LAB MATTERS

analysis|answers|action

Summer 2021 Issue 3



THE TRUE PROMISE OF METAGENOMICS

Inside:

16 New Jersey Laboratory Pioneers Prenatal Lead and Mercury Screening

20 The Role for NGS-based Technologies in a Post-Pandemic World

28 Kansas Department of Agriculture Laboratory: Protecting Animals, Humans and the Land They Share

ASSOCIATION OF PUBLIC HEALTH LABORATORIES

APHL Newborn Screening Symposium 2021

october 5–14 tue wed thu virtual conference

Top Reasons to Attend the APHL NBS Symposium

Learn about new technology, trends and issues regarding a variety of topics in newborn screening and genetics.

Discover new products and services for your program from an assortment of exhibitors.

Listen to a thought-provoking keynote session on Health Inequities and Disparities and Emerging Therapies, featuring renowned speakers from around the country.

Reconnect with old friends and meet new ones! Get inspired by your peers. **Renew excitement** about your science, your work, your mission and public health.

Recognize your colleagues for their amazing accomplishments during the Newborn Screening Awards event.

Earn credits: P.A.C.E.®, CME, CNE, CHES, CPH and Genetic Counselor Credits are available.

Have fun, unwind and connect with colleagues at events like a virtual dance party, restorative yoga or the trivia showdown!

20+ Scientific Sessions

25 Exhibitors

75+ Scientific Posters

Parent / Patient Panel

Awards Ceremony

Meet the Manufacturers Event

Access to the platform for 12 months after the event

#APHLNBS

Don't miss this one-of-a-kind event. See you in October!

Register today at www.aphl.org/NBS2021

APHL™



LAB MATTERS SUMMER 2021 | CONTENTS

COLUMNS

2 President's/Chief Executive Officer's Message

DEPARTMENTS

Environmental Health

10 Assessing and Advancing Public Health Research and Practice Through Exposomics

12 CDC and NCBI Coordinate Wastewater-based Genomic Surveillance Data

Food Safety

14 A Whole New World: Metagenomics and Food Safety

From the Bench

16 New Jersey Laboratory Pioneers Prenatal Lead and Mercury Screening

Global Health

18 APHL Responds to COVID-19 Crisis in India

19 The Unanticipated Benefits of Virtual Trainings

Industry Matters

20 The Role for NGS-based Technologies in a Post-Pandemic World

Infectious Diseases

22 An Evaluation of Spartan Bioscience's Environmental *Legionella pneumophila* qPCR Field Test

Public Health Preparedness and Response

23 US Virgin Islands Immunization Program Begins Vaccine Awareness Campaign

24 Engaging Non-traditional Partners to Build Biosafety Practices

Quality Systems & Analytics

26 Southeast ColLABorators Convene Virtual Tabletop Exercise

Membership

28 Kansas Department of Agriculture Laboratory: Protecting Animals, Humans and the Land They Share

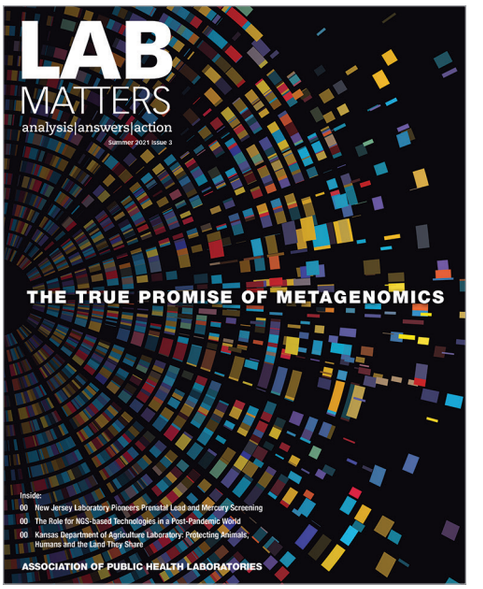
30 APHL 2021 Award Winners

Fellows

32 APHL Fellows: Endings and Beginnings

Digital Extra

33 APHL 2021 Poster Abstracts



FEATURE

4 The True Promise of Metagenomics

Microbes are everywhere—in the water we drink, the food we eat and in our natural and built environments. Metagenomics—the direct sequencing of clinical specimens and environmental samples—makes it possible to investigate microbes within the complex communities where they live with precise interpretation in a short period of time, compared to traditional methods which can take days or even weeks. While metagenomics is being used extensively in academia for medical research, and by government organizations, what does metagenomics look like within a public health laboratory? The quick answer is… it's complicated.

8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

Phone: 240.485.2745
Fax: 240.485.2700
E-mail: info@aphl.org
Web: www.aphl.org

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.

APHL LAB MATTERS STAFF

Gynene Sullivan, MA, editor
Karen Klinedinst, art director
David Fouse, advisor

To submit an article for consideration, contact Gynene Sullivan, editor, at gynene.sullivan@aphl.org.

APHL 2021-2022 BOARD OF DIRECTORS

Denise Toney, PhD, HCLD(ABB), president
Daphne Ware, PhD, president-elect
Godfred Masinde, PhD, MBA, HCLD(ABB), secretary-treasurer
Michael Pentella PhD, D(ABMM), member-at-large
Scott Shone, PhD, HCLD(ABB), member-at-large
Timothy Southern, PhD, member-at-large
Sally Flowers, PhD, associate institutional member representative
Sanjib Bhattacharyya, PhD, local institutional member representative
Megan Crumpler, PhD, local institutional member representative
Grace Kubin, PhD, past president
Scott Becker, MS, ex officio, chief executive officer, APHL

In Praise of the Backbone:
The Public Health Laboratory Workforce



Denise Toney, PhD
President, APHL

"We sometimes get used to doing things a certain way, especially if the process is working well and while public health laboratories are always engaging in critical thinking and evaluations, our response to COVID-19 really forced us to think outside the proverbial box."

Scott Becker: Eighteen-plus months into the pandemic and I feel like there are so many lessons learned and so many things that we are still stepping into that we do not necessarily know. But the one thing I am sure of is that our workforce has been the bedrock to whatever success we have had—they are the key to the future. It is not only about the people who are doing the work, it is about the people who we are serving. So even with all of the challenges we have faced, what are some of the successes that we've seen?

Denise Toney: The pandemic, more than any other public health emergency, has truly highlighted the critical work that public health does, and the role that we, as laboratorians, play in responding to something that is impactful to our communities. With the current workforce, and definitely with the younger generation, I have noticed more interest in public health and public health careers. So many individuals are reaching out to us wanting to find out more because they see the great work we are doing, and hear our public officials talking about it. We have more people than ever before wanting to join us in our work, which is so exciting. Now is the time to capitalize on that attention—strike while the iron is hot, because people know so much more about public health and we need to use that knowledge to our advantage to expand our reach.

S: I do think that is really important right now, especially how tired the current public health workforce is. We are tired but I also know how resilient we are. This has been the most stressful experience in our professional lifetimes, and I continue to be concerned about our mental health. APHL partnered with other public health organizations and CDC to encourage a large-scale study—the first of its kind—of the mental health status of the public health workforce. And the results were not surprising. At some point in the next few months, APHL will be able to get a more definitive report on the responses from the laboratory community. Through that, we will be able to develop programs and have more dialogue on things that we can do to support this very important segment of the workforce. CDC also extended the opportunity to APHL's staff and other public health organizations to participate in a similar study, which shows the critical role that our staff has played in supporting our members.

D: Another critical success is the amount of cross-training that organically happened during our response to the pandemic. Even though it started out as a necessity for laboratories to respond, the fact that we were able to implement a new model of thinking and learning during an emergency emphasizes the fact that we can entertain a new mindset about how our workforce can expand. Bringing in folks who may not have the same training and competencies and get them up to speed to where they are contributing, is a best practice that needs to continue moving forward. In Virginia, we are trying to look at how we can not only be more efficient, but more importantly, how we can make our processes more efficient so that no matter what happens next, we are prepared to streamline how we do things. We sometimes get used to doing things a certain way, especially if the process is working well and while public health laboratories are always engaging in critical thinking and evaluations, our response to COVID-19 really forced us to think outside the proverbial box.

S: Thinking about it from the association's standpoint, one thing we are going through right now as an organization is wrestling with this idea of a hybrid workplace and how to best support our own workforce. APHL is a member-centric organization and always will be. Our members enjoy coming out of the laboratory and visiting a physical place called APHL and collaborating with not only association staff, but with other laboratory leaders as well. So we will be looking very closely at what the future will look like for us from a work perspective, a member service perspective

and a member gathering perspective. Because we are member-centric, I doubt that we will ever be a fully virtual workplace. But I have also seen from the laboratory perspective that you need laboratory staff in the brick-and-mortar workplace, and I've also seen a number of positions be very effective outside of the physical laboratory…I've seen the inside of more laboratory director's homes than I ever thought I would! And you have been very effective leaders no matter where you are—that's something we never would have thought about pre-pandemic.

D: I think we have also increased the exposure for our staff to public health and created more learning opportunities for them because of the virtual environment. There have been opportunities to attend conferences that they may not have had before. Additionally, training is something that I think will never go back to the way it was before. There is such potential to provide high-quality training virtually and in a way that is convenient for folks who desire work/life balance, yet want to take advantage of professional development opportunities by spending time listening to webinars or seminars—either live or after the fact—instead of trying to carve out the time needed to attend an in-person training. So between training and other opportunities for education and professional development, I think the pandemic has pushed us into a new era where we can transition into a hybrid program, instead of going back to pre-pandemic days.

S: Exactly. For APHL, it gave us the realization that we can go deeper into the laboratory and serve more lab staff who did not have that access or opportunity before. I am really excited at the challenge and opportunity to test our innovation muscles and continue to serve our membership better.

D: I also think that this new way of training can provide us with the opportunity to tap into new talent that may not necessarily have the years of experience behind them. With minimal resources, we can bring them up to a certain level of understanding quickly through virtual training, then partner them with subject matter experts in the laboratory to complement and strengthen what they have learned virtually. I think this will improve quality and safety, as well as their ability to perform laboratory work more accurately. And hopefully, educating them virtually in the "why" of doing things will complement the in-person "what" of doing things, creating stronger scientists and stronger leaders.

S: When we think about virtual and laboratory, it seems like they are at opposite ends of the spectrum. But there are aspects of the laboratory workforce that are knowledge workers as well as hands-on workers. I'm excited that CDC is thinking and investing in virtual trainings, but another area that is going to provide an opportunity is the idea of linking with academia. One path will be on workforce development into careers, using the public health laboratory as a living, learning laboratory. That is an important function and many labs in the past did not have the ability to make that relationship happen. The other path will be on innovation in informatics and diagnostics. We have had such an opportunity to work with the academic community in a new and different way, thinking about collaborations with not only traditional laboratory science programs, but also biomedical engineering, data science and others.

