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CE The benefits of automation in SARS-CoV-2 testing

LIS product guide

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LAB INNOVATOR

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MBA, MT (ASCP)
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with less within the laboratory is felt worldwide and the trend will continue based on the future availability of lab resources, the need to reduce costs, the aging population and the increasing need for laboratory testing. Automation plays a key role in helping laboratories maximize efficiency, simplify operations and establish a scalable and sustainable approach to minimize disruption to the services they provide and patients they serve.

The demand for serology-based antibody testing will likely increase as clinicians begin to assess patient immunity once vaccines become available. The ability for lab automation and diagnostic IT to accommodate the specific workflow needs of the laboratory will be extremely important to help labs overcome the challenges of testing during this pandemic and future unknown challenges we may face.

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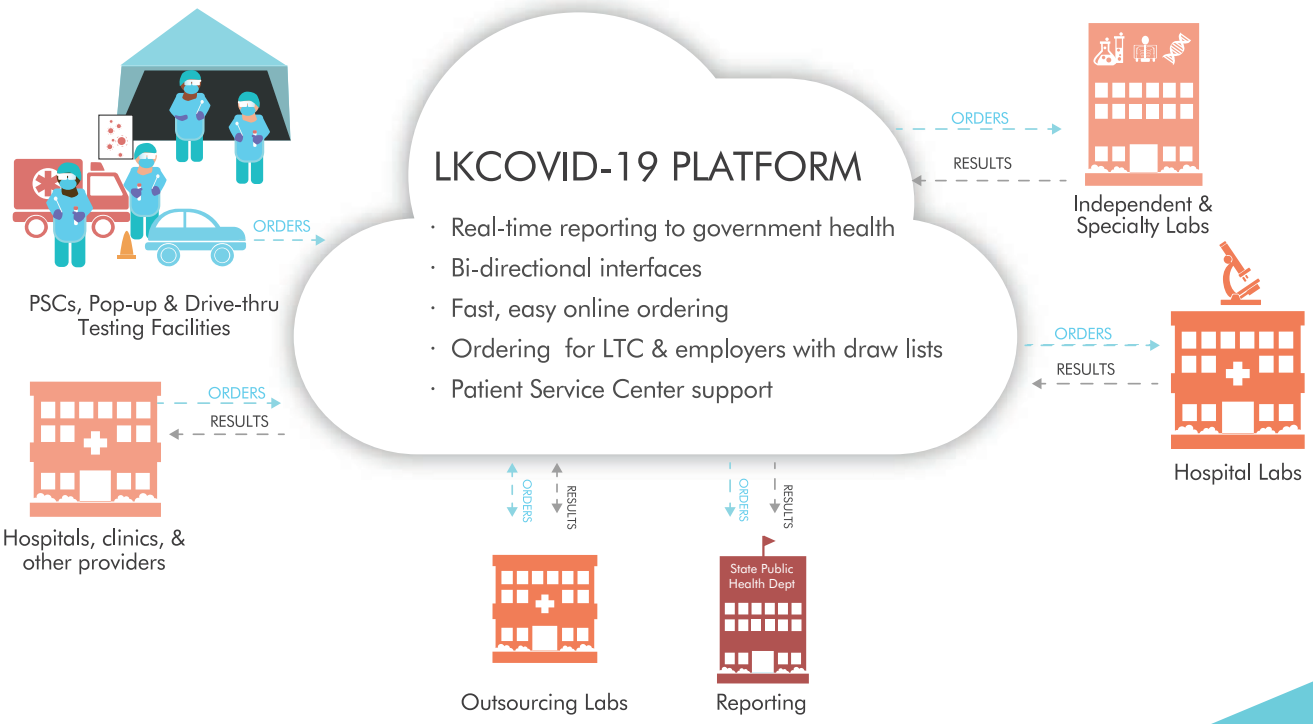

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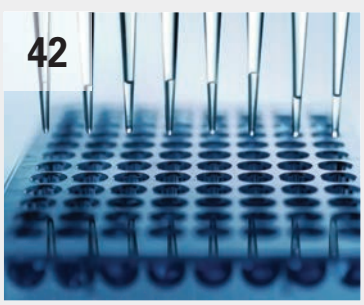

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Moving away from paper processes

By Linda Wilson
Senior Editor

Planning for flu season amid the COVID-19 pandemic not only involves procuring reagents, swabs, and personal protective equipment (PPE) but also reengineering processes to remove steps that involve paper.

This is important because some lab managers have concluded that reimbursement rates for SARS-CoV-2 molecular assays do not cover their testing costs. David Nichols, a lab industry expert I spoke to earlier this year, said labs are spending between $40 and $150 per test. In addition to the cost of test kits, PPE, and other supplies, there also are overhead costs, such as rent, utilities, and labor.

Labs at hospitals and health systems, in particular, say they also must cover the cost associated with sending overflow specimens to reference labs for testing.

Then there is billing. Manual processes throughout the revenue cycle, cost healthcare providers overall an average of $29.27 per patient encounter, according to CAQH, a nonprofit alliance focused on streamlining administrative processes in healthcare.

Reacting to concerns about covering testing costs for SARS-CoV-2 specifically, the Centers for Medicare & Medicaid Services (CMS) in April upped the amount it pays for a test performed with a high-throughput analyzer from $51 to $100. However, in October, the agency revised those payment rates to encourage faster turnaround times. Beginning January 1, 2021, CMS will pay $100 per high-throughput test in which a lab completes testing within two calendar days from the time a specimen is collected from a patient. When a lab takes longer than two days to complete testing, CMS will pay $75.

Putting costs aside, patients are anxious to get their test results quickly. They do not want to wait seven days, which has occurred at times this year with COVID-19 testing.

Getting rid of paper will help solve these problems by speeding up turnaround times and reducing costs, allowing labs to maximize reimbursement from CMS and other payers. As we report in *Medical Laboratory Observer's* first-annual LIS Product Guide, manual procedures exist in pre-analytical, analytical, and post-analytical phases of testing as well as in billing processes. (The guide also includes an informational product chart.)

In an ideal process, a web-based portal allows healthcare providers or patients to enter test orders and demographic and insurance information into an electronic system, which creates an order and a bar-coded label for the specimen. Once the specimen arrives at the lab, it can be routed to testing quickly. The same portal allows providers and patients to access test results easily, while also allowing information to flow easily to an electronic revenue cycle module.

Paper processes in the pre-analytical phase invite errors, leading to issues in subsequent phases of the process. For example, missing demographic information for patients results in payers rejecting claims and inaccurate reporting to state health agencies.

In the analytical phase, electronic processes include real-time pending work queries, electronic quality control reports, and auto-verification, which applies to up to 80 percent of testing results.

The bottom line: manual processes tend to be inefficient and do not scale well, particularly in the current environment where labs test thousands of symptomatic people daily for SARS-CoV-2, influenza, and RSV. And those testing demands will only increase as surveillance testing of asymptomatic people ramps up across the country.

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

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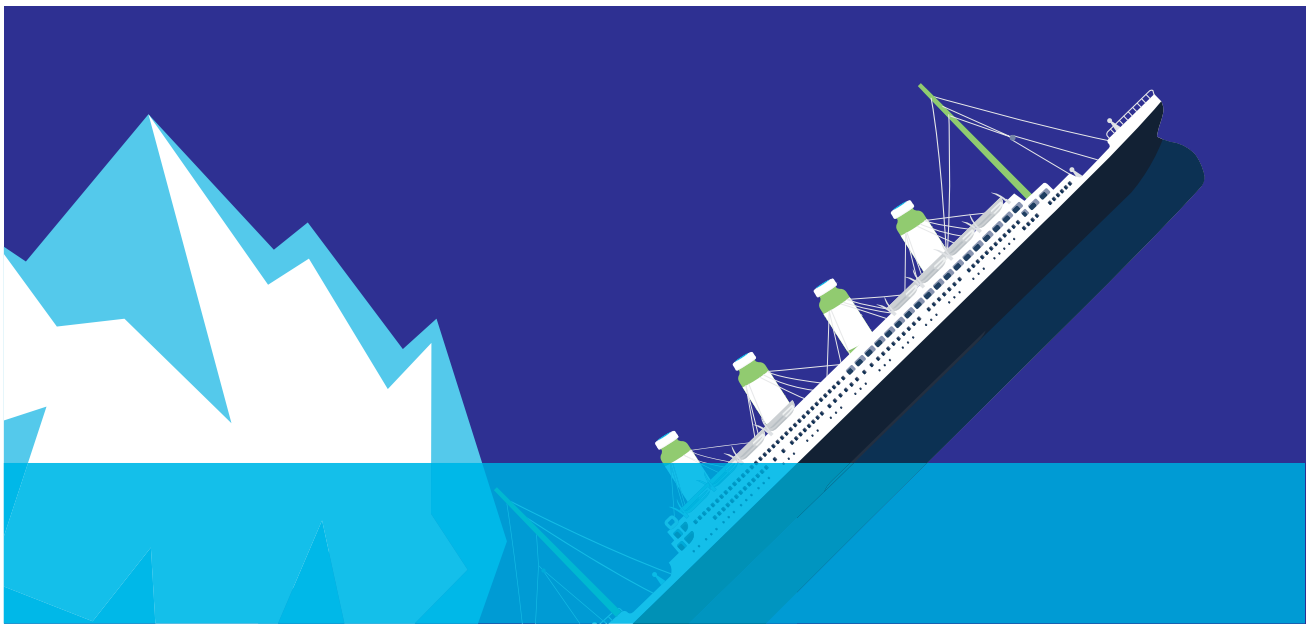

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Fast Facts COVID-19

Healthcare personnel with COVID-19 who are hospitalized report direct patient contact, underlying medical conditions, and severe disease

5.9

is the percentage of hospitalized COVID-19 patients who work in healthcare settings

67.4

is the percentage of hospitalized healthcare personnel with COVID-19 who are in professions with direct patient contact, including 36.3 percent in nursing roles.

49

is the median age of hospitalized healthcare personnel with COVID-19

89.8

is the percentage of hospitalized healthcare personnel with COVID-19 who have at least one underlying medical condition, including 72.5 percent who are obese, 40.6 percent with hypertension and 30.9 percent with diabetes.

27.5

is the percentage of hospitalized healthcare personnel with COVID-19 who are admitted to an ICU, while 15.8 percent require mechanical ventilation.

56.7

is the percentage of hospitalized healthcare personnel with COVID-19 with a discharge diagnosis of pneumonia.

4.2

is the percentage of hospitalized healthcare personnel with COVID-19 who died while in a hospital.

Source: https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6943e3-H.pdf

Scientists use human genome to discover new inflammatory syndrome

Researchers from the National Institutes of Health (NIH) have discovered a new inflammatory disorder called vacuoles, E1 enzyme, X-linked, autoinflammatory and somatic syndrome (VEXAS), which is caused by mutations in the UBA1 gene, according to a press release. VEXAS causes symptoms that include blood clots in veins, recurrent fevers, pulmonary abnormalities and vacuoles (unusual cavity-like structures) in myeloid cells. The scientists reported their findings in the *New England Journal of Medicine (NEJM)*.

Nearly 125 million people in the U.S. live with some form of a chronic inflammatory disease. Many of these diseases have overlapping symptoms, which often make it difficult for researchers to diagnose the specific inflammatory disease in a given patient.

Researchers at the National Human Genome Research Institute (NHGRI), part of the NIH, and collaborators from other NIH Institutes took a unique approach to address this challenge. They studied the genome sequences from more than 2,500 individuals with undiagnosed inflammatory diseases, paying particular attention to a set of over 800 genes related to the process of ubiquitylation, which helps regulate both various protein functions inside a cell and the immune system overall. By doing so, they found a gene that is intricately linked to VEXAS, a disease which can be life threatening. So far, 40 percent of VEXAS patients who the team studied have died, revealing the devastating consequences of the severe condition.

Risk score predicts prognosis of outpatients with COVID-19

A new artificial intelligence-based score considers multiple factors to predict the prognosis of individual patients with COVID-19 seen at urgent care clinics or emergency departments, according to a press release. The tool, which was created by investigators at Massachusetts General Hospital (MGH), can be used to rapidly and automatically determine patients who are most likely to develop complications and need to be hospitalized.

The impetus for the study began early during the U.S. epidemic when Massachusetts experienced frequent urgent care visits and hospital admissions.

As described in *The Journal of Infectious Diseases*, a team of experts in neurology, infectious disease, critical care, radiology, pathology, emergency medicine and machine learning designed the COVID-19 Acuity Score (CoVA) based on input from information on 9,381 adult outpatients seen in MGH's respiratory illness clinics and emergency department between March 7 and May 2, 2020. "

CoVA was then tested in another 2,205 patients seen between May 3 and May 14, 2020. In this prospective validation group, 26.1 percent, 6.3 percent and 0.5 percent of patients experienced hospitalization, critical illness or death, respectively, within seven days.

Among 30 predictors – which included demographics like age and gender, COVID-19 testing status, vital signs, medical history and chest X-ray results (when available) – the top five were age, diastolic blood pressure, blood oxygen saturation, COVID-19 testing status and respiratory rate.

Nurse-led antibiotic stewardship intervention reduces unnecessary urine cultures

Nursing education and a clinical tool to enhance discussions on the necessity of urine cultures (UrCx) among nurses and hospitalists were associated with a reduction in UrCx. The report,"A Pilot Study to Evaluate the Impact of a Nurse-Driven Urine Culture Diagnostic Stewardship Intervention on Urine Cultures in the Acute Care Setting," was published in the November issue of *The Joint Commission Journal on Quality and Patient Safety*.

Working with nurses to reduce unnecessary UrCxs may improve the diagnosis of urinary tract infections (UTIs) and, indirectly, antibiotic use, particularly overtreatment of asymptomatic bacteriuria (ASB), which is a major driver of inappropriate antibiotic use in hospitals.

