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2022  
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**CE Autoimmune testing**  
**Big data in hematology**  
**Glucose monitoring**



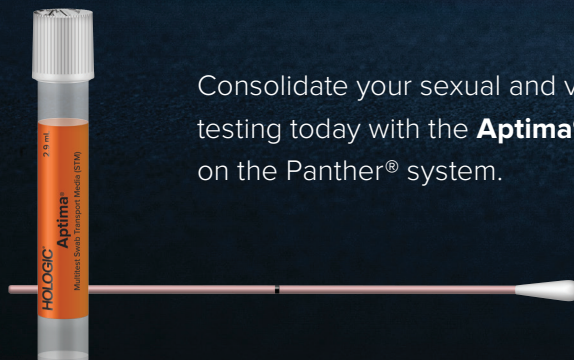
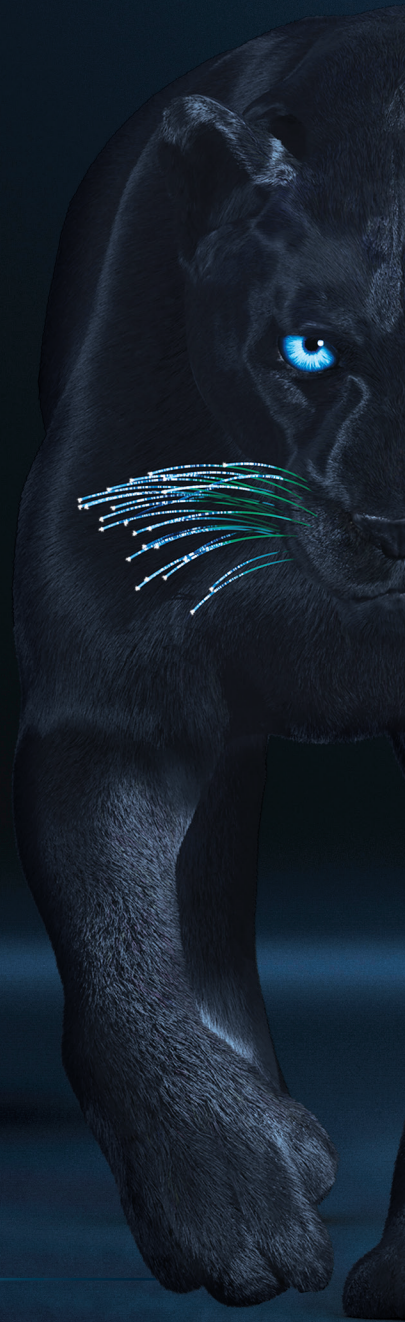
**LAB INNOVATOR**

**Laura Miller, MLS(ASCP)**  
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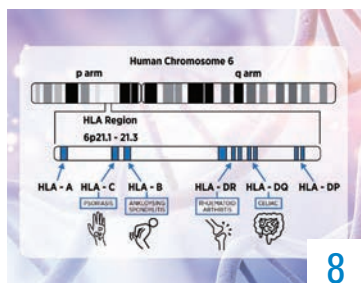
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# Talking about burnout in the lab



**By Linda Wilson**  
Senior Editor

In the International Classification of Diseases, the World Health Organization (WHO) classifies burnout as “a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed.”

The WHO, which approved this definition in 2019, also describes three dimensions of burnout:

- feelings of energy depletion or exhaustion
- increased mental distance from one’s job, or feelings of negativism or cynicism related to one’s job
- reduced professional efficacy

The WHO’s definition may resonate with *Medical Laboratory Observer’s* readers, particularly as the world grapples with the third year

of the COVID-19 pandemic, even as it, perhaps, reaches a less crisis-oriented phase.

It is worth noting that laboratorians dealt with burnout even before the pandemic began. In a survey of 4,613 lab employees published in February 2020, the American Society for Clinical Pathology found that 85% of those surveyed said they’d experienced burnout during their career as a lab professional, with about 50% saying it was a current problem.

In response to feelings of burnout, survey respondents said they considered changing careers (44%); switching to a different laboratory (40%) or job in a related field (33%); or retiring (25%). In other words, burnout not only causes human suffering but exacerbates already high vacancy and turnover rates in clinical labs.

The study also found an association between burnout and stress, with 78.3% of survey participants who were feeling high stress levels also experiencing burnout.

It’s also possible that you haven’t experienced all three of the WHO’s dimensions of burnout, but you may have been burdened by at least one of them at some point in your career.

Officials at the Department of Health and Human Services (HHS) recently divided \$103 million among 45 organizations to respond to the staffing crisis in healthcare by promoting mental health and wellness. The grants are designed to pay for evidence-based programs that address burnout, such as by helping workers develop resilience in the face of “high patient volumes, long work hours and workplace demands.”

In a news release, HHS officials acknowledge the role that the pandemic has played in worsening burnout, fatigue, and stress.

As this is April — the month during which Medical Laboratory Professionals Week occurs — I think it is a perfect time to begin addressing burnout through a variety of initiatives, such as promoting respectful behavior, encouraging wellness activities, providing behavioral health services for employees, and reducing reliance on overtime.

In closing, I’d like to tell you that this is my last column for *MLO* because I am moving to another publication owned by Endeavor Business Media, *MLO’s* parent company. But you and the vital work you do will always have a special place in my heart. Thanks for serving patients by providing timely and reliable test results for acute and chronic diseases.

I welcome your comments, questions, and opinions — please send them to me at [lwilson@mlo-online.com](mailto:lwilson@mlo-online.com).



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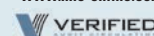
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# Ionized Magnesium ( $Mg^{++}$ ) A Critical Piece of the Electrolyte Puzzle

Electrolytes ( $Na^+$ ,  $K^+$ ,  $Ca^{++}$ ,  $Cl^-$ ) are all measured as ions because that is their only clinically active form. Now  $Mg^{++}$  can be measured the same way.

Ionized Magnesium ( $Mg^{++}$ ), not Total Magnesium (tMg), is the only physiologically active form of magnesium. Magnesium bound to protein, or chelated to phosphate, citrate, sulfate, or carbonate is inactive.

tMg is an unreliable substitute for  $Mg^{++}$ .  $Mg^{++}$  may be abnormal while tMg is normal, and vice versa.<sup>1,2</sup>

$Mg^{++}$  and  $Ca^{++}$  can now be measured in the lab or at the point of care to provide a complete electrolyte analysis:  $Na^+$ ,  $K^+$ ,  $Ca^{++}$ ,  $Mg^{++}$ ,  $Cl^-$ ,  $HCO_3^-$

**If you are measuring  $K^+$  and  $Ca^{++}$ , you should also be measuring  $Mg^{++}$**

$Mg^{++}$ ,  $Ca^{++}$ , and  $K^+$  ion abnormalities are common in critical care medicine.

$Mg^{++}$ ,  $Ca^{++}$ , and  $K^+$  ions are interdependent and play a role in numerous disease processes, including diabetes, hypertension, kidney disease, cardiovascular disease, cardiac arrhythmia, and sepsis.

$Mg^{++}$  is a vasodilator,  $Ca^{++}$  is a vasoconstrictor. Both are synergistic in maintaining vascular and bronchial smooth muscle tone.

$Mg^{++}$  ion is an antagonist to  $Ca^{++}$  ion entry into cardiomyocytes.<sup>3</sup>

Serial monitoring of  $Mg^{++}$ ,  $Ca^{++}$ , and  $K^+$  ions are all important in correcting or avoiding cardiac arrhythmias and cardiomyocyte necrosis.<sup>4,5,6</sup>

Hypokalemia may be unresponsive to potassium repletion unless hypomagnesemia is first corrected.<sup>7</sup>



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COHb, tHb, ePV



**STAT PROFILE<sup>®</sup>  
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**Test Menu**

$Na^+$ ,  $K^+$ ,  $Ca^{++}$ ,  $Mg^{++}$ ,  $Cl^-$ ,  
pH, Hct

Contact us for a bibliography of more than 25 recent publications about the importance of  $Mg^{++}$  in disease processes.

**$Mg^{++}$**



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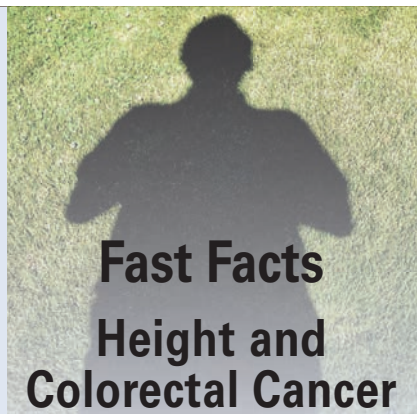
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## Fast Facts

### Height and Colorectal Cancer

Taller adults may be more likely than shorter ones to develop colorectal cancer or colon polyps that can later become malignant, according to new research from Johns Hopkins. One possible reason for this link is that adult height correlates with body organ size. More active proliferation in organs of taller people could increase the possibility of mutations leading to malignant transformation.

**24%**

higher risk of developing colorectal cancer was found in the tallest individuals, within the highest percentile of height, rather than the shortest within the lowest percentile

**5'9"**

is the average height for a male, and females average 5'4"

**10**

centimeter increases (about 4 inches) in height were found to be associated with a 14% increased risk of developing colorectal cancer

**50**

year-old and younger individuals' deaths from colorectal cancer have increased 2% per year from 2007 to 2016

**50%**

reduction in the colorectal cancer death rate in the next 25 years is the goal of President Biden's Cancer Moonshot initiative from early detection

Source: Johns Hopkins Medicine  
<https://www.hopkinsmedicine.org/surgical-critical-care/article/21259041/john-hopkins-studies-show-possible-link-between-height-and-colorectal>

### A disruption in lung cell repair probable cause of acute respiratory distress syndrome in COVID-19

Investigators studying lung cells have discovered that the normal repair process that occurs after lung disease or injury appears to be incomplete but still ongoing in patients who died of COVID-19 and non-COVID acute respiratory distress syndrome, according to the University of Michigan.

In patients who survive but develop scarring in the lungs, it appears that the repair process is permanently arrested, leading to chronic fibrotic lung disease. These findings may lead to novel therapies to promote healthy regeneration to increase survival and prevent fibrosis, they report in *The American Journal of Pathology*.

The alveolar epithelium in the lungs is made up of two types of cells. Type 1 alveolar epithelial cells (AEC1) are flat and broad and cover most of the alveolar surface. They play a critical role in barrier integrity and facilitate efficient oxygen absorption. Type 2 alveolar endothelial cells (AEC2) are small cuboidal cells that cover the rest of the surface. They produce a pulmonary surfactant to inflate the lungs and remove the fluid. AEC1 and AEC2 are damaged in ARDS due to COVID-19 or other causes. It is known that during lung injury in mice, AEC2 proliferate, exit the cell cycle, and enter a transitional state before changing into AEC1 to repair the alveolar epithelium. In humans with idiopathic pulmonary fibrosis (IPF), AEC2 never leave the transitional state, and change into AEC1, leading to the development of scar tissue known as fibrosis. The state of epithelial injury and regeneration in COVID-19 and non-COVID-19 ARDS without fibrosis had not been well characterized.

The investigators recovered lung tissue from the autopsies of patients who died of COVID-19 or non-COVID-19 ARDS within two weeks of hospitalization. They were compared with patients with IPF. The tissue was examined for evidence of AEC2 proliferation, transitional cells, AEC1 differentiation, indications of the loss of the ability to divide (senescence), and fibrosis. Investigators also compared the gene expression profiles of transitional cells in two mouse models of physiological regeneration without fibrosis, early human COVID-19 and non-COVID-19 ARDS, and human IPF.

The early ARDS lungs had extensive epithelial damage and a regenerative response in which AEC2 proliferated and entered the transitional state. The transitional cells occasionally assumed a flat AEC1 morphology but rarely ex-

pressed AEC1 markers. In contrast to patients with IPF, these lungs had not yet developed fibrosis.

The investigators propose that in COVID-19 survivors who recover normal lungs, the transitional cells ultimately regenerate the damaged cells. However, in survivors who develop scarred lungs, AEC1 are never regenerated; cells are stuck in the transitional state which can lead to scarring and lifelong respiratory impairment.

### Alternative approach for the treatment of prostate cancer uses sound waves

UC San Diego Health is first in San Diego County to employ high-intensity, focused ultrasound for minimally invasive prostate cancer treatment, according to University of California San Diego Health.

High-intensity focused ultrasound (HIFU) is a minimally invasive, outpatient treatment for localized prostate cancer. The technology uses high-frequency sound waves directed at the cancerous tissue through an ultrasound probe inserted into the rectum.

The sound waves target and heat the cancerous tissue to temperatures high enough to cause cell death.

HIFU provides an alternative to surgery or radiation for eligible patients. UC San Diego Health is the only hospital system in San Diego County to offer HIFU to prostate cancer patients.

Ideal candidates for HIFU are those who have early-stage, low- to intermediate-grade cancer that is confined to the prostate. HIFU is used to treat a single tumor containing part of the prostate, half, or in all the gland.

Through the advanced HIFU system, high-resolution images are combined with biopsy data and real-time ultrasound imaging to provide urologists with a 3D view of cancerous tissues. Physicians can then draw precise contours around the diseased tissue, ablate only that portion of the affected organ and minimize damage to surrounding structures, which include nerves important for erectile function, blood vessels and muscle tissue. For the patient, the approach minimizes the risk of urinary incontinence and erectile dysfunction.

### Researchers' findings could help improve bone marrow and stem cell transplantation

A recent study led by researchers at Massachusetts General Hospital (MGH) and Boston University School of Medicine has revealed the unique signature of genes, hematopoietic stem cells (HSC) have the capacity to both self-renew and



differentiate into all mature blood cell types, indicating promising treatments for a variety of diseases.

The findings, which are published in *Nature Communications*, could enable scientists to expand these cells outside of the body or to convert other types of stem cells into cells that can repopulate the blood system. However, the mechanisms involved in engraftment—when the cells start to grow and make healthy blood cells after being transplanted into a patient—are poorly understood.

In adults, HSCs are found in the bone marrow and bloodstream, but before birth, they can be found to a greater extent in the liver, where they multiply, or proliferate, into additional HSCs at a very high rate. Moreover, research in animals has shown that HSCs in the fetal liver are more capable of engraftment than HSCs from bone marrow.

