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MEDICAL LABORATORY OBSERVER

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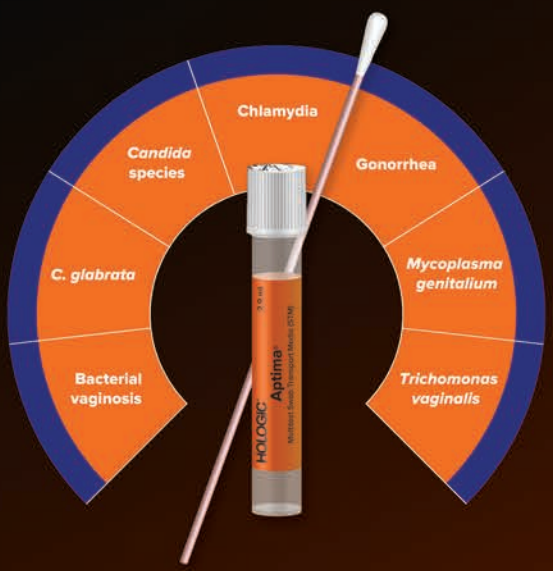

ONE SAMPLE

References: 1. Aptima Combo 2 Assay [package insert] #502446-IFU-PI_012 San Diego, CA; Hologic, Inc., 2021. **2.** Aptima Mycoplasma genitalium assay [package insert] #AW-17946_002, San Diego, CA; Hologic, Inc., 2021, **3.** Aptima CV/TV assay [package insert] #AW-18812, San Diego, CA; Hologic, Inc., 2021. **4.** Aptima BV assay [package insert] #AW-18811, San Diego, CA; Hologic, Inc., 2021.

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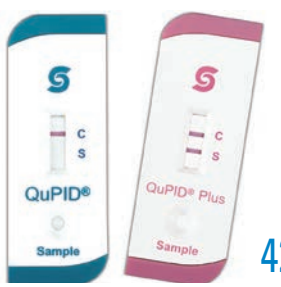

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The process of creative problem-solving

By Linda Wilson
Senior Editor

In this issue, the editors at *Medical Laboratory Observer* celebrate the spirit of creative problem-solving with profiles of *MLO*'s 2021 Lab Innovators Worth Watching.

This is a recognition program we launched in 2020 to encourage laboratorians to nominate co-workers who had developed innovative solutions. The program is open to nominations of lab employees at the individual, group or department level. It is also an opportunity for lab managers to garner public recognition for the successes of their employees.

At *MLO*, we wanted to find out how individuals and teams defined a problem, developed an innovative solution and measured success. We profile their stories in this issue. For example, the lab at University Medical Center of Southern Nevada built from scratch a dedicated PCR COVID-19 lab, while the Clinical Chemistry Laboratory at Yale-New Haven Hospital developed automated methods to solve common interference problems affecting lab tests in chemistry.

This year's Lab Innovators Worth Watching involved not only teams but also a single employee. A lab employee at UnityPoint Health built custom acrylic trays, allowing employees to remove petri dishes from incubators much more easily than was possible before.

In a 2019 article, Gallup writes about how to inspire innovation among employees. In a survey, the organization found that only about one-fifth of employees surveyed in the United States believed they work at an organization "where people can try, fail and learn from their mistakes." That kind of environment is essential to fostering innovation, Gallup says. It also encourages employees to speak up when they see potentially harmful errors, which is essential in a clinically focused business like a laboratory.

To nurture a culture of innovation, Gallup says managers should embrace a trial-and-error approach to improving processes and products and "create a constructive, non-punitive method for fixing problems."

In an online toolkit on problem-solving and escalation, the Agency for Healthcare Research and Quality (AHRQ) encourages problem-solving at all levels of an organization because it helps lead to safer patient care.

The agency also says it is equally important to train employees on when to inform managers about an issue. The decision on whether to escalate an issue depends on the type of solution required to solve a problem, the agency says. AHRQ defines two types of solutions to problems: Type 1 solutions, which solve a problem immediately and often involve only frontline employees and supervisors, and Type 2 solutions, which prevent the problem from recurring in the future. Type 2 problems often are those that are symptomatic of a larger issue and require escalation to management, the agency explains.

Clearly, the managers involved in this year's Lab Innovators Worth Watching have tapped into their employees' enthusiasm and creativity. We hope their experiences will inspire you to develop innovative solutions to problems in your lab. We also hope you will nominate your teams for *MLO*'s Lab Innovators Worth Watching in 2022.

I welcome your comments, questions, and opinions – please send them to me at lwilson@mlo-online.com.

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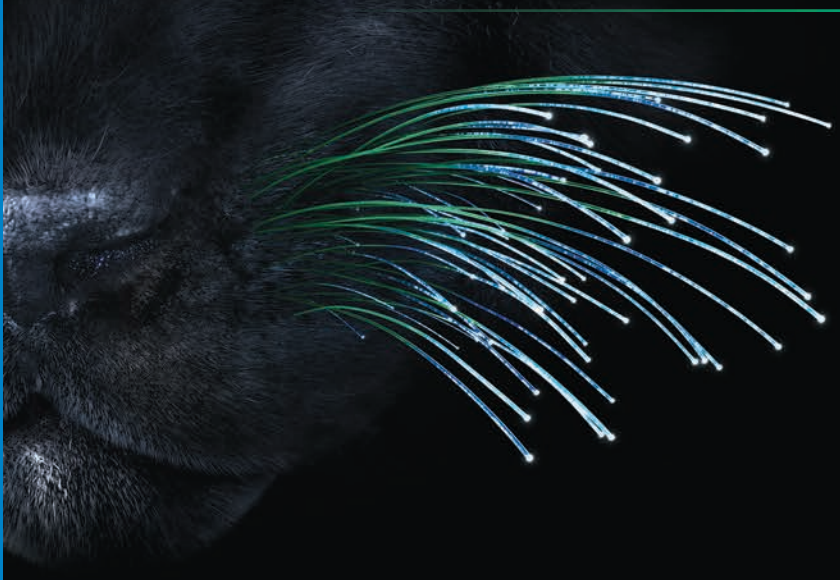

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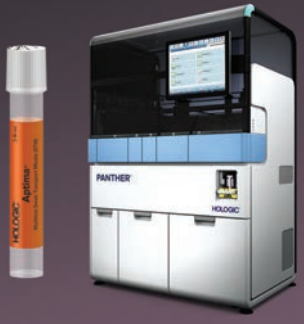

GROW ON **PANTHER**

References: 1. Aptima Mycoplasma Genitalium Assay [package insert] AW-17946, San Diego, CA; Hologic, Inc., 2019. **2.** Le Roy C, et al. French prospective clinical evaluation of the Aptima Mycoplasma genitalium CE-IVD assay and macrolide resistance detection using three distinct assays. J Clin Microbiol. 2017;55(11):3194-3200. **3.** Frølund M, et al. Urethritis-associated pathogens in urine from men with non-gonococcal urethritis: a case-control study. Acta Derm Venereol. 2016;96(5):689-694.

Image by PDPics from Pixabay

Cancer statistics show fastest declining death rate is melanoma, followed by lung cancer

6

male cancers decreased between 2013-2017: lung and bronchus, larynx, urinary bladder, colon and rectum, stomach, and brain and ONS.

5

male cancers increased: testis, melanoma of the skin, kidney and renal pelvis, oral cavity and pharynx, and pancreas.

2.5%

decrease of lung and bronchus cancer in men

6

female cancers decreased between 2013-2017: ovary, lung and bronchus, colon and rectum, urinary bladder, thyroid, and brain and ONS.

8

female cancers increased: liver and intrahepatic bile duct, melanoma of the skin, corpus and uterus, myeloma, pancreas, kidney and renal pelvis, breast, and oral cavity and pharynx.

2%

decrease of thyroid cancer in women

3

most common in children: leukemia, lymphoma, as well as brain and other nervous system cancers

2.3%

decrease of larynx cancer in men

1.4%

increase of kidney and renal pelvis cancers in men

1.6%

decrease of ovarian cancer in women

Source: https://seer.cancer.gov/report_to_nation/statistics.html

Tool helps when to test for bacteria in critically ill pediatric patients

Researchers at Johns Hopkins Medicine have developed a new bedside tool that helps clinicians better determine when to test for bacteria in endotracheal tubes being used for critically ill patients in the pediatric intensive care unit (PICU). The findings were reported in the journal *Pediatrics*.

To diagnose potentially serious bacterial respiratory infections in a PICU patient receiving invasive mechanical ventilation with an endotracheal tube, physicians and nurses often obtain secretions from inside the tube (known as an endotracheal aspirate) and culture it in the laboratory. The problem with these endotracheal aspirate cultures (EACs) is they may lead to a case of mistaken identity that could do the patient more harm than good, says study lead author Anna Sick-Samuels, MD, MPH, Pediatric Infectious Disease Specialist at Johns Hopkins Children's Center and Assistant Professor of Pediatrics at the Johns Hopkins University School of Medicine.

"The human respiratory tract is far from a sterile environment, so bacteria cultured from aspirated samples may just be part of the body's normal microflora and not be causing an infection that needs antibiotics," says Sick-Samuels. "However, the detection of any bacteria in these cultures is often misinterpreted as a sign of a ventilator-associated infection, which then may result in unnecessary — and potentially harmful — antibiotic treatment."

To address the problem, Sick-Samuels and her colleagues developed a clinical decision support algorithm for use in the PICU. The algorithm is a simple flow chart of progressively more definitive, "yes or no" criteria by which clinicians can make an informed, rather than speculative, decision about whether an EAC is needed.

For a PICU patient with a tracheostomy (a surgically created airway directly into the trachea) or an endotracheal tube in place for more than 48 hours, Sick-Samuels explains that the algorithm asks clinicians to consider obtaining an EAC only if:

- The patient has an increased quantity of secretions in the tracheostomy or endotracheal tube over time.
- There is at least one additional supporting sign of infection, such as fever greater than 38 degrees Celsius (100.4 degrees Fahrenheit), an increase in white blood cell counts, or a chest X-ray that indicates a developing pneumonia.
- The patient has not had another EAC within the past 3 days.

Surgery before chemotherapy for aggressive ovarian cancer patient

Certain patients have a better chance of a cure through surgical removal of a tumor before chemotherapy, instead of the reverse, a new study shows. Led by researchers at NYU Langone's Perlmutter Cancer Center and Dana-Farber Cancer Institute, the study used a mathematical tool to examine how doctors should coordinate available treatments for high-grade serous ovarian cancer (HGSC).

Ovarian cancer is the eighth most common cancer and a major cause of cancer death in women worldwide. HGSC constitutes roughly 70 percent of ovarian malignancies and has the worst prognosis. Patients with the condition typically have surgery and chemotherapy, but there has been long-standing controversy over the best order of treatment.

Published online in Proceedings of the National Academy of Sciences, the new analysis argues that patients who can have "complete debulking" surgery first, with chemotherapy added after (termed primary debulking surgery or PDS), should have a superior outcome to the other main treatment option: giving patients a few cycles of chemotherapy to shrink the tumor before surgery (neoadjuvant chemotherapy, or NACT).

"The issue of whether PDS or NACT should be used was highly controversial, and a major reason for it lies in the different characteristics of patients in different clinical studies," says study first author Shengqing Gu, PhD, Graduate from University of Toronto and now Instructor at Dana-Farber Cancer Institute. "We therefore built a mathematical model to simulate HGSC clinical course, which allows us to compare treatment outcomes in the same virtual patients and examine which group of patients may respond differently to PDS versus NACT."

The researchers found that in patients who are well enough for surgery, debulking provides better results because it has the best chance of removing cancer cells resistant to chemotherapy. For patients who are too ill for debulking surgery, the study suggests that a shorter period of initial chemotherapy, rather than the currently recommended interval, might provide a greater benefit. The current analyses suggest several questions that future randomized clinical trials should examine. These include how much the influence of the time gap between surgery and subsequent chemotherapy may affect treatment outcome, whether there is a link between the number of initial chemotherapy cycles and outcomes, and whether a complete secondary surgery on relapsed tumor improves prognosis.

COVID-19 and Beyond: what's next for respiratory diagnostics?

Rosemary She, MD,
Associate Professor of Clinical Pathology,
Keck School of Medicine at USC

What were you doing for respiratory testing in your laboratory prior to the onset of the COVID-19 pandemic?

Prior to the COVID-19 pandemic, we were doing multiplex respiratory panel testing using the BioFire® Respiratory 2 (RP2) Panel. We also perform a separate influenza A/B PCR.

Tell me about your experience during the COVID-19 pandemic. What were the biggest challenges you faced day-to-day as a clinical laboratory director?

Like other clinical labs, the initial biggest challenge was securing the ability to test for SARS-CoV-2, then facing issues of test supply allocation. We ended up purchasing additional systems to increase our testing capabilities. Still, our sample-to-answer testing capacity remained limited, and it was a crazy time working with the hospital to figure out who could get rapid testing and who could not. On another front, there was a sudden shortage of nasopharyngeal swabs once the pandemic hit. Our providers were accustomed to using flocked NP swabs for respiratory virus testing, so we actively provided education as we introduced alternative collection kits. In time, new vendors started to offer NP swabs and transport media. This kept me busy conducting in-house evaluations to vet these new products before giving the OK to our sourcing team to purchase them.

What made you decide to bring in the BioFire® Respiratory 2.1 (RP2.1) Panel?

We had already been performing the BioFire RP2 test and were familiar with it and satisfied with it. It was important for us to maintain the ability to perform syndromic testing, which was needed for our patient population, and not just SARS-CoV-2 testing. However, we were also willing to run the panel just to get the SARS-CoV-2 result, because reagents for molecular SARS-CoV-2 testing were in such short supply.

What has your experience been so far using the BioFire RP2.1 Panel?

