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MEDICAL LABORATORY OBSERVER

APRIL 2023 • Vol 55 • No 4

CE:
Tuberculosis testing
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2023 LAB of the YEAR

Department of Pathology and Laboratory Medicine
Avera McKennan Hospital and University Health Center

LAB INNOVATOR
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Laboratory Director of the Clinical Laboratories of Alameda Health System


APRIL
STI Awareness
Month

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Mycoplasma genitalium (M. gen) is often missed because it can be mistaken for other STIs.[1]

The CDC recommends testing patients with recurrent cervicitis, PID, and urethritis with NAAT for detection of M. gen.[2] The Aptima Mycoplasma genitalium assay offers a sensitive, rRNA-based NAAT that can accurately identify the 40% of patients missed by a DNA-based test.[3]

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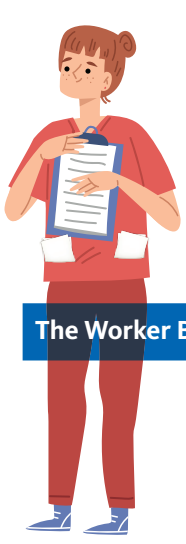
Introducing

The Laboratorians

Medical Laboratory Professionals Week
LABORATORY PROFESSIONALS GET RESULTS
April 23-29, 2023
#LABWEEK



The Worker Bee

Pockets full of emails and notes. Knows every SOP by heart.

The Newbie

Wants to learn everything. Doesn't know what he's in for.

The Lab Sage

She's been through it all. Remembers mouth pipetting and coffee in the lab.

The Troubleshooter

Saves the day one crisis at a time. Carries a screwdriver.

The 3rd Shifter

Hard at work while everyone else is sleeping.

The Scopist

Diffs, fluids and gram stains—nothing abnormal gets past her.

The Natural Born Teacher

Every student and new hire (and some pathologists) have him to thank.

The Do-It-All

Will do anything asked of them. Voted MVP of the lab 4 years in a row.

The Whisperer

Whether it's QC or a vein, she always gets it on the first try.

The Storyteller

Loves to talk about gross samples. Fun to eat lunch with.

The Pee Queen

Urine is her jam. Into crystals.

The Hoarder

Has a hidden drawer full of pens and calculators. All labeled with her name.

You're smart. You're dedicated. You're essential. We get you.

Regardless of how you define yourself, you contribute in countless ways by combining your unique style and laboratory expertise. During Lab Week — and every day — we celebrate you and your contributions to healthcare. **#LabWeek2023**.

Find Lab Week ideas and downloads, win a poster and more.

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Happy Medical Laboratory Professionals Week!

By Christina Wichmann
Senior Editor

April has always been a special issue for *MLO*. This is the month that Medical Laboratory Professionals Week is celebrated (April 23–29, 2023), which highlights the vital role played by laboratory professionals and pathologists in the field of medicine. Medical Laboratory Professionals Week, also known as Lab Week, is now in its 47th year. According to the American Society for Clinical Laboratory Science, there are approximately 300,000 practitioners of clinical laboratory science in the United States.

To coincide with this celebration, *MLO* publishes its annual Lab of the Year award. Our first Lab of the Year award was in 2003 — twenty years ago! Before 2003, *MLO* held an Outstanding Laboratorian Contest. Our first Lab of the Year winner was Family Doctors of Boulder City. Family Doctors offered an extensive set of testing services and procedures necessary for a comprehensive, preventive healthcare program on site. The laboratory staff worked with medical assistants and nurses to ensure proper sample collection and even worked with the billing department to ensure proper CPT codes were used for lab testing.

This year, we received a lot of impressive nominations. This was my first year being a part of the process, and I enjoyed reading every nomination. One Texas laboratory's nomination even put a tear in my eye describing all their efforts during the COVID-19 pandemic. Thank you so much to all the labs that submitted thoughtful nominations, and thank you to the judges for your time reviewing and scoring the labs in the six categories: customer service, education and training, productivity, teamwork, lab inspections, and strategic outlook.

It is clear that labs' dedication to excellence, customer service, education, teamwork, and improvement is a year-round commitment. And some labs in the country really stand out. This year's Lab of the Year award goes to the Department of Pathology and Laboratory Medicine at Avera McKennan Hospital and University Health Center in Sioux Falls, South Dakota. The two runners-up are North Kansas City Hospital Laboratory in North Kansas City, Missouri and Radeas Labs in Wake Forest, North Carolina. We feature all three labs in this issue beginning on page 18. Characteristics that I would like to highlight of each of these winners include the following:

- Process improvement is an integral part of the Avera McKennan Laboratory— improvements do not occur occasionally but are a result of the collective efforts of staff involved in the day-to-day processes.
- The employee culture is exemplary at North Kansas City Hospital Laboratory. Collaboration, celebrations, and charitable activities have created a strong team. In addition, the laboratory provides a robust education and training program.
- Radeas stands out for its agile approach to serving customers. Radeas' mobile labs provided walk-up services in underserved communities and long-term care settings and when setting up a drive-up COVID testing site in its parking lot, a local restaurant known for its drive-through efficiency helped Radeas orchestrate a well-organized system.

Again, thank you to all of our laboratories!

I welcome your comments and questions — please send them to me at cwichmann@mlo-online.com.

MEDICAL LABORATORY OBSERVER

MEDICAL LABORATORY OBSERVER Vol.55, No. 4

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www.mlo-online.com

Medical Laboratory Observer USPS Permit 60930, ISSN 0580-7247 print, ISSN 2771-6759 online is published 12 times annually (Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Sep CLR, Oct, Nov, Dec), with an additional issue in September, by Endeavor Business Media, LLC. 1233 Janesville Ave., Fort Atkinson, WI 53538. Periodical postage paid at Fort Atkinson, WI, and additional mailing offices. POSTMASTER: Send address changes to Medical Laboratory Observer, PO Box 3257, Northbrook, IL 60065-3257. SUBSCRIPTIONS: Publisher reserves the right to reject non-qualified subscriptions. Subscription prices: U.S. $160.00 per year; Canada/Mexico $193.75 per year; All other countries $276.25 per year. All subscriptions are payable in U.S. funds. Send subscription inquiries to Medical Laboratory Observer, PO Box 3257, Northbrook, IL 60065-3257. Customer service can be reached toll-free at 877-382-9187 or at MLO@omeda.com for magazine subscription assistance or questions.

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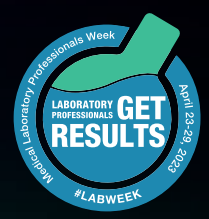
Thank you for your dedication to patient care.

April 23rd marks the start of **Medical Laboratory Professionals Week**. At Hologic, we recognize the vital role you play year-round in ensuring people receive the best health care possible. You are on the front lines, and we thank you.

We are constantly striving to develop innovative diagnostic testing solutions that deliver life-changing disease detection – to help you make the biggest impact in patient lives. Together, with our relentless desire to empower labs with confidence and your dedication to your patients, we can continue to enable healthier lives everywhere, every day.

Explore the portfolio laboratories trust.



Fast Facts

Colorectal cancer is swiftly shifting to more advanced disease and younger individuals according to Colorectal Cancer Statistics 2023, a new report on cancer facts and trends by the American Cancer Society (ACS).

For the report, researchers used incidence data available through 2019 from 50 states and the District of Columbia from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute and the National Program of Cancer Registries of the Centers for Disease Control and Prevention, as provided by the North American Association of Central Cancer Registries. National mortality data available through 2020 were provided by the National Center for Health Statistics.

Key findings from the report include:

8%

increase of individuals in the United States diagnosed with advanced-stage colorectal cancer (CRC) from the mid-2000s to 2019 (52% to 60%).

1 in 5

people under 55 years of age were diagnosed with CRC in 2019 (20%), double the amount from 1995 (11% or 1 in 10).

153,020

people are estimated to be diagnosed with CRC in the U.S. in 2023.

52,550

people are estimated to die from the disease in 2023.

33%

higher CRC incidence rate higher in men (41.5 per 100,000) than in women (31.2 per 100,000) during 2015-2019, likely reflecting differences in risk factor prevalence, such as excess body weight, processed meat consumption, and historical smoking.

88.5 per 100,000

CRC incidence in people who are Alaska Native (highest). American Indian (46.0 per 100,000), or Black (41.7 per 100,000; versus 35.7 per 100,000 in Whites); mortality patterns are similar, with rates highest in people who are Alaska Native (50.5 per 100,000), American Indian (17.5 per 100,000), or Black (17.6 per 100,000; versus 13.1 per 100,000 in Whites).

Source: https://pressroom.cancer.org/CRC-FactsFigures2023#:

FDA authorizes first over-the-counter at-home test to detect both influenza and COVID-19 viruses

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for an over-the-counter (OTC) at-home diagnostic test that can differentiate and detect influenza A and B, commonly known as the flu, and SARS-CoV-2, the virus that causes COVID-19. The Lucira COVID-19 & Flu Home Test is a single-use at-home test kit that provides results from self-collected nasal swab samples in roughly 30 minutes.

The Lucira COVID-19 & Flu Home Test is a single use test for individuals with signs and symptoms consistent with a respiratory tract infection, including COVID-19. The test can be purchased without a prescription and performed completely at-home using nasal swab samples self-collected by individuals ages 14 years or older or collected by an adult for individuals 2 years of age or older.

The test works by swirling the sample swab in a vial that is placed in the test unit. In 30 minutes or less, the test unit will display the results that show whether a person is positive or negative for each of the following: Influenza A, Influenza B and COVID-19. Individuals should report all results obtained to their healthcare provider for public health reporting and to receive appropriate medical care.

In individuals with symptoms, the Lucira COVID-19 & Flu Home Test correctly identified 99.3% of negative and 90.1% of positive Influenza A samples, 100% of negative and 88.3% of positive COVID-19 samples and 99.9% of negative Influenza B samples.

A woman dies every two minutes due to pregnancy or childbirth

Every two minutes, a woman dies during pregnancy or childbirth, according to the latest estimates released in a report by United Nations agencies. This report, *Trends in maternal mortality*, reveals alarming setbacks for women's health over recent years, as maternal deaths either increased or stagnated in nearly all regions of the world.

The report, which tracks maternal deaths nationally, regionally and globally from 2000 to 2020, shows there were an estimated 287,000 maternal deaths worldwide in 2020. This marks only a slight decrease from 309,000 in 2016 when the UN's Sustainable Development Goals (SDGs) came into effect. While the report presents some significant progress in reducing maternal deaths between 2000 and 2015, gains largely stalled, or in some cases even reversed, after this point.

In two of the eight UN regions – Europe and Northern America, and Latin America and the Caribbean – the maternal mortality rate increased from 2016 to 2020, by 17% and 15% respectively. Elsewhere, the rate stagnated. The report notes, however, that progress is possible. For example, two regions – Australia and New Zealand, and Central and Southern Asia – experienced significant declines (by 35% and 16% respectively) in their maternal mortality rates during the same period, as did 31 countries across the world.

In total numbers, maternal deaths continue to be largely concentrated in the poorest parts of the world and in countries affected by conflict. In 2020, about 70% of all maternal deaths were in sub-Saharan Africa. In nine countries facing severe humanitarian crises, maternal mortality rates were more than double the world average (551 maternal deaths per 100,000 live births, compared to 223 globally).

Toxic protein linked to muscular dystrophy and arrhinia

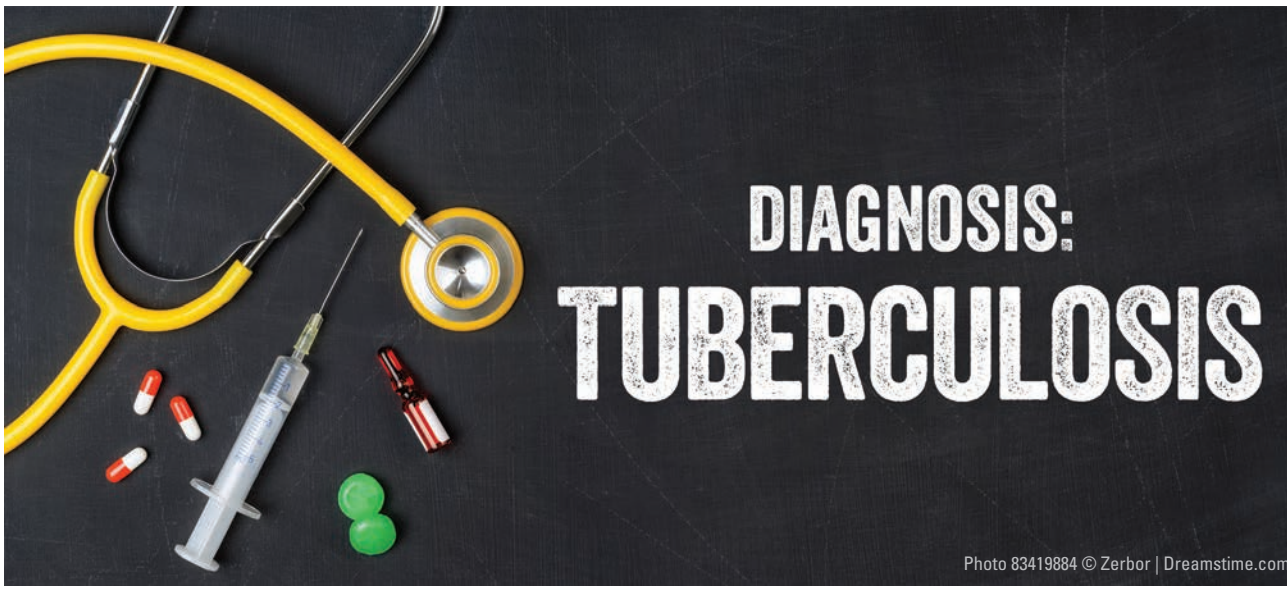
Researchers at the National Institutes of Health and their colleagues have found that a toxic protein made by the body called DUX4 may be the cause of two very different rare genetic disorders. For patients who have facioscapulohumeral muscular dystrophy (FSHD), or a rare facial malformation called arhinia, this research discovery may eventually lead to therapies that can help people with these rare diseases.

The team found that the combination of the mutated SMCHD1 gene and an environmental modifier such as a virus, may trigger the DUX4 toxic protein. This may be what causes arhinia to occur. Using stem cells created from patients with the two diseases, the researchers conducted studies in cranial placode cells, the cells that lead to the development of the body's sensory organs, such as the nose. As the placode cells started to form, they began to produce the DUX4 protein which caused cell death.

The researchers showed that DUX4 is responsible for cell death in placode cells as it is in muscle cells, but they still do not understand why the nose cells do not die in muscular dystrophy or why the muscle cells are not dying in arhinia.

Not all tests are created equal.

When it comes to results, rapidly mutating viruses can continue to evade quantification with viral load assays that do not have built-in redundancy. Make sure patients receive accurate results. Count on assays trusted in clinical trials for HIV, HBV, and HCV therapeutics since 1996.



Can medical laboratories give humanity the edge over tuberculosis?

By Parth Patel, DMSc, PA-C and Valerie Hazley-Anyiwo, RN, BSN, CICBP

Tuberculosis (TB) disease is both preventable and curable, and yet — much to the surprise of many who mistakenly consider its threat extinguished or unremarkable — TB was the 13th leading cause of death worldwide in 2021.[1] Among infectious disease killers, the World Health Organization has ranked it the top infectious disease killer, second only recently to COVID-19.

And in much the same way laboratory testing and analysis have played a critical role in diagnosing, reporting, and monitoring COVID-19 — and informing treatment decisions — so too can the laboratory community play a crucial role in stopping TB.

