MLO-online.com

MEDICAL LABORATORY OBSERVER

MLO®

MAY 2022 ▪ Vol 54 ▪ No 5

The Peer Reviewed Management Source for Lab Professionals since 1969

CE The rise of molecular diagnostics for common maternal & fetal tests

PLUS

State of the Industry:

Best Practices for Lab Management in 2022

Supply limitations forecasted

Preventing cross-contamination

LAB INNOVATOR

Dr. Esther Eke, BS, MBA and PhD in Epidemiology
Laboratory Director,
Jack Hughston Memorial Hospital

Dedicated to Innovation in Cytology for the Betterment of Patient Care

A commitment to patients and cytology labs – *everywhere.*

At Hologic, we know that every sample represents a patient, requiring careful handling and accurate identification – because of this, labs need to be confident in their results without compromising productivity.

That is why we are committed to new cytology innovations that will help detect cervical cancer earlier and more effectively, so labs can benefit from groundbreaking technology, and women from great care.

Enabling Cytology Labs to Do More

ThinPrep® Genesis

Explore Genesis

Advanced automation in a small footprint.

Offering automated chain of custody, streamlined cytology processing, and hands-free sample aliquoting in a single instrument, the ThinPrep® Genesis™ processor **provides advanced automation in a small footprint.**

Hologic is **Redefining Cytology Screening.** Again.

HOLOGIC®

A new version of the free education website is now available – with added features to enhance your experience and immerse you in the world of digital cytology.

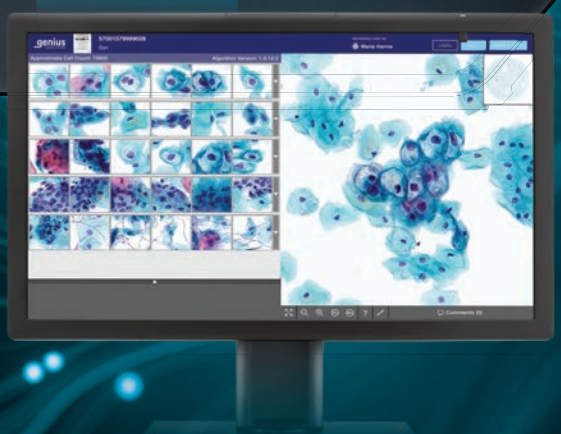
Register for free today

NEW

Follow the Cells and Make a Diagnosis Beyond the Glass

The Next Evolution in **Cervical Cancer Screening** is Coming

CE-MARKED



Powering Healthcare with Technology to Shape the Future of Digital Diagnostics

The Genius™ Digital Diagnostics System* is the first digital cytology platform to combine a new artificial intelligence (AI) algorithm with advanced volumetric imaging technology to help cytotechnologists and pathologists identify pre-cancerous lesions and cervical cancer cells in women – transforming cervical cancer screening and ushering in a new era of cytology innovation.

genius™ DIGITAL DIAGNOSTICS

Scan to discover more

* Genius Digital Diagnostics is CE-marked for diagnostic use in Europe and is not currently available for sale in the U.S. May not be available in all markets. Contact your local Hologic representative for availability in your country.

MEDICAL LABORATORY OBSERVER
MLO
The Peer Reviewed Management Source for Lab Professionals since 1969


8


16

22


34


48

Thermo Fisher SCIENTIFIC

Clinical Mass Spectrometry

Time for the convenience of automation

Discover the Cascadion SM Clinical Analyzer

Clinical mass spectrometry designed for ease of use

- √ **Free up time for your clinical laboratory staff** by removing repetitive and laborious tasks
- √ **Decrease laboratory risks** and potential for errors
- √ **Streamline quality assurance** with simplified staff training and compliance

Incorporate fully automated IVD testing solutions into your plans for clinical mass spectrometry specialty chemistry testing with the Thermo Scientific™ Cascadion™ SM Clinical Analyzer

Learn more at **thermofisher.com/cascadion**

thermo scientific

Forecast still cloudy on COVID

By Kristine Russell
Executive Editor

COVID-19 reports, with the exception of maybe weather and the stock market, are the most viewed (and most impactful) numbers in our daily lives in spring of 2022.

They are also changing more and, as a result, are harder to predict, than any changes in weather or business.

Over the past month alone, we have seen both the highs and the lows. After sharp increases in the first half of March, the CDC reported that COVID-19 cases have been on a steady decrease for the latter half of said month. Indeed, rates of infection and mortality have been on steady declines throughout the country.

However, international headlines, particularly in the UK and China, can hardly be encouraging.

In fact, COVID in China is raging as the country is in the midst of their worst outbreak since the pandemic began (and far surpassing the height of the initial spread in Wuhan in 2020).

China shut down Shanghai and other surrounding areas with an ongoing lockdown of around 26 million people, again bringing factory shutdowns and future potential shortages of supplies back to the forefront of concern.

According to NPR, China sent more than 10,000 health workers from around the country to help the city with mass testing of the Shanghai residents.

In Britain, COVID is surging as well, and a new Omicron variant, XE, has been identified and detected.

And, while overall national rates here in the U.S. have been falling, on a state-level things are much different, as close to half of the states are seeing their COVID numbers on the rise.

Thus, we laboratorians cannot rest on our laurels or put away our COVID test procedures yet.

COVID-19 will continue to be a fact of our lives for the foreseeable future, and we, the laboratorians, the epidemiologists, the scientists, must continue to consider ourselves as not just valued public servants, but also as community leaders.

In these troubling times, we in the laboratories are shaping and influencing the lives of everyone.

We are responsible for detecting and responding to a public emergency, and every action we take has reverberations throughout our community and throughout the world. And it looks like for now, our labs and our laboratorians are still going need to be ready to tackle the next variant or the next twist on COVID care.

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

MEDICAL LABORATORY OBSERVER Vol.54, No.5

Group Publisher/Executive Editor
Kristine Russell
krussell@mlo-online.com

Managing Editor
Gail Castanho
gcastanho@endeavorb2b.com

Assistant Editor
Erin Brady
ebrady@endeavorb2b.com

Graphic Artist
Patti Connors
pconnors@endeavorb2b.com

Audience Development/List Rentals
Laura Moulton
lmoulton@endeavorb2b.com

Ad Traffic Coordinator
Ray Porter
rporter@endeavorb2b.com

ADVERTISING

East Coast/Midwest Sales (except IL)
Classified/Recruitment Advertising
Carol Vovcsko
(941) 321-2873
cvovcsko@mlo-online.com

South/West Coast/Illinois Sales
Lora Harrell
(941) 328-3707
lharrell@mlo-online.com

2477 Stickney Point Rd., Suite 221B Sarasota, FL 34231
Phone: (941) 388-7050 Fax: (941) 388-7490
www.mlo-online.com

VERIFIED

MLO - MEDICAL LABORATORY OBSERVER
(Print ISSN: 0580-7247/Online ISSN 2771-6759). Published monthly, with an additional issue in AUGUST, by Endeavor Business Media, LLC., 2477 Stickney Point Rd, Suite 221B, Sarasota, FL 34231 (941) 388-7050. Subscription rates: $128.00/year in the U.S.; $155.00 Canada/Mexico; Intl. subscriptions are $221.00/year. All issues of *MLO* are available on microfilm from University Microfilms International, Box 78, 300 N. Zeeb Rd., Ann Arbor, MI 48106. Current single copies (if available) $15.00 each (U.S); and $20.00 each (Intl.). Back issues (if available) $1760 each (U.S.); $22.00 each (Intl.). Payment must be made in U.S. funds on a U.S. bank/branch within the continental U.S. and accompany request. Subscription inquiries: subscriptions@endeavorb2b.com. *MLO* is indexed in the *Cumulative Index for Nursing and Allied Health Literature* and *Lexis-Nexis. MLO* Cover/CE, Clinical Issues, and Lab Management features are peer reviewed. Title® registered U.S. Patent Office. Office of publication: Periodicals Postage Paid at Nashville, TN 37209 and at additional mailing offices. **Postmaster:** Send address changes to Omeda (MLO Medical Laboratoy Observer), PO Box 3257, Northbrook, IL 60065-3257. Printed in U.S.A.


Image by Claire51700 from Pixabay

Fast Facts

In a study of children born after a pregnancy of less than 24 weeks, nearly all (96 percent) had some degree of development disorder. According to the study, from the University of Gothenburg, neuropsychiatric and somatic diagnoses are prevalent as these extremely preterm infants grow into adulthood.

Among these children born before 24 weeks of pregnancy:

One-year

survival rates for infants born alive 2014–2016 with gestational age 22 and 23 weeks were 30% and 61%

75 %

Of the premature babies had neuropsychiatric impairments,

30 %

Of the premature infants had Attention-Deficit/Hyperactivity Disorder, ADHD.

20 years

the survival rate among extremely premature babies has risen sharply, especially in those born in gestational weeks 22 and 23

88 %

Of the premature infants had other medical diagnoses, such as Asthma (63 percent) or postnatal growth restriction (39 percent).

55 %

Of the premature infants required habilitation support.

Source: University of Gothenburg, Neurodevelopmental disorders and somatic diagnoses in a national cohort of children born before 24 weeks of gestation; https://www.gu.se/en/news/wide-ranging-diagnoses-in-children-born-before-24-weeks-gestation

Scientists discover new pathogenic mechanism in hematological malignancies

Scientists at Yale Cancer Center have discovered new consequences of specific gene mutations that play a role in the development of myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML), according to a news release.

Approximately half the patients diagnosed with MDS and 10% of patients with AML are found to have splicing factor mutations leading to ineffective blood cell production and malignancy. The new research revealed that mutations in the splicing factor U2AF1 improve the ability of the cancer cells to respond to and survive stress. The findings were published in Molecular Cell.

Splicing factor mutations are particularly common in MDS and leukemia but also occur in other cancers. RNA splicing is a fundamental process accounting for cell diversity. The genetic code is transcribed from DNA to RNA molecules, which have to be processed to function properly. During splicing, RNA molecules are cut and select pieces are reconnected by splicing factors, including U2AF1. Mutations in splicing factors result in mistakes in this process.

In the new study, the research team demonstrated that mutations in U2AF1 alter RNA binding, splicing, and turnover of numerous RNAs, and enhance the formation of so-called stress granules, biomolecular condensates of RNAs and proteins, that mediate cellular adaptation to stress. This improved stress response may explain the clonal advantage of mutant cells and the development of MDS or AML.

"The discovery that U2AF1 mutations enhance stress granule formation may open novel avenues to prevent or treat myelodysplastic syndromes and acute myeloid leukemia," said Giulia Biancon, PhD, Postdoctoral Associate in the Halene Laboratory at Yale Cancer Center and lead author on the paper.

"This discovery was possible by developing new experimental and analytic methods integrating big data. The mechanism of enhanced stress granule formation was not easy to detect because it's not caused by a single large change to one RNA molecule, but by the sum of many small changes to hundreds of RNA molecules," said Toma Tebaldi, PhD, Assistant Professor at the University of Trento, Adjunct Assistant Professor at Yale School of Medicine, and co-senior author on the paper.

MDS are most common in patients over 70 years old and are conditions that can occur when the blood-forming cells in the bone marrow become abnormal. AML also starts in the bone marrow and is most commonly diagnosed in older patients, but most often it quickly moves into the blood, as well.

CDC reveals effect of COVID-19 on tuberculosis

New data suggests that the pandemic has had a substantial effect on TB trends in the United States, according to the Centers for Disease Control (CDC).

Before COVID-19, TB disease diagnoses typically declined between 1% and 2% each year. The 2020 and 2021 declines may be related to factors associated with the COVID-19 pandemic, including a true reduction in incidence as well as delayed or missed TB diagnoses.

Efforts to prevent COVID-19, such as wearing masks and distiancing, may also reduce the spread of TB.

Widespread disruptions to healthcare during the COVID-19 pandemic may have delayed TB diagnoses. The COVID-19 pandemic has strained public health services, including TB prevention and control services.

Similarities in symptoms between COVID-19 and TB disease may have led to missed TB diagnoses. Case reports have revealed some people with TB disease were evaluated for COVID-19 — but not tested for TB — during multiple encounters with healthcare systems. Initial misassumptions might have contributed to missed diagnoses, or delayed diagnoses until more advanced stages of disease.

TB prevention and control activities are essential public health functions for communities throughout the United States. To assist in these efforts, CDC launched the Think. Test. Treat TB campaign to help raise awareness of TB and recognize the importance of TB prevention.

Philip LoBue, MD, FACP, FCCP, Director of CDC's Division of Tuberculosis Elimination, said, "Delayed or missed tuberculosis disease diagnoses are threatening the health of people with TB disease and the communities where they live. A delayed or missed TB diagnosis leads to TB disease progression and can result in hospitalization or death – and the risk of transmitting TB to others. The nation must ensure that healthcare providers understand how to diagnose and distinguish TB disease from potential cases of COVID-19."

EVENT SESSIONS

BACK TO THE LAB:

CELEBRATING OUR PAST AS WE LOOK INTO OUR FUTURE

LAB WEEK 2022 – APRIL 24-30

WE INVITE YOU TO JOIN US FOR LAB WEEK 2022.

We're highlighting the importance and value of the lab during this year's Lab Week. Connect with us during this engaging webinar series, designed to celebrate the impact of laboratory diagnostics on the global community.

Monday, April 25, 10am CDT

WELCOME TO THE CORE DIAGNOSTICS EXPERIENCE CENTER

Presented by Abbott's Core Diagnostics Team

Monday, April 25, 2pm CDT

HIV/HCV AND OTHER STI CO-INFECTIONS: APPROACHES IN TACKLING THE RISING PROBLEM*

Presented by Michelle Rose
Population Health Manager, Norton Healthcare

Tuesday, April 26, 10am CDT

BIOTIN (VITAMIN B7): WHAT OUR PATIENTS AREN'T TELLING US*

Presented by Saleh Aldasouqi, MD, FACE, ECNU
Professor of Medicine and Chief of Endocrinology
College of Human Medicine at Michigan State University

Wednesday, April 27, 10am CDT

THE CONTINUING OPIOID EPIDEMIC: SPECIAL CONSIDERATIONS FOR FENTANYL: DETECTION AND TREATMENT*

Presented by Bonnie R. Nolan, PhD
Addiction Services Coordinator, Woodbridge Township, NJ

Thursday, April 28, 10am CDT

SIX SIGMA METHODOLOGY AND ITS IMPACT ON THE CEDARS-SINAI CORE LABORATORY*

Presented by Kimia Sobhani, PhD, MS, FAACC
Medical Director, Core Laboratories
Cedars-Sinai Medical Center

Friday, April 29, 10am CDT

NEW EGFR EQUATION FOR KIDNEY FUNCTION ASSESSMENT: THE ROLE OF ENZYMATIC CREATININE*

Presented by Ramani Wonderling, PhD
Associate Director, Scientific Affairs
Abbott Core Diagnostics

SCAN THIS QR CODE TO REGISTER

*PACE CREDITS WILL BE OFFERED FOR THESE SESSIONS.

corelaboratory.abbott.com

ADD-138788-USA-EN

Abbott

Image by Iuliia Bondarenko from Pixabay

One of the highest-impact areas of women's health involves testing pregnant women for viral and bacterial pathogens that may affect the baby.

The rise of molecular diagnostics for common maternal and fetal tests

Increased focus on identifying viral and bacterial pathogens commonly passed

By Michelle Tabb, PhD

In the broad medical domain known as women's health, one of the highest-impact areas involves caring for women during pregnancy. After all, any testing or treatment performed in this window affects not only the health of the expectant mother but also the health of the baby.

Obstetricians and their clinical laboratory partners are increasingly focused on the identification of viral and bacterial pathogens commonly passed on to the developing fetus during gestation or to the infant during birth. Common infectious disease targets include the herpes simplex virus — both HSV1 and HSV2 — and group *B Streptococcus* (GBS). A congenital infection of particular concern, cytomegalovirus (CMV), is a well-known healthcare issue, however screening for primary CMV infection or reactivation during pregnancy or for CMV in newborns is currently not included in universal screening recommendations.

All three pathogens are pervasive among the general public and can infect their hosts without triggering symptoms, often for years. As a result, many people are unaware that they are silently harboring these pathogens, leading to increased transmission, possibly to vulnerable pregnant women. While these pathogens can be relatively harmless for healthy adults, infection *in utero* or during birth can be much more dangerous for a baby's health and development. This is why testing expecting mothers is essential for delivering effective healthcare for women.

In recent years, technological improvements have made molecular diagnostics an attractive alternative to traditional testing techniques for this particular area of women's health needs. Molecular detection of HSV1, HSV2, and GBS have produced reliable results with high sensitivity and faster turnaround times, often delivering information in just a few hours, compared to the days or even weeks it can take with culture-based methods.

Earning CEUs

See test on page 14 or online at www.mlo-online.com under the CE Tests tab. Passing scores of 70 percent or higher are eligible for 1 contact hour of P.A.C.E. credit.

LEARNING OBJECTIVES

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

1. List common pathogens that is passed from mother to infant.
2. Discuss limitations of culture-based pathogen screening methods.
3. Discuss the benefits of molecular-based pathogen screening methods.
4. Describe the etiology, pathogenicity, and past and current screening methods for mother-to-infant pathogenic infections.

Now, the advent of sample-to-answer molecular diagnostic systems — instruments that handle everything from sample preparation and pre-analytics to analysis and reporting results with minimal intervention from clinical lab members — offer a new approach to molecular diagnostics for this type of maternal/fetal or mother/newborn testing. These streamlined systems make it easier for even small clinical laboratories to expand their test menus and introduce women's health testing in a feasible and cost-effective manner.

Why molecular diagnostics matter

For as long as any current practitioner can remember, culture-based testing has been considered the gold standard for diagnosing most infectious diseases. It's inexpensive, does not require advanced training, and has the advantage of being familiar to pathologists and laboratorians worldwide. After all, direct observation of an organism provides a definitive result.

So why look for alternatives to a testing methodology that has served us well for more than a century? Culture's one great weakness: time. While culture-based tests generally give reliable results, they do so at their own pace, which is not necessarily in-line with the pace of healthcare. Typical cultures might generate results in 48 hours; with certain slow-growing pathogens, results may take weeks. When additional cultures need to be added, such as for antibiotic susceptibility testing, answers often cannot be produced quickly enough to make a difference in the treatment of a patient.

Fortunately, speed is where molecular diagnostics shine. These tests do not require growing microbes over time; they simply detect and quantify the nucleic acids present in a sample, allowing for diagnosis of known — and sometimes even novel — pathogens based on their DNA or RNA signatures. Depending on the test, results may be generated in an hour or just a few hours. Typically, molecular diagnostics can achieve excellent sensitivity and specificity because of their genomic foundation.

Across many clinical testing indications, molecular diagnostics (often called NAATs for nucleic acid amplification tests) are now included in diagnostic guidelines alongside stalwart methods like culture. In some cases, particularly viral detection, molecular diagnostics have actually supplanted culture to become the recommended laboratory method to aid in diagnosis.