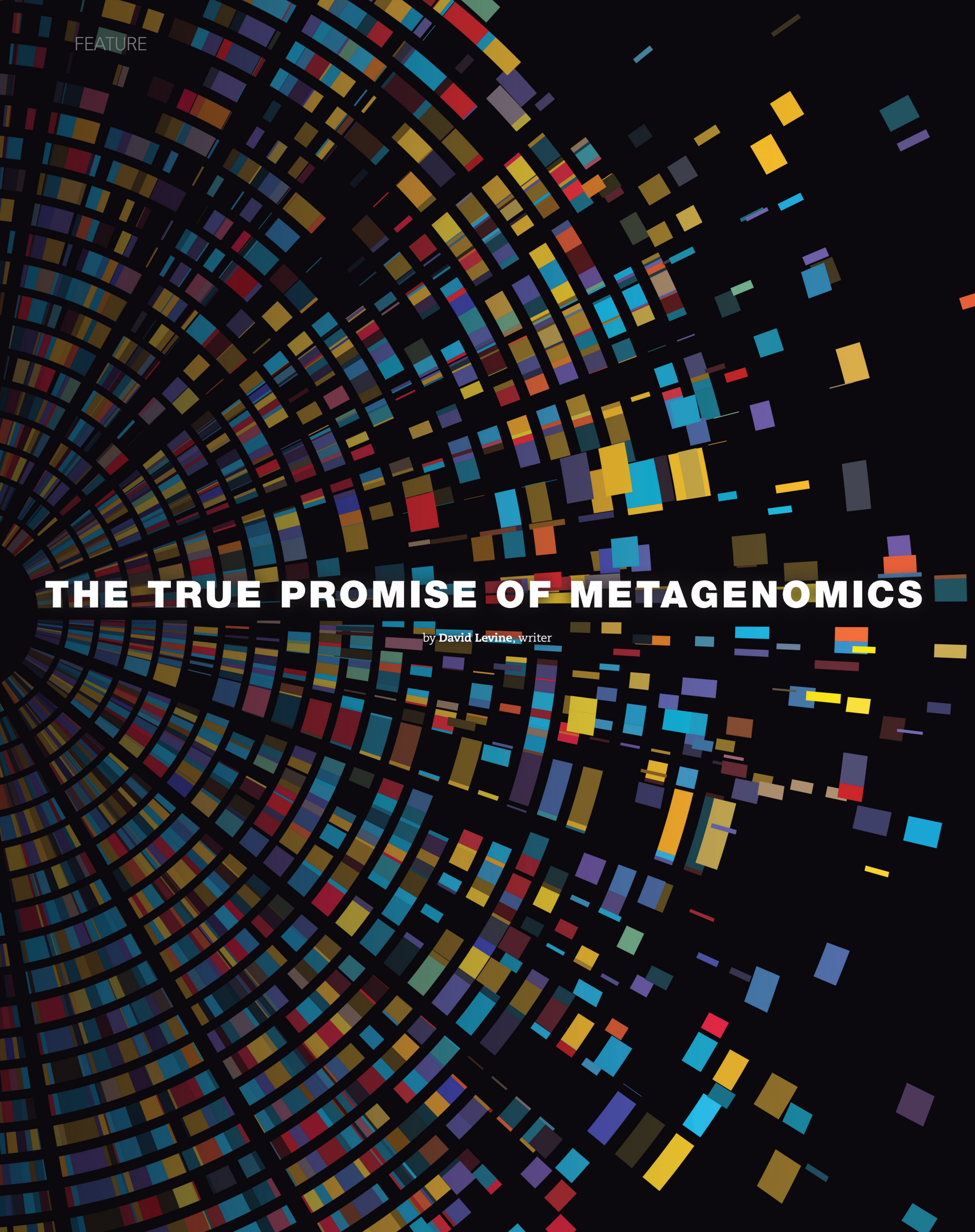
D: In Virginia, we have always had a strong collaboration with our academic partners, but COVID-19 really opened up opportunities to collaborate on a common testing initiative. We worked together to figure out ways to support each other in our testing capabilities and capacities—ensuring that the testing that was being performed in academia was comparable with the testing being performed at the state public health laboratory. We were working on a common initiative, and making sure that everything we did was seamless and transparent.

S: This is definitely the time to invest in these relationships…if we have not formed these connections, let's do it now. Like you said before, Denise, we need to strike while the iron is hot. ■



Scott Becker, MS
Chief Executive Officer, APHL

"APHL partnered with other public health organizations and CDC to encourage a really large-scale study—the first of its kind—of the mental health status of the public health workforce. And the results were not surprising. At some point in the next few months, APHL will be able to get a more definitive report on the responses from the laboratory community."



THE TRUE PROMISE OF METAGENOMICS

by **David Levine**, writer

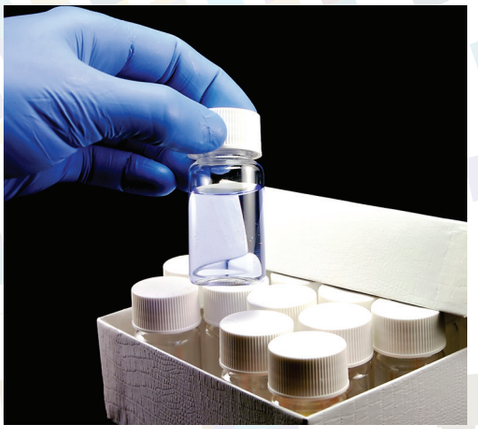
"Metagenomics was used to identify SARS-CoV-2 in the community where traditional testing has faced barriers such as correction facilities, college dorms and nursing homes. We know that not everyone can or is willing to be tested for the virus, but everyone goes to the bathroom! So, we can test for SARS-CoV-2 in water samples and assess its impact in community settings." *Mia Mattioli, PhD*

Microbes are everywhere—in the water we drink, the food we eat and in our natural and built environments. The invention of microscopes in the 18th century made them visible to us, and laboratory cultivation methods have enabled us to study them in detail. While these studies have provided immense value, all study has been done in ideal conditions—within a laboratory. Metagenomics—the direct sequencing of clinical specimens and environmental samples—makes it possible to investigate microbes within the complex communities where they live with precise interpretation in a short period of time, compared to traditional methods which can take days or even weeks.

Metagenomics is also being used to study water, soil, stools and food, human and animal guts and has been used to study the spread as well as the predominance of pathogens in a particular locality or specimen. While metagenomics is being used extensively in academia for medical research, and by government organizations such as the US Food and Drug Administration (FDA) and the US Centers for Disease Control and Prevention (CDC), what does metagenomics look like within a public health laboratory? An environmental laboratory within a public health laboratory? A standalone environmental laboratory? An agricultural laboratory? The quick answer is…it's complicated.



Wastewater surveillance sampling for SARS-CoV-2 tracking in Thailand. Photo: CDC



> **"One way that we have applied metagenomic methods in our laboratory is through characterization of microbial contamination in flood waters. These studies serve to identify microbial hazards that accompany natural events and provide information that public health agencies and professionals can use to reduce potential exposure to disease-causing microorganisms."**
>
> *Jeffrey W. Mercante, PhD*

The Public Health Impact of Metagenomics

Christopher J. Grim, PhD, research microbiologist at FDA's Center for Food Safety and Applied Nutrition (CFSAN) Office of Regulatory Science said that one way FDA/CFSAN is using metagenomics is in the evaluation and improvement of culture-based bacterial analytical methods. Even though most methods are based on commodity-pathogen pairings and have good sensitivity, they can be laborious and tedious, and not every method is optimal.

"Metagenomics has allowed us to evaluate the food associated microbiome, not just the target pathogen, at each step of the culture enrichment process to understand the limitations and advantages of many of the variables that can be manipulated to optimize pathogen recovery. More sensitive methods lead to better analytical results."

According to Mia Mattioli, PhD, an environmental engineer in CDC's Environmental Microbiology and Engineering (EME) Laboratory of the Waterborne Disease Prevention Branch, the COVID-19 pandemic not only showed the value of metagenomics, but accelerated its use across government agencies.

"Metagenomics was used to identify SARS-CoV-2 in the community where traditional testing has faced barriers such as correction facilities, college dorms and nursing homes. We know that not everyone can or is willing to be tested for the virus, but everyone goes to the bathroom! So, we can test for SARS-CoV-2 in water samples and assess its impact in community settings."

While the science is still rapidly developing and not yet available for implementation, CDC envisions one future use of metagenomics in outbreak response, alongside other next generation sequencing tools, to conduct pathogen source tracking from wastewater samples. For example, early in the pandemic SARS-CoV-2 genomes shed into wastewater on the West Coast may have been more closely genetically related to SARS-CoV-2 strains originating from China, while genomes in wastewater from the Northeast may have been more closely related to strains circulating in Europe. Together this metagenomic application could have the potential to inform transmission dynamics and develop more effective community-level mitigation strategies.

Jeffrey W. Mercante, PhD, a research microbiologist in the EME Laboratory, notes that metagenomic exploration of environmental water is a fascinating area of study for their laboratory.

"One way that we have applied metagenomic methods is through characterization of microbial contamination in flood waters. These studies serve to identify microbial hazards that accompany natural events and provide information that public health agencies and professionals can use to reduce potential exposure to disease-causing microorganisms."

A Cross-Disciplinary Approach

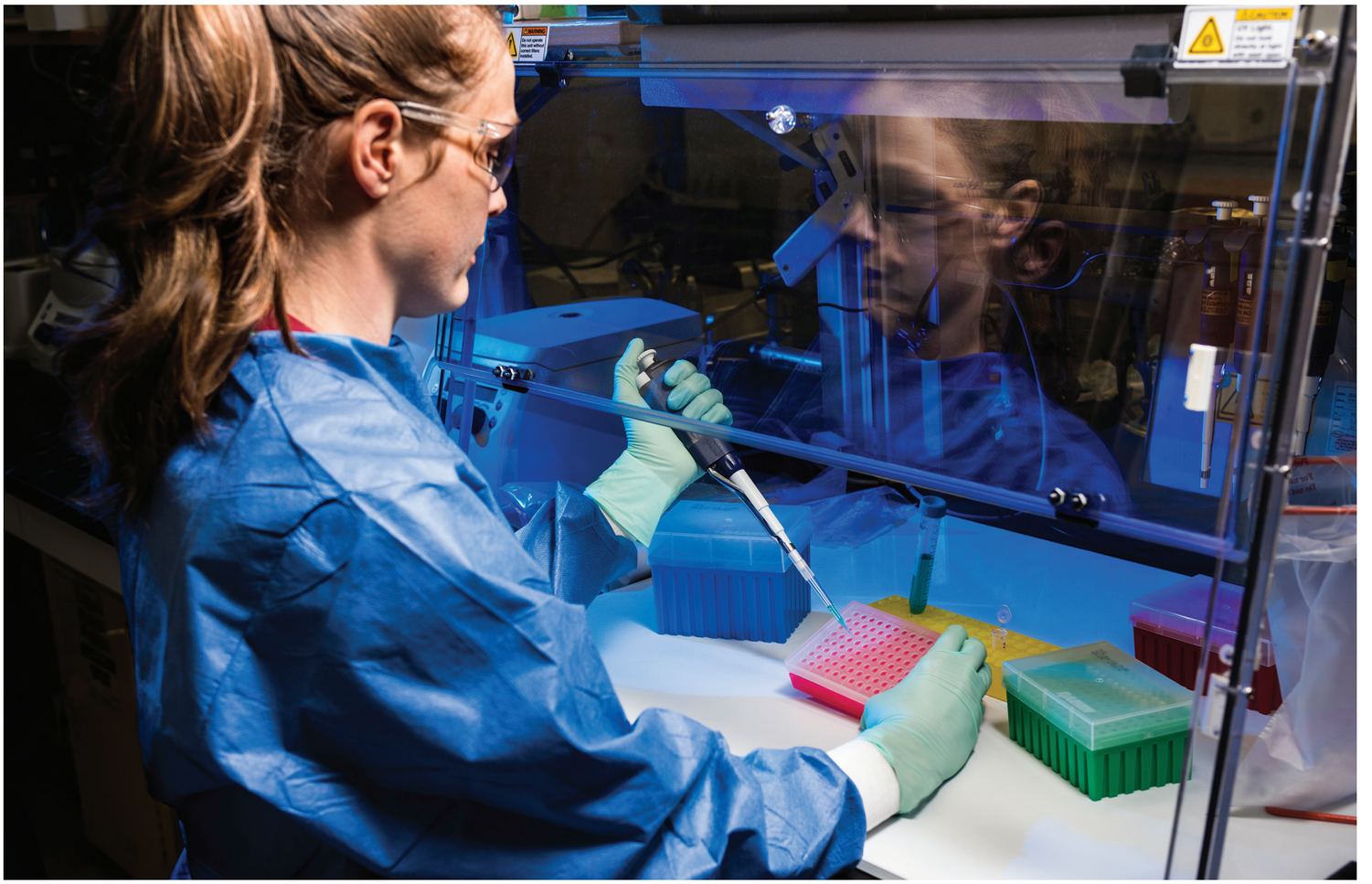
Metagenomics is a widely applicable tool that can capture a lot of information. As such, its usage commonly spans multiple disciplines, according to Padmini Ramachandran MA, researcher at FDA/CFSAN.

"Metagenomics can tell us at high resolution which microbes are present in a setting, how dangerous they are and other traits, and what functions they are performing, just to name a few. As such, its usage commonly spans multiple disciplines."

FDA/CFSAN has engaged with several stakeholders in regions in the West as an example of public-private partnerships outlined in FDA's New Era of Smarter Food Safety and as a component of FDA's Leafy Greens STEC Action plan to understand environmental or landscape factors that are impactful in the persistence and spread of foodborne pathogens.

"It has been important to engage with all stakeholders, including growers, academic collaborators, our internal partners and other state and federal partners, in order to take a holistic, One Health approach to this continuing problem." said Ramachandran.

Mercante reflected that metagenomics



A CDC microbiologist prepares a sample of wastewater for PCR molecular testing. Photo: CDC/Laura Bishop

works best when used in conjunction with other next-generation sequencing approaches or with traditional methods of microbial characterization.

"Our laboratory has explored combining metagenomics with other approaches. I would like to expand and evaluate using combined approaches for some of our US-based and international activities where it has not yet been employed."