A brief snapshot of TB history

TB is not a new disease. It can be traced back 9,000 years where it was found in the human remains of a mother and child buried together in a city now submerged beneath the Mediterranean Sea. The earliest written mentions of TB were in India 3,300 years ago and in China 2,300 years ago. Between the 1600–1800s in Europe, TB caused 25% of all deaths, with a similar impact in the United States. The New York City Department of Health and Hygiene published its first report on TB in the city in 1893. On March 24, 1882, Dr. Robert Koch announced the discovery of the bacterium that causes TB. Each year, public health agencies and organizations around the world mark World TB Day on March 24 to raise public awareness about the global TB epidemic.

Today, an estimated one quarter of the world's population is infected with a latent TB infection (LTBI), and in 2021 an estimated 10.6 million people around the world became actively sick with the disease, including 6 million men, 3.4 million women, and 1.2 million children.[3] Every year, about 1.5 million people die from TB all over the world, and while a majority live in low- and middle-income countries, TB is everywhere.[4] In the United States, the Centers for Disease Control and Prevention (CDC) says an estimated 13 million Americans have LTBI and 7,882 active cases of the disease were reported in 2021.[3]

Understanding TB

Highly contagious, TB is an airborne infectious disease caused by Mycobacterium tuberculosis (MTB). It usually affects the lungs but can also impact other parts of the body such as the kidneys, spine, or brain.[5]

A TB infection historically had two general states — latent TB infection (LTBI) and active TB disease. Recent research has demonstrated that human TB infection, from LTBI to active TB disease, exists within a continuous spectrum of metabolic bacterial activity with antagonistic immunological responses. This paradigm shift in thinking has led to the proposal of two additional clinical states: incipient and subclinical TB.[6] See **Figure 1.**

When incipient and subclinical TB are identified, latent and active TB

Earning CEUs

See test on page 12 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. Discuss healthcare statistics and the causative agent of Tuberculosis (TB).
2. Describe the differences in documented TB infections.
3. Describe detection methods and types of assays for TB and their benefits and limitations.
4. Discuss the current recommended protocols for the identification and diagnosis of TB.

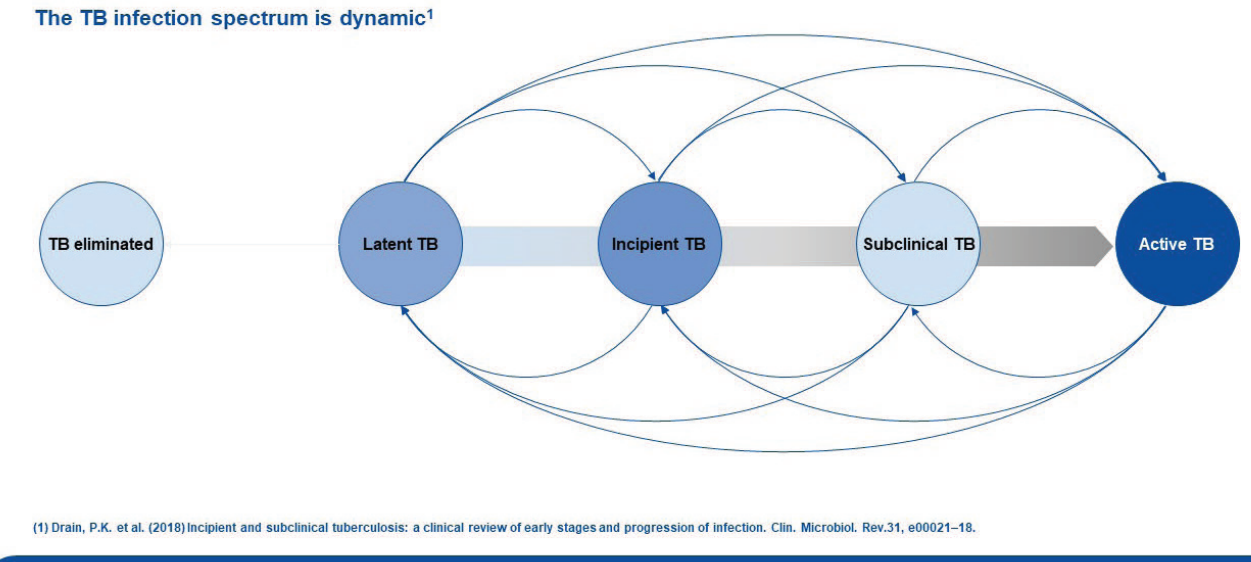


Figure 1.

cases can be divided along the clinical disease spectrum, providing opportunities for diagnostic and therapeutic interventions to prevent progression to active TB disease and transmission of TB bacilli. Therefore, not everyone infected with TB bacteria progresses to an active TB infection but can be somewhere within the spectrum of TB. Without treatment, LTBI can progress to TB disease. But both can be treated. LTBI regimens generally take three to four months to complete, although some protocols can take up to nine months.[7] TB disease regimens generally take from four to nine months to complete.[8] Drug resistant TB is more difficult and costly to treat and regimens may take up to two years.

Screening, accurately diagnosing, and treating LTBI have become focal points of global efforts to end TB.[9] LTBI causes no symptoms or discomfort and is not contagious so most infected people are unaware of their condition. But unless it is treated, one in ten people with LTBI will become ill with TB disease in the future, according to the CDC.

The risk is elevated for people with HIV, diabetes, or other conditions, and for those on treatments that affect the immune system. In fact, TB is the leading cause of death among the 38.4 million people living with HIV.[9]

Clearly medical science, public health agencies and care delivery professionals have made incredible strides to diminish TB's impact on humans. Due to diagnosis and treatment of both LTBI and TB disease, the CDC estimates that more than 66 million lives were saved between 2000 and 2020.[9] But much more needs to be done.

Ending TB through better diagnostics

Globally, world health leaders are working toward TB elimination by 2035.[10] The effort is multi-faceted and involves more than 25 countries. The core of this work is to find and treat latent TB through better screening, contact tracing, and diagnostics, including providing training and technical support to scale use of new and faster diagnostic tools.

Without question, today's laboratories have a growing role to play in support of newer, more specific, less subjective, and faster testing solutions and can spur use of new diagnostic tools over outdated skin testing techniques.

The Mantoux tuberculin skin test

Tuberculin skin tests (TSTs) date back more than 100 years. The tine test, a multi-pronged tuberculin skin test was used for about a century but was abandoned in about 2000 in favor of the Mantoux test. Still in use today, the Mantoux test is generally administered in a physician's office or, more recently, in occupational health settings, and even pharmacy-based walk-in clinics. This test is not done in the laboratory setting.

Due to diagnosis and treatment of both LTBI and TB disease, the CDC estimates that more than 66 million lives were saved between 2000 and 2020.

The Mantoux test is a delayed-type hypersensitivity reaction used to detect if a patient is infected with M. tuberculosis. The skin test involves intradermal administration of tuberculin units of purified proteins (PPD) solution. A follow-up visit is required within 48 to 72 hours so the results can be interpreted in the office. The reading of the test is subjective and therefore the experience level of the reader can affect the results.

The results record the induration as the reaction to the PPD in millimeters (mm) by measuring the induration. The TST can require up to four patients visits, which correlates to a high "no-show" rate. The test then must be redone with another follow-up visit. Additionally, the results of the TST test can be affected by the Bacille Calmette-Guérin (BCG) vaccination—a vaccine for TB. TST can have a specificity as low as 59% in

BCG-vaccinated patients translating to an increase in false positive results from cross reaction with patients who have had the BCG vaccination.

The interferon gamma release assays

Interferon gamma release assays (IGRAs) are tests that measure the immune response to TB proteins to determine if a patient is infected with Mycobacterium tuberculosis. These tests are conducted and analyzed in a laboratory setting from a blood sample instead of a primary care or other clinical settings. For specific patient populations, the CDC encourages their use over TSTs.[11]

IGRAs provide many benefits for both clinicians and patients. IGRAs are a single-visit screening test, they are highly accurate, and they have reproducible results. It is an objective, lab-based test in comparison to the TST which is a subjective test.

Two IGRAs are approved by the U.S. Food and Drug Administration (FDA): QuantiFERON-TB Gold Plus (QFT-Plus) and T-SPOT.*TB*.

Both IGRAs measure secretion of cytokine interferon gamma (IFN-g) as a marker of cell-mediated immune response to TB-specific peptides. They also elicit both a CD8 and CD4 T-cell response, and in the case of QFT-Plus, the response attributed to each cell type can be approximated, which allows for a comprehensive assessment of cell-mediated immune response to TB infection. This interferon gamma is measurable, stable, and typically absent from normal circulation.

QuantiFERON-TB Gold Plus (QFT-Plus) is a whole blood stimulation followed by ELISA or Chemiluminescent detection of IFN-g. In the registration trials and publications by Barcellini, et al[12-14] on QFT-Plus, the isolated CD8 response was calculated by subtracting the quantitative values of TB1 from TB2 and potentially found to be enhanced in the following conditions:

- Frequently in active untreated pulmonary tuberculosis
- Among some persons with higher risk for TB exposure
- Among some persons recently exposed to active TB
- Among some contacts who had higher association to cumulative exposure and being European born (as opposed to being born in higher burden settings)

T-SPOT.*TB* isolates peripheral mononuclear cells from a whole blood sample, and after washing and adding the prescribed number of cells to each well for stimulation, uses an enzyme-linked immunospot (ELISPOT) methodology to count M. tuberculosis-sensitized T cells by capturing interferon gamma in the vicinity of the T-cells from which it was secreted.

No science? Blame it on vampires.

In New England during the late 18th and 19th centuries, entire families succumbed to TB, then called "consumption." Many New Englanders feared that family members who had died became vampires and preyed upon remaining family members. These beliefs led to exhumations and grisly rituals.[2]

Today's recommended test protocols

Both TST and IGRA tests are approved for use in the United States, and both are generally covered by Medicare, Medicaid, and private insurance plans.

The Infectious Disease Society of America recommends IGRA tests rather than TSTs in individuals five years or older who meet the following criteria:

- They are likely to be infected with MTB
- They have a low or intermediate risk of disease progression
- It has been decided that testing for LTBI is warranted
- And they either have had a BCG vaccination or they are unlikely to return to have their TST read (strong recommendation, moderate-quality evidence)[15]

The TST is recommended by the CDC for children under the age of five, primarily because blood tests can be more difficult for young children, however, IGRAs are approved for use with children under five years old.

Who should be tested

Current testing guidelines focus on people who are at higher risk of being infected with TB bacteria. The CDC recommends that the following people be tested:[16]

People who could likely be exposed to TB disease:

- People who have spent time with someone who has TB disease
- People from a country where TB disease is common which include: most countries in Latin America, the Caribbean, Africa, Asia, Eastern Europe, and Russia
- People who live or work in high-risk settings such as long-term care facilities or nursing homes, homeless shelters, or prisons
- Healthcare workers who care for patients at increased risk for TB disease
- Infants, children, and adolescents exposed to adults who are at increased risk for LTBI or TB disease

People who are likely to develop TB disease if they have LTBI:[17]

- People with HIV infection
- People who became infected with TB bacteria in the last two years
- Babies and young children
- People who inject illegal drugs
- People who are sick with other diseases that weaken the immune system.
- Elderly people
- People who were not treated correctly for TB in the past
- People who are receiving immunosuppressive therapy (TNF-alpha antagonists, corticosteroids ≥15 mg/day of prednisone, or immunosuppressive drug therapy following organ transplantation
- People with silicosis; chronic renal failure; leukemia; or cancer of the head, neck, or lung
- People with diabetes mellitus

Labs can be powerful players in the drive to end TB

Despite strong progress to eradicate TB around the world, it remains a serious infectious disease that has plagued humanity continuously throughout history. People today are more globally mobile than ever, and we take our health status with us, as the world was reminded recently with COVID-19.

Powerful modern diagnostics give us a significant advantage to find and treat TB before people become sick or contagious. As increasingly important partners in the healthcare delivery system, medical laboratories can bring precision and expertise to make diagnosing LTBI faster, easier, and less subjective than in the past, making now the time to end TB for good.

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Can medical laboratories give humanity the edge over TB?

APRIL 2023 *[This form may be photocopied. It is no longer valid for CEUs after OCTOBER 31, 2024.]*

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TEST QUESTIONS

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

1. The World Health Organization has ranked TB as a top infectious disease killer, second to

- ○ A. Strep A/B infection
- ○ B. MRSA
- ○ C. Influenza
- ○ D. COVID-19

2. TB can be traced back _____ years.

- ○ A. 5,000
- ○ B. 9,000
- ○ C. 15,000
- ○ D. 29,000

3. Who originally discovered TB and in what year was it discovered?

- ○ A. Robert Koch; 1882
- ○ B. Karl Landsteiner; 1892
- ○ C. Louis Pasteur; 1923
- ○ D. Alexander Fleming; 1891

4. To raise public awareness about the TB epidemic, _____ is marked as World TB Day.

- ○ A. March 4
- ○ B. March 14
- ○ C. March 24
- ○ D. March 30

5. In 2021, there were over _____ reported active cases of TB disease.

- ○ A. 7,000
- ○ B. 10,000
- ○ C. 18,000
- ○ D. 24,000

6. TB typically affects the brain but can also affect other parts of the body such as the kidneys, spleen, and spine.

- ○ A. True
- ○ B. False

7. While there are currently two general states of TB, two additional states have been proposed and named

- ○ A. Incipient and cessation
- ○ B. Cessation and secondary
- ○ C. Cessation and subclinical
- ○ D. Incipient and subclinical

8. If earlier and inactive forms of TB can be identified, the progression to active TB can be halted and thus, transmission will be reduced.

- ○ A. True
- ○ B. False

9. TB disease regimens typically take _____ to complete.

- ○ A. Four to nine days
- ○ B. Four to nine months
- ○ C. Four to nine years
- ○ D. None of the above

10. The focal point(s) of global efforts to end TB include

- ○ A. Screening
- ○ B. Accurate diagnosis
- ○ C. Treatment
- ○ D. All of the above

11. One in _____ people will get sick with TB disease if latent TB infection goes untreated.

- ○ A. Five
- ○ B. Ten
- ○ C. Twenty
- ○ D. Fifty

12. The Mantoux test is a _____ hypersensitivity reaction used to detect if a patient is infected with M.tuberculosis.

- ○ A. IgE antibody mediated
- ○ B. Cytotoxic IgG mediated
- ○ C. Delayed-type
- ○ D. Immune complex mediated

13. The limitations of the Mantoux test include

- ○ A. Subjective reading of results, interference from BCG vaccine, and low specificity
- ○ B. Interference from BCG vaccine, high no-show rate of visits, and low specificity
- ○ C. Subjective reading of results, interference from BCG vaccine, high no-show rate of visits, and low specificity
- ○ D. None of the above

14. Interferon gamma release assays (IGRAs) are a _____ -based test to determine if a patient is infected with TB.

- ○ A. Skin
- ○ B. Plasma
- ○ C. Whole blood
- ○ D. Saliva

15. There are many benefits to IGRAs that include a single visit, high accuracy, highly reproducible, and objective resulting.

- ○ A. True
- ○ B. False

16. Which IGRS FDA–cleared test(s) is/are currently used?

- ○ A. QuantiFERON-TB Gold Plus
- ○ B. T-SPOT TB test
- ○ C. Both A and B
- ○ D. None of the above

17. IGRA tests use the _____ immune response to measure the amount of interferon gamma to TB-specific peptides.

- ○ A. Cell-mediated
- ○ B. Humoral
- ○ C. Immune complex
- ○ D. All of the above

18. The tuberculin skin test is recommended for

- ○ A. Adults over the age of 50
- ○ B. Immunocompromised individuals
- ○ C. Individuals that have had the TB vaccine
- ○ D. Children under the age of 5

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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:

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Nova Biomedical's Educational Webinar Series Presents:

Blood Ketone Management in Pediatric DKA

Diabetic ketoacidosis (DKA) can occur in patients with Type 1 and Type 2 diabetes and is frequently present at diagnosis of younger children with type 1 diabetes. Children less than 2 years-old are at higher risk of DKA. Complications include hypoglycemia, acute kidney injury, cardiac arrthymias and cerebral injury. DKA, along with these complications, is the most common cause of hospitalization, mortality, and morbidity in children with type 1 diabetes mellitus. The fatality rate is approximately 0.15-0.31% of cases.