To understand what allows fetal liver HSCs to have these superior proliferation and engraftment characteristics, investigators examined the gene expression patterns that are unique to these highly potent stem cells. They combined this examination with a variety of experimental methods to characterize the protein expression and functionality of those same cells.

The enhanced understanding of the genes involved will also help scientists propagate HSCs with high engraftment potential in the lab and manipulate them to fight blood cell-related dis-

eases, such as sickle cell anemia, HIV, and certain types of cancer, more efficiently. “Altogether, this work has resulted in a detailed blueprint of the most potent blood stem cells and will lead to a better understanding of why these cells have such an extraordinary regenerative capacity. Such insights will allow us to create safer and more efficient therapies for patients suffering from blood disorders,” says lead author Kim Vanuytsel, PhD, a Research Assistant Professor of Medicine at Boston University School of Medicine.

Co-senior author George J. Murphy, PhD, an associate professor of medicine at Boston University School of Medicine and co-founder of the BU and BMC Center for Regenerative Medicine (CRoM), adds that the team’s openly shared resource will enable new biological insights into engraftment potential and stimulate a broad range of future studies. “This important work would not have been possible without the potent, collegial collaborations that took place between Boston area institutions. This project is also a shining example of ‘open-source biology’ at work where the freely shared information and insights can be harnessed by all for future discovery,” he says.

### Link found between cholesterol crystals and heart infections

A study by researchers from the Michigan State University College of Human

Medicine is the first to establish a link between the formation of cholesterol crystals and bacterial infections in the heart, according to a news release from the university.

The bacteria attach and feed on the cholesterol crystals, the study found. The microscopic crystals, which are jagged, imbed in heart valves, allowing the bacteria to grow and causing endocarditis, a life-threatening inflammation of the heart valves.

A key event is when liquid cholesterol transition to crystals, which assume a greater volume in the arteries. Even a moderate drop in body temperature can trigger crystallization, which likely explains why many heart attacks occur early in the morning.

As the jagged crystals flow through the bloodstream, they scrape and damage blood vessel walls, causing them to spasm and constrict and possibly triggering a heart attack, he said.

The researchers found crystals protruding from heart valves, allowing bacteria to grow and infect the valves. An earlier study found that statins could prevent the valve damage, but only if given before the onset of the disease.

Future studies could lead to new treatments to prevent cholesterol crystals from forming. Abela referred to these as “sort of super statins,” something that has the capacity to dissolve crystals rapidly. 📌

## MAIT cells may be key to the next wave of immunotherapy and vaccine development

Mucosal-associated invariant T (MAIT) cells, an unconventional form of immune cell, exercise several complex roles during healthy and disease states and may help to serve as a benchmark for future research on these cells as targets for immunotherapies and vaccines, according to new research as described in a news release from Stony Brook University.

The findings were published in the *Journal of Immunology*.

In recent years, MAIT cells have received increasing attention by researchers because of their abundance in the human body, the fact that they can be rapidly activated by non-peptide vitamin intermediates from microbes, and because of their involvement in both infectious and non-infectious disease processes. Despite emerging interest in MAIT

cells, it is not fully understood how they are involved in fighting disease.

“We used single cell RNA sequencing technology and immunologic techniques to reveal that despite being ‘one cell type with a semi-invariant T cell receptor,’ MAIT cells demonstrate marked heterogeneity that recapitulates conventional T cell biology,” explains lead author Charles K. Vorkas, MD, Assistant Professor in the Departments of Medicine, Microbiology and Immunology at the Renaissance School of Medicine at Stony Brook University.

Vorkas and colleagues demonstrated in the laboratory that this marked heterogeneity includes distinct CD4+ and CD8+ lineages, as well as “killer,” “helper,” and “regulatory” cell phenotypes — an indication that MAIT cells exercise complex

functions.

He emphasizes that in light of recent studies showing that MAIT cells respond to infectious diseases like COVID-19, as well as during inflammatory events of autoimmune disease such as in lupus, or during tumorigenesis, a better understanding of their roles will help us to develop new therapies.

Vorkas and colleagues are now trying to identify MAIT cell subpopulations responding to initial infection with *Mycobacterium tuberculosis*, the causative agent of TB disease, as well as to tick-borne infections endemic to Long Island. His lab hopes to harness MAIT cells and other innate lymphocyte populations to develop immunotherapeutic alternatives to antibiotic drugs and to design novel vaccines.





# Molecular genetic testing for autoimmune diseases

By Ilana Heckler, PhD, Azadeh Bojmehrani, PhD, and Madhuri Hegde, PhD, FACMG

**T**he human leukocyte antigen (HLA) system is a complex of genes responsible for the regulation of the immune system. HLAs feature a high level of genetic polymorphism, which enables the immune system with a selective advantage against the diversity of antigens that a host may be exposed to. Different variants of HLA genes have been associated with specific autoimmune or autoinflammatory diseases such as celiac disease (HLA-DQ2 and DQ8), rheumatoid arthritis (HLA-DRB1), ankylosing spondylitis (HLA-B27), and psoriasis (HLA-CW6). Molecular genetic HLA determination is a tool for the diagnosis and predic-

tion of autoimmune disease risk. The following examples illustrate how genetic parameters are now an integral part of routine autoimmune diagnostics.

## HLA-DQ2 and DQ8 in celiac disease

Celiac disease (CD) is an immune-mediated systemic enteropathy triggered by gluten consumption. The genetic risk for CD is related to specific HLA DQ2 and DQ8. HLA-DQ2 and/or -DQ8 markers are present in >98% of CD patients.<sup>1</sup> The absence of HLA-DQ2 and -DQ8 markers, due to their high negative predictive value, allows for the exclusion of CD if both markers are not detected. However, the presence of HLA-DQ2/DQ8 alone, is not sufficient to cause celiac disease, as around a third of the healthy population exhibits DQ2/DQ8 alleles.<sup>2</sup> Therefore, the value of HLA-DQ2/DQ8 analysis lies predominantly in exclusion diagnostics.

The role of HLA-DQ2/DQ8 in celiac disease diagnostics has been highlighted in guidelines from the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).<sup>3</sup> Proactive testing for HLA-DQ2 and -DQ8 markers is recommended for screening asymptomatic patients having a family history of CD or other autoimmune diseases. In symptomatic patients, HLA-DQ2 and -DQ8 can be used to confirm CD. Additionally, the detection of these genetic biomarkers can be used to confirm CD in patients with inconclusive biopsy or serology results. For example, in cases where CD patients are on a gluten-free diet, who therefore have very low CD-specific antibody titers, genetic testing is a useful option.<sup>3</sup>

Using DNA microarray solutions, the identification of the disease-associated alleles HLA-DQA1- and HLA-DQB1, which code for the subunits HLA-DQ2.2, -DQ2.5 and -DQ8, can be done.<sup>4</sup> Such microarray testing can differentiate between the

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## LEARNING OBJECTIVES

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

1. Describe the human leukocyte antigen (HLA) system and how different variants of HLA are associated with specific autoimmune or autoinflammatory diseases.
2. Summarize how genetic parameters are now an integral part of routine autoimmune diagnostics using DNA microarrays.
3. Describe the disease characteristics and genomic variants associated with celiac disease, rheumatoid arthritis, ankylosing spondylitis, and psoriasis.
4. Discuss how HLA genotyping plays a role in solid organ transplantation, hematopoietic stem cell transplantation, and transfusion practice for platelet refractoriness patients.<sup>15</sup>

homozygous and heterozygous presence of the alleles that code the alpha and beta subunits of HLA-DQ2.2 and -DQ2.5, which enables improved risk assessment in the case of a positive HLA-DQ2 result.<sup>4</sup>

### HLA-DRB1 in rheumatoid arthritis

Rheumatoid Arthritis (RA) is a chronic autoimmune disease that causes joint pain, stiffness, swelling and decreased joint motility and affects an estimated 1.28-1.36 million Americans.<sup>5</sup> RA is considered to develop because of interactions between genetic factors and environmental factors. RA is characterized by the production of rheumatoid factors (RFs) and antibodies against citrullinated proteins, or anti-citrullinated protein antibodies (ACPAs). The HLA-DRB1 gene is the strongest known genetic risk factor for RA development and in ACPA-positive RA, the genetic risk is mostly carried by shared epitope (SE)-positive HLA-DR molecules.<sup>6</sup> HLA-DRB1 genotypes with HLA-DRB1\*04SE (HLA-DRB1\*0404, HLA-DRB1\*0405, HLA-DRB1\*0408), HLA-DRB1\*04:01, HLA-DRB1\*01 are associated with a high risk for developing ACPA-positive RA.<sup>7</sup>

Additional antigenic targets have been identified in RA including antibodies against citrullinated -enolase peptide-1 (anti-CEP-1). Anti-CEP-1 antibodies are associated with an erosive disease course, interstitial lung diseases and occur in a subtype of RA associated with smoking and genetic factors.<sup>8,9</sup> In a study, antibodies to the immunodominant citrullinated  $\alpha$ -enolase CEP-1 epitope were detected in 43–63% of the anti-CCP-positive individuals, and this subset was preferentially linked to HLA-DRB1\*04.<sup>9</sup>

### HLA-B27 in ankylosing spondylitis

Ankylosing spondylitis (Bechterew's disease) is a type of inflammatory autoimmune disease that primarily affects the axial skeleton, tendon insertions, and joints. Ankylos-

ing spondylitis (AS) affects men between the ages of 15 and 30.<sup>4,10</sup> Unfortunately, there is no cure for ankylosing spondylitis. Managing pain and symptom alleviation are the only treatments now accessible.<sup>10</sup>

Tissue antigens, located on the short arm of chromosome 6 of the MHC (Human Major Histocompatibility Complex), are known as HLA. HLA is classified into three classes, one of which is HLA-B, which controls T-cell immunological responses. The class I molecule HLA-B27 is closely associated with ankylosing spondylitis.<sup>4,10,11</sup>

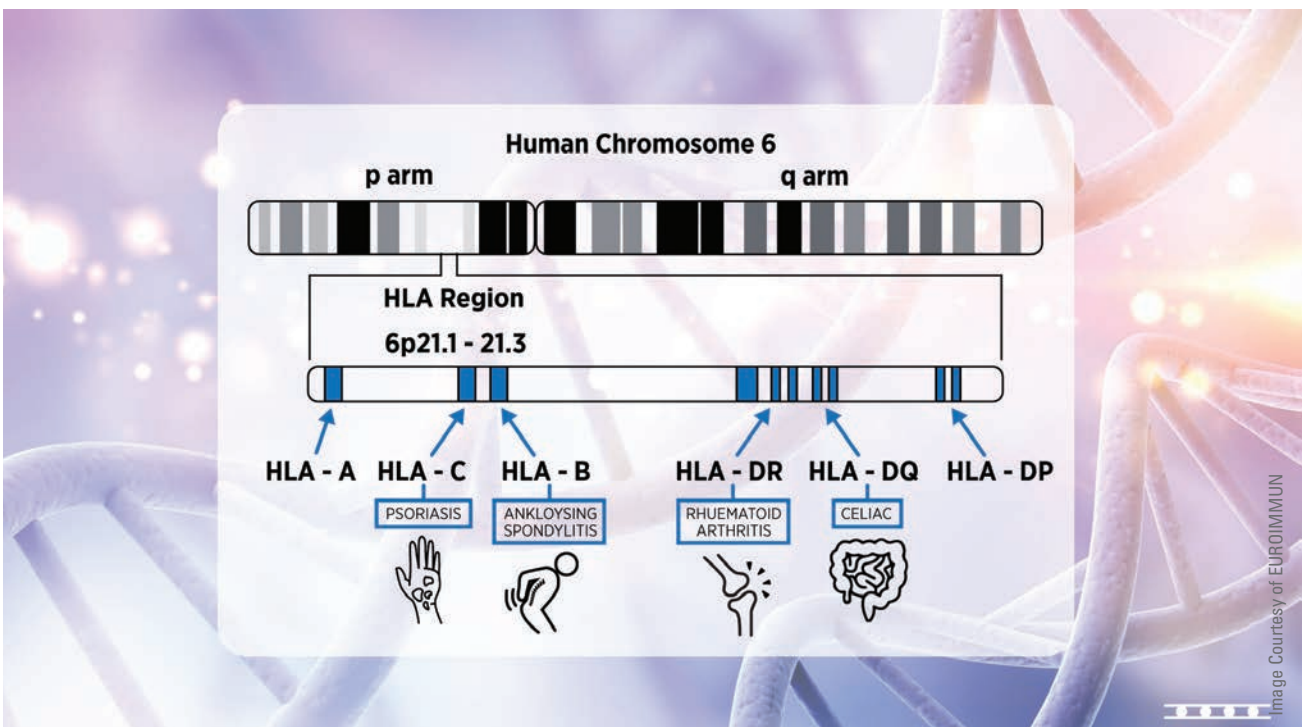
In 90% of AS patients, HLA-B27 has been identified. However, not all HLA-B27 carriers end up with AS; about 3–6% of HLA-B27 positive carriers develop AS. HLA-B27 can be detected in other conditions such as Reiter's syndrome, chronic inflammatory bowel disease, inflammatory eye diseases, and various forms of arthritis.<sup>10,11</sup>

HLA-B27 is currently divided into over 100 subgroups. HLA-B27 detection is crucial in the diagnosis of AS and other rheumatic disorders. It is critical to distinguish between distinct HLA-B27 subtypes because only some of them are linked to AS, while others aren't.<sup>10</sup>

The detection of HLA-B27 can be completed using molecular techniques. Particularly for the numerous HLA-B27 subtypes, a PCR approach using allele-specific primers has the potential to deliver trustworthy results. Using the patient's genomic DNA, molecular detection with DNA microarray technologies can identify HLA-B27 reliably and precisely with just one PCR reaction.<sup>4</sup>

### HLA-Cw6 in psoriasis

Psoriasis is a type of inflammatory autoimmune disease that primarily affects the skin. Other organs, such as the eyes, joints, and vascular system, might also be affected by psoriasis. Unfortunately, people with this ailment are socially isolated and stigmatized, and no cure is currently