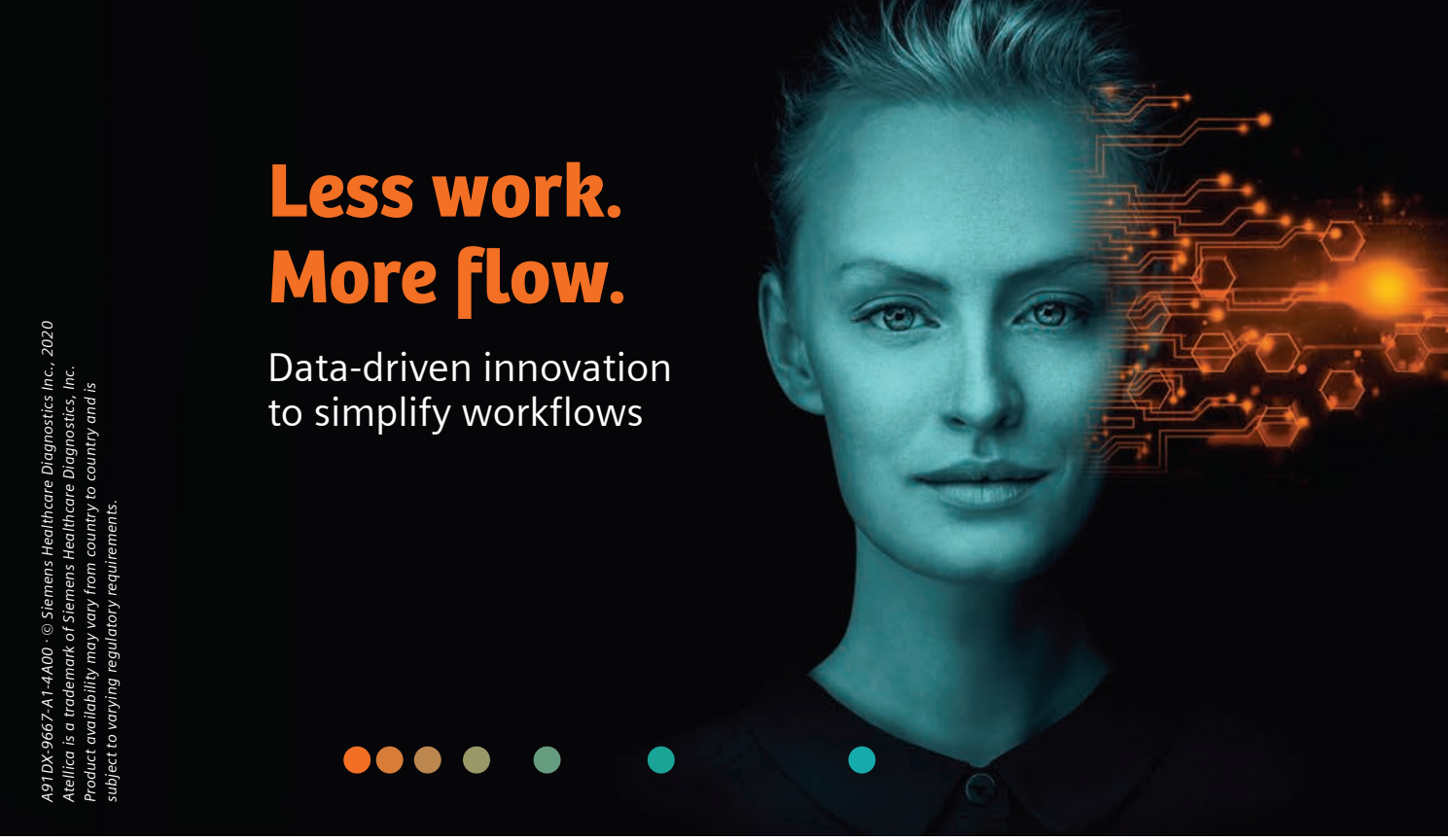
The nurse-driven stewardship intervention was carried out in a 24-bed adult medicine unit staffed by rotating providers from a group of 27 hospitalists and 37 nurses at the Johns Hopkins Hospital.

The intervention included:

- Education on the principles of diagnostic stewardship.
- Identification of a nurse champion to serve as liaison between nursing staff and the antibiotic stewardship program.
- Implementation of an algorithm to guide discussions with hospitalists about situations when UrCx may not be needed.

With the intervention, the mean UrCx rate per 100 patient-days decreased from 2.30 to 1.52, while without intervention it increased from 2.17 to 3.10.

In addition, with the intervention, the rate of inappropriate UrCx decreased from 0.83 to 0.71.



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The benefits of lab automation to facilitate testing for SARS-CoV-2

By Jamie Gramz, BSE, MBA

Fear, anxiety, uncertainty, and worldwide economic disaster have all been factors stemming from the COVID-19 pandemic. Disruption is the new normal to daily life with very few areas of our personal or professional lives not impacted in some way. Although measures to "flatten the curve" and reduce the number of new COVID-19 cases from one day to the next have helped to prevent healthcare systems from becoming overwhelmed, the pandemic has exacerbated many of the existing challenges laboratories commonly face and also has introduced a number of new ones to overcome.

Test menu expansion, fluctuations in testing volumes, consistent supply of consumables, access to personal protective equipment and ongoing changes in management to a new way of working were all new challenges to which laboratories have had to adapt throughout the pandemic. Automation and leveraging technology and innovation within the lab can play a key role in helping laboratories minimize disruption and overcome the challenges of testing for COVID-19.

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LEARNING OBJECTIVES

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

1. Describe the challenges in the lab that have been exacerbated by COVID-19
2. Describe the role of serology testing during the COVID-19 pandemic
3. Describe the challenges that automation in the lab addresses
4. Discuss the key capabilities lab automation provides during the pre-analytical, post-analytical and data management phases of lab testing

Testing for a new pandemic

As of early October, the number of confirmed COVID-19 infections surpassed more than 35 million confirmed cases and accounted for more than 1 million deaths worldwide.[1] Within the United States, there have been more than 7,679,908 cases, and 215,039 deaths since the first domestic case of COVID-19 was reported on January 21, 2020. Diagnostic testing was quickly identified as a critical component to battle the pandemic and multiple initiatives were put in place to help increase the availability of testing. Some of these included accelerating technology availability through emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA), expanded testing capacities and enabling federally funded surge testing in partnership with communities experiencing outbreaks.[2]

The need for laboratories to expand testing services to support viral testing for SARS-CoV-2 diagnosis was one of the earliest new challenges introduced. Labs were forced to either expand their menu of testing services or identify an alternative process to outsource viral testing to other laboratories. Diagnostic testing was quickly made possible and testing rates increased drastically, growing from 20,000 tests per day in April to more than 1,100,000 tests per day in early October.[3]

Testing capabilities were then further expanded with serology-based antibody testing. These tests detect the presence of antibodies in the blood based on the body's immune response to the COVID-19 infection. Laboratories prepared for antibody testing to ramp up in mass numbers, anticipating demand as results would provide greater detail and data to help safely reopen communities. Meanwhile, antibody testing evolved in sophistication from simple

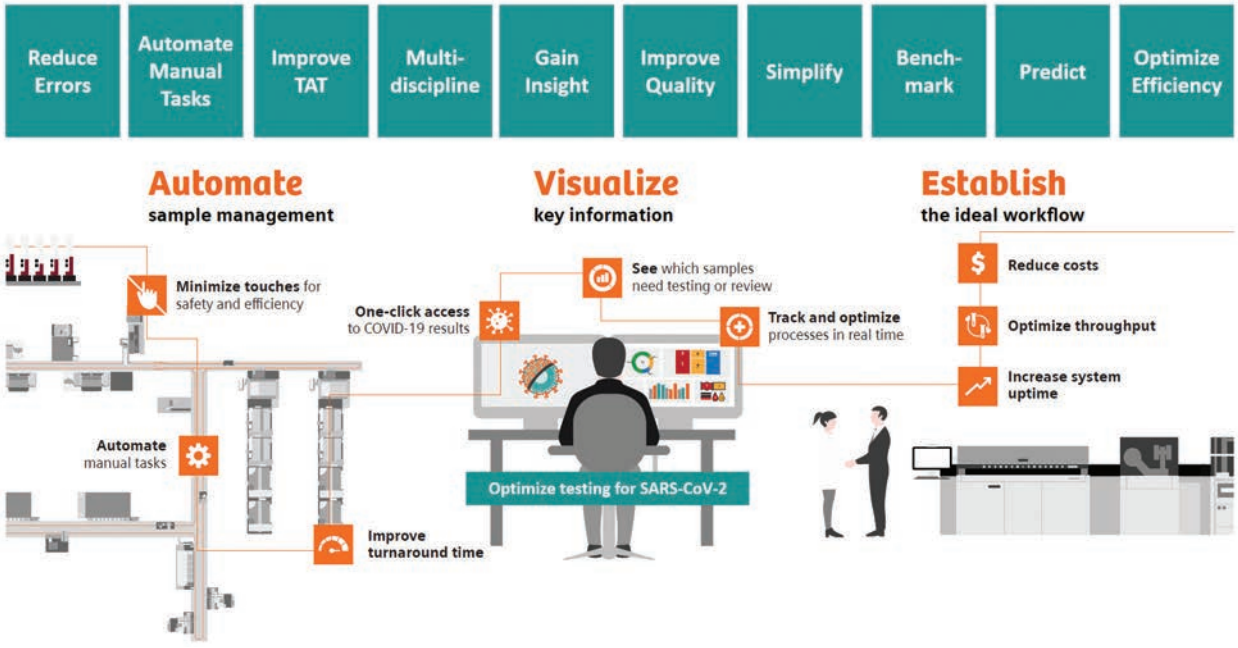

Figure 1. Lab automation for SARS-CoV-2

qualitative positive/negative results to semi-quantitative numerical measurements gauging the specific level of IgG antibodies within a patient's blood sample.[4]

The expansive rollout of such tests, however, was not immediately realized. The pandemic was still in its infancy and, as a result, confirmatory diagnostic tests remained in greater demand. While antibody testing is not deemed suitable for diagnosis of COVID-19, studies to help determine the appropriate use of serology testing for SARS-CoV-2 are underway. Potential benefits may include helping healthcare professionals identify individuals with an immune response to SARS-CoV-2, as well as blood donor candidates to enable convalescent plasma therapy for patients seriously ill from COVID-19.[5]

Other key benefits could include enabling clinicians to assess a patient's natural immunity acquired through viral infection, as well as helping to determine the potential effectiveness of vaccines. To help make this possible, IVD vendors and public health institutions – like the Centers for Disease Control and Prevention (CDC) within the United States and the JRC (Joint Research Centre) of the European Commission – are working together to establish a standardized process related to SARS-CoV-2 assays that will enable clinicians to track their patients' antibody concentrations, regardless of the test method or manufacturer used.[6]

New crisis, same key issues

A recent health-crisis readiness survey conducted by consulting and lab optimization firm Accumen assessed the level of preparedness hospitals and health systems had with respect to the COVID-19 pandemic. The survey included responses from 242 health system leaders with representation ranging from small hospitals to large integrated systems and from rural areas to large cities across the United States.

When asked to identify the key challenges hospital labs are facing, staffing (26 percent) and turnaround time (23 percent) were identified as the top priorities, with information technology/laboratory information system resources (17 percent) and supply chain (17 percent) also receiving high response rates as priorities.[7]

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 percent 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 percent, between 2012 and 2025. In addition, vacancy rates remain high, averaging 7.2 percent across the nation.[8] Interject the COVID-19 situation, with the potential to reduce availability of lab staff due to personal or health reasons, together with the need to expand services for SARS-CoV-2 testing, and the age-old problem of the lab needing to do more with less is compounded.

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.

Turnaround time (TAT) may be king of laboratory metrics when it comes to monitoring key performance indicators, with some medical professionals seeing TAT as something almost as important as the quality of test results themselves.[9] Establishing the logistics needed to enable new testing services for COVID-19 – coupled with the lead time to collect and process samples – and the extreme surge in testing volumes has led to much attention and consternation on the amount of time it takes for patients to receive results from testing for COVID-19. Turnaround times for COVID-19 testing can vary significantly, depending on the type of test being performed, the analyzer or device being used, and the logistics involved in ordering the tests. The processes for collecting and receiving the sample, performing the test and reporting the results also impact turnaround times.

TAT for the actual processing of tests for COVID-19 varies greatly depending upon the type of testing being performed, and can range from as little as 10 minutes for industry-leading serology-based antibody tests, 15 to 30 minutes for antigen-based POC testing, 15 to 45 minutes for POC-based molecular testing and up to 7 hours for reverse transcriptase (RT) polymerase chain reaction (PCR) testing.[10] For serology-based testing, fully automated laboratories are better positioned to optimize TAT by eliminating the need for human intervention between phases and leveraging the added benefits of full transparency and control over where the samples are throughout the process.

For many labs where information technology or LIS resources already pose a challenge, the incremental impact of COVID-19 adds fuel to the fire. With many labs quickly expanding menus to include additional testing for both viral- and serology-based antibody testing, the demand for what their existing lab IT solutions can offer and the service and support needed to make it happen come into

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play. The challenges can vary with some labs positioned to simply add new tests to existing testing platforms, while other labs face the need to procure, implement, interface and commission new analyzers and support data workflows. And then beyond these common scenarios, comes the incremental challenge for all COVID-19 diagnostic and screening test sites to report results to the appropriate state or local public health department daily and within 24 hours of test completion.[11]

Leveraging automation in the wake of COVID-19

Adoption of laboratory automation has advanced significantly since the first total laboratory automation solution was implemented in North America back in 1996.[12] Overcoming challenges with staffing, fluctuations in testing volumes, improving TAT, and reducing errors and costs are all proven benefits that have fueled adoption of laboratory automation. Today, even labs processing smaller volumes of samples – ranging from 1 million to 3 million tests per year or as low as 500 samples per day – often leverage the benefits of lab automation to help address their challenges. (See figure 1)

The good news for many labs already equipped with automation technology and innovation is the built-in capabilities and scalability they may have available to help overcome many of the COVID-19-related challenges. This includes physical laboratory automation systems used to automate and reduce the number of process steps and manual touchpoints and then to expedite the physical handling, sorting and distribution of samples. It also includes software-based lab IT solutions to automate and optimize workflows associated with generating patient and Quality Control (QC) results and the visualization and management of all the information they need. Those laboratories already leveraging the benefits of total lab automation to perform multidisciplinary testing have been well equipped to not only accommodate the need for serology-based antibody testing but also the incremental volume of coagulation, hematology and immunochemistry testing necessary for patients impacted by COVID-19.

When expanding lab services to include serology testing for COVID-19, there are several key workflow considerations that need to be evaluated for the lab to establish an ideal workflow. Which instrument(s) will work best for antibody testing? What is the expected testing volume and how will it fluctuate over time? Will other tests need to be processed on the same sample and which ones should be processed first? Should I integrate testing onto my automation system or manage it directly on a stand-alone instrument? Will testing be performed on demand or will COVID-19 samples be batch tested? Is there any special post-processing sorting or storage criteria?

All of these questions require careful evaluation to establish the right strategy and implement the right workflow. Ensuring that the solution provider has the expertise, consulting capabilities and tools needed to help you design, implement and operate the right automation solution for your laboratory is key.

Manual Laboratory Processes that Automation Can Optimize

	Lab Activity	Potential Risk of Human Error	Use of Resources	Potential Biohazard Exposure
Pre-Analytical	Sample Reception / Accessioning	2	3	1
	Pre-sorting	2	3	1
	Sample Integrity Check	3	3	
	Centrifugation	1	3	3
	Decapping	1	3	3
	Aliquoting / Labeling / Capping	2	3	3
	Instrument Delivery	2	3	1
Post-Analytical	Post-sorting	2	3	1
	Sealing / Desealing	1	2	3
	Sample Storage	1	3	1
	Sample Disposal	1	1	1
Data Management & Visualization	Result Review / Validation	3	3	
	Reflex Testing	3	1	3
	Repeat Testing	3	1	3
	Dilution Processing	3	1	3
	Quality Control Testing	2	3	1
	Equipment Monitoring	1	2	
	Inventory Management	2	3	
	KPI Reporting	2	2	

1 symbol = low, 2 = medium, 3 = high

Figure 2.

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Optimizing the pre-analytical phase

The pre-analytical phase of testing can be resource-intensive and highly prone to error. A study done to evaluate the frequency and types of errors that occur in laboratory medicine provided evidence that most errors occur during the pre-analytical phase of testing and can include anywhere from 31 percent up to 75 percent of total laboratory errors.[13] Some of the most common types of pre-analytical errors include hemolyzed samples, insufficient sample volumes, incorrect or mislabeled samples and clotted samples. For COVID-19 patients at risk of complications, and whose treatment is often dependent upon sometimes minor differentiations across comparative test results, erroneous error can gravely impact timely treatment.