Monitoring levels of Beta-hydroxybutyrate (BHB) is an integral part of DKA detection and management. BHB is the most common ketone body produced in the body and increases during states of ketosis and ketoacidosis. Quantifying ketosis with BHB allows accurate distinction between simple hyperglycemia and metabolic decompensation in DKA, and provides a guide for therapy to reverse DKA.

This presentation will describe:

- Ketones in physiological and abnormal conditions
- Diabetes ketoacidosis, etiology, mobidity, mortality
- DKA during illness
- BHB in the differential diagnosis of hypoglycemia in neonatal patients

Primary Presenter

Assoc. Prof. Irena Aldhoon Hainerova, Ph.D.
Consultant in paediatrics, paediatric endocrinology and diabetes
Department of Children and Adolescents Faculty Hospital Kralovske Vinohrady
Third Faculty of Medicine, Charles University
Prague, Czech Republic

Blood Ketone Testing at the Bedside

Early diagnosis is important in managing DKA. This presentation will review The American Diabetes Association and Diabetes UK recommendations for blood glucose and ketone testing for early detection and management of DKA. Performance of a hospital meter (Nova StatStrip®) for bedside monitoring of blood glucose and ketone will be described.

Presenter

Marcin Pacek, Ph.D., MBA
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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 24451. 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.

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Blood glucose monitoring

By MLO Staff

Blood glucose monitoring looks at patterns in the fluctuation of blood glucose (sugar) levels that occur in response to diet, exercise, medications, and or pathological processes associated with blood glucose fluctuations such as diabetes. Unusually high or low blood glucose levels can potentially lead to acute and/or chronic, life-threatening conditions. Blood glucose level (BGL) or blood sugar level (BSL) monitoring undertaken in the home/community are often referred to as capillary blood glucose (CBG) tests, while blood glucose tests carried out at clinical facilities may include CBG and (plasma glucose) venous blood tests.[1] The American Diabetes Association (ADA) generally recommends the following target blood sugar levels: between 80 and 130 milligrams per deciliter (mg/dL) or 4.4 to 7.2 millimoles per liter (mmol/L) before meals; less than 180 mg/dL (10.0 mmol/L) two hours after meals.[2]

Pathophysiology

Most food products contain complex carbohydrates that are broken down to supply energy to the cells in our body. Once ingested, carbohydrates are broken down in the gastrointestinal system into simpler sugars such as glucose. In the small intestine, glucose molecules are absorbed into the bloodstream and transported to cells across the body and to the liver. Insulin is produced by the beta cells in the pancreas in response to elevated blood glucose levels.[1]

In conditions like diabetes, there is either a lack of insulin or the body does not appropriately respond (otherwise called insulin resistance) to the actions of insulin (to facilitate cellular uptake of glucose or storage of excess glucose). Patients with impaired blood glucose levels and impaired fasting blood glucose are at high risk for developing diabetes. Patients are diagnosed with diabetes if their BGL's are high. Some organs such as the brain, kidneys, liver, and red blood cells do not have insulin receptors and do not require insulin for the uptake of glucose. These organs, especially the brain, are significantly affected by acute, chronic, and/or recurrent drops in blood glucose levels and are associated with significant morbidity.[1]

Insulin is used in the management of type 1 diabetes and some cases of type 2 diabetes. Insulin therapy has a well-known adverse side effect of hypoglycemia if its administration is not managed effectively. Patients with insulin-dependent diabetes benefit from regular blood glucose monitoring.[1]

Diagnostic tests

Capillary blood glucose test[1]

A capillary blood glucose test is a blood drop sample usually collected from a fingertip prick. Blood samples can also be sourced from alternate sites such as the earlobe, heel, forearm, palm. Alternate site testing provides similar results to finger-prick testing, especially when fasting and within two-hours post-meal. Check with the manufacturer of the glucometer if the machine can be used for alternate site testing.

Equipment used includes a lancet used to prick the skin, glucometer, and test

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strips. Glucometers require a very small sample of blood (from 0.3 to 1 microliter) and have a range of features, including Bluetooth capabilities that synchronize data with paired applications (apps) on smartphones. These machines and apps record data and provide trends in glucose measurements undertaken. Further, some apps also provide options to record diet, medications used, and types of physical activity undertaken, which may be useful to the healthcare practitioner when managing the care plan for the patient with diabetes.

One disadvantage of a CBG test is the accuracy of the results is dependent on the clinical presentation of the patient, i.e., it may not be very reliable in patients with hypoglycemia, anemia, altered hematocrit, hypotension, or those who are critically ill. Older machines may need calibration with test strips, and results could be compromised if the calibration is not undertaken appropriately.

Venous blood sample[1]

The venous (plasma) blood sample is collected via venipuncture by a phlebotomist, medical laboratory scientist, nurse, etc. The equipment used for venipuncture includes collection tubes, needles, tourniquet, wipes/swabs, gauze, bandages, gloves, laboratory forms and blood specimen labels, transportation bags, and sharps container. The most accurate blood glucose measurements are obtained from venous specimens that are analyzed in a clinical laboratory.

Venous blood samples are considered accurate measurements of blood glucose and are superior to the capillary blood glucose test. There are some slight risks associated with venipuncture that may include pain, excessive bleeding, light-headedness, fainting, nerve damage, hematoma (accumulation of blood under the skin), and infection.

Continuous glucose monitoring[1]

Continuous glucose monitoring (CGM) involves insertion or application of a water-resistant disposable sensor on the abdomen or back of the upper arm. The sensor can be scanned with a reader, which displays the patient's current glucose level. Seeing glucose levels in real time can help individuals make more informed decisions throughout the day about how to balance food, physical activity, and medicines. Individuals can also review glucose changes over a few hours or days to see trends. Data from the CGM device can be shared with family and care providers via a smartphone application, and the apps are often capable of sending alerts, such as for hypoglycemia, a particular benefit during the night while sleeping. Some CGM's can work with compatible insulin delivery devices and can stop insulin delivery if the machine predicts and or recognizes a drop in blood sugar level. However, glucose is first seen in the blood before it is seen in interstitial fluid, which the CGM measures. As such, the CGM may not always be a reliable indicator in rapidly changing blood glucose levels.

Hyperglycemia

Etiology of hyperglycemia includes:

- Inadequate insulin administration in patients with type 1 diabetes
- Insulin resistance with type 2 diabetes, which inhibits glucose metabolism
- Stress-related experiences (such as critical illness) inducing glycogenolysis and gluconeogenesis
- The dawn phenomena where there is a surge in blood glucose levels

Symptoms of hyperglycemia include polyuria (increased and frequent urination), polydipsia (increased thirst), blurred vision, headache, fatigue, and glucosuria. Acute symptoms of hyperglycemia are not usually seen at levels below 14 mmol/L or 250 mg/dl.[1]

Episodes of hyperglycemia for an extended period could lead to either diabetic ketoacidosis or hyperglycemic hyperosmolar state. Diabetic ketoacidosis is a life-threatening scenario where an individual could potentially go into a state of coma from a lack of insulin production. Individuals may also have symptoms of fruity odor (from the ketones being produced in the body as a result of fat metabolism), dry mouth, shortness of breath, nausea, or vomiting.[1,3]

In the hyperosmolar state, a rare condition seen in patients with type 2 diabetes, the body in its attempt to get rid of the high glucose levels in the blood, produces large amounts of urine causing life-threatening dehydration and potentially coma.[1,3]

Long-term high blood glucose levels could potentially delay wound healing, damage nerves (peripheral neuropathy), and damage organs such as the eyes (diabetic retinopathy), kidneys (renal failure), brain (stroke), and heart (myocardial infarction).[1]

Hypoglycemia

Hypoglycemia is a condition in which a person's blood sugar (glucose) level is lower than the standard range. Symptoms of hypoglycemia are seen when low blood glucose levels deprive the body of essential fuel to sustain life. The most common reason for low blood sugar is a side effect of medications used to treat diabetes.[1,4]

Symptoms of hypoglycemia include sweating, irregular heartbeat, blurred vision, lightheadedness, or difficulty concentrating. If individuals do not recognize the onset of symptoms of hypoglycemia, they may put themselves at risk for injury. As hypoglycemia worsens, symptoms include loss of coordination, confusion, and blurred vision.[1,4]

Emergent treatment to restore normal blood glucose levels is imperative as certain organs (e.g., brain) do not store glucose and need a constant supply of blood glucose to sustain life. Antidiabetic therapy needs reevaluation when BSL falls below 5.6 mmol/liter (100 mg/dl), and modification of antidiabetic therapy is essential if BSL drops below 3.9 mmol/liter (70 mg/dl).[1]

Conclusion

Blood glucose monitoring is an essential part of management of patients with diabetes. Having very high or very low levels of blood glucose could impair cellular function and may be lethal if not managed appropriately. Patients need education on the importance of regulating diet, exercise, and medications to prevent acute and or chronic complications that are seen in extreme blood glucose fluctuations in conditions like diabetes. The use of glucose management protocols, with nurse-initiated treatment protocols, is ideal for the management of hyperglycemia and hypoglycemia in the hospital setting.[1]

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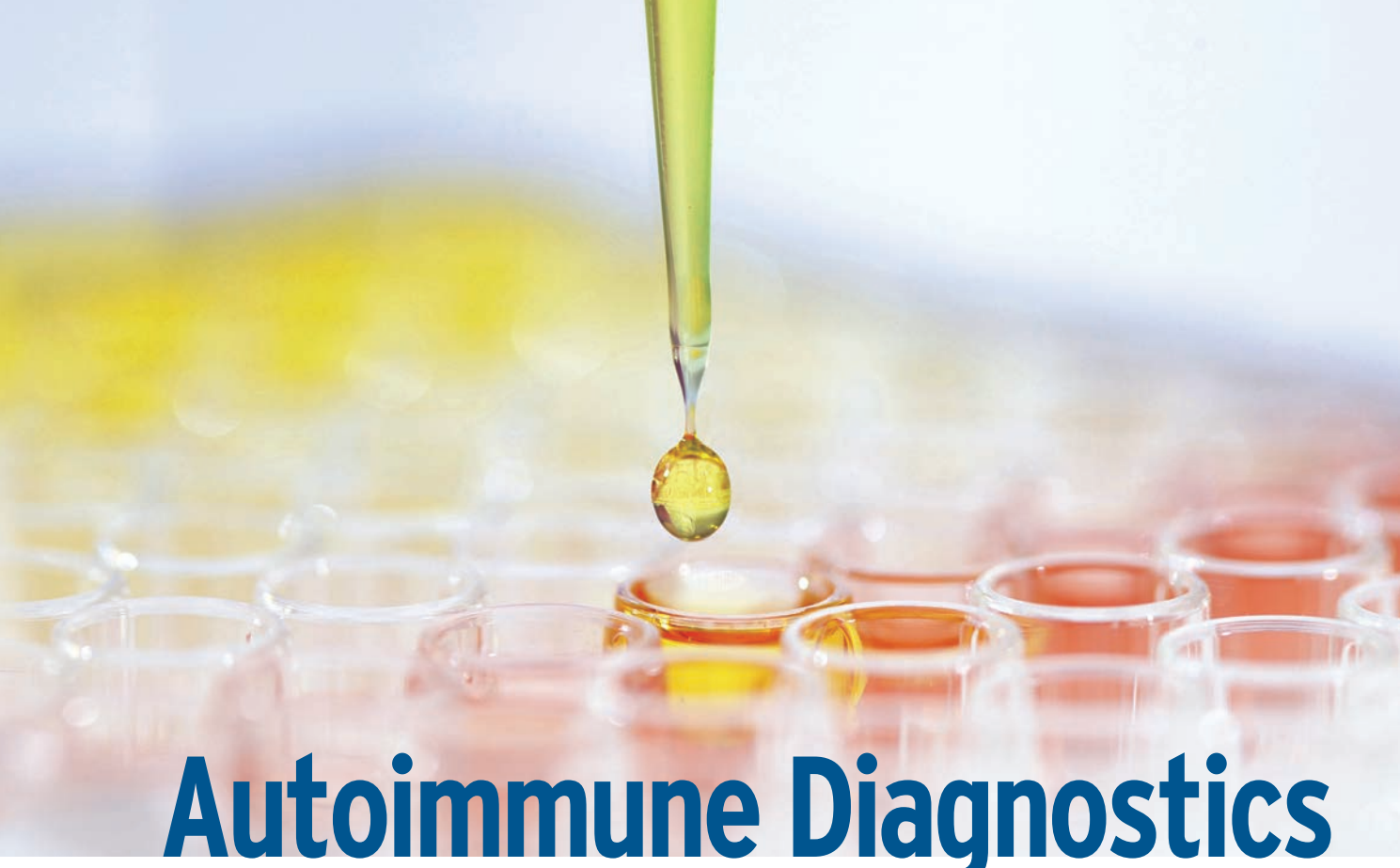

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Department of Pathology and Laboratory Medicine, Avera McKennan Hospital & University Health Center — a culture of quality improvement focused on patients

By Christina Wichmann

Photo courtesy of Department of Pathology and Laboratory Medicine, Avera McKennan Hospital & University Health Center

Medical Laboratory Observer's 2023 Lab of the Year is the Department of Pathology and Laboratory Medicine at Avera McKennan Hospital & University Health Center. The Avera Health system serves Upper Midwest residents of South Dakota, North Dakota, Minnesota, Nebraska, and Iowa and covers a 72,000-square-mile footprint. Avera McKennan, the flagship facility for the health system, is based in Sioux Falls, South Dakota. Here, the Avera McKennan Laboratory serves as the clinical laboratory for the 545-bed hospital and its local clinics, as well as the reference laboratory for the whole Avera Health system. The laboratory consists of 16 departments and covers testing from basic hematology and chemistry to cutting-edge cell therapies, in-house human leukocyte antigen (HLA), and specialized chemistry. And the laboratory will soon include liquid chromatography-mass spectrometry analysis.

Lab of the Year nominations are judged on achievements across six categories: customer service, education and training, lab inspections, productivity, strategic outlook, and teamwork. *MLO* received many outstanding nominations this year, and this annual feature is one of the most popular in the magazine. The Avera McKennan Laboratory stood out for its many efforts to take quality to a higher level. These efforts range from its Pre-Analytical Department implementing processes to improve patient communication and satisfaction—and performing scheduled audits of the processes; the Histology Department taking on a project to evaluate specimen submissions for osteomyelitis and identify opportunities for improvement in the handling of these lab tests; and being one of the few medical laboratories in the United States with ISO 15189 accreditation through the College of American Pathologists (CAP), which it first achieved in 2008.

Other notable features of the Avera McKennan Laboratory in each of the six categories follows.

Photo courtesy of Department of Pathology and Laboratory Medicine, Avera McKennan Hospital & University Health Center

Hannah Olson (front) and Natosha Hiipakka working in histology on the microtomes.

Customer service

Over the past year, Avera McKennan Lab's Pre-Analytical Department has focused on ways to improve Press Ganey outpatient satisfaction survey scores. The whole staff understands that patient care is everyone's job, and everyone participates in creating a quality patient experience during daily huddles and staff rounding. One outcome from the Pre-Analytical team was the creation of a patient pamphlet provided by the phlebotomists. On the pamphlet, the phlebotomist provides his or her name and provides the patient a direct phone number for questions and comments. In addition, the Pre-Analytical team strategically places a primary staff member at each service center, so repeat patients are more likely to see a familiar face.

The Pre-Analytical team also implemented the AIDET framework for inpatients and outpatients, which stands for acknowledge, introduce, duration, explanation, and thank you. Through this process, staff understand the importance of acknowledging the patient and introducing themselves, giving accurate wait times, explaining the procedure, and thanking the patient before they leave. Implementing AIDET resulted in a more than 10% increase from the previous quarter in the Press Ganey score surrounding staff's explanation of tests. The department performs scheduled audits of this process to support continual improvement.