DNA microarrays are a proven method for accurately detecting HLA-Cw6



available.<sup>12</sup> Psychological therapy and symptom alleviation are the only treatments now accessible.<sup>12,13</sup>

The class I molecule HLA-Cw6 is closely associated with psoriasis. HLA-Cw6 has been discovered in 67% of psoriasis sufferers. Psoriasis runs in families in about 40% of instances.<sup>4,12</sup> The HLA-Cw6 allele is found in a wide range of people around the world, with White people having a higher frequency than Asians. In Caucasians, the HLA-Cw6 allele raises the likelihood of acquiring psoriasis by a factor of ten. HLA-Cw6 has been linked to psoriasis arthritis. Patients with HLA-Cw6 have a faster onset of psoriatic arthritis, with cutaneous symptoms appearing before musculoskeletal symptoms.<sup>13</sup> HLA-Cw6 identification can be distinguished from other types of arthritis, especially in patients who have no family history or unclear skin changes. HLA-Cw6 has been shown to have an impact on illness progression, phenotypic traits, severity, comorbidities, and treatment outcomes on numerous occasions.<sup>12,13</sup>

DNA microarrays are a proven method for accurately detecting HLA-Cw6.<sup>4</sup> Using a blood sample, the HLA-Cw6 gene can be tested. HLA-Cw6 is strongly linked to type I psoriasis vulgaris and psoriasis gutta in 83% of patients and is very weakly linked to type 2 psoriasis vulgaris. HLA-Cw6 positivity is seen in only 44% of patients with type 2 psoriasis vulgaris.<sup>12,13</sup>

### Non- HLA autoimmune diseases The inherited component

Autoimmune diseases are a family of more than 80 chronic illnesses that are often disabling. Autoimmune diseases are characterized by immune system dysfunction leading to the loss of tolerance to self-antigens, presence of increased level of autoantibodies, inflammatory and mediatory cells thereby leading to chronic inflammation<sup>14</sup>. Multiple studies have been published demonstrating evidence common genetic etiology in ADs. These studies have shown evidence of clustering of multiple autoimmune diseases in families and in individuals, associated with genetic regions predisposing to several autoimmune diseases primarily through GWAS. This genetic overlap is exemplified by the well-known associations of the human leukocyte antigen (HLA) region, and other loci/ SNPs associated with multiple autoimmune disease, such as IL23R, TNFAIP3 and IL2RA. More than 40 regions with evidence for selection and associated with at least one autoimmune disease have been reported. Many of these loci are associated with a single disease, and many are shared between more than one AD such as PTPN22, TNFSF4, ARHGAP31-CD80, TNIP1 and TYK2. Given the complexity of ADs further assessment of variants using functional studies is required to understand the clinical consequences of the association of the genomic variants.

### HLA typing in transplantation

The human leukocyte antigen (HLA) system plays an essential role in the regulation of the body's immune system to counteract pathogens through antigen presentation and the recognition of "self" and "nonself." HLA matching remains a standard immunologic strategy to determine organ compatibility for recipients. HLA genotyping has a significant role to play in solid organ transplantation (SOT), in hematopoietic stem cell transplantation (HSCT), and in transfusion practice for platelet refractoriness patients.<sup>15</sup> The determination of the alloantibodies before transplant

is useful for the estimation of risk for antibody-mediated rejection. Crossmatching is used to detect anti-HLA antibodies and allows exclusion of donors with unacceptable HLA antigens. Advancements in tissue typing have introduced HLA matching at the epitope level. HLA-Matchmaker (<http://www.epitopes.net>) is a computer algorithm that determines HLA compatibility between donors and recipients by assessing the 3-dimensional molecular modeling of the epitope-paratope interfaces of antigen-antibody complexes. Even though there are ambiguities with regards to the clinical significance of immunogenic epitopes and identification of immunogenic epitopes remains a work in progress, clinical application of epitope matching in transplantation has been implemented.

### HLA and severe cutaneous adverse drug reactions (SCARs)

Severe cutaneous adverse drug reactions (SCARs) are delayed T cell induced hypersensitivity (DTH) including Stevens–Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), drug reaction with eosinophilic and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) as described elsewhere.<sup>16</sup> These conditions have variation of critical clinical course, skin rashes and severe systemic multi-organ involvement. HLA genotyping for HLA-A\*31:01, HLA-A\*33:03; HLA-B\*57 = HLA-B\*15:02, HLA-B\*15:08, HLA-B\*15:11, HLAB\*15:21 has been recommended for implementation in routine clinical practice for optimizing safety of medications. The cost-effectiveness of genetic testing, such as screening of HLA, is often an important part of debate especially in the case of reimbursement issues and more studies are being undertaken to demonstrate the benefit.

### Conclusion

The identification of specific HLA alleles represents a tool to assess genetic susceptibility to specific autoimmune diseases. Specialized molecular techniques, such as diagnostic microarrays, have been developed for the detection of such disease-associated alleles and have the advantage of high sensitivity and specificity. It is important for the clinician to understand the advantages and disadvantages of different assays such as the most commonly used solid phase assays. As discussed here, molecular techniques offer the identification of HLA alleles related to celiac disease, rheumatoid arthritis, psoriasis, and ankylosing spondylitis. ➔

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## TEST QUESTIONS

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- What specific autoimmune or autoinflammatory diseases have different variants of HLA genes been associated with?
  - ☐ Celiac disease
  - ☐ Psoriasis
  - ☐ HIV
  - ☐ A and B
- What triggers celiac disease (CD)?
  - ☐ Cholesterol levels
  - ☐ Gluten consumption
  - ☐ High fat diet
  - ☐ Protein rich diet
- Proactive testing for HLA-DQ2 and -DQ8 markers is recommended for screening asymptomatic patients having a family history of CD or other autoimmune diseases.
  - ☐ True
  - ☐ False
- What factors cause the development of RA?
  - ☐ Environmental and genetic
  - ☐ Genetics and hypertension
  - ☐ Diet and physical inactivity
  - ☐ Gender and obesity
- Even though there is no cure for ankylosing spondylitis, managing pain and symptom reversal are two treatments now available.
  - ☐ True
  - ☐ False
- The class 1 molecule, HLA-B27, can be detected in other conditions besides AS, such as:
  - ☐ Reiter's syndrome
  - ☐ chronic inflammatory bowel disease
  - ☐ inflammatory eye diseases
  - ☐ all of the above
- Using the patient's \_\_\_\_\_, molecular detection with DNA microarray technologies, can identify HLA-B27 reliably and precisely with just one PCR reaction.
  - ☐ Complete family history report
  - ☐ genomic DNA
  - ☐ current cholesterol levels
  - ☐ latest MRI report
- Psoriasis is a type of inflammatory autoimmune disease that primarily affects the skin; however, it can also affect what other organs?
  - ☐ Kidneys
  - ☐ Liver
  - ☐ Joints
  - ☐ Ears
- What class I molecule is closely associated with psoriasis?
  - ☐ HLA-Cw6
  - ☐ HLA-B27
  - ☐ HLA-DQ2
  - ☐ DQ8
- What ethnicity accounts for the highest frequency of psoriasis?
  - ☐ Asians
  - ☐ Blacks
  - ☐ Whites
  - ☐ Hispanics
- In patients with HLA-Cw6 who have a faster onset of psoriatic arthritis, which symptoms appear first?
  - ☐ musculoskeletal symptoms
  - ☐ cutaneous symptoms
  - ☐ pulmonary symptoms
  - ☐ None of the above
- \_\_\_\_\_ are a proven method for accurately detecting HLA-Cw6.
  - ☐ RNA sequencings
  - ☐ Genome-wide association studies
  - ☐ DNA microarrays
  - ☐ Single-nucleotide polymorphisms
- What percentage is seen in HLA-Cw6 positivity for patients with type 2 psoriasis vulgaris?
  - ☐ 83%
  - ☐ 30%
  - ☐ 4%
  - ☐ 44%
- Autoimmune diseases are characterized by immune system dysfunction, leading to the loss of:
  - ☐ tolerance to self-antigens
  - ☐ autoantibodies
  - ☐ chronic inflammation
  - ☐ none of the above
- Multiple studies have been published demonstrating evidence of common etiology in autoimmune diseases (AD).
  - ☐ racial
  - ☐ regional
  - ☐ genetic
  - ☐ environmental
- What system plays an essential role in the regulation of the body's immune system to counteract pathogens?
  - ☐ Circulatory system
  - ☐ Human leukocyte antigen system
  - ☐ Nervous system
  - ☐ Endocrine system
- What is used to detect anti-HLA antibodies and the exclusion of donors with unacceptable HLA antigens for solid organ and stem cell transplants?
  - ☐ Crossmatching
  - ☐ Enzyme-linked immunosorbent assay
  - ☐ Enzyme immunoassay
  - ☐ Serology test
- What is the name of the computer algorithm that determines HLA compatibility between donors and recipients?
  - ☐ Antigen-antibody complex
  - ☐ Transplantation.com
  - ☐ HLAMatchmaker
  - ☐ 3-dimensional molecular
- Severe cutaneous adverse drug reactions (SCARs) are delayed T cell induced hypersensitivity (DTH) including what syndrome?
  - ☐ Stevens-Johnson syndrome
  - ☐ Gilbert's syndrome
  - ☐ Hutchinson-Gilford syndrome
  - ☐ Trisomy syndrome
- One condition associated with SCARs is \_\_\_\_\_.
  - ☐ high blood pressure
  - ☐ skin rash
  - ☐ watery eyes
  - ☐ loss of appetite

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# What does big data have to do with hematology?

By Daniel Johnson, MBA

**M**ore than one thinks. Hematology is moving into a digital age where data is a goldmine of innovations and insights. While moving into a digital age is exciting and comes with some fantastic opportunities, there are some real challenges. Today, healthcare organizations are challenged with actualizing tangible outcomes of IT investments, organizational adoption and change management, and securing patient data. These organizations also rely on their educated and experienced staff to be the supercomputers of consistent clinical decisions. But sometimes people do not make the best supercomputers. We have limitations, especially when overworked or rushed and we find ourselves frustrated.

This is why laboratories and healthcare organizations need to advance and shape healthcare with technology. The opportunities in hematology are limitless. The world is moving fast into this digital age with real-time CBC monitoring, predictive disease alerts, and true data integration. However, is healthcare ready to take on these challenges? Absolutely.

## How are healthcare organizations advancing healthcare?

Hematology data is one of the richest information sources in the laboratory for clinical decision-making. It can tell a deep patient history with dozens of parameters and even help predict the likelihood of disease states. The next step of true advancement and innovation is a deep integration of laboratory data.

Consider iron deficiency anemia's (IDA) predictive value. Today, IDA may occur when there are low amounts of iron in the body to make hemoglobin. With low amounts of iron, fewer,

smaller RBCs are created. The typical CBC will indicate low amounts of hemoglobin (Hgb), Hematocrit (Hct), and Red Blood Cells (RBCs). The Mean Corpuscular Volume (MCV) and Mean Corpuscular Hemoglobin (MCH) are present in the normal range but often drift lower due to the smaller RBCs (microcytic). Most laboratories have rules or algorithms that pull in these five parameters of the CBC. However, true clinical decision power is increased when it includes other clinical chemistry parameters like ferritin, total iron-binding capacity (Transferrin), and transferrin saturation (TSAT). Combining these clinical parameters provides a sharper focus on the interpretation and improves clinical efficacy.

Another example is acute Leukemia. White blood cell (WBC), platelet count, and hemoglobin may be used to identify abnormal samples that would require visual investigation of the cells. Advanced laboratories would have algorithms based on agreed-upon thresholds that would trigger manual differential to a digital imaging system.

This digital imaging system uses complex artificial intelligence (AI) to count, identify, and pre-classify cells, reducing ambiguity and time for clinical decisions. What can maximize these innovations is fine-tuning these algorithms. These parameters can be maximized for full clinical impact using machine learning and AI.

## So, how can this be accomplished?

Refinement of these algorithms needs lots of data, not just text data or excel spreadsheets. It needs a systematic, quality-centered process to clean, standardize, and organize this data,

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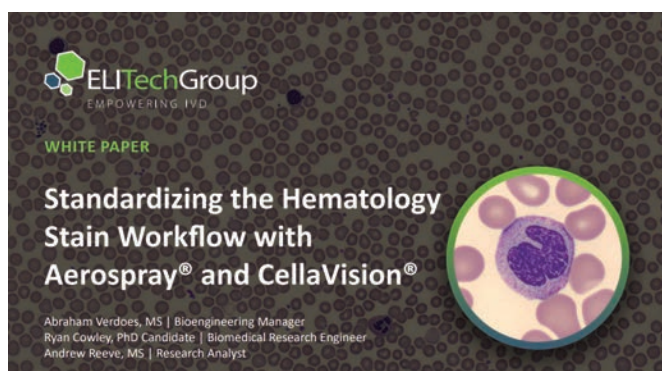


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ensuring robustness. However, this can be difficult. Standards for managing and reporting quality data for health research simply do not exist. Also, this type of research does not fare well with shortcuts. These shortcuts may ultimately lead to compromises that lead to poor patient care. The center of this research always needs to be patient-centric. Also, the skills required for this type of research are often beyond the laboratory's skill set.

Data science is a growing field where data scientists are trained to build databases and use standard frameworks and a programming language called "R." Many healthcare systems are putting together teams of data scientists and healthcare professionals to approach this challenge. Once the team is together, a clinical challenge is identified, the data is organized in the proper format, and the algorithm creation process can start.

New big data research indicates that stress can show up in the CBC, particularly in WBCs. Nevertheless, WBC alone is not an accurate indicator, one needs to also consider other factors. Cholesterol levels, interleukin-6 (IL-6), and C-Reactive Protein (CRP) all factor into stress sensitivity. When other layers like sleep, BMI, working hours, mobility, gender, and zip code, are incorporated, it can paint an even better picture. Stress.

Having this algorithm in alignment with annual health checkups could translate to disease prevention and promoting mental health.

### What is the ultimate dream?

The ultimate dream is to pull data beyond the laboratory, like connecting pharmacy data, radiology, anatomic pathology, even personal online purchase history. We are starting down this path with healthcare system standardization of hospital information systems (HIS) and breaking down the barriers between interoperable databases.

