

LAB MATTERS

analysis|answers|action

Spring 2022 Issue 1

To All The Other Pathogens:
WE'RE STILL TESTING!



Inside:

- 11 Fine-tuning Environmental Health Preparedness and Response with HRMS
- 18 APHL, CDC Prioritize Hepatitis C Elimination in Meeting, New Publication
- 25 Mystery Melioidosis: Minnesota's Response to a Rare Outbreak

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COLUMNS

- 2 President's & Chief Executive Officer's Message

DEPARTMENTS

Environmental Health

- 10 Connecting with Environmental Health System Partners During a Pandemic
- 11 Fine-tuning Environmental Health Preparedness and Response with HRMS

Global Health

- 12 Building a Global Repository of Laboratory eTools
- 13 APHL Conducts Global Bioinformatics Virtual Training for SARS-CoV-2

Industry Matters

- 14 Old Pathogens Meet New Testing Practices: Updates to STI and HIV Testing Routines
- 16 Automation Streamlines Arbovirus Sample Pooling in New Hampshire

Infectious Diseases

- 18 APHL, CDC Prioritize Hepatitis C Elimination in Meeting, New Publication
- 19 Infectious Disease Laboratory Fellows Prepare for Careers in Public Health

Informatics

- 20 Maryland Undertakes Food Safety Data Exchange Journey
- 21 Advancing Mobile Testing in the Nation's Capital

Newborn Screening & Genetics

- 22 APHL 2021 Newborn Screening Symposium: Collaboration Continues Virtually

Public Health Preparedness & Response

- 24 The What and How of ISO 35001:2019 Biorisk Management for Public Health Labs
- 25 Mystery Melioidosis: Minnesota's Response to a Rare Outbreak

Membership

- 26 Approaching 150 Years of Service in Milwaukee

Fellows

- 28 APHL Continues to Expand Fellowship Programs for 2022



FEATURE

4 To All the Other Pathogens: We're Still Testing!

Even as SARS-CoV-2 has taken the world by storm, other pathogens have continued their own inexorable spread and evolution in the past two years. For public health laboratories, finite capacity—staff time, equipment, reagents and other resources—has necessitated difficult decisions and creative solutions to keep abreast of both existing and emerging pathogens.



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The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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Coping with COVID-19, Inside and Outside the Laboratory



Denise Toney, PhD
President, APHL

“Staff burnout has remained a big issue and one that continues to challenge our public health systems. And we are only beginning to find out how deep the problem goes.”

Lab Matters: So let's talk about Omicron. How are you and your team doing, Denise?

Denise Toney: Well...very busy and very tired, as I am sure is the case for so many of our members. With the emergence of Omicron over the past couple of months, we have seen a significant increase in the number of samples submitted for testing and to make things more challenging, we are also seeing an increase in our folks and their family members contracting COVID-19. Unfortunately, I can speak first-hand about this in that I contracted COVID-19 in mid-January. Believe me, reading about the virus and working with the virus on a daily basis is much different than *having* the virus. Trying to balance my staff needs and my own challenges of keeping my family safe has not been easy. Also, maneuvering through the healthcare system with a COVID-19 infection has been eye-opening. There are so many new provisions and prerequisites for medical care that just weren't there before the pandemic.

Scott Becker: I know that things have radically changed for everyone as far as healthcare. From quarantining and testing before surgeries to wait times for urgent care, our health systems were not constructed for this kind of prolonged stress. For the East Coast, Omicron hit early and hit hard. On Monday, January 3, 2022, over 1 million new cases of COVID-19 were reported in the US. And even though this number also encompassed holiday backlogs, that led to a seven-day average of almost 800,000 daily new cases. Included in that number are the many members of the medical and public health communities who have gotten sick themselves, have had to quarantine, and have not been able to provide care...they have needed to be

cared for themselves.

Denise: I know, I was truly lucky to have been able to get the care that I needed. My doctor was amazing and allowed me to recuperate at home, calling in any medications that I needed to my pharmacy. There are so many more people out there who don't have the access to care that they need to get through this disease. Believe it or not, as sick as I was, I ended up being “too healthy” to qualify for any of the current infusion therapies!

Scott: I think that's a good problem to have, right?

Denise: – Absolutely!

Scott: Did you end up getting your sample sequenced?

Denise: Yes, I did and it was Omicron. I still don't quite know how I got it, since I've only been around my family and a few close friends and I don't go into stores or out very much. I will say that my COVIDwise app did notify people that I wouldn't have thought would have been considered exposures. I tried to remember who I had been in close contact with, but could only really remember about five people. The app covered people that I hadn't really thought of as a close contact and being at risk of being exposed.

LM: This new surge has been incredibly hard, both professionally and personally, for many of our members. How can we continue to support them?

Denise: We really need to keep in mind what Scott said before: our systems were not constructed for a prolonged surge—and neither were our laboratorians and administrators. Staff burnout has remained a big issue and one that continues to challenge our public health systems. And we are only beginning to

find out how deep the problem goes. As you well know, the work of our members does not change...it doesn't matter if there's a pandemic, a flood or a fire. The work has to continue.

Scott: It really does. In June 2021, CDC released an MMWR report on the state of mental health among state, tribal, local and territorial public health workers during the COVID-19 pandemic. After seeing that over 50% of public health workers reported some symptoms of depression, anxiety, post-traumatic stress disorder and suicidal ideation, CDC performed another analysis at APHL's request among public health organizations who have been serving these workers. In a January 31 call with APHL, CSTE, and NACCHO we shared those results (which largely mirrored the national study) and are committed to working together to find resources for our staff.

For our members who are experiencing any mental health issues, we need to find ways to acknowledge that they are struggling and that we know how hard it is to continue in this essential work given all of the obstacles that keep popping up. Keeping morale up and addressing these issues are challenging, but it's critically important that we find ways to help both locally and nationally.

LM: Even after two years of COVID-19, is there a bright side to Omicron?

Denise: Great question and something I try and focus on as much as I can. The positive side is that schools are ready to graduate new laboratorians, and the perspective they have is vastly different than many of our current laboratorians.

Having lived and been educated through a pandemic will color their work for decades to come, and will hopefully effect real, lasting change in how populations view the science of public health.

Scott: The new and expanded APHL-CDC Fellowship and Internship programs are hopefully going to help us put a dent in the staffing shortage as well. Eighteen new fellows started working in laboratories in February, and we've just closed out the most successful recruiting effort in the program's history; securing hundreds of applications from many interested undergraduates and graduates.

We are also having conversations with CDC on normalizing exposure notification for not only COVID-19, but opening the dialogue also for other use cases. There have been a lot of improvements that have come into being since we started the program in mid-2020, but many states are still not using the apps, let alone the improvements. But as new cases continue to drop here in the DC/MD/VA region and our focus turns to surveillance instead of diagnostics, I'm hopeful that APHL will continue to be a force and a voice for change within our critical public health laboratory systems. As I have said many times before, we will persevere. ■



*Scott Becker, MS
Chief Executive Officer, APHL*

“ From quarantining and testing before surgeries to wait times for urgent care, our health systems were not constructed for this kind of prolonged stress.”



To All The Other Pathogens:

WE'RE STILL TESTING!

By **Jill Sakai**, PhD, writer

Even as SARS-CoV-2 has taken the world by storm, other pathogens have continued their own inexorable spread and evolution in the past two years. For public health laboratories, finite capacity—staff time, equipment, reagents and other resources—has necessitated difficult decisions and creative solutions to keep abreast of both existing and emerging pathogens.

“The pandemic brought a wholesale pivot of our healthcare infrastructure toward managing this novel and devastating disease,” said Tim Southern, PhD, director of the **South Dakota Public Health Laboratory**. As clinic visits and non-essential care dropped, so did some laboratory testing demands. But fewer tests does not necessarily mean fewer infections. In some cases, he added, “now we’re seeing that there was some collateral damage from being so COVID-focused.”



Microbiologists Laura Tsaknaridis and Vanda Makris are ready to get to work. Photo: Oregon PHL

Communities have continued to grapple with recurring outbreaks, such as sexually transmitted infections and gastrointestinal pathogens, and are now in the midst of an active influenza season. Some places have seen growing emergence of antibiotic-resistant *Candida auris* and other organisms. As the pandemic enters its third year, public health laboratories are drawing on a variety of strategies to keep up with a full gamut of pathogens amid ongoing COVID-19 testing needs.

Clear Focus

When there is always too much work to do, setting clear priorities is essential—which often means getting external guidance on what not to do, said Megan Crumpler, PhD, HCLD, director of the **Orange County Public Health Laboratory** in California. Their administration helped them prioritize specific public health groups rather than tasking their laboratory with mass community COVID-19 testing.

“Now we’re down to about 900 to 1,000 samples a week, so it’s become manageable,” she said.

It also means knowing what’s most critical.

“Some things we can put off—maybe syphilis for a day or so—and we wouldn’t impact our turnaround time,” said Shane Sevey, virology and immunology manager of the **Oregon State Public Health Laboratory**. “You start with the most important results that need to get out that day, and then you kind of work backward.”

National and regional reference laboratories, for example, have to maintain those testing responsibilities regardless of a pandemic.

“We can’t say, ‘well, there’s COVID, we can’t do [National Influenza Reference Center] testing;’ or ‘sorry, there’s COVID, we can’t do [Antibiotic Resistance Laboratory Network] work.’ That’s just not an option,” said Allen Bateman, PhD, MPH, D(ABMM), director of the communicable disease division of the **Wisconsin State Laboratory of Hygiene**. “We’re the only lab in the state that can do rabies testing and the level of tuberculosis testing that we do. That’s what we should be and

“Coordinating and planning—that’s the bottom line. You have an action plan. And then the next day, something changes, and you have to make adjustments”

Vanda Makris

need to be focusing on.” The state health department has been a key partner in setting and holding those priorities. “There has never been higher testing capacity, ever, for any other test than [there is now] for COVID-19,” Bateman added. “Massive COVID testing is not our role anymore.”

In South Dakota, Southern and his staff work closely with the Office of the State Epidemiologist and the Office of Disease Prevention Services to set testing priorities.

“The communication between those three principal teams—epidemiology, laboratory and disease prevention—is absolutely critical to determine what tests we need to escalate in importance, and what we can deescalate or send to someone else,” he said. That helped them manage immediate needs and stay focused on surveillance, outbreak detection and facilitating investigation.

Through creative use of some federal funding, the South Dakota team is reinforcing laboratory infrastructure to help absorb some of the additional testing and surge attributed to both COVID-19 and non-SARS-CoV-2 pathogens. Part of that process has also involved helping other clinical laboratory partners develop programs and infrastructure that can support public health needs, such as supporting matrix-assisted laser desorption/ionization (MALDI) mass spectrometry for tuberculosis testing

and opening a BSL-3 facility in a clinical reference laboratory.

Plan, Plan, Plan—But Don't Get Too Attached

Public health laboratories are accustomed to planning for short-term outbreaks. But maintaining surge capacity during a prolonged public health emergency is a different beast, one that takes meticulous planning paired with the flexibility to scrap and rework those plans at a moment's notice.

"Coordinating and planning—that's the bottom line," said Vanda Makris, a microbiologist in the Oregon laboratory. "You have an action plan. And then the next day, something changes, and you have to make adjustments."