The experience for our laboratory staff with the RP2.1 has pretty much been the same as it was for the RP2 panel. There have been very few issues with the instrument or the panel. The only downside is that sometimes providers will ask about cycle threshold value for a positive result, and the system doesn't have one. Otherwise, the system has been reliable. Its rapid turnaround time, combined with having 4 test modules, has made the RP2.1 workflow quite smooth for us. The test has been robust with alternative transport media and bronchoalveolar lavage specimens, which we had validated separately. Supply shortages for the RP2.1 were difficult at first but have gotten better with time. As of now, we use the RP2.1 when both SARS-CoV-2 and respiratory-panel PCRs are ordered. We also use it as a backup method for STAT SARS-CoV-2 PCR requests.

Now that vaccine availability is more widespread and the world is beginning to open back up, what do you anticipate the upcoming respiratory season might look like? And where do you see a syndromic respiratory panel fitting in to your post-pandemic testing strategy?

I think we will continue to have difficulties predicting what happens with the respiratory viruses, which ones will emerge and when. I wouldn't dare to predict what will happen even in the upcoming season! But with masking mandates going away and society returning to normal activity levels, I would definitely want to be prepared for recirculation of respiratory viruses. If they return to pre-pandemic rates, I think it would be important to differentiate SARS-CoV-2 from other respiratory virus infections by testing, even vaccinated individuals, in whom we've seen breakthrough cases.

In regards to syndromic testing, I've always been a proponent of respiratory virus panels, and I was very happy to have panel testing available when SARS-CoV-2 first emerged. I think it helped clinicians distinguish heads from tails during what was already an active respiratory-virus season. Many were grateful that they could get results back within hours, even if only for the common respiratory viruses. It also helped them gauge the likelihood of COVID-19 for a patient in the days when SARS-CoV-2 testing was not locally available and had long turnaround times. So, I think respiratory panels have a frontline role to play in either identifying the causative agent or in ruling out common players in the event of an outbreak.

Photo by

Minimizing laboratory errors with automation

By Jacqui Reithel, MBA, MT (ASCP)

Laboratories play a crucial role in both individual and population-based healthcare — and use various methods to reduce errors, ensure patient safety, and improve quality.

Laboratory testing is often used to confirm initial impressions or rule out differential diagnoses. It is estimated that 70% of all healthcare decisions affecting diagnosis or treatment involve laboratory testing,[1] and at least 10% of all diagnoses are not considered final until laboratory testing is complete.[2,3] Published data suggest that 24-30% of laboratory errors influence patient care, while actual or potential patient harm occurs in 3-12% of cases.[4,5,6]

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LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Describe the type and rates of errors in the three stages of the laboratory testing process.
2. Describe the reasons for pre-analytical errors and their impact.
3. Describe how pre-analytical efficiency can be improved.
4. Explain how the COVID-19 pandemic has renewed the urgency for automation.

There is clear evidence that most laboratory errors fall outside the analytical phase, and pre- and post-analytical processes are more vulnerable to error.[7,8] Pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation and preparation for analysis and storage.[9]

Research shows that, on average, the cost per pre-analytical error in the United States is $208; and without intervention, an average laboratory can expect to incur approximately $180,000 per year in costs related to mislabeling, wrong samples, and insufficient sample volumes. For example, a typical mid-sized hospital laboratory processes around 182,500 tubes per year. Studies show that approximately 0.66% of these tubes will come into the laboratory with pre- or post-analytical errors, and 72% of those tubes will directly contribute to additional costs.[10,11] Given the expense, laboratorians must focus their attention on pre-analytical and post-analytical processes,[12] as these phases seem to present the greatest potential for quality improvement once reliable strategies have been identified and properly applied.

The error factor

In a one-year study, researchers found that for inpatients, there was a pre-analytical error rate of 1.9%. The variable receiving the highest frequency rating was specimen hemolysis at 1.10%. The error rate was 1.2% for the outpatients, and the variable with the highest frequency rating was insufficient volume for testing.[13] Some of the other common pre-analytical errors that are found on average at the rate of 46%–68.2% in laboratories include:[14]

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- Order entry errors
- Misidentification of patient
- Inappropriate container
- Sample collection error and inadequate transport
- Inadequate sample/anticoagulant volume ratio
- Insufficient sample volume
- Sorting and routing errors
- Labeling errors

The human factor

The healthcare environment is competitive, and laboratories continue to face constant pressure to reduce costs and improve quality and time-to-test results. Highly skilled technicians perform repetitive manual tasks, such as specimen preparation, centrifugation, aliquot preparation, decapping, pipetting, and sorting. These laborious and time-intensive tasks create bottlenecks, reduce the ability for these technicians to do high value tasks, and increase the risk for human error.

Health system costs in clinical laboratories are incurred daily due to human error. Indeed, a major impetus for automating clinical laboratories has always been the opportunity it presents to simultaneously reduce cost and improve the quality of operations by decreasing human error.[15]

Approximately 60% of laboratory technicians are spending their time in the pre-analytical phase: accessioning, sorting, decapping, centrifuging, transporting, etc. Up to 75% of testing errors take place during the pre-analytical phase,[16] all of which can lead to reporting delays and errors. This is mainly attributed to the difficulty in achieving standardized procedures for sample collection,[17] posing a great challenge for laboratories.

The various ways in which automation can reduce errors

Automation	Details
Computerized physician order entry	• Bar coding technology • Optical character recognition • Magnetic stripe recognition • Magnetic ink character recognition • Voice identification devices • Radio frequency identification (RFID)
Positive patient identification by	• Touch screens • Light pens • Fingerprint identification for tablets • Optical mark readers • Smart cards • Active tubes (chip-integrated containers)
Transport systems	• Active tubes (chip-integrated containers) • Pneumatic tubes system (PTS) • Robots • Transportation monitoring systems
Instrumentation	• Automated sampling devices • Devices to find the vein (real time digital imagery) for sampling • Tube labeler and preparer • Automated specimen sorter • Automated specimen submission to laboratory • Query-host communication • Primary tube processing • Volume/clotting/bubbles sensors • Serum indices • Automated centrifugation • Decapper, aliquoter, barcode labeler, recapper • Automated specimen storage and retrieval • Secondary tube sorter
Informatics	• Query-host communication • Automated verification • Expert systems • Delta check technology • Error-recording software • Process–controlling software

Source: Bakan, Ebubekir and Umudum, Fatma Zuhal. Automation of extra-analytical phase for clinical laboratory. Turkish Journal of Biochemistry, vol. 46, no. 2, 2021, pp. 115-128. https://doi.org/10.1515/tjb-2020-0138

The automation advantage

Overcoming challenges with staffing, fluctuations in testing volumes, improving turnaround time, and reducing errors and costs are all proven benefits that have fueled the adoption of laboratory automation. Today, even labs processing smaller volumes of samples – ranging from one to three million tests per year or as low as 500 samples per day, often enjoy the benefits of lab automation to help address their challenges.[18]

Automation allows for taking over the bulk of many manual ordinary activities (i.e., specimens sorting, loading, centrifugation, decapping, aliquoting, sealing) from humans, thus minimizing substantial differences among persons and from sample to sample.[19] Such improved process standardization can yield tangible benefits on the quality of the total testing process, and lower the risk of diagnostic errors, especially those emerging from the manually intensive activities of the pre-analytical phase.[20] In addition, automation helps to mitigate bottlenecks that occur during sample preparation by processing samples quicker and more efficiently with less variation than humans.[21]

Improving pre-analytical efficiency

The aim of introducing automation in the pre-analytical phase is to prevent human error, which is exacerbated by the fact that laboratory workers are currently handling ever-increasing workloads alongside a reduction in personnel, leading to physical and mental exhaustion. Automated robotic workstations effectively reduce the number of laboratory errors that occur in sorting, labeling, and aliquoting specimens, which improves the integrity of those specimens throughout the steps of specimen processing.[22] Research shows that effective integration between automation and information management is key to assuring a more sophisticated control of laboratory processes.[23] In fact, automation technologies have had a big impact on the proficiency of clinical laboratories. To improve standardization, organization, efficiency, and quality of the total testing process, many manual tasks have now been partially or completely automated by labor-saving instrumenta-

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Types and Rates of Error in the 3 Stages of the Laboratory Testing Process		
Phase of Total Testing Process	**Type of Error**	**Rates**
Pre-analytical	• Inappropriate test request	46%–68.2%
	• Order entry errors	
	• Misidentification of patient	
	• Inappropriate container	
	• Sample collection error and inadequate transport	
	• Inadequate sample/anticoagulant volume ratio	
	• Insufficient sample volume	
	• Sorting and routing errors	
	• Labeling errors	
Analytical	• Equipment malfunction	7%–13%
	• Sample mix-ups/interference	
	• Undetected failure in quality control	
	• Procedure not followed	
Post-analytical	• Failure in reporting	18.5%–47%
	• Erroneous validation of analytical data	
	• Improper data entry	

Source: Lippi G Guidi GC . Risk management in the pre-analytical phase of laboratory testing. Clin Chem Lab Med. 2007;45:720–727.

tions, and the cost of the investment will possibly return on a long-term basis.[24,25]

The impact of automation on human resources

Staffing challenges, including employee turnover and the inability to hire qualified staff, remain long-term chronic problems facing the laboratory. The Bureau of Labor Statistics (BLS) projects a nationwide increase in the demand for medical and clinical laboratory technologists of 13% between 2016 and 2026. The Human Resources and Service Administration (HSRA), within the Department of Health and Human Services (HHS), projects a growth in demand of nearly double that amount, or 22%, between 2012 and 2025. In addition, vacancy rates remain high, averaging 7.2% across the nation.[26]

Automation plays a key role in addressing staff shortages, while enabling precious and highly skilled human resources to focus on high-value clinical tasks, particularly during the COVID-19 pandemic.[18] Even though molecular testing, which is the gold standard for diagnosing COVID-19, is not included in current workflow automation solutions, automating manual processes for routine tests frees up lab resources to do more COVID-19 or other dedicated scientific work.[27]

Automation solutions also play an important role in improving morale and work quality for laboratory staff. For example, manual labeling of tubes is not only tiring and time-consuming, these routine tasks of labeling, filling, uncapping, and capping of tubes can result in stress injuries in the fingers; in many cases, it leads to carpal tunnel syndrome. Automation can complete these tasks and decrease the risk of repetitive injuries from manual labeling. In addition, using automated solutions for repetitive tasks enables laboratories to lighten the workload on staff, so they can focus on more important high-value functions.[28]

The impact of automation on laboratory logistics

All laboratories, regardless of their size, can benefit from some level of automation, but implementing an automation system should not be done haphazardly. Rather, the design and implementation of such a system must follow a thorough analysis of a laboratory's current — and future — testing requirements. Only then will all of the information be available to determine what level of automation is sufficient[29] and acceptable within the logistical parameters of the lab (example: space and budget).

The design and layout of a clinical laboratory impacts the operational efficiency, flexibility, and costs of a healthcare organization throughout its operational life.[30] Optimal space requirements should be adhered to as to ensure work remains unhindered and employee safety is upheld.[31]

The instrumentation required to perform the test menu in the laboratory and the degree of automation are the primary drivers of space, which is expensive and a precious commodity in the acute care setting. Therefore, optimization of specimen processing is the central focus within most clinical laboratories. Among the key clinical lab design principles are workflow efficiency for improved specimen processing; flexible and modular space allocation to accommodate robotic instrumentation; and safe, people-centric design to promote healthy work environments.[32]

As lab work continues to move away from manual bench testing to increasingly more automated processes, open-plan designs provide the flexibility necessary for labs to easily add analyzers or adapt to provide more efficient workflows.[33]

Automation solutions can offer laboratory managers greater control over their workspace, while allowing flexibility to scale according to test volumes, laboratory size and cost requirements.

COVID-19: a renewed cry for automation

The ongoing COVID-19 pandemic has underpinned the central position of diagnostic testing in outbreak control.[34] Ending the pandemic globally involves the accurate application of diagnostic testing in high volumes and the rapid use of the results to help implement the appropriate therapy and prevent further spread.[35]

COVID-19 has put the human factor of laboratory technicians to the test. Laboratory staff is facing tremendous pressure resulting from the sheer magnitude of the pandemic, including keeping up with the high volume of tests per day and adhering to COVID-19-related regulations, all while staying safe. With testing volumes higher than ever, laboratory professionals are working extended hours and across multiple departments and laboratories. Post-pandemic, the number of tests needed are predicted to increase, as those who put off annual check-ups, about 41% of U.S. adults according to the CDC,[36] will start testing again. In August 2020, an AACC survey found that 58% of laboratories noted staffing as an issue, up from 35% in May,[37] and the gap between laboratories finding available, qualified medical laboratory technicians and the demand for that skillset continues to expand. Consequently, the late shift,

when fewer people are around, is being assigned to less-experienced technicians. This coupled with the laborious, repetitive nature of lab work leaves additional room for human errors to occur, leading to increased lab operating costs.[38]

Automation plays a key role in helping to address staff shortages while enabling precious resources to focus on high-value clinical tasks, and this is particularly true during the COVID-19 pandemic. Among the changes that the COVID-19 pandemic has affected is an acceleration in laboratories automating their workflows. The driving force behind increasing automation was the need to increase efficiency as test volumes soared during the peak of the pandemic. Another key component was the need to reallocate staff to tasks that required more critical thinking and a human touch, rather than basic sample preparation that could be done by a robot. Many laboratorians also noted the ongoing shortage of qualified lab technicians and said that automation had helped them make the best use of the techs they have.[39]

Beyond instruments and equipment, lab leaders should adopt an entirely new mindset when it comes to workflow improvements. Some of the greatest limitations in the lab aren't technical at all — they're mental. Resistance to automation and inability to be flexible to new technological demands will almost certainly impede success in future crises. With a critical eye, each area and manual/mechanical process in the lab should be examined for efficiency. Those that prove to be a bottleneck in the process are where automation is best focused.[40]

Conclusion

There are many advantages to introducing automation during the pre-analytical phase. These advantages include a decrease in repeat specimen collection; reduced specimen volume; secure patient and specimen identification; achievement of effective specimen integrity and preservation; decreased specimen handling, which helps laboratory personnel to avoid blood-based infection; containment of biohazardous materials; avoiding risk of human error; and reduction of the number of test tubes used.[41]

The sheer magnitude of the pandemic means that laboratory automation technologies are being embraced more than ever for their ability to drastically reduce the bottlenecks in sample prep and process samples at a much faster rate than humans. Although COVID-19 testing and research efforts are currently the main drivers, the need for lab automation has been accelerated in other laboratories, too, as a means of helping them operate more safely and efficiently.[42] The facts are clear. Laboratories play a central role in safeguarding the well-being of patients. Automation is a tool that enables laboratorians to perform this role much more efficiently and effectively.