Advancing healthcare is not easy because all this data comes in complex and unique formats. Cracking this code can tip the scales with more accurate clinical decision-making instead of relying on arbitrary interpretation.

### So what hematology innovation is trending?

Daily wearables are now common and some people are even wearing two. These wearables currently can monitor heart rate, temperature, glucose, and sleep, but some are now advancing to monitor RBCs and WBCs levels. What does that even mean to an average person? Does everyone understand what high or low RBC or WBC levels mean?

Over time, it will be a standard, just like understanding heart rate. People today impacted by anemia can take advantage of this innovation. Monitoring RBCs does not stop there. Understanding how real-time RBC fluctuations can indicate menstrual cycle timing, early indications of cancer, the health of a pregnancy, or even uncover something as dire as bleeding in the digestive tract. Weight loss surgery that sometimes causes iron deficiency is a real problem, and real-time monitoring helps maintain a healthy diet. One atypical use is to monitor RBCs when on vacation in exotic areas. Parasites found in some parts of the world cause blood loss and having a wearable may prevent a dream vacation from turning into a nightmare.

Monitoring WBCs has its advantages, too. In general, one can trend an uptick in WBCs that may represent the start of a cold or flu. Immune-compromised people can monitor their WBC levels and take preventive action before seeing an enormous spike or dip in their WBC levels. Cancers like leukemia have abnormally high or low indications of WBCs, too. Temporarily, these wearables may be used for pre-surgery to evaluate readiness. They are even pulling this data in real-time to a physician's tablet.

But will this technology flood patients to doctors and hospitals? Managing large amounts of data, especially data transparent to the end-user, will need a solution. Perhaps one consideration is for call centers to be established to triage escalations, thus preventing increased admissions. Another perspective is this leads people to live healthier, catching problems sooner, stopping them before they are critical, thus preventing increases in hospital admission.

The technology is still new and in development. Universities and private companies worldwide are racing to build this technology since its application can drastically improve the quality of life for so many.

It is not just about the hardware that we can wear on our fingers, wrists, or even ears. It is also about the data collected. Both laboratory-generated data and real-time data collected from wearables help the patient. One advantage wearables already have is that it's an already adopted technology. It's more common to see someone with a smart wearable than a traditional watch. These devices to truly make an impact just need some new features and maybe it's a full CBC on your wrist.

### Big data is the future of hematology

Ready or not, hematology is moving into this digital age. This article addresses many unique and exciting future concepts, but they all come with real challenges. Early adopters need to be fearless and take a big risk. They will do the heavy lifting, and the impact is limitless. They will also need to avoid pitfalls by collaborating with teams of data scientists and healthcare professionals. They will need to continue approaching problems systematically and carefully, creating new clinical decision rules and technology that provide consistent, robust care while reducing the burden on our healthcare professionals. Advancing and shaping the future of healthcare with data is still in its infancy. It is an exciting time to be innovating and learning. 🚀



**Daniel Johnson, MBA**, is the Assistant Director Integrated Technology Solutions for **Sysmex America**.

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# Mary Greeley Medical Center Laboratory — improving culture, retention, and performance

By Linda Wilson

**M**edical Laboratory Observer's 2022 Lab of the Year is Mary Greeley Medical Center Laboratory in Ames, IA.

The lab stood out for the depth and variety of initiatives its managers and staff members have undertaken to improve operational performance, employee retention, and the lab's culture. Their achievements were measured across six categories: customer service, productivity, teamwork, education and training, laboratory inspections, and strategic outlook.

As is the case every year, judging the entries for *Medical Laboratory Observer's* Lab of the Year award is a daunting job. *MLO's* staff and judges read many inspiring stories about how laboratorians worked diligently to provide diagnostic services to their customers: providers and patients.

Mary Greeley Medical Center is a 220-bed regional hospital that serves people in a 13-county area in Central Iowa. So far in fiscal year 2022, the lab is experiencing a record year, averaging 48,432 tests per month, compared with 45,151 in fiscal year 2021. This includes assays processed in chemistry, hematology, coagulation, urinalysis, microbiology, immunohematology, and immunology/serology.

The growth in test volumes follows on the heels of growth in previous years. "Over the last 5 years, the lab testing

volumes for the emergency department has increased over 40% and inpatient testing has increased by 20%. The COVID pandemic has been a part of that increase as well. The lab has also taken on additional reference laboratory work in microbiology," Melanie Vorsten, MHS, MLS(ASCP), Lab Director, said.

## Customer service

Service to both providers and patients at Mary Greeley Medical Center's lab is fostered, in part, through electronic communications using Epic's electronic medical records system, including Beaker, the company's laboratory information system (LIS). This allows providers with Epic and patients, through the electronic portal, to have immediate access to test results.

For providers without access to Epic, the results are faxed. If fax failures occur repeatedly, the lab's employees follow up to ensure providers get the test results they need.

To help patients manage their health, the lab, with 38 full-time equivalents (FTEs), also offers self-pay labs tests. Patients who have signed up for the electronic patient portal have immediate access to results from those wellness labs. The screenings include cholesterol profiles, a complete lipid profile, screen-

ing tests for bone, liver, heart, kidney and thyroid function, and many others.

"It has also become a valuable tool for physicians and other healthcare providers to recommend to patients who may not have adequate health insurance, or who want to avoid the higher costs of regular laboratory testing," Vorsten and Sarah Bower, MPA, MT(AMT), Laboratory Manager, wrote in their nomination submission.

The prices for tests range from \$10 for a cholesterol test to \$50 for an anti-tissue transglutaminase (tTG-IgA) test that screens for celiac disease.

Another aspect of customer service that is important at Mary Greeley is patient safety. For example, the lab has notched 100% compliance with hand hygiene rules for 24 consecutive months — the highest rate among hospital departments. One key to the success with hand hygiene has been incorporating it as a metric when managers evaluate staff members performing phlebotomy draws. The lab also tracks and then posts its hand hygiene metric on its huddle board and discusses it monthly lab meetings.

## Productivity

In addition focusing on its customers, the lab has honed in on productivity. In 2020, for example, the lab implemented a com-



prehensive lab metrics reporting system. A monthly quality report is created both by lab department and for the entire lab. The metrics are included in the reports, which are shared throughout the lab. They include critical results called within 15 minutes, STAT turnaround time (TAT) failure, and proficiency testing scores of at least 90%.

To improve inventory management, the lab adopted a Kanban system, which allows the lab to reorder supplies only as needed, or just-in-time. To adopt the system, the lab established standard reorder points and quantities. "Productivity increased because staff spent less time trying to decide what needed to be reordered and how much to order of each item," Vorsten and Bower wrote in their submission for Lab of the Year.

As one might expect, the lab has had to revise the Kanban system during the COVID-19 pandemic because many supplies, such as test tubes, are difficult to get, making just-in-time ordering hard to achieve. "Having the inventory system better prepared us to handle the delays and backorders. Depending on the supply item, we have either increased our order level, increased our ordering frequency, decreased our par level, or found a replacement," Vorsten said.

Another example of increased productivity is the way the lab has managed test volume, which has grown by nearly 10,000 tests per month over the last five years. In 2017/2018, the average monthly volume of tests was 39,197, compared with 48,432 in 2021/2022. The lab has managed the increased test volume with only two new full-time equivalents. How? Lab managers have cross trained staff, retained experienced staff, and invested in new analyzers with faster TATs.

The lab also measures productivity rates by phlebotomist. "This is a tool used to reward great performers, not a punishment for underperformers," Vorsten and Bower wrote. Productivity is calculated by hours work, expected draws completed, and actual draws completed.

The lab also measures redraw rates and blood culture contamination by phlebotomist. The current average redraw rate is 7.3%, compared with a goal of less than 5%, while the blood culture contamination rate varies from zero to 15%, compared with a goal of less than 3%. The lab posts the results by phlebotomist and department, but each phlebotomist is assigned a number to protect confidentiality. "Individual phlebotomy metrics are hugely popular with the phlebotomists, and they often ask when they will be



Laboratory Group Photo

posted," Vorsten and Bower wrote.

The lab proactively tracks overtime, with a goal of reducing the number of extra hours that employees work. In the current fiscal year (July-June), the lab has averaged 19.02 hours per week of overtime, compared with 24.04 hours per week in the last fiscal year. "We hope to stay on track and save the lab thousands of dollars per year," they wrote.

### Teamwork

The current seven-member leadership team has focused on improving employees' engagement in their jobs — one of four goals at the hospital level. A key aspect of improving employee engagement is creating a culture of respect and teamwork.

In the first step of the process, all employees were asked to describe examples of disrespectful behavior they've seen at work — not mentioning names, just the behavior. Based on that feedback, the leadership team developed a list of disrespectful actions. They then posted the list.

"We definitely felt as a leadership

team that we could improve respect in the laboratory. In addition to being aware of our low respect scores on the (employee) engagement survey, we heard from staff during monthly rounding that there were disrespectful things going on in the lab. Some of the behaviors we heard about and focused on included people raising their voices when they were angry or stressed, too much gossip about coworkers, lack of patience with newer employees, and jumping to conclusions about someone else's actions or intentions," Bower explained.

Both Vorsten and Bower round with each staff member monthly, and they made a point discussing respect during each meeting for an entire year to keep the goal at the forefront of everyone's mind. They also hired an outside consultant to work with the leadership team, and each member of the team was required to come up with a personal action item that they would work on improving.

The management team also created a laminated card that is hidden behind each employee's badge with the phrase





Courtney Mitra, MLS, works with student Keagan

“Drama llama” written on it. The card “can be flashed in the laboratory as a light-hearted way to let someone know that they are acting in a disrespectful way. We have seen this card in use, in the breakroom and during morning huddle, to remind someone nicely to be respectful,” Vorsten and Bower wrote.

The management team also continually reminds everyone that it takes 6 months to 2 years for a new employee to become fully competent in his/her job, meaning that veteran staff members need to remain patient with their newer colleagues.

Another way the lab has fostered a sense of teamwork is through a weekly fun exercise. Called “Who am I?”, the lab’s shared decision-making council posts five random facts about an employee as well as his or her approximate years of service on the huddle board, so that everyone can see the information. Employees submit guesses on who the employee is. The names of those who guessed correctly are posted to the board, and two of those names are drawn as the winners of the contest, and they receive a candy bar. The name of the featured person also is posted as are other popular guesses.

### Education and training

Creating a culture of respect helps reduce vacancy and turnover rates. Other measures help achieve those goals, too.

One position where reducing those metrics is particularly important is phlebotomy, which has a perennially high vacancy and turnover rate nationally. That is why Mary Greeley has rolled out initiatives to attract and retain employees to those positions. The minimum wage of phlebotomists was increased in 2022, and

some phlebotomists saw their wages rise as much as 11%.

The lab also launched a career ladder in which phlebotomists earn a salary increase if they pass the certification exam. They can earn another raise if they are willing to cross train in specimen processing, including handling send outs to reference or specialty labs.

To help phlebotomists pass those exams, Mary Greeley purchased access to the Phlebotomy Exam Simulator from MediaLab, which includes electronic

practice tests with content pertinent to the four providers of certification exams.

In 2022, the lab also converted full time and regular, part time phlebotomists to lab assistants. Before the change, the lab had four lab assistants and 16 phlebotomists, compared with 14 lab assistants and six phlebotomists after the change.

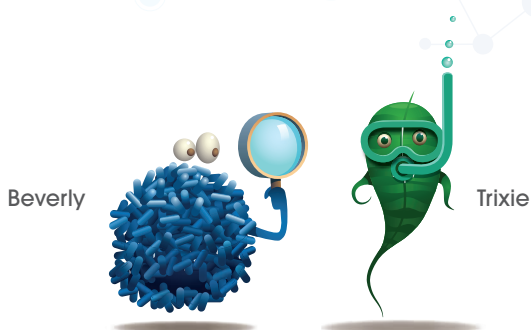
“We made this change to reward our more career-minded staff, and also to increase their feeling of connectivity to the lab (more opportunities to work closely alongside technical staff). Phlebotomy is still a main job duty, but they learn much more about the lab itself. We have already received positive feedback that what they are learning in lab has made them better phlebotomists! This has also increased our scheduling flexibility when it comes to covering open shifts,” Bower explained.

On a broader scale covering many positions, the laboratory has developed a strong relationship with the Des Moines Area Community College in Ankeny. “We currently have two students rotating through the lab, and a third student will join us after March 1. We have two phlebotomy students performing clinical rotations in February-March and have a third MLT student who will perform a phlebotomy rotation in March,” Vorsten and Bower wrote. “We believe we take a very high



Lisa Miller, MLS, processing specimens in core lab

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Princess Borja, MLS, plate reading in microbiology

number of students despite our modest laboratory size.”

As a key outcome of the recruitment and retention work, the lab does not have vacant positions in medical laboratory technology (MLT)/medical laboratory science (MLS). Vorsten attributes this success to numerous factors: the lab’s close relationship with local community colleges, support for career development, and the improving culture of respect in the lab.

### Lab Inspections

In 2021, the lab had its first inspection with a new accreditation organization.

Despite an unfamiliar survey process and five of seven leaders being new to their roles, the lab had only two standard level deficiencies — 493.1236(c)(1), and 493.1253 for which the lab immediately implemented corrective action.

To further help with the survey process, the lab expanded its subscription to MediaLab to include the company’s compliance module. The lab is now in the process of converting all paper documents for training and competency assessments into electronic checklists. This has already reduced the lab’s paper use significantly and has eliminated the chance that an employee will lose an almost completed paper copy. The goal is to be paperless by the end of 2022. All departments within the lab have already been converted except chemistry, which will switch over soon.

### Strategic outlook

When it comes to the strategic outlook, the lab follows four big hospital-wide initiatives: eliminate preventable harm, improve patient engagement, improve workforce engagement, and meet or exceed an operating margin of 1%.

Improving patient engagement has been a key focus at the lab. For example, managers recently implemented NRC Health Real-time Feedback software, which automates the process of collecting and analyzing feedback from customer surveys. The software tracks net promoter

scores, which measure customers’ willingness to recommend a product or service, based on an index ranging from -100 to +100. The NRC software measures the score in real time, with drill down capabilities for analysis.