Another reason for the increasing use of molecular diagnostics is their flexibility for expansion. The conserved DNA or RNA genomic targets or signatures of multiple pathogens can be combined in a panel test, allowing laboratorians to test for several of the most common culprits in a single assay. This streamlined approach is instrumental when symptoms of infection overlap, such as testing respiratory infections or gastrointestinal infections. The panel-based approach delivers answers for all pathogens together quickly, while serial testing for each pathogen could drag on for days.

Below, we will review molecular diagnostics in the context of testing for HSV1 & 2, GBS, and CMV.

HSV testing

The herpes simplex virus is one of the most pervasive human pathogens, globally. HSV1, primarily transmitted through saliva, causes both oral herpes (recognizable through telltale cold sores) and genital herpes. HSV2 is sexually transmitted and causes genital herpes as well as oral herpes. According to estimates from the World Health Organization, some 67% of adults under the age of 50 — that's 3.7 billion people — have acquired HSV1, while more than 490 million people from 15 to 49 years of age have HSV2.[1]

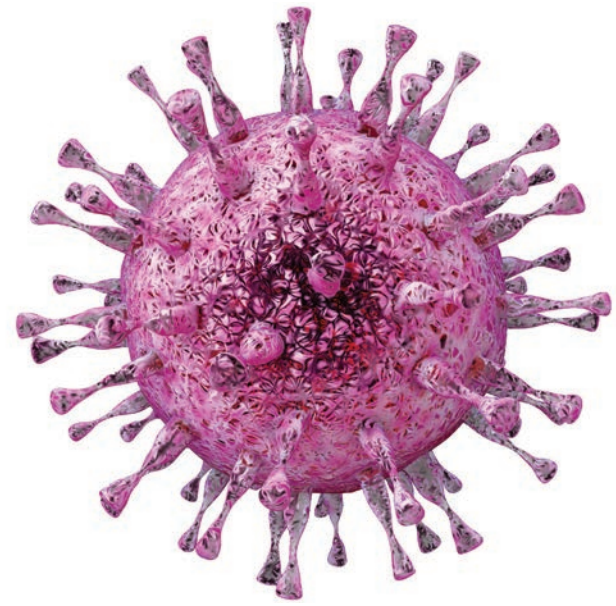


Photo coutesy of Luminex

Screening for CMV is not yet universally recommended, even though congenital infections pose a serious health risk for newborns.

Both types of HSV lead to lifelong infections, but in many cases, people are asymptomatic and never realize they have the virus. Those who develop symptoms may experience episodic mucocutaneous or cutaneous lesions, or even fulminant encephalitis. In developing babies, exposure to either type of HSV could lead to a dangerous central nervous system infection; left untreated, the infection can be fatal. HSV can be passed by the mother to the infant during birth, or less commonly, in utero or after birth.[2-4]

For these reasons, it is essential to understand the risk of a mother passing either type of HSV to her baby, particularly if the mother experiences her primary infection while pregnant or has an active outbreak at the time of birth. If a pregnant woman exhibits lesions associated with herpes infection, she should be tested for HSV1 and HSV2. In some cases, it can be challenging for clinicians to distinguish between herpes lesions and lesions from other infections, such as syphilis or varicella-zoster virus (VZV) making panel tests that cover some or all of these pathogens in one assay useful for a definitive diagnosis.

The ability to test for several infectious etiologies simultaneously is one reason that molecular diagnostics are a good fit for HSV1 & 2 testing. Another is speed. Culture-based testing for these viruses typically takes a minimum of two to three days, the ability to maintain mammalian cell-culture lines and specialized staff, while commercially available molecular diagnostic tests can generate highly accurate results in just 60 minutes. That kind of turnaround time may not be essential for the mother, but every minute counts for a potentially infected baby.

When doctors know that a mother had evidence of an active HSV infection while giving birth, they can immediately test the newborn. Comprehensive testing may include "surface specimens" which include eye, mouth, nose and anal swabs as well as swabs of any skin lesions if present, whole blood, and a lumbar puncture to check the cerebrospinal fluid for the presence of the virus.[5] Rapid molecular diagnostics can provide results for all of those samples in an hour, but it is important to select a platform that can be used with all sample types.

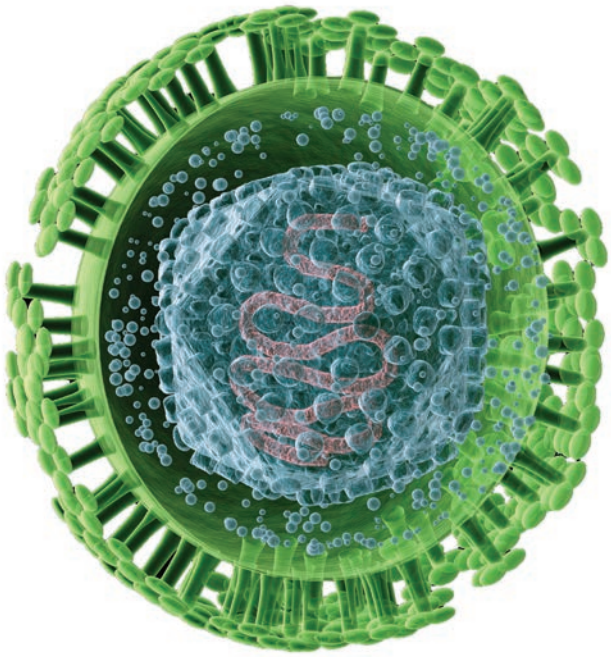


Photo coutesy of Luminex

HSV1 and HSV2 both lead to lifelong infections, but many people never realize they have the virus. Without testing, pregnant women may be unaware of the risk to their babies.

In addition to providing an accurate diagnosis, the speed of molecular testing helps ensure that a newborn gets the best treatment. When a mother is known to have HSV — especially if she was first infected while pregnant, which may be the most dangerous situation for the developing baby — doctors often start the baby on antiviral and antibiotic treatments immediately. Getting reliable answers about the baby's infection status in an hour means that at least one of those treatments can be de-escalated quickly.[6]

GBS testing

Among newborns, infection by Group *B Streptococcus* is one of the leading causes of both meningitis and sepsis, making it a serious concern for neonatal care. According to an estimate from the U.S. Centers for Disease Control and Prevention, 25% of pregnant women are asymptomatically colonized with GBS in genital and rectal mucous membrane areas that a baby would be exposed to during vaginal birth.[7] Half of the babies born to infected mothers get infected themselves.[8] Vertical transmission of GBS to the newborn occurs either shortly before or during delivery, and can result in an invasive infection known as early-onset disease (EOD). Infants with EOD will present with fever, lethargy, sepsis, pneumonia, and, more rarely, meningitis within the first 24 to 48 hours of life. In the 1970s, GBS emerged as the primary cause of infection of infants in the first week of life with fatality rates as high as 50%. In 1990, the CDC estimated an incidence of GBS disease of 1.8 cases per 1,000 live births, but as a result of universal screening and intrapartum antibiotic treatment, GBS EOD has been reduced to an incidence of 0.23 infants per 1,000 live births as of 2015.[9] On average, even with universal screening in place, 1,000 babies in the United States develop EOD each year, with approximately 4 to 6% leading to death. Late-onset disease (LOD) can also occur in the neonate around 3 to 4 weeks of age and typically manifests as bacteremia or meningitis with approximately 1,000 babies in the United States affected per year.[7]

Current clinical practices are focused on the identification of women who are colonized with GBS and are, therefore, at highest risk of transmission to the newborn infant to target administration of intrapartum antibiotic prophylaxis (IAP).[10] Universal GBS screening for pregnant women is recommended between the 36-38-week mark using a vaginal-rectal swab.[8] Eighteen to twenty-four (18 to 24) hour broth enrichment of the swab is recommended prior to detection of GBS by either subsequent culture or PCR-based detection because enrichment has been shown to increase the sensitivity of detection.[11-12] If the results are positive, the patient can be treated with antibiotics during labor. This approach demonstrably reduces the risk of mother-to-baby transmission, reducing EOD occurrence.[13]

There are several FDA cleared NAATs available for antepartum or intrapartum detection of GBS organisms from vaginal-rectal swab specimens collected from pregnant women. However, the sensitivity of NAATs may be significantly decreased when used for rapid testing while a mother is in labor because the 18-24 hour enrichment step cannot be included in those situations. Neonatal cases of GBS disease have occurred in babies born to mothers whose screens were negative during pregnancy, which underscores the need for high sensitivity testing.[5]

In the event an infected mother passes GBS to her baby, time is of the essence. Severe infections in the infant can trigger dangerous symptoms within the first day or two after delivery. Rapid diagnosis of GBS infection in the newborn is essential for positive outcomes.

Conventional testing for GBS is performed with culture using blood agar plates followed by a confirmation test such as Christie, Atkins, and Munch-Peterson (CAMP) factor reaction or latex agglutination, which can be labor-intensive and delay results up to 48 hours.[9] While this time-consuming process may be acceptable for testing the expectant mother at 36-38 weeks, it is not suitable for testing a newborn who may quickly spiral into a severe and time-sensitive infection crisis. The presence of GBS DNA in normally sterile body fluids such as CSF provides presumptive evidence of neonatal infection.

More and more, physicians are turning to GBS molecular diagnostics instead of conventional culture both for newborns and mothers. These tests' high sensitivity and specificity outperform that of culture.[12] Multiplex panel PCR assays are available in many clinical laboratories for direct testing of CSF that include GBS and other central nervous system pathogens. And given the severity of the risk to an infected neonate, obstetricians cannot afford to miss a positive case in a pregnant woman. Rapid results from a molecular test can also be a significant benefit if the patient goes into pre-term labor, allowing her healthcare team to manage risk carefully through the use of prophylactic antibiotics during labor.

For pregnant women allergic to penicillin — the antepartum treatment typically prescribed to reduce GBS transmission — culture and subsequent susceptibility testing remain helpful for characterizing the pathogen's antibiotic resistance profile and selecting the best course of treatment.

CMV testing

Human cytomegalovirus (CMV) infection is common and usually results in a mild, non-specific illness in otherwise healthy individuals followed by asymptomatic latency. It is estimated that 50% of adults are infected by age 40 in the U.S. alone.[14] However, congenital CMV can wreak havoc during fetal development, and perinatal CMV can cause severe symptoms in newborns. CMV causes more cases of congenital disease than the 29 most commonly screened metabolic and endocrine disorders combined. About 90% of babies born with congenital CMV infection will

We recognize your passion for providing accurate results which help diagnose and drive treatment decisions. We also know you are resilient and must navigate through some difficult and chaotic days while providing the best possible service to physicians, patients, and your organization.

At SEKISUI Diagnostics, we are committed to providing high-quality, U.S. made Women's Health rapid tests that are accurate and easy to use, allowing you to get the answers fast.

Like you, we understand there is a patient behind every answer—and that's what matters most.

For more information, visit osomtests.com or call 800-332-1042

OSOM® TRICHOMONAS RAPID TEST

OSOM® BVBLUE® TEST

SEKISUI DIAGNOSTICS
Because every result matters™

appear healthy at birth, but up to 20% of these babies may die due to complications from the infection. Later in life, children with CMV may suffer developmental delays and hearing loss — congenital CMV is the leading cause of non-genetic sensorineural hearing loss and neurodevelopmental abnormalities in infants.

Saliva swabs and urine are the preferred sample types for testing newborns for CMV infection. Testing must be performed before the neonate is 21 days old given, after that timeframe, CMV infections may be acquired via environmental exposure. The possible long-term sequelae associated with congenital infection is much more severe than if the infection is acquired post-birth, so knowing the timing of infection is critical for appropriate support. If saliva is used for the initial testing, confirmatory testing with urine is required since CMV seropositive mothers can shed CMV in their breastmilk, potentially contaminating a neonatal saliva swab after a baby has breastfed. Symptomatic congenital CMV infections can be treated with antiviral medications like ganciclovir and valganciclovir. Treatment can potentially decrease the severity of long-term impacts such as hearing loss and developmental delays, and is most efficacious when administered within the first 30 days post-birth.[15,16]

While the risk of mother-to-baby transmission would argue for universal CMV screening of pregnant women, historically there have not been tests available with sufficient sensitivity and specificity to make this approach helpful or actionable.[17] Most laboratory tests currently available to identify a first-time maternal infection can also be challenging to interpret and cannot predict if the fetus may become infected. Because of this, routine screening for primary CMV infection in pregnant women is not recommended in the United States, even when it is part of TORCH screening. In cases where there is strong reason to believe a mother has been infected with CMV, maternal infection and transmission risk may be assessed through antibody testing.

Molecular diagnostics for CMV is recommended to detect the virus in the developing fetus and newborns. Fetal diagnosis can be made with amniocentesis using CMV PCR after 21 weeks of gestation. The standard laboratory test for diagnosing congenital CMV infection in newborns is PCR using saliva swabs with urine collected and tested for confirmation.[15] As molecular diagnostic developers continue to expand the number of infectious diseases their tests cover, new options for CMV testing are emerging. As these tests are evaluated and validated through clinical studies, molecular CMV assays to diagnose congenital CMV infection will likely be more broadly available.

Sample-to-Answer systems

For most molecular tests mentioned above, there are many combinations of reagents, kits, and analysis platforms to produce the desired information. Many clinical labs choose to design and validate their own laboratory-developed tests (LDTs) to suit their testing needs. These can be designed on the lab's platform of choice, making it possible to introduce new tests without investing in new instrumentation.

However, LDTs are not the right choice for all labs. Smaller laboratories that lack deep experience in assay development or where extensive molecular workflows are not common, may prefer to use an FDA-cleared kit.

A recent trend among molecular diagnostic developers has been in response to lab professionals seeking easier-to-use systems that require less hands-on time. These instruments are often known as "sample to answer" or "sample in, answer out." As the name suggests, sample-to-answer systems handle all the processing steps internally, from sample preparation to thermal cycling and analysis.

Currently available sample-to-answer systems offer low to medium throughput, making them a good option for lower-volume testing needs. They are typically not a viable alternative for testing workflows where labs need to run hundreds or even thousands of samples at a time.

For tests where such high-volume capacity is not required, sample-to-answer systems can allow labs to expand their test offerings quickly without investing in new equipment or validating a new process each time. Some systems are designed to perform all of the benchtop steps for molecular diagnostics within a sample-to-answer workflow. Some of these systems are designed to work with cartridges that perform both the extraction and amplification steps, and other systems eliminate the extraction process altogether through direct testing. There are several sample-to-answer systems available today that offer different cartridges or kits for HSV1/2 and GBS testing as well as for congenital CMV. Because these tests are developed by diagnostic manufacturers and are FDA-cleared as in vitro diagnostics, they do not require the extensive internal development and validation needed for LDTs.

Conclusion

In the arena of women's health focused on pregnant women and their developing babies, molecular diagnostics offer significant advantages compared to the previous gold standard of culture-based testing. Molecular assays allow clinical laboratory teams to generate answers faster, test more comprehensively, and expand their test menus to meet the needs of their patient population. For HSV1 & 2, GBS, and CMV testing, molecular diagnostics are attractive alternatives to other more laborious and time-consuming assay techniques.

REFERENCES

1. World Health Organization. Herpes simplex virus (10 March 2022). Retrieved March 17, 2022, from https://www.who.int/news-room/fact-sheets/detail/herpes-simplex-virus.

2. Brown ZA, Wald A, Morrow RA, et al. Effect of serologic status and cesarean delivery on transmission rates of herpes simplex virus from mother to infant. *JAMA*. 2003 Jan 8;289(2):203-9. doi: 10.1001/jama.289.2.203. PMID: 12517231.

3. Kimberlin DW. Herpes simplex virus infections of the newborn. *Semin Perinatol*. 2007 Feb;31(1):19-25. doi: 10.1053/j.semperi.2007.01.003. PMID: 17317423.

4. James SH, Sheffield JS, Kimberlin DW. Mother-to-Child Transmission of Herpes Simplex Virus. *J Pediatric Infect Dis Soc*. 2014;3 Suppl 1(Suppl 1):S19-S23. doi:10.1093/jpids/piu050.

5. American Academy of Pediatrics. Herpes Simplex. In: Kimberlin DW, Brady, MT, Jackson MA, Long SS, eds. *Red Book*: 2018 Report of the Committee on Infectious Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:410-11.

6. Tam T. Van, Kanokporn Mongkolrattanothai, Melissa Arevalo, et al. (2017) Impact of a Rapid Herpes Simplex Virus PCR Assay on Duration of Acyclovir Therapy. *J Clin Micro*. 55 doi: 10.1128/JCM.02559-16.

7. Centers for Disease Control and Prevention. (2018). Group B Strep Fast Facts. Retrieved March 17, 2022, from https://www.cdc.gov/groupbstrep/about/fast-facts.html.

8. Prevention of group B streptococcal early-onset disease in newborns. ACOG Committee Opinion No. 797. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2020; 5: e51-72. doi: 10.1097/AOG.0000000000003668.

9. Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. Published 10 March 2020. Updated 23 July 2021. Guidelines for the Detection and Identification of Group B Streptococcus. American Society for Microbiology. https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of.

10. Puopolo KM, Lynfield R, Cummings JJ; Committee On Fetus And Newborn; Committee On Infectious Diseases. Management of Infants at Risk for Group B Streptococcal Disease. Pediatrics. 2019 Aug;144(2):e20191881. doi: 10.1542/peds.2019-1881. Epub 2019 Jul 8. *Erratum in: Pediatrics*. 2019 Oct;144(4): PMID: 31285392.

11. Philipson EH, Palermino DA, Robinson A. Enhanced antenatal detection of group B Streptococcus colonization. *Obstet Gynecol* 1995;85:437–9.144 doi: 10.1016/0029-7844(94)00412-7.

12. Brianne A. Couturier, Trent Weight, Haley Elmer, et al. (2014) Antepartum Screening for Group B Streptococcus by Three FDA-Cleared Molecular Tests and Effect of Shortened Enrichment Culture on Molecular Detection Rates, *J Clin Micro* 52, 3429-3432. doi: 10.1128/JCM.01081-14.

13. Teatero, S., Ferrieri, P., Martin, I., Demczuk, W., et al. (2017). Serotype Distribution, Population Structure, and Antimicrobial Resistance of Group B Streptococcus Strains Recovered from Colonized Pregnant Women. *J. Clin. Microbiol*, 55(2), 412-422. doi: 10.1128/JCM.01615-16.

14. Jean Beltran PM, Cristea IM. The life cycle and pathogenesis of human cytomegalovirus infection: lessons from proteomics. *Expert Rev Proteomics*. 2014;11(6):697-711. doi:10.1586/14789450.2014.971116.

15. Centers for Disease Control and Prevention. (2020). Babies Born with Congenital Cytomegalovirus (CMV). Retrieved March 17, 2022, from https://www.cdc.gov/cmv/congenital-infection.html.