The Histology Department undertook a project this year to evaluate the turnaround times from specimen collection to result reporting for osteomyelitis patients. The department used a process map to review its current workflow, which generally took five to six days from collection to results. Having the step-by-step process laid out on a map, staff were able to identify an improvement during the pathology review. The old process had the pathologist reviewing the slides on day four, which could cause a greater delay of one or two days if the sample was collected mid- to late week due to lack of pathology staffing on the weekends. The Histology Department made changes so that slides are assigned to a pathologist the same day the slides are prepared. Due to this change, the turnaround time has been reduced by a minimum of 24 hours (often 48 to 72 hours) compared to the old process.

This change in the process now allows physicians to have results sooner in order to start proper treatment. Patients are positively affected by both treatment and discharges happening sooner. In December there were 24 osteomyelitis cases. The new process equaled a reduction of between 576 and 1,728 hours waiting for results. As a result, the hospital's quality department is in the process of studying this project's impact on patient length of stay.

Education and training

The Avera McKennan Laboratory had many laboratory assistants who held bachelor's degrees in biology or chemistry, and through their time in the lab, many gained an interest in becoming medical laboratory scientists (MLS). However, moving, going back to school, and leaving their job to obtain their degree created obvious hurdles. Avera McKennan Laboratory had strong relationships with several universities in the area, particularly South Dakota State University (SDSU).

The laboratory and SDSU came together to discuss ways to build career ladders and roadmaps for students with science degrees to streamline their paths to becoming an MLS. This partnership resulted in an accelerated MLS program for staff and others who already held a science or healthcare-related degree and were interested in the advanced laboratory degree. The program would take one year to complete, with the majority of learning online.

Michael Billion in the liquid nitrogen freezer room.

The laboratory invested in equipment and made room to host SDSU-accelerated students for their clinical rotations. Avera McKennan brought additional technology into its education classroom, such as microphones and cameras, to allow students to interact with other students and listen to lectures virtually. Avera McKennan also purchased a microscope for the instructors to conduct slide reviews that would display on a large television allowing students at other sites to view lessons with the students in the room.

The laboratory also proposed to SDSU to place accelerated students on an opposite schedule of traditional four-year students. This has allowed the laboratory to host clinical rotations of the accelerated students in the fall and the four-year students in the spring, allowing the accelerated students to graduate in December. Previously, hiring during the winter was challenging, whereas, in the spring, there was a large pool of candidates due to students graduating. Avera McKennan is now able to hire new graduates twice a year in December and in May.

Lab inspections

The Avera McKennan Laboratory is very diverse and is inspected by several different organizations. Avera McKennan is CAP accredited and also one of the leading laboratories in the ISO 15189 program. In 2008, they became the first hospital-based laboratory and one of the first two medical laboratories in the United States with ISO 15189 accreditation. There are still less than 100 laboratories with CAP ISO 15189 accreditation. Laboratories implementing ISO 15189 strive to create systems that are as efficient and failure resistant as possible, identify opportunities for improvement at all times, and involve and empower staff in the solving of problems and implementation of solutions.

The laboratory is also inspected by the Association for the Advancement of Blood & Biotherapies (AABB) and the U.S. Food and Drug Administration (FDA) for transfusion services, the American Society for Histocompatibility and Immunogenetics (ASHI) for histocompatibility, and the Foundation for the Accreditation for Cellular Therapy (FACT) for the cell therapy program.

The laboratory resources used to maintain quality and inspection-readiness include Visiun and MediaLab. Visiun is a software program used to analyze laboratory performance data. Through this system, the laboratory automates daily, weekly, and monthly performance metrics reports. MediaLab's software has simplified the lab's document control tracking and significantly improved the lab's occurrence monitoring. Management can quickly and easily provide feedback on laboratory errors (occurrences) entered into MediaLab and the quality team monitors MediaLab's IQE for trends in order to develop process improvements.

Avera McKennan's laboratory began its Lean process improvement journey in 2004. The laboratory has a dedicated Quality Assurance team of medical laboratory scientists to ensure the rigorous Quality Management System plan is followed. The team works with all departments to organize process improvements,

Cory Gunderson loading the WASP instrument in microbiology.

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conduct root cause analyses for occurrences, and develop quality indicators focused on patient impact. A monthly quality meeting is organized with all coordinators, supervisors, and managers, along with the lab director and medical director to recap the previous month. With a dedication to utilizing technological solutions and Lean tools, Avera McKennan has obtained nearly perfect inspections year after year.

Productivity

The Avera McKennan Laboratory has 94.2 full-time equivalent (FTE) staff who are performing 2,915,657 tests annually. In addition to providing services for the 545-bed attached hospital and its local clinics, the laboratory serves as a reference lab for over 300 locations including hospitals, clinics, and other care facilities in the region. During the COVID-19 pandemic, Avera's rural footprint presented challenges when it came to turning around a high-quality test result quickly. Early on, the laboratory diversified its testing options in-house; however, the need for a new testing solution that was fast, accurate, but also available closer to the patient was identified.

Avera entered into a partnership with LumiraDx and began evaluating their point-of-care solution: the SARS-CoV-2 Ag Test. Study results were encouraging and the process of distributing the devices throughout the system's 72,000-square-mile footprint began. Testing that initially took days became minutes as individuals could receive their COVID results close to home, wherever that may be. Systemwide turnaround times dropped from 38 hours to under 8 hours across all methodologies throughout the five-state testing area. The project was selected for a poster abstract at the 2022 AACC International Critical and Point-of-Care Symposium in Montreal, Canada.

During the past few years, retirements and staffing challenges led to difficulty in maintaining microbiology services at smaller sites. The Avera McKennan microbiology laboratory expanded its department and streamlined workflows to support the smaller sites. When grant money was available to help prepare laboratories for pandemic response, the laboratory requested and received a Copan WASPLab automated microbiology system. The line sets up, incubates, and reads plates to assist microbiology technicians with the increased workload. The Copan Colibri system was also installed and Avera McKennan currently has the first fully FDA-approved system in the United States. The Colibri will plate MALDI targets and prepare bacterial suspensions for automated susceptibility instruments, further freeing up microbiology staff to do more technical work.

Photo courtesy of Department of Pathology and Laboratory Medicine, Avera McKennan Hospital & University Health Center

Erin Fernholz working in the molecular lab.

Teamwork

The Avera McKennan Laboratory has many individual departmental accomplishments that keep the laboratory first in its class, but where it really shines is when they work together across departments. Using the laboratory's occurrence documentation software, an interdepartmental task group reviews trending issues and works to resolve them — making sure that pre-analytics, analytics, and post-analytics are involved in the conversation. Two examples of the lab's teamwork include rectifying misplaced specimens in the lab and working to improve the laboratory test order process.

After a major library information system (LIS) update changed processes throughout the hospital, the team got together to resolve specimens being misplaced in the laboratory. Using data reports and daily management practices over the course of three months, the number of misplaced specimens dropped by 60%.

Another success of the task group involved analysis of a laboratory test order process that was prone to error. In previous years, individual departments and groups tried to address the issue, but were unable to make meaningful changes. The interdepartmental task group began by creating an overall process map, as well as listing out all the risk points and current countermeasures involved. Root cause analysis showed that there was not a good understanding of the factors that contributed to the errors in this process. Additional departments were invited to share their processes and risk points, which were added to the process map. The process was followed from the laboratory to histology to radiology to registration to scheduling, and finally to the clinics.

The task group presented its findings and recommendations to laboratory administration, which was then brought before the hospital administrative council, as well as stakeholders in the IT Department. The laboratory continues to be involved in high-level discussions as the hospital works toward solutions.

Strategic outlook

In 2023, the strategic outlook of the Avera McKennan Laboratory includes evaluating, integrating, and expanding its capabilities. One major milestone is that the Avera Institute for Human Genetics will be integrating with the Avera McKennan Laboratory to become a stronger, more unified laboratory that is able to offer its combined talents and resources to the entire Avera system, along with other organizations, under one umbrella. Several teams will be evaluating workflows, testing capabilities, and patient and provider needs. Through the integration, Avera McKennan Laboratory plans on adding the additional services of liquid chroma-

tography-mass spectrometry testing, next-generation sequencing, DNA microarray, and pharmacogenomics.

Additional plans of the laboratory for this year include the following:

- In the Histology Department, major construction will add over 1,000 square feet to its space expanding the immunohistochemistry, histology, and gross room spaces. Additionally, the department will be implementing a new digital pathology instrument.
- In the Flow Cytometry Department, after years of work, the department will move to 10 color flow, which will lead to increased accuracy in population identification and ability in obtaining detailed information from paucicellular specimens.
- In the Cellular Therapy Department, the laboratory is slated to become a treatment center for the first commercially approved TIL (tumor infiltrating lymphocyte) used to treat metastatic melanoma. FDA approval is expected in the first quarter of 2023 with go-live shortly thereafter. Additionally, the department is planning to onboard the CAR-T product Carvykti, which is a new product on the market for multiple myeloma.
- The Avera McKennan Blood Bank has validated at-home blood transfusion and will be moving forward with this process in 2023.
- Through the partnership with LumiraDx, Avera McKennan Laboratory has agreed to become a pilot site for various upcoming tests and products creating opportunities to provide better patient care across the laboratory's rural footprint.

Closing

Medical Laboratory Observer commends the Avera McKennan Laboratory for its strides in providing first-rate quality in its testing services. The laboratory has a strong culture of continuous improvement where staff are driving change to improve services for their wide-ranging patient population. When *MLO* shared the news with Avera McKennan Laboratory, its leaders expressed it best when describing this special laboratory and its entire staff:

Laboratory Director – Jessica DesLauriers, MBA, MLS (ASCP)CM: "This level of achievement cannot be obtained alone — it took the hard work and dedication by each member of our laboratory team. We thank them for showing up every day ready to share their knowledge, skills and talents to provide our patients with the highest level of quality care!"

Vice President of Hospital Pharmacy and Laboratory Services – Tom Johnson, PharmD: "Once again, the Avera McKennan Laboratory Team has demonstrated dedication to excellence. Being recognized as Laboratory of the Year is a testament to the vision and engagement of the entire team. We are very proud of each and every one of our team members for their commitment and teamwork."

Medical Director – Raed Sulaiman, MD: "I am very proud of our lab team members and colleagues. Their dedication, work ethic and quality work are superior, always striving for excellence. This award is a perfect reflection of that. Thank you everyone for making the Avera McKennan Laboratory stand out."

2023 Lab of the Year Runner Up: North Kansas City Hospital Laboratory

By Erin Brady

North Kansas City Hospital Laboratory team.

North Kansas City Hospital (NKCH) Laboratory is a 450-bed acute care hospital with 31 health clinics and 550 physicians. They have 98 full time equivalents in the lab and their scope of responsibilities include a level II trauma center, a teaching hospital, and 24/7 clinical and pathology lab services.

The laboratory performs 9 different categories of tests adding up to over 1.5 million tests annually.

Customer service

NKCH Laboratory monitors their customer satisfaction rate, striving to stay above 96%, exceeding it in September 2022 and fiscal year 2023.

"Just like members of the chorus singing together to make beautiful music, each member of our laboratory works together to provide exceptional customer service," said Antoinette Martin, Phlebotomist, North Kansas City Hospital Laboratory. "Outside the lab our phlebotomists often see patients who are not at their best and having the empathy to treat them with kindness and understanding is a priority. We also interact with those at the bedside and support them in providing the best patient care possible. Inside the lab, it is common to see our staff helping each other out while also trying to have a good time and take care of one another. Just like a perfectly orchestrated song, good customer service takes all of us doing our part!"

In addition to the lab's customer satisfaction metrics, they review patient feedback monthly and created a "WOW" system for positive employee recognition.

Productivity

How do we monitor productivity in the lab at NKCH, asked Sean Tucker MBA MLS(ASCP)CM, Director of Laboratory

Photo of the front of the hospital.

Medical Laboratory Science Class of 2022-2023 on their first day in the lab at NKC Hospital.

Services. "We measure ourselves against our peers across institutions with similar sized facilities. While not always apples to apples, based on complexity and turnover, our goal is to be above the 50th percentile and we consistently achieve that goal!"

They also use metrics and a productivity performance scorecard to monitor the lab's productivity. Their combined "roll-up" worked hours per unit of service has an average of 105% productivity.

Teamwork

The mission of North Kansas City Hospital is "to provide hope and healing to every life we touch."

The employees of NKCH Laboratory have a great working relationship, said Deana Gialde MLS, SM(ASCP)^{CM}, Microbiology Supervisor. "I believe this stems from the hospital's core values, which rate an employee's performance not only on how well they perform a job, but forty percent is dedicated to behavior expectations. I honestly love the people I work with! I know without a doubt that we not only provide quality results, but we do so with care and compassion."

Several employees are cross trained so they can be ready to help other departments when needed. The laboratory has all staff teaching others. Scientists volunteer for student lectures and the first shift lab techs educate daily on the bench.

The lab team also conducts daily departmental huddles and hosts celebrations and recognitions for employees to encourage them. The team creates special bonds with each other through fun activities inside and outside of work.

They also collaborate with Community Blood Center to host 12 hospital wide blood drives every year, resulting in an average of 600 units of blood products collected annually.

Education and training

NKCH Laboratory scored the highest on their education and training. There are many services they provide that earned them runner-up, to name a few:

- Total Quality Management program for quality control and performance improvement.
- Added a career path for histology techs.
- Implemented a career ladder program for career advancement, with five recent laboratory participants.
- Requires a certain amount of CEUs for each job skill and attempts to make them free.
- Maintains a budget so department supervisors can attend national conferences.
- Internal enrichment experiences like having laboratory students attend open-heart surgery and shadowing and observing other departments.
- External enrichment experiences so laboratory students can attend off-site training.

Additionally, they have their own North Kansas City Hospital School of Medical Laboratory Science, one of six programs in the state. The lab's day shift scientists teach the students and 70% of NKCH's MLS staff are graduates of the program.

Strategic outlook

To improve efficiency and maximize output in the lab, NKCH Laboratory is adding Coagulation and Hematology to the automation line. They created a new position for a Phlebotomy Education Coordinator and started a 'grow your own' Phlebotomy Training Program. They also developed a career ladder for lab assistants in phlebotomy and processing.

To help minimize nonessential lab testing, the laboratory started a "Choosing Wisely" campaign with a utilization review committee. With the ultimate goal of cost savings in mind, they use a health information management system to decrease unnecessary testing and blood product transfusions.

To reduce patient misidentification and increase efficiencies with automation, the lab implemented CareAware, a positive patient ID at bedside.

NKCH Lab's new automation line.

"Our patients deserve the best, so it's important that the North Kansas City Hospital laboratory delivers the highest quality of patient care as efficiently and cost effectively as possible," said Dr. Brett Sramek, DO, Medical Director. "In order to meet that expectation, we are continually reviewing processes and implementing new technology. Our overarching goal is to constantly think strategically in order to set the benchmark not only for other institutions, but also for our industry."

Lab inspections

At their most recent lab inspection on November 15, 2022, NKCH Laboratory was only given two deficiencies: the Microbiology Department outgrowing their space and a missing competency assessment documentation. Both of these have been addressed and responded to by the lab.

Their CAP Inspection Summary said, "This is the best laboratory I've seen in Kansas City," Dr. Lyle Noordhoek, MD, Lead Inspector.

2023 Lab of the Year Runner Up: Radeas Labs

By Erin Brady

Team Radeas.

Radeas Labs, derived from the words radical ideas, was founded in 2013 by Dr. Phil Radford to help facilitate trust between patients and healthcare providers.

Based in Wake Forest, North Carolina, nearly 300 Radeas employees work together to serve healthcare facilities, hospital systems, collegiate football teams, county governments, cruise ships, universities, and individual patients throughout the nation. Their scope of responsibilities includes comprehensive clinical solutions in toxicology, clinical labs, and infectious disease testing. In 2022 alone, they released tens of millions of clinical tests.