Lab automation can lead to dramatic improvements in staffing, TAT, and error reduction. It can even reduce the risk of staff exposure to biohazardous materials. (See figure 2) Some of the key capabilities that lab automation provides to support pre-analytical activities include:

- Flexible sample loading options, which can accommodate different scenarios, with multiple entry points and for different volumes of samples, including individual sample loading, rack loading and automated bulk loading for large volumes of samples. The benefits include centralized loading for multiple tube sizes, multiple sample types, capped and uncapped tubes, spun and unspun samples, STAT and routine samples. This reduces effort for laboratory staff by eliminating the need to presort and standardize samples.
- Priority routing, presorting and batch-testing management, which enable labs to manage how and in what sequence samples are processed for COVID-19. Options include the ability to specify and automate which instruments are used and which tests get processed first, as well as the ability to presort samples and automate batch-testing processes.
- Sample inspection modules, which can be used to quickly and automatically evaluate sample integrity and identify potential errors due to incorrectly capped or uncapped tubes, mislabeled or unreadable samples, incorrect sample types or tube types, hemolyzed samples and samples with insufficient volume.
- Online centrifugation, which saves time, reduces the need for manual handling and can reduce the risk of exposure to biohazardous materials through offline centrifugation. Additional benefits include automated load balancing to accommodate multiple sample types, configurable wait times, spin cycle times and rotation speeds, temperature setting and STAT sample priority unloading.
- Decapper modules, which increase productivity and safety of lab staff while decreasing risk of sample contamination for better quality results.
- Aliquoting and recapping, which automates sample handling for send-outs and special storage scenarios (long-term and frozen) while reducing exposure to biohazardous materials.

Streamlining the post-analytical phase

The same study showed that errors occurring during the post-analytical phase of testing also have a significant impact and contributed to anywhere from 9 percent up to 30.8 percent of total laboratory errors.[13] Similar to the pre-analytical phase, lab automation offers a number of specific capabilities that can help address challenges within the post-analytical phase of testing including:

- Post-processing sorting and output modules, which enable quick operator access to "problem" samples and sorted tubes and provides temporary storage leading to fast, automated sample retrieval and analyzer delivery for reflex testing, repeat testing, add-on tests, and other custom scenarios that may require sending samples to output racks or sorting lanes. These capabilities may be especially beneficial for labs processing multiple tests on SARS-CoV-2 samples where add-on and reflex testing may be necessary.
- Refrigerated storage and de-sealing, which enables all of the benefits of automated sample retrieval and routing for reflex and repeat testing for temperature-controlled samples stored for longer periods of time. In addition, automated sample disposal based on test-life viability enables samples to be automatically discarded while reducing the risk of exposure to biohazardous materials.

The need for diagnostic software

The ability to visualize key information and understand how the lab is performing is critical. Identifying where attention is needed and enabling lab staff to quickly take the appropriate action to resolve issues is key for any laboratory. To accommodate this need, many labs leverage middleware to complement and supplement the capabilities of their laboratory information system. These often include solutions for advanced data management, process management, inventory management and analytics that include tight integration with the analyzers and lab automation systems and play a key role in simplifying operations and accommodating the specific workflow needs of the lab. Specific functions include:

- Advanced data management, which enables the lab to standardize operations for patient and QC result management while maximizing staff efficiency, reducing errors, improving TAT and simplifying the management of daily QC. It includes key capabilities like dashboard visualization of testing status with alerting capabilities to create awareness and drive action. It enables the efficient review of patient results through review by exception, ensuring lab staff focus on the results that need attention and skip the ones that do not. It enables the efficient, real-time monitoring of quality control with the ability to quickly identify, troubleshoot and resolve problems. And it often includes clinical decision support capabilities central to the needs of the laboratory like panic value monitoring and algorithms to support specific testing protocols.
- Process management, which provides centralized oversight and control of the analyzers and automation systems used within the lab and across multiple sites. It enables real-time monitoring and alerting of system issues and on-board consumable inventory status, enabling labs to maximize system uptime and minimize unplanned downtime. It also enables remote view and control of the analyzers and helps avoid the need for staff to walk around the laboratory to physically inspect each system.
- Analytics, which play a crucial role in empowering laboratories to assess performance, identify inefficiencies and determine the root cause of problems. It enables the lab to quickly and easily benchmark performance and drive continuous improvement with the ability to monitor common KPIs through use of reports for TAT, TAT exceptions, throughput, reagent efficiency, automation utilization, auto-validation rates, hemolysis, problem samples and other key metrics important to the laboratory.
- Inventory management, which helps labs reduce cost and improve efficiency by automating many of the manual steps involved with ordering, receiving, utilization and reordering of consumable materials needed to operate their lab.

On the IT side, there are additional needs from an information management perspective when expanding lab services to include serology testing for COVID-19. Labs need to be able to quickly identify how many and which samples are ready for SARS-CoV-2 testing. Which samples resulted for SARS-CoV-2 need review? How many and which samples were tested for SARS-CoV-2? How many and which samples were positive for SARS-CoV-2? All of these can be efficiently managed through the advanced capabilities of diagnostic software.

Conclusion

The impact of the COVID-19 pandemic exacerbated many of the existing challenges labs face with staffing shortages, improving TAT and reducing diagnostic testing errors. The need to once again do more

with less within the laboratory is felt worldwide and the trend will continue based on the future availability of lab resources, the need to reduce costs, the aging population and the increasing need for laboratory testing. Automation plays a key role in helping laboratories maximize efficiency, simplify operations and establish a scalable and sustainable approach to minimize disruption to the services they provide and patients they serve.

The demand for serology-based antibody testing will likely increase as clinicians begin to assess patient immunity once vaccines become available. The ability for lab automation and diagnostic IT to accommodate the specific workflow needs of the laboratory will be extremely important to help labs overcome the challenges of testing during this pandemic and future unknown challenges we may face.

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CONTINUING EDUCATION TEST

Benefits of lab automation to facilitate testing for SARS-CoV-2

DECEMBER 2020 *[This form may be photocopied. It is no longer valid for CEUs after June 30, 2022.) This article is accredtited for 1.0 CEU.*

TEST QUESTIONS

Circles must be filled in, or test will not be graded. Shade circles like this: ● Not like this: ✗

1. **To facilitate testing for SARS-CoV-2, the United States instituted which of these strategies:**
   - A. emergency use authorizations from the U.S. Food and Drug Administration
   - B. expanded testing capacity
   - C. federally funded surge testing in hot spots
   - D. all of the above

2. **Antibody testing evolved in sophistication from simple _____results to _____ numerical measurements, gauging the specific level of IgG antibodies within a patient's blood sample.**
   - A. semi-quantitative; fully quantitative
   - B. qualitative positive/negative; semi-quantitative
   - C. qualitative; fully quantitative
   - D. none of the above

3. **Potential benefits of serology tests may include the following:**
   - A. identify blood donors for convalescent plasma therapy
   - B. identify individuals with immune response to influenza
   - C. identify active SARS-CoV-2 infections
   - D. all of the above

4. **IVD vendors and public health institutions are working together to establish a standardized process related to SARS-CoV-2 assays that will enable clinicians to track their patients' antibody concentrations, regardless of the test method or manufacturer used.**
   - A. True
   - B. False

5. **When asked to identify the key challenges hospital labs are facing, _____ and turnaround time were identified as the top priorities.**
   - A. reducing costs
   - B. staffing
   - C. reducing errors
   - D. managing regulations

6. **The Bureau of Labor Statistics (BLS) projects a nationwide increase in the demand for medical and clinical laboratory technologists of ___ percent between 2016 and 2026.**
   - A. 8
   - B. 11
   - C. 13
   - D. 15

7. **_____ may be king of laboratory metrics when it comes to monitoring key performance indicators, with some medical professionals seeing _____ as something almost as important as the quality of test results themselves.**
   - A. turnaround time; TAT
   - B. days in accounts receivable; AR
   - C. Cost per test; CPT
   - D. average price per accession; APPA

8. **Which factors can cause turnaround times for COVID-19 testing to vary significantly?**
   - A. type of test performed
   - B. logistics in ordering tests
   - C. type of analyzer being used
   - D. all of the above

9. **For serology-based testing, fully automated laboratories are better positioned to optimize ____ by eliminating the need for human intervention between phases and leveraging the added benefits of full transparency and control over where the samples are throughout the process.**
   - A. cost per test
   - B. billing rate
   - C. TAT
   - D. staffing

10. **Adoption of laboratory automation has advanced significantly since the first total laboratory automation solution was implemented in North America back in _____.**
    - A. 1990
    - B. 1996
    - C. 1999
    - D. 2005

11. **Overcoming challenges with _____, fluctuations in testing volumes, improving TAT, reducing errors and _____ are all proven benefits that have fueled adoption of laboratory automation.**
    - A staffing, A/R
    - B. staffing; costs
    - C. A/R, costs
    - D. costs, diversifying tests types

12. **Today, even labs processing smaller volumes of samples – ranging from_____ tests per year or as low as 500 samples per day – often leverage the benefits of lab automation to help address their challenges.**
    - A. 250,000-500,000
    - B. 500,000-750,000
    - C.750,000-1 million
    - D. 1-3 million

13. **Laboratories already leveraging the benefits of total lab automation to perform multidisciplinary testing have been well equipped to not only accommodate the need for _____ but also the incremental volume of coagulation, hematology and immunochemistry testing necessary for patients impacted by COVID-19.**
    - A. molecular testing
    - B. serology-based antibody testing
    - C. next-generation sequencing
    - D. point-of-care testing

14. **A study done to evaluate the frequency and types of errors that occur in laboratory medicine provide evidence that most errors occur during the _____phase of testing and can include anywhere from 31 percent up to 75 percent of total laboratory error.**
    - A. pre-analytical
    - B. analytical
    - C. post-analytical
    - D. billing

15. **Some of the most common types of pre-analytical errors include _____, insufficient sample volumes, incorrect or mislabeled samples and clotted samples.**
    - A. improper data entry
    - B. hemolyzed samples
    - C. operator error
    - D. instrument malfunction

16. **Some of the key capabilities that lab automation provides to support pre-analytical activities include:**
    - A. flexible sample loading options
    - B. priority routing
    - C. sample inspection
    - D. all of the above

17. **The same study showed that errors occurring during the post-analytical phase of testing also have a significant impact and contributed to anywhere from 9 percent up to ____ percent of total laboratory errors.**
    - A. 15.3
    - B. 20.8
    - C. 25
    - D. 30.8

18. **Lab automation offers a number of specific capabilities that can help address challenges within the post-analytical phase of testing including:**
    - A. post-processing sorting, refrigerated storage
    - B. quality control, refrigerated storage
    - C. quantifying results; post-processing sorting
    - D. quality control; quantifying results

19. **Many labs leverage middleware to complement and supplement the capabilities of their laboratory information system. These often include solutions for advanced data management, process management, inventory management and _____.**
    - A. analytics
    - B. coding invoices
    - C. quality control
    - D. specimen tracking

20. **Diseases such as hemoglobinopathies or thalassemia may be clinically silent but may cause reductions in ____ circulation time.**
    - A. plasma
    - B. platelets
    - C. white cell
    - D. red cell

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   P ① ② ③ ④ ⑤ E
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† In development and not for sale.

Mitigating the risks of C. diff infections and antimicrobial resistance

By Brenda Silva

Antibiotic treatment options for suspected and confirmed *C. difficile* infections (CDI) have clinicians taking more time to consider the increased risks of antimicrobial resistance (AMR) potentially faced by the patient in the future. As a fairly common hospital-acquired infection (HAI) with an estimated 200,000 cases diagnosed each year according to the Mayo Clinic, CDIs have become the subject of debate when it comes to treating the infections with antibiotics. While treatment decisions made today may address a current CDI, clinicians are also forced to consider a patient's potential for future AMR as well.

An "opportunistic" pathogen

With its basis in gut microbiota disruption, *C. difficile* appears to lie in wait for a healthy gut to become disrupted, putting the patient at risk of a CDI that requires additional treatment.

According to David M. Lyerly, Chief Science Officer at TechLab, "*Clostridioides difficile* is a prime example of an opportunistic intestinal pathogen. This anaerobic pathogen can germinate and grow in the large intestine when our gut microbiota has been depleted. Without competition from our healthy microbiota, *C. difficile* spores germinate and when growing as vegetative cells, produce toxins that can cause life-threatening colitis due to mucosal damage and severe uncontrolled inflammation. The spores can persist long after the symptoms of *C. difficile* infection (CDI) have resolved, probably months to years in some patients, explaining why some patients relapse repeatedly after CDI."

He added, "Any disruption of the gut microbiota – whether by antibiotics, chemotherapy, proton pump inhibitors, other gastrointestinal infections or conditions – can result in CDI and can lead to *C. difficile* colonization in asymptomatic persons. Probably the most striking and thoroughly studied are the high number of hospitalized patients who carry *C. difficile* but who remain asymptomatic. These patients meet the description of a "carrier" as defined in the 2016 ESCMID guideline for the diagnosis of *C. difficile* disease."

Explaining the most common route of acquiring a CDI, Ted E. Schutzbank, PhD, D(ABMM), Science Affairs Manager at Meridian Bioscience, pointed out, "Acquisition of *C. difficile* in the hospital setting due to poor handwashing practices and poor disinfection of hospital rooms between patients is the most common route, as the *C. difficile* spores can persist for months in the hospital environment. In addition, asymptomatic colonization of individuals with *C. difficile* has been demonstrated. Various studies have shown asymptomatic colonization of between 0-17.5 percent depending on the population group studied; colonization with toxigenic strains ranges from 1-5 percent."

Continuing, Schutzbank noted that "prevalence in healthy individuals is low, but rises significantly in various populations, especially in adults that have had contact with healthcare settings, and the elderly in long-term healthcare facilities or nursing homes. Healthcare workers have also been shown to have a higher prevalence for asymptomatic *C. difficile* colonization. Neonates in the first four weeks of life have also been shown to be asymptomatically colonized, but such colonization clears as a healthy gut microbiome is established."

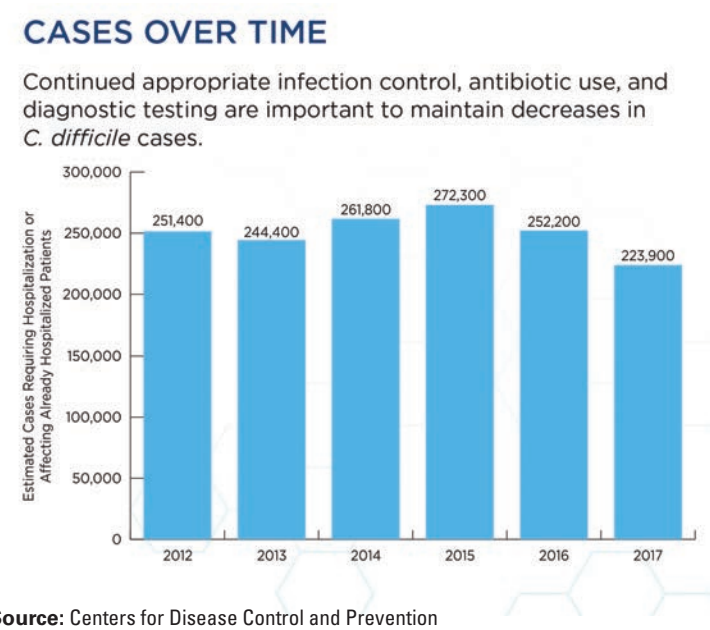
Antibiotic use risk factors

At the heart of debate over antibiotic use with CDIs remains the issue of the potential for an increased risk of AMR with every *C. difficile* infection that a patient is treated for. Many clinicians assert that the more antibiotics that are prescribed as treatment for CDIs, the higher the risk they will have a lower treatment effect in subsequent or future CDIs. This issue has clinicians and laboratorians alike looking to find an acceptable way to treat CDIs while mitigating the level of AMR risk involved for patients.