Good communication among personnel allowed them to coordinate and triage the most pressing needs.

"Oftentimes people may feel comfortable juggling multiple benches, so maybe they're doing chlamydia, gonorrhea and our serologies at the same time and, as they have downtime, they'll bounce from one instrument to the other," Sevey said.

It helped that laboratory personnel had to work in person throughout the pandemic, Bateman said, because that facilitated the quick communication and discussion needed to adapt to daily needs and situations.

"We can walk down the hall and immediately touch base."

Planning also has to happen at the instrumentation and supply level. Resource limitations sometimes necessitated some influenza samples being triaged for later analysis, said Kirsten St. George, PhD, MAppSc, director of the virology laboratory at the **Wadsworth Center** in New York. And in

South Dakota, a surge in syphilis—with cases rising more than 1000% between 2019 and 2021—prompted a new public health campaign aimed at improving healthcare for vulnerable populations that has brought an influx of specimens to the public health laboratory for sexually transmitted infection (STI) testing.

"There's been a mad dash for syphilis reagents of all kinds," Southern said. "We have learned that we have to be very mindful of the amount of reagents and supplies that we keep. We've also brought on some new instrumentation and we're really thinking about how we're going to approach syphilis in the future, so that we can better accommodate a surge like what we're seeing now."

Find Efficiencies...

To stretch capacity as much as possible, Southern and others are turning to systems with higher throughput and automation wherever possible.

"The surge in syphilis is really pushing us towards automation of some of the algorithms that we use," he said. Crumpler echoed this, saying that shifting STI testing from a traditional manual assay to the more automated reverse sequence screening algorithm helped the Orange County laboratory maintain syphilis testing throughout the pandemic.

The Wisconsin team has shifted a lot of their COVID-19 testing to more automated instruments as well, a move that enables anyone from the serology team to step in and help if the virology staff are needed elsewhere—which has proven especially beneficial during the first season of concurrent influenza and COVID-19. At Wadsworth, too, St. George said, "Significant efforts have been made in recent years to develop and implement more automated testing platforms and

more multiplexed assays that provide concurrent test results for multiple respiratory agents simultaneously."

The Oregon laboratory is similarly ramping up use of a multiplex assay, BioFire, to streamline testing for a panel of gastroenteritis-associated pathogens. In collaboration with the **US Centers for Disease Control and Prevention** (CDC) and APHL, they are also helping develop a new, next-generation sequencing assay for norovirus as a faster, higher throughput replacement for traditional Sanger sequencing.

In some cases, increased efficiency has even enabled new capabilities. Prior to the pandemic, the Orange County laboratory had started testing some clinical samples for *C. auris* by 16S sequencing, a multi-step, labor-intensive process. In mid-2020, demand began to increase and despite the throes of COVID-19 testing, the laboratory added *C. auris* outbreak testing and PCR screening to facilitate patient transfers between facilities. In 2021, the team switched to a MALDI platform to speed up the confirmation process. For PCR screening, they obtained an instrument, collaborated with CDC and the **Washington State Public Health Laboratory** to get specimens for validation of the assay, and went live in September, becoming the first local laboratory in California to offer this type of testing.

Although demand still far exceeds their capacity, Crumpler said, Orange County is hoping to receive funding through the CDC's **Strengthening HAI/AR Program Capacity** (SHARP) program and is now working with the state of California to figure out how to increase capacity for resource-intensive *C. auris* point prevalence surveys.

Oftentimes, it's more than just the testing itself that backs up. The detail-oriented,

“We can't say, 'well, there's COVID, we can't do [National Influenza Reference Center] testing;' or 'sorry, there's COVID, we can't do [Antibiotic Resistance Laboratory Network] work.' That's just not an option.”

Allen Bateman, PhD, MPH, D(ABMM)

hands-on work of sample accessioning, preanalytical data entry and result reporting can also create bottlenecks. In Oregon, a LIMS administrator added barcoding and automated parts of their reporting platform, slashing the time needed to create and check reports. The improvements have also decreased the human error that comes with manually handling hundreds or thousands of samples, said Laura Tsaknaridis, a microbiologist in the laboratory.

“Now it’s so automated that it’s very difficult to get a specimen switched up or get the wrong accession number in there. That’s helped out a lot.”

...But Build in Redundancies

Despite the need to keep workflows as streamlined as possible, an element of strategic redundancy can help maintain operations throughout the volatile circumstances of a prolonged pandemic. Overwhelming demand and shifting manufacturer priorities have created ongoing supply challenges. And when gonorrhea and chlamydia tests, for example, use the same platforms as COVID-19 tests, completing a day’s work takes careful planning and allocation of available resources.

Diversification was a hard lesson learned from the pandemic, Southern said.

“For our non-COVID-19 programs, sometimes we need to be able to pivot between different platforms” to ensure that something is always up and running despite inconsistent supply chains. That represents significant investments in infrastructure, training and time, as scientists must establish proficiencies and competencies in redundant assays and complete additional validation and verification testing. But, he added, “those kinds of strategic changes will allow us to [handle] surge in other areas beyond COVID-19.”

Cross-training staff can also help fine-tune a laboratory’s effective capacity day-to-day. Wisconsin has shifted much of its COVID-19 testing to more automated instruments and trained their full serology team on those instruments, so they are able to step in if the virology staff are all unavailable. Similarly, virology staff can shift over and help with STI testing if needed. Such contingency planning has become even more pressing as Omicron sweeps the country, to manage both testing demands and the likelihood that some staff may be out sick or caring for family members.

Take Care of Your People, and They’ll Take Care of You

To keep things running, “it comes down to having an amazing crew,” Sevey said.

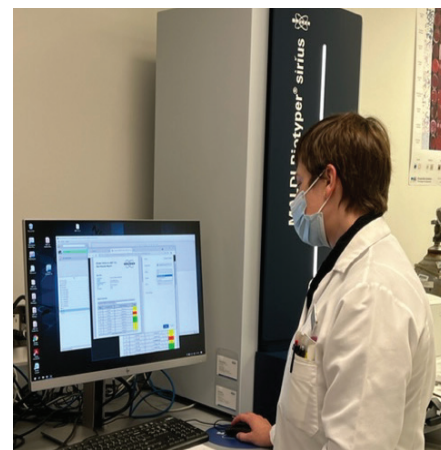
“If people weren’t willing to come in and they weren’t passionate about what they did—I don’t know where we would be at this moment. We just have exceptional people working in public health.”

In the early stages of the pandemic, many laboratories adopted an all-hands-on-deck approach, with personnel stepping into new roles where possible to prioritize COVID-19 testing. But as other needs returned, staff have largely resumed their regular duties.

“We were trying to hire new people,” Bateman said. But “government systems don’t move at the speed of a pandemic.”

Like most public health laboratories, Oregon implemented overtime and extended work weeks to get more done with the same number of employees—stopgap measures that have now stretched on for years.

“We kind of scrambled, like everyone else in the country, to bridge these gaps. And they’re still there,” Sevey said, echoing a common sentiment. Many temporary positions are now expiring, and filling specialized needs, such as informatics, can be especially hard.

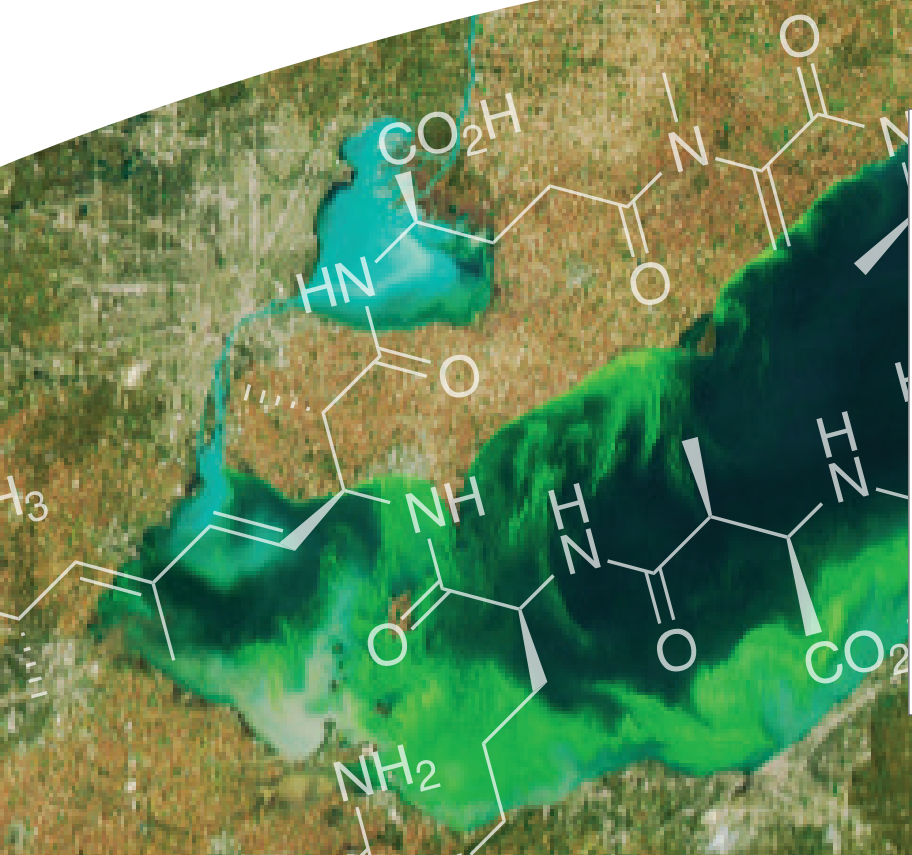
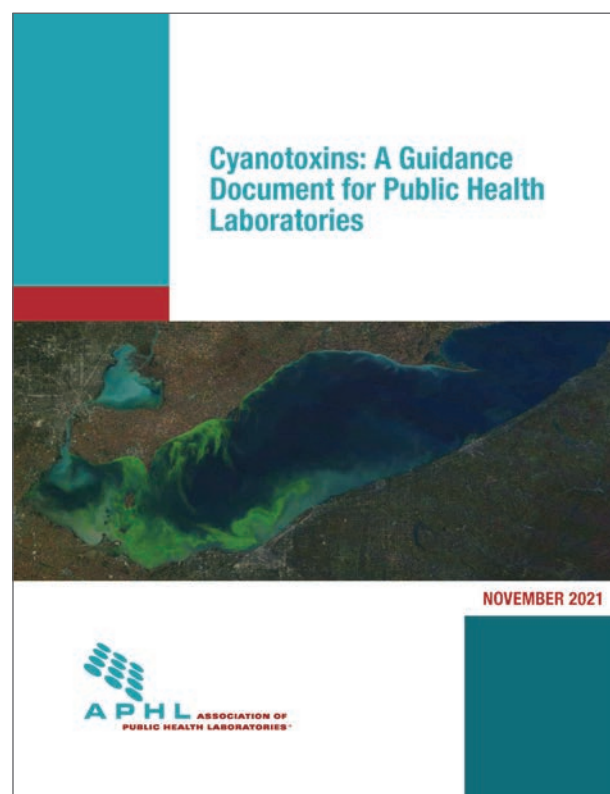


Public Health Microbiologist II Kristina Davidovich performs *Candida auris* confirmation by MALDI-TOF on the Bruker Biotyper. Photo: Orange County Public Health Laboratory

Workforce issues are nothing new for Southern—“we traditionally have a very difficult time recruiting staff to central South Dakota”—and the pandemic’s challenges have refocused his attention on honing his existing team’s skills, coordination and morale. The efficiencies and collegiality born out of the COVID-19 response will boost the group moving forward, he said.