Using the data from the surveys, lab managers noticed that patients commented on the courtesy and respect behavior of patient access representatives stationed at the lab’s front desk. With further analysis, they realized that “when the desk is very busy, patients don’t always feel acknowledged as soon as they walk in,” Bower and Vorsten wrote.

The solution turned out to be a new script, which was implemented in January 2022:

- Old response: None, or “Have a seat. I’ll be with you as soon as I can.”
- New response: “Welcome to the lab! Please make yourself comfortable, and I’ll be with you as soon as I can.”

“Since the change, we have seen a huge improvement in the courtesy and respect question. The score for this category improved from 71.4 to 85.7. The lab’s overall Net Promoter Score improved from 79.8 to 89.9,” Vorsten said.

Taken together, Mary Greeley Medical Center Laboratory’s achievements in strategy, productivity, customer service, teamwork, inspections, and training positioned it well to exceed its improvement goals in 2021, despite the pandemic, turnover in phlebotomy, increasing test volumes and new lab leadership. Those achievements also position the lab to succeed in the future — no matter what challenges come its way. 📈



Melanie Vorsten, MHS, MLS runs the daily staff huddle



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# 2022 Lab of the Year Runner Up: Cincinnati Children's Hospital Medical Center Clinical Laboratory

By Gail Castanho

**C**incinnati Children's Hospital Medical Center (CCHMC) is one of the oldest and most distinguished pediatric hospitals in the United States, established in 1883. The academic pediatric acute care hospital has 634 beds.

## Customer service

Cincinnati Children's clinical laboratories' customer service efforts strive to improve child health, transform delivery of care, and achieve the best

medical outcomes, experience, and value for patients.

As a result of these laboratories' commitment to customer service, several noteworthy accolades have been awarded in the past year. For instance, CCHMC clinical laboratories, which includes 10 outpatient collection sites, received the 2021 Outstanding Site of Care Award. This award recognizes a site of care that helped its team create a patient-centered culture.

Not only did the CCHMC laborato-

ries receive awards, collectively, there were also awards given to individual employees within the laboratories for their outstanding customer service efforts.

John Simpson, a lab support technologist at the Liberty Campus, earned the 2021 All Star Award, which celebrates four stand-out individuals in the whole institution who show passion and commitment to patient family experience, putting the institution's values in action in their everyday work.



Cincinnati Children's Hospital Medical Center  
Photo courtesy of CCHMC

Additionally, Emily Kimball, physician liaison and outreach associate in Clinical Laboratories, earned the Blood Drive Coordinator of the Year Award for 2020/2021 in Greater Cincinnati for going above and beyond expectations to increase blood donations among hospital staff.

To alleviate the rapidly growing influx of testing during the COVID pandemic, CCHMC laboratories worked to provide COVID-19 testing not only for patients, but also for our institution's employees. They implemented approximately 25 molecular-based testing instruments, interfaced with the LIS, for rapid testing and coordination with the PCR laboratory for additional testing, adapting to be able to quickly transition to a high throughput model during times of high positivity rates. This included rapidly standing up drive-through testing for patients and employees, as well as shifting patient/employee testing between the central lab and PCR lab.

This adaptive care approach led to molecular based COVID testing turnaround times that were the benchmark for the region. Average TAT had historically been less than 15 hours with rapid testing being available in as little as 7 minutes.

### Productivity

Throughout the COVID pandemic, CCHMC laboratories performed over 350,000 COVID tests. During the peaks of the pandemic, systems were stressed, and the supply chain was precarious. Labs were able to absorb the influx of patients and samples with few added positions by optimizing the workflow via IT and decentralization efforts. Taking the testing to the patients presented an opportunity for improved family satisfaction but also reduced the stress to the normal patient-flow processes. This was significantly important during the most recent nationwide staffing challenges.

In addition to improved COVID-19 productivity, CCHMC labs underwent some major upgrades, including moving the central laboratory to a new location; the creation of a Rapid Testing pod/bench that performs COVID-19, Rapid Strep A, Influenza A & B, blood gases, urine toxicology, urine hCG, mononucleosis, HIV, and RSV to allow prompt turnaround times of important tests for patient care; as well as centralization of staffing for similar platforms; and implementing one of the first au-

tomated line systems in a children's hospital, with 6 integrated instruments, enabling transitions to working in pods instead of bench-based assignments.

CCHMC's move also prompted the evaluation of the cesium blood irradiator, pushing the lab to participate in the Cesium Irradiator Replacement Project (CIRP) offered by the Department of Energy/National Nuclear Security Administrator's Office of Radiological Security, successfully replacing 2 cesium irradiators, thereby decreasing national security threats, with one X-ray irradiator, increasing output and decreasing irradiation turnaround times (Figure 1).

### Teamwork

To illustrate CCHMC's laboratory's commitment of teamwork, a seamless merge and relocation occurred, allowing almost 200 team members and all laboratory equipment to be relocated with no significant disruption in patient care, executed over a 4-week period and utilized a multiphase approach. The cross-functional move team ensured each laboratory section was kept abreast of the move plans and developments while maintaining service levels, sometimes at multiple locations.

The Omicron surge jumpstarted a sense of teamwork within CCHMC's labs. During the rapid spread of the Omicron SARS-CoV-2 variant, CCHMC implemented a "One CCHMC" program to help with the staffing challenges.

The Laboratory Administration and Leadership teams stepped in to assist with COVID testing at one of the employee and patient collection locations within the community. Lab leaders who were formerly technologists came out of "retirement" and were trained and certified to run testing to provide same day turnaround for many of the employee collections. This enhanced the organization's quick return-to-work initiative during this challenging time. These measures, as well as other volunteers across the organization, allowed CCHMC to maintain high levels of care for the children of the region.

### Education and training

CCHMC prides itself on being a leader in supporting the growth, education, and development of its employees. Numerous educational and training initiatives have been implemented throughout the laboratory.

Over the past few months, CCHMC labs adapted to handle staffing chal-

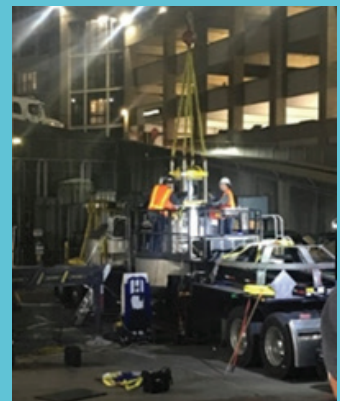
Figure 1



Cesium irradiator



Removal of cesium irradiator



New X-ray irradiator





CCHMC

Photo courtesy of CCHMC

allenges. Especially with regard to certified technologists, the clinical lab had to rethink how to approach staffing within the lab. Didactic modules for multiple laboratory disciplines were created to further educate those with science degrees but with minimal to no clinical lab exposure, eliminating the need to seek outside support for laboratory testing.

In addition to this added educational support for some staff, a career ladder was implemented, which improved the engagement of team members while also providing advancement opportunities to individuals who wish to grow within the laboratory setting. 44 team members took advantage of this opportunity to grow and advance within the organization. This initiative provides strength to the current retention strategy and awards individuals, in title and compensation, for learning new skills. The organization benefits from having staff members with a broadened scope of knowledge and expertise, thus strengthening our core of services.

### Strategic outlook

Implementing and utilizing a strategic outlook plan within the clinical laboratories at CCHMC has been an ongoing project for the past 2 years, having established several specific avenues for strategy, as well as planning. All avenues focus on the organizational plan, with categories of Care, Cure, Community, and Culture. The avenues are an integrated operational plan, mul-

To illustrate CCHMC's laboratory's commitment of teamwork, a seamless merge and relocation occurred, allowing almost 200 team members and all laboratory equipment to be relocated with no significant disruption in patient care.

tiyear capital plan, and the Laboratory Practice Council.

The laboratory Practice Council focuses on 6 important domains of laboratory activity. Each domain has a delegated leader and medical staff representative as well as interested staff members from across the lab locations.

- Activities accomplished through the practice council include:
- Development of project vetting and scoring process
- Situational Awareness and Shared Mental Model activities
- Standardized on-boarding activities
- Lab week, and other employee appreciation events
- Improved self-inspection process

### Lab inspections

The Cincinnati Children's clinical laboratories are CAP accredited at

9 physical locations and hold CLIA certificates. They are also subject to The Joint Commission for waived point of care testing at several locations, as well as FDA for transfusion services, and CMS and department of health inspections. This past year was a busy one for CCHMS regarding inspections. The pandemic changed the course for inspections, and CCHMS' laboratories adapted very quickly by conducting one of the first "hybrid" inspections with primarily virtual TEAMS-based inspections with minimal on-site presence. The laboratory conducted 2 inspections via this route in June and August of 2020 and then spent the following year perfecting the process with the sharing of learnings with CAP and within the Children's Hospital Association membership to aid in keeping the inspection process moving across the country.

In June 2021, CCHMS labs were inspected at the main campus by CAP colleagues. During this inspection, 19 different sections of the laboratory were reviewed covering 57 CAP checklists. Because much of the inspection was conducted remotely, the team had more time to review evidence and accumulate findings for a very thorough inspection.

In November 2021, the Liberty Campus laboratory and 5 neighborhood location laboratories experienced a more traditional onsite inspection. The 2-day inspection process covered 6 locations and 29 checklists. Additionally, the Ohio Department of Health selected the Liberty location as a subject of a validation survey. This resulted in an additional survey event in early January that verified the high-quality lab with no findings.

Overall, CCHMC laboratories experienced a very successful inspection cycle and were pleased with the quality of work coming from the teams. Laboratories attribute this success to a dedicated Quality Assurance team, consisting of a manager and 3 QA Specialists under the Laboratory Administration department, who coordinate and organize all regulatory activities. Additionally, there are 3 other QA specialist imbedded in the departments of Anatomical Pathology, Cancer and Blood Disease, and Human Genetics laboratories to help coordinate across the organization and laboratory structures. 📌

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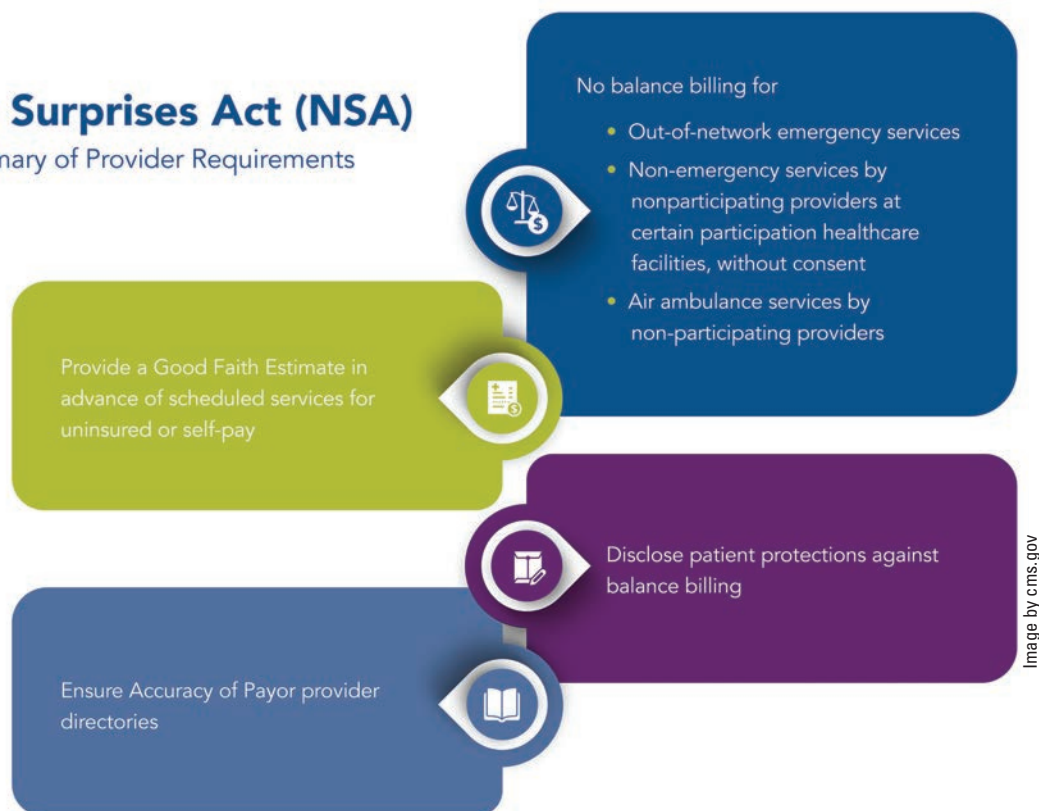
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## No Surprises Act (NSA)

### Summary of Provider Requirements



NSA established federal protections for patients against surprise medical bills

# Setting labs up for success amidst the No Surprises Act roll out

By: Kyle Fetter, MBA

**P**rice transparency has been a contentious issue for our country's healthcare system for many years. The No Surprises Act (NSA)<sup>1</sup> finally went into effect on January 1, 2022, after a multitude of delays. At its core, the Act established federal protections for patients against surprise medical bills and balance billing for services received from out-of-network providers — usually without their knowledge. While the legislation is new, the concept behind it is not.

As of January 1, 2022, consumers have billing protections when getting emergency care, non-emergency care, and air ambulance services from out-of-network providers. These new rules protect people by restricting excessive out-of-pocket costs and ensuring that these services continue to be covered without any prior authorization. Here's what diagnostic laboratories need to know to make sure they are compliant.

### What are surprise and balance billing?

Surprise billing is when patients unknowingly receive care from healthcare providers that worked with other providers that were outside their health plan's network, resulting in high balance billing charges to the patient. This includes occasions when patients receive ancillary services, such as

laboratory testing or diagnostic imaging, where they have little visibility into providers who are "behind the scenes."

Balance billing occurs when an out-of-network provider bills the patient the difference between the provider's charge amount and the payor's allowed amount. This practice was often experienced when people received unplanned, or emergency care, which resulted in unexpected and (often) high medical bills. Over the years, this lack of information around charges for care have cost individual patients thousands of dollars in out-of-pocket expenses that they hadn't planned for or anticipated.

