary pain, can help

“Everybody tries to do their homework in the beginning and look at the ceiling and behind walls, but until you start demolition, you don’t know what’s there.” — Reid Rosehill

staff get through the renovation, too, Rosehill said. That's especially true if your laboratory is being renovated in phases instead of moving from one space to another. For UCSF, half of the space was remodeled at a time, which meant that managers' offices were moved to a different floor and some testing benches were put in a different room. Once the first half of the work was finished, they moved into the renovated part and vacated the old space so it could be renovated, too. "It was pretty disruptive for a while. Our team had to transport samples to two different rooms. But it was doable," Rosehill said.

The remodeled lab opened in mid-2020. Rosehill said automation hasn't fixed every issue the lab had, and having staff learn an entirely new system when their lives were already disrupted by the pandemic was a unique challenge. But the new space is a less siloed laboratory with automated lines. They've seen improved turnaround times, increased capacity, and they experienced fewer errors and delays.

Stanford's new lab went live in 2018, and they're already making changes by adding new equipment and reconfiguring the space to

accommodate it. Bowen said he learned from the remodel process how important it is to have everyone involved. He might know what items he wants, but the vendor is going to know what kind of electrical outlet and other support systems their equipment will need and can communicate that with the design and construction teams. "Before we moved on, we made sure we got sign off from everyone," he said.

While the construction process can be mystifying for people who are more used to working with assays and centrifuges than RFIs and change orders, clinical lab staff are still essential to the process, and Lloyd said that construction and design professionals should never talk down to the people who will be the end users of the new space. "It's important for us to be able to come in and just take it step by step," Lloyd said. "It's like peeling an onion. Yes, sometimes you want to cry, but it's important to understand all those layers so we're understanding the whole." ■

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Regulatory Roundup

FDA Releases Draft Guidance on Full Approval for SARS-CoV-2 Tests

New Food and Drug Administration (FDA) draft guidance makes recommendations to manufacturers about moving SARS-CoV-2 tests and other medical devices from emergency use authorization (EUA) to full marketing and regulatory approval once the COVID-19 public health emergency ends and normal operations resume.

Once FDA sets an EUA expiration date, developers cannot distribute their tests without full approval, the draft guidance notes. Manufacturers seeking full approval should include in their submissions a “transition implementation plan” that covers both approval and denial. That plan should include the estimated number of tests currently distributed in the U.S. and address how the manufacturer will dispose of already distributed products if FDA denies the marketing submission. The plan should also explain how the manufacturer will deal with previously distributed products if FDA approves the marketing

submission. The draft guidance calls upon manufacturers to explain rationale for leaving already distributed products in place and to detail a process for notifying patients, consumers, providers, healthcare facilities, and distributors about the device’s regulatory status.

If the manufacturer has submitted its test for marketing approval and FDA accepts it before the EUA termination date, the manufacturer can continue distributing the test until the agency makes a final decision, provided the label is updated. Tests from manufacturers that did not seek their full approval may be used for 2 years after the EUA termination date, or until they expire.

FDA is seeking feedback on the draft guidance through March 23, 2022. Comments can be submitted at www.regulations.gov.



FDA SAYS OMICRON REDUCES CERTAIN TESTS' SENSITIVITY

The Food and Drug Administration (FDA) has found that mutations in the omicron variant lead to reduced sensitivity in certain SARS-CoV-2 PCR tests with genetic targets that cover the portion of the gene where the omicron mutations occur.

The agency recommends against using two such tests until their manufacturers resolve issues with

significantly reduced sensitivity that are caused by the omicron variant. The first of these tests is Revogene SARS-CoV-2, marketed by Meridian Bioscience. The second is the Linea COVID-19 assay kit, marketed by Applied DNA Biosciences. FDA is working with these manufacturers to address the issues with their tests.

Meanwhile, the DTPM COVID-19 RT-PCR test marketed by Tide Laboratories has been modified so that it can detect the omicron variant, FDA notes.

At www.fda.gov, the agency also lists 28 tests, all with multiple genetic targets, that it considers sensitive enough to detect the omicron variant.

ROCHE GETS CE MARK FOR SALIVA SARS-COV-2 TEST, LAUNCHES OTHER INFECTIOUS DISEASE TESTS

Roche has announced that its cobas SARS-CoV-2 Qualitative test has received the CE mark for

use on saliva samples on the widely available, high-throughput cobas 6800/8800 systems. This noninvasive test is for all individuals suspected of having COVID-19, including those without symptoms.