With 25,000 square feet of facility space and 8 fully functioning CLIA high-complexity mobile labs, Radeas served millions of patients in 2022.

Customer service

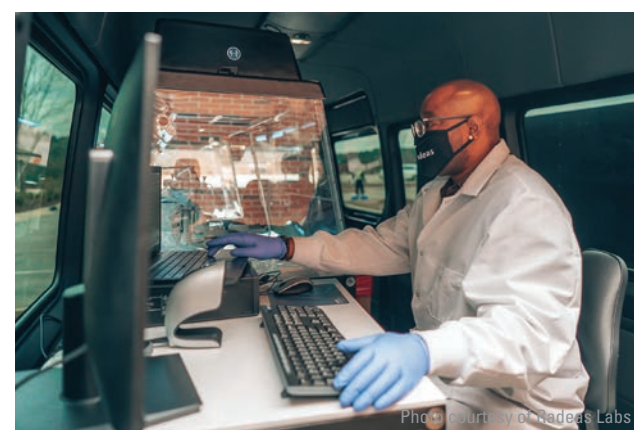
The goal of Radeas Labs is to insert trust between patients and doctors through systems that produce high-quality data with an error rate of less than one in a million. They maintain a standard of providing clinical data the next business day, prioritizing accuracy. Dr. Radford said, "We did that the first day we opened, and we are committed to continuing that level of service today."

Throughout the COVID-19 pandemic, Radeas established 150 testing clinics throughout the country. With their mobile labs, Radeas was able to reach underserved communities and patients in long-term care settings by providing them with walk-up and curbside testing and vaccinations.

Radeas staff are proud of the volume of testing services they provided during the pandemic to ensure cruise lines, businesses, healthcare facilities, schools, and states could operate. "My favorite memory from 2022 was watching an 80 foot–high cruise ship disembark, knowing everyone had been tested and cleared. Hearing the horn go off and knowing that this group was now safe, and that they could relax and enjoy vacation together again was incredible. There was a lot of pressure to get families vacationing together again and keep them safe while doing so. This was an emotional moment to watch the ship cruise away knowing they were safe, protected, and gathered together," Dr. Radford said. From 2020–2021, cruise ships had been unable to sail for 450 days.

Productivity

During the pandemic, Radeas Labs staff worked to make sure patients had their results within 24 hours. All staff worked extra hours to achieve this. During peak outbreaks, Radeas Labs processed an average of 10,000 PCR tests per day.



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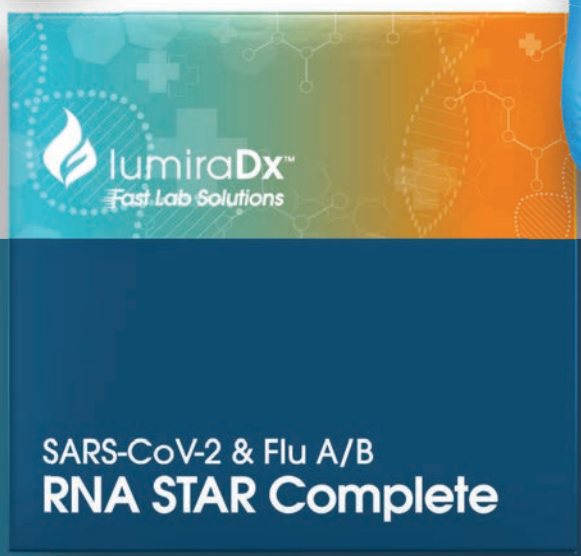

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Photo courtesy of Radeas Labs

PCR data analysis.

Due to the demands of the COVID-19 outbreak, Radeas invested in Thermo Fisher's KingFisher automation to bring turnaround times down to 8 hours. This speed improvement facilitated scalability and sustainability of offering same day results 6 days a week. Following that success, Radeas worked closely with scientists at LumiraDX to update the SARS-CoV-2 RNA Star Complete EUA to improve throughput on additional thermocycler platforms. Moving from the previous 96-well format to a 384-well format quadrupled the specimens that could be run at a time. Further workflow optimization synergized sample collection, with accessioning processes, to allow for Integra adjustable multichannel pipettes to bring average turnaround times down to 1.5 hours. This process allowed them to initiate mobile testing through 8 mobile labs.

Teamwork

What makes Radeas special is that the 'why' is understood by many of the team players, Dr. Radford said. "That is what is inspiring and motivating. People understand why we are doing what we are doing and want to provide that service as efficiently and accurately as possible."

The team at Radeas Labs is mission driven and values trust not only with the patients, but with each other as well. To strengthen the team, Radeas offers extracurricular endeavors inside and outside the lab. The team also has celebrations and activities for holidays, and departmental incentives when goals are achieved. Additionally, Radeas offers extensive employee benefits to enhance overall health and human flourishing both inside and outside the workplace.

During the pandemic, staff worked together to assure that testing was being conducted safely and accurately with quick turnaround times. They also partnered with Gladwell Orthodontics to provide testing to patients and served as an information source. Dr. Jason Thomas Gladwell of Gladwell said, "It's those things that you don't find in a typical lab group. They've got our business for life. I don't think we could have gotten through the pandemic the way we did without their partnership."

Education and training

Radeas Labs adheres to strict quality control assurance in all its lab processes. Its proprietary QR code platform allows them to ensure that the right sample is matched with the correct patient. The lab's testing process requires that lab experts sign-off on each step of the testing checklist to confirm the time and dates of accessioning, test plates transferring, machine placements, and all other steps. Radeas maintains these records and audits them randomly to ensure all precautions and steps are taken. The lab also validates its samples, performs periodic retesting to confirm results, and recalibrates and checks machines daily to ensure they are functioning properly. Continually educating Radeas staff on these in-house standards is key to maintaining the low error rates achieved over the years.

All employees are required to complete a HIPAA and Compliance training course every year. Additionally, continuing education is made available consistently and certain staff members are selected to complete training programs offered by the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA).

Lab inspections

Radeas Labs is accredited by the Commission on Office Laboratory Accreditation (COLA) and inspected every two years. In preparation for their inspections, Radeas does evaluations of their practices for quality assurance and regulation compliance.

Radeas Labs proficiency testing (PT) is distributed through the American Proficiency Institute (API) and College of American Pathologists (CAP) for certain tests, which have 2–3 shipments annually depending on the test. They compare the results of their split sample testing (SST) to ten other labs. They investigate and correct as needed every result out of range for PT or SST.


Photo courtesy of Radeas Labs

Data analysis.

Radeas Labs is certified through CLIA to test in: virology, syphilis, general immunology, routine chemistry, urinalysis, endocrinology, toxicology, and hematology.

Strategic outlook

The mission statement of Radeas Labs is, "Bringing Truth and People Together through Clinical Laboratory Science." In addition to building trust with patients, they also want to achieve the goal of being the most caring laboratory. They plan to execute this through the training of their employees.

During the COVID-19 pandemic, Radeas came up with new laboratory methods, software solutions, and dynamic staffing programs to meet the need for quality testing options in their community. They strategically chose instruments and layouts for speed and accuracy in the lab. For their community testing sites, they enlisted the help of a restaurant to orchestrate their drive through testing. They also used drone footage to keep an eye on site traffic.

In 2023, Radeas is looking to optimize operations by utilizing artificial intelligence to analyze patient lab results and then convert those results into customized data to help physicians create care plans. They believe this will help them continue to fulfill their mission.

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Helix Lab Partners

Gregg Brandush, RN, JD
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Centers for Medicare & Medicaid Services

Captain Daniel Hesselgesser, MLS(ASCP)cm
Manager, Southern Operations Branch (Atlanta, Dallas)
Centers for Medicare & Medicaid Services

General Session: Workforce Shortage Panel Lineup

Edna Garcia, MPH
Senior Director, Scientific Engagement and Research ASCP

Marisa James
Chief Executive Officer, National Accrediting Agency for Clinical Laboratory Sciences

Shawn Wierzbowski
Chief Executive Officer
Intro

Cary Montalvo
Executive Director, Laboratory Services
Texas Oncology

Breakout Session Speaker Lineup

George Fritsma, MS, MLS
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Emily Garnett, PhD, DABCC
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Platelets in the pipeline: Advancements in platelet technologies

By Abigail Kasberg, PhD and Olivia Stricker, PhD

Proper platelet function is an important component of many hemostatic disorders and a critical therapeutic target for cardiac and stroke prevention. Thus, a key objective of laboratory testing is to detect and understand the mechanisms of platelet dysfunction. The ability to diagnose platelet function deficiencies rapidly and accurately is vital to managing many bleeding conditions. Despite its importance, there are currently no tests available to assess platelet function in all situations. However, there are technologies in the pipeline that have potential for clinical adoption. The hope is that new strategies and technologies will expand platelet testing and antiplatelet therapy monitoring, while also providing improved turn-around-time, user-friendliness, reproducibility, and standardization.

Common platelet function tests aim to analyze a component of complicated platelet functions. While there are many instruments and systems available for measuring platelet function in the clinic, there are hurdles that make the task difficult. Problems include lack of standardization, time-sensitivity, dependence on fresh plasma, and highly technical hands-on time. These issues have driven variable results between clinical labs.[1] In addition, mild bleeding disorders are difficult to diagnose due to subtleties in platelet dysfunction that may not be obvious or identifiable with current testing options using superphysiological conditions. Samples with thrombocytopenia have complex challenges that require careful data interpretation, especially when utilizing assays that require platelet-rich plasma (PRP). Most tests fail or provide aberrant data when using low platelet count samples. These challenges have stimulated the development of new platelet function devices and technologies to better meet the clinical needs of platelet function disorders and antiplatelet therapies.

> Physiological alterations to the mechanical properties of blood clots are linked to bleeding, thrombosis, cancer, heart disease, and more.

Instrument additions offer fresh life to platelet function

As platelet knowledge and technologies advance, so does the horizon of opportunities to improve platelet testing. From automation advancements for existing technology to expanding the scope of analysis, a platelet analyzer shake-up could be just around the corner **(Figure 1)**.

New FDA-cleared platelet analyzer—one test, one result

Platelet testing typically starts with a global primary hemostasis test to identify functional vs dysfunctional samples.

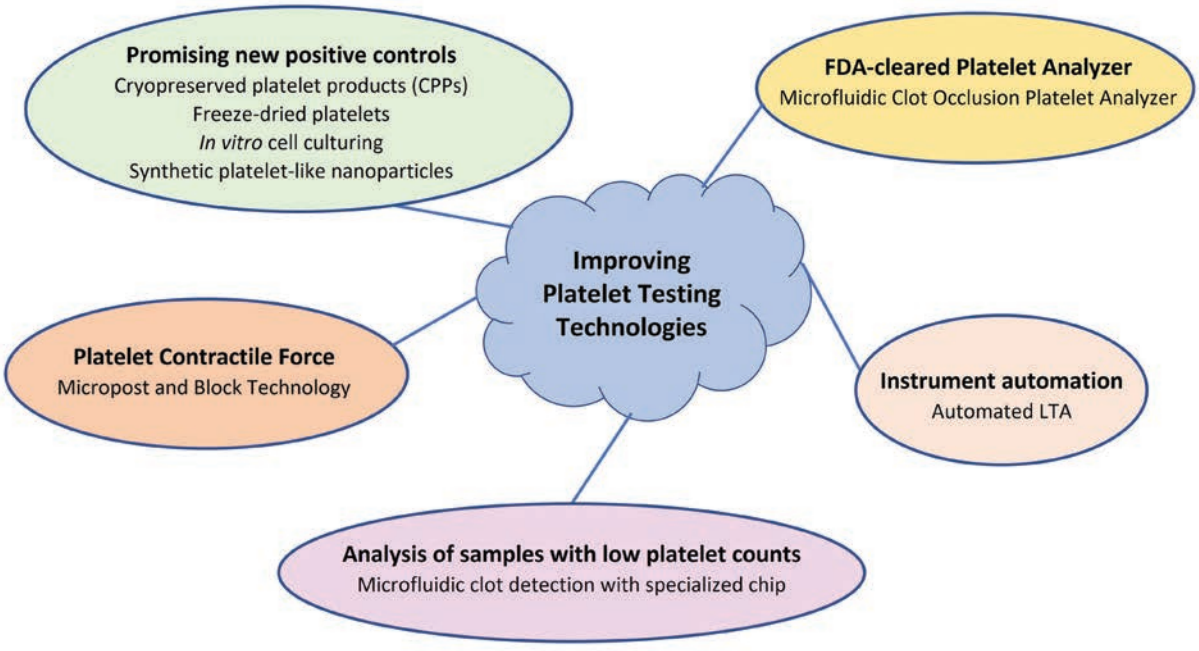

Figure 1: Improving Platelet Testing Technologies. LTA, light transmission aggregometry

A single test result is often unable to detect every cause of platelet dysfunction, thus multiple tests may be needed to determine a platelet function deficiency. To combat this, a newly cleared global testing system utilizing microfluidic clot occlusion with pressure sensing technology has arrived in the U.S. market (**Table 1**).[2,3] This device fills the clinical need for global physiological testing parameters and empowers a single test result to detect primary hemostatic abnormalities or antiplatelet therapies. This technology has the potential to streamline global functional testing through the elimination of additional pathway-specific tests.

Lowering the thrombocytopenia roadblock

Most platelet function tests are sensitive to platelet counts, such that samples with low platelet counts may be problematic for the analytical abilities of platelet aggregometers and other assays.[4] To address this, a specialized chip has been developed for microfluidic clot detection. It activates primary and secondary hemostasis in blood samples with platelet counts as low as 10,000/µL **(Table 1)**.[5] These chips contain a flow chamber that is coated with collagen and thromboplastin (tissue factor) through which blood flow mimics that typically seen in small arteries. As platelets become activated, plate-

Platelet Analyzer Technology	Function	Regulatory Approval Status
Microfluidic Clot Occlusion Platelet Analyzer	An automated microchip flow-chamber system is designed for the rapid and comprehensive analysis of global primary hemostasis.[2,3] This technology enables the rapid and comprehensive monitoring of patient hemostasis in a clinical setting.	IVD
Specialized Chip for Microfluidic Clot Detection Analyzer for Thrombocytopenia samples	A specialized chip contains a flow chamber that is coated with collagen and thromboplastin (tissue factor) to activate both primary and secondary hemostasis.[5] This technology is effective when utilizing blood samples with platelet concentrations as low as 10,000/µL.	RUO
Micropost and Block Technology	This technology analyzes platelet contractile force under microfluidic shear gradients.[9]	RUO
Automated LTA	Automation of the widely used LTA technology aims to improve reproducibility and standardization of pathway-specific platelet disorder detection.	RUO

Table 1: A list of the newest and upcoming technologies and instruments to analyze and measure platelet function. IVD, in-vitro diagnostic use; RUO, research use only.

Platelet Products	Benefits to Platelet Function Testing
Cryopreserved Platelet Products	Cryopreserved platelets can be stored long-term and are active or activatable.
Freeze-dried Platelet Units	Freeze-derived platelet units can be stored at ambient temperatures and rehydrated in sterile water for use.
In vitro Cell Cultures	Stem cell and differentiated cell culture protocols have been developed to generate platelets.
Synthetic Platelet-like Nanoparticles	Synthetic platelet-like nanoparticles are in development to mimic platelet function.

Table 2: Platelet products that have potential to alleviate the need for fresh donor plasma during platelet function testing.

let aggregation blocks channel flow, which increases flow pressure over time. This innovative technology may prove beneficial for analysis of hemostatic function in individuals with thrombocytopenia but is not approved for clinical use in the United States.

