

LAB MATTERS

analysis|answers|action

Summer 2022 Issue 2

THE COVID-19 ENDEMIC

**Building Strong
Surveillance Systems in
Public Health Laboratories**

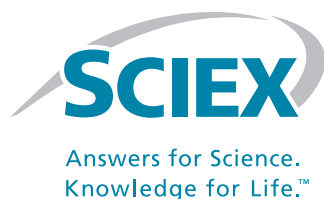
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Public health laboratories across the United States were consumed by COVID-19 diagnostic testing in the pandemic's early months. But after clinical laboratories began to do most of the testing, and as more people tested themselves at home with rapid antigen tests, public health laboratories shifted from diagnostic to surveillance testing. Nearly two and a half years into the pandemic, public health laboratories are developing new surveillance systems, taking advantage of new equipment and staff, and improving programs based on lessons learned from COVID-19.



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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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Reflections on Transitions

When I was asked to consider moving into the track for APHL president, not only was I very honored but I have to admit I was also extremely nervous. APHL is such a spectacular organization—everything the association coordinates is just huge across the nation and has such an impact on so many areas of public health. I was truly worried that it would be too much on top of my current responsibilities as a laboratory director. Not to mention, I agreed to accepting the nomination prior to the pandemic, which added another level of complexity that I was not expecting!

Supporting our members and leadership and working to provide them what they need has been my goal since day one. There is no question that APHL has an amazing support structure, without whom I wouldn't have been able to perform my duties. While the role of president is not an easy one, the wealth of support from APHL certainly does make it easier. Even though I had served on the Board, and on several committees and subcommittees, I don't think I had an appreciation for all the "behind the scenes" coordination, advocacy and networking that occurs at APHL.

There is no question that the past couple of years have been tough for all of us in public health. From bench-level scientists to administration, we have all experienced a sea change in the way public health is perceived. It has been my privilege, as president, to welcome so many new laboratory directors and laboratory leaders into the APHL community. Some of you have worked in your laboratory for years, while others are taking on a position at a new laboratory. So I thought I would share a few thoughts that I hope may help on your path forward.

For those of you who are coming into new laboratories, invest the time and learn about your laboratory—the people, the facilities and the processes. Don't arrive with the "I just want to change things"

mindset. There is a reason your laboratory does what it does, so understanding the "why" as well as the "how" things are done will be important and you work to make improvements.

For those of you who have been promoted into higher-level positions, take the time to figure out who you are as a leader. Think about what is important to you and what you really want to accomplish for your organization. There will never be the perfect time, the proper funding, or significant decreases in workload so please do not get discouraged. Focus on small, attainable goals that together will help you to address the larger needs of the laboratory. I know it sounds silly but don't worry about being the best—just focus on being better each day. Always remember what it was like to be at the bench when you're being pulled in many different directions. In your new role, you are no longer responsible for doing the actual work—instead you are responsible for providing the support needed to make sure the work gets done safely and accurately, but most importantly, your job is to ensure the people under your leadership have what they need to be happy and successful.

Get to know the folks you will be working with at every level. Knowing what makes them tick and why they come to work every day will really help you as a leader, especially in challenging times. They have to be able to trust and respect you and know that they can come to you when they have ideas, suggestions, concerns or reservations. One thing I absolutely enjoy doing as director is greeting every new person to our organization, regardless of where they are going. I meet them, I take the time to learn a little bit about each of them personally, and I also share with them my professional journey and a bit about my personal life—my kids, my puppies, my interests outside of work—so they have a chance to get to know me as a director and as a person. I find this exchange so important because it allows



*Denise Toney, PhD
President, APHL*

“Looking forward, I think it goes without saying that the pandemic has opened doors that we in public health have been trying to open for decades.”

me to very early on, establish a different connection with our new folks in a very informal and personal way.

Looking forward, I think it goes without saying that the pandemic has opened doors that we in public health have been trying to open for decades. It is truly going to take strong leadership to make sure that we can keep those doors open and that is a role that the leadership at APHL and the Board of Directors are perfectly positioned to support. Watching APHL as it has grown and evolved into the dynamic organization it is today, with such a strong leadership team, I am confident they will lead APHL and our laboratories to where we need to go in the coming months and years. Please know they will be there for you and I will be too!! For those of you who know me, you know that I am only a phone call, text or email away if you need anything and that will continue even as I step into my new role as immediate past president. Thank you so much for your support this past year. I wish you all the best and I look forward to our future collaborations.

It Is Time to Move Forward

As the days get longer and the weather gets warmer, I am looking back at where we have been and what we have accomplished, both as public health professionals and as human beings, over the past two and a half years.

There is no question that our world has undergone a seismic shift. Even as pandemic restrictions fall and our lives open back up, we really must take the time and acknowledge the collective trauma that we have undergone. Early this year, the US Centers for Disease Control and Prevention redistributed their mental health survey to state, tribal, local and territorial public health workers. You can read about the [previous survey](#), but one startling statistic that came out of the new survey was that almost as many people responded to the second survey as to the first survey. That kind of return was completely unexpected to me, but it indicates a critical need for the conversation to continue around the mental health of our members, our staff and our community.

Another thing that will be changing a bit is how APHL structures its work as an association. While we remain a “member-first” organization, we are also in the middle of some adjustments in how our staff work. When we were forced to move to all-remote in March 2020, we found that while a lot of processes had to be rethought, our staff really appreciated having the chance to focus a bit more on the “me” work that is just as important as the group work that takes place in our physical space. We are conducting surveys and focus groups within our staff and senior management in order to better understand staff work styles across and within groups, to better engage staff to be their best and most productive selves and to use our physical space more effectively. We have also engaged with the Board of Directors to get a member perspective on how they see APHL as an organization and

what members expect in APHL's physical space. We are really looking forward to our first staff dedicated “APHL Week” in mid-July 2022.

Being at APHL 2022 in-person was such a change from the past two years of Zoom and Teams meetings. I also had the opportunity to speak at the 2022 Preparedness Summit in late April. In both instances, while masks and other COVID-19 mitigation protocols were in effect, the hope and positivity from conference attendees was infectious. Everyone is ready to move forward and into a new phase...I will not say “new normal” because the concept of “normal” is different for every person. And I do not think it is possible to return to the way things were done, even if we wanted to. What we need to remember as we move into this new phase is that we did not, and have not, failed in our duties and responsibilities. In the words of my friend Michael Fraser, PhD, CEO of ASTHO and one of my fellow panelists at the Preparedness Summit: “Don't let this loud narrative drown out the fact that your response was anything other than successful. We were not perfect, but the notion that public health failed is total bull****.”

There is still a need to sustain the work and infrastructure that we have built out during the pandemic. And that is the big job ahead of us. It will take a lot of advocacy in communities that we have never turned to before. Our field is ready for the next generation, but it will take all of us to get that next generation interested, involved and ready to take on future challenges. We may be tired, but I know we are also ready, willing and able to do what it takes. Be open to telling your unique stories to those who will listen. And above all, do not stop believing in yourself, in your teams or in your work. ■



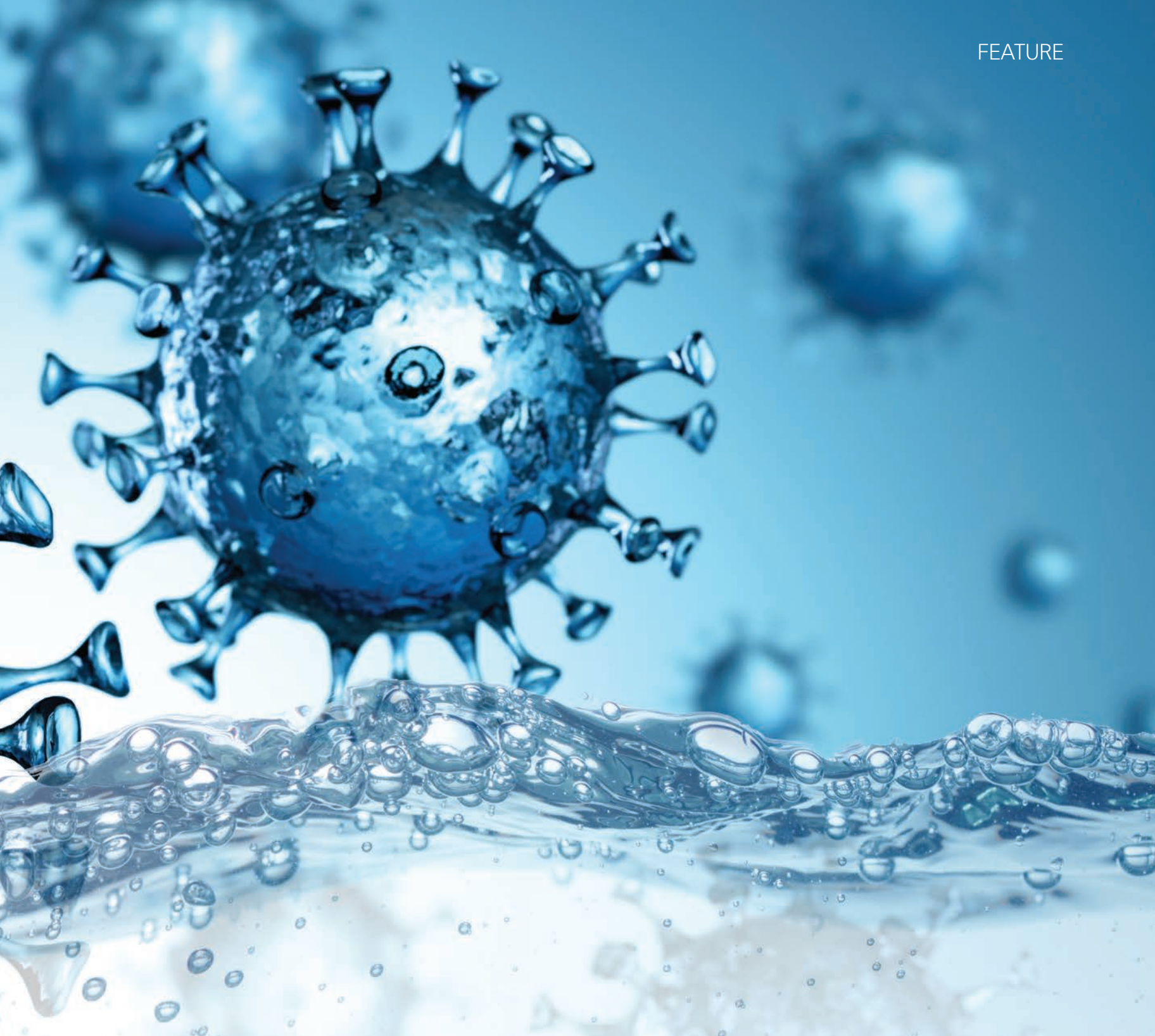
*Scott Becker, MS
Chief Executive Officer, APHL*

“What we need to remember as we move into this new phase is that we did not, and have not, failed in our duties and responsibilities.”