“We’re focusing on resiliency, self-care, making sure that we all have a little bit of juice left in the tank to get us over that next whatever—the next week, the next month, the next testing campaign, the next surge,” Southern said. “I want to do the best I can to take care of that small team of mine, because there’s great power in what they can do. If I can keep culture and morale high in the laboratory, I know we’ll be able to navigate months [or even] another year of really difficult COVID and non-COVID programming.” ■

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Methods	Cytotoxins			
	Arabinoside	Cytidinearabosides	Minocyclins	Sarcolins
Biological Assays				
Mixed	Yes	Yes	Yes	
Polypeptide Inhibitor Assays (PIPA)	No	No	Yes	
Neurochemical	Yes	No	No	
Enzyme-Linked Immunosorbent Assays (ELISA)	Yes	No	Yes	Yes
Chromatographic Methods				
Gas Chromatography				
Gas Chromatography with Flame Ionization Detection (GC/FID)	Yes	No	No	No
Gas Chromatography with Mass Spectrometry (GC/MS)	Yes	No	No	No
Liquid Chromatography				
Liquid Chromatography / Ultraviolet-Visible Detection (LC/UV or LC/PPAD)	Yes	Yes	Yes	Yes
Liquid Chromatography/Fluorescence (LC/FL)	Yes	No	No	Yes
Liquid Chromatography Combined with Mass Spectrometry				
Liquid Chromatography on Thin Mass	Yes	Yes	Yes	Yes
Liquid Chromatography Time/Flight Mass Spectrometry (LC/TOF MS)	Yes	Yes	Yes	Yes
Liquid Chromatography Single Quadrupole Mass Spectrometry (LC/Q)	Yes	Yes	Yes	Yes
Liquid Chromatography Triple Quadrupole Mass Spectrometry (LC/MS/MS)	Yes	Yes	Yes	Yes

After these two structural steps and after water sorption, the methods described

To streamline cyanobacteria reporting processes, it is possible that the same protocols and systems used for other emergency reporting (i.e., foodborne outbreaks or flu) can be leveraged for cyanotoxins. An interagency response coordination plan, such as the one *My Water Quality California* uses, may be helpful to create. The *EPA Incident Action Checklist—Harmful Algal Blooms* may be another helpful resource.

Laboratories or other cyanobacteria system partners might be responsible for sampling drinking or recreational water bodies for cyanotoxin analysis purposes. EPA's [drinking](#) and Oregon Health Authority's [recreational](#) water sampling guideline examples may be a useful reference for establishing proper protocols for your jurisdiction.

Environmental public health laboratories use analytical methods to detect and count cyanobacteria and to measure cyanobion concentrations to inform public health advisories and warnings. To fully characterize the immediate threat of an observed cyanobial observation and microscopic identification/enumeration should be coordinated with a biochemical and/or chemical determination of cyanotoxins. The methods described below can generally be applied to drinking, source and recreational waters, depending upon the desired sensitivity level. They are the most common methods used in the United States and are not intended to be used as a sole method for cyanobacteria detection. These methods should not be viewed as an exhaustive list. The following flow chart outlines these methods.



erated in subsequent test.

or tools can be used to analyze a water sample or homogenate lysed (ruptured) cells, printing kits) to complex (LC/MS/MS), and produce qualitative, semi-quantitative methods have been developed for determination of the pesticides targeted in US and cytidine deaminase. The microarray methods include nucleic acids and the uses of nucleic acids. The 2015 US EPA drinking water health advisories have the best methods to those capable of measuring targeted compounds at or below the

Connecting with Environmental Health System Partners in a Pandemic

By **Marilyn B. Freeman**, PhD, deputy director, Department of General Services, Division of Consolidated Laboratory Services; **Lucas Beversdorf**, MS, PhD, assistant laboratory director, City of Milwaukee Health Department Laboratory; **Kristin Schieble**, MLS(ASCP)CM, laboratory operations manager, City of Milwaukee Health Department Laboratory; **Julie Plevak**, program assistant, City of Milwaukee Health Department Laboratory; **Sanjib Bhattacharyya**, PhD, laboratory director and special deputy health commissioner, City of Milwaukee Health Department; and **Erin Morin**, MHS, associate specialist, Environmental Health

In 2020, APHL, with funding support from the **US Centers for Disease Control and Prevention (CDC)**, awarded the **Virginia Division of Consolidated Laboratory Services (DCLS)** and the **City of Milwaukee Health Department Laboratory (MHDL)** funding to facilitate environmental health system meetings. The goal of these meetings was to help organizations within their respective environmental health systems to better meet community environmental health needs, such as testing for biological and chemical contaminants of emerging concerns in water sources, and emergency response. Unfortunately, pandemic-related restrictions forced DCLS and MHDL to alter their plans for in-person meetings.

Virginia Division of Consolidated Laboratory Services

COVID-19 restrictions prevented DCLS from fulfilling the original goal of the grant—to engage stakeholders face-to-face regarding forever chemicals such as per- and polyfluoralkyl substances (PFAS). DCLS project managers determined many of the issues the laboratory faced were exacerbated by the lack of available information on the DCLS website. DCLS sought to better inform and connect with health system partners and the public by providing a detailed test catalogue with a clear explanation of offered services, while adding a section for frequently asked questions and new developments at DCLS.

The website project team conducted internal surveys to inform proposed content changes and reached out to key stakeholders to discuss information that would be of value. Website additions were targeted to provide the most essential information, while allowing flexibility for future updates and the ability to link to partner agency sites. While the

project was not completed as originally designed, it improved the health literacy related to environmental topics by ensuring basic information was easier to find and understand, contributing to the empowerment for all stakeholders and promoting engagement in a different way.

Laboratories intending to complete a similar project should incorporate the web design team as early as possible when determining content changes. While an updated presentation of the environmental test catalog was one of the key updates targeted for the site, the management team envisioned a format that was not attainable using the capabilities of the current website design platform.

City of Milwaukee Health Department Laboratory

Despite the COVID-19 pandemic, MHDL held a virtual meeting to strengthen public health laboratory and environmental health relationships with the goal of improving water quality and reducing risk of waterborne pathogens within the Southeastern Wisconsin water systems. Experts in drinking, waste and recreational water gave overview presentations on current trends, regulations and technologies.

Approximately 50 regional stakeholders met in breakout groups to discuss successes, knowledge gaps and potential improvements.

APHL's **Laboratory System Improvement Program (L-SIP)** criteria were used to assess essential public health services. Common themes included major strengths in enhanced monitoring, risk assessments, quality research and data, and public-academic partnership. However, knowledge gaps were evident in areas of public access to data and data sharing, data modernization, sustained funding, and a lack of early childhood education in water quality and safety. Partners agreed that environmental health systems (EHS) could benefit from a unified champion to integrate systems, create a community of practice, improve citizen science and science communication, and promote environmental health and laboratory careers.

Funding support for the meeting was received from APHL and CDC. It was facilitated by **UW Madison-Extension**, and active participation from EHS partners. A **final report** highlighted achievements and next steps to **strengthen EHS partnerships** with stakeholders' input in focusing and prioritizing specific areas for system improvements. ■

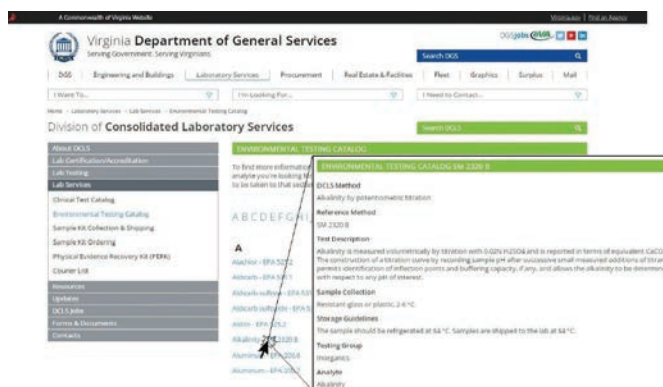


Figure 1. Screen shot of DCLS's new website

Fine-tuning Environmental Health Preparedness and Response with HRMS

By **Nicholas Ancona**, MPH, specialist, Environmental Health

The use of sophisticated high-resolution mass spectrometry (HRMS) enables public health laboratories to identify a variety of environmental contaminants and exogenous compounds such as per- and polyfluoroalkyl substances (PFAS), pesticides and drugs. The availability of reference libraries for these applications also enhances chemical emergency preparedness and response capabilities. Thus, HRMS libraries can be powerful identification tools for emerging and unknown chemical threats.

“HRMS techniques will have a significant impact on the landscape of chemical threat preparedness and response in the future,” said Amy Watson, PhD, LRN-C program director at the **US Centers for Disease Control and Prevention’s** (CDC’s) National Center for Environmental Health. “By leveraging the analytical collaborations that occur amongst **Laboratory Response Network for Chemical Threats** (LRN-C) laboratories, the LRN-C is already well positioned to expand its detection capabilities to include the identification of unknown chemical threats.”

Shawn O’Leary

Program Manager, **New Jersey Department of Health Public Health Laboratory**

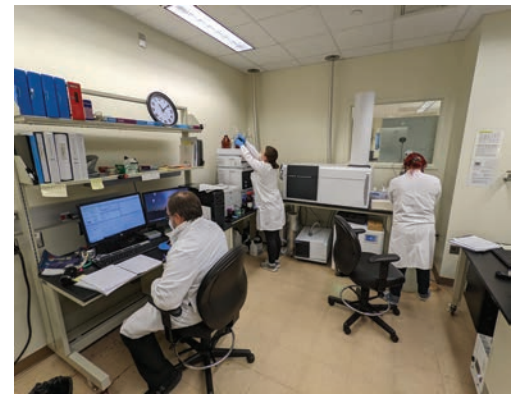
New Jersey’s ultra-high pressure liquid chromatography (UHPLC) quadrupole time of flight (Q-ToF) instrument has expanded Chemical Terrorism capacity for performing food and medicinal marijuana analysis. The ability to increase flow rate has reduced run times by 10 minutes and thus increased throughput. A laboratory-developed method for the detection of pesticides in fruit juices was completed in February 2022. The increased sensitivity gained with UHPLC improved the method to reliably measure pesticides below the levels set by current government

regulations. This instrument will also be validated to determine pesticides in medicinal marijuana. These two new methods will now be able to detect trace levels of toxic pesticides in juices and medicinal marijuana, essential for protecting public health.