It's also important to remember that over the past few years, prior to the passing of the national legislation, more than 18 states<sup>2</sup> had implemented legislation to address this issue and ban balance billing. In its current form, the NSA does not overrule existing legislation, but the Centers for Medicare & Medicaid Services (CMS) continues to monitor the prevalence of surprise billing for the possibility to expand the definition in future rulemaking.

### The No Surprises Act and its requirements

NSA prohibits balance billing for emergency services, air ambulance services, and non-emergency services provided at participating healthcare facilities. It also provides pro-



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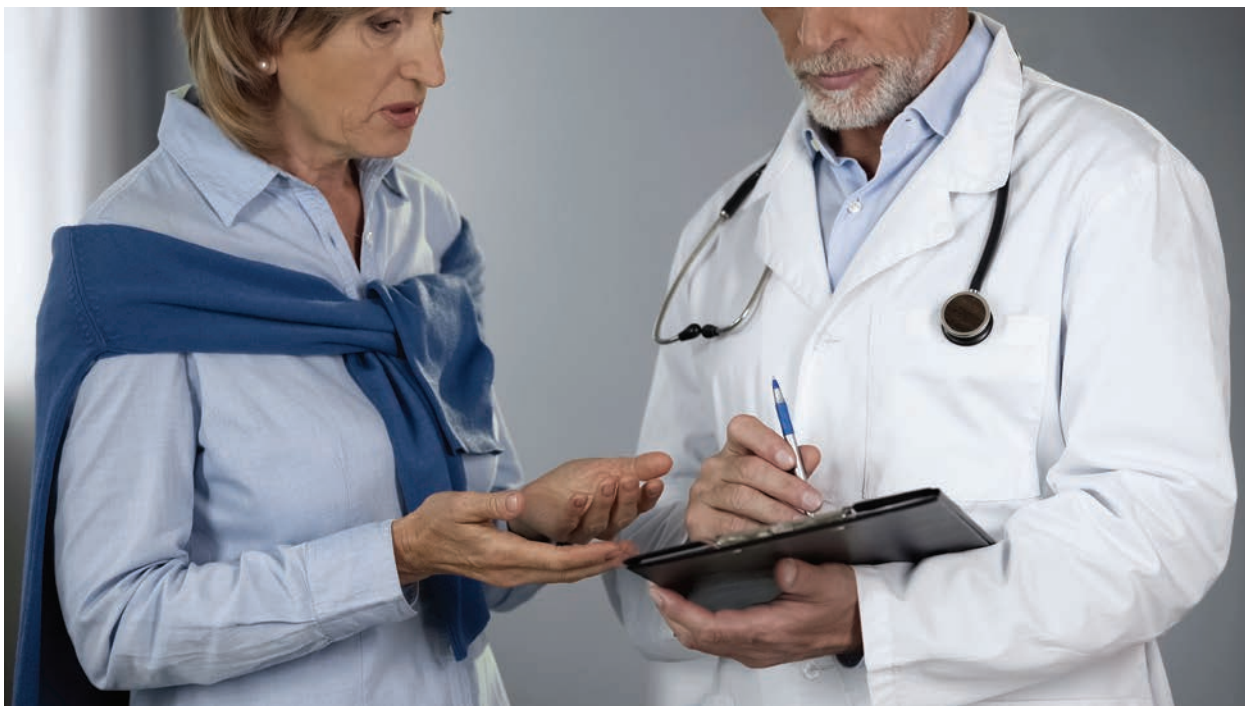
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tection for uninsured (or self-pay) individuals from unexpected “surprise” medical bills. A healthcare provider or facility must now provide a good faith estimate of the expected charges after an item or service is scheduled, or upon request.

This estimate includes expected charges for the service received, or for any other items that would reasonably be expected to be provided as part of the same scheduled service, which includes diagnostic and other ancillary services.

Ultimately, the act can be broken down into four requirements, which are outlined in the chart below.

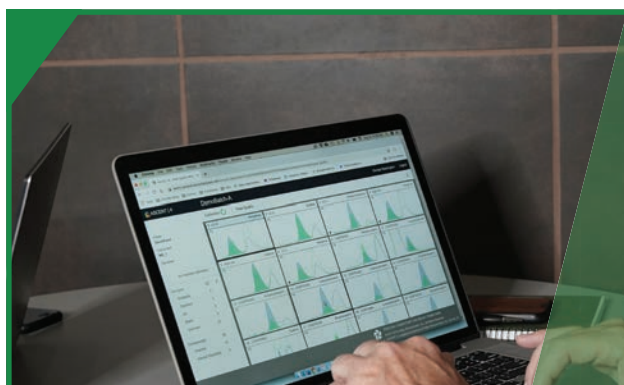
Providers are also required to notify patients of protection under NSA by posting a notice at the provider’s physical location, posting a link on the searchable homepage of the provider’s website, and when requesting payment.

### Six ways a billing vendor can help with compliance

Given these legislative changes, there are numerous reasons a healthcare provider may be out-of-network with a payor, and it’s more important than ever to leverage your billing system to help. In some cases, payors have closed networks and aren’t accepting new providers, or the provider and payor weren’t able to come to an agreement on rates for treatment. In addition, due to the numerous payors in the market, it’s often difficult to contract with every payor. As a result, most healthcare providers will not be in-network with all payors, and many will be impacted by the No Surprises Act.

Fortunately, revenue cycle management technology can help. In response to the evolving needs of patients, it’s crucial for labs to work with a trusted solution partner that can help guide the organization through this changing regulatory environment and maximize their RCM system and investment. The following are six ways providers can leverage their billing system to assist with compliance:

- Determine in-network rates — Identify any out-of-network payors and establish what their in-network rate is or work with the payor to outline a consistent approach, such as a percent of the fee schedule. This will allow providers to bill at an agreed-upon out-of-network rate from the start.
- Establish well-organized fee schedules — Within your billing system, categorize payors as contracted or non-contracted, and associate the specific fee schedule by payor.



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For out-of-network payors, your charge should equal the payor in-network allowable if it's defined upfront.

- Contact patients sooner and proactively – When applicable, consider sending a letter to patients, informing them that their claim should be processed as in-network under the No Surprises Act. When utilized strategically, proactively educating patients can help alleviate patient confusion and patient phone calls.
- Educate representatives to better support patients – Educate patient service representatives on NSA so they're prepared to handle incoming calls from patients. Additionally, look to implement a customer service workflow process to help ensure a consistent response to the incoming calls.
- Give patients greater cost visibility — Price estimation tools can improve the overall patient experience by helping them understand their out-of-pocket expenses. Leveraging an out-of-pocket estimation tool — which can be embedded into a patient portal and integrated with a lab's RCM system — can proactively educate patients and help them understand any potential costs they are responsible for before a service is received, or a test is performed.
- Place holds on out-of-network payors — If your billing system doesn't have the functionality to establish individual fee schedules by payor, consider placing out-of-network payors on hold for manual review to ensure the patient is billed the corresponding in-network rate.

By leveraging technology, a healthcare organization's patients will experience greater price transparency and

control over how and where they pay for services before tests are performed or services are received. With the right solution, labs can improve the process and management of their financial and communication strategies to be compliant right from the start. Working with a vendor that is steeped in knowledge and has a history of advocating for the lab industry will equip an organization with the tools and insights needed to navigate through this changing environment. ↻

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# The importance of accurate glucose monitoring in critically ill patients

By Dennis Begos, MD

**W**hat makes a patient “critically ill”? The term gets used often, but it can be difficult to define.

Certainly, being in an intensive care unit (ICU) should satisfy this, but, paradoxically, not every patient in the ICU is critically ill, and patients outside of the ICU setting have the potential to be considered critically ill. Very sick patients are often not in intensive care units, but throughout the hospital: emergency departments, post-anesthesia care units, operating rooms, and labor and delivery. These patients require specialized, timely, and individualized care to achieve the best outcomes. To say that only patients residing in the ICU require this stepped-up level of care is to potentially underestimate their disease severity and overlook factors which may adversely affect outcomes. One such factor is glycemic control.

Although controlling blood sugar is an obvious necessity for diabetic patients, glycemic control is a component of care in most, if not all, critically ill patients as dysglycemia is prevalent in these patients. There is now quite a bit of data that shows improved outcomes with insulin therapy in critically ill patients.<sup>1-3</sup> Although there is debate about

how “tight” this control should be, there is consensus that it is beneficial.<sup>4-6</sup>

There is also observational evidence that dysglycemia is actually the primary cause of poor outcomes rather than merely a marker for more severe disease.<sup>5</sup> Glucose control is also being increasingly recognized as a prognostic factor in COVID-19 patients. Preexisting diabetes increases morbidity and mortality in COVID-19 patients, and well controlled blood glucose in this population is associated with improved outcomes.<sup>7</sup> Importantly, in non-diabetic patients with COVID-19, those with uncontrolled hyperglycemia had a mortality rate of over 40%.<sup>8</sup>

## Point-of-care measurement of blood glucose

The cornerstone of proper glycemic control is accurate and timely measurement of blood glucose. Point-of-care testing (POCT) appears to be an obvious answer for accomplishing this, but it is not as simple as it appears. Many POC blood glucose monitoring systems (BGMS) simply are not accurate enough in this patient population to be trusted.<sup>9,10</sup> In fact, only one BGMS has been approved by

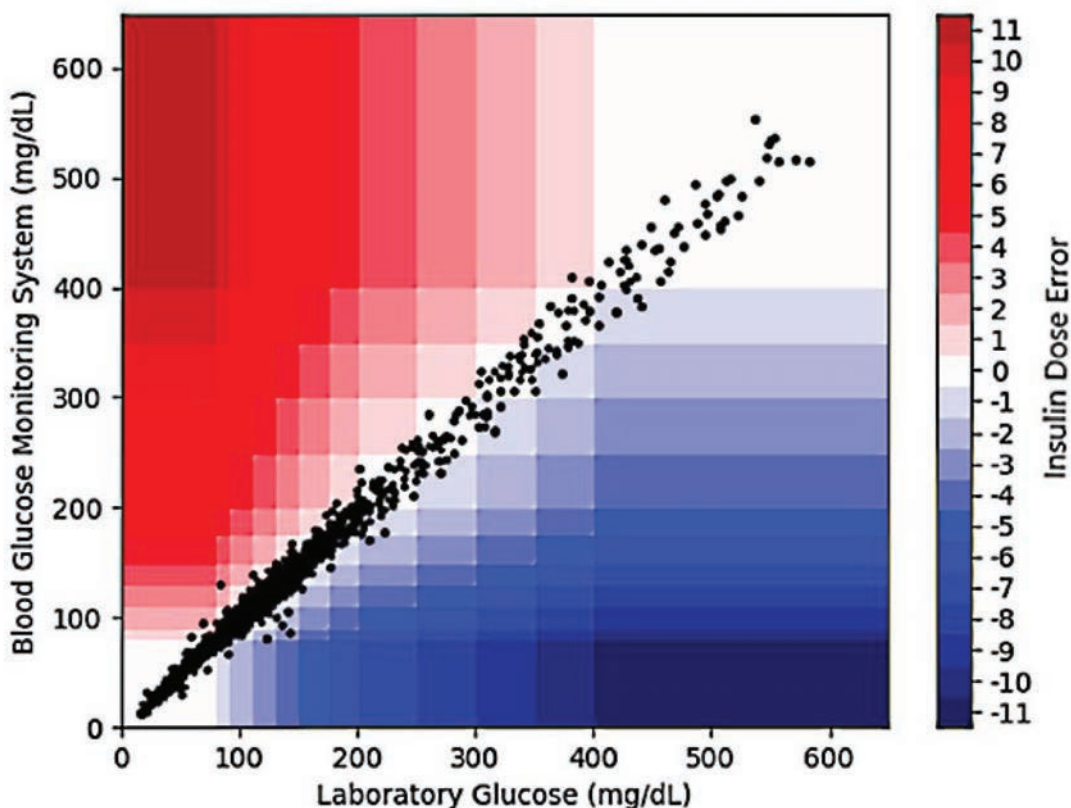


Figure 1: Insulin Dose Error Assessment Grid showing minimal deviation between the BGMS and central laboratory analyzer. Red represents over-administration of insulin, blue represents under-administration, based on the BGMS result[26].



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the U.S. Food and Drug Administration (FDA) for use in critically ill patients.<sup>11</sup>

A significant factor accounting for poor performance in some BGMS is from interfering agents. These can be endogenous (anemia, hypotension), or exogenous such as medications. Commonly used drugs such as acetaminophen, dopamine, acetylcysteine, icodextrin, and ascorbic acid are known to cause falsely elevated glucose readings in many meters. Anemia is present in over 70% of ICU patients and typically worsens the longer a patient is in the hospital.<sup>12</sup> Anemia is a common cause of factitious hyperglycemia with certain BGMS,<sup>13</sup> although some meters do correct for this.

In addition, high dose ascorbic acid (vitamin C) is increasingly being used to treat patients with a variety of conditions, including sepsis, burns, cancer, and COVID-19, to name a few.<sup>14-17</sup> A recent search on clinicaltrials.gov shows over 100 active or recently completed studies using high dose ascorbic acid. Ascorbic acid is notorious for causing pseudohyperglycemia, which could lead to overdosing of insulin;<sup>18</sup> in fact, it has led to death in this exact scenario.<sup>19</sup>

For this reason, two currently active trials looking at vitamin C in critically ill patients recommend using a BGMS validated for use in patients on ascorbic acid.<sup>15,17</sup> One such trial, the LOVIT study (which looks at vitamin C to lessen organ dysfunction) states in its protocol that “blood glucose can only be measured by one of the following three methods: hospital core laboratory instruments; a point-of-care arterial blood gas machine whose glucose measurement has been validated in the setting of high blood concentration of ascorbic acid; and a point-of-care glucometer with measurements that have been shown to be accurate in the presence of high blood concentration of ascorbic acid.”<sup>15</sup>

### Adverse outcomes from erroneous measurements of glucose

Erroneously elevated glucose, regardless of the cause, can lead to overtreatment with insulin, resulting in hypoglycemia and poor outcomes. In addition to the death described above, there are now numerous case reports of significant and permanent neurologic damage due to inappropriate insulin administration in the setting of other interfering agents.<sup>19,20,21</sup> So, this is not just a theoretical concern.