THE COVID-19 ENDEMIC

**Building Strong Surveillance Systems
in Public Health Laboratories**

By Melanie Padgett Powers, writer



About a week before the first COVID-19 positive case was identified in Minnesota in March 2020, Myra Kunas, MS, was sitting in a conference room with about 12 other people trying to budget for the testing that was about to hit her laboratory division. No one was wearing masks or social distancing yet, as the team huddled over their laptops and brainstormed on how many samples the laboratory might receive.

Kunas was assistant laboratory director of the **Minnesota Public Health Laboratory Division** at the time, but she would be promoted to director two months into the pandemic, after her director retired.

“So, we were up there discussing budgets, and we estimated we would have to test for a month, 300 samples per week, and then 200 after that, and then 100 probably for another six months. And then that’s it,” Kunas said. “And we got 1,000 in one day about one week after our first positive case.”



Photo: Minnesota Public Health Laboratory Division

“We’re thinking beyond COVID-19: How can we use wastewater surveillance as a mechanism of pandemic preparedness? And we’re looking at other types of pathogens that might have health importance.”

Priscilla Seabourn, MS, PhD

State public health laboratories across the United States were consumed by COVID-19 diagnostic testing in the pandemic’s early months. Many laboratories didn’t have enough staff, enough equipment or even enough space to manage and test all of the samples. They were overwhelmed with work—while also trying to stay safe from the virus. But after clinical laboratories began to do most of the testing, and as more people tested themselves at home with rapid antigen tests, testing at public health laboratories shifted from diagnostic to surveillance.

Nearly two and a half years into the pandemic, public health laboratories are developing new surveillance systems, taking advantage of new equipment and staff, and improving programs based on lessons learned from COVID-19.

“We’re not buried under specimens at the moment,” said Edward Desmond, PhD, laboratory director and administrator of the [Hawaii Laboratories Division](#). Instead, Hawaii is using whole genome sequencing (WGS) to investigate the spread of COVID-19 and to detect new variants in communities. WGS showed

that in the vast majority of cases the virus was spread by state residents, not tourists as some had assumed. “What that means is we need to have community mitigation because we can’t blame it all on the tourists,” Desmond said.

The ability to detect new variants helps show the community when renewed mitigation measures might be recommended, he said. And, it allows the laboratories division to know what mutations exist in the state, which can help guide treatment.

Establishing Wastewater Surveillance Systems

Several states, including Hawaii, have implemented new wastewater surveillance testing, which can detect early signs of diseases beyond COVID-19 through viral RNA that infected people shed in fecal matter. In Hawaii, Priscilla Seabourn, MS, PhD, established the wastewater surveillance infrastructure—one of several COVID-19 projects she worked on during the pandemic in Hawaii, first as an APHL-CDC COVID-19 Laboratory Associate and then as an APHL-CDC Antimicrobial Resistance Fellow.

During her nine-month fellowship, Seabourn researched and ordered the proper equipment, optimized protocols and established collaborations with wastewater treatment plants. The new system has the potential to detect new COVID-19 variants, as well as markers for antimicrobial resistance and other diseases such as influenza and norovirus.

“We’re thinking beyond COVID-19: How can we use wastewater surveillance as a mechanism of pandemic preparedness? And we’re looking at other types of pathogens that might have health importance,” Seabourn said.

Seabourn established collaborations with 12 wastewater treatment plants in Hawaii that will regularly gather and send wastewater samples to the laboratories division for surveillance. The facilities were also enrolled in the [National Wastewater Surveillance System](#), which the [US Centers for Disease Control and Prevention](#) launched in September 2020 in response to the pandemic.

Colorado's state laboratory division has also implemented wastewater surveillance. "Before the pandemic, we were doing sequence analysis for foodborne pathogens. We capitalized on that knowledge to quickly pivot to doing [WGS] on clinical samples for COVID-19," said Emily Travanty, PhD, laboratory director of the [Colorado Department of Public Health and Environment](#). "And then the wastewater surveillance piece came into play, so we added capacity for that type of digital droplet PCR."

With the clinical sequencing workflow already set up, the state laboratory was able to easily "slide the water samples that were positive for COVID-19 into those same sorts of pathways," Travanty explained.

"I'm certain that it is going to go a long way," she continued. "It is a pillar of our ongoing surveillance that we're going to continue in Colorado to ensure that we understand the ongoing impact that COVID-19 has in our state, as well as use the same samples and the same network of samples to expand what we're testing for in wastewater."

Learning About Congregate Settings

Colorado also learned how to test in congregate settings, but one unique to the US West: fire camps. August 2020 was the start of the worst fire season in Colorado history. Because of the magnitude of the fires, fire crews poured in from other states and lived together in camps, creating "ripe conditions" for COVID-19 spread, Travanty said.

At the time, PCR test results were not quick enough to learn who was infectious and who should quarantine. But the laboratory did track the data to see how COVID-19 moved through the camps. The Cameron Peak Fires lasted for five months, and fire crews from multiple states were deployed every two weeks. Firefighters were tested before they arrived and encouraged to practice social distancing.

On-site tests showed 78 firefighters tested positive for COVID-19. WGS was performed on 42 positive cases, identifying five sequence types. The types were not in clusters, which suggests COVID-19 spread among the crews.

On-site tests showed 78 firefighters tested positive for COVID-19. WGS was performed on 42 positive cases, identifying five sequence types. The types were not in clusters, which suggests COVID-19 spread among the crews, according to the APHL 2021 poster abstract "The Use of Whole Genome Sequencing (WGS) to Investigate the Spread of COVID-19 in Fire Camps During the Cameron Peak Fires (August 2020) in Larimer County, Colorado."

In addition, individuals may not have suspected they had COVID-19 because of the bad air quality—if someone is coughing is that because of the smoke or COVID-19? In future fire seasons, Travanty said, it will be important to have stronger fire camp guidelines for testing, including additional use of over-the-counter rapid tests (which were not widely available during previous fire seasons), quarantining, social distancing and use of personal protective equipment.

"If we have fires this summer, we will definitely be able to deploy," she said. "We have teams that can deploy rapid tests, as well as teams that can go into the field now and respond and swab people for PCR testing."

For congregate settings in Hawaii, laboratory workers learned it was necessary and possible to quickly create training materials. When point-of-care tests were distributed to congregate facilities in 2020, it was apparent that staff, such as those at prisons and nursing homes, needed test-specific training.

Seabourn quickly created a couple of slide presentations teaching people how to administer the tests, complete with [embedded videos](#) of Seabourn showing the step-by-step process. She shot the videos using only her iPhone with the help of a postdoctoral fellow.

"Everyone was just hitting the ground running, considering the pandemic," she said. "I basically took two weeks to get updated on the literature, made sure I was very familiar with the protocol and all the different specifications, and then I just quickly made the videos."

Creating a professionally shot and edited video would have taken longer and cost more. "I think sometimes you have to ask yourself, 'What is the need?' And if it's something that you can just quickly do, it's better to just have it out in the public and ready for everyone."



Photo: Minnesota Public Health Laboratory Division

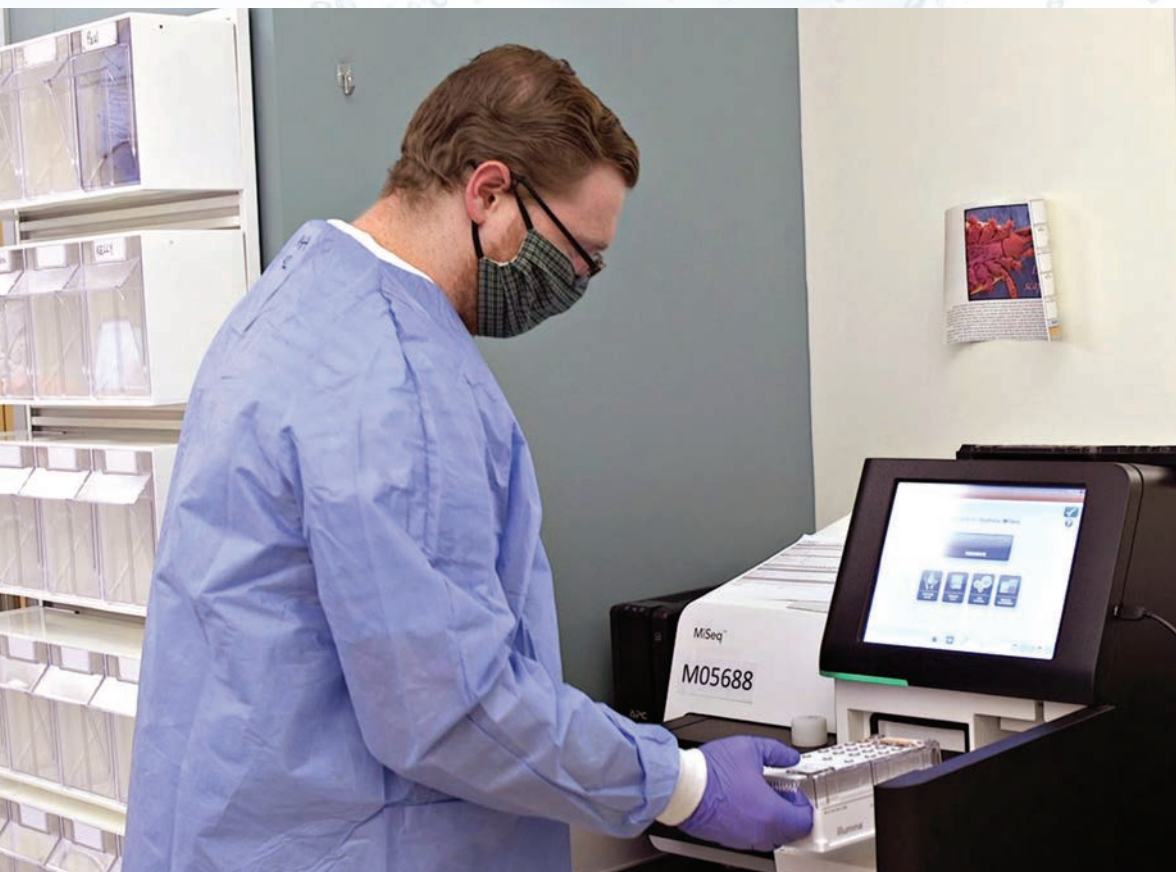


Photo: Minnesota Public Health Laboratory Division

The Minnesota Molecular Surveillance of SARS-CoV-2 (MN-SOS) system led to the discovery and investigation of the first identified case of the P.1 variant in the US, from someone who had traveled to Brazil.