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TEST QUESTIONS

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1. **It is estimated that _____ of all healthcare decisions affecting diagnosis or treatment involve laboratory testing.**
   - A. 30%
   - B. 80%
   - C. 50%
   - D. 70%

2. **At least _____ of all diagnoses are not considered final, until laboratory testing is complete.**
   - A. 70%
   - B. 10%
   - C. 25%
   - D. 50%

3. **This occurs in 3-12% of cases: _____.**
   - A. mistakes in sample collection
   - B. preparation errors
   - C. potential patient harm
   - D. analytical errors

4. **Most laboratory errors _____ the analytical phase and that pre- and post-analytical processes are more vulnerable to error.**
   - A. fall outside
   - B. are within
   - C. occur around
   - D. are accidents at

5. **Problems in patient preparation, sample collection, transportation and preparation for analysis and storage are _____.**
   - A. avoidable
   - B. pre-analytical errors
   - C. post-analytical errors
   - D. collection errors

6. **The cost per pre-analytical error in the U.S. is _____.**
   - A. $308
   - B. $803
   - C. $208
   - D. $609

7. **An average laboratory can expect to incur approximately _____ in costs related to mislabeling, wrong samples and insufficient sample volumes.**
   - A. $180,000 per year
   - B. $160,000 per year
   - C. $160 per day
   - D. $180 per day

8. **Studies show that approximately _____ of processed tubes will come into the laboratory with pre- or post-analytical errors.**
   - A. 12%
   - B. 0.5%
   - C. 68%
   - D. 0.66%

9. **Inpatient pre-analytical error rate was _____.**
   - A. 1.9%
   - B. 18%
   - C. 8.9%
   - D. 0.8%

10. **The variable receiving the highest frequency rating was _____.**
    - A. specimen collection
    - B. specimen hemolysis
    - C. insufficient volume for testing
    - D. anticoagulant volume ratio

11. **All are common pre-analytical errors, except _____.**
    - A. inadequate sample/anticoagulant volume ratio
    - B. container inappropriate
    - C. a needle stick
    - D. labeling errors

12. **Erroneous validation of analytical data is an example of what type of error?**
    - A. Collection
    - B. Pre-analytical
    - C. Analytical
    - D. Post-analytical

13. **A major impetus for automating clinical laboratories has always been the opportunity it presents to simultaneously _____ and improve quality of operations by decreasing human error.**
    - A. comfort patients
    - B. reduce cost
    - C. take away jobs
    - D. be environmentally responsible

14. **Approximately _____ of laboratory technicians are spending their time in the pre-analytical phase: accessioning, sorting, decapping, centrifuging, and transporting.**
    - A. 60%
    - B. 80%
    - C. 47%
    - D. 20%

15. **Up to 75% of testing errors take place during the _____.**
    - A. collection phase
    - B. pre-analytical phase
    - C. analytical phase
    - D. pre-analytical phase

16. **All are proven benefits that have fueled the adoption of laboratory automation, except for _____.**
    - A. overcoming challenges with staffing
    - B. fluctuations in testing volumes
    - C. improving turnaround time
    - D. raising costs

17. **Automation allows for taking over the bulk of many manual ordinary activities, except for _____.**
    - A. specimens sorting
    - B. sample collection
    - C. decapping
    - D. centrifugation

18. **Automation helps to mitigate bottlenecks that occur during sample preparation by all of the following except _____.**
    - A. more efficiently
    - B. processing samples quicker
    - C. with less variation than humans
    - D. preventing accidental needle sticks

19. **Automation for computerized physician order entry includes all of the following except _____.**
    - A. magnetic strip recognition
    - B. radiofrequency identification (RFID)
    - C. typing in an order on a lab's website
    - D. optical character recognition

20. **Post-pandemic, the number of tests needed are predicted to increase from those who put off annual check-ups, about _____ of U.S. adults.**
    - A. 51%
    - B. 41%
    - C. 14%
    - D. 91%

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2. **To what extent was the article well-organized and readable?**
   P ① ② ③ ④ ⑤ E
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Managing the four-prong threat of CDI, antibiotics, the flu season and COVID-19

By David M. Lyerly, PhD, and Jodie Y. Lee, MS, MBA

Antibiotic use increases during winter months because of the diagnosis or threat of secondary bacterial pneumonias following primary viral respiratory infections. Viral respiratory infections weaken the host's immune and innate responses, allowing bacterial pathogens, such as *Streptococcus pneumoniae* and *Staphylococcus aureus*, to infect and inflame the lung alveoli. Physicians may implement antibiotic therapy after diagnosing bacterial pneumonia, but also often use antibiotics empirically as a preemptive strike when they suspect bacterial pneumonia.

The broad-spectrum antibiotics used to treat bacterial pneumonias are highly efficacious against lung bacterial pathogens. Unfortunately, they also are highly active against healthy intestinal microbiota. As a result, treatment for bacterial pneumonia results in a precipitous and unavoidable — at least until more specific antibiotics become available — drop in the diversity of the intestinal microflora. The consequence of this action may be devastating to patients because it compromises their defense against *Clostridioides difficile* infection (CDI). A patient treated with antibiotics for secondary pneumonia triggered by a viral respiratory infection now may face a third infection, a potentially life-threatening intestinal infection caused by a very dangerous toxin-producing bacterium.

The overuse of antibiotics in patients who have viral pneumonia hinders the efforts of antibiotic stewardship designed to minimize evolutionary stress that leads to antibiotic resistance.

This is a medical illustration of *Clostridioides difficile* bacteria, formerly known as *Clostridium difficile*, from the Centers for Disease Control and Prevention (CDC)

According to the Centers for Disease Control and Prevention (CDC), almost a third of *S. pneumoniae* isolates are resistant to one or more antibiotics, and methicillin-resistant *S. aureus* continues to pose a serious risk, especially to elderly patients. *C. difficile* ribotype 027, a hypervirulent strain that grows rapidly and produces higher levels of toxins A and B in the intestine, spread swiftly in the early 2000s because of its resistance to fluoroquinolone antibiotics. It continues to cause outbreaks in hospitals and healthcare facilities in Europe, Canada, and the U.S.

Antibiotics are prescribed more during a typical flu season, resulting in an increase in CDI

During the 2019-2020 flu season in the United States, a statistically typical flu season, there were roughly 50 million cases of seasonal flu, resulting in 40,000-50,000 deaths. Hundreds of thousands of patients who had the flu developed secondary bacterial pneumonia caused most often by *S. pneumoniae* and *S. aureus*, but also by gram-negative pathogens, such as *Klebsiella*, *Hemophilus*, and *Pseudomonas*. In the more severe 2009 H1N1 flu epidemic, hundreds of thousands of people died from the disease, and it has been estimated that up to a third of these people may have developed secondary bacterial pneumonia. Due to patterns in increased antibiotic use, CDI shares epidemiologic characteristics with flu. A higher incidence of flu and bacterial pneumonia during winter months will be followed in a matter of weeks by a higher incidence of CDI, approximately 20% higher.

One of the first studies to examine the association of CDI with flu came from data collected over a 7-year period (1998-2005) in the Nationwide Inpatient Sample. Influenza activity preceded increased CDI activity both nationally and regionally.[1] A 23% increase in CDI over summer months was observed, leading to the key observation that linked the increased use of antibiotics during flu season with increased rates of CDI. In another study, the seasonality of CDI was linked not only with influenza, but also with respiratory syncytial virus (RSV), another RNA virus associated with outbreaks in the winter.[2] RSV is typically associated with respiratory infections in infants and young children, but it affects people of all ages. The increased rates of CDI were again associated with increased use of antibiotics; in this instance, primarily fluoroquinolones and macrolides that were administered to patients to lower the risk of bacterial pneumonia.

In one of the larger studies performed to date using U.S. National Hospital Discharge Survey data,[3] pneumonia and influenza peak prevalence preceded peak CDI incidence by about 9 weeks. Importantly, there were intestinal effects from the CDI that, in some cases, lasted up to a year. Pneumonia and influenza peaks occurred earlier in some regions of the country, with similar early patterns being observed for increased rates of CDI. In all of these studies, the association of CDI seasonality was linked with increased use of antibiotics during the flu season. Other factors, such as hospital crowding and interhospital transfer, were considered, but increased antibiotic use was determined to be the primary triggering event.

The incidence of flu so far in 2021 has been historically low, and the 2020-2021 flu season has been anything but typical.

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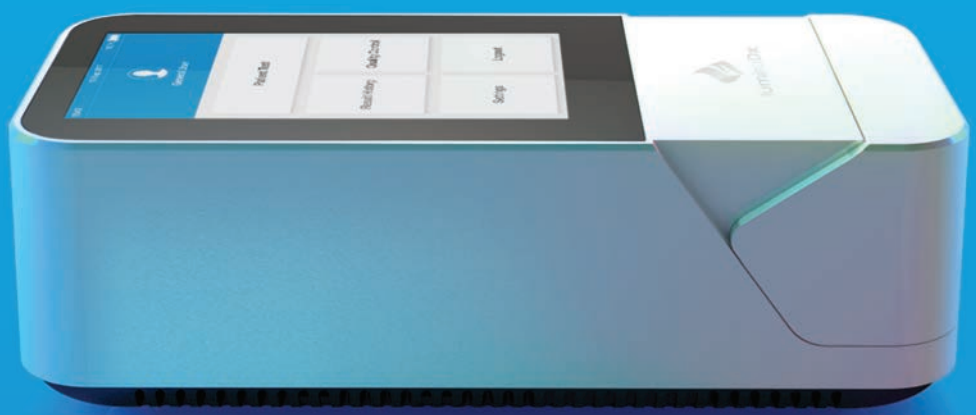

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Last year at this time, there were predictions of a very severe flu season for 2020-2021, in combination with the COVID-19 pandemic — a "twindemic" as some put it. However, the increased public health awareness and safety measures put in place for COVID — masks, social distancing, and reduced person-to-person contact — have led to a very low incidence of influenza infections. As countries that have an earlier flu season reported strikingly low numbers of cases, forecasts of a bad flu season in the U.S. turned instead to accurate predictions of a mild season. As of Spring 2021, only thousands of flu cases have been reported, compared to the millions reported in the previous year. The mitigation procedures used for COVID-19 have not only reduced flu rates, but the health and safety precautions used in healthcare facilities have helped to lower hospital-acquired infections such as CDI, even when the rate of antibiotic use has not been reduced.[4]

Another reason for reduced flu rates? People have been more inclined to get their flu vaccinations in the 2020-21 season. Because of the low flu rates, and probably also in part because of the decrease in hospital admissions during the 2020-2021 season, CDI rates that typically rise at the tail end of flu season likely will be steady or perhaps slightly lower this year. This is fortunate, but even so, CDI continues to be the predominant hospital-acquired infection in the United States, and *C. difficile* will continue to cause diarrhea and colitis in significant numbers of hospitalized patients and cause community-acquired disease.

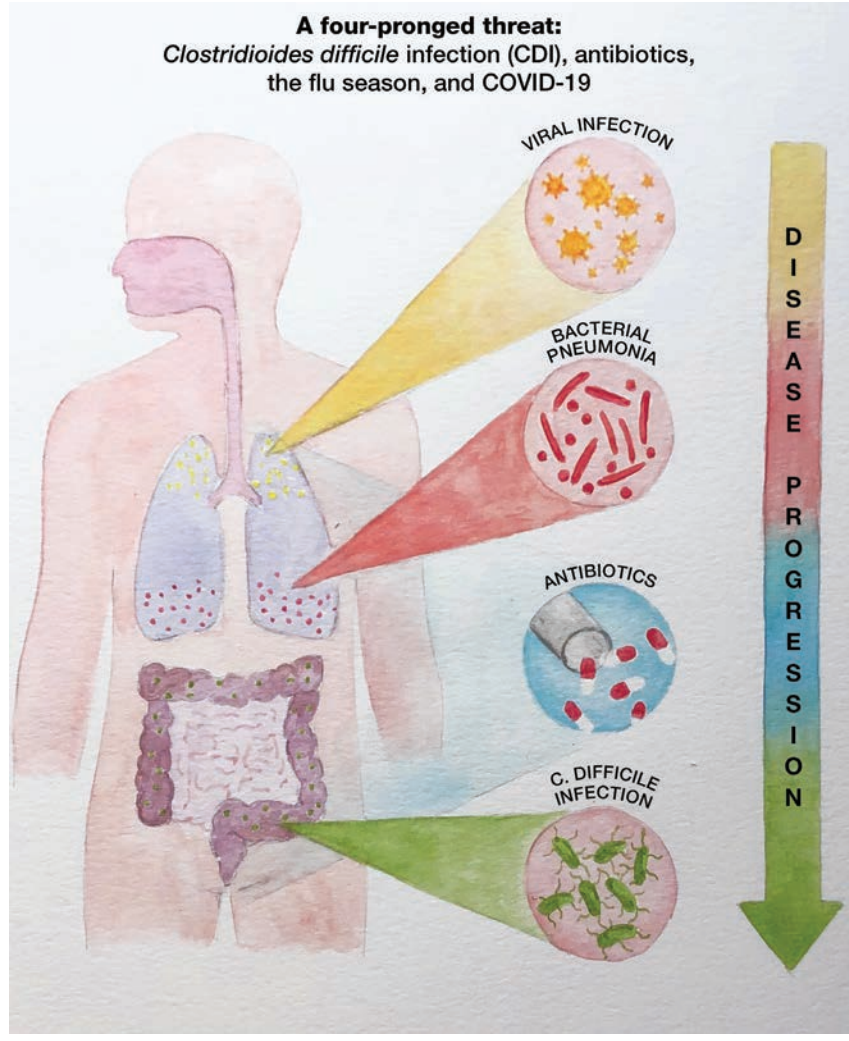

Image Courtesy of TECHLAB

COVID-19 infections early in the pandemic led to an overuse of antibiotics

In the early months of the pandemic when COVID-19 cases began to increase dramatically in the U.S. and in other countries, physicians started treating large numbers of patients with antibiotics in an effort to circumvent what they thought would be high numbers of bacterial pneumonia. In many locations in the U.S., more than 50% of COVID-19 patients were being treated with antibiotics. In some countries, the number approached 70%. The flu model of a close association of viral respiratory disease with complications caused by secondary bacterial pneumonia was the basis for this empirical approach early in the pandemic. Additionally, there were few, if any, other treatment options at this early stage in the pandemic. As this practice of empirical antibiotic therapy grew, infectious disease experts raised concerns about the appearance of antibiotic-resistant bacterial strains, along with possible consequences, such as CDI.[5,6]

Fortunately, by mid-2020, it became apparent that secondary bacterial pneumonias were not being seen at rates that were initially predicted. In fact, the opposite was true — secondary bacterial pneumonias were only being seen in low numbers of COVID-19 patients. Additionally, experts did not identify and associate any particular bacterial pathogens with the small number of patients who did develop bacterial pneumonia. Recommendations followed shortly thereafter, advising physicians to curtail empiric treatment of COVID-19 patients with antibiotics.[7]

Currently, researchers have not found a clear association between increased CDI cases and the high number of COVID-19 patients who received antibiotics in the early stages of the pandemic. The high use of antibiotics in the early months would suggest the possibility of a higher incidence of CDI. However, little data exist to confirm this hypothesis, or even to suggest that it was investigated, probably due to the overwhelming demands already placed on healthcare staffs, testing facilities, resources, and instrumentation.