"Ultimately our goal at FDA is to be able to use metagenomics in some capacity in our regulatory decision making," Grim observed. "We see metagenomics and related culture independent sequencing-based methods as the next progression from isolate whole genome sequencing." FDA's GenomeTrakr initiative has been extremely important in outbreak investigations, providing increased resolution in microbial forensics. But this technique would still require the pathogen to be cultured from a food sample. Metagenomics could circumvent the dependence on culture enrichment, which could shorten turnaround time considerably. But the levels of foodborne pathogens at the harvest and retail stage are often quite low compared to the intrinsic microbiota.

"This challenge needs to be solved," said Grim.

> **"We see metagenomics and related culture independent sequencing-based methods as the next progression from isolate whole genome sequencing."**
>
> *Jeffrey W. Mercante, PhD*

Challenges and Barriers

Enoma Omoregie, PhD, associate director of Environmental Sciences at the New York City Department of Health and Mental Hygiene, has used metagenomic techniques to look at New York City's water microbiome and detect pathogens in people's blood.

"Our water, food and built environment can provide a pathway for pathogen transmissions. Traditional environmental microbiological tests are limited to specific pathogens or indicators. Metagenomics methods allow the rapid and simultaneous detection of many pathogens." However, Omoregie notes that besides proof-of-concept studies, metagenomics is not being used in New York City at this time.

> **"How much sequencing do you need before you are confident about results? We need a set of criteria, and the guidelines and recommendations don't exist."** *Enoma Omoregie, PhD*

Mark Pandori, PhD, director of the Nevada State Public Health Laboratory (NSPHL) agrees.

"I don't know of any public health laboratory actively using metagenomics. They either don't have the capacity, or the personnel trained to do it." Pandori is advancing NSPHL's research and collaboration opportunities throughout Nevada by facilitating partnerships with CDC, the Federal Bureau of Investigation, state and federal agencies, hospitals, state and county health districts and departments.

Omoregie says the biggest barrier to implementing metagenomics in public laboratories is the lack of standards and protocols.

"How much sequencing do you need before you are confident about results? We need a set of criteria, and the guidelines and recommendations don't exist." He also cites a need for bioinformatic knowledge and some public health laboratories may not have the necessary expertise.

"Although the concept of running one set on a sample—whether human, water or waste—is valuable, it requires advanced bioinformatic analyses and/or significant biochemical modifications to the preparation process," said Pandori.

Joel Sevinsky, PhD, founder of Theiagen Genomics and former member of the Molecular Science Laboratory at the Colorado Department of Public Health and Environment, said because of their size and limitations, some public health laboratories may be much better off using metabarcoding metagenomics rather than shotgun metagenomics. Metabarcoding is the barcoding of DNA or eDNA (environmental DNA) that allows for simultaneous identification of many taxa within the same environmental sample, however often within the same organism group.



A CDC microbiologist begins an NGS run of nucleic acid extracted from water samples. Photo: CDC/Laura Bishop

"Through DNA metabarcoding, you can use high-throughput sequencing and circumvent the sorting and isolation of the thousands of individuals in bulk mixed samples of organisms," Sevinsky said. He also notes that metabarcoding is higher throughput and less costly than shotgun metagenomics, which he calls a valuable tool but not practical for public health laboratories due to its expense, the time it takes to sequence and the staff.

Grim said FDA is fortunate that there have been few barriers or challenges in implementing these systems.

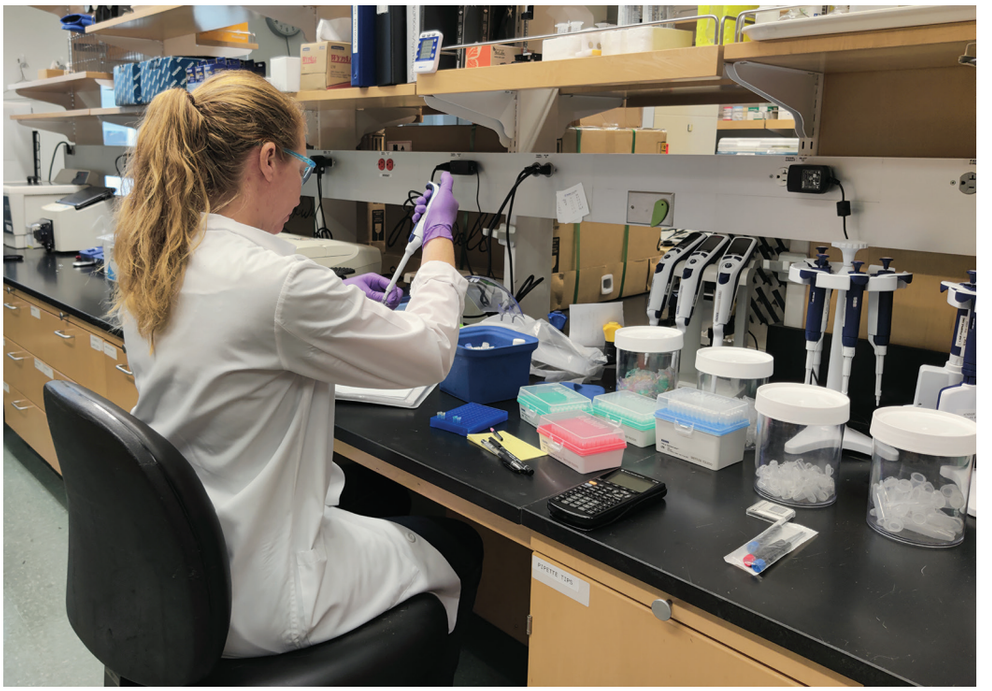
"One of the challenges to maintaining these systems are the frequent hardware and software upgrades from vendors and integrating those upgrades with our internal scientific system security configurations. Most vendors are working towards keeping the government scientific systems securities in mind when implementing the upgrades."

In contrast, the FDA has automated platforms and instrumentation that they utilize for all sequencing workflows.

"Our Regulatory Genomics team utilizes a Genomics LIMS system to coordinate all our foodborne isolate genomics workflows," said Grim. "We are working to integrate metagenomic sequencing data collection and analysis workflows into the same system. Additionally, we have recently developed a metadata standard for essential contextual data collection."

In terms of materials utilized (e.g., sputum, wastewater, etc.) Grim said they include DNA extracted from environmental samples (water, soil, air, compost, animal scat), several food matrices (leafy greens, flour, low moisture food, high moisture foods), and culture-based bacterial enrichments that are pathogen-specific but paired with the commodity (quasi metagenomics). For diagnostics and industry applications, FDA is using metagenomic-based approaches and results for research-only purposes for evaluation and improvement of culture-based bacterial analytical methods.

As for data privacy on samples, especially when more than one condition is found, FDA/CFSAN is using metagenomic-based approaches for evaluation only and not for regulatory decision making. In addition, it does not process or analyze human clinical samples, so data privacy in that regard does not apply, according to Grim.



FDA CFSAN Research Biologist Amanda Windsor performs target capture with oligonucleotide probes for enrichment of Salmonella enterica signatures from shotgun metagenomic sequencing libraries. Photo: FDA

"For research studies, such as our longitudinal research studies in Yuma and California, we keep participant identifiers private, including when the research work is published."

Consider the Data

Since sequencing technologies have rapidly increased their throughput and reduced the cost of sequencing per base pair, a great amount of data is being generated and a careful evaluation regarding their use, analysis and storage is needed.

"Currently, there is no unique consensus regarding the best assembly strategy, since it has been noticed that the assembler performances depend on both biological and technical factors, and different assemblers work better on different datasets," Grim said. "And since the data obtained with metagenomic sequencing is complex, created pipelines should offer a comprehensive view of genomes of all the microbes present in the sample."

This approach also requires high sequence coverage, so that taxa in small proportion are represented in the data. The large amount of data that are generated require additional data storage and specialized analysis pipelines to efficiently discern the sequences.

Metagenomics is clearly the way of the future and, due to the pandemic, has shown its worth in promoting public health. The challenge is implementing it within the public health laboratory system. As Omoregie and others noted, today's metagenomics is not being used in public health laboratories due to multiple factors. How to make the transition to use metagenomics in public health laboratories is the next step researchers will be studying in the next few years. ■

Assessing and Advancing Public Health Research and Practice Through Exposomics

by **Mark D. Hoover**, PhD, CHP, CIH, health and safety scientist

The exposome was proposed in 2005 by Dr. Chris Wild as a complement to the genome and has been defined as the totality of exposures that individuals experience over their lives and how those exposures affect health.[1] The premise was that interactions of an individual's exposures with their unique individual characteristics leads to their health status. Understanding an exposure and the role of genetics, lifestyle and other factors in disease has also been called "exposure biology" *(Figure 1)*.

Exposomics is the study of the exposome and relies on fields such as genomics, adductomics, metabonomics, lipidomics, transcriptomics, and proteomics *(Figure 2)*. These omic fields involve collective characterization and quantification of pools of biological molecules that translate into the structure, function and dynamics of an organism. Common threads are:

1. Use of biomarkers to determine exposure, effect of exposure, disease progression, and susceptibility factors.
2. Use of technologies that result in large amounts of data.
3. Use of data mining techniques to find statistical associations between exposures, effect of exposures, and other factors such as genetics with disease.

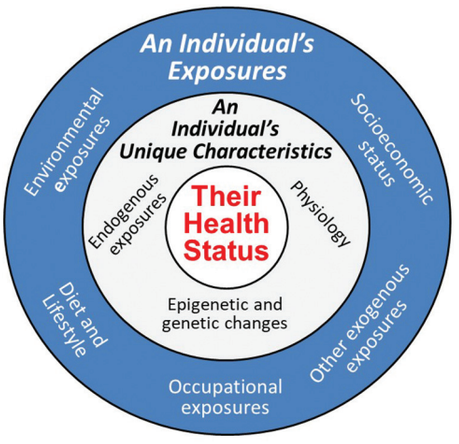


Figure 1: An individual's exposure begins before birth and includes contributions from all manner of endogenous, environmental and occupational sources. Tools in exposomic studies include biomarkers, sensors, geographic information systems and epidemiological surveys.[2] (Figure adapted from DeBord et al. 2016)

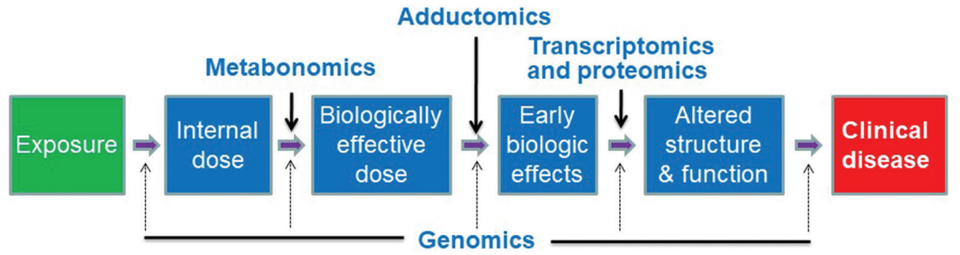


Figure 2: Genomics and the other "omics" play a role in the many events and activities leading to disease. Improving our understanding of the influence of "omic"-related processes on the progression of exposure to disease can lead to more effective disease prevention and treatment.[3] (Figure adapted from Decker et al. 2010)

Exposomics potentially includes the study of exposures in the environment that might improve or enhance health or the opportunity to attain health in greater measure.[2]

Challenges and Responding Steps

Obvious challenges limit progress in the field of exposomics. The exposome is highly variable and dynamic as it evolves throughout the lifetime of an individual. Ultimately, the impact of a specific exposure—regardless of its origin—may be different at the individual level for different people. Relating a disease to an exposure that occurred in the past can be challenging, and even present exposures are difficult or impossible to quantify.

As part of the exposome component of its exposure assessment program, the National Institute for Occupational Safety and Health has identified some specific steps that can help meet the exposomic challenges:[4]

1. Develop more sensitive exposure assessment methods and tools to improve the ability to measure exposures.
2. Develop and characterize biomarkers to improve measurement of exposure, effect of exposure and susceptibility for determination of disease relationships, including identification of "legacy biomarkers" that could quantify past exposures or effects from past exposures.
3. Develop improved statistical tools and data sharing to help evaluate the relationship of disease to the many facets of exposure, increase statistical power and provide a more thorough analysis of all exposures, including through improved bioinformatics tools, pattern matching techniques and artificial neural network models.
4. Develop gene expression matrices to assess and understand the interrelationships of environmental, occupational, dietary, lifestyle and other exposures.
5. Develop standardized criteria for designing studies and reporting results to improve the collection and storage of data that incorporates information on epidemiology, genetics and other omics; enable more holistic exposure assessment; make the information more accessible for data mining; and enhance the interpretation and reproduction of experimental results.