Conducting Whole Genome Sequencing

To better track and understand COVID-19 outbreaks in Minnesota, the state public health laboratory, in partnership with universities and clinical laboratories, created the Minnesota Molecular Surveillance of SARS-CoV-2 (MN-SOS) system to conduct whole genome sequencing to detect variants of concern.

Beginning in December 2020, the public health laboratory began receiving 50 specimens a week from each of its clinical partners, according to the 2021 APHL poster abstract “Minnesota Molecular Surveillance of SARS-CoV-2.” This new system led to the discovery and investigation of the first identified case of the P.1 variant in the US, from someone who had traveled to Brazil. (A second P.1 case was positive in that person’s travel partner or household contact.)

“It was just by chance that we found that case,” Kunas said. “We received it as part of the 50 samples per week that we were getting from clinical labs. ... The importance of the P.1 case was to detect and identify cases quickly and to reduce potential spread. Our partners

and epidemiologists did a lot of case investigation and contact tracing to identify close contacts.”

Other investigations focused on the first case of the B.1.1.7 variant in Minnesota and the second Omicron case in the US, according to Kunas.

A more recent challenge that Kunas and her team problem-solved was the overwhelming number of samples they were receiving from clinical laboratories for sequencing during the Omicron surge. They requested 50 samples a week from laboratories but were sometimes getting up to 500. Kunas admitted the backlog wasn’t truly addressed until the public health laboratory had around 11,000 samples in the queue. She pulled in staff from other areas and they worked through the samples over five weeks to eliminate the backlog.

That included identifying laboratories that were submitting too many samples, reducing how many samples were being sent from all laboratories and working with epidemiologist partners to truly prioritize their needs. This meant “going through freezers to identify how many samples there were, what they were, where they were coming from, and then working with our epis to have a real sit-down like, ‘We can’t do all of these, so let’s figure out what makes sense.’”

Next, a project manager created a dashboard to quickly visualize the samples that were arriving each day and to monitor capacity.

“It’s helped everyone with tracking so that we could focus on testing and supporting the team through that challenge,” Kunas said. “The lesson learned there is when a team is struggling, they might not have the resources or the capacity to even ask for help until it’s a much bigger problem.”

Now, laboratory professionals know to check in and trust the newly-developed dashboard, and leadership knows to support staff differently when they’re getting overwhelmed, she said.

Recognition from Lawmakers

Another change at most public health laboratories since the pandemic started is how they are viewed by state and federal lawmakers.

“Historically, I likened our laboratory to poor church mice looking for crumbs and largely ignored,” Desmond said. “That’s not the case now. Federal funds have come in, and we also have a great deal of support from the state.”

In fact, his division in Hawaii has received federal funding to turn its biosafety level 3 (BSL-3) laboratory into a BSL-3+ laboratory, providing a higher level of precautions. “We think this is important because of concerns about future pandemics,” Desmond said. “If the pandemic is caused by the worst virus you can imagine, and you had an accident in one of the laboratory rooms, the virus could be discharged through the exhaust ventilation, and we don’t want that to happen.”

Hawaii has also received funding to purchase new equipment, refurbish one of the laboratory suites into a molecular biology suite, and hire new staff, including

a bioinformatics specialist and a molecular biologist who together created a bioinformatics pipeline. Several state legislators have also introduced a bill that would fund public health laboratory upgrades. (As of March 2022, House Bill 2515 was with Hawaii’s House Ways and Means Committee.)

Minnesota also received federal dollars that covered new staff, COVID-19 testing and sequencing, infrastructure enhancements, updates to information technology systems and interoperability, Kunas said. And though the laboratory building is only 16 years old, Kunas said there have been significant problems through the years, including a major flood in 2014. There has been ongoing work to repair valves and corroded duct work. The laboratory had requested state money several times for repairs and additions, but it wasn’t until October 2020 that a large amount was provided: \$20 million for building repairs and upgrades.

“Historically, I likened our laboratory to poor church mice looking for crumbs and largely ignored. That’s not the case now. Federal funds have come in, and we also have a great deal of support from the state.”

Edward Desmond, PhD

“I have to admit that I do think that COVID-19 played a role in us getting those funds,” Kunas said. “I think there’s been significant understanding from the Legislature that when you say monitoring of contaminants, that doesn’t mean you collect a sample and you get a result. There needs to be this testing infrastructure in place in order to make that all happen. ... So, I do think that there’s a lot more acknowledgement of the importance of labs throughout the country.” ■

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Biomonitoring and Environmental Justice

By **Kenneth Aldous**, Division of Environmental Health Sciences, Wadsworth Center, New York State Department of Health and **Antonia M. Calafat**, Division of Laboratory Sciences, National Center for Environmental Health, US Centers for Disease Control and Prevention

Over 200 people from 34 states attended APHL's virtual National Biomonitoring Meeting: *A Systems Approach for State Biomonitoring Programs*, planned by the **National Biomonitoring Network** (NBN) Steering Committee. NBN members requested environmental justice be a priority at this year's meeting, and attendees awarded the environmental justice session with highest ratings in the post-meeting evaluation.

The environmental justice and biomonitoring session offered attendees three engaging presentations:

- Gary Adamkiewicz, PhD, MPH, associate professor of Environmental Health and Exposure Disparities and director of the Healthy Cities Lab at the **Harvard TH Chan School of Public Health**, discussed the connections between the built environment and health, and why many disparities in environmental exposures closely relate to where individuals live and to systemic and racist policies.
- Esther Erdei, PhD, MPH, MSc Hons, MEd, research assistant professor at the **University of New Mexico Health Sciences Center** and the core director of Community Engagement and Outreach at the **National Institute of Environmental Health Sciences Center for Native American Environmental Health Equity Research**, spoke about integrating biomarkers of exposure and effect in studies of underrepresented communities, especially tribal communities in the southwest and midwest United States. Substantial portions of tribal land are contaminated with heavy metals originating from mine waste. Erdei highlighted important considerations for engaging communities that use lands for subsistence and have a close cultural connection with environmental stewardship.



- Yoshira Ornelas Van Horne, PhD, a postdoctoral research associate in the **Division of Environmental Health at the University of Southern California** and the assistant director of Curriculum Development & Cohort Engagement at **Agents of Change in Environmental Justice**, shared thoughtful recommendations on how best to engage people living in structurally marginalized communities facing disproportionate exposure to contamination.

A lively panel discussion was moderated by Marc Nascarella, PhD, chief toxicologist at the **Massachusetts Department of Public Health**. Presenters offered practical considerations when designing a biomonitoring study for engaging individuals from diverse racial, ethnic or tribal community populations. Ornelas Van Horne suggested that offering community members an opportunity to visit a state public health laboratory and talk with scientists would help demystify some study details and the experience of

being a biomonitoring study participant. She offered this hands-on approach as a practical way to engender trust within a community and provide an opportunity to discuss actual biomonitoring study procedures, including a realistic timeframe for the many needed study steps (e.g., results reporting). Erdei urged state public health laboratory scientists to consider how structural racism combined with potential loss of funding for laboratory services may contribute to marginalized communities' reluctance to engage with study investigators. For example, loss of funding for a specific environmental testing service once offered (e.g., community water testing) may contribute to systemic distrust of laboratory studies within a community. Adamkiewicz recommended that states ensure environmental justice is a deliberate consideration within any study design that seeks to address environmental exposures. He described how differences in access to certain consumer products (e.g., cleaners,

personal care products, toys), through a process known as “retailer redlining,” has resulted in certain communities disproportionately being exposed to certain contaminants in consumer products from discount retailers.

All experts agreed that partnerships are key to ensuring community participation. Ornelas Van Horne stressed “nothing about us, without us,” encouraging state public health laboratory scientists to consider meaningful engagement of the community in the design of any studies. Seemingly simple details, like providing outreach material in the spoken languages of the communities sought to engage, are often overlooked. Erdei described how study procedures should be “flexible” as to accommodate specimen collection from

people of all abilities, including those with mental, sensory or physical disabilities. She also emphasized that some communities may consider the matrix of choice to achieve study goals (e.g., blood, urine, hair, nails) as sacred and that matrix selection should be considered in the study design.

The **NBN Steering Committee** recognizes the inequitable burden of exposure among low-income, minority, tribal and indigenous communities. This session and the suggestions from its panelists provide examples for incorporating environmental justice into all aspects of biomonitoring programs, from study design to results communication, a worthy goal for the future of the NBN. ■

Environmental justice is defined as the fair treatment and meaningful involvement of all people regardless of race, color, national origin or income, with respect to the development, implementation and enforcement of environmental laws, regulations and policies.

(Source: https://www.epa.gov/sites/default/files/2021-01/documents/2020_ej_report-final-web-v4.pdf)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC.

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Wastewater Surveillance for More Than SARS-CoV-2

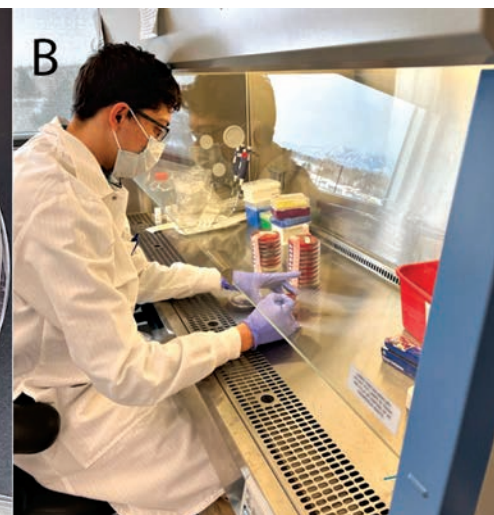
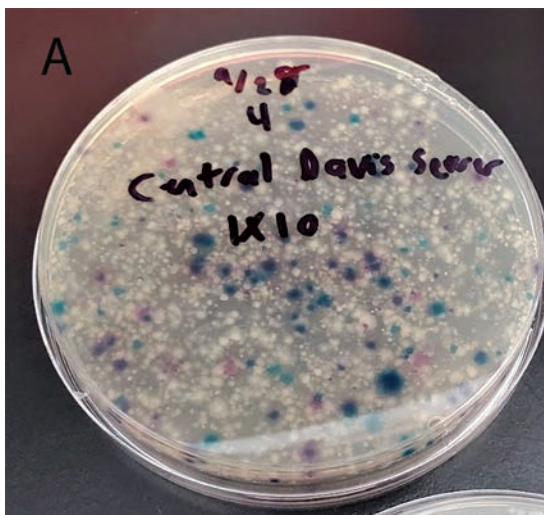
by **Alessandro Rossi**, PhD, infectious disease laboratory chief scientist, Utah Public Health Laboratory; **Stephanie Dela Cruz**, group manager, Virginia Division of Consolidated Laboratory Services; **Jessica Maitland**, PhD, lead scientist, Virginia Division of Consolidated Laboratories; **Sarah Wright**, MS, manager, Environmental Laboratories; and **Erin Morin**, MHS, associate specialist, Environmental Health

Over the course of the pandemic, wastewater surveillance has been known for providing bellwether community data on COVID-19 case trends and variant presence through the **National Wastewater Surveillance System** to inform local, state and national response. As public health laboratories acquire additional resources, they are now considering how this wastewater surveillance infrastructure can also be used to track other pathogens and targets of public health concern.