SARS-CoV-2 may have multiple effects in the intestine

Recent clinical findings have revealed that up to 25% of COVID-19 patients develop diarrhea, and that large numbers of COVID-19 patients have detectable SARS-CoV-2 RNA in their feces.[8] Perhaps this observation is not unexpected, since other respiratory viruses are known to trigger diarrhea in some patients. These findings also suggest the possibility of fecal-oral transmission of SARS-CoV-2. The ACE2 receptor for the virus exists in brush border membranes in the small intestine and in colonic crypts. The ACE2

receptor may, in fact, be present in higher amounts in the intestine than in the lungs. The binding of the virus to its receptor in the intestine is a plausible mechanism for COVID-19-associated diarrhea.

The ACE2 receptor may increase in amounts as we age, which seems contradictory to observations showing that COVID 19-associated diarrhea is more prevalent in younger adults.[9,10] However, most of what is known about the binding of SARS-CoV-2 in the intestine is preliminary, and much remains to be discovered about the binding and action of SARS-CoV-2 in the intestine.

Although the binding of SARS-CoV-2 to its intestinal receptor probably represents the triggering event in COVID 19-associated diarrhea, physicians are now identifying COVID-19 patients who are co-infected with toxigenic *C. difficile*. In one study that looked at critically ill COVID-19 patients who received antibiotics and who were infected with *C. difficile*, 9 of 49 patients developed CDI.[11] Other studies have confirmed co-infections with SARS-CoV-2 and *C. difficile*, and have shown that co-infected patients have more severe prognoses.[12,13] The data at this time are slim, but more studies will provide additional information on the clinical relevance of *C. difficile* in COVID-19 patients.

In addition to the binding of SARS-CoV-2 to its intestinal receptor, the virus may have a negative impact on the healthy protective commensal bacteria in COVID-19 patients. This possibility has only recently been reported, but it suggests that SARS-CoV-2 infections may reduce the diversity of the microbiota.[14,15] This finding is worth noting, because the disturbance of the microbiota is a predisposing factor for CDI. Other diseases and chronic conditions (e.g., norovirus, inflammatory bowel disease) that lead to a reduction in microbiota diversity have been associated with CDI.

We are at the infancy of our understanding of the SARS-CoV-2 mode of action and epidemiology and have much to learn about CDI. However, some early indications of the ability of some respiratory viruses to bind to intestinal receptors, cause diarrhea, and disturb our protective microbiota, which may serve as a triggering event for CDI, lead to important questions about the role of SARS-Co-V-2 infection in *C. difficile* epidemiology.

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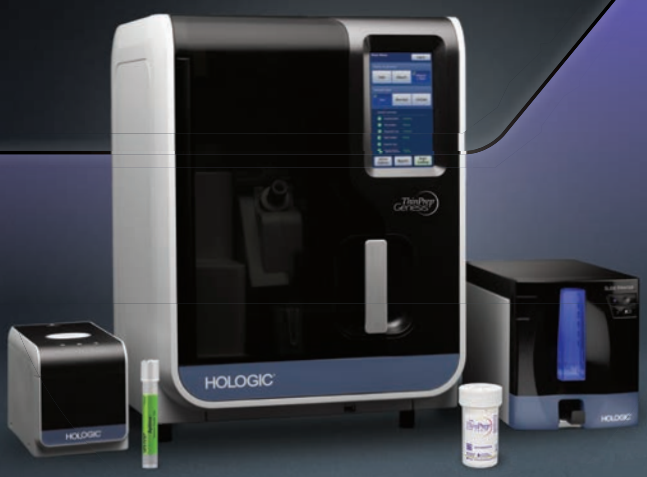

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Innovators creatively conquer COVID-19 challenges

by Marisa L. Williams

The impact of the pandemic resulted in labs devising plans to cope with supply and personnel shortages. Implementing necessary changes in the chaos of the COVID-19 pandemic, a few labs rose above and beyond to conquer unforeseen challenges in creative ways amongst the increased demand, sharing stories that make them Labs Worth Watching.

Medical Laboratory Observer is proud to announce and congratulate the 2021 Lab Innovators Worth Watching (in alphabetical order): Michigan Technological University; UnityPoint Health; University Medical Center of Southern Nevada, PCR Lab; University of Arkansas for Medical Sciences; and the Yale School of Medicine.

UnityPoint Health in Cedar Rapids, IA

Julie Behr, MHSA, MT(ASCP), Director Laboratory Operations at UnityPoint Health in Cedar Rapids, IA, shared how her lab responded to patient influx with new processes implemented by MedLabs' management team of Jennifer Metzen, Amanda Vaske, Chelsea Leonard and Nicholas Ball.

"MedLabs patient service centers are small, with limited waiting room space. For leveling out the patient flow and to provide the social distancing recommendations that aligned with COVID respiratory precautions, MedLabs moved away from walk-ins to appointments using Epic in combination with (a) WELL.com application for the patient to safely wait in their car." The system would text the patient appointment information on what to do when they arrive and additional appointment reminders. They were the first lab in their health system to implement routine laboratory services by appointment.

UnityPoint St. Luke's

Others within UnityPoint had to make creative solutions for the lab during the pandemic, such as Tara Kress when UnityPoint St. Luke's Hospital began to provide microbiology services to two area hospitals. "In preparation for this change in volume, the microbiology department purchased larger incubators. The previous incubators had convenient smaller trays that allowed technologists to easily remove a single tray of petri dishes. With the new larger incubator, the trays were much too large to manage," Behr recalled.

To solve the problem, Kress went to the UnityPoint Health Innovation Center, a space, known as Generate, dedicated to developing ideas to help provide better care and unique experiences for UnityPoint Health patients. Kress created custom, laser cut, acrylic trays to work seamlessly with the new incubators to improve workflow in the lab.

University Medical Center of Southern Nevada, PCR Lab in Las Vegas, NV

Innovation during the pandemic did not end with things inside the lab, as many labs popped up amidst the pandemic, such as University Medical Center of Southern Nevada, Department of Laboratory Services, Covid PCR Lab in Las Vegas, NV. Scott Keigley, General Laboratory Services Manager, described the project.

"Our team was able to work with various areas of the hospital to build, from scratch, a dedicated COVID-19 PCR laboratory in the span of several weeks. Normally, we have at least several months to accomplish a project this size (and we also don't have to compete against every other lab on the planet for the exact same supplies!), but through the focused dedication of numerous government and hospital individuals, we were able to begin community testing in record time. Since the beginning of the COVID-19 pandemic, we have and continue to perform over 30% of all COVID-19 PCR testing for the entire State of Nevada. Although our daily test volume has significantly been reduced by the vaccination, we continue to be the main testing source for travelers heading outside the U.S. We are also starting a dedicated lab in the Las Vegas airport to perform PCR testing on site."

Some of the biggest challenges in creating a COVID-19 lab in only four weeks included the inability of many vendors to provide test materials and collection kids in the volumes needed within a short time frame, requiring multiple sources for testing contracts, hiring and training people, as well as creating the information technology necessary for registration, scheduling, collection and for smart phone applications.

Requiring the help of all available, "the local community college had med tech students make collection kits during their free time." Keigley described the urgency to get the lab up and running. "To be honest, the first two months of planning and implementation were all done 'on the fly' for the most part, not having the time to fully research all project aspects like we normally would."

To keep up with demands, UMC hired more than 90 full- and part-time people to process samples and perform COVID PCR testing, even enlisting the National Guard to help when needed. This demand helped other displaced employees.

"Last year, like many parts of the country, our local hospitals experienced a significant reduction in patient census due to surgical and other hospital service closings." Keigley shared that this caused several healthcare facilities to furlough employees. "We were able to incorporate many of those people into our operation, providing a valuable source of income for them."

Healthcare workers from across the local area were trained to participate in specimen collection and processing, as well as testing.

"This has resulted in increased local awareness of what a great work environment we provide and created significant interest in working here long term. We have already hired several people who had worked on our COVID-19 team into the main lab. Having the opportunity to see potential employees in action, versus just going through the traditional interview process, is one benefit of having such a diverse team," explained Keigley.

Their team worked with various information technology resources to create a smart phone application that patients can use for scheduling and viewing results. They have also had other innovative solutions.

"COVID-19 has had a negative impact on the tourist-based economy in Las Vegas. Concepts like on-site casino PCR labs have become a reality with our assistance," said Keigley. "We are currently working on identifying 'other' uses for the PCR and immunochemistry equipment we had purchased originally for COVID-19 testing. These platforms will soon be used for a variety of testing we currently do not perform, such as HLA typing, infectious disease detection, antibiotic resistance, and various kinds of genotyping."

In hopes of expanding diagnostics, now that the pandemic has begun to slow, the lab employees are currently researching other tests they can use their newly purchased equipment for, such as HIV, CT/NG and Hepatitis B & C PCR testing. Looking into a variety of genotyping options for their oncology program, HLA typing is being considered, since the hospital operates the main transplant program in the state. Keigley added, "We have also moved an immunoassay analyzer that was originally purchased to do COVID-19 IGG testing into that area to do Quantiferon testing. We are creating a dedicated Molecular team to perform this testing as well."

Michigan Technological University

The team members at Michigan Technological University were researching wastewater, monitoring the campus as part of their strategy for combating COVID-19. Studies have shown that SARS-CoV-2 levels in wastewater predict the number of symptomatic individuals infected with COVID-19,[1] as people generally begin shedding the virus in feces, before they become symptomatic.

Located in a remote and rural community, Michigan Tech was closely monitoring the wastewater for potential outbreaks. "Weekly monitoring of wastewater flows on campus reveals trends in the number of infections, even if infected individuals are asymptomatic. If SARS-CoV-2 levels increase in the wastewater stream generated by a particular residential building, University officials

MTU water sample courtesy of MTU

can increase diagnostic testing of the asymptomatic residents of that building to limit the spread of the virus among their contacts," explained Stefanie Sidortsova, JD, Head of Communication Strategies at Michigan Technological University.

"We get a signal before people become symptomatic. Several studies, both in the U.S. and elsewhere in the world, have shown [researchers] were able to predict outbreaks of the virus based on the signal in the wastewater," said Jennifer Becker, Associate Professor of Civil and Environmental Engineering, who leads the wastewater testing initiative. "It gives us advance notice. It can help us determine where we need to direct resources, such as diagnostic COVID-19 testing or disseminating information about how to limit the spread of the illness."

Stefanie Sidortsova

Measuring virus flows at residence halls and other locations multiple times a week, the process they used to quantify the virus in wastewater has three main steps. First, concentrate the virus genetic material (ribonucleic acid or RNA), then extract the virus RNA from the wastewater, and quantify the amount of virus RNA in the samples using a technology known as reverse transcription-quantitative polymerase chain reaction (RT-qPCR).

Converting viral RNA to DNA that binds with primers and are tagged with a fluorescent dye, the DNA is copied in repetitive cycles, increasing the amount of fluorescence in the sample proportionally. "To quantify the abundance of the virus in a wastewater sample, the number of cycles required to generate a certain amount of fluorescence is compared to the number of cycles required to create the same amount of fluorescence in solutions containing known concentrations of the viral RNA. Quantifying the amount of viral RNA in a sample goes a step further than diagnostic testing of human biospecimens, which also uses RT-qPCR, but is primarily designed to determine only whether a sample is positive or negative for the virus," said Sidortsova.

The Michigan Department of Environment, Great Lakes, and Energy and the Michigan Department of Health and Human Services announced in November 2020 that they were awarding $6 million in grants and $3 million in laboratory equipment to 20 Michigan teams to support a three-month pilot program to assess the potential for using wastewater-based monitoring to assess COVID-19 dynamics in Michigan communities.[2] Working with the Western Upper Peninsula Health Department, Michigan Tech was awarded $352,721 to quantify SARS-CoV-2 levels in samples collected by 18 municipalities throughout the five counties in the western Upper Peninsula of Michigan (Baraga, Gogebic, Houghton, Keweenaw, and Ontonagon).

Becker's lab processed and analyzed virus levels in approximately 70 samples per week using droplet digital PCR instrumentation acquired through this initiative.