In addition, Roche has received the CE mark for the first infectious disease tests for use on its new cobas 5800 system. These tests support patient management of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV), and include the cobas HIV-1, cobas HBV, cobas HCV, cobas HIV-1/HIV-2 Qualitative, and the cobas omni Utility Channel kit. Along with the cobas 5800 system, they are designed to provide standardized performance and efficiencies across low, medium, and high-volume molecular testing laboratories.

■ FDA CLEARS 1-HOUR SEPSIS TEST

Immunoexpress has announced that its SeptiCyte Rapid sepsis test has received 510(k) clearance from the Food and Drug Administration (FDA). The fully automated, 1-hour test quantifies the relative expression levels of genes involved in a patient's immune response to infection. Used in conjunction with clinical assessments, vital signs, and other laboratory findings, the test helps differentiate actual sepsis from infection-negative systemic inflammation in patients suspected of sepsis.

Using reverse transcription PCR, SeptiCyte Rapid quantifies relative expression levels of host response genes isolated from whole blood collected in the PAXgene Blood RNA Tube. The test then generates a score that falls within discrete interpretation bands based on the increasing likelihood of infection-positive systemic inflammation. SeptiCyte Rapid is designed for use on the Biocartis Idylla system.

■ NGS-BASED COMPANION DIAGNOSTIC FOR NON-SMALL CELL LUNG CANCER GETS FDA APPROVAL

The Food and Drug Administration (FDA) has

granted premarket approval to Thermo Fisher Scientific's Oncomine Dx Target test for use as a companion diagnostic. The test, which simultaneously evaluates 23 genes associated with non-small cell lung cancer, identifies patients with tumors carrying epidermal growth factor receptor exon20-insertion mutations. Patients with these mutations could potentially benefit from treatment with Rybrevant (amivantamab-vmjw), a targeted therapy developed by Janssen Biotech.

According to Thermo Fisher officials, the Oncomine Dx Target test is the first and only FDA-approved next-generation sequencing companion diagnostic on formalin-fixed, paraffin-embedded tissue for determining Rybrevant eligibility in patients whose disease has progressed on or after platinum-based chemotherapy. The test is also approved and reimbursed by government and commercial insurers in more than 15 countries.

■ BD EXPANDS FULLY AUTOMATED HIGH-THROUGHPUT MOLECULAR DIAGNOSTIC PLATFORM

BD (Becton, Dickinson and Company) has expanded its BD COR system to include a new MX instrument for high-throughput molecular testing for infectious diseases. The new MX instrument and its first test for sexually transmitted infections have both been CE marked. The instrument is the final piece of the BD COR system, which also includes an instrument that prepares diagnostic samples by automating appropriate preanalytical processing steps, as well as an instrument that leverages the BD Onclarity HPV assay with extended genotyping to screen for HPV infections.

The first test available on the MX instrument is the BD CTGCTV2 for BD COR system assay. The single test detects the three most prevalent nonviral sexually transmitted infections, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.

■ APPLIED BIOCODE GETS EUA FOR RESPIRATORY DISEASE TEST

Applied BioCode has received Food and Drug Administration (FDA) emergency use authorization (EUA) for its BioCode CoV-2 Flu Plus assay. The PCR-based, multiplex assay simultaneously detects and differentiates between SARS-CoV-2, influenza A with subtypes (seasonal H1, 2009 H1N1, H3, and influenza B), and respiratory syncytial virus using nasopharyngeal swab specimens. The test runs on the automated high-throughput BioCode MDx-3000 molecular system and enables labs to process up to 564 samples per day.



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Qidel Corporation Buys Ortho Clinical Diagnostics

Qidel Corporation has acquired Ortho Clinical Diagnostics, one of the world's largest in vitro diagnostics companies. The transaction is expected to close during the first half of fiscal year 2022.

The combined organization will unite the companies' technologies and platforms to benefit customers with expanded access to clinical chemistry, immunoassay, molecular diagnostics, immunohematology, donor screening, and point-of-care diagnostics offerings, Qidel said. They added that the combined company will be poised to meet patient testing needs at all points

of the care continuum, including reference labs, hospitals, physicians' offices, urgent care centers, retail locations, and homes.