Utah Public Health Laboratory

The **Utah Public Health Laboratory (UPHL)** is currently the Mountain Regional Laboratory for the **US Centers for Disease Control and Prevention's (CDC's)** national **Antibiotic Resistance Laboratory Network (AR Lab Network)**. Given the availability of SARS-CoV-2 surveillance samples collected from Utah wastewater treatment plants (WTPs), UPHL started to explore the feasibility of monitoring AR threats in wastewater in fall 2021.

UPHL has worked to develop methods to isolate **Carbapenem-resistant Enterobacterales (CREs)**, a difficult-to-treat bacteria group resistant to last-resort carbapenem antibiotics, and the yeast *Candida auris*, a multi-drug-resistant nosocomial pathogen not yet detected in Utah. UPHL has been successful in isolating about 300 CREs from 24 of the 32 WTPs sampled. Whole genome sequencing analysis showed that these isolates express carbapenemase (enzymes inactivating carbapenems) genes that have also been identified in CRE-colonized individuals resident in Utah. Interestingly, in some instances wastewater isolates were highly genetically related to clinical CRE isolates previously tested at UPHL and shared a similar geographical origin. These preliminary data indicate that wastewater monitoring may provide awareness of a community AR threat and



A) Wastewater samples plated on a chromogenic medium (CHROMagar™ mSuperCARBA™) plates containing the carbapenem antibiotic meropenem. Pink, blue and purple colonies are selected for further characterization as presumptive CREs. B) APHL AR Fellow Jorge Chavez, who is leading wastewater AR testing efforts, in action in the lab. Photo: UPHL

inform infection prevention interventions. While UPHL has been able to isolate *Candida* species from wastewater, establishing a protocol to specifically detect *C. auris* has been challenging. Work is currently in progress to implement strategies that may suppress the growth of environmental yeasts found in wastewater that are able to break through the selection conditions originally designed for clinical samples.

Virginia Division of Consolidated Laboratory Services

In summer 2021, the **Virginia Division of Consolidated Laboratory Services (DCLS)**, in collaboration with the Virginia Department of Health (VDH) and Hampton Roads Sanitation District (HRSB), began establishing a wastewater surveillance system infrastructure throughout the Commonwealth of Virginia. DCLS leveraged existing courier contracts and university and utility partnerships, as well as comparable laboratory testing technology and expertise to rapidly and effectively implement statewide surveillance testing. DCLS provided

weekly SARS-CoV-2 quantification from composite and grab wastewater influent for six months using the BioRad QXOne™ fully-automated droplet digital PCR system. Virginia's wastewater surveillance data trend aligned with clinical infection case counts, providing state and local health departments geographically specific data to complement clinical testing surveillance. In the future, DCLS will expand its SARS-CoV-2 wastewater surveillance program to include other targets of public health concern. In collaboration with VDH, several enteric pathogens are under consideration for surveillance, including *Salmonella* and *Norovirus*. Wastewater surveillance of these two pathogens has the potential to complement existing DCLS clinical surveillance for seasonal pattern detection and strain characterization trends. The wastewater testing infrastructure already developed for SARS-CoV-2 positions Virginia to be prepared for the next pandemic to be able to quickly address the wastewater surveillance needs for new emerging pathogens. ■

Improving Information Sharing for *Cyclospora cayetanensis*

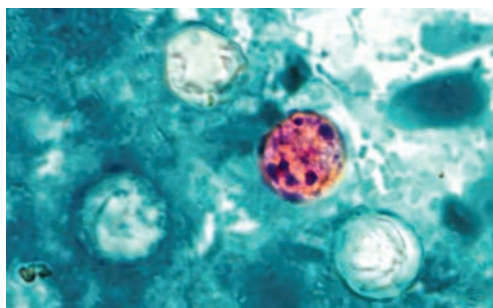
by Rhodel Bradshaw, senior specialist, Food Safety

Information sharing is an integral part of human advancement—everything from learning to tie our shoes to building the tallest skyscraper requires the sharing of information. The same can be said for surveillance of public health threats. Information shared amongst health agencies can be used to understand disease occurrences and has the potential to impact populations. For example, agencies can learn best practices on monitoring threats, provide methods to control the spread of a threat, communicate risks to those affected and so much more. Specific to sharing information created by the laboratory, data transfer is important for public health domestically and globally. The **US Centers for Disease Control and Prevention** (CDC) is working with a small number of states to improve data sharing related to *Cyclospora cayetanensis* national surveillance.

Tracking a Tricky Parasite

Cyclospora cayetanensis is a parasitic pathogen that requires a human host to continue its life cycle. In the environment, the organism remains dormant until the right conditions—such as warm temperatures and time—allow for maturation into its infective sporulated phase. Unaware, victims become infected by ingesting contaminated water or food products such as raspberries, basil, snow peas, lettuce, cilantro or other fresh produce. The host then develops cyclosporiasis, an illness characterized by gastrointestinal distress and diarrheal episodes. Consequently, parasitic material is shed in the feces, and the pathogen enters the environment to restart its life cycle. As of now, the only known route of transmission for the organism is via ingestion of contaminated food or drink, and there are no known animal reservoirs.

Annually, *C. cayetanensis* is estimated to cause approximately 11,000 cases of foodborne illness, although many fewer cases are reported, with an estimated \$9.3 million in total economic burden.



This photomicrograph of a fresh stool sample revealed the presence of four *Cyclospora cayetanensis* oocysts in the field of view. Photo: CDC/DPDx/Melanie Moser

Although reported year-round, cases increase during the spring and summer months (May through September), which is known as the cyclosporiasis season. In 2021 there were 1,020 laboratory confirmed cases of cyclosporiasis reported from 36 different states and one city municipality. Of those, CDC investigated 170 laboratory confirmed cases linked to two multi-state outbreaks involving *C. cayetanensis*. Both outbreaks were presumed to be caused by consumption of contaminated leafy greens, however investigators were unable to identify the source.

Preparing for Cyclosporiasis Season

Outbreaks, such as the two mentioned previously, are detected when specimens and/or data are received in public health laboratories and shared with federal partners. State or local public health laboratories send confirmed *Cyclospora* specimens for genotyping at CDC or send in-house generated genotyping data to CDC with a submission form. Bioinformaticians assign each sample to a specific temporal-genetic cluster using measures of genetic distance and date of testing, and results are passed to CDC epidemiologists, who can compare genotyping clusters to epidemiologically identified clusters to facilitate outbreak investigations. Throughout the cyclosporiasis season, CDC sends weekly reports to laboratories that outline the status of submitted specimens and an

epidemiological report that includes additional detail such as the temporal-genetic clusters to which specimens were assigned. CDC epidemiologists also remain in close contact with state epidemiologists throughout the cyclosporiasis season as potential outbreaks are investigated.

Surveillance efforts would not be complete without bi-directional sharing laboratory data and other investigation-related information between and among public health agencies, and the same can be said with *Cyclospora cayetanensis* national surveillance. Information received for any pathogenic agent creates a comprehensive safety program and helps public health officials monitor, detect, and prevent the spread of disease and illnesses.

If interested in submitting specimens or sequence data in 2022, contact CDC subject matter experts at cyclosporaAMD@cdc.gov. For other questions regarding the network, contact rhodel.bradshaw@aphl.org. ■

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Collaborations Yield Success in North Carolina

By **Kate Koehler**, chemical terrorism and threat coordinator and Hemachemistry manager, North Carolina State Laboratory of Public Health

The **North Carolina State Laboratory of Public Health** (NCSLPH) Chemical Terrorism and Threat (CTAT) unit deemed 2021 the year of the collaboration.

Agriculture and Academia

In January and October 2021, the CTAT unit collaborated with the **North Carolina Department of Agriculture & Consumer Services** and the **North Carolina State University College of Veterinary Medicine** (CVM) to investigate two unrelated livestock illness clusters. Blood and serum specimens were collected from eight horses in central NC to investigate the January cluster. No compounds of public health concern were identified by non-targeted screening of serum specimens by gas chromatography-mass spectrometry (GC-MS). Neither heavy metals nor compounds of concern were identified in blood specimens analyzed using the **Laboratory Response Network for Chemical Threats** (LRN-C) blood metals or volatile organic compounds (VOC) panels. Further investigation by CVM identified **Equine Coronavirus** (ECoV) in three of the affected horses.

The second livestock illness cluster resulted in four donkey fatalities that occurred within 48 hours of ingestion of suspect poultry feed. Botulinum toxin was suspected, but, to date, the National Veterinary Services Laboratories tests are still pending. Initial specimens and samples submitted to the CTAT unit

included gastric contents, liver, kidney, water from multiple sources, hay and poultry feed. All specimens and samples were subjected to a GC-MS non-targeted analysis screen as well as a liquid chromatography quadrupole time-of-flight mass spectrometry (LC-Q-ToF-MS) illicit drug panel screen. Neither screen identified any compounds of concern. In addition, all specimens and samples were subjected to a qualitative panel for heavy metals, which yielded elevated uranium levels for all gastric content specimens and poultry feed samples. Furthermore, the CTAT unit collaborated with the NCSLPH's Environmental Sciences Unit to determine if dissolved trace elements could be detected using the EPA 200.8 method to analyze liver and kidney specimens and poultry feed samples. Uranium results of this testing are shown in Table 1.

Additional submissions of feeds from the manufacturer's feed mill and other local feed mills yielded results that aligned with the high levels of uranium found in unconsumed poultry feed at the farm. The results obtained from local feed mills are depicted in Table 2. Normal uranium levels in poultry feed is under investigation.

Toxicology, Local Health and Law Enforcement

In July 2021, the CTAT unit collaborated with the Sampson County Health Department and Sheriff's Office as well as the Toxicology group in North Carolina's Office of the Chief Medical Examiner (OCME) to investigate an exposure to a suspicious substance found in a suspicious package that resulted in a hospital admission. An initial GC-MS non-targeted screen identified MDMA-4en-PINACA (96% match). The CTAT unit worked with the OCME Chief Toxicologist to procure appropriate standards to confirm the screening results. The procured MDMA-4en-PINACA standards were used to create a LC-Q-ToF database library, and a 99% match was obtained when the original sample was analyzed using the established database. To further confirm results, the OCME Toxicology Unit used a validated method that incorporated the use of Orbitrap instrumentation. Qualitative analysis confirmed the presence of MDMA-4en-PINACA. Prosecution was initiated by the Sampson County Sheriff's office as a result of the collaborative findings.