16. Ross SA, Kimberlin D. Clinical outcome and the role of antivirals in congenital cytomegalovirus infection. *Antiviral Res*. 2021 Jul;191:105083. doi: 10.1016/j.antiviral.2021.105083.

17. Akpan US, Pillarisetty LS. Congenital Cytomegalovirus Infection. [Updated 2021 Aug 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK541003/ and https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/02/prevention-of-group-b-streptococcal-early-onset-disease-in-newborns

Michelle Tabb, Ph.D., is Chief Scientific Officer at **DiaSorin Molecular LLC.**

The rise of molecular diagnostics for common maternal and fetal tests

MAY 2022 *[This form may be photocopied. It is no longer valid for CEUs after November 30, 2023.]*

Passing scores of 70 percent or higher are eligible for 1 contact hour of P.A.C.E. credit.

TEST QUESTIONS

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

1. **Obstetricians and their clinical laboratory partners are increasingly focused on the identification of _____commonly passed on to the developing fetus during gestation or to the infant during birth.**
   - ○ viral and bacterial pathogens
   - ○ rubella
   - ○ West Nile virus
   - ○ Colored blindness
2. **Screening for primary CMV infection or reactivation during pregnancy or for CMV in newborns is currently included in universal screening recommendations.**
   - ○ True ○ False
3. **What type of detection of HSV1, HSV2, and GBS has produced reliable results with high sensitivity and faster turnaround times?**
   - ○ Ultrasound
   - ○ Environmental
   - ○ Microbial
   - ○ Molecular
4. **What type of system includes instruments that handle everything from sample preparation and pre-analytics to analysis and reporting results?**
   - ○ Sample-to-answer system
   - ○ All-in-One system
   - ○ Prep-to-Report system
   - ○ Direct-Diagnostics system
5. **What is the benefit of streamlined systems for small clinical laboratories?**
   - ○ Because of these systems, they are exempt from women's health testing
   - ○ They make it easier to expand their test menus and introduce women's health testing
   - ○ They are able to charge higher fees if they conduct women's health tests
   - ○ None of the above
6. **Culture-based testing has been considered the gold standard for diagnosing most infectious diseases. Why?**
   - ○ It's inexpensive
   - ○ It does not require advanced training
   - ○ It has the advantage of being familiar to pathologists and laboratorians worldwide
   - ○ All of the above
7. **Culture-based tests generally give reliable results, but what is their one weakness?**
   - ○ Possible contamination
   - ○ Readability
   - ○ Testing limitations
   - ○ Timing not in pace with healthcare needs
8. **Newer diagnostics tests detect and quantify the nucleic acids present in a sample, allowing for diagnosis of known — and sometimes even novel — pathogens based on their DNA or RNA signatures.**
   - ○ True ○ False
9. **Molecular diagnostics have become the recommended laboratory method to aid in diagnosis of _____.**
   - ○ viral infections
   - ○ bacterial infections
   - ○ fungal infections
   - ○ parasitic infections
10. **The conserved DNA or RNA genomic targets or signatures of multiple pathogens can be combined in a panel test, allowing laboratorians to test for several of the most common culprits in a single assay. When is this helpful?**
    - ○ When labs are short-handed, and testing is back logged
    - ○ When symptoms of infection overlap, such as testing respiratory infections or gastrointestinal infections
    - ○ During COVID-19 pandemic
    - ○ Whenever working with DNA and RNA genomics
11. **How is HSV1, primarily transmitted?**
    - ○ Through blood transfusions
    - ○ Through saliva
    - ○ Through open cuts
    - ○ Through unsanitary restrooms
12. **According to estimates from the World Health Organization, _____ of adults under the age of 50 have acquired HSV1.**
    - ○ 34% ○ 78%
    - ○ 59% ○ 67%
13. **Which type(s) of HSV lead to lifelong infections where, in many cases, people are asymptomatic and never realize they have the virus?**
    - ○ HSV1 ○ Neither
    - ○ HSV2 ○ Both
14. **In developing babies, exposure to either type of HSV could lead to _____.**
    - ○ Low birth weight
    - ○ central nervous system infection
    - ○ breathing difficulties
    - ○ jaundice
15. **How can HSV be passed by the mother to the infant?**
    - ○ during birth
    - ○ after birth
    - ○ A and B
    - ○ None of the above
16. **Culture-based testing for these viruses typically takes a minimum of two to three days, while commercially available molecular diagnostic tests can generate highly accurate results in _____.**
    - ○ 60 minutes ○ 30 minutes
    - ○ 24 hours ○ 18 hours
17. **What can doctors do when they know that a mother had evidence of an active HSV infection while giving birth?**
    - ○ immediately quarantine the mother
    - ○ immediately quarantine the newborn
    - ○ immediately test the mother
    - ○ immediately test the newborn
18. **Among newborns, infection by Group B Streptococcus is one of the leading causes of_____, making it a serious concern for neonatal care.**
    - ○ blindness
    - ○ meningitis and sepsis
    - ○ pneumonia and strep
    - ○ ear, nose, and throat infections
19. **About 90% of babies born with congenital CMV infection will appear healthy at birth, but what percentage of these babies may die due to complications from the infection?**
    - ○ 20% ○ 43%
    - ○ 4% ○ 62%
20. **Treatment with antiviral medications can potentially decrease the severity of long-term impacts of CMV, in infants, such as _____.**
    - ○ hearing loss
    - ○ developmental delays
    - ○ weakness in limbs
    - ○ A and B

Tests can be taken online or by mail. Easy registration and payment options are available through NIU by following the links found at www.mlo-online.com/ce.

PLEASE PRINT CLEARLY

NAME _____ MAILING ADDRESS _____ ☐ HOME ☐ WORK

CITY _____ STATE _____ ZIP _____ INSTITUTION/FACILITY _____

PHONE _____ E-MAIL ADDRESS _____

Send your $20 check payable to Northern Illinois University with this form to: University Outreach Services, Northern Illinois University, DeKalb, IL 60115-2860 Phone: 815-753-0031

FEE NOT REFUNDABLE OR TRANSFERABLE

P = Poor; E = Excellent

1. **To what extent did the article focus on or clarify the objectives?** P ① ② ③ ④ ⑤ E
2. **To what extent was the article well-organized and readable?** P ① ② ③ ④ ⑤ E
3. **How will you use the CE units?** ☐ state license ☐ employment ☐ recertification ☐ other

CE Licensure Information for FL and CA:

FL: Your FL license number:_____ ***(required for CE credit)***

CA: Accrediting Agency: 0001 ***(for use in submitting your CE credits to CA)***

MLO and Northern Illinois University (NIU), DeKalb, IL, are co-sponsors in offering continuing education units (CEUs) for this issue's CE article. CEUs or contact hours are granted by the College of Health and Human Sciences at Northern Illinois University, which has been approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® program. Approval as a provider of continuing education programs has been granted by the state of Florida (Provider No. JP0000496). Continuing education credits awarded for successful completion of this test are acceptable for the ASCP Board of Registry Continuing Competence Recognition Program. Readers who pass the test successfully (scoring 70% or higher) will receive a certificate for 1 contact hour of P.A.C.E.® credit. Participants should allow three to five weeks for receipt of certificate. The fee for this continuing education test is $20. **This test was prepared by Amanda Voelker, MPH, MT(ASCP), MLS, Clinical Education Coordinator, School of Health Studies, Northern Illinois University, DeKalb, IL**

Luminex®
A DiaSorin Company

DiaSorin Molecular

Together, DiaSorin Molecular and Luminex Can Provide Even More for Your Laboratory Needs

Respiratory Infections

Neonatal Testing

Gastrointestinal Infections

Bloodstream Infections

Women's Health

Hospital-Acquired Infections

ARIES®

LIAISON® MDX

VERIGENE®

Visit **molecular.diasorin.com** and **luminexcorp.com** to learn more.

Product availability subject to required regulatory approvals.

Photo by tumisu@Pixabay.com

The impact of next-gen sequencing on tracking SARS-CoV-2 variants

By Baha Abdalhamid and Ramin Khaksar

The evolution of SARS-CoV-2 has been unpredictable. Factors such as inequitable global vaccine distribution, long-haul COVID-19 among immunocompromised patients, and possible transmission between humans and other mammals, have contributed to the rapid increase in the number of mutations. The continued emergence and spread of new variants reinforce the critical role that genomic sequencing has in the enhanced surveillance of COVID-19.

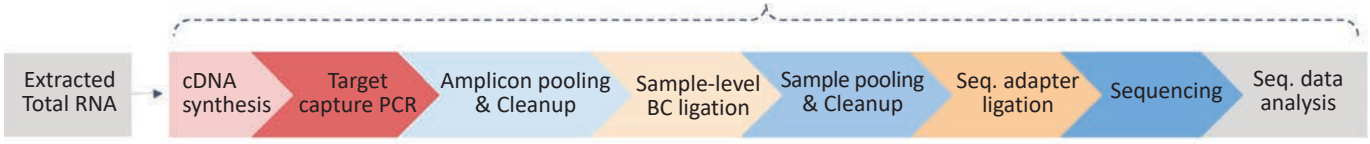
To keep pace with an ever-evolving virus, efficient identification, and characterization in near real-time is critical. There are several ways to achieve this objective. PCR-based methods are efficient and sensitive but are limited in their ability to detect novel disease agents or aggressive mutations of known pathogens. Additionally, it only offers a binary, presence or absence result.

Next-generation sequencing (NGS) is a promising technology that overcomes these limitations. It is paramount to employ rapid and reliable genomic surveillance tools that track viral evolution. Through sequencing, specifically whole genome sequencing (WGS), researchers can determine the novel cause of infection and characterize the pathogen's genetic material to better understand pathogenic virulence, transmission, susceptibility to antiviral agents, resistance to treatment, or vaccine targets aimed at curbing the pandemic.

Unfortunately, NGS methods have traditionally been labor-intensive, expensive, and time-consuming, with sequencers taking several days to generate data along with a significant amount of bioinformatics analysis to interpret meaningful results. This is far too long to have any meaningful impact beyond academic utilization and does not achieve the goal of reducing the immediate spread of infection. While these barriers dissuade many laboratories from adopting sequencing technology, there are examples of laboratories incorporating novel approaches to NGS-methods and adapting them for a rapidly changing landscape for infectious disease detection and public health intervention. The Nebraska State Public Health Laboratory (NPHL) is located on the University of Nebraska Medical Campus (UNMC) and is supported by both UNMC as well as the Nebraska Department of Health and Human Services. As the Assistant Director at NPHL, we knew early-on in the pandemic that, even though sequencing would be time-consuming, it would be integral to monitoring the virus.

At the start of the pandemic, NPHL was approached by a California based start-up, Clear Labs, that developed an automated solution for sequencing. NPHL piloted the system and was able to increase sequencing by three-fold to approximately 320 samples per week with minimal training, removing the requirement for staff to have expertise in sequencing. The Clear Dx WGS SARS-CoV-2 assay (RUO)* can process extracted RNA for up to 32 clinical samples in one run with a sample to result within 20 hours. The platform does this by automating PCR, library preparation, sequencing, and bioinformatic consensus genome creation (see Figure 1). The adoption of the Clear Labs Clear Dx SARS-CoV-2 WGS platform, and its turnkey approach, is helping NPHL better serve the residents of Nebraska and ensure that the Nebraska public health system has access to innovative technology that can help identify and manage future health events. Having an automated system builds laboratory capacity because staff and resources can be re-deployed to other testing needs to respond efficiently and effectively during the pandemic. The NPHL has been able to manage the sequencing workload of the entire State with 5 staff members due to the minimal hands-on time needed to set up a run (20-30 minutes) and the automated bioinformatics pipeline that allows staff to quickly analyze the data for a fast turn-around time for results

In addition to sequencing being able to provide information about disease trans-



mission, it was important for public health officials to understand the distribution in the community. NPHL can track the rise and introduction of new variants such as Omicron through information gained from viral sequencing to implement appropriate public health countermeasures for an impacted area or population.

In the Fall of 2020, a novel mutation was detected and clustered to a group of elderly patients who lived in a nursing home. The patients had no symptoms, however, had high viral levels detected suggesting there may be an increase in transmissibility but decrease in virulence. NPHL researchers discovered that a specific mutation in the spike protein was impacting protein structure, conferring decreased virulence. Discoveries like this allow the scientific community to develop a more in-depth understanding of mutations that may have an impact on viral infectivity, pathogenicity, and transmission. Thus, NPHL continues to request and sequence samples across the state to actively monitor and track SARS-CoV-2 as part of pandemic preparedness.

With the onset of the SARS-CoV-2 pandemic, Clear Labs quickly added clinical sequencing to expand beyond its core business of food safety testing to help with the fight against the COVID-19 pandemic. It used its automated platform as the framework for development of two NGS assays, a SARS-CoV-2 diagnostic/strain surveillance assay, and a SARS-CoV-2 whole genome sequencing (WGS) assay. Currently, more than 50% of state public health laboratories (PHLs) use the Clear Dx platform for WGS. The assays have significantly increased the PHLs SARS-CoV-2 sequencing efforts and have aided in the identification and surveillance of existing and emerging strains, such as the Omicron sub lineage, BA.2. Both assays are fully automated and use integrated bioinformatic pipelines to generate high quality consensus genomes.

The Clear Dx platform is custom-built with a PCR instrument and sequencers housed within a robot that automates pipetting, minimizing the requirement for manual pipetting by staff. Once sequences are generated, the data is analyzed through a bioinformatics pipeline that produces raw sequencing data (FASTQ) and high quality assemblies (FASTA) that can be exported for further analysis or to public databases such as the Global Initiative for Sharing Avian Influenza Data (GISAID) and National Center for Biotechnology Information (NCBI), allowing for data sharing with the national and international scientific community in near real time.

There are numerous benefits associated with adopting an automated system:

1. Minimal personnel time required for sequencing set up and analysis, freeing up staff to perform other required tasks in the laboratory
2. Ease in set up and training so that laboratory staff with varying expertise and training have the ability to run the instrument, resulting in minimal disruption in laboratory operations and testing
3. Fast turn-around time (<20 hours) from starting the instrument to obtaining a result, resulting in a faster response to outbreak investigations, variant tracking, and surveillance
4. Increasing the testing volume to meet the demands of the pandemic
5. Reduction in user errors to ensure accurate and consistent results

The clinical community has embraced automation to enhance laboratory capacity and workflow efficiencies. Automation of sequencing will allow for all laboratories to contribute to generating data with regards to pathogens that are seen regularly in the clinical laboratory, such as multi-drug resistant organisms, organisms associated with Hospital Acquired Infections (HAI), and many more. Utilization of NGS on a routine basis will enable collection of data that can help to expand development of more precise clinical diagnostics, new antibiotic formulations, vaccines, etc. to tackle these organisms that continue to affect the health of our communities.

As we are envisioning a future with increased availability of automated solutions, the complement to automating sequencing will be to automate technology-enhanced analytics that have the capability to analyze data in a standardized and accessible fashion. Automation of genomic data analysis can remove the burden of manual analysis to enable faster identification of outbreak clusters; clearer understanding of the course of spread of a pathogen through a hospital or community; predicting the evolution of the pathogen as a form of risk modeling for public health policy decision-making; and many more benefits. In addition, cloud-connected systems can enable near real-time data extraction and insights, minimizing the lag time that currently exists for data consolidation across states. To have an effective national and international pathogen surveillance system, it is important to recognize and overcome the persisting challenges with multi-jurisdictional data stewardship, data privacy protection, and data sharing..

Academic, clinical, and public health laboratories have been integral in the pandemic response through their sequencing efforts. Whole genome sequencing has been an important tool for obtaining insight about SARS-CoV-2 that assisted public health officials design targeted strategies to help minimize the spread and curb the reach of the virus across all communities. The utilization of NGS for SARS-CoV-2 surveillance has been a great asset for the public health and scientific communities. Prior to COVID-19, sequencing was conducted for special projects, and in a limited capacity, due to cost and the extensive time requirement for set up. The pandemic has introduced the necessity for performing sequencing more frequently and for more pathogens. Democratizing genomics through lowering costs, automation, integrated bioinformatics, and a curated public database, paves the way for the establishment of a critical genomic infrastructure that can accelerate rapid data exchange and deliver near real-time pathogen insights to better prepare for future pandemic that may arise.

Ramin Khaksar, Chief Scientific Officer of **Clear Labs,** a supplier of fully automated, next-generation sequencing (NGS) for genomic surveillance and diagnostics

Baha Abdalhamid, MD, PhD, D (ABMM), Assistant Professor, Department of Pathology and Microbiology at the University of Nebraska Medical Center

Photo by Michail_Petrov-96@Getty images

More than cost: The true impact of errors

By Andy Quintenz

The cost of errors and its antithesis, the cost of quality, is often written about in terms of financial impact to medical laboratories and the healthcare system. This article will highlight the human impact of errors, ways in which the errors can occur within the auspices of the laboratory, and the need for more transparency in discussing the challenge in order to reduce the impact.

Medical errors rarely make the headlines and when they do, it's typically coverage of the most catastrophic events. The public tends to think of these as being attributable to errors by overworked and hurried doctors, such as surgery performed on the wrong side of the body, or a cancer missed on a scan, or simply misinterpreting a patient's symptoms.

In 2000, the Quality of Healthcare in America project through the Institute of Medicine published a landmark report titled To Err is Human: Building A Safer Health System in which the extent of medical errors was detailed along with recommendations for improvement. The report reviewed several studies and estimated that between 44,000 to 98,000 deaths occur in the United States each year due to medical errors, leading to national costs between $17 and $29 billion annually. In 2016, the BMJ published a paper detailing a new analysis indicating that medical errors were the third leading cause of death in the United States. It further estimated the number of US deaths annually due to medical error at 250,000 minimum, and as high at 400,000. This range equates to 500–1000 deaths every day.

This data clearly pointed to a national crisis and despite the time between the 2000 and 2016 reports and now, there has been no indication that the trend has been reversed. While the Institute of Medicine categorizes medical errors into four groups: Diagnostic Errors, Treatment Errors, Preventative Errors, and Communication / Equipment or Other Errors, this profession's natural focus is in Diagnostic Errors.