In support of more effective exposure assessment, the NIOSH Center for Direct Reading and Sensor Technologies has promoted the Right Sensors Used Right approach to assist data customers, creators, curators and analysts with a life-cycle decisionmaking framework and process for effective selection and use of analytical methods and data.[5]

Opportunities for Laboratorians

To advance technologies that can lead to better understanding of the exposome and the exposure-to-disease continuum, laboratorians can seek and increase the intersections and research opportunities with molecular biologists, geneticists and other professionals to advance the assessment and understanding of the genomic and other omic relationships to disease. The informative primer by DeBord et al.[2] on use of the exposome and omic technologies in the practice of epidemiology includes overviews of what has been done in the field, funding initiatives and resources, exposomic tools, challenges in study design and the future prospects of exposomics. Laboratorians can be especially impactful in promoting the concept of "right sensors and methods used right"—viewing public health through the concept of the exposome can help integrate and harness the promise of exposomics.

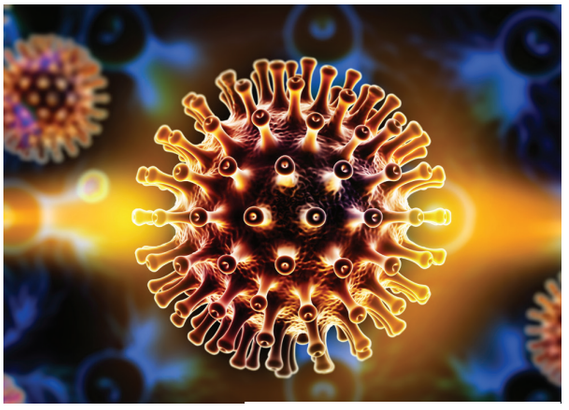
References:

1. Wild, CP. *Complementing the genome with an "exposome": The outstanding challenge of environmental exposure measurement in molecular epidemiology.* Cancer Epidemiol Biomarkers Prev. 2005;14(8):1847-1850. Available from https://cebp.aacrjournals.org/content/14/8/1847
2. DeBord, DG, Carreón, T, Lentz TJ, Middendorf, PJ, Hoover, MD, Schulte, PA. *Use of the "Exposome" in the Practice of Epidemiology: A Primer on –Omic Technologies*, Am J Epidemiol. 2016;184(4):302–314. Available from https://doi.org/10.1093/aje/kwv324
3. Decker, JA, DeBord, DG, Weston, A, Hoover, MD. *Exploring the Exposome - A Focus on Totality of Exposures Could Mean New Opportunities for Industrial Hygienists*, The Synergist, 2010;21(6):32-33.
4. National Institute for Occupational Safety and Health, *NIOSH Safety and Health Topic: Exposome and Exposomics.* Available from https://www.cdc.gov/niosh/topics/exposom5
5. Cauda, E, Hoover, MD. *Right Sensors Used Right: A Life-cycle Approach for Real-time Monitors and Direct Reading Methodologies and Data. A Call to Action for Customers, Creators, Curators, and Analysts.* NIOSH Science Blog. Available from https://blogs.cdc.gov/niosh-science-blog/2019/05/16/right-sensors-used-right

Prior to retiring in 2018, Dr. Hoover was coordinator of the NIOSH Exposure Assessment Program and co-director of the NIOSH Center for Direct Reading and Sensor Technologies. He continues to serve on national and international standards and scientific committees. ■

Test with Confidence

When you need to be sure, *Vio*One™ HIV Profile™ Supplemental Test delivers results with confidence. *Vio*One HIV Profile is an enzyme-linked immunosorbent assay (ELISA) for confirmation and differentiation of individual antibodies to HIV Type 1 (HIV-1 Group M & Group O) and Type 2 (HIV-2) in human serum or plasma.



*Vio*One HIV Profile has shown comparable or better performance in peer to peer studies with other confirmatory tests and can be run on your existing microplate ELISA equipment.

*Vio*One HIV Profile should be your first choice when a confirmatory assay is required—**Test with Confidence.**

***Vio*One™ HIV Profile™**
Supplemental Assay

For In Vitro Diagnostic Use

For more information, visit our website avioq.com; or contact your Avioq representative at infor@avioq.com.

Avioq

AVIOQ, INC. 76 TW Alexander Drive Research Triangle Park, NC 27709 | Phone: 919-314-5535 | Fax: 919-294-6420

CDC and NCBI Coordinate Wastewater-based Genomic Surveillance Data

by **Mia Catharine Mattioli,** PhD, National Wastewater Surveillance System, Waterborne Disease Prevention Branch, Centers for Disease Control and Prevention and **Ilene Karsch Mizrachi***, PhD, Intramural Research Program, Information Engineering Branch, National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health.

In September 2020, the US Centers for Disease Control and Prevention (CDC) launched the National Wastewater Surveillance System (NWSS) to provide national coordination and support to public health departments implementing this new surveillance tool. Wastewater surveillance is supporting the COVID-19 pandemic response by serving as an early indicator of community infection trends in advance of reported cases and hospitalizations.

Benefits of Wastewater Sequencing

Since wastewater is essentially a pooled community sample, one of the most promising applications of wastewater surveillance is community-level variant tracking. Variant tracking in wastewater is currently done using two different approaches: by targeting known mutations through reverse transcriptase polymerase chain reaction-based quantification (RT-qPCR or digital RT-PCR) or by genomic sequencing. Wastewater sequencing methods are still under development and evaluation, but the methods currently being assessed include sequencing a specific genome region, tiled amplicon sequencing across the entire genome (similar to clinical approaches), and metagenomic sequencing of all nucleic acid within a sample. To support the continued advancement and coordination of wastewater genomic surveillance worldwide, CDC collaborated with the National Center for Biotechnology Information (NCBI) to develop metadata requirements ("data package") that must accompany the submission of any pathogen-associated wastewater sequencing data.

NWSS partner Dr. Sean Norman at University of South Carolina samples wastewater for SARS-CoV-2 surveillance. Photo: CDC



Coordinating Wastewater Sequencing Data Submission

In response to the COVID-19 pandemic, NCBI streamlined SARS-CoV-2 genome sequence submission processes to GenBank® and the Sequence Read Archive (SRA). This resulted in quicker submission turnaround times through both the web and genomic program interfaces and rapid dissemination of data to users worldwide. NCBI launched new metadata packages—also known as BioSample packages—to improve the quality of submitted contextual metadata, which include rich descriptions of the clinical and environmental conditions under which associated viral genome sequences were obtained. Together, these improvements make the sequences submitted for SARS-CoV-2 more meaningful and useful. NCBI sequence databases are also publicly available, which allows for increased global coordination of genomic wastewater data.

For wastewater surveillance data, CDC and NCBI collaborated to develop a BioSample package specific for wastewater samples sequenced for disease surveillance. The goal of this standardized data submission process was to:

1. Create a centralized, internationally available repository of wastewater-derived pathogen genomic data for disease surveillance.
2. Standardize wastewater metadata and ensure it is consistent with other clinical and environmental sequence databases globally.[1]

METADATA FOR WASTEWATER SURVEILLANCE BIOSAMPLE PACKAGE

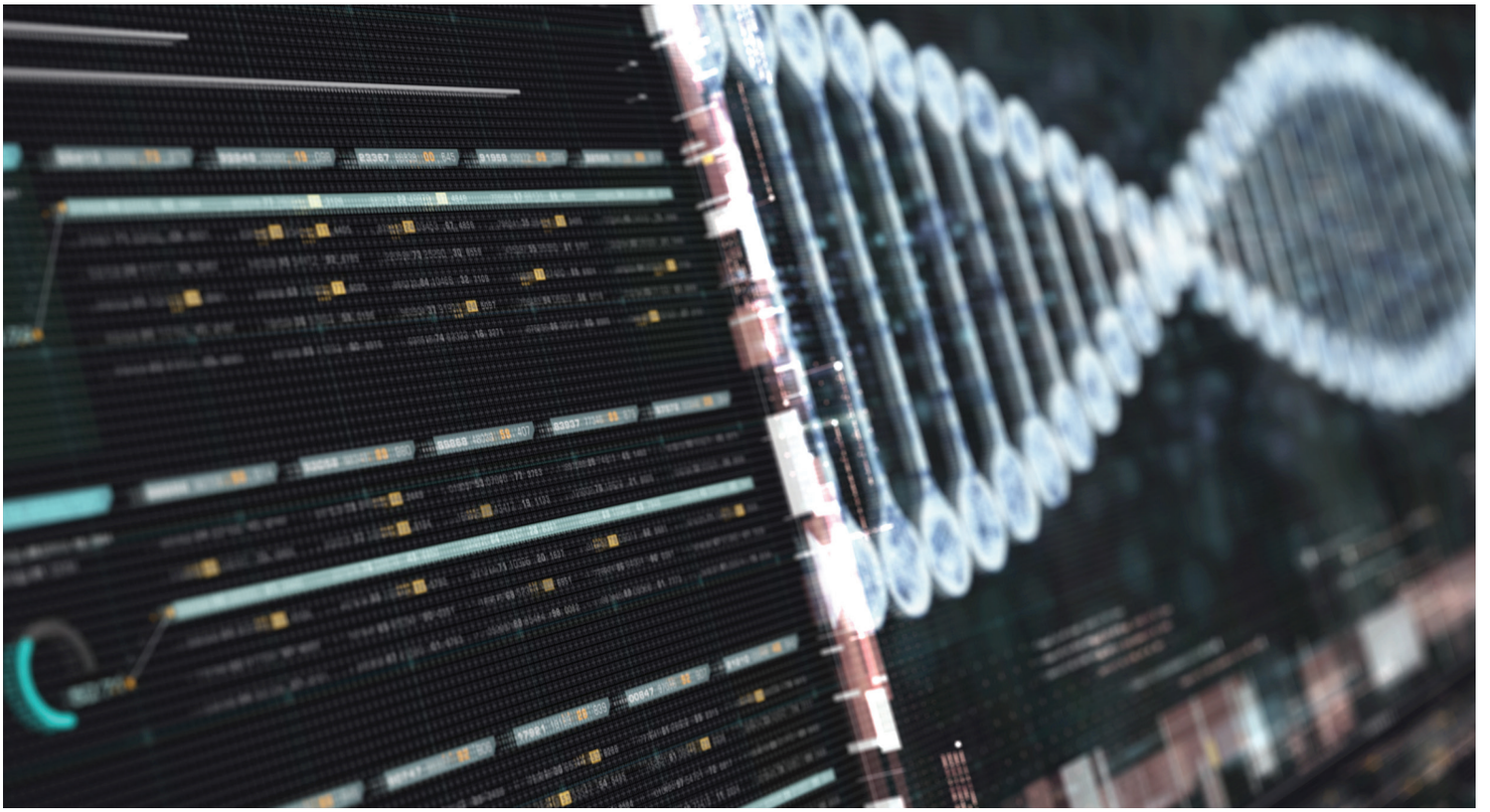
Mandatory

- Collection date
- Location
- Wastewater sample matrix** and collection methods
- Population represented by the wastewater sample
- Wastewater surveillance target.

Suggested but optional

- Sequencing purpose
- Sampling site total daily flow, and
- Levels of human fecal content in the sample.

*** Defined as the wastewater matrix that was sampled. Response options include raw wastewater, sewer pipeline sediments, post grit removal, primary sludge, primary effluent, secondary sludge, secondary effluent, other, restricted access, not applicable, not collected, not provided and/or missing.*



NCBI, a part of the National Library of Medicine at the National Institutes of Health, provides an integrated biomedical information resource consisting of more than 40 open-access databases and tools that help scientists around the world conduct their research. These databases range from the PubMed archive of published biomedical literature, to data on human variation and viral pathogens, as well as information on genetic tests and clinical trials.

3. Facilitate association of the wastewater sequence data with other wastewater and disease data collected by wastewater surveillance programs, such as the NWSS database collected by the CDC Data Collation and Integration for Public Health Event Response (DCIPHER) platform.
4. Allow for a single wastewater sample to be associated with sequence data on multiple microbial surveillance targets, including targets beyond SARS-CoV-2.