The CTAT unit continues to foster relationships with local, state and federal partners while striving to enhance capabilities and capacity through collaboration with a wide variety of partners to ensure continued success of the program. ■

Table 1: Trace element levels in specimens and poultry feed (mg/L, ppm)

Sample	Be	Al	V	Cr	Mn	Fe	Co	Ni	Cu	Zn	As	Se	Ag	Cd	Ba	Mo	Sb	Tl	Pb	U
Poultry Feed	0.04	75.77	1.34	3.11	59.7	172.9	0.16	0.78	5.17	24.7	0.50	0.41	0.02	0.14	3.93	1.11	0.009	0.009	0.071	1.113
Liver	0.001	3.40	0.14	0.42	1.88	168.36	0.09	0.018	3.14	34.1	0.005	0.16	0.002	3.76	0.16	1.48	0.002	0.001	0.077	0.006
Kidney	0.00	1.03	0.08	0.29	0.93	93.81	0.02	0.016	3.057	31.14	0.003	0.707	0.00	26.15	0.165	0.287	-0.001	0.001	0.01	0.004

Table 2: Trace element levels in local feed mills (mg/L, ppm)

Sample Id	Be 9	Al 27	V 51	Cr 52	Mn 55	Fe 57	Co 59	Ni 60	Cu 63	Zn 66	As 75	Se 82	Ag 107	Cd 111	Ba 137	Mo 98	Sb 121	Tl 205	Pb 208	U 238
CT102621-001A	0.04	112.6	1.27	3.60	84.58	379.84	0.20	1.43	11.52	36.87	0.77	0.99	0.05	0.31	8.57	1.90	0.01	0.010	0.109	1.031
CT102621-002A	0.001	4.11	0.47	1.78	27.17	75.22	0.05	0.81	5.67	36.13	0.05	0.28	0.001	0.04	5.82	0.71	0.00	0.001	0.017	0.012
CT102621-003A	0.056	142.2	1.60	4.26	111.8	497.61	0.23	1.38	24.35	37.61	1.78	0.79	0.17	0.62	5.96	4.95	0.01	0.010	0.259	1.398
CT102621-004A	0.008	23.25	0.69	2.29	21.62	81.22	0.04	0.17	3.78	20.93	0.08	0.07	0.004	0.03	4.55	0.21	0.001	0.002	0.033	0.222
CT102621-005A	0.095	263.7	2.29	4.87	77.38	643.27	0.54	2.10	24.28	152.64	0.57	0.62	0.003	0.15	11.10	1.72	0.03	0.019	0.312	1.601



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Infection Prevention and Control of Infectious Diseases in Vietnam

By **Samantha Musumeci**, MPH, senior specialist, Global Health; **Ninh Tran**, MScM, senior specialist, Global Health; **Chi Nguyen**, MSc, laboratory technician, Advanced Diagnostic Unit, Global Health; **Nhung Le**, PhD, laboratory specialist, Advanced Diagnostic Unit, Global Health; and **Sherrie Staley**, MPH, deputy director, Global Health

The infection prevention and control (IPC) of infectious diseases is a key component of preventing the spread of healthcare-acquired infections (HAI) in healthcare facilities. As with many countries, the COVID-19 pandemic has highlighted the critical need for the strengthening of IPC efforts in Vietnam. These efforts are important not only in COVID-19 response efforts, but also in response to other infectious diseases of significance such as tuberculosis (TB).

Over the past 18 months, APHL has contributed to strengthening IPC efforts in Vietnam, for both COVID-19 and TB. In collaboration with the Ministry of Health (MOH) in Vietnam, APHL has supported the development of guidelines for the prevention of SARS-CoV-2 infection. The updated guidelines are aligned with Vietnam's epidemic prevention strategy, which have contributed to the prevention of SARS-CoV-2 infection in healthcare facilities, the infection prevention and management of healthcare workers at high risk of infection with SARS-CoV-2 and the selection and use of personal protective equipment in the prevention of COVID-19.

Additionally, APHL has organized dozens of online trainings on the prevention of SARS-CoV-2 infection among healthcare workers and preventing the spread of COVID-19 in healthcare facilities. Over the course of these trainings, more than 10,000 healthcare workers have been trained, increasing their skills and knowledge in a short timeframe and in the context of social distancing according to the regulations of Vietnam. In addition to training topics on SARS-CoV-2 infection prevention for healthcare workers in general, APHL has also organized more than 10 training sessions for specific target groups, such as care and treatment of COVID-19 patients within multiple healthcare settings.

APHL ESTABLISHES ADVANCED DIAGNOSTIC UNIT IN VIETNAM, AIDS IN SEROPREVALENCE STUDY

Through a Memorandum of Understanding with the National Institute of Hygiene and Epidemiology, APHL, in collaboration with CDC Vietnam, has established an Advanced Diagnostic Unit (ADU) equipped with advanced molecular detection equipment including a 7500 Fast Real-Time PCR system, Varioskan™ LUX Multimode Microplate Reader, NanoDrop™ One/OneC Microvolume UV-Vis Spectrophotometer, MiSeq® System and MAGPIX® System. The ADU has played a key role in Vietnam's COVID-19 response as part of a seroprevalence study. The study, which aims to research SARS-CoV-2 antibody levels in serum of the population in Vietnam, began in June 2021 with specimens collected from two provinces. There are two main targets for the study: Vietnamese



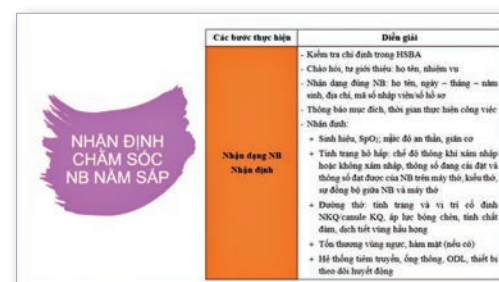
MAGPIX® System utilized for specimen testing in SARS-CoV-2 Seroprevalence Study.

healthcare workers before and after receiving two doses of ChAdOx1 nCoV-19 vaccine; and citizens who have different vaccination status, living in a province which had a high COVID-19 infection rate. These specimens were collected at multiple sites and sent to the ADU for testing utilizing the Tetracore FlexImmArray SARS-CoV-2 15 plex test. To date, approximately 7,500 samples have been tested and data analysis is underway.

Recently, APHL has contributed to updating the TB IPC guidelines for healthcare facilities and communities in coordination with the Vietnam Administration for Medical Services and has completed the procurement of masks and fit testing kits for upcoming IPC trainings.

Despite its short duration, APHL's IPC program has had close partnerships with many agencies and organizations of Vietnam such as VAMS, Vietnam Chief Nursing Club, Vietnam Infection Control Society and Ho Chi Minh City Infection Control Society. These close relationships have greatly contributed to the implementation of highly effective activities. ■

APHL has organized dozens of online trainings on the prevention of SARS-CoV-2 infection among healthcare workers and preventing the spread of COVID-19 in healthcare facilities.



Slide on Patient Assessment from training on Guidelines for the Care of COVID-19 Patients in COVID Hospitals

NGS Expansion and Capacity Building in Kenya for COVID-19 and Beyond

By **Eugene Yeboah**, MSc, senior specialist, Global Health; **Noah C. Hull**, PhD, MPH, manager, Global Health; and **Lucy Maryogo-Robinson**, MPH, director, Global Health

On March 12, 2020, the Kenya Ministry of Health confirmed its first case of COVID-19 in Nairobi. As of March 27, 2022, the ministry had reported 323,374 total confirmed COVID-19 cases and 5,647 cumulative fatalities. In addition, **GISAID**—a global science initiative that provides open access to genomic data of influenza viruses and the coronavirus—has published 8,239 coronavirus specimens as of March 28, 2022, accounting for 8.4% of all submitted submissions specimens in Africa.

“No country can securely eliminate COVID-19, or its devastating economic domino effects, if the disease becomes rampant across a continent of 1.3 billion people,” said John Nkengasong, director of **Africa CDC**. “For Africa to get ahead of the pandemic, we need to scale up testing fast.” Increasing quality diagnostic testing as well as sequencing for monitoring new variants are key strategies Kenya is implementing in the fight against COVID-19.

To support laboratory capacity building in Kenya, APHL worked with the **US Centers for Disease Control and Prevention** (CDC) Global Disease Detection (GDD) program within the **Division of Global Health Protection in Kenya** (DGHP-Kenya) to provide next-generation sequencing (NGS) support and training to **CDC-Kenya Medical Research Institute** (KEMRI) laboratories and the National Public Health Laboratory (NPHL) under the Department of Laboratory Services of the Kenyan Ministry of Health and Population (MoHP). Trainings were conducted over the course of three weeks at the KEMRI CDC Diagnostics and Laboratory System Programs (DLSPs) in Nairobi and Kisumu, and at MoHP-NPHL in Nairobi.



NPHL NGS trainees take a break after loading the Oxford Nanopore Sequencer. Photo: NPHL

CDC DLSP KEMRI Nairobi

Ten laboratory staff were trained on NGS using Illumina COVIDSeq protocol on the Illumina MiSeq™. In addition, nine staff members were trained in genomic characterization and epidemiology using the Terra.bio platform and data repository submission to GISAID and the **National Center for Biotechnology Information** (NCBI). Training and guidance were provided on primer design and protocol optimization using ARTIC protocols to sequence Chikungunya virus, Dengue (serotypes 1-4), Rift Valley Fever virus and Yellow Fever virus.

CDC DLSP KEMRI Kisumu

Eight laboratory staff were trained on NGS using Illumina COVIDSeq protocol on the Illumina iSeq™ 100. All 23 positive samples passed. The iSeq™ 100 was a new instrument, and it was the first NGS run at the CDC DLSP KEMRI Kisumu laboratory. Twelve staff members were trained in genomic characterization, genomic epidemiology, using the Terra.bio platform, and data upload to GISAID and NCBI. As a result, the laboratory staff was able to take nucleic acid extracts from SARS-CoV-2 positive specimens and obtain consensus genomes to upload to GISAID in a matter of four business days. This work was supported by a generous donation made by Illumina to provide iSeq™ 100 sequencing flow cells and cartridges.

MoHP-NPHL

Four laboratory staff were trained on NGS using Oxford Nanopore (ONT) SARS-CoV-2 Midnight protocol on the ONT Mk1b instrument. Four staff members were trained in genomic characterization, genomic epidemiology, using the Terra.bio platform, and data upload to GISAID and NCBI. Support for this training was possible with a generous donation from Oxford Nanopore of sequencing reagents, flow cells and a Mk1b sequencer.