Platelet contractile force analysis

During primary hemostasis, platelets anchor to and aggregate at sites of vascular injury. Platelet contraction is the result of cell-signaling pathways that influence platelet shape, granule secretion, clot stiffness, and response to the stiffness of surrounding microenvironments.[6,7,8] In essence, blood clots are dynamically active due to the contraction of platelets. Physiological alterations to the mechanical properties of blood clots are linked to bleeding, thrombosis, cancer, heart disease, and more.[6] Platelet contraction is not currently measured nor approved for use in existing clinical assays but has potential to diagnose multiple types of platelet-driven deficiencies or dysfunctions.

New nanoscale technology has enabled the activity of platelet clumps and single platelets to be measured.[6] The most advanced contraction measurement is with micropost and block technology which assesses platelet contractile forces under microfluidic shear gradients **(Table 1)**.[9] This technology could be used to better understand when platelet transfusions may be needed, titrate antiplatelet therapies, provide a global view of all steps of primary hemostasis, and characterize general clot formation and strength at various times. Collectively, careful analysis of platelet contractile forces provides insight into the biophysical outcomes of platelet function disorders.

Automated light transmission aggregometry

The gold standard for detecting pathway-specific platelet disorders has historically been automated light transmission aggregometry (LTA). LTA is flexible and can probe multiple platelet activation and aggregation pathways with various agonists in parallel.[13] Despite these benefits, the LTA assay is manually intensive, time-consuming, is plagued by a lack of standardized laboratory practices, requires specialized technical training, equipment, and large sample volumes. To overcome the lack of standardization, new technology is in development to automate LTA **(Table 1)**. Automated aggregometry could enable the ability to execute reproducible, gold standard platelet function testing without being dependent on specialized technicians. This automated instrumentation is being used in Europe but is not available in the U.S. market.

Platelet product innovations—promising controls

Platelet function testing frequently requires fresh donor plasma to serve as positive controls. Fresh donor plasma is a limited resource for many facilities and stands as a significant obstacle impeding the ability to provide platelet function services. To overcome the need for fresh donor plasma, cutting-edge blood product technologies are in development that may alleviate some of the related issues **(Table 2)**.

Cryopreserved platelet products (CPPs) offer the advantages of long-term storage coupled with platelet products that are active or activatable. Cryopreserved platelets are utilized in self-contained heparin induced thrombocytopenia (HIT) functional assays as alternatives to radioactive HIT functional assays.[14] The ability of CPPs to control bleeding and blood loss during cardiopulmonary bypass surgery is also under investigation.[15] Given that these platelet cryopreservation protocols produce active and functional platelets, it would be of great interest for future studies to assess the utility of CPPs as positive controls in platelet function assays.

An additional platelet product in the pipeline is freeze-dried platelets. Freeze-dried platelets are advantageous due to their ability to be stored at ambient temperatures for up to three years and can be rehydrated in sterile water to produce ready-to-use activated platelets.[16] A phase 2 clinical trial is currently underway further investigating freeze-dried platelet units.[17]

To overcome the need for fresh donor plasma, cutting-edge blood product technologies are in development that may alleviate some of the related issues.

In addition to purified platelet products from human plasma, platelets can be generated from various stem and differentiated cell cultures.[18,19] Synthetic platelet-like nanoparticles are also being developed to mimic platelet hemostatic function to control bleeding.[20] These proof-of-concept studies are promising, yet further developments are needed to meet clinical needs.

Utilization of these developing platelet products has the potential to eliminate the requirement of freshly drawn donor platelets for controlled platelet function testing. If effective, platelet function testing could become decentralized, technically simplified, and more accessible.

Conclusion

The recent boost of innovative technologies aims to fill the holes that are limiting accessible, accurate, and specific platelet function testing capabilities. The newly available clinical instruments and the up-and-coming platelet function tests are promising in being able to meet the clinical demands surrounding platelet function analysis. While most are still very much in the developmental pipeline, the future for better platelet testing options looks bright.

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Why a real-time QC reporting system is critical in the modern lab

By Quality Systems Team at Bio-Rad Laboratories

Quality control (QC) remains one of the most important tasks of the medical laboratory to ensure the reliability and accuracy of reported patient results. Whenever results are sent to physicians that need to be corrected, or any time prolonged quality troubleshooting is necessary within the laboratory, it can affect patient safety, laboratory credibility, operating costs, turnaround times, and regulatory or accreditation compliance. Recently, the industry buzz related to QC has focused on the concept of risk management, most notably the Clinical and Laboratory Standards Institute's (CLSI) EP23: Laboratory Quality Control Based on Risk Management and the Centers for Medicare & Medicaid Services' (CMS) individual quality control plan (IQCP). When applied properly, risk management can help minimize the risk of reporting incorrect patient test results.

Real-time connectivity

One of the most important attributes of a real-time quality control reporting system is the ability to capture and process QC data automatically from laboratory information systems (LIS) or middleware systems. Laboratories cannot afford to lose time waiting for the green light to begin testing patient samples. In today's environment, it is not possible to use paper Levey-Jennings charts in which laboratorians manually plot the QC results or manually enter results in long spreadsheets. Laboratories need QC data management with connectivity solutions that will integrate seamlessly within their workflow for real-time results. The best solutions include bidirectional connectivity that automatically directs instruments to stop reporting results for QC failures even before a laboratorian has seen a result. This technology is called auto-verification.

Digital management of quality control data provides opportunities and benefits for laboratories, starting with the design of the QC process. Laboratory staff can use new integrated algorithms for the selection of the most appropriate QC rules to detect clinically significant errors, minimizing the risk of reporting incorrect patient results. With current data management solutions, labs no longer have to rely on easy to remember, but poor, rule selection for all tests, such as one QC result out more than two standard deviations (1-2s). Modern laboratories now base their QC design upon their bias, imprecision, and selected total allowable error for each analyte. In order to estimate the bias for each analyte, participation in an interlaboratory program or proficiency testing (PT) program is necessary. Some software is capable of transmitting the QC or PT results directly to the corresponding interlaboratory program in order to complete the QC design as part of an integrated process.

Monitoring the QC process

Once the QC process has been designed, it is important to review and manage trends at regular intervals to judge the effectiveness of the process. QC is not a static process but rather a dynamic evolving system. New instrument reagent

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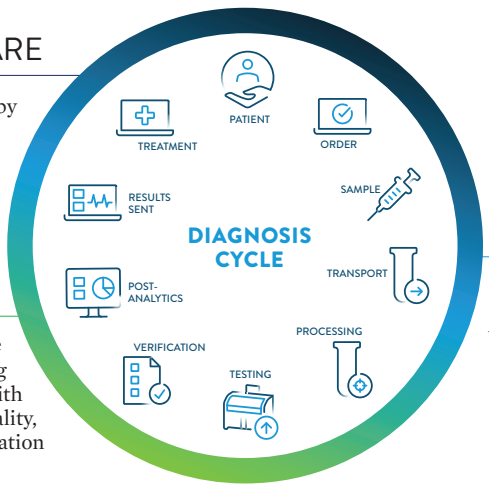

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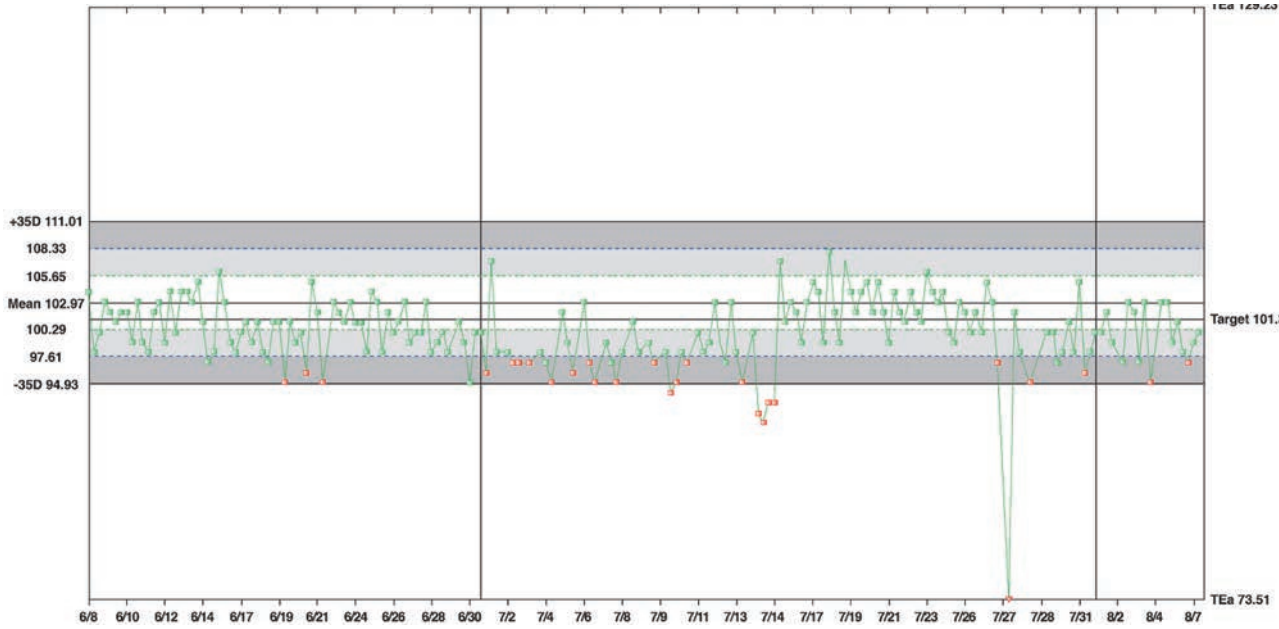

Figure 1. Levey-Jennings Chart displaying evaluation mean and standard deviation (left scale) and analytical goal (desirable biological variation—right scale). This chart helps to show that many rejected QC results are false rejections due to the tight SD limits in combination with poorly selected QC rules. Using QC design would result in a more appropriate set of QC rules.

lot, new calibrator lot, new QC lot, instrument maintenance, and many other factors can all influence and modify the behavior of testing systems over time. The use of multiple instruments or modules in the laboratory environment is also a contributing factor. Detecting changes and estimating the influence on patient results has become an important part of the process.

It is not the large shifts that should be the top concern in a laboratory today, since these shifts can be detected relatively quickly and corrected before they can do any harm. The top concern should be the moderate to small shifts that go undetected for a longer period of time, only affecting a few results each day. Those errors are the ones that will go unnoticed for a longer time and might affect some results and ultimately patient safety. In order to detect these moderate shifts, laboratorians can use automated tools that are often integrated in QC data management software packages. Data analysis grids can help to compare the differences between instruments and indicate the size of errors. Multiple Levey-Jennings charts displayed next to each other or overlaid in one complete chart can help identify trends or shifts across instruments. These charts can be created by QC level or across QC levels to determine whether there are systematic errors in the test system or just random errors.

Analytical performance specifications

In addition to these statistical tools, laboratorians can also use quality specifications and analytical goals to evaluate whether shifts or trends are clinically significant. The use of regulatory or scientifically based specifications such as CLIA or biological variation can add valuable information about test criteria that might

not be set appropriately and thus create unnecessary repeat QC testing, instrument calibration, and troubleshooting. These quality specifications can also be included on the Levey-Jennings charts and are powerful visual tools to evaluate test performance (**Figure 1**).

To monitor operational performance and quality over time, dashboards can provide information that is clear and easy to act upon for the most critical issues and failures. Laboratory staff can review QC data and add corresponding actions and comments to the QC results for audit trail documentation.

With the use of these new integrated technologies comes the risk that in case of a connectivity failure, results could be unreported to the QC data management program. Advanced QC tools can alert users, scanning the program at fixed intervals to verify the presence of the QC results. If results are missing, alerts are displayed in the program and email notifications are sent to laboratory staff. All aspects of these features are tracked in an audit trail that provides complete traceability. This is an important step for regulatory and accreditation purposes. Laboratories can easily generate reports that can be shared with an auditor or filed for future inspections.

Future developments

Digital programs are able to more quickly integrate new QC concepts. Several new developments for QC are gaining popularity and will change workflow and design. There are significant advancements being made in the areas of risk management, QC frequency determination, measurement uncertainty, patient moving averages, and much more. Integrating these concepts into a digital program can help laboratories more rapidly adopt new QC practices and tailor processes to their current infrastructure. Future digital solutions may include modules for method evaluation or other less frequent statistical evaluations such as linearity assessments, contamination or carry-over studies, detection limits, and so on. These data management tools are all part of a digital QC management solution.

The integration of digital management of QC into the modern laboratory is critical. Not only does it allow for real-time decisions, but additional features such as QC design, risk management, data analysis, audit trails, reports, graphical representations, and interlaboratory participation are all part of a complete data management system.

Decline in COVID testing creates retraining opportunities for labs amid staffing shortages

By Alex Mitchell

With the COVID-19 Public Health Emergency finally set to expire May 11, it is safe to say the decline in the volume and frequency of COVID testing that labs have experienced over the past year will be the new normal for the foreseeable future. But despite this shift, clinical laboratories of all sizes and sub-specialties are still struggling with staffing issues as many of the lab professionals trained primarily for molecular COVID testing fail to meet employers' qualifications and required experience for open positions. On the flip side of that coin, some potential candidates are holding out for ideal opportunities after realizing the leverage they hold due to the number of open positions.


Maggie Morrissey

"There's still a huge need for sub-specialties such as histotechnology, cytotechnology, toxicology, LC/MS, etc.," says Maggie Morrissey, Director of Recruiting and Staffing for Lighthouse Lab Services, a North Carolina-based recruiting and consulting firm "Lighthouse has many people who are available to work, but most don't have any experience in those sub-specialties because of the recent focus on COVID."

Given that reality, labs should explore meeting this problem head-on by considering candidates who may not meet their exact requirements, but who could be trained to fit an open role over a short period of time.

The current landscape

In early 2022, the overall testing landscape for U.S. labs was still being dominated by demand for molecular COVID testing.

> According to a report last year from *Forbes* on the shortage of medical technologists in the United States, there has been a 7% decrease in the total number of medical technologist and medical laboratory scientist training programs since 2000.

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While many continue to do an admirable job advocating for legislative issues and laws impacting the profession, not enough attention has been paid to the ongoing staffing crisis, let alone tangible solutions.

Much of this was due to the fact that at-home testing was not as prevalent during that time and most international travel still required a negative COVID test.

However, that changed around April of 2022 as the country made at-home tests more widely available and more scrutiny was placed on federal reimbursements for widespread surveillance testing. Fast forward to today, and even more labs built specifically for COVID testing are closing their doors or shutting down their molecular testing lines.

"Everything kind of slammed to a halt when it came to COVID testing," Morrissey says. "Those labs stopped hiring and some couldn't make a transition into infectious disease for a lot of different reasons."

But despite that initial shockwave from those closures, demand from labs for staffing assistance remains high. According to a 2022 wage and morale survey of medical lab professionals conducted by Lighthouse, 40% of more than 1,100 respondents indicated their lab was moderately understaffed, while another 33% described their lab as significantly understaffed. Just 27% of respondents felt their lab was adequately or well-staffed.

How labs could benefit from a fresh approach

Considering the disconnect between open positions and what labs are searching for in ideal candidates, there is ample opportunity for large and mid-sized labs to consider offering their own internal training to help elevate individuals who may be lacking experience in the specific specialties an employer may be seeking.

According to a report last year from *Forbes* on the shortage of medical technologists in the United States, there has been a 7% decrease in the total number of medical technologist and medical laboratory scientist training programs since 2000.[1] While labs should not be solely responsible for solving that long-standing issue, Morrissey believes it is one they can help alleviate in the short term.

"Laboratories of the right size should take it upon themselves to train because many of the candidates they're currently seeking are not just going to come out of the woodwork," she says. "Recruiters are helpful, but we're not wizards. We can only find candidates if there are candidates to be found for a particular location."

Additionally, the push to find a perfect candidate who can immediately hit the ground running may actually cause the position to remain open longer as the search continues, impacting the morale of the remaining lab staff. Out of the 73% of our survey respondents who said their labs were understaffed, 44% described themselves as extremely or moderately unsatisfied in their role, while 24% stated their morale was neutral.