Looking at treatment options for symptomatic and asymptomatic patients, Rodney C. Arcenas, PhD, D(ABMM), Director of Clinical Sciences, Microbiology, at Roche Molecular Systems, said "There is little debate about treating symptomatic persons, with the IDSA 2018 guidelines recommending the use of vancomycin or fidaxomicin over metronidazole for initial episodes of CDI. Metronidazole may be used in settings where vancomycin or fidaxomicin may be limited. The treatment choices are similar for fulminant CDI and recurrent CDI, with the potential for fecal microbiota transplantation recommended only for multiple recurrences of CDI in patients who have failed appropriate antibiotic treatments. There have been instances of increased MICs of metronidazole from *C. difficile* clinical isolates."

He added, "The utility of antibiotics in asymptomatic and/or known carriers of *C. difficile* remains a topic of debate. Although it is recognized that carriers may present a level of risk to themselves for the development of CDI and also as a potential reservoir of transmission, the benefit of eradicating any *C. difficile* carriage is, so far, unproven. There are other confounding factors to consider in asymptomatic *C. difficile* carriers, such as the use of potential offending antibiotics, age, use of proton pump inhibitors, healthcare environmental exposure, underlying disease such as ulcerative colitis, and immune status, which have all been shown to contribute to the development of CDI."

Lyerly summed up, "CDI most often is triggered by an antibiotic and ironically, the therapy for this antibiotic-associated disease is another antibiotic. CDI can be triggered by most antibiotics, although some seem to be more closely associatedwith the disease, perhaps because of increased



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use of those particular antibiotics. CDI most often is treated with metronidazole, vancomycin, or fidaxomicin, and fortunately, most patients respond well to treatment.

In recent years, metronidazole has not been prescribed as much as vancomycin for CDI patients. Fidaxomicin is the newest antibiotic for CDI and has lower relapse rates than those associated with vancomycin. Although any of these three antibiotics can effectively treat CDI, they also can kill much of the normal gut microbiota. This is a concern because if a patient is incorrectly diagnosed with CDI and receives inappropriate treatment with any of these antibiotics, the patient can be predisposed to true CDI."

Schutzbank also pointed out some of the more common antibiotics used to treat CDIs and their potential for resistance, saying, "*C. difficile* is known to be resistant to a broad range of antibiotics. The most common antibiotics associated with CDI are ampicillin, amoxicillin, cephalosporins, clindamycin, and fluoroquinolones. The most common choice of antibiotics for treatment of CDI include metronidazole, vancomycin, and fidaxomycin. The use of metronidazole has essentially been discontinued due to the high rate of resistance to this antibiotic. According to the current IDSA *C. difficile* guidelines metronidazole is no longer recommended as first-line therapy for adults."

He added, "Resistance of *C. difficile* to vancomycin has also been reported, although the levels of resistance vary appreciably in different areas of the world and depend on which resistance break-point system is used. A sentinel survey in the U.S. found that 17.9 percent of *C. difficile* isolates were resistant to vancomycin based on the EUCAST breakpoints. This suggests a serious problem for the use of vancomycin should the rates of resistance increase in the future. Indeed, in Israel, one strain of *C. difficile*, ribotype 27, with reduced susceptibilities to both metronidazole and vancomycin now predominates. For this reason, appropriate testing, following the published guidelines by the IDSA as well as other organizations, must be rigorously followed to ensure a proper diagnosis of CDI, since overdiagnosis due to false positive results will result in inappropriate antibiotic therapy for those patients, which has long-term consequences for the development of antibiotic resistance."

Looking for other options

As the debate continues about the use – and potential overuse – of antibiotics for *C. difficile* infections, clinicians remind the lab industry of the challenges they face in finding an acceptable option that will not only treat the CDI, but also help maintain antimicrobial susceptibility for the patient in the future.

Arcenas reported, "Interestingly, the topic of screening asymptomatic patients for *C. difficile* has been considered as a means of identifying carriers upon admission into the hospital.[1] In a recent study, patients being admitted for surgical services were screened for the carriage of *C. difficile* by collecting perirectal swabs and positive patients were flagged in their system. Treatment for *C. difficile* was considered only if they became symptomatic for CDI. The study authors stated they observed a decrease in CDI rates during this 10-month period of screening compared to before this intervention period where no screening was performed. It should be noted that the IDSA guidelines state that there is insufficient data to recommend screening for asymptomatic carriage and implementing contact precautions at this time. However, the data is promising as a means of controlling CDI in healthcare institutions."

He continued, "Additionally, healthcare institutions can institute mechanisms to control the rates of CDI in their institution with an antibiotic stewardship program that has input from the clinical laboratory, pharmacy, infection control, and infectious disease clinicians. Currently, the IDSA strongly recommends minimizing or restricting the use of high-risk antibiotics (fluoroquinolones, clindamycin, and cephalosporins) and the total number of antibiotics prescribed."

Also asserting the benefits of antimicrobial stewardship, Lyerly summarizes, "Diagnostic testing for CDI continues to be challenging, and laboratories have to weigh the benefits and limitations of the various types of tests now available. Toxin testing provides the highest positive predictive values, but concerns have been raised about the lower sensitivity. GDH and NAAT assays provide higher sensitivity but detect the organism and not toxin. NAAT assays offer the highest sensitivity for the organism but over-diagnose patients who are colonized and who carry spores."

He added, "For these reasons, guidelines have recommended algorithm testing that brings together the advantages of these tests when multiple tests are implemented. The strength of this approach is built on the ability to determine if a patient is carrying *C. difficile* and whether a patient's diarrhea is caused by *C. difficile*. By using this approach, CDI patients are more accurately diagnosed, inappropriate treatment is minimized, and importantly, antimicrobial stewardship is practiced."

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Assessing the risk of preterm birth with fetal fibronectin testing in conjunction with transvaginal ultrasound

by Michael S. Ruma, MD, MPH

A substantial body of evidence suggests the use of fetal fibronectin (fFN) testing can help differentiate between expectant mothers presenting with symptoms of preterm labor who are truly at higher risk of imminent preterm birth from the vast majority whose symptoms will resolve spontaneously without hospitalization and treatment. As the COVID-19 pandemic continues, it is imperative that we are accurate in deciding on when to admit pregnant women to the hospital where resources are overwhelmed and potential risk of exposure to the virus may increase. Laboratories can help by offering fFN testing to aid in the healthcare providers' decision-making process, improving patient care and reducing unnecessary interventions.

Preterm birth is a global medical problem

Preterm birth, defined as childbirth before 37 weeks of gestation, is a major global healthcare issue. Worldwide, the preterm birth rate is 11 percent, with 15 million preterm children born every year. Most preterm births (84 percent) occur between weeks 32 to 36 of gestation. Unless medically indicated, pregnancy through 39 weeks of gestation is recommended for optimal health of the infant.

Image by Regina Petkovic from Pixabay

Most women who have preterm labor symptoms before 32 weeks of gestation do not deliver within a week; therefore, prediction of who will actually deliver preterm is important to avoid unnecessary treatment, lower costs, and reduce maternal stress

In the United States, the preterm birth rate rose for the fourth consecutive year, with 10 percent of infants being born prematurely in 2018. The rates differ between racial and ethnic groups, with a preterm birth rate of 14 percent for black women compared with 9 percent for white women. Preterm birth and low birth weight are the second leading cause of death in infants in the United States, accounting for approximately 17 percent of infant deaths.[1]

Preterm birth interrupts growth that would normally be completed in utero and the shorter the gestational age at birth, the greater the risk of long-term disability and/or death of the infant. Infants born preterm experience short-term complications from prematurity that affect most organs and systems, as well as possible intellectual and developmental deficits and other long-term health problems.

Similarly, from an economic standpoint, the earlier the birth occurs, the greater are the costs. The average cost per preterm birth in the United States was $65,000 in 2016, totaling $25.2 billion in societal costs, which include medical costs for the delivery, early intervention and special education services for the preterm child, and lost productivity in the workplace for the parents.[2]

Due to the overwhelming issues for both mother and child, it is crucial for laboratories to consider offering testing approved by the U.S. Food and Drug Administration (FDA) to rapidly screen all women presenting with symptoms of preterm birth to help reduce the burden on the mother, her unborn child, and the healthcare system overall.

Fetal fibronectin is a biomarker capable of predicting preterm birth

The glycoprotein fFN helps bond the amniotic sac with the chorionic layer of the uterus during gestation.[3] fFN is normally not found in vaginal secretions from weeks 16 to 35 during pregnancy.[4] As the mother prepares to give birth, fFN leaks into the vaginal fluid.[5] Testing for fFN can help differentiate between expectant mothers presenting with symptoms of preterm labor at higher risk of imminent preterm birth and the vast majority whose symptoms will resolve spontaneously without hospitalization and treatment, enabling efficient use of healthcare resources, especially during the time of the COVID-19 pandemic, when hospitalization may pose other potential health risks and consume critical resources.

Most women (75 percent to 95 percent) who have preterm labor symptoms before 32 weeks of gestation do not deliver within a week; therefore, prediction of who will actually deliver preterm is important to avoid unnecessary treatment, lower costs,

and reduce maternal stress. fFN testing has a high negative predictive value for symptomatic women, meaning a negative fFN test indicates a <1 percent chance of delivery within two weeks.[5]

Numerous studies showing the positive impact of fFN testing have been published for clinical outcomes and cost effectiveness, including preterm birth management algorithms developed by experts that incorporate fFN testing.[6,7] A recent systematic review of clinical trials stated that fFN levels of ≥50 ng/mL at 22 weeks of gestation or later is one of the best predictors of preterm birth in all populations studied and can help select which women are at significant risk for preterm birth.[8] Another systematic review concluded that fFN testing had the potential to reduce unnecessary use of healthcare resources by identifying women who do not require medical intervention as an inpatient.[9]

Implementation of a standardized preterm labor screening protocol that included fFN testing at three hospitals within the WellStar Health System allowed for more efficient allocation of provider time and hospital resources. After implementation, the proportion of patients who received fFN testing at these hospitals increased from 52 percent to 95 percent.[7] This increased fFN test uptake was accompanied by a significant reduction in the average time for an assessment by a nurse and led to appropriate and prompt initiation of antenatal corticosteroids and tocolytics as recommended by the American Congress of Obstetricians and Gynecologists. Additionally, cost savings of $264,000 were recognized, stemming from reductions of medical interventions and unnecessary patient hospitalizations.[7]

Fetal fibronectin testing in conjunction with transvaginal ultrasound is the most effective way to assess the risk of preterm birth

The value of fFN testing in assessing preterm birth is already beneficial, but when combined with a transvaginal ultrasound (TVUS) cervical length measurement <30mm, the positive predictive value in determining if a woman is at risk of spontaneous preterm birth is dramatically higher. In fact, in a large study completed in the Netherlands, the combination of a short cervical length with a positive fFN test nearly doubles the risk of preterm birth in seven days.[6] Preterm birth screening that includes fFN testing with a transvaginal cervical length assessment, when a women presents with symptoms of preterm labor, is the most effective way to determine her risk of an imminent spontaneous preterm delivery, leads to better perinatal outcomes, and reduces health care costs.[6]

In general, fFN testing and TVUS have been underutilized to identify women at risk of preterm delivery. In a retrospective study of more than 23,000 women presenting with symptoms of preterm labor to an emergency department using the Medical Outcomes Research for Effectiveness and Economics Registry, a national multipayer claims database, only 12 percent of patients received an fFN test and only 21.5 percent had a TVUS.[10] The proportion of women who underwent fFN testing was significantly higher for patients discharged home (14.2 percent) versus those admitted to the hospital (5.0 percent; P<0.0001). Overall, accurate assessment of a patient's risk of imminent preterm delivery was poor, as 76 percent of the women were discharged home, yet 20 percent of these women proceeded to deliver within three days of being discharged. Of the discharged women who suffered a preterm delivery, only 3 percent received fFN testing, only 18 percent received a TVUS, 1 percent received both fFN testing and TVUS, and 78 percent received neither a fFN test, nor a TVUS during their hospital evaluation for symptoms of preterm labor. The overall proportion of women who delivered within three days of assessment in the emergency department was lower among women who only had fFN testing (6.6 percent) compared to those who only had TVUS (21.6 percent), suggesting fFN testing may have provided valuable information for patient care, while TVUS may have provided false reassurance to providers in their decision to discharge the patient. Importantly, preterm delivery was significantly lower among women who had both tests (4.7 percent; P<0.0001).

Given the current strain on the healthcare system due to the COVID-19 pandemic, it is more vital than ever to ensure provider time and system resources are used efficiently and effectively without compromising quality of care. To that end, use of fFN testing with or without TVUS should be incorporated as the standard evaluation to help identify women with symptoms of preterm labor who are at very low risk of imminent preterm birth. Laboratories with fFN testing rapidly available are invaluable in helping healthcare providers make the important decision of whether to admit pregnant women with preterm labor symptoms to the hospital, implement medical interventions beneficial to the infant, or confidently discharge women at low risk of preterm delivery, thereby supporting patient wellbeing and conserving valuable hospital resources.

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Using laboratory analytics to improve performance in a value-based world of change

By Tim Bickley, MT(ASCP), MBA, CPHIMS

Laboratory administrators and department supervisors routinely manage supplies, perform risk assessments, and balance workloads and staffing. But managing these areas of operational performance has become even more challenging as laboratory administrators grapple with both the onslaught of COVID-19 testing and the healthcare industry's move from fee-for-service to value-based reimbursement. For these reasons, making data-driven decisions based on laboratory analytics has become more important than ever to identify and manage change.

There are several issues that laboratory managers tackle on an hourly or daily basis. These include, but are not limited to, responding to requests for data, implementing new platforms for testing, and filling vacant positions. Not only are lab leaders faced with maintaining these and other routine day-to-day demands during the pandemic, but they must also sustain a competitive edge as a laboratory service.

As labs look inward and focus on addressing performance improvement and overall lab operations, there are many questions and challenges to successful daily management. Some of these include: Is our lab meeting turnaround times for all departments within the health system? Are we monitoring laboratory quality appropriately? How do we staff during a pandemic? What tests are being unnecessarily ordered? What follow-up tests are being missed? Where are we going to get our testing reagents, instruments, and supplies for molecular testing?

Using data analytics, lab managers can predict workloads and improve test utilization

The answer to these questions resides in electronic data but accessing and interpreting data can be a time-consuming manual process. This is why laboratories are increasingly implementing solutions like laboratory analytics to automate and expedite this process and help with their daily management and process improvement effort. Laboratory analytics brings data to your fingertips with reports that can be run ad hoc or scheduled when needed, allowing the laboratory managers to be in control of their data. By automating this process, which when done manually can take days or weeks, laboratory managers can make faster, actionable decisions on process improvement measures. Data management and analytics play a critical role in helping labs transition to value-based care by harnessing the power of data to improve operational efficiency, financial performance, and productivity.