Diagnostic errors

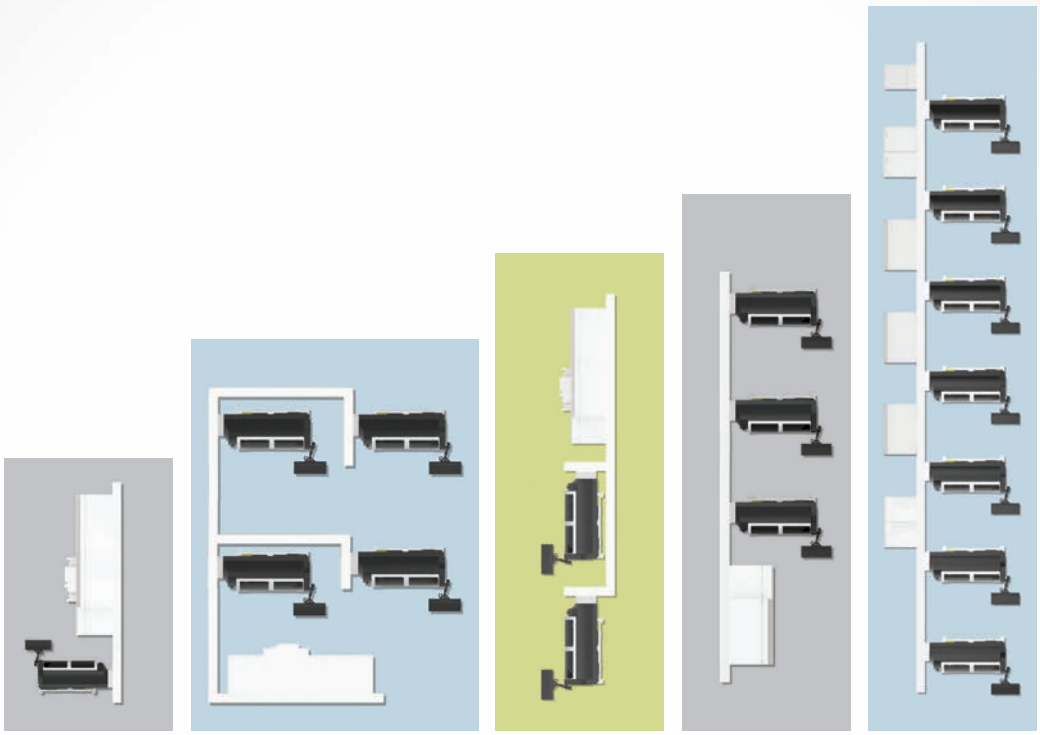
Consider a few real-life stories.

- A couple that had been married for 50 years were healthy except he required blood thinner medication for a treatable heart condition. However, incorrect prothrombin test results led to several increases in his medication. He died shortly after of a brain hemorrhage from over-medication.
- Over 100 patients tested positive for prostate cancer when in fact the test results from a prominent institution were wrong and some patients underwent treatment for non-existent tumors. The problem was later determined to be errors by equipment, personnel, and procedures.
- As part of a routine military physical, a soldier was told he was HIV positive. This led to him and his wife separating. Later the soldier found out he was actually HIV negative and the first test had been incorrect.
- A young couple was proud parents of a baby girl until routine tests cast doubt on the father's paternity. The couple split up over this issue but reunited some years later and had another child. Knowing the first child wasn't his, he insisted on a paternity test. They subsequently learned the first child was his and the original test had been compromised.

In each of the four cases, something went wrong between tests being ordered and clinicians acting upon results. And in each case, the errors led to traumatic experiences for the individuals and families involved, unintentional death, incorrect treatment, or the demise of a relationship.

A diagnostic error is simply an incorrect diagnosis of a patient condition and typically falls into one of four categories: error or delay in diagnosis, failure to

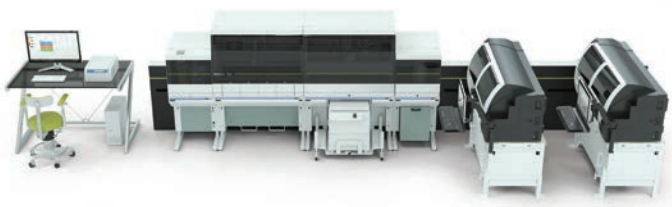
HemoCELL™
SPECIALIZED
LAB AUTOMATION



Hemostasis automation that works on so many levels.

HemoCell delivers workcell efficiency, quality and standardization for Hemostasis labs. Featuring ACL TOP® 750 LAS and HemoHub™ Intelligent Data Manager, it's the only workcell to combine the leading Hemostasis testing system with specialized lab automation. And, because it can be customized to your lab's specific needs, HemoCell lets you design the automation layout that's right for you.

Make your lab a HemoCell lab.



For more information, contact your local Werfen representative.

werfen.com

werfen

> "US deaths annually due to medical error at 250,000 minimum, and as high at 400,000. This range equates to 500–1000 deaths every day. [1]" —Andy Quintenz.

employ indicated tests, use of outmoded tests, or failure to act on results.

In its 2015 report, Improving Diagnosis in Healthcare, the Institute of Medicine estimated that diagnostic error is the cause of 10% of patient deaths, 17% of hospital adverse events, and the leading driver of malpractice claims. Perhaps even more surprising was the report's estimate that, in the US, an individual will be incorrectly diagnosed at least once in their lifetime. This is not just receiving an incorrect diagnosis but that the doctor will also have acted upon it.

It should be noted that not all diagnostic errors originate in the clinical laboratory. The reported statistics include other types of diagnostics such as imaging, diagnostic errors stemming from misinterpretation of results, and diagnosis and treatment with inadequate information. Unfortunately, very few medical institutions have processes in place, or the resources to track diagnostic errors or determine their causes. Therefore, it's unknown how many are attributable to laboratory errors.

Laboratories, hospitals, and clinicians alike are naturally reluctant to share information about diagnostic errors due to the litigious nature of society. While almost every laboratory has experienced a laboratory error being acted upon, it is rare that these are shared outside of the institution, even for the sake of educational enlightenment.

US laboratories routinely run upwards of 500 tests, larger laboratories may have another 500 that are run less frequently. This requires each lab to be able to maintain equipment and competency for up to 1000 tests, and the larger reference labs even twice that, with tests running the gamut of highly automated instrumentation to very manual methods. All of these tests require reliance on equipment and staff performing at the highest level. But instruments fail and human nature being what it is, people make errors as well.

Categories of errors

It's important that laboratorians, and others who are involved in the testing process, understand potential sources of error so they remain alert and bring attention to a situation that needs to be evaluated before reporting out results. Not all errors are created equally. There are errors that are limited in impact, affecting a single or small number of test results, while other errors have the potential to affect a large number, even across days or weeks of testing. Below are examples of these types of errors

Errors that typically affect multiple patients:

- *Lab equipment isn't working properly*. Equipment failures can be small enough to impact sample results without causing an obvious failure. Certain components can begin to react to wear, and will still allow operation but may use an inadequate amount of reagents or cause the calibration to shift.
- *Improper storage or handling of reagents*. Reagents that are left out or stored at improper temperatures may degrade before their expiration dates and lead to incorrect test results until replaced with reagents that have been handled properly.
- *Procedures aren't followed*. A hastily trained employee may not understand a procedure well and apply a shortcut that inadvertently affects all the samples they are running.
- *Samples are not properly handled*. Samples that are collected offsite may be stored properly until pickup or left for courier pickup and then exceed storage temperatures after leaving the facility.

Errors that typically affect a single patient:

- *A sample isn't collected or labeled properly*. The sample may be collected in the wrong tube, it may be poorly drawn and hemolyzed, or not labeled at the time of draw with an incorrect label applied later. In these instances, the impact is to the tests designated to be run on that particular sample tube.
- *Samples aren't properly handled*. This can be caused by not rocking the tube to cause mixing with the anti-coagulant. Excessive vibration from transport can cause hemolysis.
- *Lab testing with time constraints are delayed in running or reading.* Certain tests require samples to be centrifuged or run within a certain amount of time from collection and when not, may lead to incorrect results. Similarly, when a test cartridge that must be read within a specified time period after inoculation is read later than required, may lead to an incorrect result.
- *A test result is entered incorrectly into the patient record, or the wrong record*. Many but not all instruments automatically communicate with an LIS and many test methods require manual entry of results. These can lead to transcription or transposition errors.

Moving forward

Sometimes a single lab test can diagnose a disease but more frequently, several lab tests are used by the clinician to gain insights as to what is happening in the body and aid in the diagnosis. These test results impact the treatment plan a patient receives, such as surgery, medication, or type of therapy. Clinicians use test results as one piece of the puzzle when diagnosing patients but it's a critical piece that provides insights that clinical observation cannot uncover.

As the reports point out, errors will always occur but steps can be taken to reduce their number and their impact.

Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. [It is] a serious concern in healthcare that, if discussed at all, is discussed only behind closed doors. As healthcare and the system that delivers it become more complex, the opportunities for errors abound.

Communication is key. One of the recommendations of the Institute of Medicine is for health systems and laboratories to create an environment where errors and near misses can be discussed and triaged for improvements. These learnings need to be shared, in a blinded way, outside the individual institutions to benefit not only the greater laboratory community but more importantly, for patients' well-being. Staff coming forward and sharing errors and near misses during monthly or quarterly quality reviews should also become standard practice. It's how we all learn.

REFERENCES:

1. Institute of Medicine. Committee on Quality Health Care in America. Kohn KT, Corrigan JM, Donaldson MS, eds. To Err is Human: Building a Safer Health System. Washington, DC: *National Academy Press*. 2000.

2. National Academies of Sciences, Engineering, and Medicine. Balogh, E., Miller, B., Ball, J., eds. Improving diagnosis in health care. Washington, DC: *The National Academies Press*. 2015.

3. Gabler, E. Hidden Errors. Milwaukee Journal Sentinel. May 17-Nov 15, 2015 (series). https://archive.jsonline.com/watchdog/watchdogreports/hidden-errors-360092411.html. Accessed March 21, 2022.

4. Makary M A, Daniel M. Medical error—the third leading cause of death in the US. *BMJ* 2016; 353 : i2139 doi:10.1136/bmj.i2139.

Andy Quintenz serves as Global Scientific and Professional Affairs Manager for **Bio-Rad Laboratories'** Quality Systems Division. He works to promote an understanding of laboratory regulations and best practices as they pertain to QC and EQA/PT programs.

Diagnose foodborne illness in **minutes**, not days

Campylobacter results in 15 minutes with Sofia 2

Accurate, objective and automated results in 15 minutes for *Campylobacter* with Sofia 2 fluorescent immunoassay technology. Detects four of the most prevalent *Campylobacter* species including *C. jejuni, C. coli, C. lari* and *C. upsaliensis* with excellent performance compared to culture.

For more information contact Quidel Inside Sales at 858.431.5814

Sofia 2 Campylobacter FIA

- Simple, flexible workflow with dual mode testing
- Various sample types including fresh, frozen, Cary Blair or C&S
- LIS Connectivity
- Room Temperature Storage

Enhanced diagnostics featuring data analytics and surveillance

with the power of Virena

QUIDEL | Sofia 2 Campylobacter FIA

AD20352100EN00 (02/22)

STATE OF THE INDUSTRY

Best Practices for Lab Management in 2022

Lab professionals focus on staffing

By Kara Nadeau, MLO Features Editor

For our second "State of the Industry" survey topic in 2022, Medical Laboratory Observer (MLO) selected Lab Management Best Practices as its focus. We gathered responses from 189 clinical laboratory professionals with 64% of respondents in director, manager, administrator, or supervisor positions.

The survey results show how the COVID-19 pandemic, continued staffing shortages, and supply chain disruptions have impacted clinical lab operations and revenues. It also reveals some of the most popular approaches for addressing these challenges, from talent recruitment and retainment strategies, to the implementation of automated technologies.

To bring the data to life, we interviewed U.S. clinical laboratory leaders and lab suppliers and service providers to gain their perspectives on the state of the industry. They shared their personal experiences and voiced their opinions on what must change to sustain lab operations moving forward.

Recruiting and retaining staff members

Staff shortages are placing intense pressure on clinical laboratories as they struggle with high demand for testing and the desire among clinicians and patients to get accurate results quickly.

"We've taken a hard hit in staffing levels from losing individuals to retirement, new techs who decided they didn't want to stay in the field, and others leaving for jobs with higher pay," said Aaron Hurst, Laboratory Supervisor for NMC Health in Newton, Kansas.

Tim Schroeder is Director of Lab for Mahaska Health, a 25-bed critical access hospital in Oskaloosa, Iowa. His team of fewer than 20 FTEs runs 24/7 testing for the hospital and for 40+ hospital-based providers through clinics and two satellite facilities, averaging 500,000 tests per year.

"Even before the COVID-19 pandemic, we were four FTEs short," said Schroeder. "Just the raw number of hours we have to cover in a week is 300. I've had three people out at once with COVID for two weeks – a lab assistant and two techs – so everybody must juggle. At times, I've been working benches at 6 a.m. and other days stayed working benches until 7 p.m."

The survey results show that labs across the country are facing these same challenges, with 76% of respondents saying they have had multiple staff members out sick with COVID-19 at the same time, up from 60% in 2021.

Competing for talent

Lab leaders are challenged to retain current staff members as they face fierce competition from other labs offering better pay. Others noted how lab professionals are increasingly leaving the field to pursue careers in other industries with less pressure and better compensation.

Among those surveyed, 27% said their labs experienced budget cuts due to lost revenue from elective procedures and tests, causing temporary staff furloughs and 24% hiring freezes, making it difficult to hire more staff.

Lee Panton

"During the ups and downs of COVID, we would have one week where we'd be flexing people off and making cost cuts, then two weeks later trying to put the same staff members on overtime," said Lee Panton, a recently retired Lab Director from California. "Because of the high cost of living in California, the majority of the laboratory staff have two jobs. During surges, both employers would be asking them to work double. Plus, most were off duty due to COVID exposures at some point."

Panton said larger health systems in her area have been able to increase wages while smaller facilities don't have the resources to match these higher pay rates. Smaller labs were even competing with retail COVID test sites and reference labs for techs during the height of the pandemic.

Quality control is in our blood.

You're meticulous, obsessed, and relentless. And you're proud of it. Patients depend on the reliability of your lab's results, and you won't let them down. That's why you expect the same precision and diligence from your quality control (QC) partner. At Bio-Rad, our obsession with quality has made us the world's #1 choice for independent QC products and services. We won't let *you* down.

Learn more at **qcnet.com**

BIO-RAD

Powering
Exceptional Labs

"We had one local hospital lose three phlebotomists on the same day because they got a $10/hour raise proposal to go to another place. I lost two phlebotomists who left for an extra $10/hour. When the grocery stores were offering an extra $5 per hour in COVID hazard pay, the people in the lab asked, 'What about us?'"

Other major roadblocks to staffing include fewer staff members in non-SARS-CoV-2 areas of the lab, making it difficult to meet turnaround-time goals (44%), fear/anxiety among prospective job candidates about working in a lab during the pandemic (36%), and more staff than usual assigned to the pre-analytical area to keep up with SARS-CoV-2 tests (33%).

"We brought in some recently graduated phlebotomists during the pandemic, but as soon as they saw the PPE they had to wear, they didn't do well and left in fear of the COVID-19 patients they were testing," said Panton.

Real-world solutions to staffing

Continuing education was noted as a popular option for retaining and recruiting staff with 60% of respondents saying their labs have pursued this route, up from 42% in 2021. More than half (53%) said their employers have offered financial incentives (sign-on bonuses, merit allowances, retention bonuses). Other tactics include:

- Partnerships with local colleges and tech schools to offer internships in their labs (44%)
- Shift changes to offer employee scheduling flexibility (44%)
- Efforts to address safety concerns, such as repetitive stress injuries and injuries from sharps (43%)

Panton and her team launched a medical lab technician (MLT) training program five years ago in partnership with two colleges to address staff shortages, taking on four-to-five MLT students per semester. She comments:

"I was told a couple of years ago that, in California, there were 66 graduates of MLT programs entering the workforce each year while there was expected to be 6,500 potential openings in the next five years. Taking on students was not easy on our staff, but once the students had basic training, they were able to be helpful. A lot of schools let students go during the pandemic, but we allowed them to work so they could continue their training."

Hurst says his lab has put in place programs and processes to help grow their own technicians. They provide tuition support and scholarships to phlebotomists who want to go back to school to become lab technicians, provided they stay with them for a specified number of years following graduation. They have also brought in lab aids who can handle basics tasks, freeing up technicians to run tests and discern results.

At Mahaska Health, Schroeder says he has successfully identified and hired technicians through networking both in the U.S. and beyond its borders. He recently hired a local tech recommended by one of his staff members. In his past positions, he had hired techs from the Philippines, and they, in turn, have recommended others for employment. He is currently in the process of hiring two additional Filipino techs.

Of those lab professionals who participated in the survey, 17% said their employers have offered perks, such as free parking, onsite gym, onsite day care, and reimbursement of public transportation costs, to try to recruit and retain staff members.

Panton acknowledged that keeping staff members happy is a challenge, particularly when the lab can't offer higher wages, and shared her approach focused on providing flexibility:

"The lab is dynamic, and personnel is your number one factor. I would put out the schedule six-to-eight weeks in advance while a typical hospital would put it out two-to-four weeks in advance. That way, my staff members had plenty of time to tell me what days they wanted off around their other jobs and personal lives. If they had any desire to make a change, they could trade among themselves without limit. We had to make daily adjustments to workload, but having the template helped everyone significantly."

The establishment of clinical ladders (structures to encourage professional development, such as from novice to expert) is a popular technique for staff recruitment and retainment, with 33% of those surveyed saying their labs have pursued this, followed by implementation of succession-planning processes that offer additional responsibilities to top performers and measure results (22%).

Addressing supply chain disruptions

Two years into the COVID-19 pandemic, the clinical lab industry is still feeling the impacts of supply chain disruptions and shortages.

When asked what best practices they have implemented to address supply-chain issues during the pandemic:

- 58% of respondents said they have utilized multiple testing platforms
- 51% have implemented standing orders (instead of just in time) for crucial supplies
- 47% have worked with state public health officials to gain access to needed testing supplies
- 22% have re-vamped product-evaluation process to measure performance of new supplies and new vendors more accurately
- 19% have switched to reusable types of personal protective equipment (PPE), such as moving from disposable to reusable lab coats

Hurst's lab has implemented multiple platforms to diversify its testing options. That way, if they face

Nova Biomedical's Educational Webinar Series Presents:

Ionized or Total Magnesium levels, What Should We Measure in Critically Ill Patients?

Monitoring and measuring magnesium values are essential to prevent the development of numerous complications in perioperative medicine and critically ill patients. Although current studies suggest that measuring free ionized magnesium (Mg^{++}) is more useful for estimating magnesium status, clinicians often still rely on measurement of total serum magnesium (tMg) to determine if supplemental magnesium is needed. Electrolytes (Na^{+}, K^{+}, Ca^{++}, Cl^{-}) are all currently measured as ions because that is their only clinically active form. Now Mg^{++} can be measured in the same way. Just as ionized Ca (Ca^{++}) is recognized as the standard for assessing Ca status, Mg^{++} is now being recognized as vital in assessing magnesium status, especially in critically ill patients. In this webinar we summarize recent literature to describe why it is better to measure Mg^{++}, not tMg, when assessing magnesium status. We will review the significance of Mg^{++} in different clinical scenarios, and its potential to help improve patient care. We will also discuss whether Mg^{++} predicts clinical outcome, and the advantages and the difficulties in measuring Mg^{++} levels in intensive care patients.