An Italian point-of-care study group recently issued a recommendation not to use BGMS in critical care settings unless the meter is certified for use in critically ill patients.<sup>22</sup> Clinicians caring for these patients, therefore, face a difficult situation: send all glucose specimens to the central lab, with its inherent drawbacks (delay in results, preanalytical errors, etc.), or use a BGMS off-label, but this may give inaccurate results and potentially result in medicolegal consequences if an adverse event occurs.<sup>23</sup>

In one large study done in five ICUs in three countries, involving nearly 1,700 patients, glucose results from a BGMS were compared to the hospital's central laboratory analyzer.<sup>24</sup> When plotted on a Parkes Error Grid, 99.3% of results were in Zone A, which means there was no clinical significance between the results from the BGMS and the central lab. The remaining results were in Zone B, representing minimal clinical significance. In a similar graphic looking at insulin dosing error (Figure 1), there was minimal clinical significance in insulin dosing based on the BGMS results.<sup>25</sup> In addition, the performance of the BGMS met the

most current standard for glucose measurement as defined by CLSI POCT12-A3 [27] with 95.4% of results <100mg/dL and 96.5% of the results >100 mg/dL falling within 12 mg/dL of the core lab. No significant interferences were identified in any patient, with patients on over 8,000 various compounds for treatment.

Given the complexity of glucose testing, it is, therefore, imperative for clinicians and laboratorians to be aware of the limitations of any BGMS that is being used in settings where critically ill patients are cared for. In a high-risk environment, where accuracy and reliability can directly impact patient outcomes, not all BGMS devices are created equally. 📌

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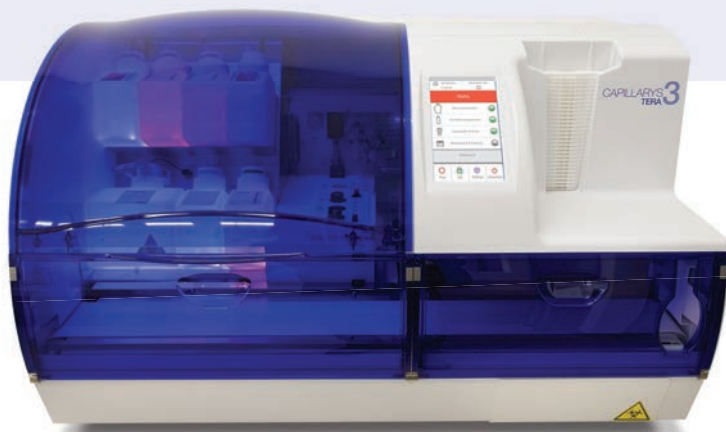
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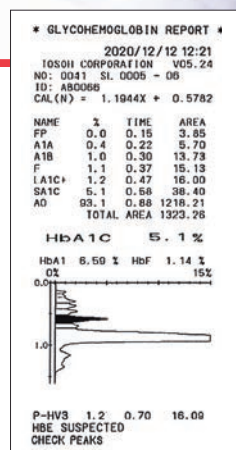
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Providence School of MLS Class of 2022 students Jacob Luna and Cathy Lee in the dedicated MLS student laboratory at Sacred Heart Medical Center.

## Hospital-based MLS program is recruiting tool

By Linda Wilson

**P**rovidence Sacred Heart Medical Center and Children's Hospital (PSHMC) offers something relatively rare: a hospital-based training program in medical laboratory science (MLS).

Launched in 1932, the program is a key recruiting tool for the hospital, as well as for its parent health system, Providence, a 52-hospital Catholic organization operating in Washington, Oregon, Montana, Alaska, Texas, New Mexico, and California.

The 12-month, full-time accredited program, designed for students with a bachelor's degree, includes eight months of lecture and work in the student lab followed by four months of clinical rotations. The hospital starts cohorts of students in July and January.



Laurianne Mullinax

"It's super intensive for them. They're on campus for forty hours and then go home and study one to two hours a night," explained Laurianne Mullinax, MS, MLS(ASCP)CM, Senior Manager of Laboratory Medical Education at Providence Inland Northwest.

The program qualifies graduates to take a national certification exam in MLS. It is one of three MLS programs in Washington. There also are three programs to train medical laboratory technicians. Universities and colleges run the other five programs.<sup>1</sup>

On a national level, slightly less than 100 hospital-based programs for medical laboratory scientists are accredited or approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS).<sup>2</sup> Sacred Heart Medical Center is one of those NAACLS-accredited programs.

Those programs are critical because the lab industry struggles to find enough employees to fill all shifts. In its 2020 survey report on staffing, the American Society for Clinical Pathology (ASCP) found that the national vacancy rate for positions in the lab varied from a high of 12.7% for chemistry/toxicology to a low of 3.9% for cytology.<sup>3</sup>

Vacancy rates also are impacted by retirements. The ASCP study found that retirement rates ranged from 6% in flow cytometry to 20.4% in chemistry/toxicology. The retirement rate was 16.3% in the core lab and 14.3% in microbiology.

### Growing demand

Demand is expected to grow. The Bureau of Labor Statistics said the employment opportunities for clinical laboratory technologists (synonymous with MLS) and technicians will grow 11% from 2020 to 2030, or a total of 36,500 positions.<sup>4</sup>

In Washington, the three MLS programs graduate about 70 students annually, which is not nearly enough to meet demand in the state, according to Mullinax. Another 50 students graduate from the MLT programs annually, she added.

That is why Sacred Heart launched a second annual cohort of students in 2021. "We've been able to almost double the number of students that we are graduating. So originally, on average, for the last few years, we've been graduating about 12 students a year with a single cohort, and now in 2021 we graduated 20, and we are on track in 2022 to graduate 22 students," Mullinax said. "We are unique as a hospital-based program because of the number of students we train annually. Traditionally, hospital-based programs only graduate 3-6 students a year."

The curriculum covers clinical chemistry, immunology, hematology/coagulation, immunohematology, medical microbiology, urinalysis/body fluids, molecular diagnostics, clinical research, phlebotomy, and laboratory management and practice.

In addition to the 12-month program, the hospital also offers an 18-month hybrid program. In that option, the first 16 weeks are full time in the classroom and student lab while the remainder of the instruction is part time. The clinical rotations also are full time.

In a third option, students enrolled at Eastern Washington University complete their last year of college in the hospital's full-time MLS program.





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Prov. Holy Family Hospital	Spokane, WA	272	58	Annual volume = 450,000 tests
Prov. St. Joseph's Hospital	Chewelah, WA	65	10	25 beds acute; 40 beds long term care Annual volume = 46,000 tests
Prov. Mt Carmel Hospital	Colville, WA	25	22	Acute care Annual volume = 170,000 tests

Figure 1: Providence Inland NW Facilities

Facility	Location	Beds
Vitalant Blood Center	Spokane, WA	NA
Multicare – Deaconess Hospital	Spokane, WA	338
LabCorp – PAML	Spokane, WA	NA
Mann-Grandstaff VA Medical Center	Spokane, WA	70
Kootenai Health	Coeur d'Alene, ID	330
Bonner General Health	Sandpoint, ID	25
Boundary Community Hospital	Bonnars Ferry, ID	52
Shoshone Medical Center	Kellogg, ID	21
Benewah Community Hospital	St. Maries, ID	19
PRL (Reference Lab)	Lewiston, ID	NA
Whitman Hospital	Colfax, WA	43

Figure 2: Local facilities that provide clinical rotations for Providence's MLS Program

Providence typically recruits about 60% of the program's graduates, and most of those new employees choose one of four hospitals in Eastern Washington, or what Providence refers to as the Inland Northwest region. (Figure 1)

However, some graduates have joined the staff of Providence's hospitals located in the Seattle region. Those students typically grew up on the western side of the state and want to return home. To facilitate their recruitment after graduation, Sacred Heart will place them in clinical rotations in Providence's Seattle-area hospitals. "We've been able to retain more graduates that way," explains Mullinax, adding that she also would like to place students in clinical rotations in Providence's hospitals located outside of Washington for the same reason.

Another strategy Providence uses to recruit graduates of the program is to offer a bonus to reimburse students for a portion of the program's \$15,000 tuition in exchange for a commitment to work at Providence for a specified amount of time.

Because it is not a university-based program, the students of Providence's program do not have access to federal loan programs, so the extra cash is welcome. "She notes that the students often are paying all education costs themselves.

### Program's operating challenges

Still, operating the training program is challenging. First, it is expensive. In addition to Mullinax, there are two other full-time employees dedicated to the program and four instructors whose job responsibilities include teaching plus other lab duties.

There are also supply costs and the intrinsic value of the

dedicated student lab space. "Hospital space is always at a premium," she notes. To help manage supply costs, she said, the student lab often uses items that are no longer suitable for processing specimens from real patients, such as nearly expired controls, but are fine for training purposes, she says.

"Hospital-based programs used to be more popular but in the nineties, quite a few programs closed, and that was fine at that point in time because we had enough staff. But they haven't reopened because they're so expensive to run," Mullinax said.

Money aside, another challenge is finding clinical rotations for the students because hosting a student through a rotation in a lab department is time intensive. (Figure 2) It is a big ask for labs that are already struggling to complete daily testing commitments. Fortunately, the program has found labs from both Providence and other organizations to provide clinical rotations. The hospital's blood banking partner, Vitalant, provides both clinical rotations and instructors for the program. Numerous hospitals in Northwest Idaho also provide clinical rotations.

### Other lab specialties trained

In addition to MLS training, Sacred Heart also operates clinical training programs for phlebotomists (4-week and 8-week courses) and histotechnicians (2 or 3 semesters) through a partnership with the University of North Dakota.

In addition, Sacred Heart's lab education program also provides ongoing continuing education programs for lab employees at the four hospitals in Providence's Inland Northwest region.

### Collaborating with other organizations

Even with Providence's commitment to training, particularly for new laboratorians, the organization cannot keep up with demand. It is not alone. That is why Mullinax and the other five directors of the training programs in Washington have started meeting regularly to compare notes and solve problems.

"I'm trying to really collaborate, so we can produce as many graduates as possible for our state," she said. For example, the directors have discussed how to operate remotely during a pandemic and still support hands-on clinical training, or how to increase the number of clinical rotations available for students, given shortages of personnel in most laboratories.

"The health of these programs is so important," Mullinax concluded. 📌

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AD1003800EN00 (02/22)





Photo courtesy of the Broad Institute

## Removing gaps to get testing to scale

By Philippe Flamant

In the last two years, the healthcare industry and world learned many lessons in adapting to rapidly changing needs. When processing massive amounts of tests amidst a pandemic, traditional lab workflows were not ready to meet the scalability required to achieve the testing numbers needed to process tests in a timely fashion. Every small delay, even just 30 seconds, adds to a process that must be repeated 10,000 times each day. A 30 second delay repeated 10,000 times adds up quickly.

### Standardization is key to scale

At the start of the pandemic, there was no standardization for lab testing. Processes for accessioning, taking samples, and reporting were haphazard. There was limited access to testing across the country, and the time for test processing was so long that it made testing negligible in slowing the spread of the pandemic. The healthcare industry was desperate for increased capacity for testing and test processing speed.

Director of Operations and Development at the Broad Institute Genomics Platform, Tim DeSmet, looked to an outside partner for assistance with their effort to transform their Clinical Research Sequencing Platform CLIA-certified lab into a high-throughput testing facility to assist Massachusetts in combatting the pandemic. DeSmet said during a recent webinar, “We knew we would have to think differently. We had to deconstruct the paradigm and have a standardized, simple solution. We needed to have a tube and a swab and to take paper off the shelf.”

The Broad Institute transformed its facility in less than two weeks to a high-throughput diagnostic testing lab, building new walls to isolate workers and infectious samples, acquiring new PPE for staff, devising a staffing model that would eventually allow for 24-hour operations, and adapting robotics to accelerate a standard processing protocol.

### The pandemic is the final goodbye to paper orders when scale is needed

While the innovation continued inside the lab throughout the pandemic, DeSmet knew they would need to address the inefficiencies outside the walls of their institute, as well. One of the early examples of innovation was the creation of digital roster orders for organizations. The team was conducting testing in long-term care facilities, and it would take 20 staff members to go into the care facility to take samples and put the order into a spreadsheet prior to sending samples to the lab. The process to get the orders into the lab was a significant factor in the processing times.

It became apparent that a solution for high-throughput COVID ordering was needed immediately. Labs needed patients to be registered quickly and to ensure all the needed patient data was collected at the time the specimen was collected. A process was developed to enter patient information for an order with a roster. Whether this roster was coming from the long-term care facility, university, or employer, orders could now come as a roster from any source outside of the EMR.

### Instrument-ready barcodes became the standard

Not only was there a need for a single type of tube and swab, where originally specimens were coming to the lab in more than 15 different tube types, but the barcode now needed to be standardized, as well. Barcodes on tubes for the Broad Institute needed a universal number that was unique to their organization and would work every time and with ease. Once this was accomplished, all information would be immediately available to Broad Institute when scanning the tube in the lab.

Additionally, demographics had to be collected in advance that were required for state reporting. The solution for collecting this information had to be nimble to adjust to the constant changes in

the data requirements that could differ for the various public health agencies. The Broad Institute would not be able to make 150,000 calls per day to verify a patient's race and ethnicity. All the patient and CARES Act-required information had to be gathered at the front of the testing process. This simplification was one of the key components that made the ramp up of testing to scale possible.

Originally the Broad Institute had planned to use prelabeled tubes, thinking it would save time and be a simpler, easier workflow. But every tube must have a connection to the patient, and the information on the barcode must be correct. With up to 150,000 orders and tests per day, ensuring every prelabeled barcode matched to a patient couldn't be guaranteed. The decision was made that labels had to be printed on site, at the time of the collection. The Broad Institute was able to acquire a large supply of printers for labels to ensure anyone submitting orders was using the same printer for barcodes and that barcodes across all orders received would be uniform. At the end of an order, the test site had no option but to print a label.