Sinisa Urban, PhD

Division Chief, **Maryland Department of Health Laboratories Administration**

PFAS are synthetic “forever chemicals” that have become widespread environmental contaminants with a variety of health effects including cancer, immune dysfunction and reduced responses to vaccines. Current analytical chemistry methods are able to detect no more than 40 of the more than 7,000 PFAS in **US Environmental Protection Agency** (EPA) databases. In contrast, HRMS is an emerging technology with the ability to measure all PFAS in a sample. The Division of Environmental Sciences at the Maryland Department of Health Laboratories Administration was awarded two APHL grants to bring on HRMS for non-targeted PFAS testing. The Division is now exploring with EPA how best to develop this transformative methodology further, and since August has subjected every water sample submitted for PFAS testing to HRMS. The Division is on track to have recorded more than 1,000 high-resolution mass spectra of waters from across Maryland by the summer, which could be the largest such dataset ever compiled for PFAS. ■



(from l to r): Daniel Wene, Sarah Desrochers, and Annie Lin work together to detect trace levels of toxic pesticides in juices and medicinal marijuana. Photo: NJ PHL

APHL HRMS ACTIVITIES

- APHL **recently surveyed** member laboratories to assess national HRMS capability and capacity. These survey data inform APHL/CDC efforts to improve the efficiency, quality and sensitivity of HRMS.
- Training in method development/ optimization, instrument operation/ maintenance, spectral library management, and LIMS integration is essential. To address these needs, APHL collaborated with Sustaining Members to provide analytical training to over 300 beginner, intermediate and advanced scientists at the spring 2021 LRN-C Technical Meeting.
- APHL continues to facilitate HRMS training opportunities through funding awards to member laboratories. A list of HRMS training opportunities and an application form for laboratories to request funding assistance is available by emailing eh@aphl.org.
- APHL awarded a total of \$250,000 to public health laboratories for HRMS through a competitive request for proposals (RFP). Awardees have made great strides in improving their analytical abilities on innovative projects.

Building a Global Repository of Laboratory eTools

By **Reshma Kakkar**, manager, Global Health and **Natalie Martinez**, specialist, Global Health

In the last decade, technological advances in laboratory instrumentation and emerging pathogens of public health significance have placed a greater demand on laboratory data to support clinical and public health decision making. These factors, as well as the sheer quantity of data being processed, have required a hard look at the needs of laboratory systems.

There has been tremendous growth in the types of e-solutions available, varying in cost, functionality and scalability. But not all laboratories are created equal, especially in the realm of resources and financing available for new solutions. APHL is working on a collaborative project with **The Global Fund** to create a repository of laboratory eTools to assist laboratory leaders in selecting and implementing appropriate electronic tools for their laboratories.

Low-resourced countries seeking to strengthen their laboratory systems can be challenged in selecting appropriate solutions. They sometimes opt for word-of-mouth recommendations instead of a robust evaluation of information systems or tools. In other instances, in-country government partners introduce systems with no focus on coordination or standardization, leaving ministries to deal with issues of data quality, system maintenance, outdated technologies and platforms, and gaps in the ability to utilize laboratory data. Ministries of Health have

also come to rely on the availability of funding and the priorities set by donors, making it challenging for governments to identify implementers that will focus on the country's overarching needs and not build disease-specific systems. Even open-source tools come with a cost and, in some cases, can be exorbitant and higher than commercially available solutions.

APHL's goal as a part of this collaboration is to provide means for country governments to overcome knowledge gaps of laboratory tools, as well as build capability to confidently assess and select appropriate solutions for their laboratories. Overarching project objectives include:

- Developing a repository and knowledge hub for laboratory tools to provide easy access to information and for viewing, comparing and evaluating appropriate options.
- Identifying available laboratory eTools and scoring on a maturity model.
- Building a community of practice for laboratory eTools and to champion the laboratory tools repository.

APHL has created a maturity model based on 13 listed criteria (Table 1) and a corresponding rating tool (Table 2) that will be sent to vendors as a self-assessment. The maturity for each tool is rated on a five-point scale. While the laboratory tools maturity model is not limited to determining maturity of interoperability, the five levels have been applied across all domains except cost. APHL is in the process of establishing a community of practice to promote the laboratory eTools repository as a place for health leaders to engage, collaborate and exchange knowledge. ■

Table 1. Maturity Model Categories

DOMAIN	CATEGORY
1	System infrastructure
2	Utilization
3	Country ehealth Strategy
4	Cost
5	Technical Support
6	Road map
7	User documentation
8	Multiple languages
9	Technical documentation
10	Implementation
11	Interoperability and Data Accessibility
12	Security
13	Scalability

Table 2. Rating Scale in Maturity Model

LEVEL	MATURITY	DESCRIPTION
Level 1	Nascent	Does not follow systematic process, isolated ad hoc efforts
Level 2	Emerging	Defined structures but not systematically documented. No formal performance monitoring
Level 3	Established	Documented structures, structures are functional, metrics for performance monitoring used systematically
Level 4	Institutionalized	Stakeholders use the product and follow standard practices
Level 5	Optimized	Developers/system providers regularly review needs and modify functionality to adapt to changing conditions

TYPES OF TOOLS INCLUDED AND ASSESSED IN MATURITY MODEL

1. PT Testing/EQA
2. Equipment Management
3. Data Integration Engine
4. Sample Referral
5. Instrument Data Capture
6. Data Centralization
7. Data Analysis for Lab Data
8. Freezer Management
9. LIMS/LIS

APHL Conducts Global Bioinformatics Virtual Training for SARS-CoV-2

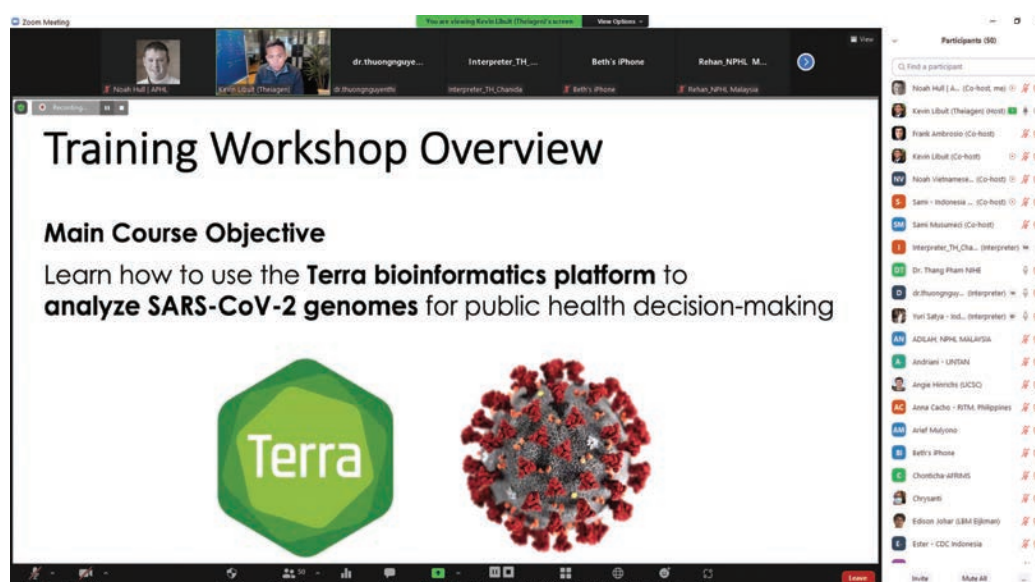
By **Noah Hull**, PhD, MPH, laboratory technical manager, Global Health; **Beth Skaggs**, PhD, laboratory team lead, Division of Global Health Protection, Thailand MOPH-US Centers for Disease Control and Prevention; and **Eugene Yeboah**, MSc, senior specialist, Global Health

On September 30, 2021, two international cohorts completed a seven-week SARS-CoV-2/COVID-19 bioinformatics and genomic epidemiology training course organized by APHL. The virtual course was conducted in collaboration with Theiagen Genomics, a company specializing in next-generation sequencing (NGS) and bioinformatics and an APHL Platinum level sustaining member. It was funded by the **US Centers for Disease Control and Prevention** (CDC) Division of Global Health Protection, Bangkok, Thailand, through an APHL-CDC cooperative agreement to strengthen public health laboratories internationally.

Starting Small

The training courses are part of US efforts to strengthen multilateral cooperation in response to and recovery from the COVID-19 pandemic by building capacity in global health. APHL staff served as faculty, providing foundational virtual training on key NGS concepts, terminology and wet-bench methodologies for nucleic acid extraction and library preparation. The bioinformatics and genomic epidemiology training utilized the Terra.bio platform, which allowed participants to work hands-on with COVID-19 data and whole-genome sequences of SARS-CoV-2 to identify genomically-linked clusters of outbreaks. The Terra.bio platform was developed by the **Broad Institute at the Massachusetts Institute of Technology and Harvard**. This same platform has been rolled out to all interested US public health laboratories through an agreement with **CDC and Theiagen Genomics**.

Course participants learned new skills from bioinformatics and genomic epidemiology to utilize raw sequencing files to generate actionable public health data pertaining to the COVID-19 pandemic response and other infectious disease-associated outbreaks.



Opening session of the virtual Genomic Epidemiology course for participants from the Asia Pacific Region, co-hosted by APHL and Theiagen Genomics

Additionally, participants were able to visualize outbreak-specific data and assess for novel or emerging variants of SARS-CoV-2. Participants receive ongoing access to resources and computational infrastructure thanks to a donation from Google.org, and ad-hoc support from APHL, CDC and Theiagen Genomics.

A Bigger Impact

These cohorts are part of a larger SARS-CoV-2 education for the Asia Pacific Region, which began May 2021. To date, a total of 223 participants from 14 countries (Brunei, Cambodia, Ghana, Indonesia, Jamaica, Malaysia, Myanmar, Nepal, Pakistan, Philippines, Singapore, Thailand, Trinidad and Tobago, and Vietnam) have been represented. This training has enabled the improved operation of SARS-CoV-2 genomic sequencing laboratories within these countries. Since the inception of these courses, over 15,000 unique SARS-CoV-2 genomes have been analyzed. In addition, several of the trained countries identified their first Omicron variants within their borders

using the Terra.bio platform and Theiagen workflows.

As countries continue building their SARS-CoV-2 genomic infrastructure, a subset of countries has begun to pivot and utilize workflows for other infectious agents and use cases. Countries are beginning to explore workflows for HIV to assess phylogenetics and antiretroviral resistance, antimicrobial resistance in hospital-acquired infections, and for tuberculosis to assess phylogenetics and antimicrobial resistance in clinical specimens. In addition, other countries are looking at onboarding wastewater surveillance for SARS-CoV-2 using the Terra.bio platform and various workflows available for analysis.