Predicting workload with laboratory analytics software helps managers with staffing in uncertain times

Labs are always being asked to do more with less, and this is compounded by COVID-19 testing demands and financial strain caused by the pandemic. Laboratory staff members are overworked, stressed, tired, and concerned about COVID infections. Lab managers also deal with the possibility of staff furloughs, balancing and rotating staff by shifts, and sometimes working with skeleton crews. Laboratory data analytics can help improve productivity by providing insight into staffing requirements based on several laboratory criteria. Analytics software allows the laboratory to monitor staffing needs by workstation, department, hours of the day, days of the week, by test, by patient location, and by priority. Once a user selects the criteria, lab analytics software can generate a report that displays by hour of the day where staffing adjustments may be necessary. Not only does this assist with staffing adjustments, but it also can help lab managers predict workload. Laboratory managers typically spend hours evaluating predictions of workload. Predictive workload reporting provides lab managers with views of how samples arrive on any given day of the week, by time, by any test or lab department. For example, predictive workload analytics can allow lab management to view activity, such as Hematology Peak AM specimen arrivals that are now arriving 30 minutes earlier than previous Tuesdays. That type of predictive information can be used to adjust schedules for phlebotomists and technologists and maintain appropriate staffing levels. For any hour that a staff member has activity captured in the LIS, staff productivity for that hour can be assessed using analytics software.

There are several opportunities to manage staffing levels with data analytics. One example is the ability to manage COVID-19 testing patterns and workflow by viewing the turnaround time (TAT) and frequency of batch COVID testing by hour and by shift. This is useful for monitoring interruptions in processing that cause turnaround time delays. It allows the laboratory to examine 24 hours of COVID-19 test processing at a glance by shift. The ability to view batch and frequency of COVID-19 testing data can assist laboratories in monitoring TAT, which is especially needed for high volumes of COVID-19 testing. The Lean ideal is Single Piece Flow, but this is not feasible for most COVID-19 testing platforms because COVID-19 instruments for hospital laboratories are typically designed for high batch-size processing. There are exceptions that support rapid, single piece flow. But the principal of smaller and more frequent batches

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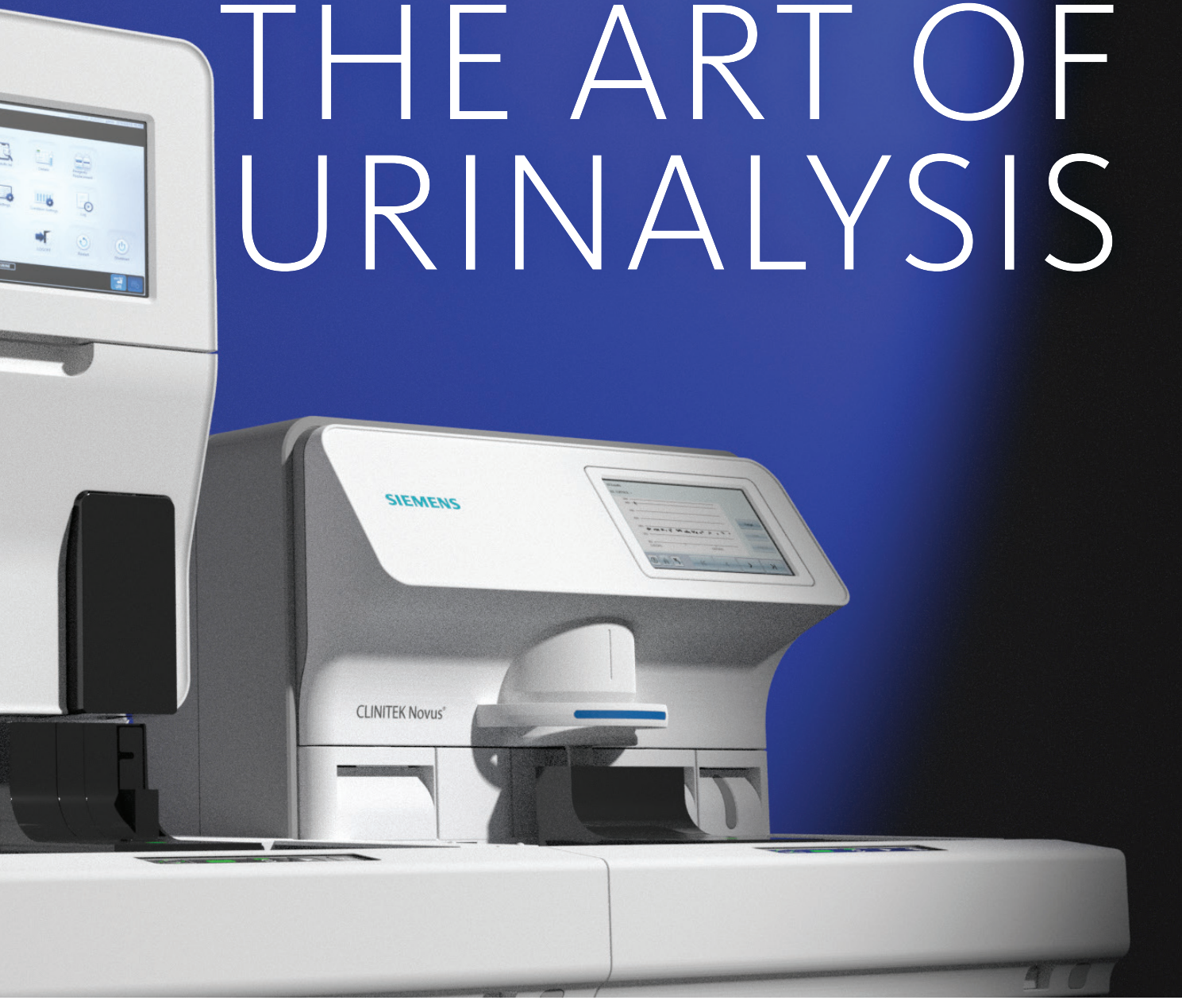

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will translate into decreased turnaround times. Smaller batches come at a cost of additional labor expended, so managers need to weigh the costs and benefits.[1]

Population heat maps also can be used to manage staffing. The heat maps reflect the volume of tests and positive COVID-19 results based on zip code and is used to identify high volume areas. This type of laboratory data management allows lab managers to predict staffing levels based on the increase of COVID-19 prevalence. Identifying areas becoming larger and darker on a heat map signals to management to prepare for changes in particular locations. As COVID-19 testing increases, decreases in routine testing will likely occur, which may impact staffing levels.

Moving to value-based reimbursement: The progression from fee-for-service to risk-based contracts occurs in four stages in the healthcare industry

Fee-for- Service	Fee-for- Service, Link to quality and value	Alternative Payment Models Alternative Payment Models	Population-based
No link to quality	Link to quality and value, such as incentives payments for meeting process measures, i.e. care coordination	Shared savings with only upside financial risk for providers	Condition-specific, such as payments per-member, per-month for specialty care
		Shared savings with downside financial risk for providers	Comprehensive population-based payments

Table 1
Source: Centers for Medicare & Medicaid Services

Improving test utilization for better financial performance during and beyond COVID-19

Over the last few years, laboratory reimbursements have declined and there has been a shift away from fee-for-service for inpatient testing, which has led to an increased emphasis on the quality and value of the services provided by clinical laboratories. With fixed reimbursement models no longer compensating for additional hospital clinical lab testing, and increased patient length of stays due to additional lab testing, test utilization has become one of the greatest opportunities for health systems to cut costs while improving patient outcomes and allowing them to meet the goals of value-based reimbursement models. (See **Table 1**)

Hospital laboratory analytics software plays a significant role in managing and supporting lab utilization stewardship. Laboratory test utilization reports illustrate the laboratory's data in a way that identifies unnecessary testing and helps laboratory management locate the areas of greatest opportunity for corrective action. Managers can see where problems with unnecessary lab testing are occurring so that hospitals can improve utilization of reagents, staff time, and scarce supplies. Examples of these unnecessary tests can include ordering an FT4 when a patient's thyroid-stimulating hormone (TSH) is normal, identifying unnecessary standing repeat orders, identifying expensive send out tests with a large percentage of normal results, or ordering prostate-specific antigens (PSAs) on male

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patients older than 75 years of age. Implementing laboratory data-analytics software strategies to identify and avoid these unnecessary tests has become particularly important with the financial strains caused by COVID-19.

Ultimately, the laboratory is sitting on a goldmine of data that has the potential to save the health system thousands or millions in unnecessary lab testing, which becomes increasingly important as value-based reimbursement becomes more commonplace. With data analytics, laboratory managers can independently generate reports to instantly identify sources of unnecessary testing. When the laboratory stewardship committee consults with physicians to eliminate these unnecessary tests or duplicate test orders, the cost savings are immediate. For example, hospital labs can reduce unnecessary inpatient sample collections by 6 percent, which provides an average $230k/year in cost avoidance (based on a hospital performing one million billable laboratory tests).[2]

Hospital laboratory analytics software enables laboratory management to monitor turnaround times to maximize reimbursement. The Centers for Medicare & Medicaid Services (CMS) announced that starting January 1, 2021, Medicare will pay $100 only to laboratories that complete high-throughput COVID-19 diagnostic tests within two calendar days of the specimen being collected. For laboratories that take longer than two days to complete these tests, Medicare will pay a rate of $75.[3] Analytics can track turnaround times for COVID-19, regardless of testing location, such as tests that are sent out to state labs or completed in-house. This view into internal processes and any outliers that occur provides management with the data needed to both improve productivity and optimize financial performance by improving cost per test.

Conclusion

Managing patient and sample data with hospital laboratory analytics is an important way to get information immediately when needed. Laboratory leadership should not have to rely solely on IT for laboratory reporting, labs should have access to their data when they need it. The ability for lab managers to monitor the laboratory daily leads to improved operational and financial performance, saving valuable time for better quality and patient care. Hospital laboratory analytics software helps laboratory management monitor key performance indicators to lead their teams toward levels of best practices. In the end, laboratory analytics empowers the lab to become a hospital-wide partner and asset, while improving patient safety and satisfaction – during COVID-19 and beyond.

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Biomarker technology in cervical cancer screening improves risk stratification

By Alexandra Valsamakis, MD, PhD

Cervical cancer, a preventable disease and curable if detected early, is the second leading cause of cancer death in women 20 to 39 years of age in the United States, causing 10 premature deaths per week in this age group.[1] Human papillomavirus (HPV) is the single most important etiological agent, with 99 percent of cervical cancers caused by a persistent HPV infection.[2] Skilled laboratorians using newer screening tests, such as HPV, in combination with Pap cytology, can provide meaningful information about a woman's risk of disease. However, some results may contribute to a diagnostic dilemma for clinical practice.[3] As biomarker technology in a triage test continues to evolve, so does the science of cancer protection and prevention.[4,5] Next-generation cytology testing using objective p16/Ki-67 biomarkers delivers greater sensitivity and offers the medical lab a simplified approach for triage that improves risk stratification and provides more definitive guidance in individual patient management.[6]

Critical role of the lab in cervical cancer screening and diagnosis

The clinical lab is at the center of any hospital or healthcare system and contributes to greater than 70 percent of medical diagnoses and decisions made by physicians each year.[7] In cervical cancer screening and diagnosis, the lab, cytologist, and pathologist have critical roles in both identifying cellular changes indicative of abnormalities (or transforming disease) and providing clinicians with evidence-based information to determine next steps for the patient.[8,9]

Screening programs have evolved

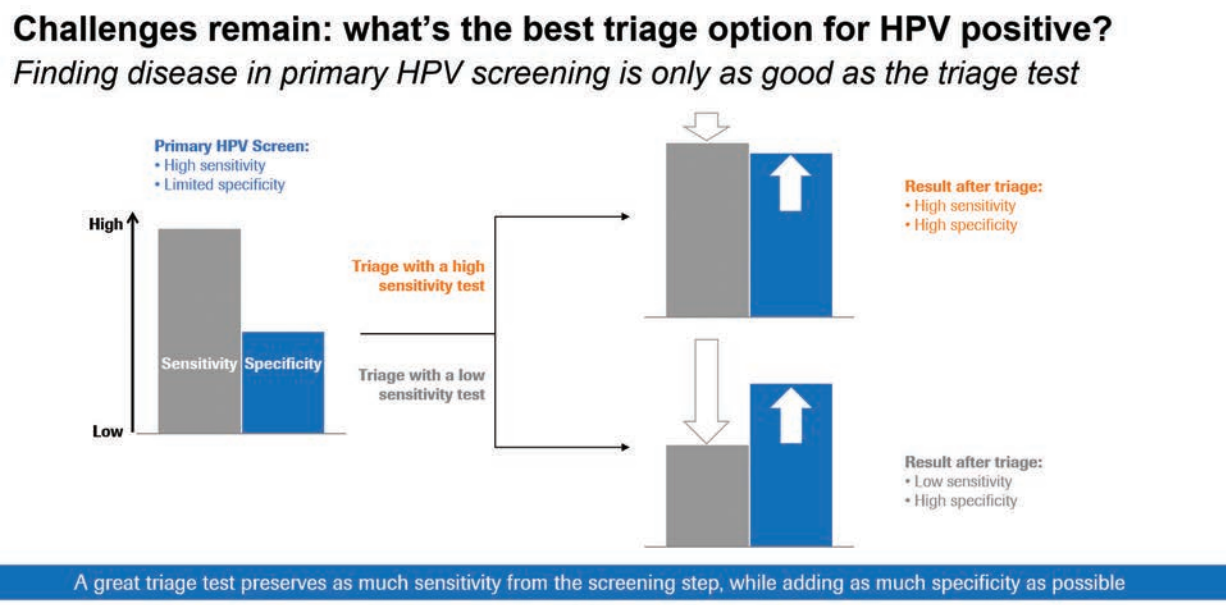
In the United States, cervical cancer screening programs have evolved from the Papanicolaou (Pap) cytology test first introduced in 1941. Today, the Pap is used alone or in combination with high-risk HPV DNA testing (co-testing).[10] There is also an option for high-risk HPV DNA screening as the primary test.[10] These developments have dramatically reduced cervical cancer incidence and deaths but some challenges remain. Not every HPV-positive woman will develop cervical cancer.[11] Additionally, discrepant results may occur in co-testing where a result can be HPV-positive but have normal cytology.[3] In these cases, following clinical guidelines by having the patient wait for up to a year before retesting may leave clinicians concerned about losing the patient to follow-up. Waiting may also create anxiety for the patient.

An effective triage step is required to identify who is truly at risk for disease and who is highly likely to self-resolve their infection in order to minimize the potential for undertreatment or overtreatment. Both carry consequences. Overtreatment may result in unnecessary colposcopy and biopsies. Colposcopy is a common and relatively safe procedure. However, evidence suggests that undergoing colposcopy after an abnormal cervical cancer screening result may have a negative impact on a woman's psychological and sexual health. Potential consequences of undertreatment are missed diagnosis with progression to more advanced disease.

Disease may go undetected if a highly sensitive screening test, such as hrHPV, is followed by a lower sensitivity triage test, such as Pap. An effective triage test preserves as much sensitivity from the screening step and adds as much specificity as possible to find most of the women with cervical disease while minimizing the risk of undetected disease. A triage test with both high sensitivity and high specificity enables more accurate risk stratification than one with lower sensitivity.