Candidates should also view the current hiring environment as an opportunity to advocate for themselves, even if they may not immediately seem like a perfect fit for an open lab role. Some large labs already have robust training programs in place, and candidates should use that knowledge to inquire about whether there may be a pathway to a new position available via temporary training.

Newer medical technologists who graduated during the pandemic should be especially open to this approach.

"If you reach out and a lab says they'd be open to training you, they may offer you a lower training salary until you complete their program or requirements to move into a new position," Morrissey explains. "But in any situation like this, you'll want to have signed agreements stating how long you'll be training, your rate of pay during that time, and what your compensation will be elevated to upon completion."

The role universities and community colleges can play

Immediate staffing fixes aside, Morrissey thinks the true solution to this problem can be addressed by community colleges and universities offering post-graduate training opportunities where individuals can learn the specifics of a specialty and increase their hiring chances in turn. While that may only involve a course or two each semester for someone who wants to simultaneously remain in the workforce, it would be a boon for the success of these programs and their graduates in the long run.

"Those opportunities just aren't available right now," Morrissey says. "There needs to be more of an effort for these programs to connect with local labs to offer internships or other opportunities to continue education."

Getting to that point will require industrywide advocacy in addition to the support of existing industry groups. While many continue to do an admirable job advocating for legislative issues and laws impacting the profession, not enough attention has been paid to the ongoing staffing crisis, let alone tangible solutions.

"Of course, labs and individuals can advocate for themselves," Morrissey says. "But we need to continue having industrywide discussions about how we can band together to solve this staffing crisis, similar to what happened with nursing 10–15 years ago. I'm confident we're moving in the right direction on that front."

Looking ahead

There remains a significant percentage of the clinical lab workforce that graduated during the height of the pandemic and has spent their career in the interim focused on COVID testing. Considering the staffing demands labs throughout the industry continue to face, it would be shortsighted to allow the skills of these individuals to atrophy to the point where they consider leaving the profession altogether.

While the long-term solution to this problem will require the combined efforts of educational program administrators, lab advocacy groups, and leaders from within the profession, labs can address hiring issues in the immediate future by considering more nontraditional candidates or those who may require some training in order to fulfill their open positions.

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Post-COVID-19: Long-term consequences with multiple manifestations

By Ilana Heckler, PhD

The COVID-19 pandemic was caused by the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in December 2019. While mild cases of COVID-19 may involve cold-like symptoms, severe cases can lead to hospitalization and/or death. Additionally, a new concern is developing, as long-term consequences of SARS-CoV-2 infection are being observed, even in patients whose disease course was mild or moderate.[1,2] This phenomenon, referred to as long- or post-COVID-19, affects all age groups and is characterized by physical, cognitive, or psychological impairment.[3] It is estimated that one in five individuals with a confirmed SARS-CoV-2 infection develop post-COVID-19 symptoms.[4] These symptoms can last for a few weeks, months, or longer. Common post-COVID-19 symptoms include fatigue, shortness of breath, headache, anxiety, persistent cough, muscle pain, and difficulty thinking (brain fog). Additionally, risk factors have already been identified such as older age, cardiovascular disease, chronic lung disease, kidney disease, hypertension, and diabetes mellitus, initial disease severity, and female sex.[2]

According to the Centers for Disease Control and Prevention (CDC), at least four weeks after infection marks the start of when post-COVID-19 conditions can first be identified, as most people recover from the acute infection after a few weeks.[5] Additionally, in 2021, the World Health Organization published the following working clinical case definition of post-COVID-19:

"Post COVID-19 condition occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually three months from the onset of COVID-19 with symptoms that last for at least two months and cannot be explained by an alternative diagnosis. Common symptoms include fatigue, shortness of breath, cognitive dysfunction but also others which generally have an impact on everyday functioning. Symptoms may be new onset, following initial recovery from an acute COVID-19 episode, or persist from the initial illness. Symptoms may also fluctuate or relapse over time. A separate definition may be applicable for children."[6]

Several mechanisms have been proposed regarding post-COVID-19 conditions including immune dysregulation, microbiota dysbiosis, autoimmunity, blood clotting with endothelial abnormalities, and neurological signaling dysfunction.[7] It has been proposed that autoimmune manifestations following COVID-19 are likely due to results of inflammatory cascade and the immune activation triggered by the virus, rather than a direct effect of the virus.[8] Autoreactivity following SARS-CoV-2 might further be explained by a study that found that immunogenic peptides of SARS-CoV-2 have a high sequence homology with some human proteins.[9]

While a recent study found that many post-COVID-19 symptoms resolve on their own a year post infection, growing evidence that SARS-CoV-2 is associated with autoimmunity, suggests the possibility of long-term consequences.[2,7,10] Such SARS-CoV-2 induced autoimmune disease might be a result of the production of disease-specific autoantibodies. This article will highlight the recent findings on the immunological and neurological manifestations of post-COVID-19 syndrome **(Table 1)**.

Immunological manifestations

Several studies have suggested that the formation of autoantibodies is involved in the development of post-COVID-19 syndrome.[12,13] The presence of autoantibodies in patients with COVID-19 has been reported in different frequencies: antinuclear antibodies (ANA) in 50%, anti-Ro/SSA in 25%, rheumatoid factor in 19%, lupus anticoagulant in 11%.[1,14,15] A meta-analysis study, that analyzed rheumatic autoimmune diseases in COVID-19 patients from December 2019 to September 2021, identified 99 patients that had fulfilled the diagnostic criteria for a specific rheumatic disease.[1] The main diseases reported were vasculitis and arthritis, and a smaller number of patients were reported to have idiopathic inflammatory myopathies (IIM), systemic lupus erythematosus (SLE), sarcoidosis, systemic sclerosis, and adult-onset Still's disease. Autoantibodies were reported in cases of IIM (anti-small ubiquitin-like modifier-1 activating enzyme, anti-Ku, anti-Mi 2b, anti-Ro/SSA, anti-Smith, anti-melanoma differentiation-associated protein 5) and SLE (anti-dsDNA antibodies, anti-Ro/SSA, anti-La/SSB, anti-histone, anti-RNP, anti-β2-glycoprotein I antibodies).[1] Another study reported an increased prevalence of ANA, anti-neutrophil cytoplasmic antibodies (ANCA), and anti-Saccharo-

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Post-COVID-19 manifestation	Autoimmune disease association
Immunological[1]	• Vasculitis
	• Rheumatoid arthritis
	• Anti-phospholipid syndrome
	• Systemic lupus erythematosus
	• Idiopathic inflammatory myopathies
	• Systemic sclerosis
	• Adult-onset Stills's disease
	• Sarcoidosis
Neurological[10,11]	• Guillain–Barré syndrome
	• Autoimmune encephalitis
	• Myelin oligodendrocyte glycoprotein-IgG-associated optic neuritis
	• Miller Fisher syndrome
	• Neuromyelitis optica-like syndrome
	• Myasthenia gravis
	• Brainstem autoimmunity

Table 1. Reported immune-related manifestations of COVID-19.

myces cerevisiae antibodies (ASCA) in 40 COVID-19 patients compared with healthy individuals. The authors proposed that autoimmunity is linked to SARS-CoV-2 infection, because none of the patients had a previous autoimmune disease.[12]

There have also been a number of studies reporting increases in anti-phospholipid antibodies in patients with COVID-19.[10,16,17] Early in the pandemic, Zhang and colleagues found that patients with COVID-19, with coagulopathy and multiple thrombi, were positive for anti-cardiolipin IgA antibodies, anti-β2 glycoprotein 1 IgA antibodies, and IgG antibodies.[18] Since then, the testing for anti-phospholipid antibodies in patients with COVID-19 has rapidly increased. Combined data from two studies depicted similar frequency of anti-phospholipid antibody positivity in COVID-19 patients admitted to intensive care units: 87% and 76% for lupus anticoagulant, 47% and 44% for anti-cardiolipin antibodies, 0% and 22% for anti-β2 glycoprotein I antibodies.[10] However, several factors must also be considered when evaluating SARS-CoV-2 as a trigger of APS such as extent of association between anti-phospholipid antibodies and thrombosis, and persistence of antibody positivity, as positivity alone does not confirm APS.[10]

While there have been many reported cases of newly developed autoantibodies in COVID-19 patients, disease-specific autoantibodies have not been identified in every report of post-COVID-19 autoimmune disease. For example, anti-citrullinated protein antibodies (ACPA) have been found in cases of post-COVID-19 rheumatoid arthritis (RA); however, post-COVID-19 RA, without increased ACPA, has been reported also.[19,20] Therefore, more research is still needed to understand the link between the autoantibodies and post-COVID-19 autoimmune diseases and to learn whether these "induced" antibodies differ from those normally occurring in RA and other autoimmune diseases.

The severity of SARS-CoV-2 infection might correlate with the specific immunological manifestation. Gracia-Ramos et al. found that more than half of the cases of post-COVID-19 arthritis (RA, spondyloarthritis and reactive arthritis) appeared in patients with mild COVID-19, vasculitis occurred in mostly mild or moderate cases, while more than half of IIM cases occurred in severe or critical COVID-19.[1] Further, one study proposed that autoantibodies may also act to drive COVID-19 disease, as over 10% of patients with life-threatening pneumonia presented with antibodies against neutralizing interferon (IFN)-1, while patients with mild or asymptomatic COVID-19 infection had none.[21] Therefore, pre-existence of anti-IFN-1 may be a risk factor for severe COVID-19 rather than a consequence of infection.

Neurological manifestations

Emerging research has shown a connection between SARS-CoV-2 and the nervous system.[11] The most common neurological symptoms of COVID-19 are fatigue, concentration, memory disorders, headache, vertigo, myalgia and neuropathy, as well as persistent smell and taste disturbances.[22] Additionally, post-COVID-19 neurological diseases have been described such as stroke, epileptic seizures, myelitis, Guillain-Barré syndrome (GBS), cranial nerve deficits, myositis, and plexopathies.[11,22-24]

Anti-neuronal autoantibodies have been found in cerebrospinal fluid (CSF) of severely ill COVID-19 patients suggesting an immune-mediated mechanism for post-COVID-19 neurological symptoms.[25] In a 2021 study, serum and CSF samples were analyzed for anti-neuronal and anti-glial autoantibodies from critically ill COVID-19 patients presenting with unexplained neurological symptoms including myoclonus, oculomotor disturbance, delirium, dystonia, and epileptic seizures.[25] Using cell-based assays and indirect immunofluorescence, anti-neuronal antibodies were detected in all samples. The autoantibodies detected were those against intracellular and neuronal surface proteins, such as Yo, myelin, and N-methyl-D-aspartate (NMDA) receptor. In another study, sera from patients with post-COVID-19 syndromes of neurological, cardiological origin, was found to contain functionally active autoantibodies targeting G-protein coupled receptors (GPCR). The specific targets of these autoantibodies included β2- and α1-adrenoceptors, angiotensin II AT1-, muscarinic M2-, MAS-, nociceptin-, and ETA-receptors. Future studies are needed to better understand the exact role of anti-GPCR antibodies in the development and maintenance of post-COVID symptoms. However, preliminary studies have begun to look at whether therapies targeting anti-GPCR antibodies could improve post-COVID-19 symptoms.[26]

A possible connection between COVID-19 and autoimmune encephalitis (AE) has been investigated. AE is a debilitating neurological disorder characterized by brain inflammation that leads to rapidly progressing encephalopathy. AE manifests with seizures and other neuropsychiatric symptoms. One study analyzed the frequency of SARS-CoV-2 antibodies in patients who underwent neural antibody testing as part of the diagnostic evaluation for AE at Mayo Clinic in 2020. This laboratory cohort was cross-referenced with the Department of Neurology's COVID-19–related consultative experience (encephalopathy cohort). Between both cohorts, a total of five patients were identified as having definite, probable, or possible AE representing 0.05% of all patients with COVID-19 illnesses evaluated. This, combined with other studies reporting anti-NMDA receptor antibodies post SARS-CoV-2 infection is evidence of

a possible connection between COVID-19 and development of AE.

Several other autoimmune neurological disorders have been described in post-COVID-19 patients. Notably, a wide number of cases of peripheral nervous system involvement in the form of Guillain-Barré syndrome have been reported.[23,24,27,28] In addition, multiple sclerosis has been reported in a patient following COVID-19 infection, and well as myelin oligodendrocyte glycoprotein antibody–associated optic neuritis and myelitis in another.[29,30] Finally, antibodies against the brainstem proteins disabled homolog 1 (DAB1), apoptosis-inducing-factor-1 (AIFM1), and surfeit-locus-protein-1 (SURF1) have been found to be elevated in COVID-19 patients.[31] Theses neuronal antigens are required for synaptic plasticity and higher cognition. While IgM levels were found to be comparable in both groups, IgG levels were significantly elevated in severely ill patients compared to controls, suggesting a pathogenic role of IgG.

Conclusion

Now over three years from the beginning of COVID-19 pandemic, there have been many reported cases of autoimmunity following SARS-CoV-2 infection. The autoimmune manifestations of post-COVID-19 syndrome include rheumatic, neurologic, dermatologic, and cardiac disorders. There are no current testing guidelines for long- or post-COVID-19 in the United States; however, guidelines have been developed in other countries, such as Germany.[32] While there is no one test for post-COVID-19 syndrome, as this condition is not a single illness, there are assays available for the detection of specific autoantibodies that are increased in post-COVID-19 patients.

More research is still needed to better understand the link between SARS-CoV-2 and new onset-autoimmune diseases. Questions that remain include: Are SARS-CoV-2 induced antibodies different from the typical disease-associated antibodies? Are post-COVID-19 autoimmune manifestations transitory or might they persist longer resulting in chronic conditions? What is the exact mechanism of SARS-CoV-2–influenced autoantibody development? This additional knowledge could then be applied to achieve the optimal testing strategy and determine the most suitable therapy.

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Elements of a general laboratory safety program

By Clinical and Laboratory Standards Institute

A comprehensive general laboratory safety program encompasses all aspects of daily laboratory operations, including engineering controls, personal protective equipment, work practice controls, transport and shipping of specimens, and waste disposal.

Throughout this article, the phrase "the laboratory needs to" explains an action directly related to fulfilling requirements of international, national, and accreditation organizations. The phrase "the laboratory should" describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.

Engineering controls

The biological safety cabinet (BSC) is the principal safety device used to minimize exposure to infectious aerosols generated in the clinical laboratory. Procedures with a potential for generating infectious aerosols should be conducted within a BSC. These may include centrifuging, pipetting, grinding, mixing, shaking, and opening containers. BSCs should also be used when working with high concentrations or large volumes of infectious agents; when the natural route of transmission of the agent is via inhalation (e.g., filamentous fungi, Mycobacterium tuberculosis); or when a highly virulent organism is suspected.[1]

There are three classes (I, II, and III) of BSCs, and Class II is further divided into four types: A1, A2, B1, and B2. In the clinical laboratory, the most commonly used BSCs are Class II, Type A1, and Type A2. When used properly, these BSCs provide protection for personnel, the environment, and the product by directional airflow and high efficiency particulate air (HEPA) filtration of exhaust air.