Primary Presenter

Giuliana Scarpati, MD
Department of Medicine, Surgery and Dentistry,
Scuola Medica Salernitana, Unit of Anesthesiology,
University of Salerno, Baronissi, Italy

A Point of Care Method to Measure Ionized Magnesium

The availability of magnesium ion-selective electrode sensor technology with commercial blood gas analyzers now provides reliable measurement of Mg^{++} in a clinical setting. Stat Profile Prime Plus measures Mg^{++} as part of a comprehensive critical menu including pH, gases, electrolytes, glucose, lactate, urea, creatinine, hemoglobin and hematocrit, estimated plasma volume.

Presenter

Germano Ferrari, PhD, MBA
European Director,
Medical and Scientific Affairs
Nova Biomedical

Webinar Dates:

Thursday, June 9th, 2:00 PM ET
Thursday, June 23rd, 2:00 PM ET

Register Now at:

novabiomedical.com/iMgvstMg-mlo

Educational Credits

This program offers 1 hour of P.A.C.E. continuing education credits. Nova Biomedical is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program.

This program has been approved by the American Association of Critical-Care Nurses (AACN), for 1.00 CERPs, Synergy CERP Category A, File Number 24144. Approval refers to recognition of continuing education only and does not imply AACN approval or endorsement of the content of this educational activity, or the products mentioned.

nova® biomedical
novabiomedical.com

allocation or shortages for reagents for one modality, they can switch to another.

"Just-in-time (JIT) inventory during a pandemic is not effective," said Hurst. "Nobody could get enough PCR tests. It has been a nightmare. The number one lesson learned is that labs must be proactive instead of reactive to get what they need."

Getting creative with ordering

Schroeder described how his lab installed a PCR testing platform in December 2020, which his team validated via a Zoom meeting with the manufacturer. At the time, they were only able to secure enough reagents to perform validation testing because the kits were on allocation with the manufacturer. The manufacturer began supplying additional reagents in April/May 2021, but the amount was still not enough to meet the lab's testing demands. Schroeder knew he had to get creative with his ordering strategy.

"I ordered 700 kits (7,000 tests) from the manufacturer, a 500 kit order to ensure that I would receive adequate allocation to perform needed patient testing."

In another case, Schroeder ordered kits for the lab's molecular platform used to run strep screen confirmations. Although the lab was performing 50 of these tests per day, the distributor sent them only 25 tests total.

"I ordered 10 kits (250 tests) from the manufacturer, but they only sent me one kit (25 tests) because they were on allocation. We were performing 40-50 tests/day. I called and talked to my sales rep. He said they only sent one kit (25 tests) because we were a 25-bed critical access hospital, and I explained how our lab does 6,000 strep tests per year and needs 10 kits per week. I got in touch with the testing platform's national product manager, and we were able to place an order for 100 kits (2,500 tests), which is a five-month supply for us. I was told that the company actually brought in people and paid them overtime to fulfill our order."

Collaborating with suppliers

"Labs are always looking to vendors to help them, but it is also important that we help the vendors," said Hurst. "Early in the pandemic, our lab offered to perform studies on COVID-19 tests for the suppliers of these tests. The benefits were all around: The suppliers had a lab to help validate their modalities and we had access to tests for COVID before many others did."


Jillian Bishop

Jillian Bishop, Marketing and Engagement Manager, Electronic Imaging Materials, stressed the importance of suppliers and labs working together to help ensure testing platforms and supplies are available when needed.

"We've found labs and their suppliers need to stay a step ahead of supply chain issues in order to be prepared," said Bishop. "[With regards to labels], the best way to do this is ensuring labels are ordered as early as possible, because many raw material shipments are being delayed and production lead times are extended."

"Another way to prepare is to qualify secondary label materials that withstand your specific lab processes," Bishop added. "Ask your label supplier to identify alternatives to your current labels - then test them thoroughly. If your current materials become difficult to acquire, you'll have another option ready to go."

Bishop says Electronic Imaging Materials sources from multiple suppliers, in multiple geographic locations. They work with their lab clients to provide alternate materials that are equal, if not better, in the event of a supplier stock-out, stating:

"Having a back-up material already chosen and vetted will save you crucial time when you need to reorder. Don't get caught without the necessary labels to keep your lab activities moving."

Balancing costs and reimbursements

As the American Clinical Laboratory Association (ACLA) states, payers have slashed reimbursements for lab services as the costs associated with providing critical laboratory services – including labor, supplies, and transportation – continue to rise.[1]

The survey found labs increasingly implementing new information technology (IT) solutions to help ensure reimbursement covers their costs. This includes:

- Solutions to reduce human error (78% for non-SARS tests, 58% for SARS tests)
- Solutions to help keep current with regulations (71% for non-SARS tests, 59% for SARS tests)
- Analyzers that provide walkaway testing to reduce staffing and FTE hours (76% for non-SARS tests, 53% for SARS tests)

Improving revenue capture

The lack of knowledge and/or IT systems to bill for services correctly is a major challenge to lab revenue, according to Jim O'Neill, Laboratory Services Business Development Manager, Advanced Data Systems. He stated:

"Many laboratories have not integrated their laboratory information system (LIS) and billing and financial system appropriately, causing workflow issues and lost or dropped charges between the LIS and billing vendor. This represents billions of dollars a year that labs are losing when charges don't come over from the LIS to the billing system."

The survey results correlate to O'Neill's observations, with 40% of respondents citing lack of interoperability between their LIS and revenue

Get more time back for yourself with QIAstat-Dx

Sometimes it feels like there aren't enough hours in the day. And with staffing shortages, your diagnostic lab can be pushed to its limits. But the sample-to-answer QIAstat-Dx® Analyzer can help you take back control of your lab and stay in step with clinician needs.

- One patient sample, multiple viral and bacterial pathogen targets
- Results in about an hour
- Fully automated, easy to pick up and use

Learn how you can simplify your diagnostic testing at **www.QIAstat-Dx.com**

Ordering **www.qiagen.com/shop** | Technical Support **www.support.qiagen.com** | Website **www.qiagen.com**

Sample to Insight


Jim O'Neill

cycle management software as a stumbling block, 38% lack of software to automate tracking/analysis of costs, and 37% insufficient staff time.

O'Neill says another roadblock to reimbursements is the inability of labs to collect, from referring physicians, appropriate and complete information required by payers, including medical notes.

"Labs must look at their internal systems to make sure their LIS front end system or their middleware company has the appropriate tools to collect the required billing information to get paid from the different payers," he said. "They should look at integrating data to flow from the LIS or middleware vendor to the billing company with regards to lab reports, requisitions, and doctor and patient chart information/medical notes."

Coding frustrations and modifications also continue to challenge lab professionals, with 80% of survey respondents indicating they had taken steps to alleviate these issues, including the creation of standard lab processes and staff education materials (78% for non-SARS and 66% for SARS testing) and standardized instrumentation workflows and checklists (77% for non-SARS and 57% for SARS testing).

Higher deductibles and co-pays mean more lab revenue is coming directly from the patient, and labs struggle financially from patients not paying their bills in a timely manner, according to O'Neill. He says staffing shortages have forced labs to get more creative with how they attempt to collect on these payments, stating:

"More labs are sending patient notices via text and email as an alternative to lab billing staff stuffing hundreds, if not thousands, of envelopes on a weekly or monthly basis and paying higher postage rates to mail them."

Uncovering new savings opportunities

Those surveyed said they are also finding new savings opportunities to help maximize reimbursements and revenue. The majority (81%) said they have adopted processes to review savings opportunities for non-SARS testing, such as evaluating analyzers on a regular schedule (46% for SARS testing). The implementation of ongoing waste and efficiency studies to find potential savings in overhead is another key initiative among lab professionals, with 79% having taken this action for non-SARS testing (43% for SARS).

With regards to efforts to improve inventory control and consumable supply costs:

- 75% evaluated inventory levels for basic supplies, such as assays and controls/reagents
- 53% worked with supply chain management on supplies that are on group purchasing organization (GPO) contracts that offer additional savings
- 37% developed supply utilization tracking and record keeping
- 36% worked with other members of the organization, such as the Chief Medical Officer (CMO) and physicians, to standardize test ordering throughout the organization
- 19% implemented vendor-managed ordering
- 15% developed ongoing review comparing supply reports to the number of invoiced tests
- 13% gained access to electronic inventory tracking from the supply chain/materials management department
- 10% implemented lease agreements that do not include volume commitments

"Labs can't control consumable supply costs, but they can use nontraditional vendors if they perform the proper vetting," said Hurst. "We were able to get many needed supplies this way."

Implementing new tests and technologies

When asked what technologies their labs prioritize in their capital budgets, 68% said technology needed to improve quality/reduce costs, 53% technology needed to remain competitive, 48% technology needed to cover staff shortages with automated equipment, and 45% technology needed to cover broken equipment.

Hurst said his lab's implementation of an automation line in December 2019 has helped the team navigate the challenges of the pandemic in terms of high testing volumes and low staffing levels. The lab has long seen the value of automation, having automated its blood bank to be completely paperless back in 2007.

The survey findings revealed that close to one-quarter of labs had automated manual processes in the pre-analytical phase of testing (24%). A similar number had implemented evidence-based test utilization backed by data (24%) and/or implemented a pre-approval program for tests that are send-outs (23%). Slightly fewer (17%) had purchased additional centrifuges to reduce bottlenecks in testing workflows.

As for best practices around adopting new tools for laboratory automation, such analyzers or software, 63% said they have analyzed workflow processes for proper space planning, 51% involved the IT department early in the process, and 29% designated a project manager to coordinate short- and long-term planning and implementation with the vendor.

With lower revenues and less money to invest in new technologies, lab leaders must do their best to ensure their equipment upgrades deliver the desired results. Corinne Fantz, PhD, Vice President, Chief Medical Partner, Core Lab and Point of Care, Cardiometabolism and Neurology Network at Roche Diagnostics North America, offers the following recommendations when evaluating analyzers.

LumiraDx™

Not all Antigen Tests are Created Equal

The LumiraDx SARS-CoV-2 Ag test utilizes next-generation microfluidic technology, bringing lab-comparable performance to the point of care.

- 97.6% positive agreement to RT-PCR • Results in minutes
- Authorized for use within 12 days of symptom onset and for asymptomatic screening
- Low-waste consumable • CLIA Waived*

Scan to learn more.
lumiradx.com

*The LumiraDx SARS-CoV-2 Ag test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

LumiraDx SARS-CoV-2 Ag test has not been cleared or approved by FDA. The LumiraDx SARS-CoV-2 Ag test has been authorized by FDA under an EUA only for the detection of SARS-CoV-2 nucleocapsid protein. The test has not been authorized for use to detect any other viruses or pathogens. The test is authorized in the United States for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

S-COM-ART-02381 R1 2022/04

"Every test result impacts patient care. Lead with the medical value of the tests you want to offer – tests that provide quality results. Performance stats beyond best case scenarios may be difficult to come by, but be sure to ask your vendors about mean up time and recalls in addition to the number of tests per hour."


Corinne Fantz, Ph.D

Fantz recommends that labs consider their institution type and size when evaluating analyzers. "[Question] whether the reagents can be shared across a family of instruments to be more efficient and harmonized to share reference intervals at sister hospitals to reduce interpretation error and improve patient safety."

"Menu can impact efficiency," Fantz added. "If you need a second analyzer to run a complete panel of tests, that is likely to make your lab less efficient and cost more. If the test needs to be sent out, delays could impact the patient and increase the chance the result is lost or never seen by the ordering provider."

With regards to improvements in the quality and efficiency of testing, more than half of those surveyed (65%) said they had standardized test ordering procedures and formularies, while 32% said they had programmed hard stops or other functionality into electronic health records (EHR) systems to guide physicians' test-ordering practices.

An important step in introducing new software is verifying that changes do not detrimentally impact patient results, according to Fantz. She states: "Human factors engineering and consulting with your manufacturer may help labs consider implementing the right safeguards necessary to ensure patient safety."

Training staff on new technology

As staffing shortages are a major challenge throughout the industry, we asked lab professionals what best practices they have developed to train staff on new software.

At the top of the list was the creation of standard workflows for all lab employees (60%), followed by the creation of a train-the-trainer model (52%). Also noted was the development of mandatory training for new lab employees that is led by the IT department (25%), development of lunch-and-learn training sessions (15%), and sending a lab person to laboratory information system (LIS) school to develop an in-house expert (14%).

With high staff turnover rates, lab leaders must also take into consideration the training of new staff members on equipment, both old and new, to maintain the quality and efficiency of operations despite changes in personnel.

"Many lab techs point to having a very strong training process that encourages repetition of tasks under supervision, before they begin to do tasks without supervision," said Maggie Morrissey, Director, Recruiting and Staffing Services, Lighthouse Lab Services. "Regardless of the new employee's experience, sometimes one lab might practice one technique and one lab might use a different technique. Making sure that lab staff/management is always available for questions or concerns and encouraging questions be asked to prevent mistakes from being made."

Making improvements for the road ahead

Clinical labs will likely continue to struggle with staff shortages and supply chain disruptions for quite some time, and nobody can predict the trajectory of the COVID-19 pandemic. When asked for their recommendations on how to alleviate the burden of these challenges moving forward, those interviewed offered these thoughts.

Improve lab culture

Work culture is one reason why lab professionals leave one employer and go to another, says Morrissey. She recommends labs take steps to establish cultures that appeal to staff members' both personally and professionally.

"We often hear candidates say they don't want to work at specific companies because of poor culture," said Morrissey. "Reevaluating culture, benefits offered, and other 'soft' aspects can really help with attracting new talent. One Lab Tech told me: 'They need to make the work environment more exciting. Do fun activities for lab week. Have a free lunch once a month or every other week for the employees. Also, make sure employees are not sitting around doing nothing for hours. Make sure there is a plan set, so techs know what they are going to do from the moment they clock in.'"

Further define career paths

Panton says most of the MLT students who participated in her former lab's training program expressed interest in becoming clinical laboratory scientists (CLS), but the state of California doesn't currently have a clear pathway to transition from MLT to CLS. She encourages the development of these career pathways, explaining how her team took steps in this direction:

"About halfway through MLT student training, we gave them the opportunity to work as clerks so they could learn the front desk. Some wanted to learn phlebotomy, too, so that helped. When they graduated, they took their exams, and many stayed about 18-to-24 months so they could get into CLS programs and be potential CLS for us to hire upon graduation."

Increase lab automation

Hurst expressed his surprised at how so few labs, similar in size to his, have embraced automated

K-ASSAY® *The Assay You Can Trust*

Immunoassay Reagents for chemistry analyzers

Looking for a D-Dimer assay for your chemistry analyzer?

Now there's a solution!

Featuring the K-ASSAY® D-Dimer reagent

- Ready to use on most popular chemistry analyzers.
- Researchers are studying D-Dimer as a biomarker for COVID-19 disease severity/mortality.
- D-Dimer aids in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring the therapy for disseminated intravascular coagulation.
- D-Dimer is also used for excluding deep venous thrombosis.
- Contact us now and see how you can run D-Dimer on your chemistry analyzer!

Over 40 other chemistry analyzer assays available

Liver
α-1 Anti-Trypsin

Nutrition/Anemia
Ferritin
Haptoglobin
Prealbumin
Retinol Binding Protein
Transferrin
UIBC

Cardiovascular
Cystatin C
Fibrinogen
hs-CRP

Lipid
Apo AI
Apo AII*
Apo B
Apo CII*
Apo CIII*
Apo E*
Lipoprotein(a)
Remnant Lipoprotein
Cholesterol*

Coagulation
D-Dimer
Factor XIII
Fibrinogen
Plasma FDP*
Serum FDP*
Urine FDP*

Lung
α-1 Anti-Trypsin
KL-6*

Inflammation
α-1 Acid Glycoprotein
Anti-Streptolysin O
β-2 Microglobulin
Complement C3
Complement C4
CRP
hs-CRP
Rheumatoid Factor

Diabetes
Hemoglobin A1c
Insulin
Microalbumin
Microtransferrin*

Immunology
IgA
IgG
IgM
Total IgE

Kidney
α-1 Microglobulin
β-2 Microglobulin
Cystatin C
Microalbumin
Microtransferrin*
Urine FDP*

Stomach
H. pylori Antibody*

*Note: Assays marked with * are for Research Use Only in the U.S.*
All others are FDA-cleared for IVD use.

KAMIYA BIOMEDICAL COMPANY
A Nittobo Group Company

www.k-assay.com/MLO.php
diagnostics@k-assay.com
800-KAMIYA-5 | 800-526-4925

technologies. He says automation of lab processes has "really saved" his lab during the pandemic, and encourages others to do the same, stating:

"If you don't think you can afford it, you can."

"Front-end automation, no reagent preparation, minimum number of calibrations, and quality control, middleware, and automated storage and retrieval can help labs address staffing challenges," said Fantz. "But labs aren't commodities. Behind every test, is a patient and behind every test result, is a laboratorian. Together, operational efficiencies, quality instruments and assays coupled with digital solutions and dedicated laboratory professionals deliver the highest quality patient care."

Diversify suppliers

"They say be loyal to your main distributor, but at the same time I have had to buy things from anybody and everybody to keep the lab running," said Schroeder. "You have to be loyal but also think outside the box."

Schroeder recommends leveraging existing relationships with distributors and manufacturers, but at the same time, exploring new partnerships. He says when a lab is facing supply shortages, it can be hard to establish a new relationship with a distributor or manufacturer in the moment. Instead, he suggests labs be proactive and place orders with various suppliers on a regular basis. That way, those suppliers will be there when the lab needs them.

Secure RCM support

O'Neill says revenue cycle management (RCM) is a top concern and challenge among Advanced Data System's lab clients. Staff shortages make it harder to manually process billing and keep up with payers' changing requirements. He sees more labs engaging with RCM service providers to perform these tasks on their behalf.

"The comments we are hearing from customers are number one staffing shortages, then the lack of system integration, and lack of experience with regards to correct panel coding and keeping up with regulatory changes with the insurance companies," said O'Neill. "In the past year, we have had a 37% increase in customers requesting RCM service versus licensing our product to do their own billing in house."

REFERENCES

1. Reimbursement & Coverage, American Clinical Laboratory Association (ACLA), https://www.acla.com/reimbursement-coverage/

American Proficiency Institute

API DataDirect

Eliminate the #1 cause of Proficiency Testing failures, **Clerical Errors!**

UPLOAD YOUR PROFICIENCY TESTING RESULTS WITHOUT AN INTERFACE!

- Automated mapping of test names
- Quantitative and Qualitative results
- No middleware or software installation
- No additional cost - it's free!

Over 5 million results have been successfully uploaded using this revolutionary technology! The process is simple:

Register PT Samples in your LIS → Order and complete testing → Export PT data & save in a file → Upload the file to API → Review & submit results

DataDirect utilizes the ability of your LIS to run a report and create a data file which is uploaded on API's website.

Not an API customer? Take API for a Test Drive.

Sign up to receive free Chemistry PT samples and CE credits for your entire lab!

Call a Key Accounts Specialist at 800-333-0958 or email KeyAccounts@api-pt.com to enroll.