DIGITAL EXTRA: **Please contact APHL and NWSS for information on setting up wastewater testing in your public health laboratory.**

Moreover, as a single BioSample can be associated with multiple SRA submissions, a wastewater surveillance BioSample can be associated with multiple sequencing approaches for a single target to provide a more robust bioinformatic analysis. This BioSample package ensures that submitted SARS-CoV-2 wastewater sequences are effective for monitoring SARS-CoV-2 genomics and guide public health decisions. The standardized submission process also provides the data infrastructure needed to globally connect these health-related genomic data for SARS-CoV-2 and other health concerns to come. ■

Reference:

1. Griffiths, EJ, Timme, RE, Page, AJ, Alikhan, N, Fornika, D, Maguire, F, et al. The PHA4GE SARS-CoV-2 Contextual Data Specification for Open Genomic Epidemiology. *Preprints* 2020, 2020080220. Available from https://www.preprints.org/manuscript/202008.0220/v1

A Whole New World: Metagenomics and Food Safety

by **Kirsten Larson**, manager, Food Safety

Public health laboratories are moving toward metagenomics, which the NIH National Human Genome Research Institute defines as the study of a collection of genetic material such as genomes from a mixed community of organisms. In food safety, the metagenomics approach will give public health laboratories new insights and tools to study the complex microbial environment that begets foodborne illness. Four members of APHL's Food Safety Committee discussed how the science and application of metagenomics relates to food safety and public health laboratories. In lieu of an in-person podcast, this discussion reflects a summary originally planned in-person before the COVID-19 pandemic.



At the federal level, the US Centers for Disease Control and Prevention (CDC) is developing an advanced metagenomics pipeline for outbreaks of undetermined etiology (OUEs) that will be available to state public health laboratories in the next year or two.

Complex Benefits and Challenges

Metagenomics offers several benefits over traditional microbiological testing and molecular and current transitional sequencing methods. Culturing of organisms requires enrichment and time for growth while molecular methods such as PCR rely on an *a priori* approach to detect a specific target of interest. Metagenomics removes that isolation effect or bias inherent to current food safety methods and provides an opportunity to look for and identify unculturable pathogens.

Kelly Oakeson, PhD, chief scientist for bioinformatics and next generation sequencing (NGS) at the Utah Public Health Laboratory, used metagenomics to successfully recover O157 *Shiga toxin-producing Escherichia coli* from positive culture independent diagnostic test (CIDT) specimens that previously tested negative by culture. In the expanding era of CIDTs, public health laboratories are increasingly tasked with recovering isolates from positive clinical specimens. Metagenomics will make that costly and time-intensive work obsolete.

Metagenomics testing will also give public health laboratories the ability to learn more about microbial community profiles, especially from the environmental standpoint. Joel Sevinsky, PhD, founder and CEO of Theiagen Genomics, points out that as laboratorians learn about such community profiles, scientists will better predict where contamination will occur and then focus efforts on prevention instead of outbreak response activities.

Although the benefits will be exceedingly rich, there are a few challenges with implementing metagenomics for enteric pathogens. For example, fecal matter is composed of undigested fats, protein, food residue and a huge diversity of microbes, which make data analysis extremely demanding.

"There is so much stuff in stool," says David Boxrud, MS, Enterics Unit supervisor at the Minnesota Department of Health. "You couldn't design a more challenging specimen."

Rich Data Improves Food Safety

In addition, the amount of data generated by metagenomics is another current limitation.

"Public health laboratories are generating a ton of data," said Kenneth Yeh, MS, senior director for Program Development at MRIGlobal. "But we're not mining everything or using big data principles to generate and look at all that data..." Lastly, the magnitude of human DNA sequenced will present more data privacy issues than sequencing for specific pathogens.

"Metagenomics comes in many flavors—depletion, enrichment, amplification or just shotgun approaches that sequence everything," says Sevinsky.

The questions asked and the answers sought will dictate the type of metagenomics approach used and the

associated resources and costs. The most limiting costs are the price of reagents, especially in low-volume settings, and the level of expertise needed to analyze the data. Highly multiplexed amplicon sequencing (HMAS), for example, may be amenable to BioNumerics or a Terra Platform already used in public health laboratories. However, for shotgun metagenomics, specialized regional or national bioinformaticists might be more appropriate; this approach could be used more widely in public health laboratories as it becomes faster, cheaper and easier over time.

Next Steps for Food Safety

At the state level, Minnesota is currently one of two pilot sites performing HMAS on CIDT-positive *Salmonella* specimens. In its pilot, the laboratory is amplifying and sequencing targeted regions of a known pathogen's genome to obtain highly useful information such as serotype, resistance patterns or areas of diversity. Thus, Boxrud observed, HMAS could take the place of traditional culture until true metagenomics is widely available.

In the expanding era of CIDTs, public health laboratories are increasingly tasked with recovering isolates from positive clinical specimens. Metagenomics will make that costly and time-intensive work obsolete.

At the federal level, the US Centers for Disease Control and Prevention (CDC) is developing an advanced metagenomics pipeline for outbreaks of undetermined etiology (OUEs) that will be available to state public health laboratories in the next year or two. The pipeline will use a tiered testing approach, including a HMAS panel with primers for known and suspected enteric pathogens, shotgun metagenomics with reference-based binning and assembly, and shotgun metagenomics with reference-free binning and assembly.

Metagenomics is an extremely valuable tool that will give public health laboratories the opportunity to re-examine assumptions long associated with foodborne disease. APHL is committed to working closely with federal and state food safety agencies and members to advocate for resources needed to make the metagenomics transition. ■



New Jersey Laboratory Pioneers Prenatal Lead and Mercury Screening

By **Jill Sakai**, PhD, writer

While part of the Maryland Department of Health and Mental Hygiene, metals specialist Eric Bind, MPP, took part in a biomonitoring collaboration with the Johns Hopkins University School of Public Health. The project team, seeking to better understand fetal metal exposures and related health outcomes, analyzed blood samples collected at birth from mothers and babies for lead, mercury and other toxic metals.

The study revealed a clear relationship between metal exposures in mothers and their babies.

"The one thing that really struck me, though, was that there was nothing we could do about it," Bind recalled. "These were samples that were collected maybe 10 years ago, in Boston—out of our jurisdiction—and there's nothing we could really do other than to let people know there's a problem."

That memory was fresh in his mind two years later when, as the Metals Laboratory supervisor at the New Jersey Public Health and Environmental Laboratories, he helped apply for a CDC biomonitoring grant to support prenatal lead and mercury screening in the state. "I saw the opportunity to not only test, but to actually expand it to the point where we can do interventions," Bind said.

Metals exposure, especially early in life, is linked to a host of neurological problems and developmental disorders. Early testing can have lifelong effects, but "this testing isn't being done, especially for mercury," said Andrew Steffens, PhD, a metals chemist in the New Jersey laboratory.

"There was a gap here and that needed to be addressed."

Forging a New Path

New Jersey seemed an ideal location for such a project. Newark, in particular, had been actively addressing elevated lead levels in the municipal water system for more than two years, and the city has large populations of immigrant, non-white and low-income residents—groups that are often more vulnerable to metal exposure. But talks with numerous potential partners fizzled due to high rates of personnel turnover at clinics, limitations on research involvement, challenges with patient recruitment and consent, high staff workloads and questions of who would provide and pay for treatment.



The New Jersey Prenatal Screening team. Back row (from l to r): David Riker, Shatal Patel, Eric Bind, Dr. Thomas Kirn, Katelin Dittmar, Dr. Andrew Steffens. Front row (from l to r): Brian Hontiveros, Veronica Chandra, Latasha Blue, Dr. Zhihua (Tina) Fan, Ana Gross, Sharon Robinson, Lauren Lettiere, Debbie Hargrave

Not to mention, the laboratory team was challenging the status quo.

"There was no precedent anywhere in the country. I never really appreciated how much precedent matters," Bind said.

At last, the laboratory team found champions at Rutgers New Jersey Medical School in Newark. Uchenna (Chris) Nwobu, MD, an assistant professor in the Department of Obstetrics, Gynecology and Women's Health, had some previous experience screening for lead in pregnant women in New York City and hoped to start a similar program in New Jersey.

Nwobu and Onajovwe Fofah, MD, a neonatologist and associate professor in the Department of Pediatrics, saw value in pursuing the project as a public health initiative. They integrated the metals screening and any needed treatments as part of the standard care for all expectant mothers and newborns at the school's main teaching hospital, University Hospital.

"Every mother who seeks prenatal care in our practice has lead and mercury tested, and then the babies and mother at the time of delivery," Fofah said.

The team relies on a network of partnerships to address exposures both medically and environmentally. At a woman's first prenatal visit, the hospital collects a blood sample that goes to the state laboratory for lead and mercury

analysis. The medical teams provide patient counseling and care, along with expertise and educational materials from the New Jersey Poison Control Center, and the city of Newark Department of Health and Community Wellness offers remediation and lead abatement services for city residents to maximize the public health benefits of the work.

At delivery, cord blood samples are collected to test newborns. The obstetrics and neonatal teams drew on experience gained from perinatal HIV transmission studies to test and associate data from mother–baby pairs at birth. As a result of implementing the program as standard of care, Bind said, "we were able to completely shatter our goals of 500 women—we're at about 6,000 or 7,000 now."

An Unrecognized Problem

Given Newark's history, the team members were pleasantly surprised when only 1 percent of the tested population exceeded the health limit for lead. But even more surprising, about 10 percent of tested babies were born with levels of mercury above the health limit, and a full 50 percent fell within a range expected to cause some health effects.

The mercury findings presented a bit of a challenge.

"The response is not as well established as with lead," Bind noted. "With lead, you have programs, you have funding, you have tracking; with mercury none of that's in place." The team has been working with APHL, CDC and other groups like the Pediatric Environmental Health Specialty Units (PEHSU) to identify protocols and resources to help the hospital track affected children.

"Until this, we didn't have any way of identifying such patients," Nwobu said. "It would have gone unrecognized."

Most of these cases occurred within immigrant communities. With mercury speciation tests, the laboratory staff helped identify exposure sources and rule out possible concerns about mercury exposure via vaccines. Most cases were linked to behaviors such as fish consumption and the use of specific skin products.

"To identify where this mercury was coming from was an epiphany for a lot of the patients," Nwobu said. That knowledge allowed the team to tailor and translate educational materials and engage relevant community partners, such as doula programs, religious organizations and family support services.

Babies found to have elevated mercury and/or lead levels were monitored through the hospital's pediatric high-risk follow-up clinic. Staff were able to collect data on how quickly lead levels drop with or without chelation.

"If we had … waited to the one-year [test], which is the [American Academy of Pediatrics] recommendation, we will have missed these patients," Fofah said.

Seeing Results

During the two years of the project, the percentage of babies born with no detectable mercury or lead has gone up. Anecdotally, the team has also seen metal levels drop in individual women during the course of pregnancy. These improvements happened concurrently with the COVID-19 pandemic, so they want to do more testing and longitudinal analysis to tease out possible factors.

"But all indications at this point are that it's coming from the increased awareness that we're seeing through the program," Bind said.

The team has received institutional review board approval for retrospective chart reviews to compare metal levels and birth outcomes such as gestational age more directly, birth weight and head circumference. Preliminary data suggest better outcomes in women who received prenatal screening and early interventions through the clinic compared with those who delivered at the hospital but did not receive prenatal care there.

They have gotten funding to extend the program in University Hospital for another two years and hope to establish standard of care testing in a second hospital. They are also seeking ways to integrate lead and mercury testing into routine prenatal care covered by insurance, much like iron testing is currently. The "pie in the sky goal," Steffens said, is to expand the program to the entire state of New Jersey and have the costs fully covered by third-party payers.

"It will probably be some time before we get to that point. … But I will say that I'm optimistic about it. We are slowly but surely moving toward that direction." ■



Onajovwe Fofah, MD



Uchenna (Chris) Nwobu, MD

APHL Responds to COVID-19 Crisis in India

By **Sarah Young**, MPH, specialist, Global Health and **Palmira Mangae**, specialist, Global Health

In March 2021, India experienced a devastating second wave of COVID-19 cases. The virus spread at a rapid pace and quickly set the world record for the highest number of deaths recorded in a single day. This surge of cases put extreme stress and burden on what was an already overtaxed healthcare system. Overwhelmed by the number of cases, India's hospitals quickly ran short of hospital beds, oxygen supplies and personal protective equipment, leaving many COVID-19 patients and providers on their own. As of August 11, 2021, the World Health Organization (WHO) reported that there have been over 32 million confirmed cases, and over 400,000 deaths in India, but many epidemiologists believe the actual number is much higher.



A medical worker in PPE observes patients who have been infected by COVID-19 inside a makeshift care facility in a sports stadium at the Commonwealth Games Village in New Delhi on May 2, 2021. Photo: Getty Images

Since 2017, APHL has worked closely with CDC-India through the Global Health Security Agenda to strengthen India's laboratory systems and build laboratory capacity. During the surge of COVID-19 cases, CDC-India immediately requested APHL's assistance in the emergency response effort. Shortly after this request, the Biden-Harris administration released a statement committing the United States to provide immediate emergency assistance deliver more than $100 million worth of supplies for urgent relief to India.