Risk stratification in triage

Risk stratification in triage enables labs to further differentiate women at risk who will benefit from immediate intervention from those who can be given more time to clear their infection without intervention before the next follow-up.[11] The risk of pre-cancer and cancer varies by HPV genotype. While almost all cervical cancers are associated with 14 genotypes of HPV, HPV16 and HPV18 are the two highest risk types, causing approximately 70 percent of cervical cancers and



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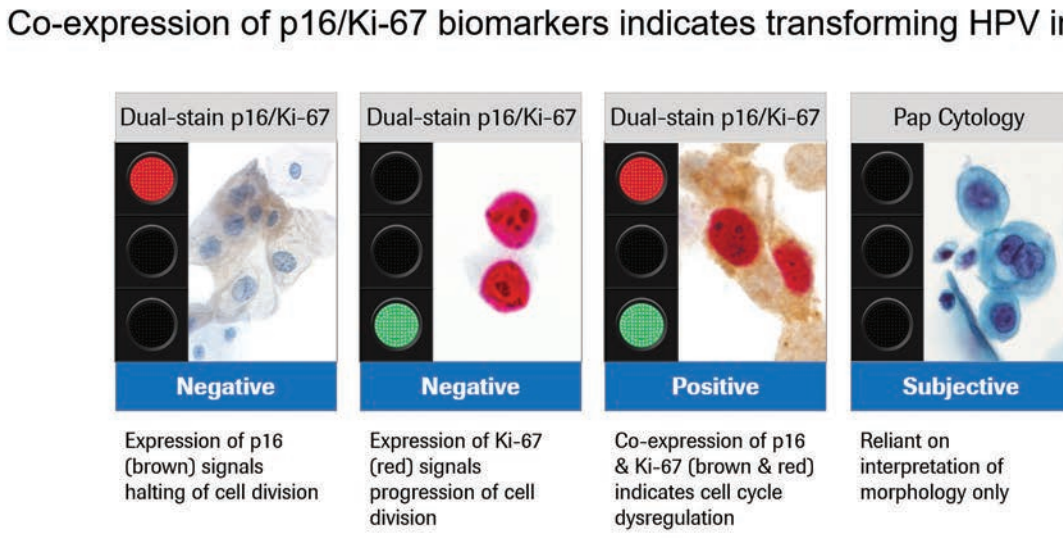

precancerous cervical lesions.[12,13] HPV16 carries the greatest risk, followed by HPV18, which accounts for approximately 13 percent of squamous cell carcinoma (SCC) as well as 37 percent of adeno/adenosquamous carcinoma (ADC) of the cervix worldwide.[12]

Currently, clinicians use Pap cytology and HPV genotyping information to categorize women into different risk levels. While the current method works well in most clinical situations, there is room for improvement.

Biomarker-based technology provides more objective, definitive answers

Biomarkers and biomarker-based technology have been evolving to improve cancer diagnosis, classification of cancer genotypes, prognosis and prediction of response to therapy.[4] Biomarker-based tests that yield objectively interpretable results can fill gaps left by Pap cytology when used in cervical cancer. Biomarker-based cytology testing relies on the detection of molecular changes happening within the cell, while Pap cytology relies on the more subjective interpretation of cell morphology.[14]

The application of biomarker technology – immunocytochemical staining for proteins to characterize cells – is useful in the diagnosis of cervical cancer. Two cellular proteins, p16 and Ki-67, have been shown to be co-expressed in HPV-infected cells that have started the oncogenic transformation process. p16 is a marker of cell cycle arrest and is overexpressed in HPV-infected cells and is an indicator of a transforming HPV infection; Ki-67 is a marker of cellular proliferation. In normal cells, these two biomarkers are never co-expressed.[15] p16/Ki-67 co-expression suggests that the cell is undergoing HPV-induced oncogenic transformation and is strongly associated with established high-grade disease.[16] A dual-stain positive p16/Ki-67 immunocytochemical stain result is strongly associated with established high-grade disease.[17] In contrast, the absence of dual staining is more informative than a normal Pap result – with a relative reduction of 53 percent in risk of undetected disease compared with Pap (3.8 percent vs 8.0 percent) – offering reassurance that the patient is highly unlikely to progress to cancer in the next few years and can be given time to allow her immune system to clear the infection.[15,16,18] Next-generation cytology using technology that detects biomarkers p16 and Ki-67 offers an important and more objective step forward in clarity of results and improved disease detection.[14,15]

Using biomarkers to objectively look for changes on the cellular level in triage improves sensitivity by 31 percent compared to triage with Pap cytology which relies on morphological interpretation.[15]

Advanced technology in triage for more sensitivity, more clarity

In March 2020, the U.S. Food and Drug Administration (FDA) approved the first cervical cancer screening triage test that uses biomarker technology.[6] The test uses dual-stain immunocytochemistry to simultaneously detect p16 and Ki-67 in the same cell.[6] This next-generation cytology test can be performed on the same sample collected for a Pap or HPV screening test, without requiring the patient to return to the clinician's office.[6,15]

Dual-stain biomarker technology provides higher sensitivity than Pap cytology triage, while maintaining high specificity.[15] This combination enables more accurate risk stratification.[17]

Biomarker technology can also be helpful in the cervical cancer screening HPV DNA and Pap co-testing paradigm, when a woman has a positive HPV DNA result but a Pap that is negative for intraepithelial lesion or malignancy (NILM).[15] Dual-stain biomarker technology identifies up to 70 percent of women with disease who would benefit from immediate follow-up.[15]

In its review of the new biomarker technology, the FDA considered data from the registrational IMPACT (IMproving Primary screening And Colposcopy Triage) trial, which enrolled close to 35,000 women in the United States. The study was designed to clinically validate the assay as a dual-stain triage test in different screening scenarios.[6] Publication of study data is pending.

Moving closer to the goal of cervical cancer prevention

The role of HPV infection in cervical cancer has been known for decades and persistent infection is recognized as the single most important cause in almost all cases. Improved understanding of the oncogenic transformation process in HPV opens up new pathways to better identify women whose HPV infections are most likely to be associated with cervical precancer or cancer. The availability of new biomarker-based dual-stain immunocytochemistry technology can enable labs and pathologists to play an even greater role in advancing personalized medicine and answering the call for action to eliminate cervical cancer.

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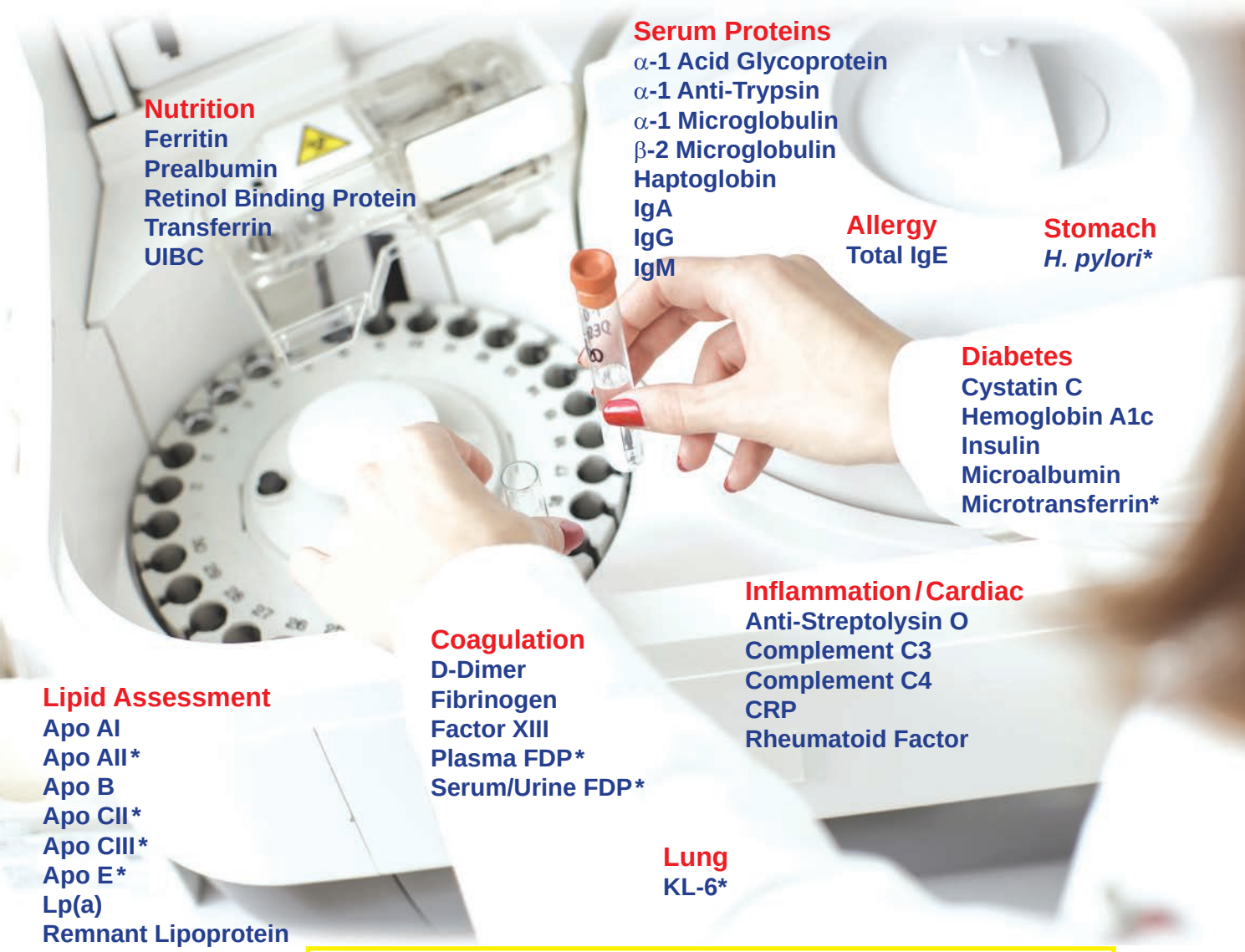

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Defining success early when transitioning biomarkers from research to the clinic

By Emily I. Chen, PhD

Within the field of biomarker research, interest in seeking early, preventive indicators of prodromal diseases has risen, as has the development of multiplex biomarker panels that better capture disease complexity, compared with single biomarkers. These efforts have the potential to transform many therapeutic areas and have been made possible by the emergence of powerful technologies, such as advanced mass spectrometry and whole genome sequencing for the discovery of protein, metabolite, and genomic biomarkers.

Biomarkers can improve health outcomes by enabling better treatment management, earlier disease detection, and improved monitoring of drug efficacy and toxicity in clinical trials.[1] However, the transition from biomarker discovery in a research laboratory to real-world application in the clinic is currently a challenging one. A significant amount of method redevelopment is often required to bridge the gap, as the demands and priorities of research and clinical laboratories differ significantly. In this article, we explore best practices for developing a streamlined proteomics workflow for large-scale biomarker detection and explain how adopting standardized protocols and automation can help smooth the transition from the research laboratory to the clinic.

A robust and comprehensive biomarker discovery pipeline enables the development of tests and therapeutics for precision medicine.

Define success with quantitative data

Having confidence in the accuracy of biomarker measurements is paramount, as the results are used to guide important decisions. For example, biomarker data may influence the management of an individual's healthcare, or it may be used to assess the safety of a new therapy in a clinical trial. High-quality data are needed to support these endeavors, and in some cases, those of future studies, as data may also be interrogated in later studies in the context of additional information.

The key to building confidence, in the case of clinical tests, lies in defining and limiting variability within the workflow. Although common practice, it is not sufficient to report a single, cumulative measurement of error. To truly assess analytical errors, we need to take a closer look at the individual components within a protocol, from sample preparation to liquid chromatography to mass spectrometry, for example. Without a detailed breakdown of the sources of error, confidently comparing data generated across different laboratories is difficult. In this context, a widely circulated quote comes to mind: "if you can't measure it, you can't improve it." That is to say, if sources of error aren't identified within a workflow, they are unlikely to be addressed.

While one individual might be able to reliably produce consistent results day to day, it is easy to underestimate the extent of manual errors that can occur when a workflow is adopted and multiplied on a larger scale. Introducing quantitative assessments at every stage of the workflow allows laboratories in any country to reproduce the method and trust the results – a critical test of method quality that is not matched by publication in a peer-reviewed journal. Establishing specific, objective checkpoints enables a laboratory technician to have greater confidence throughout the process, allowing them to ensure the assay is robust before sharing biomarker results with the patient or clinician.

Consider statistical power as early as possible

While the adoption of quantitative assessments helps generate accurate biomarker measurements, the data will be of no real value if the study is too small. To ensure results are meaningful, it is wise to consider statistical power early in the development of biomarker tests for clinical use – rather than as an afterthought. The statistical power of a study is sometimes referred to as sensitivity and is a measure of how likely the study is to distinguish an actual effect from one of chance. If the sample size is too small, the statistical power will be low and the validity of test results will be compromised, as the probability of making a Type II error increases. In other words, in a study with a low statistical power there will be a higher chance of failing to detect a difference between groups.

Tests that seek to determine the presence or absence of a biomarker are few and far between; it is more common to compare the magnitude of a biomarker across groups in order to detect a concentration above a certain threshold (e.g. two- or three-fold). Ensuring sample sizes are reflective of realistic expected differences

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Ensuring sample sizes are reflective of realistic expected differences helps improve the chances of detecting true biological differences; a greater sample size will be needed to detect smaller differences in magnitude as assessed by repeatability and specificity. Even at the early stages of research, it is important to consider the size of the cohort and the specific population in which the biomarker will be measured.

Streamline steps and remove room for interpretation

Although research and clinical laboratories share many common goals and values, their priorities differ. Maximizing the sensitivity of a biomarker test is a fundamental priority in the research laboratory, while in clinical applications, reproducibility becomes more important as it is critical that biomarker test results can be reproduced across laboratories for them to be of benefit. Without an efficient and standardized protocol, reproducibility is impossible to achieve. On a larger scale, small inefficiencies are amplified, creating a high demand for time and labor. In order to remove this unnecessary bottleneck, protocols should be developed with clarity and efficiency in mind.

Removing ambiguous language allows the workflow to be more easily adopted in multiple laboratories; the method should be written in a way that allows any technician to follow the procedure and have confidence in their results. Instructions such as "shake gently" are common yet are devoid of the details needed to ensure that every technician would execute the step in the same way. Without clarity, operators will be left to navigate unclear instructions, experimenting with trial and error to find a protocol that works.

Reduce variability in reagent source and dispensing

Even the clearest, most efficient method, performed to perfection, will be difficult to reproduce at scale if standardized reagents are not used. Often, reagents produced in-house are not subject to rigorous quality control (QC) assessment, so there is no guarantee they will be produced consistently to enable the generation of reproducible results. As such, they are not suited to use on a wider scale. Likewise, commercially produced reagents are not immune to variability, as not all companies have the same QC standards.[2] Therefore, selecting reagents with minimal batch-to-batch variability is paramount.

In addition to reagent reliability, another challenge lies in dispensing them accurately and consistently. Over time, biomarker tests implemented at scale may be executed by thousands of scientists across multiple laboratories. As a result, some variability in pipetting is inevitable – even if most laboratory technicians are highly accurate. Implementing liquid-handling robotic systems removes this variability and is often a necessity for laboratories faced with a high volume of samples.