"We all think of food and water as being essential to life. They are, but waste is also a critical part of life," Becker said. "All organisms generate it, and it's something people don't really want to deal with. However, we all produce waste, and we have to manage it appropriately to protect public health and the quality of our environment. This

Yale New-Haven Lab_courtesy of Yale

is one of the key responsibilities of environmental engineers, and it's really essential to sustaining livable communities." Moreover, wastewater-based monitoring has shown that human waste contain valuable clues that helps monitor and manage COVID-19 in our communities.

Yale School of Medicine

Yale University School of Medicine

With advances, there are unfortunately errors, and the Yale School of Medicine has been researching how to get the best results possible. Joe M. El-Khoury, PhD, DABCC, FAACC, Director, Clinical Chemistry Laboratory, Co-Director, Clinical Chemistry Fellowship Program at Yale-New Haven Health and Associate Professor of Laboratory Medicine at Yale School of Medicine, has focused on reducing errors.

"Our team has implemented innovative solutions using middleware to automate and resolve common interference issues affecting clinical chemistry tests. The first involved automatically managing samples with icteric interference by building rules that trigger automated sample dilution on-board the analyzer to resolve the interference and report the results. The second involves preventing pseudohyponatremia (work currently under review for publication) by building rules that evaluate protein and lipemia index to automatically trigger a reflex to a direct ion selective electrode method for a more accurate plasma sodium measurement."

Their latest published research on pseudohyponatremia, an online video, suggests clinical laboratories should lower the tolerance for lipemia on certain machines, and they recommend reflexing to direct ISE when the L-index exceeds 700 (Roche) or when samples contain total proteins greater than 9 g/dL (90 g/L). They advise those with other indirect ISE methods to evaluate the effect of lipid interference using hyperlipidemic human samples, instead of Intralipid.

To spread the word in the medical community, El-Khoury made an informative video, explaining the difference between pseudohyponatremia and pseudohypernatremia, direct and indirect ISE, as well as the electrolyte exclusion effect and more, which can found at https://www.youtube.com/watch?v=NASuk9bfU_I&t=133s.

University of Arkansas for Medical Sciences

The impact of the pandemic is a reminder to look to the future. The leaders of the laboratory must have educational opportunities to rise to the top; thus, having chances for those curious about labs to hone their skills under the guidance of professionals is an important aim for the future.

"Our team at UAMS has committed to increasing the availability of educational resources to the rural communities of Arkansas and the United States," explained Nathan H. Johnson, PhD, MASCP, MT(ASCP)DLM, SC, SLS, FACHE, Chair, Department of Laboratory Sciences, University of Arkansas for Medical Sciences, who joined the university in November of 2017 after retiring from the military. He was met by faculty and staff that had been strategically planning to increase the number of laboratory technicians to serve rural areas. This included the incentive of online students being able to receive in-state tuition rates to make their program more affordable.

"Starting with a SWOT analysis in 2018, our program has more than tripled the number of rural MLTs who have advanced to obtain their bachelor's degree and Medical Laboratory Scientist certification, and this increase also includes underrepresented populations. We have plans to do even more to serve the rural laboratories in our area of concern. I believe what we are doing is really making a difference in many labs across the United States!"

Their plan involves visiting all rural labs in the state to really see what is happening in their labs, characterizing their needs, with a goal of implementing training platforms to help the labs grow.

Johnson added, "The rural labs started the pandemic with critical staffing shortages, and that was made only worse by the pandemic. My belief is that many rural labs are forced to hire individuals who have no formal lab training or education. On the job training for these individuals is very difficult and with the shortage of staff, it is very difficult to train someone. Many of our students form rural areas reported supply shortages."

As many medical diagnoses rely on laboratory results, the significance of laboratory work is much more than looking through a microscope. Building a solid foundation for the future laboratorians might be based on what people learned during a few stumbles amidst the pandemic, for necessity is the mother of invention. It's exciting to see the what the future holds for labs.

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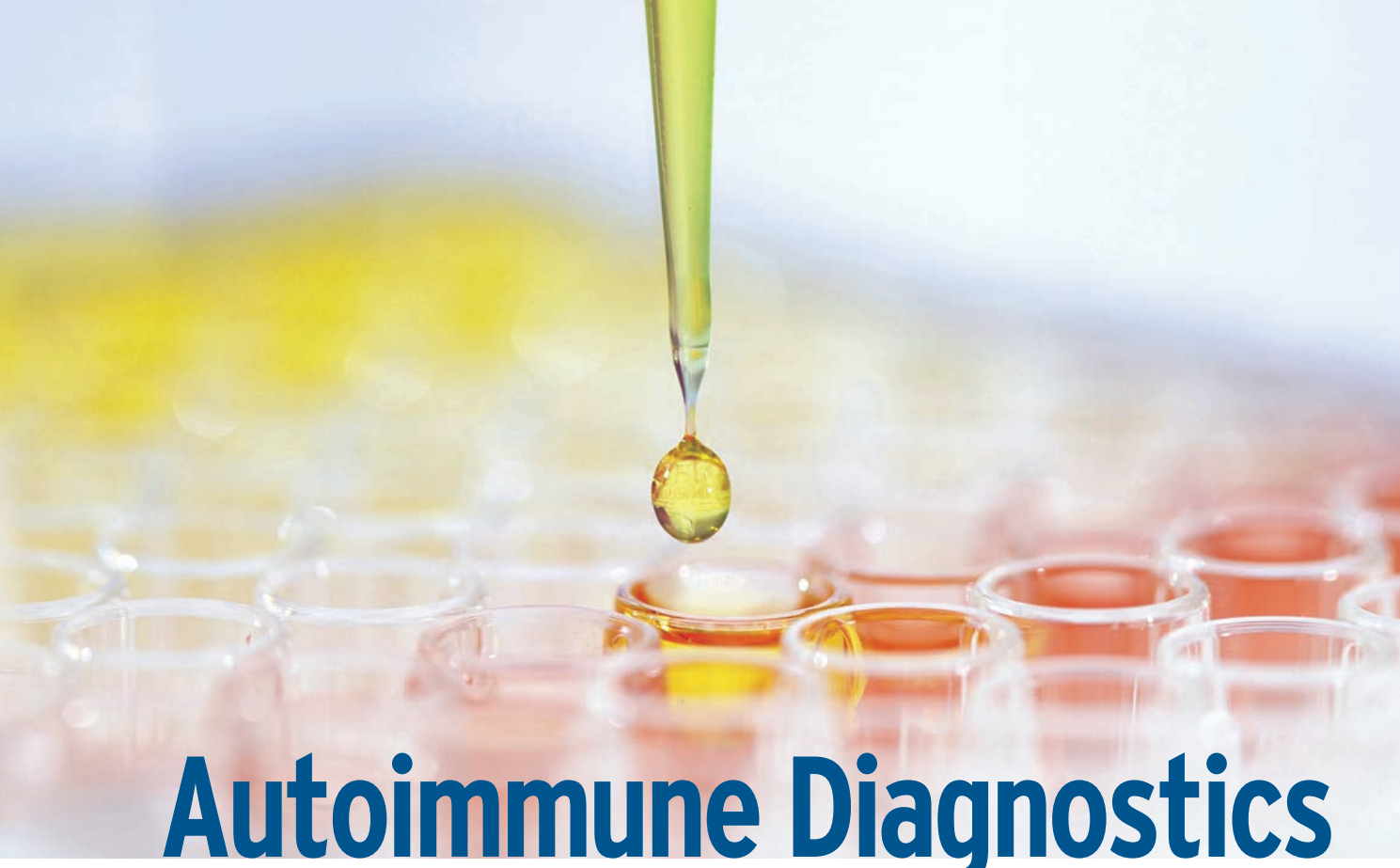

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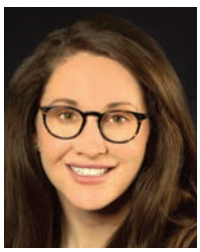
Clinical tips for consumable supply shortages

By Marisa L. Williams

When the basic consumables that clinical laboratorians need are in short supply, laboratory professionals and supply distributors must act quickly and creatively. The COVID-19 pandemic resulted in shortages of necessary medical laboratory supplies, so *Medical Laboratory Observer* contacted some suppliers for their perspectives on the pandemic and advice on future availability.

Pandemic stressed supply chain

Virginia Templet, Marketing Director for Puritan Medical Products Co., noted, "The sales of the swabs and microbiology specimen collection kits all increased significantly during the pandemic." She recalled, "Supplies used in the microbiology lab and production, such as chemical raw materials, culture media, pipets, and sterilization services were in high demand, and we had to find alternative sources throughout pandemic."



Virginia Templet

She noted that most items went on backorder at some point during the pandemic; alternatives were needed, and guidance was appreciated. "Early on in the pandemic, there seemed to be confusion in hospitals and point-of-care facilities about the best transport media or collection device to use for COVID sampling; with the CDC's (Centers for Disease Control and Prevention) help and guidance, that confusion was short lived."

Mark Krhovsky, Vice President of Laboratory Sales, Medline also felt the demands of the pandemic. "Like all distributors, Medline was not immune from laboratory supply challenges during the pandemic. We had trusted national brand manufacturer partners run into unprecedented obstacles, including plant shutdowns, labor deficiencies, and raw material shortages. As both a manufacturer and a distributor, Medline was able to pivot quickly and develop practical solutions though our global sourcing/self-manufactured vertical. The ability to be self-reliant in these circumstances provided a level of flexibility and ingenuity that allowed us to support customers under the most difficult of circumstances."

Mark Krhovsky

Amidst the COVID chaos, nobody really knew what to expect or what supply would next be added to the shortage list and put on backorder, requiring quick thinking for conflict resolution. Krhovsky said, "I think there were plenty of 'surprises' through the pandemic. I don't think anyone foresaw the tremendous challenge on swabs and transport media." The increased demands stressed supply chains unexpectedly during the pandemic. "Being surprised by certain events was inevitable."

Worldwide lab supply shortages continue

Shortages from the pandemic continue to plague laboratories across the globe. In June 2021, the FDA released conservation strategies for sodium citrate blood specimen collection tubes, adding them as the latest item on the device shortage list.[1] The FDA recommends not including sodium citrate tubes, which typically have a light blue top, in routine collections of a variety of specimens at the time of other blood sampling or IV insertion, saying not to use them unless it is medically necessary or for difficult blood collections. The FDA advises labs not to use the light-blue top tubes as discard tubes, instead suggesting clear top or red stopper tubes, with no additives, as an alternative. These include vacuum sample tubes, with anticoagulant, sodium citrate only, as well as additional tubes, vials, systems, serum separators, and blood collection with sodium citrate only. The shortage is expected through the end of the year.

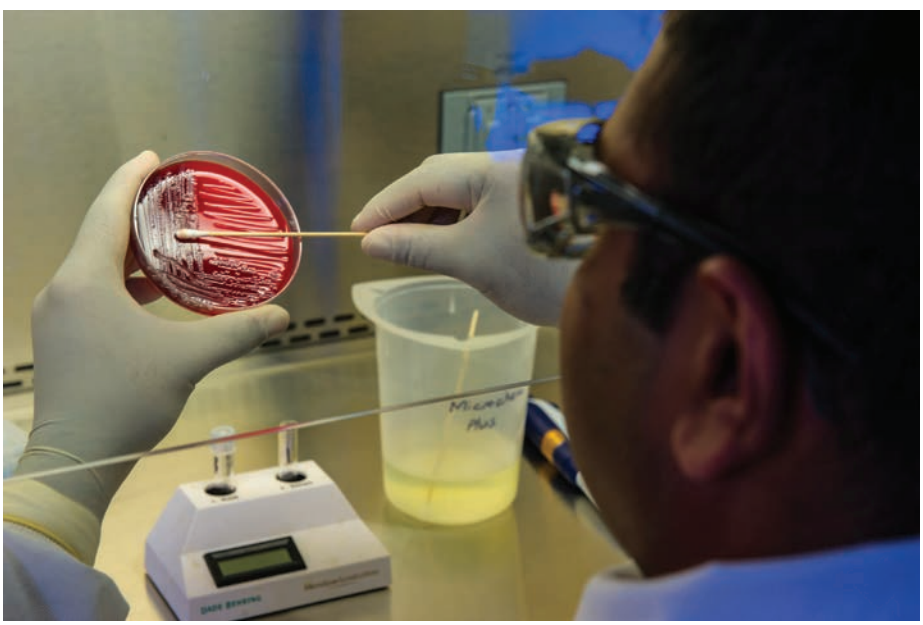


Photo by CDC on Unsplash

In May, multi-target respiratory-specimen nucleic acid tests, including SARS-CoV-2 and other microbial agents, were added to the shortage list.[1] Plastic for things like pipettes, general purpose reagents, transport culture medium, ventilators, masks, gowns and gloves, as well as microbial nucleic acid storage and stabilization devices continue to be in short supply, which may last for the duration of the pandemic.