In collaboration with the administration and this response effort, APHL successfully procured and delivered oxygen concentrators, oxygen cylinders and personal protective equipment to healthcare facilities in the states of Assam, Chhattisgarh and Jharkhand. Although the surge of cases has begun to slow, APHL continues to work closely with CDC-India and India's National Center for Disease Control to provide emergency assistance and strengthen their laboratory capacity. ■

Share your story with your peers!

APHL

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

Told from the unique perspective of laboratory scientists, administrators or staff, we welcome articles covering topics across public health laboratory science, administration, careers and management.

For more information on writing guidelines, contact:

Gynene Sullivan, MA
Communications Manager
gynene.sullivan@aphl.org
240.485.2750



The Unanticipated Benefits of Virtual Trainings

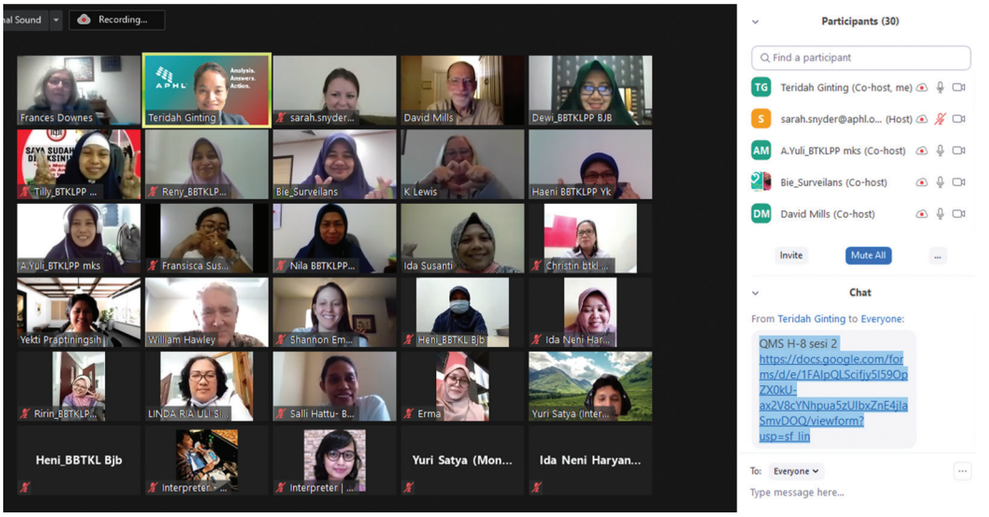
By **Sarah Snyder**, specialist, Global Health

At the beginning of the COVID-19 pandemic, APHL staff, like many others, learned to adapt to full-time teleworking. For the Global Health department, working across 14 countries and numerous time zones prepared us for this change. However, as the virus continued to spread, it became clear that without being able to meet in-person, we would need to find new ways to provide trainings in a time when competent laboratory staff were more important than ever.

Adapting to a Virtual Classroom

In the summer and fall 2020, APHL staff and consultants began the task of converting a one week, in-person Quality Systems Management (QSM) Training for Indonesia to a virtual platform. With over 30 hours of content in this training, there were concerns about participants experiencing Zoom fatigue or not committing their full attention to the training. To prevent this, it was decided to break the training into eight four-hour sessions, Monday through Thursday, over two weeks. Sessions were pre-recorded in the participants' language, Bahasa Indonesia, to ensure accurate scientific translations, and the recordings were played live with breaks for Q&A and group work.

Traditionally, at the end of the in-person training, participants are tasked with creating a quality manual for their laboratories. In the past, due to budget constraints, APHL had not been able to effectively follow-up with participants on development of the quality manuals. The cost savings from conducting virtual training enabled APHL to establish a post-training mentorship program, allowing participants to meet monthly with APHL consultants Kim Lewis, Frances Downes and Dave Mills to discuss the progress of their manuals and receive mentorship on the QSM activities in their laboratories. This mentorship program has been a tremendous success and would not have been financially possible had the training been conducted in person.



While there is a lot to consider when choosing whether to conduct a training in person or virtually, we learned that cost savings and learner flexibility can result in net positive outcomes for both facilitators and participants and should be considered when developing future training plans.

Establishing New Connections

In May 2020, Becton, Dickinson and Company (BD) approached APHL to help develop a virtual leadership training in partnership with the William Davidson Institute at the University of Michigan (WDI). BD recognized the need to continue providing trainings during the pandemic and wanted to utilize APHL's technical expertise and WDI's educational expertise to convert an in-person training to a virtual format. APHL's "Foundations of Laboratory Leadership Management" training was re-worked into an eight week virtual training, "Laboratory Leadership and Management Essentials." This training was disseminated using WDI's online ExtendEd platform, a proprietary learning management system designed for online adult learning programs.

Participants from across East Africa logged in each week to complete a pre-recorded session and weekly assignment. The pre-recorded sessions offered participants the flexibility to learn at their own speed and pause the recording when needed, thus accommodating different schedules and learning styles. At the end of each week, participants joined a weekly call with APHL staff members Clement Phiri and Edwin Ochieng to discuss the assignment and ask any questions. This gave participants the ability to fully digest the information in their own time and work on activities at their own pace, resulting in more thoughtful discussions during the weekly call.

Over the past year, APHL has faced numerous changes in the way it works due to the pandemic. While there is a lot to consider when choosing whether to conduct a training in person or virtually, we learned that cost savings and learner flexibility can result in net positive outcomes for both facilitators and participants and should be considered when developing future training plans. ■

The Role for NGS-based Technologies in a Post-Pandemic World

By **Prasanna Thwar**, PhD, director, Assay Development, Clear Labs



Illustration: Curtis Nishimura for Clear Labs

Next-generation sequencing (NGS)-based methods have existed for more than a decade, but their utility has been predominantly limited to research and applied life sciences. It has had limited use in clinical laboratories and is used more extensively by public health laboratories for foodborne outbreak investigations. Its adoption for other applications in public health laboratories has varied due to a number of challenges. The COVID-19 pandemic, however, has showcased how NGS is paramount to addressing a global biothreat.

First, metagenomic NGS helped identify SARS-CoV-2 as the pathogen responsible for COVID-19. Then, whole genome sequencing (WGS) of the viral isolate provided the exact genome sequence that led to the development of nucleic acid diagnostic tests and an mRNA vaccine. As the pandemic has evolved, WGS has become the go-to method for tracking transmission, resolving outbreaks, monitoring new variants, choosing clinical trial cohorts and even helping to inform quarantine measures.

Several hurdles have limited the widespread adoption of NGS technologies thus far—cost vs. value, workflow complexity, lack of proper standards and controls, and subsequent apprehension from regulatory bodies and payors. Some of these hurdles will continue to exist beyond the pandemic. For assisting public health laboratories to adopt the best platforms for their specific laboratories, here are 10 considerations that can help with successful implementation of NGS-based technologies in the post-pandemic world.

1. NGS workflows are often long, cumbersome and prone to human error. For successful widespread adoption, the entire workflow needs to be automated with preferably no human intervention, similar to commercial nucleic acid amplification tests (NAATs).
2. While partial, segmented solutions provide flexibility to customize or use different vendors, end-to-end integrated solutions should include hardware, consumables, reagent kits and all the workflow steps that enable adoption, reduce variability and lessen validation burden.
3. While existing tools for NGS analysis cater to general use cases, there is a critical need for software that is optimized for, and seamlessly integrated with, sequencing platforms.
4. If NGS is to be used on a regular basis for detecting pathogens, the time-to-result needs to be improved to generate results within an actionable timeframe.

5. To truly democratize NGS for clinical or surveillance applications, multiple options with different price points are needed to accommodate needs of laboratories with different sample throughputs.
6. NGS methods typically have higher analytical specificity than other NAATs. But, depending on the nature of the NGS workflow (targeted vs. non-targeted or unbiased), the analytical sensitivity could be a function of the method itself. This can be further impacted by complexity of the sample, choice of sequencing library preparation method, depth of sequencing, and read accuracy of the sequencing technology. Assay developers must design and optimize workflows based on the specific needs of the test.
7. While a metagenomic approach is ideal for the *de novo* identification of unknown pathogen(s) in a sample, there is a great risk of wasting the sequencing bandwidth on unwanted sequences and losing sensitivity to detect lower abundance pathogens. Targeted approaches such as 16s rRNA (for bacteria), ITS (for fungi) sequencing or multi-pathogen primer panels can be good alternatives providing higher sensitivity, especially if the pathogen composition can be narrowed down *a priori*.
8. In metagenomic applications, the sample preparation steps such as lysis and nucleic acid capture must be unbiased so that all groups of microbes (gram-positive or gram-negative bacteria, fungi, protozoa, other eukaryotes) are included in the downstream library preparation steps.
9. A significant hurdle to the clinical adoption of a metagenomic or a pan-pathogen sequencing approach is the difficulty in proper validation. Test developers should use microbial standards that are well-defined and accurately characterized, preferably from certified vendors, for benchmarking their assay performance. Since complex NGS workflows can have more failure modes, the test developer should also design appropriate assay and quality controls for troubleshooting and mitigating risks such as contamination and operator error.
10. While this is not a concern under normal circumstances, a test developer should be mindful of designing NGS assays such that critical reagents, enzymes and buffers can be sourced from alternate vendors, in times of severe global supply chain limitations. ■

Clear Labs is an APHL Gold Level Sustaining Member.

MEMBER EXCLUSIVE

The Public Health Pricing List

The Public Health Pricing List is a *members-only* listing of discounts and special offers that APHL negotiates with corporate partners.

You can get **special pricing for instruments, service agreements, equipment, testing supplies, PPE and more** from companies such as Bio-Rad, Luminex, Roche Diagnostics, QIAGEN, Promega, SCIEX and Waters.



Check out the savings!

Log in to APHL.org and visit MyAPHL
Your Resources > Member Resources > My APHL

This list is only available to the APHL member representatives and member associates who have been given membership rights under your lab's APHL membership.

For more information about the public health pricing list discount offerings, please contact Camille Walker, Manager, Corporate Relations, camille.walker@aphl.org.

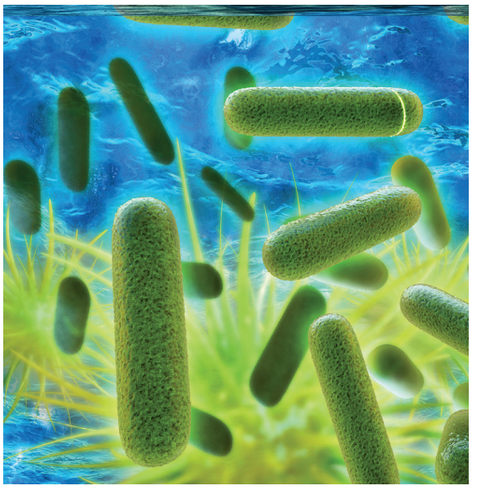
An Evaluation of Spartan Bioscience's Environmental *Legionella pneumophila* qPCR Field Test

By **Elizabeth Toure**, MPH, senior specialist, Respiratory Diseases

The rapid identification of environmental sources of *Legionella* linked to transmission during an outbreak is critical in limiting exposure and further illness. Infection with *Legionella* spp.—most commonly *L. pneumophila*—can lead to severe respiratory illnesses, including Legionnaires' disease. Quantitative polymerase chain reaction (qPCR) tests for use on environmental samples in the field offer more rapid detection of *Legionella* spp. for outbreak response. One such test, the Spartan Biosciences *L. pneumophila* test, reportedly quantifies the amount of live *L. pneumophila* in a water source in 45 minutes using their portable qPCR system, the Spartan Cube.

APHL collaborated with the US Centers for Disease Control and Prevention's (CDC's) Pneumonia Response and Surveillance Laboratory, the State Hygienic Laboratory at the University of Iowa, the Missouri State Public Health Laboratory and the New Jersey Public Health and Environmental Laboratories to evaluate Spartan's *L. pneumophila* qPCR test with the goal of assessing its performance and understanding its utility for public health responses. APHL provided each participating state laboratory a Spartan Cube, accompanying laptop with software, Spartan *L. pneumophila* test kits and on-site training.

The public health laboratories participated in a two-phased evaluation between March 2020 and March 2021. The first phase evaluated intra- and inter-laboratory enumeration variance using the Spartan *L. pneumophila* test with spiked sterile water samples of *L. pneumophila* serogroup 1, *L. pneumophila* serogroups 2–15, and a mixture of *L. pneumophila* serogroups. In the second phase, enumeration precision was evaluated as a factor of water sample holding times using spiked potable and non-potable water matrices to simulate on-site testing vs. transport back to the laboratory. A third phase in which the devices would be field tested was not completed due to the ongoing COVID-19 pandemic response.