For laboratory scientists unaccustomed to automation, the transition to using programmed robotics may be unappealing. Fortunately, many developers are appreciative of this barrier and are actively working to remove it. User-friendly platforms are becoming more widely available and expected.[3] Indeed, there is a strong and growing view that experience with liquid-handling robots should not be a prerequisite for using them. Instead, the goal for many in the space is to offer a "plug and play" platform that enables scientists to easily control the platform and obtain consistent results.

Place quality control at the core

Although quality assurance (QA) of biomarker protocols is a widely acknowledged issue, few workflows include standard QC/QA procedures. Consistent QA/QC procedure not only drives quality, but also facilitates a comparison of the data among different laboratories. Part of the solution lies in having reference samples available. For example, using a standard peptide assay to assess peptide recovery after sample preparation and prior to mass spectrometry analysis, enables reproducibility to be assessed within and across laboratories. Similarly, frequent testing of pooled, known blood samples across longitudinally different runs can help identify any analytical issues as they arise.[4] Data from pooled blood samples help operators assess whether a seemingly outstanding data point is simply a result of biological variability, or an indication that an analytic error has occurred, such as a mass shift in the mass spectrometer. Such tools are beneficial for technicians in the laboratory who can stop and address any sources of error before continuing.

Standardization of the method itself is a crucial aspect of maintaining quality results at scale and is beneficial when considering protocol changes in the future. By collecting thorough, concrete data, protocol developers can gauge a baseline level of quality, variability, and throughput, and can objectively consider what criteria should be superseded in order to move forward with more innovative approaches. Achieving a truly optimized end-to-end workflow solution requires close scrutiny of important parameters at each step. For instance, asking "what is the highest throughput that can be achieved while continuing to meet the quality criteria?" Scientific progress is built on precision and defined parameters; building workflows with this mindset is the best way forward.

Conclusion

Currently, transitioning biomarker identification from a research laboratory to application on a large scale is highly challenging, largely because the priorities of research laboratories differ from those in a clinical setting. To address this gap, it is important to incorporate quantitative checkpoints into defined workflows to ensure biomarker measurements can be reproduced – a prerequisite for delivering real-world value. Harmonizing methods while removing ambiguity within the protocol, enables laboratories to implement optimized workflows that deliver reliable results. For many laboratories, the transition to automation is necessary to ensure they can control the variability that occurs on a larger scale, while maintaining quality and throughput. If those in the field of biomarker discovery can maintain awareness of the demands, best practices and priorities of a clinical laboratory, the upscaling transition will be a lot smoother when the time comes.

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Use of molecular assays differentiates between flu and COVID-19

By Brenda Silva

Since the initial emergence of the SARS-CoV-2 virus in late December 2019, COVID-19 has evidenced many of the same respiratory-based symptoms as influenza. As the 2020-2021 flu season approaches, COVID-19 has already been associated globally with millions of deaths and many people in high-risk age and health categories are taking no chances in catching either disease. However, because of their similar onset of initial symptoms, clinicians are looking to use tests that can distinguish one disease from the other.

Similar yet different

By developing tests that are intended to confirm the existence of more than one virus, such as influenza A/B, RSV and/or SARS-CoV-2, cost-effectiveness of tests increases while time to results and treatment decreases.

According to Michelle Tabb, PhD, Chief Scientific Officer at DiaSorin Molecular, "RNA viruses such as influenza are well known to mutate or change from season to season. Because of this, molecular diagnostic companies with tests for RNA viruses such as influenza or SARS-CoV-2 face the challenge of identifying conserved regions of the viral genome to be used as targets for Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) test design. Influenza virus has had a multitude of viral sequences identified over the past decades, which are available in public databases. This allows for an alignment comparison for identification of the most highly conserved regions, which can then be used as the best targets for RT-PCR assay design."

She continued, "Most commercial manufacturers have developed influenza A and influenza B assays targeting the highly conserved matrix genes of each virus. However, with the emergence of a new virus such as SARS-CoV-2, there are fewer historical examples to use for designing a molecular assay. The recent, very rapid analysis of viral sequences available combined with comparison to previous coronavirus conserved sequences from SARS and MERS has led to the test designs available today. There are different examples of the gene targets and approaches employed for these test options."

Focusing on the use of two different targets to detect SARS-CoV-2, Tabb added, "Some tests have taken the approach of using two different targets to identify SARS-CoV-2 including one target that is less specific that identifies the virus as a coronavirus family member paired with another target that is SARS-CoV-2 specific. These tests typically require that both the coronavirus target and the SARS-CoV-2 target are positive for a SARS-CoV-2 positive interpretation. Other tests have taken the approach of using two very specific SARS-CoV-2 target genes, and employed an algorithm allowing either one or both of the targets to be detected for a positive interpretation. Within these two approaches, there are many different SARS-CoV-2 specific genes that have been used as targets in these new test designs including RdRp, ORF1a, ORF1ab, S gene, E gene and N gene."

Adding to Tabb's comments is Garrett Heinrich, PhD, Application Scientist with Enzo Life Sciences. He asserted, "For influenza and SARS-CoV-2, laboratories are looking at RNA, viral protein, and human antibody to viral protein. Detecting viral RNA is the most sensitive method. Due to mutations and recombination testing for influenza, RNA can be limited to detecting types A and B, or additional considerations can be made to further detect subtypes based on the hemagglutinin and neuraminidase sequences."

Assay speed versus accuracy

Tests that offer multi-identification disease results are only advantageous if they provide accuracy along with faster times to results. Elaborating further on the issue of speed versus accuracy, Heinrich asserted, "The COVID-19 pandemic struck at a time when our capabilities to sequence the viral genome are fairly advanced, but it still took time to determine the unique sequences present, develop the primer/probe assays, and make sure the tests for this novel coronavirus would detect the correct virus and ignore others. There still exists a tradeoff between speed versus accuracy in any testing for flu and SARS-CoV-2, but molecular nucleic acid testing remains the gold standard."

He continued, "Rapid molecular assays, while they provide results in a shorter amount of time, do so at the cost of sensitivity. Standard molecular assays using RT-PCR are more sensitive and specific for detecting influenza and SARS-CoV-2, resulting in a lower likelihood of a false positive or false negative result. Most RT-PCR assays are generally more expensive."

Multipurpose test availability

Heinrich forecasts increased efforts to address cost-effectiveness and reduced turnaround times in daily use test options. "Testing for SARS-CoV-2 has added a new strain to clinical laboratories that will soon also be facing the seasonal rise of influenza and common cold. To maximize resource efficiency and ensure minimal turnaround time, assays are being developed to simultaneously detect multiple threats. One example of an automated liquid handling platform allows the extraction of viral RNA and detection of influenza A/B, RSV, and SARS-CoV-2 concurrently."

He continued, "An influenza and COVID panel acts as an important tool to test for the most common respiratory pathogens from a single swab. The ability to offer both tests from a single swab should help ease the pressures on supply chain. Instead of having two swabs and double the reagents testing COVID and flu together will alleviate time, resources, and costs. Laboratories will be faced with an unprecedented amount of respiratory testing this year, but they should continue to develop solutions to better integrate SARS-CoV-2 testing with the regular clinical lab workflow to maximize efficiency and cost-effectiveness through flexible platforms."

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Northwest Laboratory processes between 10,000 and 12,000 molecular tests to detect SARS-CoV-2 per day, with samples from 31 states.

Deleting paper processes improves COVID-19 testing throughput

By Linda Wilson

The large volume of testing for SARS-CoV-2 has exposed process-flow bottlenecks in clinical labs. That is why labs should prepare for an expected onslaught of COVID-19, flu and other diagnostic testing demands by eliminating as many manual steps in workflows as possible, experts said.

Northwest Laboratory in Bellingham, WA, knows all about the bottlenecks that paper processes can cause. The independent lab processes between 10,000 and 12,000 molecular tests to detect SARS-CoV-2 per day, with specimens coming to the lab from 31 states. It has the capacity to process as many as 30,000 SARS-CoV-2 tests daily with its current equipment – 12 biosafety hoods, five primary high-throughput analyzers and several backup analyzers – and staffing.

The lab reengineered processes to get to that scale, particularly in the pre-analytical phase. For example, it installed a commercial web portal that allows consumers to self-register for a test and then print or download to their phone a requisition – which includes a barcode – to take to a specimen-collection site. Now specimens arrive at the lab already labeled with the patient's name and unique barcode. Results are automatically available for patients and their providers through the portal, which is also integrated with the laboratory information system (LIS).

Northwest Laboratory is not alone. Paper processes exist at clinical labs in pre-analytical, analytical and post-analytical phases of testing as well as in billing processes.

"If you are still on paper, I think you will struggle. Labs need to focus on how they can increase their throughput," said Philippe Flamant, Vice President of Solutions Engineering at ELLKAY, who adds that testing demand in 2021 is likely to be greater than in 2020 because of surveillance efforts associated with reopening businesses and schools. "You have more employers who want people to come back into the office. You have people who want to go back to work. You have students who want to go back to school," he said.

Pre-analytical

Once of the biggest sources of bottlenecks is in the pre-analytical phase. As David Metrena, Vice President of Healthcare at LabVantage Solutions, explained, "We're seeing increased reliance on paper or manual processes to accommodate non-standard sources – when testing facilities don't have established relationships with the labs where they are sending samples. A pop-up COVID-19 testing center in a school parking lot, for example, may not have the resources for electronic data capture at the time of sample collection, so a paper requisition joins the sample when it's delivered to the lab. The lab then either manually enters the data, or perhaps scans it to convert it to electronic form."

That's exactly the situation at Northwest Laboratory, which has many new clients that will probably not be customers after the pandemic is over, making it financially untenable for Northwest Laboratory to build a bidirectional electronic interface between its LIS and the client's electronic medical record. These clients also are unlikely to want to use the web-portal software, Test Directly, that Northwest Laboratory uses to automate specimen collection and testing processes.

In these cases, the paper requisition associated with each specimen is scanned into the LIS. Transcriptionists working from home pull up the scanned document and then add the patient's demographic information into the appropriate fields in the LIS, allowing the lab staff to focus on testing. "We took the data entry out of the lab completely. We have one dedicated person who does quality checks for people doing data entry at home just to make sure we are not having data entry errors," Jennifer Bull, Chief Operating Officer at Northwest Laboratory, said.

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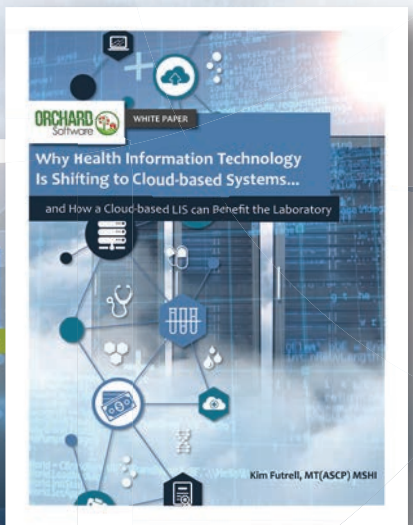

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Despite those steps, paper requisitions can be "riddled with errors – missing ICD-10 codes or other billing information, incorrect or incomplete test orders, illegible writing, manual labels, etc. – causing an increase in specimen intake time to correct the orders and even jeopardizing patient safety due to incomplete information, or mislabeled or mismatched patient records," Michelle Del Guercio, Vice President of Marketing at Sunquest Information Systems, said.

As is the case at Northwest Laboratory, the ideal solution includes a web-based portal tied to the LIS, allowing patients and providers to order the tests, according to Metrena. "In this scenario, samples collected at the drive-through testing center would be immediately entered into the system – whether from a laptop or tablet – and a label printer could print the label affixed to the sample, eliminating an actual paper trail. Results could then be accessed from the LIS portal, delivered to their EHR/EMR, or even electronically faxed or sent directly to a printer at the requisitioner's location. This adds speed and reduces errors, which is critical as labs strive to keep up with growing testing demands," Metrena said.

Another source of manual processes is the printing of lists of pending reports or other work logs, noted Sandy Laughlin, Sales Enablement Manager for the Lab Division at CompuGroup Medical. For example, she said hospital or health system labs "often use paper logs to track when specimens are sent to and results are received from a reference lab. This process is more easily managed using an LIS with order-routing rules and memorized queries to determine which in-house or reference lab tests are pending," she said. "The LIS also can generate real-time pending queries to save valuable time" for other types of work lists, she said.

Analytical

Labs also can eliminate paper processes in the analytical phase of testing. For example, Laughlin said many labs use paper worksheets to document the results of manual tests before entering the results in the LIS. They also use paper reports to document each step of complicated tests, such as for molecular and genetic assays.

Kim Futrell, MT(ASCP), MSHI, Senior Strategic Marketing Manager at Orchard Software, agreed, saying, "In the core lab, decision support rules in the LIS are instrumental for process streamlining. Rules can be implemented at every stage of the lab testing workflow (e.g., order entry, reflex testing, reporting, etc.)."

However, Futrell, added, "The single most valuable process improvement is likely auto-verification, where depending on the lab menu and patient population, up to 80 percent of results are eligible for auto-verification. Having results that meet a laboratory's criteria for 'normal' release to the provider automatically can save an enormous amount of technologist time and significantly speed turnaround time."

Quality control is another source of manual processes, such as paper copies of Levey-Jennings reports, which are graphs depicting quality control data, Laughlin said. "LIS systems should have the ability to document the electronic review of QC and generate ad hoc reports as required." In addition, she said, "an electronic document management system eliminates paper storage and manual reviews while assisting laboratories in achieving regulatory compliance. Alerts and notifications make it easy for managers and staff to review and sign off on documentation digitally," she said.

Post-analytical

Suren Avunjian, Co-Founder and Chief Executive Officer at LigoLab, said that manual processes in the post-analytical phase involve reporting of results to patients, physicians, and public health agencies. But "paper forms create friction that adversely affects test turnaround times and the lab's ability to handle higher test volumes," he said.

Marci Dop, lab industry expert and CIO, MHC Management Consulting, said the most efficient way to share results with patients is through a web-based portal. "If you are doing 1,000 tests a day, you can't be getting 1,000 phone calls a day wondering: 'Where is my result?'"

Reporting information on testing to state public health agencies is another source of potential bottlenecks. If information is missing, "you also are going to have the state reporting agency telling you that you are not in compliance and calling you for the missing information. It is critical to report to the state those values of ethnicity, race, address, and phone number because the majority of the states are calling positive cases," Flamant said.

The problem is magnified for laboratories that are reporting COVID-19 testing information to more than one state. While they may have set up electronic processes with their home state, that is not likely the case with other states. "What we are seeing a massive need for is assistance in reporting to those states. If the lab has the reagents and the turnaround time, they are able to go get business outside of their normal catchment area," Flamant said.

Dop said many reference specialty labs that have added COVID-19 molecular testing to their service offerings are reporting results to multiple states, while health systems and hospitals are increasing the number of external labs they use for overflow testing.

Billing

Bottlenecks occur in billing, too. Bull at Northwest Laboratory said the biggest revenue cycle issue for the organization is simply the large number of new clients. Lab employees have been instructed to make sure that each patient case has the information necessary for billing, such as a scanned health insurance card, before a specimen is tested. The usual process is further complicated by rules labs must follow to receive payment from the federal government for SARS-CoV-2 testing of uninsured or underinsured patients. Patients must register for the program, sign an attestation about their insurance status, submit a copy of their state identification card, and provide their social security number. At Northwest Laboratory, lab employees check to make sure all of that information has been entered into a patient's electronic record.