The Terra.bio training courses will continue into 2022 and will remain dynamic based on the needs of the regions and the progression of the COVID-19 pandemic and associated responses. Additional trainings will also be delivered to meet increasing need for sequencing and genomic epidemiology. ■

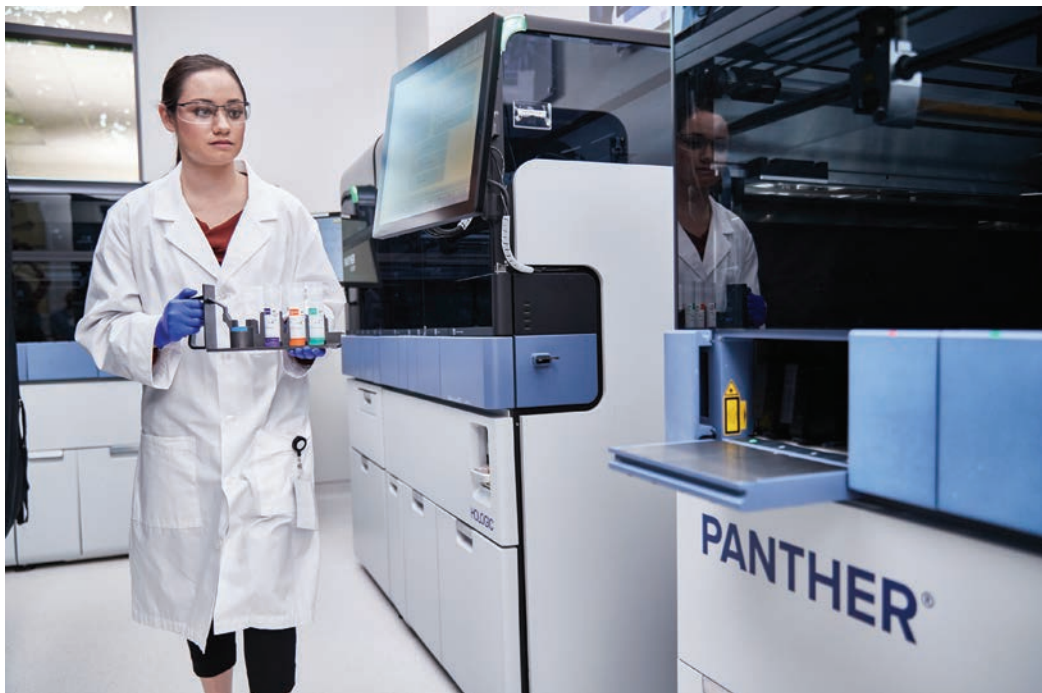
Old Pathogens Meet New Testing Practices: Updates to STI and HIV Testing Routines

By **Ashley Nenninger**, PhD, Scientific Affairs, Hologic and **Karen Harrington**, PhD, Scientific Affairs, Hologic

While the pandemic has necessitated significant focus on laboratory testing of a single pathogen, the last two years have also brought critical changes to testing for other important pathogens such as those associated with sexually transmitted infections (STIs). In March 2020, many clinical and community-based services shut down or moved to virtual platforms. There were dramatic declines (50-60%) in HIV and STI testing, and many areas are still observing lower testing numbers relative to pre-pandemic levels.¹

Despite significant impacts to testing, important recent updates to recommended STI laboratory testing have been issued in the **2021 US Centers for Disease Control and Prevention (CDC) STI Guidelines**. With this new guidance, there is an opportunity to implement testing updates as laboratories seek to return to routine practices, and help bring STI testing rates back. New considerations for chlamydia and gonorrhea testing, such as implementing opt-out screening of young women (<25 years) and including extragenital testing using tests cleared by the US Food and Drug Administration (FDA) for these sample types, were introduced in 2021. The guidelines include other newly FDA-cleared testing options so laboratories can consider bringing on new tests for emerging pathogens like *Mycoplasma genitalium* or tests that detect bacterial vaginosis via molecular methods. Additionally, universal once-in-a-lifetime hepatitis C virus (HCV) screening is now recommended for all adults (≥18 years) and all women during each pregnancy, except where prevalence is <0.1%.

Along with STI guideline updates, updates to HIV testing are actively being considered. The **current CDC three-step HIV testing algorithm** has been in place since 2014. An alternative algorithm in which a quantitative nucleic acid test (NAT) with a diagnostic indication as the second step in the algorithm has been suggested,² but until a year ago such a



A laboratory technician prepares to load Aptima assay reagents onto the Panther system. Photo: Hologic

NAT did not exist. FDA approval for a diagnostic claim for the Aptima® HIV-1 Quant Dx assay was granted in late 2020. It is the first and only HIV-1 NAT that can be used as an aid in diagnosis and for viral load monitoring.

Providing diagnosis confirmation and viral load directly following Ag/Ab HIV screening is advantageous by decreasing result turnaround time, leading to faster linkage to care, initiation of antiretroviral therapy (ART), reduced transmission and better patient outcomes. Furthermore, HIV-1 NAT as a second step would reduce the number of ambiguous Ab differentiation results, lowering testing costs. CDC HIV laboratory surveillance has conclusively demonstrated that prevalence of HIV-2 continues to be low in the US and HIV-1/2 differentiation can be done as the third step if necessary. The ability to meet the **Ending the HIV Epidemic: A Plan for America** goal of reducing HIV diagnoses by 90% by 2030 will require a renewed commitment to improving HIV testing that includes consideration of new testing algorithms to streamline diagnosis

and reduce transmission.

During the COVID-19 pandemic, continued public health messaging, interventions and outreach programs to restore STI and HIV testing and treatment to pre-pandemic levels remains important. Diagnostic platforms that can do much of this testing on a single instrument, like the Panther system, offer efficiencies in consolidation of testing on a single device. As laboratories return to routine testing, using broad menu, high-throughput platforms with tests that have comprehensive indications is more important than ever. ■

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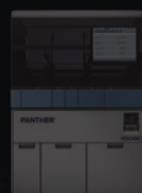
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† In development and not for sale.

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Automation Streamlines Arbovirus Sample Pooling in New Hampshire

By **Carol Loring**, MS, field applications specialist, INTEGRA Biosciences

Denise Bolton, supervisor of the Arbovirus Testing Laboratory at the New Hampshire Public Health Laboratories, knew changes to the laboratory's mosquito surveillance program for West Nile /Eastern Equine Encephalitis viruses (WNV/EEE) were needed.

"We always strive to make best use of resources by right-sizing our arbovirus surveillance program through evidence-based testing," she said. "We use mosquito ecology data to determine when to start testing mosquitos in the summer, and test sensitivity data allowed us to increase the numbers of mosquitos in each sample batch." But as summer 2020 approached and the SARS-CoV-2 pandemic showed no signs of slowing down, Bolton knew that more drastic change was needed.

"We had been thinking about trying out a pooled testing model for arbovirus surveillance prior to the pandemic. When we realized the surging demand for testing supplies, limited availability of polymerase chain reaction (PCR)

instrumentation and incredible strain on laboratory staff would continue through summer 2020, we knew it was time to implement pooled testing."

Moving to Pooled Testing

Bolton researched pooling methods and wrote a procedure. She performed a "proof of concept" study by testing combinations of WNV/EEE positive samples in varying concentrations. Her initial studies demonstrated that even very low positive samples would still be detected in a pool of four specimens.

"Our validation showed really high accuracy and sensitivity. We implemented pooled testing in summer 2020, but initially, construction of the pools was performed manually." Bolton soon realized that the additional step of mosquito pool construction complicated the workflow and occupied over an hour of analyst time, requiring high concentration and focus right when the energy level of the mosquito processor may be flagging.

“We always strive to make best use of resources by right-sizing our arbovirus surveillance program through evidence-based testing.”

Denise Bolton

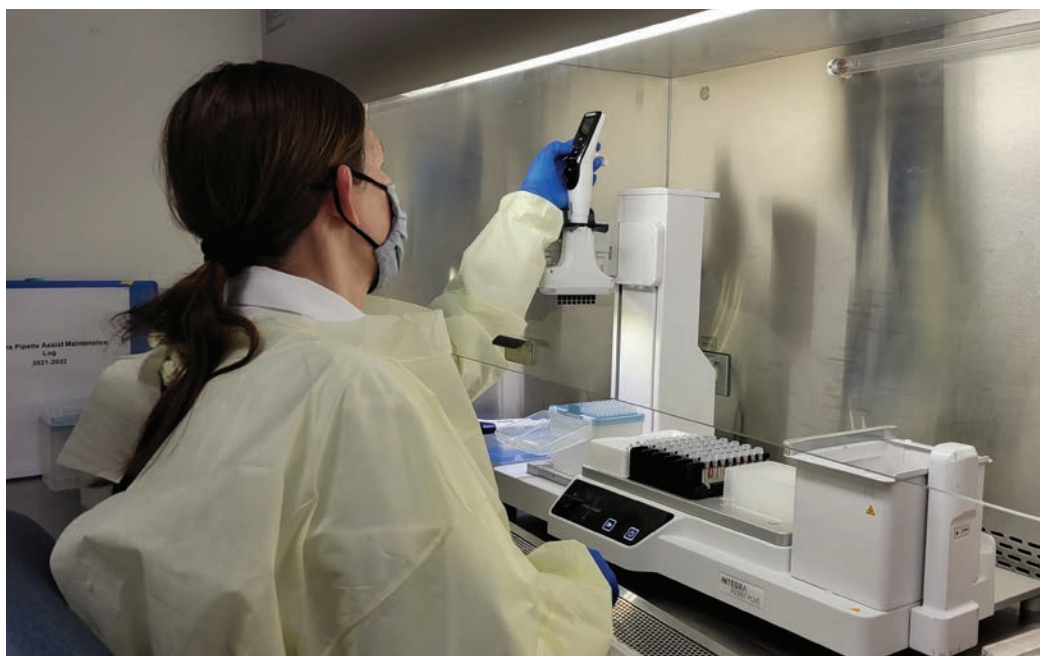
"Mosquito processing is really labor intensive. There are many steps requiring uncapping and capping of tubes and pipetting of samples, and all must be performed while following strict safety protocols. Adding a manual pooling step at the end of process was quite risky from a quality standpoint. I worried about the opportunity for analyst error in constructing the pools."

Reducing Opportunity for Error

Bolton decided to automate the pooling of samples on the INTEGRA ASSIST PLUS pipetting robot.

"I was already familiar with the ASSIST PLUS, as we use it for handling our COVID-19 samples," she said. "It was easy to write a pooling program on the VIALAB software that comes with the instrument, and the flexibility of the INTEGRA pipettes meant there was no need to change our mosquito processing method."

Bolton uses the INTEGRA VOYAGER eight channel pipette on the robot. This adjustable tip spacing pipette transfers sample from 2ml tubes into a 96-well plate for the pool construction. Bolton added that in the simplified pooling process they developed, a 200µl pool is constructed from four samples. After pooling is completed the ASSIST PLUS pipetting robot then adds lysis buffer directly to the sample pools.



Arbovirus Laboratory Supervisor Denise Bolton prepares the INTEGRA ASSIST PLUS pipetting robot for pooling arbovirus specimens. Photo: INTEGRA Biosciences

“We streamlined the process by using the entire pool for nucleic acid extraction,” Bolton explained. “This saves time and reduces the use of plasticware since we aren’t first constructing high volume pools and then transferring an aliquot for nucleic acid extraction. Using the ASSIST PLUS in this way has automated two steps in the process that were previously performed as manual pipetting steps.”

Saving Time and Money

Bolton says the adoption of pooled testing for arbovirus surveillance has resulted in a 75% savings in extraction and PCR reagents and reduced use of PCR instrumentation. While using the INTEGRA ASSIST PLUS pipetting robot to construct the pools saves precious analyst time, Bolton states, “most importantly, I appreciate knowing that the most complex step in the process is being performed error free.” ■

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APHL, CDC Prioritize Hepatitis C Elimination in Meeting, New Publication

By **Anne Gaynor**, PhD, deputy director, Infectious Diseases

A once incurable and potentially deadly bloodborne pathogen, hepatitis C virus (HCV) still causes nearly 1.5 million infections each year and as much as 40% of the nearly 58 million persons infected worldwide are unaware that they are infected, based on estimates from the World Health Organization.¹ In the United States, rates of hepatitis C tripled between 2011 and 2018 with an estimated 2.4 million Americans living with HCV in 2016.² Beginning in 2014, a cure became much more realistic when highly effective antivirals for HCV became available.