There are several other laboratory engineering controls. The use of centrifuge safety equipment protects against the release of aerosols. Centrifuge safety cups, rotors with covers, removable centrifuge rotors and O-rings are also effective controls for reducing aerosols. Pipetting aids such as bulbs or autopipettes, or pipettes with cotton plugs or filters, are recommended for the safe use of pipettes. Additionally, splatter guards or shields can protect one from exposure when opening specimen containers or transferring specimens to additional containers. Enclosed electrical incinerators reduce splatters when decontaminating bacteriological loops. Hand hygiene sinks that operate hands-free and centrifuge tubes with caps also help prevent the spread of infectious material.[2]

Personal protective equipment

Personal protective equipment (PPE) is equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.[3]

Some elements of PPE include:

- Protective clothing
- Face and body protection
- Gloves
- Footwear
- Respiratory protection

Detailed information on PPE can be found in M29—Protection of Laboratory Workers From Occupationally Acquired Infections.[4]

Work practice controls

Work areas should be free from clutter and distractions. The laboratory technical areas should be clearly designated as "clean" or "contaminated." All equipment and devices coming in direct contact with any of these materials should be considered contaminated. The designation of the technical area as either "clean" or "contaminated" determines work and housekeeping practices. If technical areas are considered "clean" areas, work practices entail efforts to prevent contamination of telephones, video display terminal keyboards, doorknobs, and other items

commonly touched by ungloved hands. To protect against gross contamination, preventive practices can include plastic coverings for computer keyboards and telephones.[1]

Gloves should be removed before handling telephones, uncontaminated laboratory equipment, doorknobs, etc. Alternatively, specific devices, such as computer keyboards and telephones, may be specially labeled as biohazards and used only with gloved hands. Care must be taken not to use these marked devices with ungloved hands. Gloves and all other PPE should be removed before leaving the laboratory. Gloves should be disposed of properly according to institutional and governmental rules. Hands should be washed after removing gloves before leaving the laboratory.[1]

Personnel responsibility

Food, drink, and substances that provide potential hand-to-mouth contact are prohibited in technical work areas. Specimens containing a variety of pathogens handled daily in the technical work area and stored in laboratory refrigerators provide a potential source of contamination of food and drink. Refrigerators reserved exclusively for food storage may be located in areas in which eating and drinking are permitted. A policy should be established to ensure that food and specimens are not stored in the same refrigerator.

Application of cosmetics in the technical work area is prohibited. Hair should be secured back and off the shoulders to prevent contact with contaminated materials or work surfaces and to prevent shedding organisms into the work area. It is also important to keep hair out of moving equipment, such as centrifuges or microtomes. Men with beards should observe the same precautions provided for hair.

Personal belongings (e.g., purses, coats, prepackaged foods, medications) should not be stored in the technical work area. For security and infection prevention and control purposes, these items should be kept in staff lockers.

Personal electronics should not be used in the technical work area in the following circumstances:[5]

- When working with hazardous materials of any category (chemical or biological)
- When wearing gloves or other PPE, with the exception of a laboratory coat
- While performing work on laboratory specimens, data, or any process that may affect testing outcomes
- When in an area in which they might distract or interrupt others
- When in an area in which accidental release of protected health information could occur
- If they cannot be worn without hanging wires or other dangling accessories that may pose a safety hazard
- If they interfere with an employee's ability to detect potential hazards, such as hearing an alarm or an approaching obstacle

All personal electronic devices should be protected from laboratory hazards and possible contamination.[6]

Transport and shipment of specimens

Any time specimens are transported, an increased risk exists for the possibility of breakage occurring and the subsequent release of hazardous materials into the environment. The use of engineering controls such as carts, leak-proof carrying containers, and absorbent materials needs to be implemented.[7] Personnel transporting the specimens should use the appropriate PPE for the materials they are handling.

The transport of hazardous materials outside the facility is governed by various government and regulatory agencies' regulations. The United Nations has developed standards for the shipment of dangerous goods.[8] The International Air Transport Association (IATA) provides a manual in consultation with the International Civil Aviation Organization for the transport of dangerous goods by commercial carriers.[9] The U.S. Postal Service and the U.S. Department of Transportation (USDOT) have synchronized their requirements with IATA in an effort to standardize the shipment of hazardous materials. Additionally, if materials are being shipped internationally, countries may have additional regulations that need to be followed.

Whether couriers are employees of the laboratory, employees of a contractor, or independent contractors, they have the potential of being exposed to highly infectious pathogens. On the job, safety is very important not only for the courier's personal safety, but for the safe handling of the specimens and safety of the general public. The organization needs to develop a system and a plan for storing specimens safely and securely during transport. The courier organization needs to have a plan in place, the necessary equipment, and appropriate PPE in case of a spill or release into the environment.

The laboratory is responsible to the community to ensure that appropriate hazardous waste handling policies are developed and rigorously followed. The disposal of chemical, radiological, and infectious wastes and effluents is strictly regulated by federal, regional, and local authorities. Details concerning the disposal of each type of waste are covered in individual sections of GP17— *Clinical Laboratory Safety*.[1] Users should refer to CLSI's M29 for additional information on infectious waste disposal.[4]

Conclusion

A comprehensive general safety program encompasses all aspects of daily laboratory operations, including engineering controls, personal protective equipment, work practice controls, transport and shipping of specimens, and waste disposal.

Detailed information on the implementation of a safety program, including roles and responsibilities of laboratory employees, specialized safety programs, fire prevention, and emergency management can be found in CLSI's GP17—Clinical Laboratory Safety.[1]

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LABORATORY INNOVATOR

Advice and lessons learned

By Christina Wichmann

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Are there particular lessons learned you can share with other laboratory directors on reducing laboratory errors?

I've learned automation provides tremendous value in reducing laboratory errors in the analytical phase. An automated specimen management system dramatically improves processes related to specimen receipt, processing, testing, storage, and retrieval. Automated test systems rely on acceptable quality assurance parameters (e.g., quality control, Westgard rules, delta checks) built into "autoverification" rules to determine when and which patient results can be released. It is primarily tests with manually performed steps remaining subject to human error.

But, as we all know, errors in laboratory testing occur most commonly in the pre- and post-analytical phases – the most common being mislabeled (label for Patient A is placed on specimen collected from Patient B, or "WBIT" — wrong blood in tube — as blood bankers like to say) or unlabeled specimens, specimens handled or transported incorrectly, or clinicians not interpreting results correctly.

So how to improve the pre- and post-analytical phases of laboratory testing?

- Specimen identification – use electronic health record (EHR) barcode scanning capabilities whenever possible as this process will weave together patient identifiers, test orders, correct collection containers and any special handling instructions (e.g., "protect from light").
- Apply a specimen label to a specimen in front of the patient and engage them — ask them to verify their information is on the label and is correct.
  - Test order – use a name understandable by users. As an example and at the beginning of the COVID-19 pandemic, we named our nucleic acid amplification test (NAAT) as "SARS CoV2 NAAT" and the antigen test "SARS CoV2 antigen." The clinicians wanted the test names "Standard COVID" and "Rapid COVID" instead, which is how they thought of them. We changed the test order names accordingly and confusion on the clinical side vanished overnight.
- Result interpretation – in addition to age- or gender-specific reference ranges, include any special interpretive comments written in easily understandable English. We must remember most clinicians are not laboratorians and do not understand our language. And now patients have direct access to their lab results, so they too need to understand what they mean. Consider using trusted clinical colleagues or non-medical friends as editors for draft interpretations.

What are some of the biggest challenges you have faced this year or anticipate facing in your health system? What do solutions to those look like?

Well, we all know what today's greatest challenge is — the absolute lack of personnel. Related is the loss of expertise with the retirement of experienced personnel. What are the solutions?

- Increasing the pool of interested applicants. This starts in middle school and high school. Get out there, partner with your Parent Teacher Associations and BE THERE on "career day" to drum up excitement about Clinical Laboratory Science and Laboratory Medicine.
- Didactic education – this is not a barrier today with the exception of creating more training schools where needed. Take advantage of CDC's OneLab for high-quality online training — including virtual reality options — both for trainees and practicing folks who want refresher or training updates.
- Practical training – this is the current big hurdle. There are not enough remaining staff in clinical laboratories to "spare" to train students, let alone have education coordinators to link with the schools providing the didactic training. How do we solve this problem? It is a grassroots effort for each of us to work with our administrative colleagues and executives; request the funding of student(s) trainee positions; and the necessary piece, a staff clinical laboratory scientist (CLS) to coordinate. The return on investment (ROI) is a no-brainer; an analysis performed by a local colleague (Danny Arimboanga) demonstrated the ROI for training a CLS student was 6 months. D 'oh.

Have your laboratories struggled with any supply shortages, such as blood collection tubes? What strategies have you implemented to ensure adequate supplies?

- Have we struggled with supply shortages? Yes. Only now do we have a sense we might be returning to pre-COVID-19 times when supplies were readily available.
- What strategies did we implement?
  i. We have three clinical laboratories in our system and we borrowed from each other. When our system ran out of supplies, we borrowed from local labs (friends) with a clear understanding of when they should expect payback.
  ii. When we exhausted the local area supply, we asked vendors and distributors to help — many times they were successful.
  iii. And then we discovered the MHOAC (Medical Health Operational Area Coordinator). MHOAC is under EMSA (Emergency Medical Services Authority), a branch

of the government not commonly used by clinical laboratories. We were able to source swabs and rapid COVID antigen tests when none were to be had. But the MHOAC was limited in what they could supply. For example, we asked but did not get a biosafety cabinet class II.

What is the current vacancy rate at your lab? What strategies have you found to be successful in recruiting and/or retaining staff?

- Our vacancy rate is ~15%–20%.
- Recruitment –
  - Our best strategy is our CLS trainees. A few years ago, we upped from 1 to 2 training slots/calendar year. There are two cycles/calendar year, and both trainees came in the same cycle. This created a burden on existing staff to train two students in the same cycle. Going forward we are still training two CLSs per calendar year, but alternating one trainee per cycle to reduce the burden on existing staff.
  - Another strategy was to hire internationally trained CLSs through international agencies. Contracts are often 1+ years, ensuring a small element of stability, and the CLSs tend to be of very high quality (iASCP certified – a well-recognized stamp of excellence!).

What do you see the future of pathology looking like?

Well, this is the 'crystal ball' question, and we all know crystal balls are never correct. I can only speak to the future of laboratory medicine as I'm totally ignorant about anatomical pathology.

- The exponential growth in molecular testing, e.g., human genomic targets for companion drug eligibility, diagnostic or prognosis testing for cancer, sequencing of bacterial isolates for identification/antimicrobial resistance markers/virulence factors. As parts of the testing process may occur in different spaces — e.g., sequencing in one lab, bioinformatics application in a second lab, interpretation in a third lab, and correlation with the individual patient's clinical situation at the local provider's end — how do we assure data is transferred accurately at all touch points? How do we assure disciplines not traditionally part of the clinical laboratory space (e.g., bioinformatics) abide by confidentiality (HIPAA) and good quality laboratory practice (e.g., analytical validity, clinical validity)? Where does machine learning and artificial intelligence (AI) fit in — as the latter is the obvious automation solution? And how can clinicians understand the incredibly complex interpretations of these tests?
- The new generation of CLSs tending to prefer generalist practice. We guess this is because automation in general lab aligns with their familiarity with electronic devices and orientation/preferences for quick tasks.
- Increased home testing as test devices become simpler to use and unlikely to fail.
- Increased home testing or specimen collection for the convenience and engagement of patients in their own healthcare and a necessary adjunct to telemedicine.
- Increased shift to molecular testing for infectious diseases as we lose the expertise for clinical microbiology testing.
- Increased shift from phenotype to genotype blood bank testing to address limited availability of esoteric test reagents and increasing lack of expertise in test performance and interpretation.

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Readers' questions answered

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What is the standard laboratory workup for pharyngeal STI detection? CT-NG from a throat cx? Should this include VCM, aerobic, and/or anaerobic swabs?

Sexually transmitted infections (STIs) involving extragenital sites (pharynx and rectum) of particular public health concern include both *Neisseria gonorrhea* (GC) and/or *Chlamydia trachomatis* (CT).[1] These infections represent a substantial proportion of overall STIs.[2-4] In addition, extragenital STIs at rectal or pharyngeal sites are most often asymptomatic. For these reasons, depending on an assessment of patient risk factors as well as community prevalence, screening may be recommended or considered. For example, different studies have demonstrated that approximately one third to two thirds of gonococcal and chlamydial infections might be missed if urogenital-only testing is performed among Men Who Have Sex with Men (MSM).[5-9] The primary diagnostic methods for detection of GC and CT at extragenital sites include culture and nucleic acid amplification tests (NAATs) and either may be used. However, for CT infections at rectal and oropharyngeal sites, NAATs have been shown to have higher sensitivity and specificity when compared to culture methods.[10-14] For GC, culture and NAATs are also available for diagnosis of infection at extragenital sites. Commercially available NAATs have been cleared by the FDA for rectal and pharyngeal swabs for both men and women.[14]

However, not all commercially available GC and CT NAATs with FDA clearance for urogenital samples have been cleared for use with extragenital samples. There are examples where testing of oropharyngeal specimens for GC might have reduced specificity due to detection of commensal organisms. Additionally, although it is generally true that NAAT sensitivity for detecting *N. gonorrhoeae* from extragenital sites is superior to culture, it does vary by NAAT type and some commercially available NAATs that have been cleared for urogenital testing have not been cleared for extragenital testing. For this reason, it is suggested that the product inserts from each NAAT manufacturer be carefully reviewed to best understand approved sample types and associated performance. However, product inserts for each NAAT manufacturer should be consulted carefully because collection methods and specimen types vary. Certain NAATs that have been demonstrated to detect commensal Neisseria species might have comparable low specificity when testing oropharyngeal specimens for *N. gonorrhoeae*. Finally, it is worth noting that self-collected swabs have been reported to be an acceptable means of collection for pharyngeal and rectal specimens, which can enhance patient comfort and reduce clinical workloads.[15-17]

The clinical utility of extragenital testing for other organisms such as *Mycoplasma genitalium* has not been established yet since there is no evidence of it causing disease. In the case of HSV infection, an appropriate swab of an active oral lesion submitted in viral transport media for testing real-time HSV PCR testing has been demonstrated to be the most sensitive method of HSV detection.

For details regarding sample collection, transport, and culture of CT and GC, please refer to the Centers for Disease Control and Prevention recommendations at: https://www.cdc.gov/std/laboratory/2014labrec/recommendations.htm.

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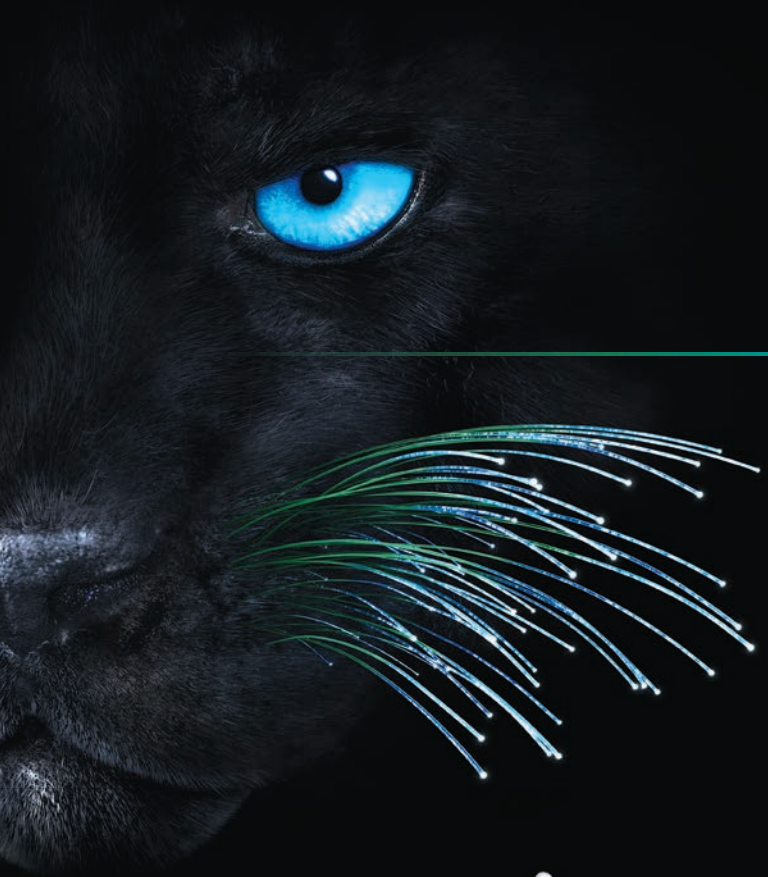

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