Legionella

Results from this evaluation indicate that the Spartan *L. pneumophila* test performed as expected. Average results from the first phase agreed between PHLs within one log, displaying an improved level of precision over traditional spread plate culture enumeration methods that typically vary by about 1.5 logs.[1] Results from the second phase simulating a 48-hour hold time of the water samples were variable and further evaluation is needed. Approximately 13% of test runs had errors that required retesting the sample.

Based on this initial evaluation, participating state laboratories identified both benefits and drawbacks to incorporating the Spartan Cube into their *Legionella* testing workflow. The device's portability, small sample volume required, ease of use and speed of results make it a useful tool for screening water samples. The device could be of particular use for a mobile laboratory. Results could be used to rapidly provide appropriate guidance for suspected sources of *Legionella* transmission while awaiting final confirmation of results by culture.

Participating state laboratories reported that the limited throughput (one sample per 45 minutes) is a challenge for incorporating the Spartan Cube into their testing workflow—a facility-based outbreak may require concurrent testing of dozens of environmental samples. Other drawbacks include the error rate due to the delicate nature of the system, potential inhibition due to poor water quality, the waste generated by the single-use extraction kits (a recycling program is available, though shipping may be costly) and the high cost of the test kits relative to standard PCR reagents.

Spartan currently offers an *L. pneumophila* test, but they plan to release an *L. pneumophila* serogroup 1 test in the future, which may increase public health utility. Further evaluation of the Spartan Cube, including deploying the devices in the field and evaluating the upcoming *L. pneumophila* serogroup 1 test, is necessary to better understand the value of this technology for public health responses. ■

APHL neither endorses nor promotes any product mentioned in this article. At the time of publication, Spartan Biosciences was undergoing a business restructure; they continue to support their *Legionella* products during this time.

References

1. C. Lucas *et al.* (2011) "Accuracy and precision of *Legionella* isolation by US laboratories in the ELITE program pilot study." *Water Res* **45**:4428-4436.

US Virgin Islands Immunization Program Begins Vaccine Awareness Campaign

By **Monife Stout**, MA, territorial director, Immunization Program, US Virgin Islands Department of Health; **Tyler Wolford**, MS, manager, Emergency Preparedness and Response; and **Jill Sutton**, specialist, Crisis Response

In the United States, annual vaccines for children and adults may sound like a regular practice. However, limited access to healthcare or a lack of understanding of the importance of vaccine preventable diseases causes vaccination rates to be low. In the US and the rest of the world, a continual effort to raise vaccination awareness is key to keeping the population healthy.

Following hurricanes Harvey, Irma and Maria in 2017, APHL received a $16.7 million cooperative agreement by the US Centers for Disease Control and Prevention (CDC) Center for State, Tribal, Local and Territorial Support (CSTLTS) to provide technical assistance for public health response and recovery efforts within three jurisdictions—Houston, TX, Puerto Rico and the US Virgin Islands (USVI). A priority activity in USVI was to assist the jurisdiction in developing and procuring resources to improve vaccination awareness in the community.

In USVI, a campaign is currently underway to increase vaccine awareness and educate the public on the importance of immunizations. The campaign highlights how annual vaccines not only benefit individuals, but also have significant impacts on population health. Community outreach in USVI is focused on all recommended annual vaccinations for both children and adults, including, but not limited to, measles, mumps, rubella, influenza and, more recently, COVID-19. The ultimate goal is to encourage the public to include annual vaccinations as a part of their healthcare plan.

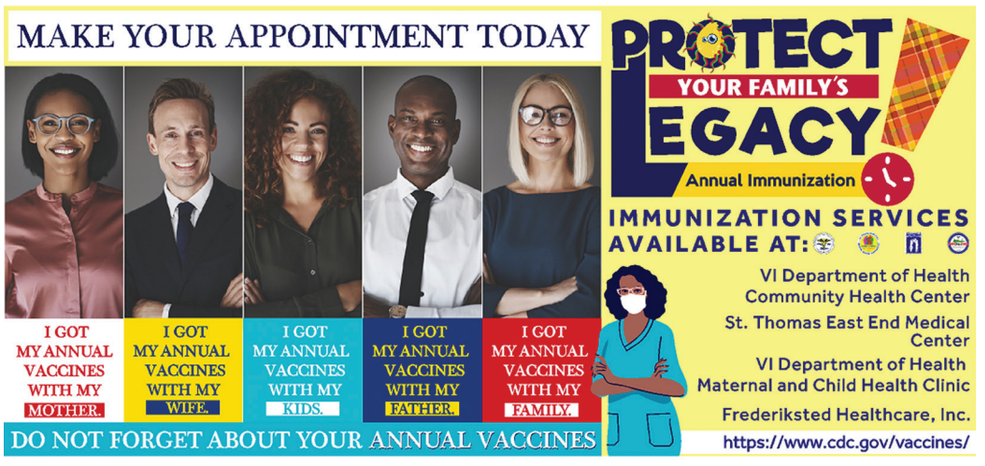
Community outreach is critical considering the impact of natural disasters and the COVID-19 pandemic on annual vaccination rates including economic shutdowns, school closures and travel restrictions. Since the pandemic began, most people were hesitant to visit healthcare facilities or private doctors' offices. In 2020, the USVI Immunization Program conducted surveys and convened focus groups with healthcare providers in an effort to determine optimal mitigation efforts to the growing problem. One result of the survey and focus groups indicated that a higher percentage of persons over 40 were less likely to maintain annual vaccinations. In USVI, unvaccinated children are allowed to attend school with an exemption. Receiving an exemption is a lengthy process and the USVI Immunization Program uses this time to educate parents on the importance of vaccines.

National Immunization Awareness Month (NIAM) is held annually in August to educate the public about the importance of vaccines for people of all ages and encourage the public to stay up to date on all recommended vaccines. Please visit CDC's NIAM site for more information.

Together, APHL and the USVI Immunization Program are improving vaccine awareness and education for the public by:

- Sharing immunization fact sheets at schools, healthcare facilities and community events.
- Running advertisements in local newspapers and radio stations.
- Distributing incentives, such as hand sanitizers and tote bags with the USVI Department of Health logo, to encourage annual influenza vaccines in children and adults.

By improving education and accessibility to vaccines, together we can eliminate the spread of preventable disease. ■



Flyers promoting vaccine awareness were developed and distributed locally in the US Virgin Islands.



In collaboration with the USVI Immunization Program, APHL developed newspaper ads for vaccine awareness.

Engaging Non-Traditional Partners to Build Biosafety Practices

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

When safely and correctly implemented, point-of-care (POC) tests can play an important role in helping to contain the COVID-19 pandemic. Such technologies are often implemented in non-traditional testing sites (NTTLs) that operate under a Centers for Medicare and Medicaid (CMS) Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate of Waiver. Since personnel at these facilities are usually non-laboratorians who can lack the experience to safely perform testing, these sites rely on public health laboratories for guidance and support. Below are three perspectives on how public health laboratories have engaged these sites across their jurisdictions.



Dallas County Health and Human Services

Mary Markarian, BSN, RN, Acute Communicable Disease Epidemiology Division

David Stringer, technical and general laboratory supervisor

Throughout the COVID-19 pandemic, Dallas County engaged long-term care facilities (LTCFs) to provide biosafety and infection control guidance. Dallas County processed over 30,000 COVID-19 specimens, of which approximately 10,000 specimens came from LTCFs within Dallas County alone. Early in the pandemic and before the surge began, the Dallas County Laboratory provided on-site consultation to LTCFs and the Dallas County Jail. Dallas County Laboratory staff toured facilities, discussed and implemented risk assessments, addressed engineering controls (or lack thereof) with LTCFs, and discussed standard procedures for operating the rapid antibody/antigen test. Instructions were also provided on packaging and shipping, since all LTCFs delivered their own samples to the laboratory. To aid facilities and ensure appropriate sample storage, shipping containers were provided by Dallas County.

Dallas County also stood up a LTCF Epidemiology Team, who provided PPE usage guidance to administrators and nurses, and discussed ways to optimize PPE and proper disinfection of surfaces. The daily guidance that the Dallas County LTCF Epidemiology Team provided to manage the COVID-19 outbreak was instrumental to LTCFs ensuring monitoring of over 150 LTCFs within Dallas County, including nursing homes and the Dallas County Jail. Of those facilities, approximately 100-120 LTCFs utilized the Dallas County Laboratory for COVID-19 testing. It is imperative LTCFs understand response strategies and who the local contacts are to obtain guidance. Public health must actively maintain the relationship established with LTCFs so when the next outbreak occurs, all stakeholders are on board.

DIGITAL EXTRA: **APHL in collaboration with the US Centers for Disease Control and Prevention (CDC), will continue to provide biosafety resources to PHLs for non-traditional laboratory outreach. For questions, please reach out to biosafety@aphl.org.**

Colorado Department of Public Health & Environment

Peter Davis, responsible official, BT coordinator and biosafety officer

Over the course of the pandemic, the Colorado Department of Public Health and Environment (CDPHE) Laboratory Services Division (LSD) has promoted cultures of safety directly and indirectly. CDPHE LSD developed guidance on many topics, including packaging and shipping, patient sampling, sampling product information, sample handling, risk assessment and large scale sampling plans. Each topic was used as an opportunity to build safety practices and guidelines into documents that did not directly reference safety. This unique opportunity made safety inherent to each procedure and did not require

further generation of individual safety documents or guidance. CDPHE LSD also promoted cultures of safety by directly providing comprehensive, standardized plans for its partners.

CDPHE LSD was the first site in the US to successfully conduct a mass sampling. With that achievement, CDPHE LSD collaborated with other institutions across the US and internationally to implement a standardized process for mass sampling in their localities, but with customized application for their individual sites. Mass sampling site plans not only included planning meetings between all participants, standardized plans and logistical coordination but also PPE, sampling kits, biohazard sample bags, cold transport materials and courier services for the site. It was observed, early on, that if the laboratory were to provide sampling kits, it should also be providing all supplemental materials to partners to ensure their safety during sample acquisition. Because the state of Colorado's supply of sampling kits was being received and distributed through the CDPHE LSD warehouse, CDPHE LSD also acquired large volumes of PPE to be distributed along with the sampling kits.

Michigan Department of Health and Human Services Bureau of Laboratories

Carrie Anglewicz, biosafety officer and state training coordinator

Biosafety outreach has been continuous in Michigan throughout the pandemic. Initially, the laboratory provided just-in-time training for packing and shipping of COVID-19 samples for new partners across the state. The tasks were broadened in October 2020 to provide a train-the-trainer class for over 100 Michigan National Guard members who were deployed to assist with antigen test training and distribution. Antigen test training has expanded and now includes non-laboratory healthcare partners and schools.

The training courses for the Michigan National Guard were held in person, and the rest of the trainings are held live virtually on Microsoft Teams. All trainings, which are tailored to non-laboratorians, include PPE usage, safe work practices, test performance, waste management and a competency component. Job aids such as YouTube videos that detail the process are also provided free to be utilized after the training. ■

Introducing

APHL™ 2021 encore

APHL™

Encore courses are a collection of 25 recorded sessions from the APHL Annual Conference. They feature experts in the field, discuss the latest in public health laboratory science and practice, and provide P.A.C.E.® credit.