In 2021 the US Department of Health and Human Services launched “**The Viral Hepatitis National Strategic Plan; a Roadmap to Elimination**” with major goals focused on preventing infections, ensuring every person knows their status, and every person with viral hepatitis has high-quality healthcare and treatment and lives free from stigma and discrimination.² This five-year framework is part of a larger effort to eliminate viral hepatitis as a public health threat by 2030.³

As part of the HHS national strategy, the **US Centers for Disease Control and Prevention** (CDC) announced **updated universal screening recommendations for HCV** and called upon its partnership with APHL to address the goals that focus on preventing infections and ensuring everyone knows their status—both which rely on an appropriate HCV diagnosis.⁴ On October 19-20, 2021, APHL convened a meeting, “**Identify High-Priority Approaches for Advancing Hepatitis C Elimination in the US**,” to bring together over 75 stakeholders from the US Food and Drug Administration (FDA), CDC and the Centers for Medicare & Medicaid Services along with subject matter experts from public health agencies, clinical providers, diagnostic manufacturers and clinical laboratories. The virtual

meeting was also livestreamed to approximately 120 additional attendees to ensure broad access.

The current CDC **recommendations for laboratory diagnosis of HCV** relies on a two-step process, initial testing with an HCV serologic assay and, if positive, confirmation of current infection with an HCV RNA test. This two-step process can also cause further bottlenecks due to both tests frequently not being ordered and/or performed at the same time.

By the end of the meeting a handful of key priorities had been identified to be addressed by the various stakeholders in attendance. One of the major focuses of the meeting—and a priority recommendation—was to ensure that the proposed down-classification of HCV diagnostic tests is finalized by FDA. Down-classification is intended to align the current risks associated with an incorrect HCV test result with the current landscape. This would allow diagnostic manufacturers of HCV tests to seek approval through a less burdensome FDA approval process (510k), which is used for most diagnostic methods in the infectious disease field—therefore more familiar to diagnostic companies—instead of the premarket approval application, which is the most stringent review at FDA.

One month after the meeting, on November 19, 2021 the proposed down-classification became final—hopefully



Hepatitis C virus

opening the door for more companies to bring HCV diagnostic tests to market in the US. Not all of the other priorities from the meeting will be as straightforward but we look forward to working with the meeting attendees and partners to improve HCV diagnostics.

APHL will be publishing a draft meeting report in the spring and a final report by June 2022. The full recorded meeting and slides are available at aphl.org. ■

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Infectious Disease Laboratory Fellows Prepare for Careers in Public Health

By **Alisa Bochnowski**, MS, senior specialist, Infectious Diseases and **Lauren Johnson**, MPH, specialist, Infectious Diseases

APHL and the **US Centers for Disease Control and Prevention (CDC)** offer several fellowship opportunities that prepare and train scientists for careers in public health. The **Infectious Disease Laboratory Fellowship** immerses fellows in high-priority infectious disease testing, research, control measures and surveillance. Fellows are matched with local, state or federal public health laboratories and complete projects related to infectious diseases of public health significance. Four new fellows joined the 2021-2022 cohort in July 2021, and are contributing to cutting-edge work on hepatitis A, influenza, COVID-19 and other respiratory and vector-borne diseases.

Crystal A. Mendoza, PhD
Infectious Disease Laboratory Fellow
Massachusetts State Public Health Laboratory

My APHL fellowship has offered me the opportunity to blend my background in virology with next-generation sequencing (NGS) technologies to identify and characterize respiratory pathogens and arboviruses. I received my PhD from the Mayo Clinic Graduate School of Biomedical Sciences in March 2021 and began as an APHL Infectious Disease Fellow at the Massachusetts State Public Health Lab in July 2021. My primary projects have focused on optimizing existing next-generation amplicon sequencing workflows for SARS-CoV-2 and on the development of NGS technologies for other respiratory pathogens. With the emergence of new SARS-CoV-2 variants such as Delta (B.1.617.2) and Omicron (B.1.1.529), our work has focused on updating and validating new primer sets for SARS-CoV-2 sequencing and establishing other workflows to reduce hands-on time and streamline future automation. Furthermore, we are developing laboratory processes that are flexible and may be adopted and used for targeted amplicon sequencing of other pathogens, such as West Nile virus or other emerging pathogens.



Crystal Mendoza



Nora Cleary

Regarding other respiratory pathogens, I have focused on developing a respiratory metagenomics panel to identify pathogens using an enrichment method. On the virology side, we aim to establish new assays for quantification of Eastern Equine Encephalitis Virus and develop serological tests for other emerging arboviruses, such as Jamestown Canyon virus and Powassan virus. Together, these projects will aid in tracking and identification of respiratory pathogens and arboviruses that could influence

human and animal health.

Nora Cleary, MPH
Infectious Disease Laboratory Fellow
New York State Department of Health-Wadsworth Center

Hepatitis A has become a serious public health issue in the United States in recent years because of low vaccination rates and increasing risk factors including intravenous drug use and people experiencing homelessness. While the current Global Hepatitis Outbreak and Surveillance Technology (GHOST) protocol for genotyping has provided rapid, effective genotyping for hepatitis A, whole genome sequencing (WGS) has the potential to offer greater detail for outbreak tracing and infection control. To establish a WGS assay, I have been working in collaboration with Thermo Fisher Scientific to develop and validate a massively multiplexed hepatitis A Ion AmpliSeq panel.

With the exception of two short gaps, I have successfully sequenced several whole genomes. I am in the process of filling these gaps using two conventional sets of primers with Sanger sequencing. Once these gaps are filled, the sequences obtained will be used to update the current AmpliSeq panel so that it will be capable of generating complete genomic sequences. The complete sequences will then be used to create phylogenetic trees to compare hepatitis A genomes from outbreaks across New York State and from sequences archived in GenBank. This will hopefully provide greater resolution than that achieved with the current GHOST genotyping assays for enhanced outbreak tracing. Additionally, the greater genome resolution may help identify point mutations in the 5' untranslated region relating to viral fitness or aid in designing new real-time detection assays. ■

Maryland Undertakes Food Safety Data Exchange Journey

By **Rachel Shepherd**, specialist, Informatics

The **US Food and Drug Administration (FDA)** Office of Regulatory Affairs (ORA) Data Exchange (DX) is a unified platform that allows FDA and state partners to securely share sample collection, receipt and analysis data on selected microbiological, chemical and radiological analytes. By using ORA DX System-to-System services, such as the National Food Safety Data Exchange (NFSDX), laboratories can seamlessly collect and report data to FDA in near real-time, enabling the rapid review of analytical data to improve food safety efforts, assist in risk assessment analysis, increase efficiencies and aid in timely and accurate regulatory decision making.

The **Maryland Department of Health (MDH) Laboratories Administration** recently implemented system-to-system services, moving from a previously paper-based process to a fully automated one.

A Better Way

“We knew we wanted to go fully electronic” says Sinisa Urban, PhD, chief of the Division of Environmental Sciences who is leading MDH Laboratories Administration’s electronic data modernization. “We were manually generating and uploading spreadsheets from paper forms, and, with a quadrupling in testing volume afforded by our Laboratory Flexible Funding Model (LFFM) cooperative agreement from FDA, we not only had more data to enter, but more lab science to do. We needed to free time for the science, not the data entry.”

Maryland saw an opportunity to integrate all of its food testing into a single stream and modernize its data reporting 18 months ago through the LFFM funding. For the integration project, Maryland leveraged a long-standing partnership with iConnectConsulting, the vendor that was concurrently working on their laboratory information management system (LIMS) upgrade.

Starting the process early had several advantages.

“The first thing we did was to take all of the different forms we used with our various partners, added the NFSDX requirements and developed one standard form,” explains Urban. It took several months to harmonize, but when Maryland was ready to integrate its LIMS, all fields had already been standardized.

“A lot of the complexity in these types of integration projects comes from having a system that has to be reconfigured multiple times during the mapping phase. We were able to avoid that.”

How It Works

When a food sample is collected and a test ordered through the laboratory’s online LIMS portal, a message is sent via NFSDX to FDA letting them know that the sample is on the way and what to expect. There are approximately 20 data elements affiliated with a collected sample, including product information, collection date and time, product codes and firm establishment numbers, as well as test-specific data (e.g., *Salmonella*). Fields are mandatory and the LIMS was configured such that tests cannot be ordered until all data elements are complete. The required information is there from the start and eliminates the need for follow-up data collecting that can be very time-consuming and labor-intensive.

When the laboratory receives the sample and confirms it is in good order, a second ‘sample receipt’ message is sent from the LIMS to NFSDX. Once the test is completed, FDA is automatically notified of the test results by the laboratory’s LIMS through a third NFSDX message.

Once configured, NFSDX communications were so seamless—requiring no



Maryland Department of Health Laboratories Administration staff conduct LIMS/NFSDX training for state food collectors. Photo: MD PHL

intervention from the laboratory—that Maryland opted to also include components for monitoring communications and correcting errors. They built a transaction log that tracks what was sent when, and lists replies, including system errors, in a form that scientists could understand. They also added a top-level error alert. Most importantly, they configured a manual control capability to correct and resend transactions to NFSDX so if an error message is returned and something needs correction, all of the required actions for system-to-system communication are available to laboratory scientists at their fingertips.

Paving The Way

Maryland is the first state laboratory to go live with system-to-system services, but they are helping to lay the groundwork for other laboratories. MDH is conducting national demonstrations to show their system in action by providing trainings, as well as sharing lessons learned and challenges faced along the way.

For additional information about how your laboratory can get involved contact AppsDesk@fda.hhs.gov ■

Advancing Mobile Testing in the Nation's Capital

By **Rachel Shepherd**, specialist, Informatics

At the onset of the COVID-19 pandemic, laboratories had to quickly strategize methods to broaden their testing capacity. One innovation that many laboratories adopted was the advancement of mobile testing. The ability to test in the field rather than exclusively in the laboratory enabled public health laboratories to deliver immediate results, reducing the spread in those instances and leading to better health outcomes for vulnerable populations. The expansion of mobile testing continues to play a critical role in this pandemic, and ideally the benefits gained now can be leveraged to address future crises.

Prior to the pandemic, the **District of Columbia's Department of Forensic Sciences Public Health Laboratory Division** had never conducted mobile testing. However, through the **US Centers for Disease Control and Prevention's** (CDC's) National Health and Nutrition Examination Survey (NHANES), the laboratory was given the opportunity to use a truck stored at the **US Food and Drug Administration** (FDA) in Maryland and no longer in use. Matthew McCarroll, chief of laboratory operations for the DC laboratory, says that it was an immediate game changer.

"It was especially helpful in dealing with new submitters who hadn't reported to us before, particularly small ones—long-term care facilities, shelters for people without housing and nursing homes," said McCarroll. "Suddenly we could go directly to the site to perform testing, give those results in real-time, and anyone who needed to isolate knew to do so immediately." People in close-contact group settings and in at-risk populations received actionable information right away, instead of waiting 24-36 hours for results, and in the meantime, exposing others.