Find out more at
api-pt.com

Supply limitations, now and in the future

By Gail Castanho, MLO Managing Editor

Forecasting supplies for laboratories and hospitals, post pandemic, is a complex task, involving a complicated bag of tricks. Suppliers are also gravely affected by the shortages, always conscious of the needs of their customers.

The Center for Biologics Evaluation and Research (CBER), within the FDA that regulates biological products for human use under applicable federal laws, identifies shortages of biologics as a threat to public safety.

"CBER's Office of Compliance and Biologics Quality (OCBQ) directs the CBER-regulated product shortage program, which includes product discontinuations. [Currently,] shortages of drugs and biologics pose a significant public health threat, delaying, and in some cases even denying, critically needed care for patients."[1]

With significant challenges, due to shortages, supply forecasting and acquisition require laboratories and hospitals to examine a number of different categories in order to acquire necessary supplies to effectively complete the tasks at hand.

Causes of shortages

The FDA is aware of the shortages, brought on by the pandemic, and explains the causes and possible other scenarios.

In a January 2022 news release entitled *Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel*, the U.S. Food and Drug Administration (FDA) stated that it"is aware the United States is experiencing significant interruptions in the supply of several blood specimen collection (blood draw) tubes because of an increase in demand during the COVID-19 public health emergency and recent vendor supply challenges. The FDA is expanding the medical device shortage list to include all blood specimen collection tubes."[2]

Photo by PeopleImages @ Getty images

In another article, *CBER-Regulated Products: Possible Causes of Shortages*, the FDA introduces the possibility of additional causes for supply shortages.

"Quality problems at the manufacturing facility are the most common causes of CBER-regulated product shortages. Other causes of product shortages include increased demand, corporate delays in manufacturing or shipping, distribution disruptions, production changes, unavailability of component materials, new indications, decisions to discontinue the product, or natural disasters,"[3] the FDA article states.

Laboratories/Hospitals:

Inventory management

Focusing on inventory management, storage and distribution, introduction of new products, the ever-changing COVID-19 pandemic outlook, and best practices that include future pandemic readiness, laboratories forge ahead with the purchasing of supply inventory and assembling a stockpile of supplies, ever mindful of unexpected events and emergency situations, similar to the COVID-19 outbreak.

Sarah Bower, MPA, MT (AMT), Laboratory Manager, Mary Greeley Medical Center, in Ames, IA, when asked who, on her team, is responsible for inventory management, replied,"We have 6-7 staff in our lab who are licensed in our system to order supplies, based on KanBan principles. After an order is placed in the online ordering system, it is routed to the email of the manager or director to approve. Very high dollar amount purchases may also be approved by administration. The buyer responsible for lab products then places the order and also notifies us any time she is made aware that a supply is on backorder."

Sarah Bower, MPA, MT (AMT)

Implementing the KanBan principles, a visual system that manages inventory control, Bower and her laboratorians are able to diagnose the potential upcoming hardships related to the ordering of necessary supplies. A Kanban bin system for inventory management, uses two bins in your supply area to visually see when it's time for restock. In general. When the first bin of materials or work-in-process is empty, it's time to reorder or restock.

Storage and distribution

Determining and forecasting, the PAR levels of supplies within the laboratories require the utilization of data in order to determine test volumes.

Bower states,"The laboratory is responsible for determining our PAR levels for lab supplies. This is done using data from our Slicer Dicer app within Epic (to determine test volumes) and also by reviewing past ordering frequencies."

Introduction of new products

When introducing new products into the laboratories and hospitals, procedures must be followed to ensure a smooth transition for all members of the staff.

According to Bower, Mary Greely Medical Center is lucky to have a purchasing agent who worked in the laboratory, prior to her current position, with a good understanding of lab supplies. When asked about the procedure for introducing new products, Bower said,"Under normal circumstances, when a brand-new product is introduced, laboratory staff try the product and then fill out an evaluation form, prior to integrating the product. Their input is instrumental to the process."

Bower said an area where the laboratory was forced to integrate new testing products and supplies involved COVID-19 testing. She stated,"This affected nursing as well as the lab.

Medical Device Shortages During the COVID-19 Public Health Emergency

Category	Product Code (Description)	Availability and Estimated Shortage Duration[2]	Additional Information	Reason for Interruption (per 506J)	Date (YYY/MM/DD)[3]
Laboratory Reagents and Testing Supplies - Testing Supplies & Equipment	JJH (Clinical sample concentrator)	• Limited supply available. • Estimated for duration of the COVID-19 Public Health Emergency.	In an effort to mitigate ongoing shortages, the U.S. government continues to support mitigations including alternatives (see COVID-19 Testing Supplies FAQ).	Demand increase for the device	2020/08/14 Initial 2022/02/04 Reverified
Laboratory Reagents and Testing Supplies - Testing Supplies & Equipment	NSU (Instrumentation for clinical multiplex test system)	• Limited supply available. • Estimated for duration of the COVID-19 Public Health Emergency.	In an effort to mitigate ongoing shortages, the U.S. government continues to support mitigations including alternatives (see COVID-19 Testing Supplies FAQ).	Demand increase for the device	2020/08/14 Initial 2022/02/04 Reverified
Laboratory Reagents and Testing Supplies - Testing Supplies & Equipment	PPM (General purpose reagents for in vitro diagnostic tests, including pipette tips[4])	• Limited supply available. • Estimated for duration of the COVID-19 Public Health Emergency.	In an effort to mitigate ongoing shortages, the U.S. government continues to support mitigations including alternatives (see COVID-19 Testing Supplies FAQ).	Demand increase for the device	2020/08/14 Initial
Specimen Collection, Swab - Testing Supplies & Equipment	KXG (Absorbent tipped applicator)	• Limited supply available. • Estimated for duration of the COVID-19 Public Health Emergency.	In an effort to mitigate ongoing shortages, the U.S. government continues to support mitigations including alternatives (see COVID-19 Testing Supplies FAQ).	Demand increase for the device	2020/08/14 Initial 2022/02/04 Reverified

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency

Our microbiology section head worked tirelessly to ensure lab staff were trained very quickly…because we still had to meet CLIA regulations with respect to introducing new tests. To keep all lab staff apprised of ongoing changes, we formed a channel in MS Teams called "COVID" and also devoted one of our white boards in the lab to just COVID related updates. We also communicated change of testing supply information to the nursing leaders of all affected departments."

Changes due to COVID-19 pandemic

The COVID-19 pandemic illuminated supply shortages, wreaking havoc on laboratories and hospitals. Fortunately, the evolution of hyper-awareness and ingenuity became the norm for those labs that continued to provide necessary testing during a most difficult time.

COVID-19 brought unprecedented challenges to clinical laboratories. While U.S. labs strove to provide quality and accurate test results in the face of 2020's adversity, the uncertainty and lack of supplies were a significant hurdle, hindering day-to-day laboratory operations and the ability to increase testing capacity.

According to the article, *Supply Shortages Impacting COVID-19 and Non-COVID Testing,* "the uncertainty and lack of supplies were a significant hurdle, hindering day-to-day laboratory operations and the ability to increase testing capacity."[4]

"In 2020, ASM partnered with the Association of Supply Chain Management to collect testing supply status for both COVID-19 tests, as well as other microbiological tests to highlight, and ultimately alleviate, these debilitating supply chain issues. Starting Sept. 11, 2020, ASM began independently collecting shortage data directly from clinical labs using the Clinical Microbiology Supply Shortage Collection (CMSSC) tool, drawing attention to the data provided by laboratory directors, and practicing clinical microbiologists without external influence. This data reflects shortages of medium, reagents, collection devices and consumables that significantly impacted day-to-day testing for both COVID-19 and other infectious diseases during the time period of Sept. 11, 2020 to Jan. 15, 2021."[4]

"147 CLIA-certified labs responded to the survey across the U.S. The CMSSC tool results also show the following non-COVID-19 shortages:

- 35.1% of labs have a shortage of supplies for the molecular detection of sexually transmitted infections.
- 47.5% of labs have a shortage of supplies for detection of routine bacteria (including the bacteria causing strep throat, pneumonia, bronchitis, and urinary tract infections).
- 29.4% of labs have a shortage of supplies for mycobacteria testing (including supplies for tuberculosis (TB), Buruli ulcer and pulmonary nontuberculous mycobacterial disease testing).

- 8.8% of labs have a shortage of supplies for routine parasite testing.
- 19.4% of labs have a shortage of supplies for routine fungal testing (ranging from superficial, localized skin conditions to deeper tissue infections to serious lung, blood (septicemia) or systemic diseases)."[4]

When asked if her laboratory's process of acquiring and/or integrating supplies has changed since the COVID-19 pandemic, Mary Greeley's Bower replied, "We still tend to utilize our KanBan system for most supplies. However, any item which has been subject to a backorder receives special treatment. We may order more than our usual number of the product, or order more frequently, depending on the advice of our buyer in the purchasing department. We have become much more "tuned in" to laboratory news with respect to national shortages."

Best practices and future pandemic readiness

Having experienced the COVID-19 pandemic, and the effects of supply shortages, the idea of a preparedness plan seems likely, and necessary, at the same time. Mary Greeley Medical Center is among those laboratories that is continuously working to institute such a plan, based on the awareness brought about through the COVID-19 pandemic. Additionally, the pandemic shown a light on collaboration with borrowing and sharing supplies among labs and hospitals and creating partnerships.

"We have not yet determined a definite plan for future pandemic readiness as it relates to supplies. However, one thing that became very apparent to us was that our collaborative relationships with nearby clinics and hospitals was instrumental to effectively managing unexpected shortages. We were able to loan blue top tubes to a very large hospital who otherwise would not have been able to get them at all. When we ran perilously low on purple and green top tubes, we received small loans of tubes from several other institutions that helped us make it to the next shipment," Bower said.

To help laboratories deal with supply shortages, The Choosing Wisely program was created, which is an initiative of the ABIM Foundation that focuses on avoiding unnecessary medical tests, treatments, and procedures.[5]

"Programs such as Choosing Wisely, and other laboratory medicine stewardship guidelines, have been designed around the patient-centric and fiscally prudent principle of reducing testing that adds no value to patient care, and that even may be associated with increased risks…COVID-19 supply chain issues have clearly created a healthcare crisis, including for the practice of laboratory medicine. But this crisis presents laboratorians with a golden window of opportunity to initiate or strengthen our effective test utilization and laboratory stewardship efforts, using Choosing Wisely and other guidelines as a foundation for engaging in interdisciplinary organizational discussions."[6]

Suppliers/Vendors:

Managing the needs of laboratories

Lee H. Hilborne, MD, MPH, FASCP, DLM(ASCP)CM, and colleagues, in an article entitled, *Laboratory Supply Shortages: Turning Crisis to Opportunity*, wrote, "as the pandemic continues to ravage the global medical community, supply chain issues have introduced new challenges that extend far beyond COVID-19 testing. Shortages of specimen tubes, personal protective equipment, and other common laboratory consumables threaten access to all aspects of diagnostic testing."

Vendors, as suppliers for laboratories and hospitals, also have been affected by the upheaval occurring, due to shortages and the pandemic. Fortunately, not all suppliers have experienced, or have been negatively affected by current pandemic-type shortages.

Richard Noel, Marketing Director, North America, Lumira DX, a supplier of COVID-19 antigen tests, was asked, "What are you doing to manage labs' needs?" Responding, Noel said his company has been fortunate and has never had "to put any customers on allocation or gone on backorder for the SARS-CoV-2 Antigen Test."

As a way to explain, Noel referred to the company's "innovative test strip manufacturing process…and automated manufacturing lines that can produce tens of millions of tests per month."


Richard Noel

While Noel's experiences regarding the on-going supply chain in the pandemic and post-pandemic timeframe are notable, they are not the norm, for suppliers. Because of the long-standing difficulties brought on by the shortages, government agencies have stepped in with suggestions for buffering such adversities.

Recommendations

For the time being, while pandemic shortages still exist, the FDA has provided recommended strategies for the conservation of supplies.

The FDA recommends healthcare providers, laboratory directors, phlebotomists, and other personnel consider the following conservation strategies to minimize blood collection tube use and maintain quality and safety of patient care[2]:

- Only perform blood draws considered medically necessary.
- Remove duplicate test orders to avoid unnecessary blood draws.
- Avoid testing too frequently or extend time intervals between tests whenever possible.
- Reduce tests at routine wellness visits and allergy testing only to those that target specific disease states or where it will change patient treatment.
- Consider add-on testing or sharing samples between laboratory departments if previously collected specimens are available.
- If you need a discard tube, use a tube type that has a greater quantity available at your facility.
- Consider point of care testing that does not require using blood specimen collection tubes (lateral flow tests)

REFERENCES:

1. CBER-Regulated Products: Shortages and Discontinuations. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-shortages-and-discontinuations
2. UPDATE: Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel. https://www.fda.gov/medical-devices/letters-health-care-providers/update-blood-specimen-collection-tube-conservation-strategies-letter-health-care-and-laboratory
3. CBER-Regulated Products: Possible Causes of Shortages. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-possible-causes-shortages
4. Supply Shortages Impacting COVID-19 and Non-COVID Testing. https://asm.org/Articles/2020/September/Clinical-Microbiology-Supply-Shortage-Collecti-1
5. ABIM Foundation, https://www.choosingwisely.org/
6. Lee H Hilborne, MD, MPH, FASCP, DLM(ASCP)CM, Greg Sossaman, MD, MACSP, Barbara Caldwell, MS, MASCP, MLS (ASCP)CM, SHCM, et al. Laboratory Supply Shortages: Turning Crisis to Opportunity. *American Journal of Clinical Pathology*, aqac035, https://doi.org/10.1093/ajcp/aqac035.

VA Western Colorado Health Care System

is recruiting a certified MEDICAL TECHNOLOGIST

The VA Western Colorado Healthcare System is one of the leading health care systems serving Veterans in the Rocky Mountain Region. We're an innovative care center within the Veterans Integrated Service Network 19 (VISN 19), which spans 540,000 square miles across 10 states. VISN 19 includes medical centers in Aurora and Grand Junction, Colorado; Fort Harrison, Montana; Cheyenne and Sheridan, Wyoming; Salt Lake City, Utah; and Oklahoma City and Muskogee, Oklahoma; and 123 other health care sites.

We currently have an opportunity for a certified (ASCP-BOC, ASCP-BOR or AMT) Medical Technologist with excellent diagnostic and communication skills to join a hospital-based practice.

Our CAP and AABB Accredited Clinical Laboratory Lab encompasses all Pathology Disciplines including Microbiology, Biochemistry, Special Chemistry, Hematology, Immunohematology, Surgical Pathology and Cytopathology.

Grand Junction is a city in Colorado's Western Slope region. It's known as the hub of Colorado's wine country. The city boast a quality of living that is unmatched across the region. Mild winters that are great for year-round hiking, biking, trail walking/running, and you are just short drives from major ski resorts and spas.

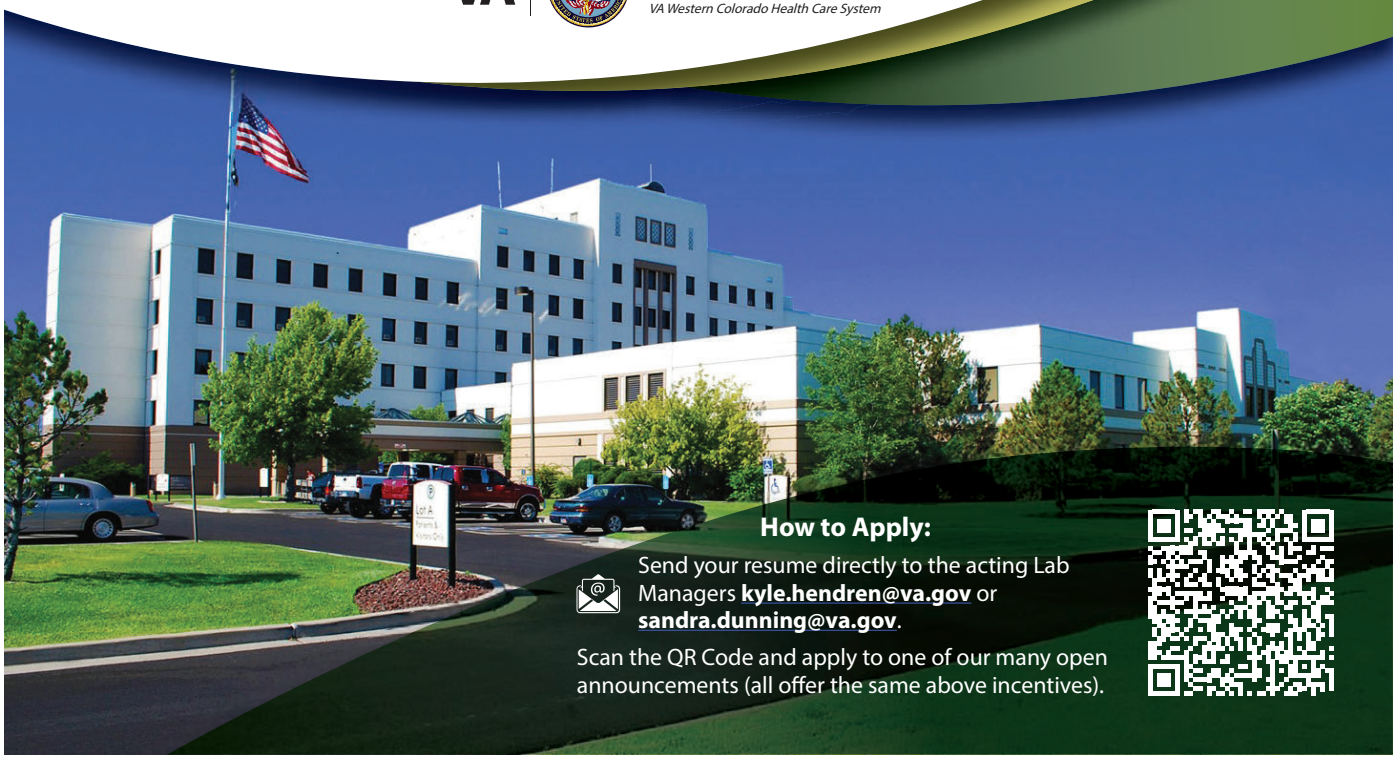
For more information, visit www.visitgrandjunction.com.

Job Description:

Medical Technologist works throughout the lab as a generalist and works the night shift, weekends, and holidays by themselves when priorities demonstrate a need. Duties include, but are not limited to:

- Performs testing procedures on a variety of biological specimens and/or environmental samples using manual and automated techniques
- Requires competency in the areas of Blood Bank, Hematology, Chemistry, Coagulation, Microbiology, Serology, Special Chemistry and Urinalysis
- Monitors the quality control systems
- Ensures timely and thorough evaluation of data, ensures discrepancies are identified and attended by troubleshooting instrument performance and/or QC material performance
- Performs, evaluates, interprets, correlates, and validates the accuracy of laboratory procedures and results

U.S. Department of Veterans Affairs
Veterans Health Administration
VA Western Colorado Health Care System



How to Apply:

Send your resume directly to the acting Lab Managers **kyle.hendren@va.gov** or **sandra.dunning@va.gov**.