The deal will include access to Ortho's broad global reach across 130-plus countries, accelerating growth for Qidel's existing product portfolio and providing exposure to new, emerging markets.

Additionally, the deal will deepen Qidel's innovation pipeline, diversify its product portfolio, and accelerate its product growth, the company said.



MAINZ BIOMED ACQUIRES EXCLUSIVE RIGHTS TO NOVEL MRNA BIOMARKERS

Mainz Biomed recently announced an agreement to access Socpra Sciences Santé Et Humaines' portfolio of novel mRNA biomarkers for potential future integration into ColoAlert, Mainz's test for colorectal cancer (CRC).

Under the deal, Mainz has exclusive global rights to five gene expression biomarkers demonstrated to effectively detect CRC lesions, including advanced adenoma (AA), a pre-cancerous polyp often attributed to this deadly disease. The company cites peer-reviewed research that shows the biomarkers have overall sensitivities of 75% for AA and 95% for CRC, respectively.

If these statistical results are duplicated when the biomarkers are

integrated into ColoAlert, company officials hope their test will be among the most robust and accurate at-home commercial diagnostic screening tests. The company plans a clinical study in Europe to evaluate whether the biomarkers improve ColoAlert's utility for identifying AA while increasing rates of diagnostic sensitivity and specificity.

Mainz is currently marketing ColoAlert in Europe through partnerships with third-party laboratories for test kit processing. The company is preparing to submit ColoAlert for Food and Drug Administration approval.

GESTALT DIAGNOSTICS AND MINDPEAK PROVIDE ARTIFICIAL INTELLIGENCE-BASED DIAGNOSTICS

BioReference Laboratories will use new artificial intelligence

(AI)-based diagnostic tools developed by MindPeak and Gestalt Diagnostics for aspects of routine clinical pathology. Specifically, BioReference Laboratories will use Gestalt Diagnostics' digital pathology solution with MindPeak's AI-based cancer diagnostics BreastIHC algorithm.

BioReference will use the BreastIHC algorithm to quantify breast cancer cells via AI software integrated in Gestalt Diagnostics' PathFlow platform for streamlined access and workflow, making BreastIHC the first AI-based pathology product used in routine clinical practice in the U.S., according to MindPeak and Gestalt.

BreastIHC enables labs to instantly detect, classify, and quantify breast cancer cells stained via immunohistochemistry. The algorithm classifies the cells into

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positively stained tumor and unstained tumor cells. By differentiating tumorous and nontumorous structures, BreastIHC can improve scoring in the tumor microenvironment, MindPeak officials said. They added that BreastIHC can increase throughput and reporting speed.

Gestalt Diagnostic officials said their platform enables quick, efficient, and fully automatic interpretation and diagnosis.

BD ACQUIRES SCANWELL HEALTH TO EXPAND AND SCALE DIGITAL AT-HOME TESTING

Becton, Dickinson and Company (BD) announced it has acquired Scanwell Health, which markets smartphone-enabled at-home medical tests.

BD collaborated with Scanwell to develop the application used with the recently launched BD Veritor At-Home COVID-19 test. It is the first SARS-CoV-2 test to use a smartphone camera and app to capture and interpret results.

According to BD, the test, smartphone camera, and application eliminate the human subjectivity involved in other visually read at-home antigen tests.

While other SARS-CoV-2 home tests use smartphones as part of their process, the BD Veritor test uses the smartphone as the analyzer to digitally interpret the test results and provide a definitive positive or negative digital display of testing results. The application also can securely store and report test results to businesses, public health authorities, and schools. The application stores test results, which can be referenced and displayed at any time by logging in.

Scanwell will become the digital platform upon which BD plans to develop at-home diagnostic tests for a range of infectious diseases including COVID-19, influenza A and B, and group A strep.

ILLUMINA AND SYAPSE PARTNER ON STUDY OF COMPREHENSIVE GENOMIC PROFILING IN ADVANCED CANCER

A new partnership between Syapse and Illumina focuses on research to evaluate large panel biomarker testing patterns across U.S. community oncology practices.

An announcement by the companies said the collaboration will explore the uptake and actionability of comprehensive genomic profiling among practices whose clinicians treat patients with advanced cancers. The collaboration seeks to understand biomarker testing patterns and actionability of test results as a first step toward facilitating improved clinical decision-making at both the provider and health system level.