While shortages sent people scrambling during the peak of the pandemic, some supplies are slowly starting to see less demand or have increased production. "There were several product categories that decreased amidst the pandemic. Plated media, routine POC testing, and histology related consumables just to

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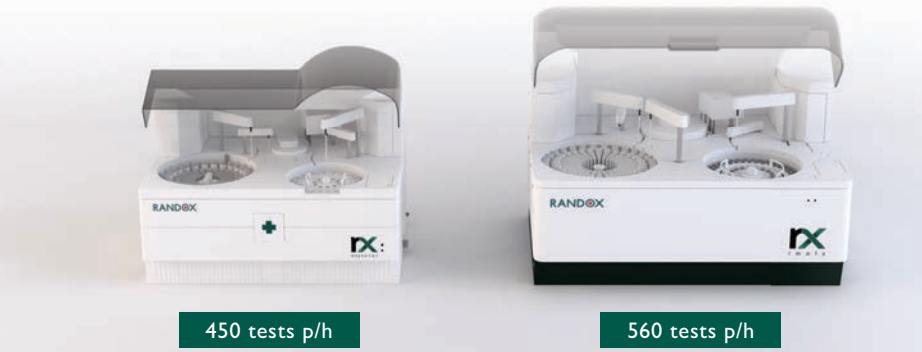

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FDA shortage list		
Category	**Description**	**Date Posted or Reverified**
Specimen Collection	**GIM** (Tubes, vacuum sample, with anticoagulant, **sodium citrate only**)	6/10/2021
Specimen Collection	**JKA** (Tubes, vials, systems, serum separators, blood collection, **sodium citrate only**)	6/10/2021
Laboratory Reagents and Testing Supplies	**QOF** (Multi-Target Respiratory Specimen Nucleic Acid Test Including Sars-Cov-2 And Other Microbial Agents)	5/24/2021
Laboratory Reagents and Testing Supplies	**JRC** (Micro pipette)	3/18/2021
Laboratory Reagents and Testing Supplies	**LXG** (Equipment, laboratory, general purposes, labeled or promoted specifically for medical use, **pipette tips only**)	3/18/2021
Transport Media Device	**JSM** (Transport culture medium)	3/18/2021
Transport Media Device	**LIO** (Microbiological specimen collection and transport device)	3/18/2021
Transport Media Device	**QBD** (Microbial nucleic acid storage and stabilization device)	3/18/2021
Specimen Collection, Swab	**KXG** (Absorbent tipped applicator)	3/18/2021
Laboratory Reagents and Testing Supplies	**PPM** (General purpose reagents for in vitro diagnostic tests, including pipette tips[4])	3/18/2021
Laboratory Reagents and Testing Supplies	**JJH** (Clinical sample concentrator)	3/18/2021
Laboratory Reagents and Testing Supplies	**NSU** (Instrumentation for clinical multiplex test system	3/18/2021
Laboratory Reagents and Testing Supplies	**OOI** (Real time nucleic acid amplification system)	3/18/2021
Personal Protective Equipment	**FXX** (Surgical mask)	3/18/2021
Personal Protective Equipment	**LYY** (Latex, non-powdered patient examination glove)	3/18/2021
Personal Protective Equipment	**LYZ** (Vinyl patient examination glove)	3/18/2021
Personal Protective Equipment	**LZA** (Polymer, non-powdered patient examination glove, includes nitrile gloves)	3/18/2021
Personal Protective Equipment	**LZC** (Specialty, non-powdered patient examination glove, includes nitrile gloves)	3/18/2021

name a few. Many of these products have subsequently bounced back in Q2 and are showing a continued uptick," said Krhovsky.

Now that the frenzy of the peak of COVID is starting to subside, Krhovsky mentioned seeing lower levels of purchasing pandemic related items while conversely seeing an uptick in the pre-pandemic tests and supplies.

Tips to surviving supply shortages

Templet's advice for surviving supply shortages: "Communication is key, staying in close contact with sales reps and providing blanket orders and forecasts wherever possible helps."

Krhovsky gave a tip that lab professionals should consider when purchasing consumables during times of shortages. "Partner with your supply chain partners who often have access to several different pathways to procure product. It also helps to have relationships and regular cadence with technical sales professionals from your prime distributors/manufacturers. That way, when an issue arises, you have an individual that has an intimate understanding of your operation and can respond accordingly. More than anything, though, stay open-minded. Clinical results are absolutely paramount, but in a time of crisis, it's important to understand what options are both viable and available. That might require thinking outside of the box and breaking away from traditional brand preferences."

Starting a system with dedicated, specific staff members who monitor products can help prevent running out of stock. Krhovsky mentioned partnering with supply chain counterparts on stock levels, ordering and procurement practices, as "often times, waste and/or scrap is commonly associated with ordering errors and inconsistencies, versus how the product is used or stored."

Finding a positive within the pandemic, Krhovsky noted the increased interest in molecular testing and products. "The pandemic shined a very bright light on the benefits and shortcomings of different testing methodologies. Whether it was POC or instrument based, I believe molecular testing was one of the few silver linings of the past 18 months."

He concluded with a nod to the behind-the-scenes heroes of the pandemic. "The labs in our country were nothing short of heroic during the height of the pandemic. There was an incredible amount of determination on the part of lab professionals and supply chain executives in terms of finding solutions on short notice. Validating and implementing new products on very short timelines represents challenges under normal circumstances. When you add staff shortages and increased workload, it becomes an even more valiant effort. I applaud these teams for getting it done under these unprecedented conditions."

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Steps to retain lab technicians and technologists

By Maggie Morrissey, MPA

While the demand for laboratory technicians and technologists is expected to increase by 7% in the next eight years (not including filling roles of those who retire or voluntarily leave),[1] the supply of qualified laboratory professionals will decrease, due in large part to a drop in interest in the field and the number of accredited training programs for medical technologists.[2] Any time an employee leaves, the laboratory is impacted by the time commitment to post, interview and hire a new employee, the knowledge loss the exiting employee takes with him or her, the loss of revenue, and the added strain placed on other employees.

For many laboratories, losing qualified employees is simply not an option; however, most do not utilize retention strategies to ensure their employees will stay long term.

Retention starts with ensuring your employees feel like they are valued and trusted members of the team. Understanding your company culture and the type of person you want to hire to add to that culture also is key for retention. Once new employees join the company, you want to ensure you are recognizing them for a job well done, meeting with them frequently to answer any questions, and confirming that any needed additional training is being carried out. Providing a great work environment and benefits are also factors in retaining and engaging your employees. Twenty percent of turnover happens in the first 45 days,[3] so it is important to engage and ensure that your new employees feel valued, connected, and invested in the laboratory and their team.

Retention issues occur for many reasons, and having a proper retention strategy is key for any laboratory seeking to hire and keep good employees. Having strong retention at your laboratory means an increase in overall productivity, coinciding with decreases in the time and costs associated with finding, hiring, and training new employees.

Photo by National Cancer Institute on Unsplash

Focus on career development

A survey by Deloitte found that lack of career progress topped the list of factors that would cause employees to look for new employment over the next 12 months.[4] Millennials overwhelmingly consider career development opportunities to be one of the most important factors they evaluate when considering whether to accept or stay in a position. In another recent study, 49% of employees said that the leadership at their organizations was adhering to the practice of fostering employee development.[5]

Despite this, however, many laboratories (especially smaller labs of less than 10 people) do not have a proper career path in place. This lack of a defined career path can reflect poorly on employers.

Many small laboratories have not felt a need to create a clear and defined career path. However, because of regulations associated with the Clinical Laboratory Improvement Amendments (CLIA), there are some clear areas laboratories can focus on. For example, in most states, CLIA allows a medical technologist to serve as general supervisor after two years.[6] Another career path example is a lead technologist growing into a laboratory manager role, then on to a laboratory operations director. Creating this ladder is the first step in showing your employees that you care about their career development and want them to grow in your laboratory.

After creating this career ladder, it is important to speak with all current employees and create a career map for them. A career map will help you recognize and understand their strengths and weaknesses in the laboratory and will help you decide who is the right fit for each role on your team.

Building a career ladder is also a great opportunity to build job descriptions for each role

Factors Affecting Retention

Actions that Boost Retention	Actions that Boost Turnover
• Offer competitive compensation	• Poor salary
• Look for employees who fit your company culture	• A lack of a defined career path
• Give employees autonomy within their roles	• Failure to meet with team members on a regular basis

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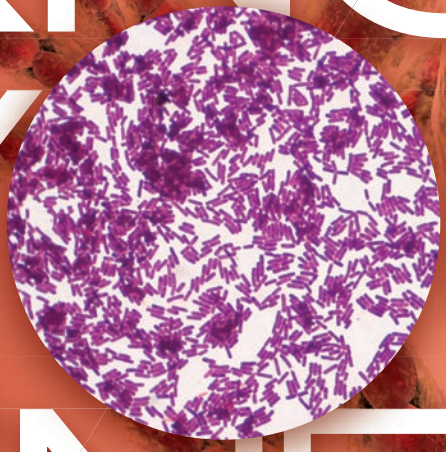

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your laboratory currently has, and to map how "a day in the life" looks. This has the added benefit of being an excellent recruiting tool for you to use with potential hires. Showing a potential hire the typical career path at your lab, as well as a specific job description and day in the life, will give them a full picture of what you expect of them. Additionally, it is imperative to understand the job market and research the job descriptions and salaries being offered by competitors. Many small laboratories have not updated their salaries in several years or potentially have never researched the proper salary for their employees. Reviewing fair pay in your region, and creating a competitive plan around that number, should be something you do every year. This will ensure that your employees are less likely to leave due to poor salaries, and it also creates pay equity across all employees at your laboratory.

Focus on engaging with your employees

Many leaders fall short of truly engaging with their employees and fail to schedule (or keep) regular one-on-ones with their team members. Regularly scheduled individual and group meetings with employees help to establish and remind them of the company's vision and goals. These meetings also show team members why their work helps the company reach its goals, which at the same time boosts employee morale. When employees see their efforts impact the company in a positive way, they also recognize the value and importance of their work to the company's overall success.

When employees see leadership truly involved in these efforts to engage and promote their ideas, it helps to promote a sense of unity. This, in turn, encourages employees to perform their jobs well, because they are more invested. Additionally, statistics show that when the leadership is present in the laboratory and providing positive feedback to employees, engagement and morale are also increased. The difference between the performance levels of engaged versus disengaged employees is striking: Engaged employees will outperform disengaged employees by almost 28%.[4]

The first step to engaging your employees is getting to know them, including their personal and professional interests, backgrounds, and hobbies. If you manage or oversee a larger group of people, it helps to keep notes on important information about them, such as family information, backgrounds, and personal goals. You should meet with your employees one-on-one monthly (at a minimum) to discuss their key performance metrics, as well as any personal or professional goals.

Keep employees informed on how the company is doing and show that you trust them by giving them autonomy within their positions. Allow them to make suggestions and listen to and act on their feedback. Many managers (especially new managers) wrongly believe they need to monitor every move of their employees. However, by providing your employees with autonomy, you will create an organization that is willing to make suggestions and improvements.

Conclusion

There are many steps to creating and maintaining a strong retention strategy, but starting with developing a clear career path, understanding employees' professional goals, and focusing on employee engagement will help to ensure that your employees have a positive view of your laboratory and that they will want to stay long term. With more than 300,000 clinical laboratory personnel employed in the United States, and an additional 35,000 jobs expected to be added before 2028, it is more crucial than ever that laboratories have a strong retention strategy in place.[7]

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GM-CSF may be a key factor in controlling cytokine storm

By Claire Hugeut, PhD

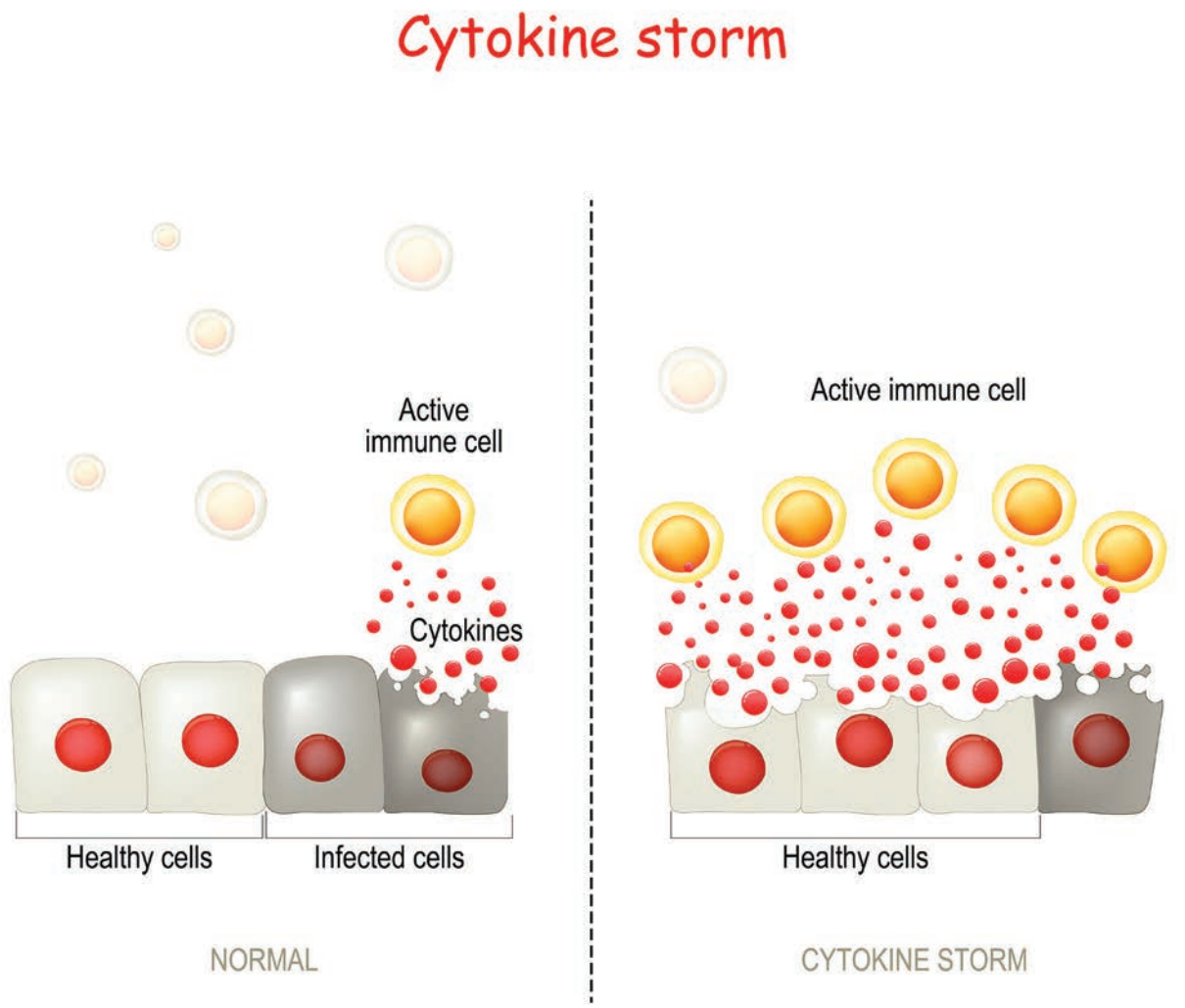
Cytokine release syndrome (CRS), also called cytokine storm or hypercytokinemia, is a potentially life-threatening condition that stems from the abnormal hyperstimulation of T-cells, resulting in the secretion of massive quantities of a variety of cytokines in the blood stream by T-cells, as well as most cells involved in the immune response, as they become engaged from the initial T-cell stimulation.