Scan the QR Code and apply to one of our many open announcements (all offer the same above incentives).

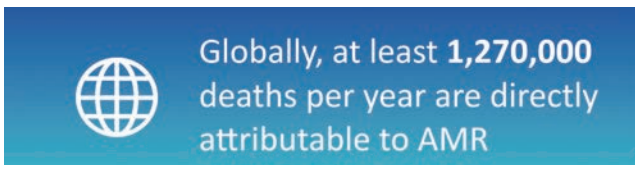
The silent pandemic is no longer silent

By Diane Flayhart, MBA

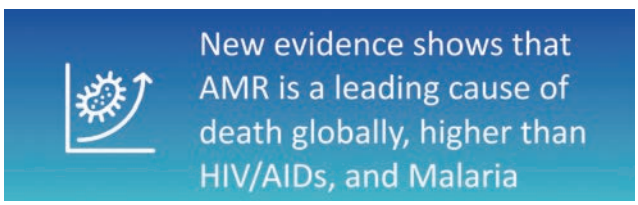
Since the introduction of penicillin in 1942, antimicrobials have transformed the treatment of infections and have saved millions of lives. But decades of misuse and outdated guidelines have driven a rise in the organisms that are resistant to these lifesaving drugs.

Antimicrobial resistance (AMR)—bacteria's ability to overcome the effects of the drugs designed to kill or disarm them—is one of the world's greatest public health threats. Today, at least 1.27 million deaths worldwide are attributed to resistant bacterial infections per year, and this number is growing.[1]

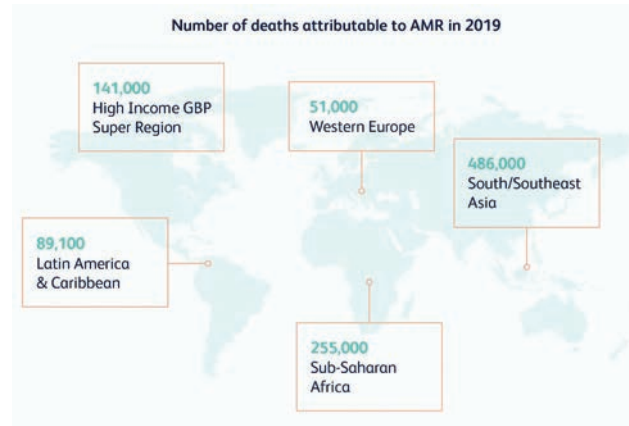
According to the Centers for Disease Control and Prevention (CDC), in the United States alone, more than 2.8 million antibiotic-resistant infections occur each year; in fact, someone dies every 15 minutes from a drug-resistant infection.[2] As it continues to increase rapidly across the world, AMR is considered a "silent pandemic," which actually threatens modern medicine. As the pathogens that cause infections become increasingly drug-resistant, common medical procedures—including surgery, childbirth, and chemotherapy—will become increasingly life-threatening. Put into perspective, if left unabated, the effects of AMR could be worse than COVID-19.[3] Future projections suggest AMR could result in millions of deaths and trillions of dollars in lost global production.[4] A recent publication, *Global burden of bacterial antimicrobial resistance in 2019*: a systematic analysis, provided in-depth insights into the global burden of drug resistant infections. It is a comprehensive assessment of the global burden of AMR, as well as an evaluation of the availability of data. The paper uses several sources for the data and an estimation model to determine rates for regions that did not have complete data resources. In total, 471 million individual records or isolates covering 7585 study-location-years were used as input data to the estimation process.



There were an estimated 4.95 million (3.62–6.57) deaths associated with bacterial AMR in 2019, including 1.27 million (95% UI 0.911–1.71) deaths attributable to bacterial AMR. This data clearly demonstrates that bacterial AMR is a leading global health issue. These numbers also make AMR more deadly than such leading infectious disease threats as malaria and HIV/AIDS.The analysis showed that AMR all-age death rates were highest in some low and low middle income countries (LMICs), making AMR not only a major health problem globally but a particularly serious problem for some of the poorest countries in the world.



The analysis assessed burden of resistance by region, as well as by type of organism causing the infection and the source of the infection. By region, Sub-Saharan Africa had the highest burden (27.3 deaths per 100,000 attributable to AMR and 98.9 per 100,000 associated with AMR), followed by South Asia (21.5/100,000 attributable and 76.8/100,000 associated deaths). In comparison, high-income regions had an AMR-attributable death rate of 13/100,000 and an AMR-associated death rate of 55.7/100,000. The lowest regional AMR burden was in Australasia (6.5/100,000 attributable and 28.0/100,000 associated deaths).



A broad analysis of pathogens causing disease was completed. There were six AMR pathogens that caused 929,000 of the 1.27 deaths attributable to AMR. The six pathogens responsible for more than 250,000 deaths associated with AMR were *E coli, Staphylococcus aureus, K pneumoniae, S pneumoniae, Acinetobacter baumannii,* and *Pseudomonas aeruginosa*, by order of the number of deaths. The prevalance of these pathogens, however, varied by region. In the high-income super-region, approximately half of the fatal AMR burden was linked to two pathogens: *S aureus* and *E coli*. By contrast, in sub-Saharan Africa, the leading pathogens were distinct from those of the high-income super-region, and each represented a smaller share of the AMR burden; *S pneumoniae* contributed to 15.9% of the deaths attributable to AMR and *K pneumoniae* contributed to 19.9% of the deaths attributable to AMR.

Three infectious syndromes dominated the global burdens attributable to and associated with AMR in 2019. The syndromes were lower respiratory and thorax infections, bloodstream infections, and intra-abdominal infections. Combined, these three syndromes accounted for 78% of deaths attributable to AMR in 2019; lower respiratory infections alone accounted for more than 400,000 attributable deaths and 1.5 million associated deaths.

Now we have the data, what are the actions we need to take

In conclusion, the authors of the paper noted, understanding the burden of AMR and the leading pathogen–drug combinations contributing to it is crucial to making informed and location-specific policy decisions, particularly about infection

prevention and control programs, access to essential antibiotics, and research and development of new vaccines and antibiotics. There are serious data gaps in many low-income settings, emphasising the need to expand microbiology laboratory capacity and data collection systems to improve our understanding of this important human health threat.

AMR is real, preventable, and actionable

There are immediate areas of action that we can take today to make an impact against drug-resistant infections.

Infection prevention

Preventing infections, particularly healthcare-associated infections (HAIs) that spread in hospitals, need to be considered as the first line of defense against AMR. According to the CDC, resistant bacteria cause 18% of central line-associated bloodstream infections (CLABSIs), 15% of surgical site infections (SSIs) and 10% of catheter-associated urinary tract infections (CAUTIs) in U.S. hospitals.[5]

- The CDC has tools available to assess infection prevention practices and guide quality improvement.
- Combatting AMR globally requires WASH (Water, Sanitation, and Hygiene) and IPC in all healthcare systems. In many low- to middle-income countries, WASH is inadequate with 1 in 3 healthcare facilities lacking hand hygiene materials at point of care and over 900 million people using healthcare facilities with no water service. Learn more about this challenge and efforts underway on the WHO, UNICEF, and WaterAid's websites.
- The Society for Healthcare Epidemiology of America (SHEA) has updated their training course in best practices in infection prevention and control for hospital clinicians with direct patient care responsibilities. The online program, known as Prevention Course in HAI Knowledge and Control (Prevention CHKC), is currently available.

Preventing infections through vaccinations is critical for reducing the need for antibiotics. Vaccines are available for only one of the six leading global AMR pathogens, *S pneumoniae.* While vaccine programs are underway for several bacterial pathogens, it is also important to note that vaccines for viruses, the influenza or rotavirus vaccines, also play a role in preventing febrile illness. A reduction in febrile illness, which can lead to a reduction in antibiotic prescribing and can reduce the development of resistance. A recent study by Gupta, et.al, demonstrates that periods of high influenza activity corresponds with high rates of antibiotic resistance in respiratory and non-respiratory infections. While this study does not demonstrate causality, it does show the anecdotal link between AMR and flu season.[6]

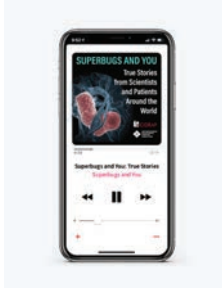
Antibiotic and diagnostic stewardship

Antimicrobial stewardship programs in healthcare settings are designed to optimize antibiotic therapies, with the intention of slowing the emergence of drug-resistance. Accurate and rapid diagnostic testing is a crucial element of stewardship. Diagnostic testing can identify the infection-causing organism, determine whether it is resistant and guide the appropriate therapeutic choice. Essentially, antibiotic stewardship means being smarter—more discriminating and more appropriate—about how we (as a society) use them.

Awareness and advocacy

To change behaviors and practices around antibiotic utilization, the risk of drug resistant infections needs to better understood by organizations and individuals. Antimicrobial resistance is a complex problem that involves human health, animal management, and agriculture practices. The Antimicrobial Resistance Fighter Coalition is a is a bold collective of like-minded organizations, leaders, and individuals united in their commitment to address the threat and burden of antimicrobial resistance

The podcast series, Superbugs and You, is co-produced by the Antimicrobial Resistant Fighter coaltion and Center for Infectious Disease Research and Policy (CIDRAP). The podcasts address this global AMR crisis through conversations with patients, clinicians, and researchers to discover how superbugs are affecting people and healthcare systems globally. It highlights sactions that the average citizen can take today to make sure the drugs we already have stay effective, in order to protect ourselves, our families, and our communities.



Are you ready to take action against drug-resistant infections? Download Activation Kits from the Anticrobial Resistant Fighter Coaltion's website. Each kit includes an introduction and overview on how the specific audience can use the kit, talking points and messaging, materials to use in digital and news media, specific action items you can take to combat AMR, and resources to use within your community to reach decision-makers.

Halting and reversing this massive challenge will require the combined resources and efforts of both public and private sectors. AMR has no single solution, and the challenges cannot be solved without multiple players working collectively on a common AMR agenda.

REFERENCES

1. Institute for Health Metrics and Evaluation. The latest estimates of global anti-microbial resistance show urgent policy action is needed to save lives. Accessed February 8, 2022. https://www.healthdata.org/news-release/latest-estimates-global-anti-microbial-resistance-show-urgent-policy-ac.

2. Centers for Disease Control and Prevention. 2019 AR threats report. Accessed February 8, 2022. https://www.cdc.gov/drugresistance/biggest-threats.html.

3. Ukuhor H. The interrelationships between antimicrobial resistance, COVID-19, past, and future pandemics. *J Infect Public Health.* 2021;14(1):53-60.

4. O'Neill J (chair). Antimicrobial resistance: tackling a crisis for the health and wealth of nations. Accessed February 8, 2022. https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations.

5. Weiner LM, Fridkin SK, Aponte-Torres Z, et al. Vital Signs: Preventing Antibiotic-Resistant Infections in Hospitals — United States, 2014. *MMWR Morb Mortal Wkly Rep* 2016;65:235–241.

6. Gupta V, Yu KC, Kabler H, Watts, et al. Antibiotic Resistance Patterns and Association With the Influenza Season in the United States: A Multicenter Evaluation Reveals Surprising Associations Between Influenza Season and Resistance in Gram-Negative Pathogens. *Open Forum Infect Dis.* 2022 Jan 25;9(3):ofac039. doi: 10.1093/ofid/ofac039.

Diane Flayhart, MBA, is the Global Program Leader for Antimicrobial Resistance at **BD.** Flayhart works to champion and support development of new Antimicrobial Resistance (AMR) program initiatives in global awareness, infection prevention/control and antimicrobial stewardship. Flayhart leads efforts for the Antimicrobial Resistance Fighter Coalition, which is mobilized by **BD**.

Preventing cross-contamination in a molecular laboratory

By Jeanne Rhea-McManus, PhD, MBA, DABCC, NRCC

Polymerase Chain Reaction (PCR) is a standard laboratory technique used to amplify a specific sequence of DNA many times over. This technique has become an important tool in clinical laboratories for the detection of infectious pathogens that do not grow in conventional culture media.[1] PCR-based methods are powerful techniques[2]; with the ability to detect a single molecule of DNA, disease can be detected at extremely low levels. Such sensitivity, however, makes PCR highly susceptible to cross-contamination, particularly from exogenous DNA sources. The most common sources of contamination include sample to sample transfer and amplicon carryover.[3]

The consequences of contamination can be severe and include erroneous results, extensive investigation to identify the source of contamination, cleanup leading to laboratory downtime and delays, as well as loss of credibility. Implementation of safeguards and strict adherence to robust protocols such as those summarized below is often sufficient to ensure that cross-contamination in the molecular laboratory is a rare event.

Laboratory Construction

The layout for a molecular laboratory should be designed to allow for areas dedicated for sample and reagent preparation and for amplification reaction and detection activities (e.g., agarose gel electrophoresis, when necessary).[4] Ideally, a molecular laboratory would be designed with three or four separate rooms, dependent on the PCR method used.[5] At a minimum, it is recommended to have two separate rooms defined as a pre-PCR/clean room where sample preparation steps such as DNA/RNA extraction and PCR preparation occur, and a post-PCR/dirty room where PCR reactions and other post-PCR analyses are performed.[5] In scenarios where space does not permit dedicated rooms, separate benches should be identified for pre-PCR activities (reagent preparation, sample preparation) and post-PCR activities (PCR amplification, PCR analysis). As an additional control when all PCR steps are performed in the same room, timetables can be established where pre-PCR and post-PCR steps are performed at different times of the day.[4]

Reagent Preparation room.[5] The cleanest of all spaces used for PCR, this room is dedicated to activities such as preparation and aliquoting of reagent stocks. In addition, reaction mixes may also be prepared here, excluding the addition of the extracted nucleic acids from the clinical sample. To reduce the possibility of contamination, extracted DNA/RNA and/or PCR products should never be present in the reagent preparation room.

Sample preparation room.[5] Because it is important to keep PCR products away from where clinical sample extraction occurs, this room is generally split into two areas: one dedicated to DNA and/or RNA extraction activities and one dedicated to nucleic acid addition to the PCR reaction mixtures. The reverse transcriptase step of reverse transcription (RT)-PCR is performed in this room, as well as the addition of DNA or cDNA, and positive controls to the PCR reaction mixture. Ideally isolated nucleic acids are added to PCR reaction mixes in a laminar flow hood.

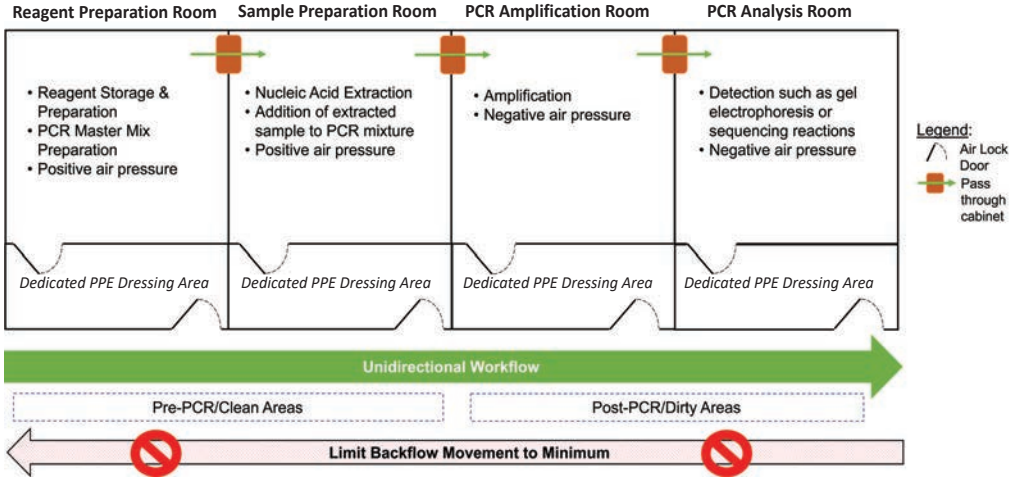
PCR amplification room.[5] PCR instruments (i.e., thermocyclers) used for amplification steps are kept in this room. Additional analysis is not required for real time PCR, and tubes containing RT-PCR products should never be opened.

Post-PCR analysis.[5] When agarose gel electrophoresis is required, it should occur in a dedicated room/area as it will be contaminated with amplicons from the PCR reaction. A laminar flow hood is recommended for any steps requiring the opening of tubes containing amplicons. To control for contamination, it is also critical that personnel performing post-PCR analysis not return to pre-PCR work areas in the same day.

Engineering Controls

Air flow.[6] The reagent preparation room should have positive air pressure to keep contaminants out. In contrast, the post-PCR analysis room should be under negative air pressure to keep amplicon contaminants in. When possible, the air handlers for the different PCR areas should be connected to separate air ducts, with each leading to a separate location for exhaust.

Air lock doors. Ideally, a vestibule provides the main access point to the clean room and is constructed with two or more doors. The interlock function allows only one door to be open at a time. By preventing both doors form being open simultaneously, air and airborne particulates are unable to enter or exit the airlock, thus reducing the opportunity for cross-contamination.



Ideal layout for a molecular laboratory to reduce contamination events. This layout ensures separation of clean reagents and equipment from exogenous DNA sources (i.e., samples and/or amplicon containing material).

Laboratory Operation

Unidirectional.[5] All steps should occur sequentially moving from clean room to dirty room. For example, PCR protocols should begin in the reagent preparation room, move to the sample preparation room, and end in the PCR amplification or post-PCR analysis room.

Explore the Broadest Range of Urinalysis QC Solutions.

Quantimetrix® puts you in control of quality with the most versatile and complete line of urinalysis quality controls, designed to meet your needs from the central lab to the point of care.

Optimize your QC with exceptional open and closed-vial stability across all analytes, lot-to-lot consistency and friendly, dedicated customer support.

Samples of all Quantimetrix products are available absolutely free – let us help you find your best fit today!

Connect with us @
quantimetrix.com

This helps to ensure reduce the risk of contamination by keeping clean areas free of amplicons.

Pass through air locks. Use of pass-through cabinets can facilitate a unidirectional workflow. These boxes are designed to maintain complete environmental separation between work areas and minimize cross contamination.

Dedicated Personnel.[5] Laboratory personnel dedicated to either clean room activities or dirty room activities is recommended. Clean lab coats and gloves should be worn when performing PCR; gloves should be changed frequently. In the event that laboratory personnel need to move from a dirty room back to a clean room, all personal protective equipment (PPE) should be changed, and hands washed.

Dedicated consumables and equipment.[5] The availability of dedicated storage (e.g., freezer, fridge) in each room prevents movement of reagents and samples between dedicated areas, thereby minimizing the potential for contamination. In addition, consumables (e.g., lab coats, gloves, goggles, disposable shoe covers, etc.) and equipment (e.g., pipettes, centrifuges, pipette tips, etc.) should never be brought from dirty rooms back into clean rooms.