Syapse officials said that a key goal is identifying a biomarker that qualifies patients for targeted therapy early enough to be effective and to spare them from potentially less effective and more difficult treatments. Illumina officials also added that the collaboration is intended to advance personalized care.

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Ask The Expert

Will Pandemic Measures Foil the Flu Again?



EXPERT

By Gyorgy Abel, MD, PhD

What happened to the flu season in 2020–2021?

A: In the Northern Hemisphere, influenza season typically starts around October and peaks between December and February. We often see cases—and in some seasons a second or even a third peak—as late as April or May, as it happened in 2019–2020

(the last pre-COVID-19 flu season). Influenza tends to spike in the fall and winter because the virus survives better in colder, dry temperatures. In a typical flu season, we see a 10%–20% positive rate among patients tested for a flu-like illness.

Flu activity in the U.S. during the 2019–2020 season began to increase in November and was consistently high through January and February 2020. However, the COVID-19 pandemic dramatically decreased the number of influenza cases in the next flu season, 2020–2021, making the virus almost disappear.

According to the Centers for Disease Control and Prevention (CDC), there have been about 1,400 positive flu cases in 2020–2021, while the previous year included more than 130,000 positive test results. The hospitalization rate in the 202–2021 flu season was just 0.7 per 100,000 people, the lowest since the CDC started to collect data in 2005. COVID-19 preventive measures such as using face masks, social distancing, staying home, school closures, improved indoor ventilation, and hand washing all were effective countermeasures that likely contributed not only to successes in the fight against COVID-19 but also to the low incidence of flu and lower hospitalizations and deaths due to infection with this virus. Another contributing factor was the high rate of influenza vaccination. A record number of flu vaccine doses (more than 190 million) were distributed in the U.S. during 2020–2021.

After this almost nonexistent flu season, a more brutal season was projected last fall for 2021–2022, with the specter of a “twindemic”. Clinical laboratories and the major diagnostic manufacturers have worked hard to prepare for this scenario. Both high-throughput and rapid SARS-CoV-2 plus influenza A/B combination molecular tests became available shortly before the new season started.

Where are we headed this year?

Flu seasons are notoriously difficult to predict due to the virus’s rapidly

changing genetic makeup, its biological behavior, and the multiple factors affecting its spread. After the quiet summer for COVID-19 in 2021, and with high full vaccination rates, some expected a repeat of the post-1918 flu pandemic merriment, with a new “roaring 20s” in the fall: Without masks and social distancing, extensive travel and social activities would resume—all contributing factors to a potentially heavy flu season.

Then came the SARS-CoV-2 delta variant, and last December, the super-contagious omicron variant with very high infection rates but relatively low mortality. By mid-January, this year we witnessed record numbers of SARS-CoV-2 infections, record testing volumes, and booster shot requirements for healthcare workers and others.

Meanwhile, influenza cases had emerged last November and reached a mild peak in December. This was considerably greater than the same time period a year earlier, but far below the numbers of previous regular flu seasons. Sporadic influenza activity continued across the country in January and early February. The majority of influenza viruses detected have been A (H3N2). According to the CDC, of the 6,774 influenza positives reported so far this season by public health laboratories in which SARS-CoV-2 testing was also performed, 402 (5.9%) were also positive for SARS-CoV-2. Cases of SARS-CoV-2 omicron have shown a precipitous decline and there is no immediate threat of a new variant on the horizon.

The positive developments with COVID-19 will likely lead to an easing of preventive measures and mandates, potentially resulting in a spring spike of flu. Fortunately, clinical laboratories are well prepared to meet the challenges ahead.

Gyorgy Abel, MD, PhD, is medical director of molecular diagnostics at Lahey Hospital and Medical Center in Burlington, Massachusetts.

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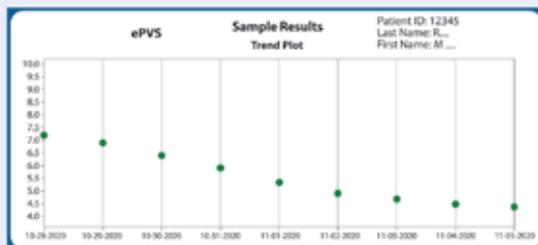
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Thomas Metkus, MD

Divisions of Cardiology and Cardiac Surgery, Departments of Medicine and Surgery
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Prime Plus trend screen showing absolute values (ePVS)



Prime Plus trend screen showing percent change (Δ ePVS)



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