### Patient self-registration is essential for speed

A key innovation was to ensure a centralized method for handling data intake and output. Large amounts of patient data had to be stored and accessible for sharing in a variety of methods to ensure state reporting, result delivery to patients, result delivery to ordering physicians or practices, and, later, connectivity directly with wellness applications.

Labs needed to be able to accept orders from a multitude of systems, not just EHRs. Interfaces have always had to solve the challenge of integrating with many varied EHRs for bi-directional connectivity. The pandemic put the phrase "vendor agnostic" to the test. Software teams had a new challenge of needed integration with human resource systems, legacy student systems, and many other personnel management software of varied processing capability.

Once the Broad Institute completed their processing innovations inside of the lab and had a partner for high-throughput automatic accessioning, the results were immediate. Broad Institute went from processing 1,000 tests per day to more than 30,000 tests per day in just 2-3 weeks. Today, the Broad Institute has capacity to process up to 150,000 COVID-19 tests every day.

### Automated reporting to public departments of health

With the Broad Institute, once their accessions and internal processes were running smoothly, it was apparent the state reporting element also had to be simplified. Just as Broad Institute staff were not able to make tens of thousands of phone calls, they were also not going to fax 150,000 test results or create CSVs for uploading results to state health department portals.

Initially, there was some faxing of results to public health departments, but it was clear this would not be scalable long-term. The Broad Institute's partner was able to validate an ELR integration with the state reporting agencies. A change for public health departments was to improve communication channels so testing information could be received electronically. A relationship was quickly developed to implement bi-directional connectivity for reporting, and to ensure results were reported to the agency in their specified format.

The value of having reporting connections to departments of health not only brought speed and agility to the testing process but helped public health departments identify how the pandemic was spreading and where the hot spots were emerging.

### Patient access is no longer a luxury

A central, cloud-based hub was an essential key to high-throughput COVID testing. The orders and results resided in the hub



Photo courtesy of the Broad Institute

so patients could gain access to their information through the patient portal whether their test was taken at a patient service center, a doctor's office, or through their employer. The CARES Act required results be delivered directly to patients to control the spread of COVID-19. When patients tested positive, state reporting was completed while also notifying the patient and the providers so they could initiate follow up.

With all the information being centralized, the burdens of the actions taken outside the walls of the lab were off-loaded from the Broad Institute. From patient intake to instrument-ready barcodes, and after results were determined, state reporting, patient reporting, and sending results to physicians for follow up, the third-party information handling ensured the actions were completed. This allowed the Broad Institute to focus on automating their processes inside the lab, like automating cap removal and standardizing test tubes. The result was going from 1,000 orders a day to 30,000, to eventually 150,000 orders and results a day, an incredible feat.

### The look ahead for infectious disease testing

A large amount of wellness applications appeared on the scene during COVID, and it continues as a trend today. As people are again able to travel, attend events, and return to the office, rapid testing has become the norm. A centralized, cloud-based platform has become an essential ingredient for efficient infectious disease testing, especially when there is a desire to test at a large scale.

COVID has accelerated the rise of point-of-care testing, as well as empowering patients to take control of their own care and complete tests in their home. The lab workflows of yesterday are put to rest, where an order could be rejected due to bad handwriting, as we make space for a more patient-centric approach, allowing the patient to complete self-registration, ensure ask on order entry (AOE) questions are complete in the front end, and contain all the required information in a barcode tied to a centralized platform. ➔



Philippe Flamant is the Vice President of Solutions Engineering at ELLKAY



## SARS-CoV-2 Variants



### MassARRAY variant panel

The MassARRAY SARS-CoV-2 Variant Panel (RUO) is a robust, cost-effective, and accurate testing solution, enabling laboratories to detect and differentiate 16 unique SARS-CoV-2 variants including Omicron and Delta. Moreover, labs can process up to 100s or 1000s of samples on a single instrument in a single workday. **Agena Bioscience**

### SARS-CoV-2 variant reference material

AccuPlex SARS-CoV-2 Omicron Variant Reference Material mimics wild-type pathogenic viruses but is safe, noninfectious, and replication-deficient. With a protein coat and lipid bilayer, this reference material serves as a true, full-process, quality solution that challenges the entire PCR test procedure, making it a preferred alternative to infectious materials. **LGC Clinical Diagnostics**



### SARS-CoV-2 variant test kit

The NEXTFLEX Variant-Seq SARS-CoV-2 Kit v2 detects all mutations associated with SARS-CoV-2 variants in a PCR-positive sample. With the incorporation of normalization beads, this kit reduces turn-around time by three hours. 1,536 UDIs incorporated in the kit enable the sequencing of 6,000 SARS-CoV-2 libraries in one flow cell. **PerkinElmer**

## Other solutions

### rRNA NAAT test for women's health

Hologic's Aptima Mycoplasma genitalium assay is a highly sensitive, rRNA-based NAAT that can detect characteristically low M. gen bacterial loads with up to 100% sensitivity. The Aptima assay is designed for a one-step, direct-load workflow on the Panther system. **Hologic**



### Multiplex testing

The QIAstat-Dx Analyzer from Qiagen automates multiplex respiratory testing with less than one minute of hands-on time. It provides comprehensive results for more than 20 pathogens in about an hour. Ct values viewable for detected pathogens. **Qiagen**

### Point-of-care solution

Using Bulk Acoustic Wave (BAW) detection technology, the Qorvo Omnia platform is designed to deliver rapid test results (about 20 minutes) for SARS-CoV-2 infections. BAW enables surface-based mass measurement using high frequency and surface binding, which enables a high degree of sensitivity. **Qorvo**



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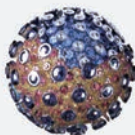
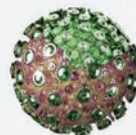



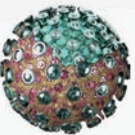

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Detect N gene, RdRP gene and S gene of SARS-CoV-2, Influenza A, Influenza B and Respiratory syncytial virus (RSV) A/B in a single tube.

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RUO	RUO	RUO	RUO	RUO	RUO	RUO
						
<ul style="list-style-type: none"> <li>- RdRP gene</li> <li>- HV69/70 del</li> <li>- E484K</li> <li>- N501Y</li> </ul>	<ul style="list-style-type: none"> <li>- W152C</li> <li>- K417N</li> <li>- K417T</li> <li>- L452R</li> </ul>	<ul style="list-style-type: none"> <li>- L452R</li> <li>- P681R</li> <li>- K417N</li> </ul>	<ul style="list-style-type: none"> <li>- F490S</li> <li>- P681R</li> <li>- L452Q</li> <li>- L452R</li> </ul>	<ul style="list-style-type: none"> <li>- L452Q</li> <li>- F490S</li> <li>- R346K</li> <li>- D950N</li> </ul>	<ul style="list-style-type: none"> <li>- RdRP gene</li> <li>- HV69/70 del</li> <li>- E484A</li> <li>- N501Y</li> </ul>	<ul style="list-style-type: none"> <li>- P681R</li> </ul>

\* Confirmed by internal inclusivity testing (in silico and wet testing)







## PCR testing at the point-of-care

The cobas Liat PCR System enables healthcare providers to receive rapid, confirmatory results for respiratory infections and other infectious diseases in 20 minutes or less at the point of care. The technology offers a “walkaway” workflow and a compact, portable design that is designed for any CLIA-waived healthcare setting. Roche has expanded the cobas Liat assay menu with multiplex testing and new disease states. **Roche**

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The T2SARS-CoV-2 Panel is a qualitative T2 Magnetic Resonance (T2MR) test designed for the direct detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens in transport media from individuals with signs and symptoms of COVID-19. The Panel is available for use on the T2Dx Instrument under the U.S. Food and Drug Administration Emergency Use Authorization (EUA). **T2 Biosystems**



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# Providing creative test options

By MLO Staff



**Laura Miller, MLS (ASCP)** is Laboratory Director at **South Peninsula Hospital** in Homer, AK, a position she has held for 11 years. She joined the staff of the lab in 1987 and spent 24 years working as a clinical laboratory scientist.

## How did you become interested in a career in the clinical laboratory?

I have always loved chemistry and math. When I was in high school, there was an extracurricular program that allowed students to shadow professionals where there might be an interest. I spent several months shadowing clinical laboratory scientists at my local hospital. Laboratory science was a good fit for three reasons: 1) I prefer limited patient contact 2) I enjoy working as a team 3) at the same time, being able to work independently.

## What prompted you to pursue laboratory management?

Management was never something I aspired to. My former boss was grooming me to cover some of her duties when she left for vacation. When she left, the lab staff approached me, asking me to consider taking the role. I had been offered the manager position earlier in my career, but it was not the right time to consider it. I didn't feel I had enough experience to do the job well. When I was approached by my peers, I realized that if I didn't step into the position at that time, I probably never would. Also, I had been a generalist bench tech for 24 years, was the lead tech for chemistry, and did all the ordering for the lab. While I

still had things to learn, I had reached a plateau. So, it was an opportunity to learn new skills and grow myself professionally.

## Turning to the work at South Peninsula Hospital, will you briefly describe the self-order and self-pay Request-a-Test program and explain why you launched it?

The Request-a-Test (RAT) program was the brainchild of my former manager, launched for a few reasons. One, it made sense that tests the community could obtain during the annual Rotary Health Fair should be available all year round. Secondly, it is expensive for individuals to pay to see a provider when they have a sore throat, for example. If they can have a rapid strep test done instead, they can schedule an appointment if the test is positive. Another reason is patients are savvier about their healthcare. Someone with elevated lipids or diabetes has a good understanding of what those values mean and what they are trying to achieve. Living in a fishing community in the spring, many fisherman and other allied industries need urine drug testing. The RAT program allows individuals to order testing, as needed, for themselves or their employees. Since the RAT program is patient driven, there is no submission of charges to insurance. Payment is required at the time of service.

We have other promotions that are done throughout the year. In February, during heart month, we offer reduced prices on heart tests. In October, as mentioned, the hospital, in collaboration with the Rotary, runs a month-long health fair where lab tests are offered at a greatly reduced prices.

## What result/benefits have you seen from the program?

The RAT program has had a foundation of education and empowerment where individuals can take charge of their health outcomes. The public is becoming more educated, due to access to the internet and mass media. Healthy lifestyle choices are promoted from many angles and allowing the community to access testing supports those efforts.

One benefit is early disease detection. We have picked up leukemia and other diseases, through the testing that we have provided. Living in the northern climes, with less daylight in the winter months, Vitamin D testing has been a very popular test on our RAT menu, as it has a large impact on mental health and physical health.

## What is the biggest challenge your lab faces in providing testing services to patients in Alaska? How have you overcome it?

One of the challenges is healthcare costs and having assistance, such as insurance or Medicaid. The hospital has several programs in place to help make testing more affordable and during open enrollment for insurance, it expands staff hours to help individuals sign up for assistance.

The senior leadership team and the hospital governing boards have been very supportive of the laboratory. During the pandemic, the biggest challenges have been the supply chain and staffing. We are still dealing with a lot of our supplies being on back order or on allocation. Currently, I have been able to bring on extra staff.

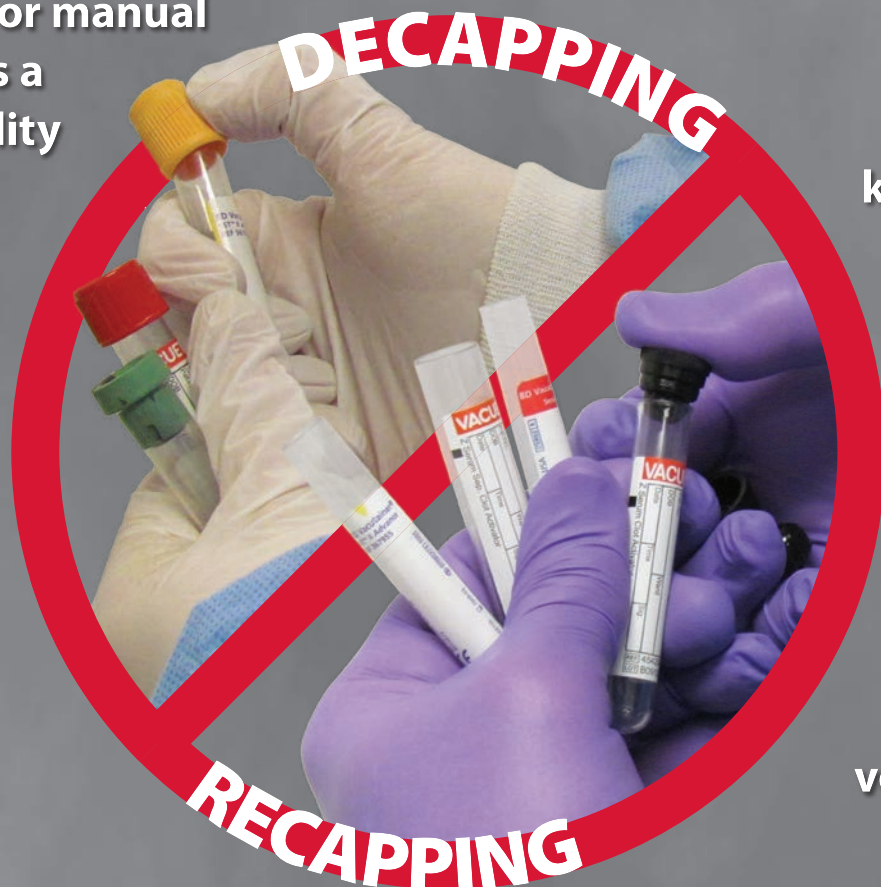
## Will you briefly describe one of the mission trips you have taken and why you pursue this work?

Eleven years ago, I went to volunteer at a women's shelter in Mexico. I fell in love with the people and being of service. I went to Mexico for nine years until COVID-19, two years ago. I began looking for medical mission opportunities, and through World Medical Mission, part of Samaritan's Purse, found a need for a technical supervisor at Soddo Christian Hospital in Ethiopia. In 2017, I spent three weeks working with the microbiology tech and returned in 2019 for more one-on-one collaboration, to invest and return, more than once, building relationships with locals.

I am working on my MPH degree because it was difficult to find a medical mission program that was geared to the laboratory. By broadening my educational base, I would have more opportunities to serve. 🙌

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