McCarroll alludes to one case in particular that showed just how life-saving mobile testing and early detection can be. Early in the pandemic, the laboratory was alerted to a small congregate of nuns caring for individuals without homes with terminal illnesses. Despite the fact that it was an isolated setting—and because it was isolated, COVID-19 precautions like mask-wearing and social distancing were not in place—some of the nuns began to feel sick. The laboratory was able to send the truck and test everyone at once. In the end, half of the group tested positive and began isolating right away, and the other half of the group never got sick. Had everyone been exposed for an additional two days while awaiting results, the infection rate could have been significantly higher, with potentially devastating consequences in such a vulnerable population.

The District also hosted several Health Resource Days, beginning in summer 2020. These events featured community resources—doctor referrals, preventative screening, children's activities—and the truck was onsite providing COVID-19 testing. In addition to identifying positive cases and providing guidance to limit exposure and spread, this sort of community involvement had the added benefit of visibility for the laboratory, educating DC residents about the role of the laboratory and public health.

Until recently, mobile testing has meant that the technicians had to print out results in the truck, enter the information into a spreadsheet, then enter data into the laboratory information management system (LIMS) retroactively. While the benefits were great, the process was inherently inefficient. However, DC recently upgraded their LIMS and McCarroll is optimistic that the addition of a patient portal remotely connected to

their LIMS will streamline and improve processes.

"The ideal scenario is to use a patient portal where the tester can scan QR codes on (pre-labeled) test kits, enter in minimal patient demographics in the field and then, when scanned again on the truck, all of the information captured is linked and logged into the LIMS from that point."

DC's patient portal is currently in beta testing and doing well. The laboratory hopes to launch it in the coming weeks for use in the city's hypothermia centers for residents without housing. As residents are taken to the centers, they would be tested upon entry. Anyone testing positive would be redirected and taken to a hospital for treatment and isolation, eliminating potential exposure.

Looking to the future, the hope is the truck will not just be used for COVID-19 testing in perpetuity, but pivot to other needs over time. It could be particularly useful for onsite sexually-transmitted disease (STD) testing, including STD health days at schools, or at similar care-facilities that have benefited from onsite COVID-19 testing.

The continued enhancement of mobile testing capabilities could be one of the most effective investments public health laboratories make. The ability to provide critical and actionable information in real time is vital to mitigate infections and prevent further spread. ■

2021 APHL Newborn Screening Symposium: Collaboration Continues Virtually

By **Dara Plath**, associate specialist, Newborn Screening and Genetics

At the start of the COVID-19 pandemic, no one anticipated how profoundly everyday lives would change. Nevertheless, babies continue to be born and need to be screened for rare disorders that could alter the course of their life. Behind the testing and follow-up are professionals whose commitment to public health forms the backbone of newborn screening (NBS).

Since 1981, APHL's Newborn Screening Symposium has convened hundreds of public health professionals from around the world to promote collaboration. Forty years later and with a pandemic in full swing, APHL shifted its NBS Symposium from in-person to online to ensure continuing support for these hard-working professionals.

Creating Lasting Connections

The challenges of going online were wide-ranging. In 2020, we learned how to structure the symposium to create an inclusive experience for all attendees. The virtual platform would need to support abstract and continuing education management, live and pre-recorded sessions, poster and exhibitor halls, and networking capabilities. We wanted to ensure that attendees could easily access each component in order to mimic the feeling of being in-person. The ability to re-watch sessions and view posters and exhibits anytime was an added benefit, as many attendees had to manage work responsibilities during symposium hours.

Once we knew the 2021 symposium would also be virtual, maintaining an inclusive environment that promoted attendee connections became the chief challenge. The conference platform allowed for private messaging, but we fostered face-to-face moments through subject-specific roundtables. Creating social events helped to generate the sense of community that is sometimes lost in a virtual platform. A baking session with a sixth-grader who raises funds for rare pediatric diseases,

and a **pre-recorded awards ceremony** that encouraged attendees to converse on the platform, reminded us of the importance of bringing joy and recognition to our colleagues. Encouraging attendees to post on social media also brought the experience of the symposium from the confines of the platform into the outside world.

Addressing Issues of the Present Moment

While the effects of COVID-19 informed many of the presentations, two sessions discussed the forces behind access to care. The keynote session focused on the social and ethical implications of genome sequencing and whether it can mitigate health disparities. The Health Equity session reminded participants that although we have recently been battling a viral foe, an epidemic of inequity within NBS requires attention.

The **Parent/Patient Panel** was a favorite among attendees, proving that the

backbone of NBS will always be families. Scheduled as the final session, the panel featured five families whose experience with NBS will help to inform new and constructive ways of communicating with parents.

Looking Forward

Although the world has changed, it remains important to create a space where we can address the issues of our present moment and find solutions for a more favorable future. As we plan for future symposia, this means creating a space that allows maximum attendance and addresses issues that affect NBS personnel everywhere. In 2022, we will consider the benefits of a hybrid model while remaining pragmatic about health concerns raised by COVID-19. As always, our goal will be to support those whose work positively changes the lives of families everywhere. ■



CALL FOR ARTICLES:

From The Bench

a regular feature of *Lab Matters*



Lab Matters, APHL's flagship publication, is seeking submissions from laboratorians at all levels of practice for "From the Bench," a member-driven section of its quarterly magazine.

We welcome both technical and non-technical articles covering topics across public health laboratory science, administration, careers and management. Articles may be 500-1200 words in length.

We're looking for a few key components in "From the Bench" articles –

- 1. A compelling story.** Tell us about an initiative that streamlined an administrative process or fostered relationships with external communities. Describe how your lab has worked with other public health partners to stop an outbreak or respond to an environmental health threat. Or tell us how you dealt with an initiative that failed.
- 2. A complete story.** Give us an article with a beginning, middle and end. The end should provide some resolution of the narrative. You don't need to have fully implemented the new algorithm, analyzed all the research data or completed the electronic laboratory reporting system discussed in your article.
- 3. An insider's view.** We want articles told from the unique perspective of a laboratory scientist that will be interesting and informative for APHL members and partners.

**Share your
story with
peers!**

We can help!

We will work with you to write the article, from connecting you to a writing consultant to providing editing assistance if you wish to write the article yourself.

If you have **questions** or would like to **submit a story idea**, please contact:
Gynene Sullivan, MA
Manager, Communications
gynene.sullivan@aphl.org
240.485.2750



The What and How of ISO 35001:2019 Biorisk Management for Public Health Labs

By **Michael Marsico**, senior specialist, Biosafety and Biosecurity

ISO 35001: Biorisk management for laboratories and other related organisations was first published in November 2019 by the International Organization for Standardization (ISO) that outlines a process to identify, assess, control and monitor the risks associated with hazardous biological materials in a laboratory setting. ISO 35001 is for any institution that works with, stores, transports and/or disposes of hazardous biological materials and is intended to complement existing standards or other guidelines for laboratories.

ISO is an independent, non-governmental international organization with a membership of 165 national standards bodies that develop voluntary, consensus-based standards based on global experts'

opinions. To date, ISO has developed more than 24,000 standards.

ISO 35001 establishes biorisk management principles by applying them in seven different areas:

- Context of the organization
- Leadership
- Planning
- Support
- Operations
- Performance evaluation
- Improvement

Each principle benefits from a systematic approach, which enables an organization to effectively assess, control and evaluate

its progress through the Plan-Do-Check-Act (PDCA) model. Using the PDCA outlined in the standard, public health laboratories can identify and mitigate the biosafety and biosecurity risks in the workplace to reduce incidents, accidents, infections and illnesses that may result from laboratory operations.

APHL, in collaboration with the **US Centers for Disease Control and Prevention** (CDC), is developing a strategy to provide guidance for public health laboratories interested in ISO 35001 implementation along with a **free webinar** on the values of ISO 35001 implementation. If you would like additional information or have any questions, please email biosafety@aphl.org. ■



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Mystery Melioidosis: Minnesota's Response to a Rare Outbreak

By **Rana Rahmat**, specialist, Laboratory Response Network

Melioidosis, also known as Whitmore's Disease, is a highly infectious disease caused by the bacterium *Burkholderia pseudomallei*. The bacterium is generally found in tropical and subtropical climates and transmission usually involves contact with contaminated soil and water. Those infected can present a wide variety of symptoms such as pneumonia, lesions, sepsis, abscesses or neurological indications.

The United States sees about 12 cases of melioidosis per year, usually associated with travel outside the US to endemic countries. This was not the case in 2021 as there were four cases of melioidosis reported in the US. The cases were spread out over a five-month period between March and July across four different states with the patients having no connection, commonality or travel history outside the US.

One of these states was Minnesota, where the third case occurred. The state typically sees one occurrence of *Burkholderia* infection per year, due to international travel. In this case the clinical laboratory sent samples from the patient, who was admitted to the hospital for the second time on June 6, to the Minnesota Public Health Laboratory on June 16. Minnesota tested for *Brucella*, *Francisella*, and *Burkholderia* immediately, by polymerase chain reaction. As soon as the sample was identified as *B. pseudomallei* on June 16, 2021 and the results shared with the **US Centers for Disease Control and Prevention** (CDC), the isolate was requested by CDC for immediate sequencing.

Identification was not the end of the laboratory's involvement in the case: buckets of cleaning products and various items also had to be collected, photographed and cataloged prior to being sampled and sent to CDC. The samples were then tested for *B. pseudomallei* to determine if any of the products had been contaminated.



Inoculated Sheep Blood Agar plate with Gram-positive *Burkholderia pseudomallei* incubated for 48 hours. Photo: Oregon State PHL/Larry Stauffer

A key component in the laboratory's response was the existence of the Laboratory Response Network (LRN) infrastructure, which provides standardized protocols and guidance for responding to biological threats. Minnesota created the Minnesota Laboratory System (MLS) which is a network of the sentinel laboratories within Minnesota's LRN structure. They used its alert system to message all the laboratories in the MLS in the wake of the *B. pseudomallei* identification. These other laboratories were asked to assess their recent samples and monitor all incoming samples for the biological agent to track any other potential cases.

Success in an outbreak response and investigation is really about persistence and the ability to work with each other, according to former Emergency Preparedness and Response Unit Supervisor Maureen Sullivan. Communication was a key aspect of this success in Minnesota's response to this incident and the subsequent investigation.

"CDC did a really good job communicating and letting us know where they were in the investigation," said Sullivan. This involved frequent conference calls that included the other states providing updates on where they were in the investigation.

It was the hard work and determination of the parties involved that the contaminated product was determined to be the Better Homes and Gardens Essential Oil Infused Aromatherapy Room Spray with Gemstones. The product has since been recalled and the investigation continues to determine which component was contaminated.

Each outbreak, particularly over the last two years, presents its own challenges and learning opportunities for the nation's public health laboratories. According to Sullivan, the impact of this outbreak across the four states was more philosophical, as it is always good to solve problems such as this and to be a part of the outbreak investigation.

"We can learn good things when we have the opportunity to work together." ■

Approaching 150 Years of Service in Milwaukee

By Jody DeVoll, MAT, writer

One of the first public health laboratories in the United States was not established in a major East Coast city, but in what was then a small city of German immigrants—Milwaukee, Wisconsin. In 1874, Dr. James Johnson, the City of Milwaukee's first health officer, founded what was to become the **Milwaukee Health Department Laboratory** (MHDL) as a chemistry and bacteriology laboratory to inspect milk and water for potential sources of disease.