Sequences analyzed during these trainings and submitted to GISAID were some of the first to be submitted by the CDC-DLSP-KEMRI laboratories and the MoPH-NPHL laboratories. This capability of NGS and successful training conducted in these laboratories will increase the genomic surveillance for SARS-CoV-2 and have built genomic capacity for pandemic preparedness. The average turnaround time in the country (extraction to upload) was averaging 4-6 weeks. However, during this training, demonstrated turnaround time was down to less than a week.

Kenya is set to become one of the leading fronts in genomic surveillance with the expertise and capabilities acquired through NGS training and expansion. These training courses have also paved the way and provided the technical know-how to optimize existing whole-genome sequencing technologies and protocols for current and future pathogens and outbreaks of unknown origin. ■

Leveraging Genomics and Automation to Address the Rise in Multi-Drug Resistant Bacteria Outbreaks

By **Michael Balamotis**, PhD, staff scientist, Clear Labs; **Andrew Lin**, PhD, staff scientist, Clear Labs; and **Kristina Hsieh**, DrPH, Scientific Affairs lead, Clear Labs



Each year in the United States, more than 2.8 million antibiotic-resistant infections occur that can lead to death and long-term infection, taking psychological, physical and financial toll on patients and families.¹ Under selective pressure due to overuse of antibiotics, new “superbugs” such as **Methicillin Resistant *Staphylococcus aureus***, **Carbapenem-resistant *Enterobacterales***, and multi drug-resistant ***Neisseria gonorrhoeae*** pose formidable challenges to our healthcare system. These bacteria evolve rapidly to thwart our current antibiotic lines of defense, making antimicrobial resistance (AR) a recognized public health threat by the **World Health Organization**.² The steady increase of AR must be met by robust, rapid methods for detection and characterization.

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Giving the Data Its Due

The data obtained from whole genome sequencing (WGS) provides the scientific leverage needed to successfully combat AR. WGS reveals the unique genomic fingerprint of a bacterium, including virulence genes associated with a resistance phenotype. WGS sequencing information is valuable because it captures long stretches of DNA, such as complex mosaic gene mutation patterns that confer resistance and novel pathogenicity islands that may be missed by PCR methods alone. Genomic sequence data has been widely adopted as a common language across a network of government, academic and private industry laboratories and has shown to be an invaluable tool for characterizing pathogens to develop a more in-depth understanding of the organism. For example, the federal government programs such as GenomeTrakr and

PulseNet utilize WGS to track pathogens that cause foodborne illness by leveraging their decentralized network of labs.

Currently, most drug-resistant bacteria are identified through a combination of lab culture work, PCR and antimicrobial susceptibility testing (AST). Pairing genomic data with these AST data creates linkage maps that can function as a powerful toolset for surveillance, intervention and treatment selection. The NCBI has a public database that contains genomic and phenotypic AST information. As more laboratories gain the capacity to upload sequence data along with AST data, the robustness and value of these databases will expand so that the entire scientific community can use the data in ways like what we have seen with the COVID-19 pandemic for detection, surveillance, and vaccine development.

Preparing WGS for Prime Time

While WGS is a powerful tool, manual WGS workflows are time-consuming, labor-intensive, and require specialized expertise for analysis³, which severely limit the practicality of WGS for routine use in clinical and public health laboratories. However, an automated system on which laboratory staff can be easily trained and one that requires minimal human touchpoints will accelerate the adoption of WGS. An ideal system would automate the entire WGS workflow, including sample lysis, nucleic acid extraction, quantitation, library preparation, sequencing, and bioinformatics analysis, thus leveraging the benefits of WGS with less labor and time at the bench.

In addition to the benchtop process, automation and standardization of the bioinformatics analysis is imperative to ensure that lab technicians who do not have an extensive background in

genomic data analysis can easily generate accurate, interpretable results.⁴ For example, several bioinformatics tools are needed to ensure sequence trimming, *de novo* sequence assembly, and alignment of raw sequence data prior to finding matches in AR databases such as the **Comprehensive Antibiotic Resistance Database** (CARD) or ResFinder. Developing an automated bioinformatics pipeline that can simplify this process will further lower the adoption barrier for WGS in all laboratories. This will also widen the bandwidth of bioinformaticians to do more useful downstream investigations with the genomic data.

Once a critical mass of laboratories are able to adopt WGS of AR bacterial isolates and share their data in near real-time, it will only be a matter of time before publicly curated AR/AST databases accumulate sufficient data to utilize machine learning tools to improve

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predictive modeling to connect genotypes to putative phenotypes in support of treatment, predicting resistance profiles, helping to engineer new antibiotics and decreasing the time needed to identify the source of an outbreak.⁵ By democratizing genomics through lowering costs, integration of automation with bioinformatics and expanding

public databases, we can establish a revolutionary infrastructure to deliver genomic epidemiological insights to meet the needs of scientists in the fight against pathogens. Through a concerted effort to deliver a simplified yet powerful automation platform, a future without multi-drug resistant bacteria is within reach. ■



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What's Next for Respiratory Diagnostic Testing

by **Emily Berlin**, vice president, Marketing and Product Management, Cardinal Health

If there can be a positive takeaway from the COVID-19 pandemic, it would be the rapid and innovative diagnostic progress that has been made so far. The major strides the diagnostics community has made in developing new respiratory pathogen tests, methodologies and approaches in such a short time will have a lasting impact on healthcare moving forward.

In addition to test development, the pandemic has also raised the level of public awareness of laboratory testing. With schools, businesses and organizations of all kinds now employing COVID-19 testing, the public has become accustomed to more frequent testing and the ability to access testing in more settings.

The Rise of Molecular Point-of-care Testing

While molecular point-of-care (POC) test menus are still maturing—currently limited to respiratory infections and strep—the benefits of near-patient technologies and testing assays are clear. Decentralized POC testing can deliver rapid, accurate results to patients without the need for sample transport. There is potential to continue expanding new testing locations, as was seen with drive-through COVID-19 testing, to increase convenience and minimize patient exposure.

The Growth of At-home Testing

In the early stages of the pandemic, the only at-home testing option available to the public was collection kits, where samples are collected at home and sent off to a laboratory for processing. Collection kits offer the benefit of PCR results without having to leave the house, but the wait for a result is much longer than for a true at-home test.



Today, there are several products available on the market for at-home COVID-19 detection. Rapid antigen tests include the Abbott BinaxNOW™ COVID-19 antigen self-test (which received FDA Emergency Use Authorization (EUA) in December 2020) and the Quidel QuickVue At-Home OTC COVID-19 test (which received FDA EUA in March 2021.) In addition to antigen tests, Cue Health released the nation's first molecular diagnostic test (which received FDA EUA, November 2021) for at-home use without a prescription and is being distributed by Cardinal Health.

Doing More with Less

Multiplex testing for more than one type of virus has become more common, particularly with the concurrence of COVID-19 and influenza. Multiplex testing enables physicians to make more comprehensive diagnoses for patients presenting with multiple symptoms associated with multiple viral respiratory infections, like SARS-CoV-2, influenza A and B and RSV. For laboratories, multiplex testing helps reduce waste and costs through the use of fewer consumables.

Genomic Sequencing to Detect Variants

Because viruses are constantly mutating, genomic sequencing is critical to learning more. In a worst-case scenario, there is potential for a SARS-CoV-2 variant to emerge that is both immunity- and vaccine-resistant. This means that we may see a greater number of laboratories start performing genetic sequencing.

A new development in genome sequencing is the recently announced collaboration between Cue Health and Google Cloud that enables real-time respiratory viral variant sequencing and tracking through artificial intelligence (AI). Technology that combines genome sequencing with AI-enabled predictive capabilities has potential to shape public health.

What Lies Beyond the Pandemic?

What does all this mean for respiratory diagnostics moving forward? It is likely that the trends we are seeing will continue in some manner. Ideally, the positive developments that have stemmed from the pandemic will continue, and the diagnostics landscape will see further collaboration and innovation.

What is clear is how the pandemic has shaped the expectations of both patients and clinicians moving forward. The tests and technology that enable faster results, improve the patient experience, save laboratorians time and empower clinicians will likely make the biggest impact on public health. ■

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Cardinal Health is an APHL Gold Level Sustaining Member.

Public Health Laboratories Respond to Familiar Avian Influenza Threat

by **Melissa Warren**, senior specialist, Influenza

Highly pathogenic avian influenza (HPAI) A(H5) emerged in the United States in early 2022 for the first time since 2016.¹ The virus was detected first in wild birds and then in commercial poultry in multiple states located in the Atlantic and Mississippi migratory bird flyways.

Getting Reacquainted with HPAI

During the US outbreak of avian influenza in 2015-2016, over seven million turkeys and 43 million chickens died from disease or were depopulated to control the spread of the virus representing a significant economic loss for the poultry industry. Of the 2015-2016 outbreak, the **US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)** states “this outbreak was the largest HPAI outbreak ever recorded in the US and arguably the most significant animal health event in US history.”²

Avian and swine influenza viruses are important to public health due to the potential introduction of a novel virus to susceptible human populations. The H5 virus recently detected in birds appears to lack ability to cross over to mammalian species and antivirals would likely be effective treatment. Based on these factors the perceived risk is relatively low, but it is not zero and merits further monitoring.

The Public Health Laboratory Response

The response to HPAI necessitates coordination across multiple agencies at both the state and federal levels. Partners may vary state to state, but are likely to include the departments of agriculture, natural resources, wildlife services, farm services, environmental management, health and homeland security. Generally, agricultural partners will screen wild birds and sick commercial poultry for HPAI. When a detection is made, the human health partners will be informed and

“Based on available epidemiologic and virologic information about these viruses, CDC believes that the risk to the general public’s health from current H5N1 bird flu viruses is low, however some people may have job-related or recreational exposures to birds that put them at higher risk of infection.”³

prepared for surveillance and testing at the public health laboratory of exposed or high-risk individuals, most often agricultural workers and individuals engaged in depopulation. An important update was made in 2022 to the testing guidance by the **US Centers for Disease Control and Prevention (CDC)**—public health laboratories may test suspected H5 specimens in parallel on the H5 diagnostics assay and the influenza A/B assays, as opposed to in succession.

Lixia Liu, PhD, MP(ASCP), D(ABMM), laboratory director and Brian Pope, Virology supervisor from the Indiana Department of Health Laboratory Division recently shared their experience with the current H5 outbreak. Six flocks of sick poultry from southern Indiana were identified by the **APHIS National Veterinary Services Laboratory** in February. The commercial turkeys were confirmed to be infected with H5N1 by the Animal Disease Diagnostic Laboratory at Purdue University. The State Veterinarian and Board of Animal Health coordinated with state partners, including arranging with the Department of Health’s epidemiology and laboratory divisions for human health surveillance.