Aerosol-resistant pipettes. Sample to sample contamination can occur due to aerosols. Use of barrier tips prevents liquids and aerosols from contacting the pipette.

Pipetting techniques. Use of proper pipetting technique can also prevent contamination. This includes ensuring the pipette tip is securely seated on the pipette and aspirating at a vertical 90° angle with consistent smooth speed and pressure. When dispensing liquid, the pipette should be held at a 45° angle with the tip of the pipette touching the side of the receptacle to minimize splashing.

No template control (NTC).[7] NTCs consist of all reagents added during preparation of the PCR reaction mixture but uses water instead of the extracted sample. Including an NTC in PCR amplification reactions allows for the identification of contamination in samples, reagents, and/or the lab environment.

Cleaning/decontamination techniques

Surface and Equipment.[8] Following appropriate cleaning and decontamination techniques both before and after PCR reduces the potential for contamination of the PCR reaction. Frequent cleaning of work areas with freshly made 10-15% sodium hypochlorite solution (bleach) followed by rinsing with 70% ethanol or cleaning with commercially available DNA-destroying decontamination products is recommended. Alternatively, cleaning of work surfaces and equipment with 70% ethanol followed by irradiation with UV light can also be done; irradiation is critical as ethanol only precipitates but does not remove DNA.

UV irradiation.[9] This technique induces thymidine dimer formation in the DNA rendering it unusable as a template for further amplification. Use of UV irradiation is recommended for laminar flow hoods for at least 30 minutes prior to use, followed by cleaning with 70% ethanol.

Additional Considerations

Quality Monitoring Statistics[10] As mentioned, the greatest risk source of contamination for PCR-based tests is from exogenous DNA. Laboratories must have clearly written procedures in place to monitor for the presence of false-positive results. This can include implementation of wipe or swipe tests on a defined schedule, positivity rate monitoring by reviewing summary statistics at the local and regional level, and investigations of physician inquiries.

Wipe or swipe tests involve dampening of a sterile swab in sterile saline and wiping potentially contaminated surfaces of a laboratory (e.g., benches, pipettes, handles of fridge/freezer, centrifuges, etc.). These swabs are then processed and tested in manner similar to patient samples. A positive result from a wipe test is indicative of environmental contamination.

Contamination from Serology Testing[11] In some scenarios, diagnosis of an infectious disease such as Hepatitis C (HCV) or Human Immunodeficiency Virus (HIV) begins by screening for anti-HCV or anti-HIV antibodies. If antibodies are detected in a sample, further testing a PCR-based method is required for confirmation. When the same sample used for serology testing is also used for nucleic acid testing the potential exists for increased risk of cross-contamination, dependent on the design of the laboratory instruments used for serology testing. For example, instruments using a washable sample probe pose a slightly increased risk for cross-contamination versus instruments that utilize a disposable tip. As a mitigation, it has been suggested that low level RNA results from samples previously tested on a serology instrument with a washable probe be rejected and a new sample requested for repeat PCR analysis. Alternatively for samples screened on an instrument using disposable tips, there may be no need for a separate tube for confirmatory PCR testing.

Conclusion

The safeguards and operational recommendations summarized above serve to prevent contamination of molecular diagnostic tests and subsequent impact to diagnostic and treatment decisions. In many scenarios,molecular testing plays a major role in the management of patients, thus prevention of contamination must be a priority in clinical molecular laboratories.

REFERENCES

1. Aslanzaden J. Preventing PCR amplification carryover contamination in a clinical laboratory. *Ann Clin Lab Sci.* 2004;34(4):389-396.

2. Hu Y. Regulatory concern of polymerase chain reaction (PCR) carryover contamination. In: Samadikuchaksaraei, A, ed. *Polymerase Chain Reaction for Biomedical Applications*. IntechOpen, 2016:57-68. DOI: 10.5772/66294.

3. Huggett J, Benes V, Bustin S, et al. Cautionary note on contamination of reagents used for molecular detection of SARS-CoV-2. *Clin Chem.* 2020;66(11):1369-1372. DOI: 10.1093/clinchem/hvaa214.

4. Mifflin TE. Setting up a PCR laboratory. *CSH Protoc*. 2007; pdb.top14.

5. Standards Unit, National Health Service, Public Health England. UK Standards for Microbiology Investigations: Good practice when performing molecular amplification assays. Updated February 19, 2018. Accessed March 20, 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/682533/Q4i5.pdf.

6. Aysal A, Pehlivanoğlu B, Ekmekci S, Gündoğdu B. How to set up a molecular pathology lab: a guide for pathologists. *Turk Patoloji Derg*. 2020;36(3):179-187. DOI: 10.5146/tjpath.2020.01488.

7. Viana RV, Wallis CL. Good Clinical Laboratory Practice (GCLP) for Molecular Based Tests Used in Diagnostic Laboratories. In: Akyar I, ed. *Wide Spectra of Quality Control*. InTech, 2011: 29-52.

8. Prince AM, Andrus L. PCR: how to kill unwanted DNA. *Biotechniques*. 1992;23(3):358-360.

9. Ou CY, Moore JL, Schochetman G. Use of UV irradiation to reduce false positivity in polymerase chain reaction. *Biotechniques*. 1991;10:442-446.

10. Wallace P, McCulloch E. Quality Assurance in the Clinical Virology Laboratory. *Encyclopedia of Virology*. 2021;64-81. DOI:10.1016/B978-0-12-814515-9.00132-6.

11. Rondahl E, Gruber M, Joelsson S, et al. The risk of HCV contamination in serology screening instruments with a fixed needle for sample transfer. *J Clin Virol*. 2014;60:172-173.

Jeanne Rhea-McManus, PhD, MBA, DABCC, NRCC has been with **Siemens Healthineers** for 7 years, previously as a Medical Officer and currently as the Senior Director of Medical Science Information and Communication.

WHICH WOULD YOU CHOOSE FOR YOUR LABORATORY SUBCULTURE PROCEDURE?

Safety SubCulture Unit 2
needleless subculture procedures

Other subculture devices
exposed needle subculture procedures

Safety SubCulture Unit 2 enables a safe and needleless subculture procedure of positive blood culture bottles to slides and media plates.

Other subculture devices transfer samples with **exposed needles.** Protect your staff with a safety oriented subculture solution.

Request your samples today at itlbiomedical.com/scu2.

The CDC estimates ~ 385,000 healthcare workers[1] sustain sharps injuries each year, resulting in an increased risk for bloodbourne virus transmission and increased costs to personnel and healthcare systems.

1.888.411.2851 sales@itlbiomedical.com **itlbiomedical.com**

[1]https://www.cdc.gov/sharpssafety/index.html

ITL BioMedical

Safety lancet for heelsticks

MiniCollect PIXIE is a safety lancet designed for capillary blood collection by heelstick. There are three options available with varying incision lengths and penetration depths adapted for different stages of infant development. The safety feature is designed for ease of use, with a blade that retracts automatically after incision.
Greiner Bio-One

Swabs for maximum cell yield collection

Puritan patented flocked swabs, with unique fibers, provide high collection and elution capacities. PurFlock Ultra with multi-length fibers engineered for maximum cell yield from a small sample size, or HydraFlock with floret-shaped fibers designed for greater surface area absorption. Available in assorted tip shapes and sizes, and various breakpoint options.
Puritan Medical Products

Capillary blood collection tubes

Microvette APT from SARSTEDT is a capillary blood collection tube that meets processing requirements for automated blood analysis systems. 250µl and 500µl options are available with K2EDTA preparation, 13 x 75 mm dimensions with space for barcode labels, and a robust sealing cap with integral pierceable membrane for direct sampling.
SARSTEDT

Unistik®

INTO THE FUTURE WITH CONFIDENCE AND CONFIDENCE
1952-2022

Right the First Time

Capillary Blood Sampling Solutions

The Unistik family of products offer multiple activation methods, penetration depths, and gauge sizes to meet nearly every capillary sampling need. From low flow fingersticks to high flow heelsticks, Unistik products are designed with the patient and healthcare professional in mind, engineered to help reduce pain during the sampling process while delivering the results healthcare professionals expect, the first time.

Unistik® 3
Side Activated Safety Lancets

Unistik® Pro
Top Activated Safety Lancets

Unistik® Touch
Contact Activated Safety Lancets

Unistik® TinyTouch™
Heel Incision Devices

Owen Mumford

For more information, **call 1-800-421-6936** or visit **owenmumford.com**

UNISTIK2021AD/OMI/0721/1/US

Safety SubCulture Unit 2 - Needleless Subculture Procedure

Safety SubCulture Unit 2 enables a safe and needleless subculture of positive blood culture bottles to slides and media plates. Other subculture devices transfer samples with exposed needles. **Protect staff with a safety-oriented subculture solution.**

ITL BioMedical

New RF (Ver.2) Assay for Chemistry Analyzers

KAMIYA BIOMEDICAL is introducing a new reagent for measuring RF. 4 times wider measuring range than most other RF assays with superior sensitivity. Applications available for most chemistry analyzers. For IVD use.

KAMIYA BIOMEDICAL

American Proficiency Institute

Celebrating its 10th year API DataDirect is the future of proficiency testing, saving time and eliminating costly clerical errors!

- ✓ **No middleware or software installation**
- ✓ **Automated mapping**
- ✓ **Quantitative & Qualitative results**
- ✓ **It's free!**

Over 4 million results uploaded utilizing API DataDirect!

www.api-pt.com

High-sensitivity POC SARS-CoV-2 Antigen Analyzer

Verify infection quickly with a rapid microfluidic immunofluorescence assay that provides lab comparable results at point of care, with 97.6 % positive agreement to RT-PCR in 12 minutes.

Authorized for use in CLIA waived settings.

LumiraDX

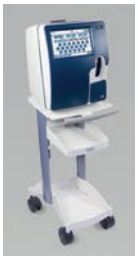
Simple, accurate vitamin D testing

LIAISON® 25 OH Vitamin D TOTAL Assay offers...

- Ease of use with calibrators included onboard each reagent integral.
- Accuracy and precision, certified by the CDC's VDSCP program.
- Consolidation with PTH and 1,25 Dihydroxyvitamin D for a complete bone & mineral testing solution. Now available in a 200-test format.

DiaSorin

Prime Plus Critical Care Blood Gas Analyzer



Stat Profile Prime Plus® whole blood critical care analyzer combines maintenance-free cartridge technology for sensors and reagents with patented, non-lysing whole blood co-oximetry technology. Test menu includes blood gases, electrolytes, metabolites, Hb, Hct, MCHC, CO-Ox, and estimated plasma volume, with results in about one minute.

Nova Biomedical

Aptima® Mycoplasma genitalium assay

Expand your offering to include Mycoplasma genitalium (M. gen) testing, now recommended in the CDC 2021 STI Treatment Guidelines for patients with recurrent cervicitis and urethritis. The Aptima® rRNA-based NAAT provides up to 100% sensitivity in the detection of M. gen.

Hologic

Clean Catch Collection

Peezy Midstream urine specimen collection device is designed to obtain a clean catch urine sample helping provide more accurate results, diagnosis and treatment.

Owen Mumford

Syndromic respiratory testing, reimagined

Simplify and automate your multiplex respiratory testing with the QIAstat-Dx Analyzer.

- Less than one-minute hands-on time
- Single-use cartridge
- Comprehensive results for >20 pathogens in about an hour
- Ct values viewable for detected pathogens
- Sophisticated connectivity features

QIAGEN

StatStrip Glucose Hospital Meter System

StatStrip is the only glucose meter with FDA clearance for use with critically ill patients, after extensive studies at Mayo Clinic and Johns Hopkins of over 17,000 capillary glucose results on critically ill patients. Use of any other glucose meter on these patients is "off-label" according to the FDA.

Nova Biomedical

Four Respiratory Tests in One

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

Quidel

Reliable Vitamin D Testing at your fingertips

Benefits of the Cascadion Mass Spec Vitamin D

- Utilizes mass spectrometry-based gold standard technology
- Complete measurement of Vitamin D2 and D3 with Total 25-OH Vitamin D reported
- No manual preparation with ready to use internal standard, calibrators, and controls

Thermo Fisher Scientific

Point-of-care test

The CLIA waived Acucy® Influenza A&B Test on the Acucy® System is a rapid (result in 15 minutes) chromatographic immunoassay that provides clinicians' flexibility in the workflow - with Read now or Walk-away mode, easy transfer of results to the EHR; and accurate, standardized results for improved patient care.

SEKISUI Diagnostics

ACL TOP® Family 50 Series

ACL TOP® Family 50 Series Hemostasis Testing systems offer the most advanced automation, quality management, and routine to specialty assays for mid- to high-volume clinical laboratories, including those with lab automation tracks.

Werfen - Hemostasis

INDEX OF ADVERTISERS

LABORATORY INNOVATOR

Laboratory operations at an orthopedic specialty hospital

By Kristine Russell

Dr. Esther Eke assumed the position of Laboratory Director at **Jack Hughston Memorial Hospital** (JHMH) in Phenix City Alabama on March 23, 2020. Before joining JHMH, Eke held various managerial positions in different hospitals in the Texas area. Dr. Eke Joined Lonestar College System in January 2008 as an Adjunct Faculty until the present. She chaired the Executive board in several Non-Governmental Organizations (NGOs).

She has worked as Lead consultant, Technical expert in several projects: Laboratory start-up, Accreditation consultant, Policy formulation, and in Monetary investments.

Dr. Eke holds a BS, MBA, and PhD in Epidemiology (Infection Disease) from Walden University USA, Master in Healthcare Management from the University of Phoenix USA, and BS in Medical Technology (Clinical Laboratory Scientist) from University of Texas Medical Branch Galveston Texas (UTMB).

Dr. Eke published a scholarly article, *Predictor of Mastectomy in Male Breast Cancer* in 2017.

How we met this Lab Innovator?

Medical Laboratory Observer (MLO), met Dr. Esther Eke in November 2021, at our Lab Directors Summit in the Chicago area. Dr. Eke was chosen by our Summit staff because of her involvement in decision-making for the products and services used and the management of her laboratory. She also was interested and willing to discuss challenges at her lab that she was looking to find solutions for. The magic of the Lab Directors Summit is the 48 hours of networking opportunity and idea sharing with other Lab Directors and participation at our round-table disscussions with suppliers and peers.

What drew you to a specialty orthopedic hospital, and what do you find different about your facility?

Jack Hughston Memorial Hospital (JHMH) is a licensed 70 bed hospital in Phenix City, Alabama. The hospital delivers the highest quality patient care in orthopedics, as demonstrated through the many awards they have received over the years. JHMH has been ranked, by Healthgrades, in the top 10% nationwide for both orthopedic and joint replacement care; in fact, it is the only hospital in Alabama to be recognized for excellence in both these areas during a given year. Furthermore, it is the only hospital in the nation to receive Healthgrades America's 100 Best for Orthopedic Surgery and America's 100 Best for Joint Replacement for eleven years in a row (2012-2022). JHMH also boasts the Medicare Top 5 rating, two years in a row.

JHMH sits on a hill overlooking River Chase and within a block of the Chattahoochee River. Individuals are drawn in by its beautiful grounds and newly updated facade. Inside, they are welcomed by friendly employees and physicians who are devoted to excellent patient care.

Many patients express that, while receiving care at JHMH, they felt as if they were treated like family."I believe that is what sets us apart from other hospitals, of which I am very proud," Eke states.

What role did JHMH play in response to the COVID-19 pandemic?

Like every hospital, worldwide, JHMH was significantly impacted by the pandemic, the novel Covid-19 outbreak. We changed several processes in order to continue patient care while minimizing the spread of the disease.

Specifically, we began testing all patients who were admitted to the hospital. We changed our cleaning procedures and chemicals. We instituted screening measures for hospital entry. Lastly, we began a free COVID-19 vaccination clinic to serve those in our community.

During the first few months of the COVID-19 outbreak, there was a significant reduction in the number of surgeries. This was due to the state government mandate to stop elective surgeries. After two months, the mandate was lifted, and the hospital quickly returned to normal surgical volume. We have remained in line with regulatory requirements and guidelines for the duration of the pandemic, including mandatory masks, vaccinations, and physical distancing.

How did you address the testing challenges as a speciality orthopedic hospital?

During COVID, diagnostic laboratory testing volume increased exponentially. At the same time, we had many difficulties filling technologist and phlebotomist positions. We managed these challenges by first creating a position for a lab assistant whose primary responsibility is receiving and performing COVID tests during our heaviest testing times. We assessed and changed salaries and offered bonuses to attract new employees. We also employed travelers to augment our staff. These strategies, along with the tireless efforts of veteran lab employees, allowed us to continue to provide excellent, uninterrupted services.

What led you to choose a career as a clinical laboratorian and your current role as a Lab director?

I cannot say enough about the outstanding job that our laboratory staff and medical technologists have done, and continue to do, during the pandemic. In my opinion, they are unsung heroes in our nation's fight against COVID-19 although you don't hear much about them in the news or other stories. But, just like other medical professionals, lab staff went above and beyond, working hard and long hours to serve patients and employees during the pandemic. We are fortunate at the "Jack" that our leadership recognizes efforts of the laboratory department as an integral part of our patients' treatment and its employees as important members of the Hughston family.

Dr. Eke mentioned that she ended up in a laboratory career on the way to a career in medicine. Having children moved her into a lab career instead.

The Accurate. Sustainable. **Molecular** Solution.

Testing beyond COVID for respiratory season.

With Solana, you can sustain your molecular testing of critical assays for which you might be considering alternate methods. Coupled with the power of Virena® cloud based analytics, you can quickly implement a more complete solution to protect the health of your patients and your facility.

Compact footprint
9.4" x 9.4" x 5.9"
Deployable *practically anywhere*

For more information contact
Quidel Inside Sales at 858.431.5814

Easy, flexible workflow – Integrated seamlessly for single specimen or high-throughput batching up to 12 tests at a time

Minimal training – Get up and running quickly

QUIDEL | Solana®

with the power of Virena

Enhanced diagnostics featuring data analytics and surveillance

*SARS-CoV-2	GAS
Influenza A+B	GBS
RSV + hMPV	HSV 1+2/VZV
Respiratory Viral Panel	Bordetella Complete
Strep Complete	Trichomonas
C. difficile	

*THIS TEST IS AVAILABLE FOR SALE IN THE USA UNDER EMERGENCY USE AUTHORIZATION. The Solana SARS-CoV-2 Assay has not been FDA cleared or approved, but has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

AD1003800EN00 (02/22)

Innovative qSTAR technology transforms molecular diagnostics and lab efficiency with fast direct amplification within 20 minutes on open RT-PCR systems.

HIGH THROUGHPUT / RAPID / ACCURATE

This test has not been FDA cleared or approved but has been authorized by FDA for emergency use under an EUA for use by authorized laboratories; this test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and the emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.