To meet turnaround requirements for testing, Futrell noted that some labs may opt not to hold up testing for billing purposes, which could lead insurers to deny claims. "With a high test volume, missed charges can have a serious effect on a healthcare organization's finances," Futrell said.

"To overcome these challenges, new pandemic-related workflows have to be designed with modifications to standard electronic lab processes so that progression is automated and the revenue cycle is not disrupted. Automating patient registration, creating instrument-ready labels at drive-thru testing sites, and developing interfaces to exchange order, result, and billing information are some of the examples of methods labs are using to address these challenges," Futrell said.

But rather than taking a piecemeal approach to eliminating manual steps throughout testing and revenue cycle workflows, Laughlin recommended that labs approach the problem globally. "Laboratories should map out their analytical processes. A visual presentation of the testing process makes it easier to understand the distinct steps of a complex process and drive the discussion about which elements show room for improvement," she said.

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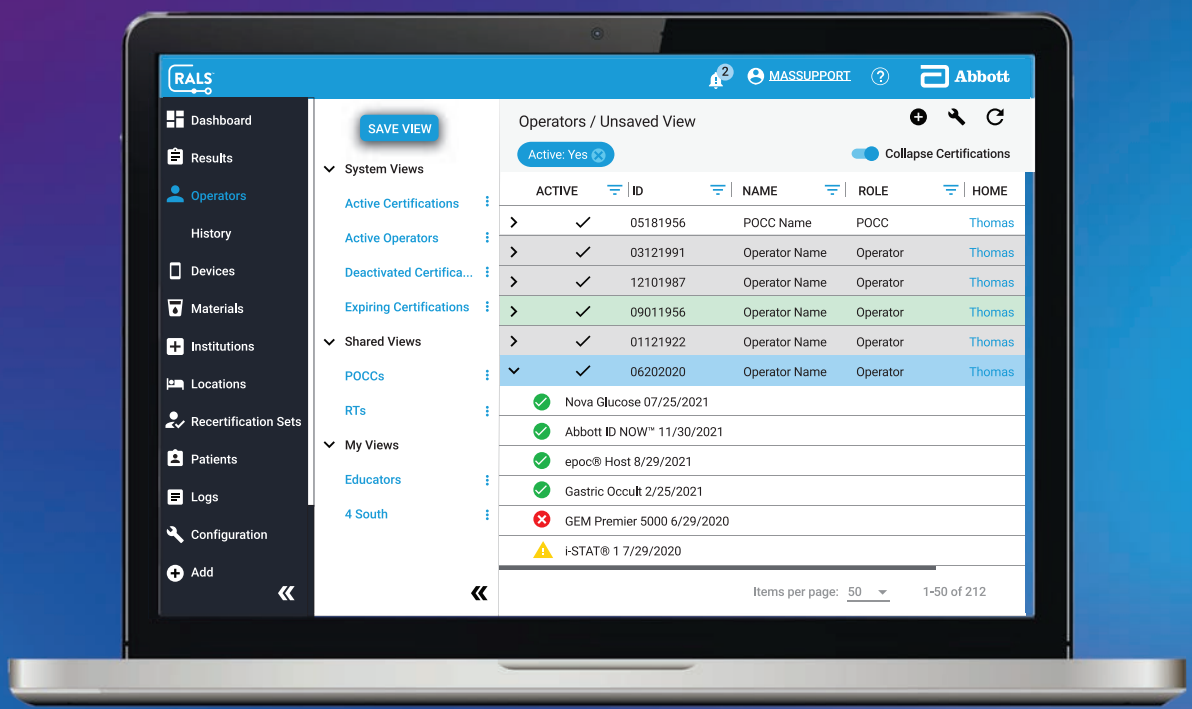

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Company Name	Clinical Software Solutions	CompuGroup Medical	ELLKAY, LLC	Epic	LabVantage Solutions, Inc.	LigoLab Information System	NovoPath LLC
Name of system (product)	CLIN1	CGM LABDAQ	LkTransfer, CareEvolve, LKLive-mapping, LKBridge, LKeMPI, LKPatientDa-taLink	Beaker	Medical Suite	LigoLab LIS & RCM Labora-tory Operating Platform	NovoPath Laboratory Information System
Website URL	www.clin1.com	www.cgm.com/labdaq	www.ellkay.com	www.epic.com	www.labvan-tage.com/your-lab-type/medical-lis/	www.ligolab.com/	www.novopath.com
2015-edition certification from the Office of the National Coordinator for Health Information Technology	No	No	Yes	Yes	Yes	No	Yes
Cloud-based version	Yes	No	Yes	No	Yes	Yes	Yes
Pre-configured interfaces with common analyzers	Yes	No	N/A	No	Yes	Yes	Yes
Pre-configured interfaces with common inpatient EMR sytems	Yes	No	Yes	Yes	Yes	Yes	Yes
Pre-configured interfaces with common outpatient EMR systems	Yes	No	Yes	Yes	Yes	Yes	Yes
Pre-configured interfaces with common pathology imaging platforms	No	No	N/A	Yes	Yes	Yes	Yes
Module for revenue cycle management	No	Yes	No	Yes	No	Yes	Yes
Automated process for tracking medi-cal necessity	Yes	Yes	Yes	Yes	Yes	Yes	No
Lab per-formance management analytics	Yes	Yes	No	Yes	Yes	Yes	Yes
Barcode speci-men tracking	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Inventory control or supply chain management	Yes	Yes	No	No	No	Yes	No
POCT module	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Genetic testing module	Yes	No	Yes	Yes	Yes	Yes	Yes
anatomical pathology module	Yes	No	Yes	Yes	Yes	Yes	Yes

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Company Name	Orchard Software Corporation	Psyche Systems Corporation	Quantum Mechanic, Inc.	SCC Soft Computer	Schuyler House	Sunquest Information Systems
Name of system (product)	Orchard Harvest LIS, Orchard Outreach (Copia), Orchard Pathology, Orchard Point-of-Care (Trellis), Orchard Enterprise LIS (Sequoia)	NucleoLIS	Toxilab	SoftLab LIS/ LIMS	SchuyLab	Sunquest Laboratory
Website URL	www.orchardsoft.com	www.psyche-systems.com/enterprise-laboratory-information-software/nucleolis-molecular-lab-testing-software/	www.toxilab.com	www.soft-computer.com	www.schuylerhouse.com	www.sunquestinfo.com/software-and-services/laboratory/
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Pre-configured interfaces with common pathology imaging platforms	No	Yes	N/A	Yes	No	Yes
Module for revenue cycle management	No	N/A	No	Yes	Yes	Yes
Automated process for tracking medical necessity	Yes	No	Yes	Yes	Yes	Yes
Lab performance management analytics	Yes	Yes	No	Yes	Yes	Yes
Barcode specimen tracking	Yes	Yes	Yes	Yes	Yes	Yes
Inventory control or supply chain management	Yes	No	Yes	Yes	No	Yes
POCT module	Yes	N/A	Yes	Yes	Yes	Yes
Genetic testing module	No	Yes	N/A	Yes	No	Yes
anatomical pathology module	Yes	Yes	N/A	Yes	No	Yes

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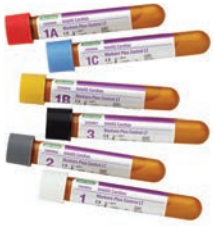
ELLKAY

OC-Auto® FIT Testing

The fecal immunochemical Test (FIT) screening method for hemoglobin in stool for the early detection of blood which may be associated with colorectal cancer. OC-Auto® FIT is the only automated method for FIT testing.

Polymedco

Bio-Rad's InteliQ Product Line Expansion Announcement



Bio-Rad's new InteliQ products can be used on Abbott Alinity and Roche Cobas systems in addition to Siemens Atellica Solution. This expansion also includes new in-use claims (off-board and on-board).

Bio-Rad

Sysmex UN-Series™ Automated Urinalysis Solution

The Siemens Healthineers CLINITEK Novus® Automated Urine Chemistry Analyzer completes Sysmex America's automated urinalysis portfolio, resulting in a modular urinalysis workflow solution that integrates urine chemistry, with the fluorescent flow cytometry of the UF-5000™ Fully Automated Urine Particle Analyzer and the UD-10™ Digital Imaging Device.

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GEM® Premier™ 5000 blood gas system with iQM®2 assures quality before, during and after every sample in lab and POC testing—for improved patient care. All-in-one, multi-use cartridge offers advanced simplicity.

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COVID-19 Antibodies Control

The Control LQ COVID-19 Antibodies (Order Number: K077M-6), is a stable, ready-to-use liquid, bi-level control for use with assays designed to produce qualitative results for COVID-19 Total Antibodies and COVID-19 IgG Antibodies.

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The BioFire Pneumonia Panel identifies 33 clinically relevant targets from sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples. For 15 of the bacteria, the BioFire Pneumonia Panel provides semi-quantitative results.

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The Solana Respiratory Viral Panel (RVP) combines Solana Influenza A+B and Solana RSV + hMPV, to detect and differentiate four common respiratory viruses from a single patient sample for improved patient management.

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Seegene Technologies will soon introduce a single tube real-time RT-PCR assay, Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay, simultaneously detecting and differentiating Flu A, Flu B, RSV A/B, and three different targets of COVID-19 (S, RdRP and N gene).

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LABORATORY INNOVATOR

Reference lab put to the test for COVID-19 results

By Brenda Silva

Karen K. Smith, MBA, MT (ASCP). Karen K. Smith currently serves as the System Vice President, Laboratory Services for **CommonSpirit Health**, which was created in 2019 through the merger of Dignity Health and Catholic Health Initiatives. Based in Chicago, it is one of the nation's largest nonprofit health systems and the nation's largest Medicaid provider, with 137 hospitals and more than 1,000 outpatient sites in 21 states. At CommonSpirit Health, Smith is responsible for the quality of services across the system, including but not limited to optimizing lab functionality. Smith oversaw the development of the health system's COVID Reference Lab, which opened in September in Scottsdale, AZ. She also develops the vision and strategy for laboratory services, ensuring they align with the health system's commitment to serving the communities in which it operates.

Whose idea was the Common Sprit Reference Lab, and what kind of lab background and/or experience did this person/group come from? How did the Reference Lab grow into what it is today?

CommonSpirit Health's' Chief Medical Officer (CMO) had the vision. He understood the spread potential of SARS-CoV-2 and the limitations of reliable testing in the country. His vision to stand-up a national lab gave us the capacity for testing that we knew we would need. I got the request from the CMO and helped make it a reality. I was involved in all the decisions, such as cost analysis, location, resourcing, contracting, finance, connectivity and hiring the manager.

What was the primary impetus for the creation of the Common Sprit Reference Lab – to assist in the processing of COVID-19 tests or to provide an organized repository for patient EMR and data?

The primary goal was to have testing capacity. Vendors in the United States still have serious restrictions on high throughput, PCR testing and the testing platforms. We could not buy 140 high-throughput analyzers. Not just from a cost and space limitation perspective, but the vendors do not have that many units to sell. Putting 10 analyzers in one space made the most sense to reach the capacity we felt we would need. Having a single data repository was not an issue.

Since the Reference Lab opened in September, how many tests (COVID-19-related and non-COVID-19-related) were expected to be processed, and how much of that became a reality?

We have the capacity to perform 10,000 tests per day. We are not at that volume yet. We slowly brought on all the CommonSpirit hospitals and are now expanding to our ambulatory clinics and home health departments, and we have the potential to test employees when needed.

Could you address the range of tests performed, turnaround times, cost-effectiveness, and so on?

The tests performed include PCR COVID and will include influenza A/B. Turnaround time is 5 hours from receipt of a specimen and 36 hours from collection. Our in-house test cost is 40 percent of the cost of a commercial lab.

What stage is the Reference Lab at now in terms of expected services and staffing? What is the next step in the growth of the Lab?

Staffing is at about 95 percent, and that is adequate for the current level of testing. We will be expanding our test menu to include influenza A/B testing, which will be offered as a combination test with SARS-CoV-2. We are still adding orders and results interfaces to support our internal patient needs.

Looking at the post-pandemic future, what new daily services will the Reference Lab provide?

We are in the process of planning for testing to support CSH Precision Medicine Programs. The majority of this testing is referred out to external labs. Insourcing that testing will reduce our costs. The Precision Medicine Alliance will offer patients from our health system faster and more accurate diagnostic and treatment protocols based on their genetic and molecular profile information. Conventional wisdom suggests patients suffering from the same condition should be treated with the same therapy.

Science now tells us that the efficacy of one-size fits all for medications and therapies varies by patient because each person has a unique DNA that responds differently to prevailing treatments. We will use the latest technology, especially in genomic sequencing, to deliver the right care to the right patients, quickly and efficiently. Through the use of genomics for diagnosis and treatments, a new degree of precision will identify the most effective treatment and/or clinical trial for each patient, as well as those treatments that would potentially be ineffective or harmful.

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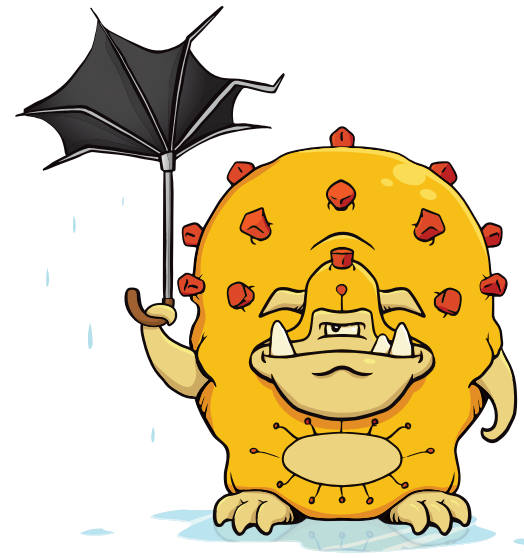

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BioFire RP2.1 Panel

1 Test. 22 Targets. ~45 Minutes.

Nasopharyngeal Swab in Transport Media: overall 97.1% sensitivity and 99.3% specificity (prospective specimens)[2]
SARS-CoV-2 98.0% sensitivity and 100% specificity (archived specimens)[3]
SARS-CoV-2 100% PPA and 100% NPA (contrived specimens)[4]

The BioFire RP2.1 Panel is a front-line test for labs to help clinicians quickly diagnose and treat upper and lower respiratory infections.

BioFire PN Panel

1 Test. 33 Targets. ~1 Hour.

Sputum/ETA: 96.3% sensitivity and 97.2% specificity, BAL/mini-BAL: 96.2% sensitivity and 98.3% specificity[5]

The BioFire Pneumonia Panel identifies the most common causes of lower respiratory tract infections by detecting 33 bacterial, viral, and antimicrobial resistance gene targets.

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Syndromic Testing: The Right Test, The First Time.

1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. 2. Based on the prospective portion of the clinical study for the BioFire FilmArray Respiratory 2 (RP2) Panel. 3. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission. 4. Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission. 5. The stated performance is the aggregate of the prospective data from the clinical study for the BioFire® Filmarray® Pneumonia (PN) Panel.

BFR0000-8834-01