“The public health veterinarian did great work and included background [information] from 2016,” Liu said. “We were prepared as partners. Everyone knows what it takes to respond.”

Pope described the communication as “early and often” between state partners and that the laboratory was kept in the loop ready to receive specimens for testing. As of April 1, the laboratory

received four specimens related to the H5 response from symptomatic patients, however all tested positive for influenza A(H3), not H5. Pope concluded with the reminder to reach out to CDC or other laboratories to learn from those who have been through a similar experience.

Tim Southern, PhD, director of the South Dakota State Public Health Laboratory echoed Pope’s sentiments.

“This is a quintessential One Health program so nothing will replace good communication between the professionals that work in the poultry industry and the human healthcare and public health sectors.” ■

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How to LOINC® and SNOMED® in Pandemic Times

by Rachel Shepherd, specialist, Informatics

The ability to identify threats, conduct surveillance and report instances of disease are the most quintessential functions of public health. However, in order to do this effectively, all public health entities—laboratories, medical providers, federal agencies—must communicate in the same language. Without the universal usage of agreed-upon terminology, all tests conducted, and their associated specimen data, would be disparate and meaningless. There could be no comprehensive review of data, and every interaction between a laboratory and external entity would require lots of human-driven, inefficient guesswork. In short, information would be chaotic and useless in the aggregate.

When a new virus emerges, it immediately needs to be named and codified before any meaningful communication about it can happen. Typically, the name is decided by the [World Health Organization](#) (WHO). Next, it needs defined data elements for everything surrounding the virus—possible tests, possible results, clinically relevant information—so that medical providers, health informaticians and laboratorians can uniformly enter the agreed upon terminology into their respective electronic health records (EHR) and laboratory information management systems (LIMS). That is where standards, such as LOINC® and SNOMED-CT®, along with their fearless creators and defenders—terminologists—come in. Terminologists submit their codes to the Regenstrief Institute where they are published centrally for widespread use.

Providing a Dictionary

[Logical Observation Identifiers Names and Codes](#) (LOINC®) and [Systematized Nomenclature of Medicine-Clinical Terms](#) (SNOMED CT®) essentially serve as dictionaries and are consulted to convey critical information. LOINC® provides the terminology for tests and their results—what type of test is being requested (e.g., blood or sputum), what is being measured (e.g., glucose in urine),

For her contributions in developing this critical shared resource, which has saved laboratories critical amounts of time and ensured interoperability in reporting across health systems, APHL's Lead Terminologist Riki Merrick was awarded the LOINC® Award for Distinguished Contributions in 2021.

and what is observed (e.g., amount of glucose detected). On the other hand, SNOMED-CT® provides the fundamental vocabulary for EHR, including patient symptoms and diagnoses.

Currently, there are over 150 unique potential laboratory tests for COVID-19 involving different specimen types (e.g., nasal swab, saliva, serum, etc.) as well as the results and how they are expressed (e.g., positive/negative or units/volume). For public health reporting, there are over 100 demographic fields for the patient to address (e.g., age, exposure, travel history, vaccination status, etc.). All these specific scenarios needed to be communicated via unique codes, which needed to be developed quickly.

Language Lessons During a Pandemic

In February 2020, after the WHO announced SARS-CoV-2 as the official designation for the emerging virus that caused COVID-19, terminologists spent their time sifting through package inserts and standard operating procedures (SOPs) for laboratory-developed tests to codify their specific attributes.

There are more than 200 LOINC® codes related to SARS-CoV-2 testing. The benefit of so many choices is that public health can communicate very specifically about specimens and testing. On the other hand, so many options made it difficult and tedious for laboratories to select the code that most accurately corresponded to the exact situation for each test conducted. Faced with thousands of samples and backlogs of data, laboratories did not have extra time to scour through all the codes and try and match them, one by one, to the package inserts of each individual test. Each laboratory independently dedicating time and resources to that

type of research for every single specimen would have led to thousands of hours lost when there were no minutes to spare.

To combat that inefficient process and to ensure that laboratories could report the data elements required by the [US Department of Health & Human Services](#), APHL developed the [LOINC® In Vitro Diagnostic \(LIVD\) Test Code Mapping for SARS-CoV-2 Tests](#). This catalog compiles all the LOINC® codes for test orders, test results, SNOMED-CT® test descriptions, specimen sources and device identifiers in one place. This file is updated regularly and published centrally, so that laboratories always have accurate information without having to search across the landscape for new or deactivated tests.

APHL Lead Terminologist Riki Merrick explains that the ultimate goal is to create a repository of information contained in the LIVD files. If fully converted to a repository accessible to systems, mapping would be automated instead of distributed as a spreadsheet, eliminating the need for labs to manually import codes into their individual systems. Test manufacturers could submit their mappings directly to the repository for review and publication and all updates would get pushed out centrally.

This type of work exemplifies what APHL hopes to accomplish—the public health community collaborating to develop and leverage shared resources, tools, and services to improve workflows for all and enhance interoperability across the landscape. ■

Building an Informatics Community

by **Rachel Shepherd**, specialist, Informatics, APHL

The public health laboratory informatics community is currently grappling with several significant challenges as well as exciting opportunities. The **Data Modernization Initiative** (DMI) is providing critical funding to laboratories to address chronic needs such as electronic test order and result (ETOR) implementation, workforce shortages and widespread system and infrastructure upgrades. Now more than ever, there is an urgent need to strongly establish, connect and engage the public health laboratory informatics community.

To that end, APHL's Informatics Committee launched the Interoperability Forum in January. The intent of this quarterly series is to feature solutions to common informatics challenges through presentations and demonstrations from laboratories, as well as provide a venue for the community to raise questions, share successes and connect. The theme for 2022 is "The Paperless Laboratory," and has been designed to specifically highlight the latest innovations and techniques that laboratories can leverage to reduce reliance on paper and manual processes.

Collaborating for Interoperability

Nearly 200 people attended the first forum, which served as an after-action review of the informatics response

to COVID-19. The session featured presentations from Frank Delin, director, Office of Information and Technology at the State Hygienic Laboratory at the University of Iowa, and from Susanne Crowe, MHA, director, Florida Department of Health Bureau of Public Health Laboratories-Jacksonville.

Attendees had the opportunity to examine Iowa and Florida's strategies and techniques for expanding capacity for electronic test orders and results during the pandemic, onboarding non-traditional partners and managing an unprecedented volume of data. Several attendees shared their laboratories' unique and often shared experiences regarding the COVID-19 response during the open discussion following the presentation.

Planning for the next Interoperability Forum is underway and details were shared at APHL 2022, and will be online at www.aphl.org once the date is confirmed.

Opportunities for Engagement

In addition to the launch of the Interoperability Forum, APHL is exploring other mechanisms to engage the public health laboratory informatics community to strategically coordinate efforts, and understand pain points. With so much funding and urgency, the opportunity to

level set as a cohesive group—learn what laboratories are doing, hoping to do and trying to figure out—will offer insight and illuminate possibilities for the group at large.

APHL is preparing to establish regular open "office hours"-type calls for this group. This free-flowing platform will serve as an informal informatics check-in and touch-base for laboratories to pose questions, seek advice, raise concerns and offer technical solutions. It will help APHL and the **US Centers for Disease Control and Prevention** (CDC) directly understand the perspectives of the laboratories, and identify technical assistance needs and potential approaches to widespread challenges.

By convening this community, APHL will identify and share important work and stories and can better advocate for needs and help inform national policy. Another goal is to facilitate an environment that empowers laboratories to form their own ad-hoc relationships and rely on community members for support, guidance, mentorship and assurance. ■

DIGITAL EXTRA: If you have stories to share or topics to suggest for the Interoperability Forum or you would like to register for the community user group, please e-mail rachel.shepherd@aphl.org.



The Future of Real-time PCR in the LRN-B

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



Biodefense Laboratory Associate Director Michael Perry performs testing at New York State's Wadsworth Center. Photo: Wadsworth Center

Change is inevitable. In scientific and technological advancement, this inevitability leads to the evolution of previous iterations of technology. However, change from the status quo is not without its consequences, particularly when it comes to technology in the **Laboratory Response Network for Biological Threats Preparedness (LRN-B)**.

From Old to New

The Applied Biosystems™ 7500 Fast Dx Real-Time Polymerase Chain Reaction (PCR) instrument has been a reliable workhorse for LRN-B testing for many years. In early February 2022, the **US Centers for Disease Control and Prevention (CDC)**, issued a network broadcast message to all LRN-B laboratories announcing the discontinuation timeline for the ABI 7500 Fast Dx, with production ceasing in May 2022 and technical support being phased out by 2027. The news has had a substantial impact on diagnostic assays throughout public health, especially for diagnostic and surveillance assays that are developed at CDC and deployed through the LRN-B and other public health laboratory programs. News of the ABI 7500 Fast Dx's departure leads to a time

of transition for its users as programs at CDC along with other stakeholders work together to identify the next generation of real-time PCR platforms.

Such changes are not easy to implement and take significant coordination between CDC, public health laboratories, APHL and vendors. CDC must provide guidance on any new standards, for which they must gather as much information as possible. Changes to instrumentation also require validation studies for both existing assays and the instrument and may alter existing strategic plans for future studies.

...And New Technicalities

A major limiting factor in the availability of platforms to choose from is **US Food and Drug Administration (FDA) 510(k)** clearance, an FDA requirement that manufacturers must register devices if there is an intent to market the instrument as a medical device. A real-time PCR instrument that has already received FDA 510(k) clearance is preferred for CDC's influenza program and the LRN-B, two groups that are a driving force in approving the use of new platforms in their respective programs. Other factors, such as throughput capacity, footprint and

cost should be considered from a public health laboratory perspective.

Before the LRN-B can invest in a new testing instrument, its functionality and repeatability must be evaluated to confirm that it will produce the same results under the same conditions, regardless of where the test is performed. Protocols need to be updated and standard operating procedures either revised or written anew. The process of choosing, validating and implementing new instruments and technology is one that can take years to finalize.

While it may be difficult initially to deal with drastic deviations that have a significant impact on its member laboratories, the LRN will rise to the occasion and meet these changes head on, leading to an even stronger and well-prepared public health laboratory system. ■

One of the long-term goals for APHL, CDC and public health laboratories has been to standardize testing platforms and reagents across the public health laboratory system. To achieve this, the Laboratory Efficiencies Initiative was co-sponsored by APHL and CDC with the goal to build a sustainable public health laboratory system. Over the years there has been success in homogenizing instrument use and testing across public health laboratories.