Despite the activation of the immune system through mechanisms similar to what triggers a normal response, the resulting cytokine and cellular proliferation that characterize CRS leads to an ineffective response, in particular, the inability to clear the infected/damaged cells at the origin of the hyperstimulation.

How cytokine storm develops

The development of a cytokine storm can result from an infection (Epstein-Barr virus, Cytomegalovirus, flu, COVID-19), an autoimmune disease (systemic lupus erythematosus, Kawasaki disease) and a number of other conditions, such as cancer and transplantation (graft-versus host disease). Another related condition is hemophagocytic lymphohistiocytosis (HLH), which includes familial, genetically driven forms triggered by defective cytolytic granule exocytosis, as well as secondary/reactive forms most often resulting from an acute infection. Meanwhile, macrophage activation syndrome (MAS), often assimilated to secondary HLH, is associated with infections, malignancies, and rheumatic diseases. Lastly, a cytokine release syndrome has also been shown to be associated with some newer T-cell engaging therapies, specifically those involving chimeric antigen receptor (CAR) T cells,[1] of which it represents the most frequent severe adverse effect.

CRS can present with a variety of symptoms ranging from mild, flu-like symptoms, such as fever fatigue, headache, nausea, rash, arthralgia and myalgia, to severe life-threatening manifestations, such as high fever and hypotension, progressing to circulating shock, vascular leakage, disseminated intravascular coagulation and multi-organ failure, which happens as the systemic inflammatory response escapes control. However, even though all cytokine storm syndromes have a fairly similar clinical



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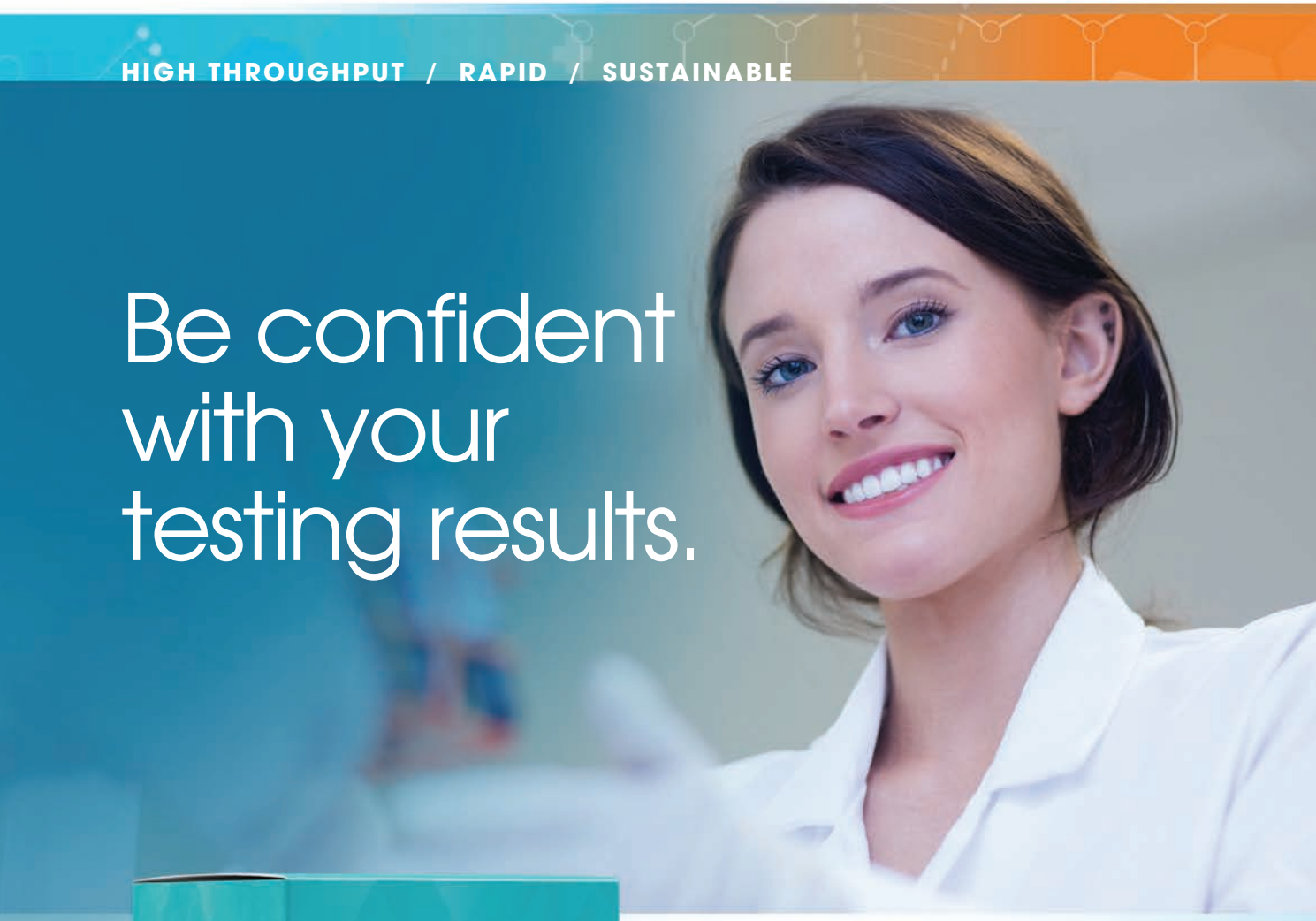

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presentation, they differ widely in the origin of the inflammatory trigger, and failure to identify the cause of the disorder may result in sub-optimal and delayed patient management.

Laboratory abnormalities that are common in patients with CRS include cytopenias (all three lineages), elevated creatinine and liver enzymes, abnormal coagulation parameters (fibrinogen, D-Dimer), high CRP and high ferritin. However, a very large number of biomarkers apart from cytokines have been shown to be involved in the CRS response, involving markers of endothelial activation, such as Angiotensin 2 and Von Willebrand factor, and markers of vascular leakage, such as hypoalbuminemia and impaired lipid metabolism, with hypertriglyceridemia being one of the features of fHLH, to name just a few.

From a cytokine standpoint, IL-10, IL-6 and IFN gamma have long been the identified as being the core biomarkers of the CRS. Typically, IFN gamma is released by the stimulated T-cells or even tumor cells directly. Secreted IFN-γ induces activation of other immune cells, most importantly macrophages.[1] The activated macrophages produce excessive amounts of additional cytokines, such as IL-6, TNF-α, and IL-10.

IL-6 plays a major role in the pathophysiology of CRS, since it has been correlated with major CRS symptoms, with a stepwise increase in levels with escalating severity, making its quantitative assessment valuable for patient management.

The double signalling pathway of IL-6, through membrane-bound as well as soluble IL-6 receptors, is thought to be key to the magnitude of the IL-6 effects. However, though targeted anti-IL-6 /anti-IL-6 R therapies have been attempted with some success in a number of CRS cases, including the ones linked to COVID-19, they didn't permit CRS control in 100% of the cases, indicating that additional mechanisms need to be sought. Because monocyte and macrophages have been shown to play an active part in the development of the acute respiratory distress syndrome seen in CRS, as well as in the neurotoxicity following CRS in CAR-T cell therapies, researchers have scrutinized the role of GM-CSF.

The role of CM-CSF

In a recent study by Thwaites et al. of severe COVID 19 cases, extensive analysis of inflammation mediators was performed that identified GM-CSF as playing a distinctive role in the development of COVID-19.[2] At the time of enrollment, IL-6, CXCL10 and GM-CSF, together with GDF-15 and CCL2, were the key biomarkers permitting patients' classification into groups of increasing disease severity. By analyzing the levels of these biomarkers in the course of the disease progression, it was found that some (among which are IL-6 and GM-CSF) were stable over time and elevated since inception, making them good candidates for an early assessment of patients. Moreover, a comparison between fatal cases of influenza and COVID-19 cases, showed that even though IL-6 was elevated in all cases, GM-CSF (as well as IL-1 alpha) was specifically elevated in the COVID-19 cohort in contrast to the influenza cohort, supporting a prominent role of GM-CSF in the COVID-19 immunopathology.

Other neutrophil biomarkers, such as CXCL8, as well as neutrophil gelatinase associated lipocalin (LCN-2/NGAL), were also correlated with severity, confirming the interest in controlling neutrophilia and making GM-CSF, an attractive therapeutic target.

Because monocytes and macrophages have been associated with the development of CRS and neurotoxicity following CAR-T cell therapies, attempts to neutralize the secretion of GM-CSF during these protocols have been investigated. Generation of GM-CSF deficient CAR T-cells, through CRISPR/Cas9 disruption of GM-CSF during CAR-T manufacturing,[3] was proven not to affect the CAR-T proliferation or effectiveness while significantly reducing neuro-inflammation and CRS.

These converging discoveries confirm GM-CSF as a key contributor in the diagnosis as well as monitoring of CRS of various origins.

Limitations of IL-6 as diagnostic biomarker

Research panels have scanned dozens of biomarkers involved in the various pathways contributing to CRS severity in an attempt to identify a handful of biomarkers that could be universally applicable to the various CRS etiologies. However, at this stage, multiple independent discovery studies have led to as many different biomarker selections, showing that we are not ready for a one-size-fits-all solution.

In contrast, measuring IL-6 only as the main feature of CRS, is not sufficient to cover all cases with the granularity needed. Therefore, custom-made multiplex panels remain the tool of choice for CRS investigation, with the nature and number of markers dependent on the research goals. Being able to deliver an accurate, fully quantitative measurement of targeted biomarkers (at the very least IL-6, IFN gamma & GM-CSF) at bedside, within a 30-minute turn-around time, remains the goal of intensive care units monitoring severe CRS patients, even more so in periods of a pandemic where early triaging of patients is needed to optimize the healthcare services provided and minimize mortality. Careful selection of the epitope of choice/antibody pairs, use of standardized calibration materials when available, and confirmation of panel analytical robustness are essential for the reliability of these tests.

Such instruments and panels are currently brewing in many R&D departments; however, it will be some time, before they can be made commercially available, given the time needed for their approval and registration. In the meantime, making these tools available to clinical research remains the best way to improving patients' prognosis, with the final IVD solution in mind.

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Standardizing genotyping assays

Linda Wilson

As pharmacogenomics becomes more common, the need to standardize best practices for detecting genetic variations in patients through testing becomes more important.

That is why the Association for Molecular Pathology (AMP) is developing testing guidelines for pharmacogenomic assays. To do so, it is working with other professional organizations, including the College of American Pathologists and the Clinical Pharmacogenetics Implementation Consortium.

Pharmacogenomics is the study of the effect of genomic variations on drugs. This involves how people metabolize medications, move them in and out of the bloodstream, and bind them to a target in the body.

The goal is to find the correct medication and dosage for each patient based on his or her genetic makeup.

Metabolizing medications

One area of pharmacogenomics in which scientists have actionable information involves how fast or slow people metabolize medications. The rate at which a person metabolizes a drug impacts the dose needed to obtain a therapeutic result. Prescribing too much or too little of a drug can cause an adverse drug event and potentially harm a patient.

The rate at which people metabolize medications also can impact whether a drug will work for them. One example is clopidogrel (Plavix). People who are poor or intermediate metabolizers cannot activate the medication, so they need an alternative therapeutic, explains Victoria M. Pratt, PhD, FACMG, Clinical Professor and Director of Pharmacogenomics and Molecular Genetics Laboratories, Indiana University School of Medicine.

Victoria M. Pratt

The enzymes involved in metabolizing and clearing many medications, which are encoded by the P450 genes, include CYP2D6, CYP2C19, CYP2C9, CYP3A4, and CYP3A5, which mostly occur in the liver.[1]

While there are some pharmacogenomic tests approved by the U.S. Food and Drug Administration (FDA) and marketed commercially, most assays are lab developed tests (LDTs) that are performed at private specialized labs, large reference labs, or labs associated with academic medical centers.

"Knowledge has changed rapidly, so when there's a platform that gets FDA cleared, it's sort of frozen in time. The platform doesn't evolve, and that does cause issues," said Pratt, who also is the chair of AMP's PGx Working Group.

On the other hand, LDTs can be developed or revised more quickly than commercial, FDA-approved assays.

As an example, Pratt cites tests to detect variant genes associated with warfarin sensitivity. One of the FDA-cleared assays does not include important variants that are common in the African American population, which means the test is not useful for this group. The lack of information about variant genes is particularly problematic for warfarin, because the medication has a narrow dosing range that varies by individual.

Another problem in the field of genotype testing is that clinical assays vary widely in the variant genes detected, and the nomenclature used to express test results, making interpretation of the tests difficult for physicians, Pratt said.

AMP guidelines

To address this problem, AMP has published four guidelines so far. Each guideline recommends a minimum set of alleles and their defining variants that should be included in an assay, known as tier 1, and an extended panel of alleles, tier 2.

The goal of the guidelines is to standardize what alleles are detected by a test. "If one laboratory does a lot of variants, it may report something different than a laboratory that reports fewer variants, because that rarer variant was not detected in a test. You can get discrepant results between laboratories, and it relates to platform differences," Pratt explains.

Another objective of the working group, she adds, is to create "standardization that is pan-ethnic and makes sure that all the ethnicities are largely represented, which helps ensure an equality in testing."

The guidelines AMP has published so far are for the following:

- CYP2C9, which is involved in the metabolism of warfarin, several blood pressure medications, numerous nonsteroidal anti-inflammatory drugs (NSAIDs), oral hypoglycemic agents, and others.[2]
- CYP2C19, which is involved in the metabolism of the antiplatelet medication clopidogrel (Plavix), proton-pump inhibitors, and the antidepressants citalopram and escitalopram.[3]
- CYP2D6, which is involved in the metabolism of about 21% of all medications, including many opioids, such as codeine; anti-depressants; beta blockers; typical and atypical antipsychotics; and antiemetics.[4]
- Warfarin, which is metabolized by CYP2C9, CYP4F2 and VKORC1.