Over its formative years, MHDL expanded its services to include food, water safety and infectious diseases testing. In 1953, MHDL became one of the first US clinical virology laboratories to investigate influenza, polio, rickettsial diseases and Q fever and received research funding from the National Institutes of Health. And as it prepares to celebrate its 150th anniversary in two years, MHDL will host APHL 2024.

Facility

Since 1959, MHDL has occupied over 16,000 sq. ft. of the Zeidler Municipal Building in downtown Milwaukee. Though the laboratory has been completely rebuilt, the space is not adequate to meet current needs and funding for a new facility is a top priority for Laboratory Director and Special Deputy Health Commissioner Sanjib Bhattacharyya, PhD. Packed within its present footprint are a BSL-3, molecular suites, chemistry, microbiology, virology and molecular science laboratories, and administrative and support services. MHDL also operates a satellite laboratory at the Keenan Health Center and provides STI, HIV and tuberculosis (TB) testing to support clinical and family planning services for central city residents.

MHDL is a member of the **US Centers for Disease Control and Prevention** (CDC) and the **World Health Organization's Global Influenza Surveillance and Response System** (GISRS) network of 124 laboratories in the US and globally.

Funding

While MHDL is mostly supported by tax levy dollars, individual programs are supported through a variety of funding streams:

- STI, HIV and TB programs are supported through Wisconsin Department of Health Services funds.
- **GC-AST surveillance** is supported by CDC's **Strengthening the US Response to Drug Resistant Gonorrhea** (SURRG) supports, one of eight national sites under SURRG and **GISP**.
- Lead testing is supported by a **US Department of Housing and Urban Development** grant.
- The **University of Wisconsin-Madison AIDS Vaccine Research Laboratory** partners with MHDL to conduct whole genome sequencing (WGS) for tracking of SARS-CoV-2 transmission during the COVID-19 pandemic.
- CDC's Epidemiology and Laboratory Capacity—Expansion and COVID-19 Enhancement funds and advanced molecular detection (AMD) funds for COVID-19 surveillance and applied research have enabled MHDL to expand next-generation sequencing and capacity.
- MHDL is also collaborating with UW-Madison, other Midwest partners and **Thermo Fisher Scientific** in a **Rockefeller Foundation** innovation grant to conduct air sampling for the SARS-CoV-2 in congregate settings. Currently air samplers are collected at COVID-19 shelters and daycares, and will be expanding to schools and airports.
- MHDL is partnering with **University of Wisconsin-Milwaukee, Wisconsin State Laboratory of Hygiene**, APHL and **QIAGEN** to onboard SARS-CoV-2 wastewater surveillance.

Director

Bhattacharyya built his career at MHDL,



MHDL staff celebrate Public Health Laboratory Appreciation Month in September. Photo: MHDL

beginning as a senior microbiologist in 2002 and advancing to chief molecular scientist, sections chief, deputy director and now the public health laboratory director and special deputy health commissioner. However, public health was not his original career goal. As a post-doctoral fellow at the **Medical College of Wisconsin** and on a clinical rotation at the **Zablocki Veteran's Administration Medical Center**, Bhattacharyya planned to pursue an academic career. But the unpredictability of academic funding led him to consider a public health career option. Bhattacharyya retains his association with academia as adjunct faculty at the **UW-Milwaukee Zilber School of Public Health**, as a clinical associate professor at the **College of Health Sciences** and lectures at **Marquette University**.

Bhattacharyya credits APHL for his evolution as a leader. He has participated in APHL's **Emerging Leaders Program**, served on multiple APHL committees and is currently a member of the APHL board of directors. In addition, MHD staff and senior administrators have strongly supported his professional development.

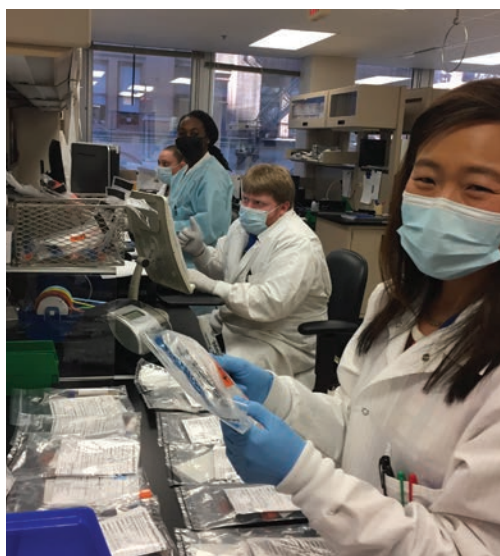
Staff

MHDL's 35 permanent staff typically work five days a week, eight hours per day. During the pandemic, the laboratory has operated seven days a week, 12-14 hours per day to support ever-increasing demands. To keep pace with COVID-19 PCR, sequencing and maintaining other laboratory services, MHDL has onboarded multiple temporary staff, including two

APHL COVID-19 Associates and one genomic specialist. A bioinformatician recently joined MHDL to strengthen AMD capacity and to support sequencing analysis and genomic data processing. In July 2022, the laboratory will welcome a [CDC Laboratory Leadership Service](#) fellow to help bridge applied laboratory science with public health programs, strengthen local, state and federal partnering and support public health laboratory surveillance.

Services

MHDL performs a variety of clinical and environmental testing as well as reference laboratory testing. It is a member of CDC's [Laboratory Response Network](#) (LRN), [PulseNet](#), [CaliciNet](#), the [National Enterovirus Surveillance System](#) and the WHO Influenza Surveillance Network. It also supports USPS, FBI and BioWatch programs. Locally, the laboratory is actively engaged with [Clinical & Translational Science Institute of Southeast Wisconsin](#) (CTSI), and [Medical College of Wisconsin's Community Engaged Research](#). MHDL brought in low-cost lead and nutrient screening services to provide soil lead mitigation advices, and was recognized with [National Association of County and City Health Officials](#) Promising Practice Award in 2021.



MHDL staff order tests for a COVID-19 run. Photo: MHDL

MHDL is concentrating on COVID-19 surveillance testing for high-risk populations and conducting limited diagnostic testing. It has the capacity to run up to 1,200 COVID-19 specimens each day and over 500 whole genome sequences per week. MHDL worked with the Wisconsin Department of Health Services and the state emergency operations center to ensure eligible facilities in the greater Milwaukee area and southeast Wisconsin had access to timely COVID testing for their residents and staff during outbreaks. While building capacity for COVID testing and genomic surveillance, MHDL has continued all other laboratory services throughout the pandemic, including STI, lead and other reference testing services, and brought in fee-for-service revenues to the city.

MHDL's technical capabilities are unusually broad for a local health laboratory. It offers advanced molecular diagnostics including real-time polymerase chain reaction (PCR), multiplexing, Sanger and next-generation sequencing, and piloted metagenomic sequencing for local area beach samples, along with matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) and other conventional capabilities. It is working to expand environmental testing, bioinformatics and data analysis capability.

Education and Professional Development

As an academic health department, MHD works to bring public health laboratories to the public. The laboratory is actively engaged in promoting public health and laboratory science, partnering with local universities, touring for students, dignitaries, and elected officials and developed [educational videos](#) to share its programs and COVID-19 activities. MHDL piloted a virtual program to promote public health laboratories to Milwaukee public school students and continues internship opportunities for local college students.

MHDL is committed to providing professional development opportunities,

including a career ladder, for its diverse staff and students. Over the last decade, over 80 students have refined their skills at MHDL, including those pursuing programs in two-year technical schools, as well as bachelor's, master's, doctoral and medical students.

Achievements

- Since 2020, MHDL staff has authored [15 publications](#), including an article in [Nature Communications](#) on the introduction of SARS-CoV-2 in Wisconsin.
- When COVID-19 outbreaks at Milwaukee food manufacturing and processing firms threatened lives and productivity, MHDL worked with local health officers and coordinated activities to bring in CDC teams to assist meat processing/manufacturing plants to limit the spread of disease.
- In 2020, MHDL distributed 15 rapid, [Abbott ID Now](#) point-of-care instruments to 10 local community sites who did not have immediate access to COVID-19 testing. It installed the instruments, trained site staff, and continues to support PCR confirmation and reporting. It also supported a portal for data transfer to the state.

Challenges

- Recruitment and retention of qualified laboratory technical, management and administration staff remains a challenge due to a lack of competitive salaries for public health laboratory professionals. Two years into the pandemic staff are tired, and some have left for better paying jobs or taken a hiatus from work.
- Limited capacity for real-time data analysis, and lack of adequate infrastructure for informatics and bioinformatics support.
- Major space constraints due to accommodating new staff and technologies, and exploring infrastructure funding for lab space expansion. ■

APHL Continues to Expand Fellowship Programs for 2022

by Heather Roney, MA, manager, Fellowships

APHL recruited for fellows and host laboratories for a large cohort of fellows to begin in summer 2022. An unprecedented number of subject area fellowships are available this year, including:

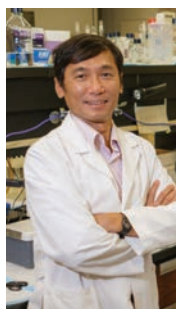
- **Bioinformatics Fellowship**
- **Biorisk Management Fellowship**
- **Environmental Health Laboratory Fellowship**
- **Food Safety Laboratory Fellowship**
- **Infectious Diseases Laboratory Fellowship**
- **Informatics Fellowship**
- **Quality Management Laboratory Fellowship**

• Ronald H. Laessig Newborn Screening Fellowship

A small cohort of Bioinformatics, Environmental Health, and Infectious Diseases Laboratory Fellows were placed in APHL member local and state public health laboratories in early 2022.

APHL plans to launch a new public health laboratory internship program in the coming months. Interns will be current students or recent graduates interested in a 12-16 week full-time or part-time experience in a public health laboratory.

For more information about the fellowship and internship programs see www.aphl.org/fellowships. ■



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APHL-CDC fellowships provide experiential training to bachelor's, master's and doctoral-level scientists in preparation for impactful careers in public health laboratory science.

Historic funding has expanded this valuable fellowship program and even more opportunities are now available!

Many Opportunities

Do you know anyone interested in starting an exciting new career in laboratory science, working collaboratively with industry leaders and developing professional networks?

There are many fellowships available in various disciplines, including:

- Bioinformatics Fellowship
- Environmental Health Laboratory Fellowship
- Food Safety Fellowship
- Infectious Disease Laboratory Fellowship
- Management and Operations Fellowship
- Quality Management Fellowship
- Ronald H. Laessig Newborn Screening Fellowship

Host Labs Needed!

We encourage APHL member laboratories to apply to host fellows. The benefits of hosting are many:

- Supports ongoing laboratory services
- Supports response to outbreaks and other investigations
- Contributes to projects that might otherwise be delayed or not initiated
- Provides supervisory and mentorship experience for host laboratory staff
- Introduces young scientists to public health laboratory science, allowing you to help shape a new generation of the workforce
- Provides a possible workforce pipeline for staff openings in your laboratory



Find
more details and
applications at
**[www.aphl.org/
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**APHL will soon
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