A lineup of various PCR instruments located at New York State's Wadsworth Center. Photo: Wadsworth Center

Maintaining the Biosafety and Biosecurity Workforce Post-COVID-19

by **Michael Marsico**, senior specialist, Biosafety & Biosecurity

The COVID-19 pandemic overwhelmed the public health workforce and laboratory professionals across the globe. New roles, especially around community outreach, emerged for biosafety and other professionals. Below two APHL Biosafety and Biosecurity Committee members share their perspectives on challenges around biosafety and biosecurity and ideas to strengthen the field of biorisk management.



Jill Power, MS, M(ASCP), CMQ/OE(ASQ)

Deputy Director

New Hampshire Public Health Laboratories

Part of my role as the biosafety/biosecurity officer (BSO) during the pandemic was to assure everyone in the laboratory was working in the safest environment possible. We didn't understand a lot about this virus, but were comfortable knowing we had processes, equipment and administrative controls in place to protect workers as they managed the specimens. Risk assessments were performed in the testing laboratories as well as our specimen receiving area, which is equipped with a small biological safety cabinet (BSC). The decision was made to place all specimens in the cabinet while verifying integrity, identity and any other quality or safety issues. If a leaking specimen was found, we developed a process to double bag it and place a tag on the bag to alert the testing team. As time went on and specimen numbers started surging, we ended up cancelling the test request on leakers and discarded them in

the receiving area. A lot of safety training had to be done for the specimen receiving group and the testing teams. The testing team supervisors managed technical and related safety training. Because we had one incident that occurred as a possible exposure early in the pandemic, it was well-documented, processes were changed and the initial risk assessment was updated. We monitored the health of the staff who were potentially exposed, and fortunately, no exposures were identified.

As BSO, I was involved externally with new partners, such as long-term care facilities (LTCF) and correctional facilities who were trying to navigate new testing process for their residents. A visit to our local state correctional facility to see how they managed incoming residents and suspected positive residents helped me better understand the restrictions and difficulties caused by the pandemic and we tailored our safe practices recommendation as best we could. I was also involved in a team that monitored and processed how COVID-19 testing was being coordinated in New Hampshire. I was able to give safety and quality recommendations that included specimen collection and handling biohazardous waste to this group, which was then used or passed along to partners.

For new public health biosafety workers, more training and experience in laboratory operations is needed. Let's get our hands dirty and dissect a biological safety cabinet, learn real-time respiratory fit testing, develop and perform a risk assessment process that suits your laboratory and train on how to evaluate your local clinical laboratories—all without watching a video or reading a book. I'm not sure biosafety is considered part of laboratory operations in general, but perhaps it is something for laboratories to consider to ensure biosafety is taken seriously in the future.



Sarah Elizabeth Totten, DrPH, M(ASCP), CIC

Metro Regional Manager, Infection Prevention
University of Colorado Health

The importance of biosafety and biosecurity has been a moving target for some time. SARS-CoV-2, along with Ebola and H1N1 before that, has provided an opportunity to see the "holes in the dam." COVID-19, due to its expansive impact and duration of pandemic status, has created the ability for public health officials to speak loudly about program limitations and overarching inability to address exposure events. The workload of biosafety professionals was huge and I doubt I was the only person that wished for cloning capabilities.

The "ideal" state was replaced with "good enough" in order to get ahead of testing needs during COVID-19. Now the challenge will be regaining traction as previously strict requirements have been replaced in the presence of extenuating circumstances including additional personal protection (i.e., masks). We have created a perception that Microbiology can be established as rapid and point-of-care testing. Ensuring safety, proper containment and preventing exposures to disease will be major points to address moving forward for biosafety and biorisk professionals. ■

APHL 2022: Where Laboratory Science and Public Health Meet (In-person and Virtually)

Over 1,400 public health scientists and administrators attended APHL 2022 in Cleveland, OH and virtually. Leandro Mena, MD, MPH, director of the Division of STD Prevention for the **US Centers for Disease Control and Prevention (CDC)**, was the Kati Kelley Lecturer, speaking about his work promoting holistic and equitable approaches to STI care. APHL was also pleased to announce the recipients of its annual awards for outstanding achievements in laboratory science, creative approaches to solving today's public health challenges and exemplary support of laboratories serving the public's health.

Lifetime Achievement Award

Recognizes individuals who have established a history of distinguished service to APHL, made significant contributions to the advancement of public health laboratory science or practice, exhibited leadership in the field of public health and/or positively influenced public health policy on a national or global level. This is not a retirement award, but a true Lifetime Achievement Award.

Richard Steece, former director, **Division of Laboratory Services, Tennessee Department of Health**

Gold Standard Award

Given to an APHL member who makes or has made significant contributions to the technical advancement of public health laboratory science and/or practice that resulted in significantly improved technology for application in public health, environmental or agricultural laboratories.

Henry Leibovitz, **Rhode Island State Health Laboratories**

DIGITAL EXTRA: Miss a session or want to claim P.A.C.E.® credit? APHL 2022 sessions are available for viewing until August 19, 2022.

Silver Award

Honors a laboratorian with 10 to 15 years of service in a governmental public health laboratory (either public health or environmental/agricultural laboratory). The honoree will be recognized as a leader both within their home laboratory as well as external to their laboratory.

Degina Booker, **Mississippi Public Health Laboratory**

On the Front Line Award

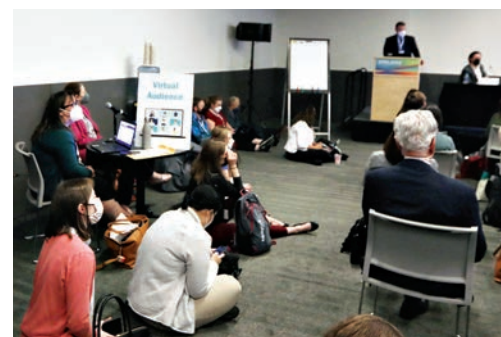
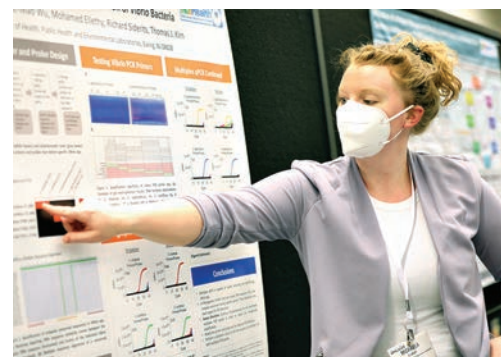
Honors an individual or laboratory outside of the APHL membership who makes significant contributions to the advancement of public health laboratory science and/or practice.

Donald Burr, **Office of Regulatory Science, US Food and Drug Administration**

Emerging Leader Award

Honors a laboratorian whose leadership has been instrumental in one or more advances in laboratory science, practice, management, policy or education within five to 10 years of working at a publicly funded laboratory that conducts testing of public health significance.

Lauren Turner, **Virginia Division of Consolidated Laboratory Services**





Leadership in Biosafety and Biosecurity Award

Honors a laboratorian with over 10 years of related service in the field of biosafety and biosecurity in a state and/or local public health laboratory, private clinical laboratory or as an external partner. This honoree is a leader both within their home laboratory as well as external to their laboratory.

Jill Power, New Hampshire Public Health Laboratories

Carrie Anglewicz, Michigan Department of Health and Human Services Bureau of Laboratories

The LEAD Award

Established in 2021, this award recognizes the legacy of Eva J. Perlman, APHL's first chief learning officer, who over three decades helped shape the public health laboratory workforce and represented the attributes of "serving those who have served." This award honors an individual who exhibits the attributes of a leader, encourager, advocate and developer, and who has 10 or more years of service in a state, local or territorial public health laboratory, or other public health laboratory partner.

Renée Ned-Sykes, Training and Workforce Development Branch, Division of Laboratory Systems, CDC

Champion of the Public Health Laboratory Award

Recognizes federal, state and local elected officials or executive branch employees who have recognized the importance of state and local governmental laboratories that perform testing of public health significance either through support of legislation or federal agency decisions.

Reynolds Salerno, Division of Laboratory Systems, CDC

APHL Presidential Award

Selected by Denise Toney during her Presidential year (2021-2022) for the significant contributions that were made to the association's work to promote policies that strengthen public health laboratories.

Brandi Limbago, National Center for Immunization and Respiratory Diseases, CDC

Timothy Stenzel, Office of In Vitro Diagnostics and Radiological Health, FDA

Healthiest Laboratory Award

Celebrates excellence in environmental stewardship and health promotion in both practice and policy. It recognizes APHL member laboratories demonstrating outstanding efforts to reduce their collective environmental impact and to promote health and wellness programs.

State Hygienic Laboratory at the University of Iowa

Thomas E. Maxson Education, Training and Workforce Development Award

Established in August of 1998 in memory of Dr. Maxson, this award honors an APHL member who is a public health or clinical laboratory practitioner, trainer or educator who has made significant contributions to public health laboratory practice by creating, delivering or developing continuing education opportunities, programs, policies or practices for the laboratory community.

Crystal Barrett, Virginia Division of Consolidated Laboratory Services ■

APHL Receives Record Number of Applications for 2022 Fellowship Programs

by **Heather Roney**, MA, manager, Fellowships

APHL received over 600 fellow applications and 200 host laboratory applications for its 2022 fellowship programs. These include applications to the following traditional and new subject areas, 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**

Current APHL fellows attended APHL 2022 in Cleveland. A special professional development and networking meeting was offered.

APHL is launching 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.

APHL Technical Assistance Available for Animal Rabies

Reliable and timely methods for data exchange are critical for the surveillance of animal rabies disease. Yet, most public health laboratories only sporadically report, using manual methods that are time-consuming, error-prone and that make national surveillance impossible.

Join an APHL Rabies Cohort and receive fully-funded technical assistance to send standardized electronic animal rabies ELR messages!

Contact vanessa.holley@aphl.org for more information.



Technical assistance team includes technical architects, terminologists and project managers who work in tandem with laboratory staff for 3 to 6 months.

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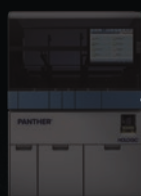
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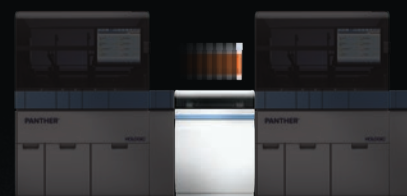
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- HPV 16 18/45
- Group B Strep
- Zika Virus*

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- HCV Quant Dx
- HBV Quant
- Flu A/B/RSV
- Paraflu
- AdV/hMPV/RV
- SARS-CoV-2*
- SARS-CoV-2/Flu A/B*
- SARS-CoV-2/Flu A/B/RSV†
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† In development and not for sale.

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