Several other guidelines, which Pratt chose not to disclose, are in the works. She also notes that the development process is an ongoing endeavor. Once the members of the working group have addressed the genotyping assays on their list, they plan to review the guidelines they have already created. "Information changes over time," Pratt notes, so the goal is to assess and potentially update guidelines. Explaining the process, she says, "What did we get right? What did we get wrong, and where do we need to alter our recommendations?"

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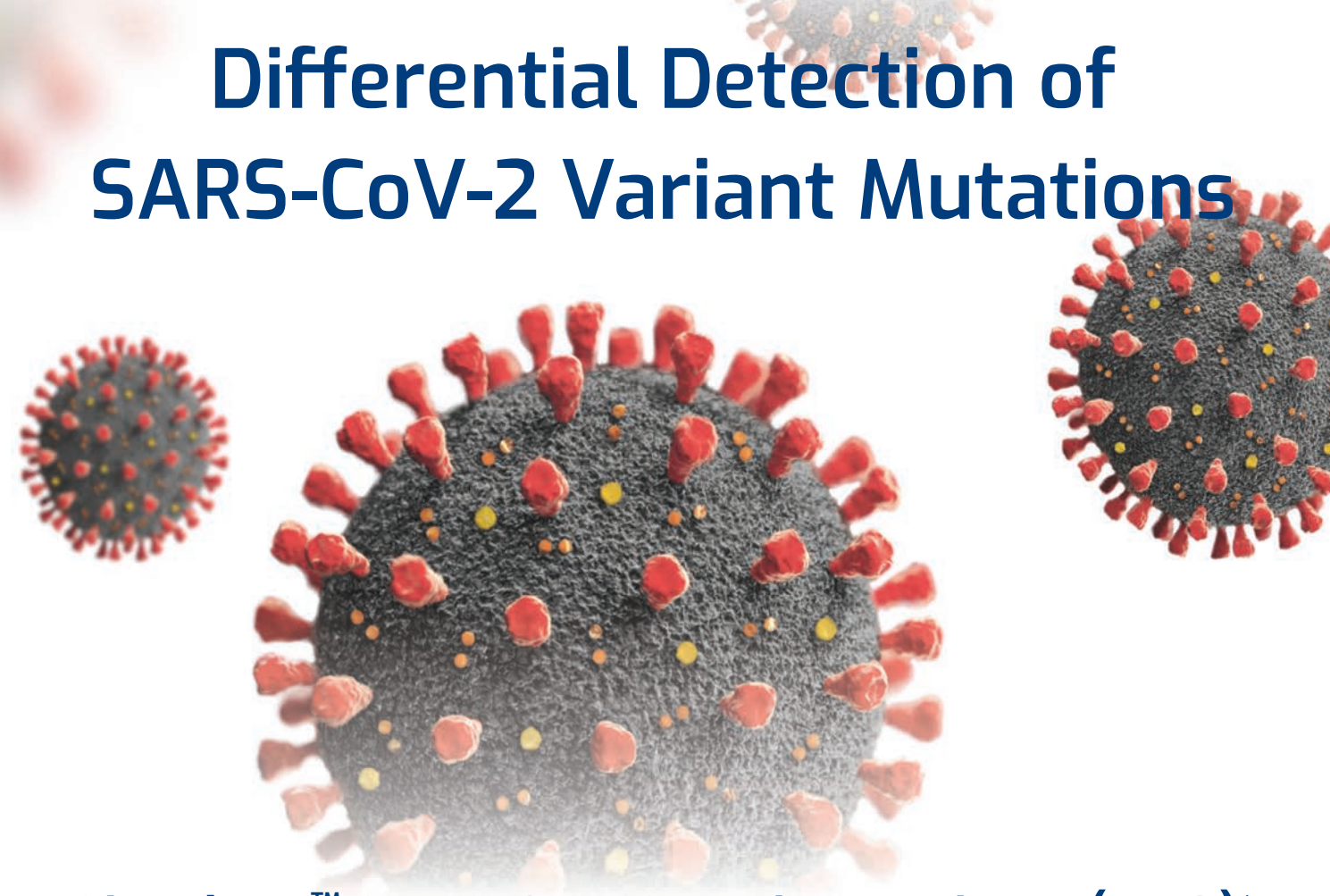
Differential Detection of SARS-CoV-2 Variant Mutations



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Saving time and money with rapid tests

By Marisa L. Williams

History of rapid testing

The first rapid test was developed in 1962 for glucose testing, and in 1976, the FDA approved the first three home pregnancy tests.[1]

"A rapid test is based on immunochromatographic, lateral flow technology or other similar platform, and has the capability to provide presumptive test results within a short period of time to allow faster medical intervention," said Charlie Huang, PhD, Head of Diagnostics and Life Science at AnteoTech Ltd.

He clarified, "There are different types of immunochromatographic rapid tests, including antigen rapid tests and antibody rapid tests, or isothermal-PCR based molecular diagnostics, that can detect analytes in a variety of biological matrices, including urine, whole blood, oral fluid and feces. Rapid tests can detect analytes present in the body as a result of disease, infection, substance abuse and status of hormones or biomarkers, etc."

Antibody testing helps understand the kinetics of the immune response to infection, disease severity and timeline. From determining whether cross-reactivity with other coronaviruses (CoV) leads to cross-protection, to determining immunity and duration, testing influences public health protective measures.

Testing is key to the diagnosis and triage of patients, contact tracing, studying lasting immunity, as well as sero-epidemiological analysis to discover the extent of a spreading disease.

Rapid testing for SARS-CoV-2

POCT immunoassays detect IgG and IgM rapidly to discover if a patient has SARS-CoV-2 antibodies. Home tests have the advantage of obtaining a diagnosis without sending samples to labs. For rural areas and communities without necessary laboratories, this enables widespread testing without a trained professional, reducing training and waiting for lab results.

Cheap to manufacture, store and distribute, digital results may also be sent instantly with some tests for contact tracing.

There are two lines on a membrane strip of lateral flow assays. The gold nanoparticle–antibody conjugates are located on one line and bind antibodies on the other when the blood hits the membrane. Proteins are drawn through the membrane strip by capillary action, as the antigen binds to the gold nanoparticle–antibody conjugate, and the complex flows across the membrane. Low antibody concentrations may result in false-negatives.[2]

Since antigen tests vary in sensitivity, people who test negative may still be infected. For COVID-19, sensitivities are highest in the first week of illness when viral loads are higher.[3]

Though antigen tests can replace laboratory-based RT-PCR when immediate decisions about patient care must be made, or where RT-PCR cannot be delivered in a timely manner, positive predictive values suggest that confirmatory testing of those with positive results may be considered in low prevalence settings.[3]

Advances in rapid testing

The pandemic inspired a plethora of new tests, including smart phones tests, such as the Clip COVID rapid antigen test. "The test is machine-read to reduce human error from misinterpreting faint lines on a lateral flow test, and also reports results automatically to reduce administrative time and errors," explained Jordan Hirsch, Sales Development Representative, Luminostics.

Huang shared how the EuGeni tests have WiFi, ethernet connectivity, fully integrated laboratory information data management system capability and a barcode scanner. "The use of rapid tests provides a reliable decision support tool, especially in low resource environments and when time to patient care is critical."

The Ellume COVID-19 Home Test has built-in sampling and reagent controls, connectivity with the smart phone app to transmit results in real-time to health authorities for tracking, and generates an error message to indicate insufficient sample.

Rapid tests are an affordable, easy to use, analytical method that enables point of care testing (POCT), providing quick test results with a noninvasive sample collection on the spot, eliminates sample transportation and storage, saving time and money.

Arvind Kothandaraman, General Manager of Specialty Diagnostics, PerkinElmer, discussed how COVID-19 testing can impact public health. "Rapid tests, such as this one, transformed the COVID-19 testing landscape and will continue to play an important role for screening both asymptomatic and symptomatic individuals in high risk environments like travel hubs, schools, sporting arenas and other large events venues. By offering users a means of simple sample collection and quick turnaround for results, individuals who test positive for SARS-CoV-2 infection can promptly isolate and seek treatment as needed."

Companies have not been pigeon-holed into only COVID testing. Jody Vacala, Manager of Marketing Communications at Quidel, compared, "As flu season approaches, it is critical for providers to be able to differentiate flu and SARS infection quickly, and with this test, that can all be done with one swab on one test cassette" with the Sofia 2 Flu + SARS FIA. Whereas, the "Triage Tox Drug Screen 94600 rapidly identifies the impact of drug use on the patient's clinical presentation, which can reduce their length of stay in the emergency department."

Quidel offers additional testing, such as the Sofia 2 Lyme FIA for detecting Lyme disease, especially important to expectant mothers, as Lyme disease is associated with placenta infection.

Of course, pregnancy tests continue to be popular rapid tests, as it is critical to test for pregnancy before a medical procedure or issuing prescriptions. Even these advanced, such as EKF Diagnostics offering serum testing in addition to urine.

Rapid tests continue to grow with blossoming technologies. On-demand results give patients less time to worry about the unknown, providing fast answers with easy-to-use diagnostics. It will be interesting to see how technology will continue to integrate into diagnostics.

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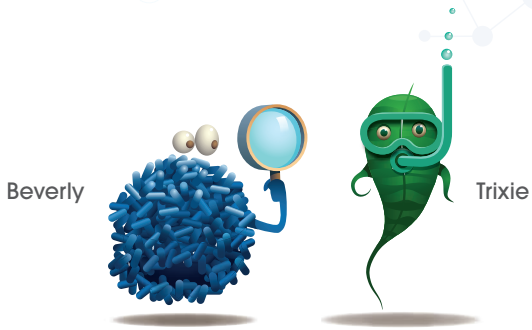

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Covid tests - Rapid tests						
Brand	**AnteoTech**	**Ellume**	**Luminostics**	**Quidel**	**Quidel**	**PerkinElmer**
Test name	EuGeni SARS-CoV-2 Ag RDT	COVID-19 Home Test	Clip COVID Rapid Antigen Test	Sofia SARS Antigen FIA	Sofia 2 Flu + SARS Antigen FIA	COVID-19 Antigen Test (NS, NP)
Menu	SARS-CoV-2 nucleocapsid antigen (N protein)	SARS-CoV-2 antigen	detect the presence of SARS-CoV-2	SARS nucleocapsid protein antigens	FluA, FluB and SARS nucleocapsid protein antigen	SARS-CoV-2 antigens
Sample collection	Nasopharyngeal swab	Nasal swab, smart phone	Anterior (lower) nasal swab	Anterior nares swab specimen	Anterior nares swab, nasopharyngeal	nasal or nasopharyngeal swab
Time to results	15 minutes	15 minutes or less	30 minutes	15 minutes	15 minutes	15-30 minutes
Throughput	1 test/minute	1 test/15 minutes	10-15 tests/analyzer/ hour	30-40 samples/hour	30-40 samples/hour	10 million+/month
Test analysis	Fluorescent signal	Fluorescent signal		Fluorescent signal	Fluorescent signal	Analysis on cartridge
Components	EuGeni Reader sold separate	Smartphone sold separate	All-in-one	Shipped with kit	Shipped with kit	All-in-one
Technology	Lateral flow, AnteoBind-acivated Europium, fluorescence immunoassay	Fluorescence immunoassay	Persistent luminescence immunoassay, lateral flow	Fluorescent immunoassays	Fluorescent immunoassays	Lateral flow
POCT	Yes	Yes	Yes	Yes	Yes	Professional
Size	165 x 140 x 175 mm	Handheld	77 x 37 x 155 mm	22 x 12 x 12 cm	22 x 12 x 12 cm	35.5 x 10 x 7.6 cm (25 test box)
Weight	650g	Lightweight	336 g	2 lbs	2 lbs	3 lbs
Shelf life	12 months	12 months	7-10 months	24 months	24 months	18 months

Non-covid tests				
Brand	**EKF Diagnostics**	**EKF Diagnostics**	**Quidel**	**Quidel**
Test name	QuPID	QuPID Plus	Sofia 2 Lyme FIA	Triage TOX Drug Screen, 94600
Menu	Pregnancy	Pregnancy	IgM and IgG antibodies to Borrelia burgdorferi	AMP, mAMP, BAR, BZO, COC, EDDP, OPI, THC, TCA
Sample collection	Urine or serum	Urine or serum	Finger-stick whole blood	Urine
Time to results	3-5 minutes	3-5 minutes	3-15 minutes	15 minutes
Throughput	1 test/3-5minutes	1 test/3-5minutes	30-40 samples/hour	20 samples/hour
Test analysis	Hormone detection	Hormone detection	Fluorescent signal	Fluorescent signal
Components	Dropper included	Dropper included	Finger-stick lancet sold separate	Glass or plastic urine container
Technology	Lateral flow hCG cassette	Lateral flow hCG cassette	Fluorescent immunoassays	Fluorescent immunoassays
POCT	Professional	Professional	Yes	Yes
Size	22 x 12 x 7cm (25 tests)	23 x 13 x 12cm (50 tests)	22 x 12 x 12 cm	22.5 x 10 x 7 cm
Weight	0.85 lbs (25 tests)	1.25 lbs (50 tests)	2 lbs	1.5 lbs
Shelf life	18 months	18 months	18 months	11 months

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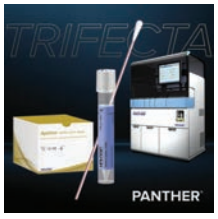

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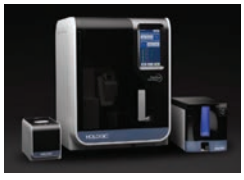

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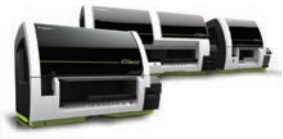

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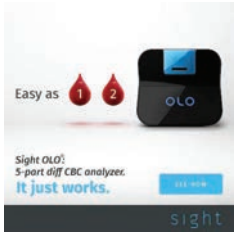

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