Courses are available individually or can be purchased through discounted bundles. To browse these and other course offerings, visit the catalog at

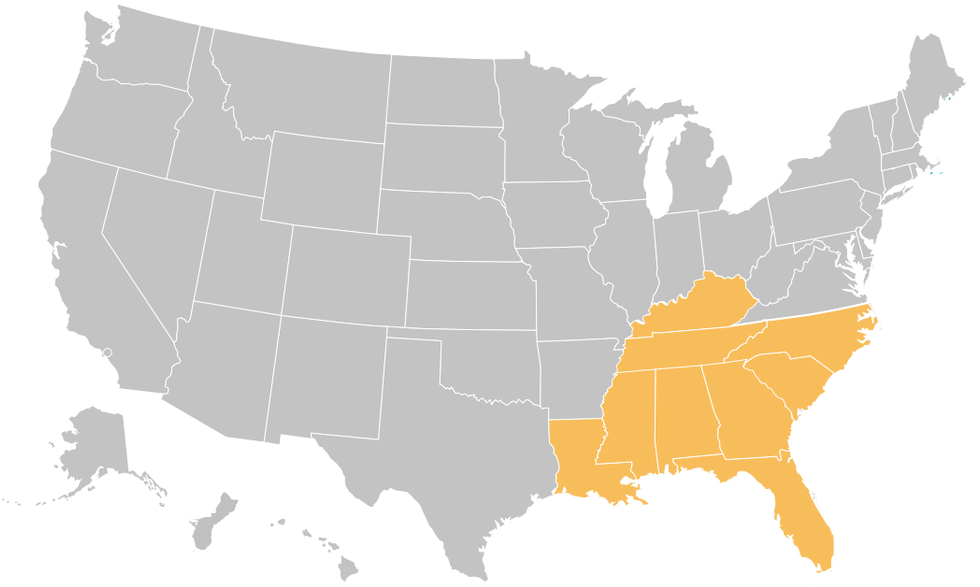
aphl.yourlrp.org

Southeast ColLABorators Convene Virtual Tabletop Exercise

By **Tina Su**, MPH, manager, Quality Systems and Analytics

In March and April 2021, the Southeast ColLABorators (SEC) regional consortium convened three, two-hour virtual tabletop exercise sessions to assess the coordination and communication between members of SEC and their continuity of operations plans (COOP). Averaging about 25-30 participants per session, SEC tackled the following hypothetical scenarios that would impact public health laboratory operations: a novel respiratory virus in Kentucky, an earthquake affecting Tennessee and South Carolina, and flooding in the Carolinas. An opening session to set the stage for the group on goals and expectations and a closing webinar to discuss major lessons learned bookended the three exercises. Staff from eight of the nine states representing the SEC participated, including its newest member, Louisiana.

Marie-Claire Rowlinson, PhD, D(ABMM), assistant laboratory director/CLIA laboratory director, Florida Department of Health Bureau of Public Health Laboratories and Matt Johnson, division director, Kentucky Division of Laboratory Services, served as the main facilitators for the series, and were supported by laboratory staff who developed the hypothetical exercise scenarios. When necessary, the group utilized APHL's Public Health Laboratory System Database (PHLSD)—an online, comprehensive test and equipment inventory built specifically for public health laboratories—to determine capabilities of consortium states and develop plans for unexpected events that cause a disruption in services. The participants also discussed surge capacity capability of SEC based on testing, personnel and equipment already on hand, and how to best strengthen partnerships and prepare for worst-case scenarios.



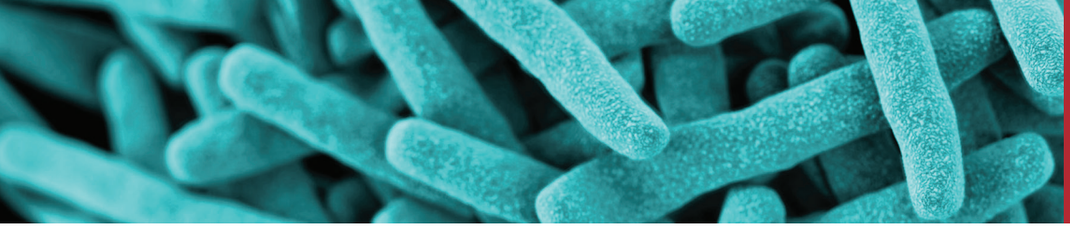
The Southeast ColLABorators regional consortium

As a result of completing the tabletop exercises, the SEC proposed several after-action activities, including:

1. Utilize the PHLSD as well as keep it as current as possible.
2. Review each laboratory's COOP, paying close attention to its strengths and weaknesses and consider many potential yet different scenarios (i.e., natural disaster, equipment unavailability, ransomware).
3. Discuss what is considered essential testing and how to manage information exchange and interoperability.
4. Establish memorandums of agreement/understanding when necessary.
5. Contact the state EMAC coordinator and Region IV Unified Planning Coalition to ensure that each PHL has the correct emergency contact information and possibly participate in state emergency meetings.
6. Add resources to APHL's SEC SharePoint site.
7. Revisit this tabletop exercise at a future SEC in-person meeting to discuss progress made as a consortium and address the opportunities for improvement identified during this event.

With the COVID-19 pandemic still impacting day-to-day operations, the series was an invaluable learning experience for the consortium and a timely review of their individual COOP.

"This exercise highlighted how we, as a regional consortium, can help each other; not just in times of need, but in preparing for potential times of need," Johnson reflected. "One outcome of this exercise that I think needs to be implemented is an annual assessment of each public health laboratory COOP, and this will be a goal for the SEC members. I feel that many public health laboratories focus on preparedness, but rarely review and update their COOP. Advocating for integration into your state's emergency management meetings is another big win, if completed. There is no better time than now to increase [our] visibility and to have our voices heard and needs delivered." ■



Updated Modules Available
www.aphl.org/TBTraining

Essentials for the Mycobacteriology Laboratory: Promoting Quality Practices

Free Training Series

The Association of Public Health Laboratories (APHL) is excited to announce our newly updated TB training modules *"Essentials for the Mycobacteriology Laboratory: Promoting Quality Practices"* are now available on APHL's Training Portal.

The series includes thirteen interactive modules designed for laboratorians at all levels of experience but are useful for anyone interested in learning more about TB testing including clinical staff, epidemiologists and TB Control staff. The updated modules include:

- Current best practices and information
- Updated recommendations, references and resources
- Certificates of completion are available for all modules
- 10 modules now eligible for continuing education credits (P.A.C.E.® credit)

APHL's Training Portal will house all of our TB training modules as well as the updated Etest® *Neisseria gonorrhoeae* module and additional training courses in Laboratory Ethics, Basic Laboratory Techniques, Laboratory Safety and Basic Laboratory Statistics. The portal tracks course progress and enables you to complete training on your own schedule and many of the courses offer P.A.C.E.® credit.

APHL Members Receive FREE Access

Select courses on the training portal are FREE to Institutional members (including all staff, not just member associates) and individual members.

Members should email phl.training@aphl.org to receive a coupon code for free access. For more information about the TB training modules contact taylor.bethea@aphl.org.

Access the series at www.aphl.org/TBTraining

Updated Modules

		P.A.C.E.® credits available
TB1	Overview of Tuberculosis	
TB2	Laboratory Safety: Work Practices for *Mycobacterium tuberculosis*	
TB3	Specimen Collection, Transport, Handling, and Processing	✓
TB4	AFB Smear Microscopy	✓
TB5	Overview of Mycobacterial Culture, Identification and Drug Susceptibility Testing	
TB6	Mycobacterial Culture	✓
TB7	Identification of Mycobacteria	✓
TB8	Drug Susceptibility Testing for MTB Complex	✓
TB9	Molecular Biology 101	✓
TB10	Molecular Detection and Identification of Mycobacteria	✓
TB11	Molecular Detection of Drug Resistance	✓
TB12	Landscape and Language of Molecular Diagnostics for TB Drug Resistance	✓
TB13	False-Positive Case Studies	✓

Modules are complemented by references and resources, and available in PDF format for use in laboratory training programs. Developed by APHL in collaboration with the Centers for Disease Control and Prevention (CDC).

Kansas Department of Agriculture Laboratory:
Protecting Animals, Humans and the Land They Share

By **Jody DeVoll**, MAT, writer

In a state where cattle outnumber people by a margin of two to one, the Kansas Department of Agriculture Laboratory (KDA Lab) plays a pivotal role, guarding the health of animals, humans and the land they share. This regulatory facility supports state inspection programs for dairy, foods, meat and poultry, pesticides, feeds, fertilizer and industrial hemp. It is accredited for a total of 50 methods. Additionally, the Kansas Metrology Laboratory provides calibration service for compliance with mass and volume standards.

The KDA Lab dates from 1953 when Kansas established a Seed and Chemical Laboratory in Topeka. The state added a Weights and Measures Laboratory in 1971, and the two laboratories were joined to form the KDA Lab in 1998.

Moving During a Pandemic: Not Recommended

To strengthen communication with agency headquarters and open opportunities for university collaboration, the KDA Lab relocated in March 2020 to a new, 20,000 square foot facility next to the Kansas Department of Agriculture headquarters in Manhattan. It opened its doors in mid-March—just as the World Health Organization declared the COVID-19 outbreak a pandemic. Laboratory staff, who had barely begun the complex process of moving into their new facility, had to go home and shelter-in-place for two weeks. Once back at the laboratory, they were able to bring the most critical instruments online within a couple of weeks, but innumerable deliveries, connections, validations and troubleshooting remained. It took six months to complete most of the work.



The Metrology Laboratory, however, did not open until May 2021 after a 15-month battle with environmental control. Metrology requires meticulous control of the laboratory environment, and Kansas weather ranges from hot and humid in the summer to cold and dry in the winter. After months of HVAC troubleshooting, the opening was a triumph.

And there was another hurdle. A year had passed since the laboratory's last ISO 17025 accreditation assessment and assessors were not working in the field due to the pandemic. Staff considered their options and proposed a virtual inspection. Using a tablet, they walked the assessor through the lab showing the setup of the instrumentation and demonstrating methods. Thanks to their ingenuity, laboratory accreditation was successfully renewed to ISO 17025.

Funding

The KDA Lab operates on a budget of $2.7 million, with $2.2 million from the state and $500,000 from the federal government. The Metrology Laboratory operates on a fee-for-service basis.

Director

Sally Flowers grew up surrounded by animals. There were chickens in the backyard and a small family "hobby" farm where she cared for her 4-H livestock. As she grew older, she did meat judging and Future Farmers of America livestock projects in addition to her work with 4-H. Given this background, it was natural that she would major in animal science at the University of Florida where she earned a bachelor's in animal science. She went to Penn State to earn a master's in animal science and began work on a doctorate when fate intervened. An advisor asked Flowers to take on a project in food science. She agreed and was soon captivated by microbiology. She decided to earn her PhD in that discipline.

With degrees in hand, Flowers was recruited to open a commercial food testing laboratory in Oklahoma City. Next came another degree in clinical laboratory science and a position leading quality control for a vaccine manufacturer. She then moved to the public sector as the director of the Nebraska Department of Agriculture Laboratory. When the directorship at the KDA Lab opened, Flowers pursued the position, which offered more regulatory testing programs and a brand-new facility.

Eight months after her arrival in Manhattan, she is thrilled with her new position. "I know this sounds a bit over-the-top but, honestly, I don't feel like I'm coming to work every day. I'm here to do something I love that gives me the ability to serve. And, really and truly, there is something new every day."

Staff

The laboratory is funded for 15 full-time staff. It is a young team due, in part, to the relocation. Vacated positions have been filled with new staff, and most applicants were new to the field. Flowers seeks opportunities for mentorship to advance the careers of her team when setting training priorities, making new hires and arranging for professional networking. She plans to supplement her full-time staff with students as part of a partnership with Kansas State University, which owns the land where the new laboratory was built. She plans to offer both part-time jobs and project-based internships for college credit.

Given the KDA Lab's broad portfolio, it helps to have versatile staff. Several microbiologists can assist in other sections of the laboratory because they



The Kansas Department of Agriculture Laboratory, which also houses the Kansas Metrology Laboratory. Photo: KDA Lab

have learned select chemistry methods on-the-job. What's more, seasonal fluctuations in testing allow certain staff to work in more than one area, for example, testing pesticides in the spring and summer and fertilizer in the fall and winter.

Services

The KDA Lab relies upon specialized laboratory sections to deliver its analytical services:

- **The Dairy Laboratory** works with the state's Dairy Inspection Program under the Pasteurized Milk Ordinance. The laboratory annually tests samples from each of the state's 228 dairy farms and all its dairy processors using official methods from FDA and the National Conference on Interstate Milk Shipments (NCIMS). Because Kansas has broad capability for analysis of dairy samples, the laboratory also tests samples of goat and camel milk for the State of Missouri. In addition to these testing services, the section's two FDA-certified Laboratory Evaluation Officers provide training and conduct onsite audits of dairy producers and plants to ensure that they perform testing, such as screening for antibiotics, correctly.
- **The Feed and Fertilizer Laboratory** combines year-round testing of livestock feeds and pet foods, with seasonal analyses of fertilizers. These analytical operations are combined because they use many of the same instruments. The laboratory verifies product label guarantees by analyzing the concentration of nutrients and/or medications in livestock feeds, pet foods and pet treats. The laboratory also analyzes grain ingredients and finished products to screen for aflatoxin and deoxynivalenol, which can cause serious health effects in humans and animals. Like feed testing, fertilizer testing is conducted to confirm that the nutrient content of a product is present at the amount indicated on the label.
- **The Pesticide Laboratory** supports investigations of pesticide drift complaints for residues and pesticide formulations to confirm label ingredients. This team can test a wide range of matrices for pesticide residues, even unusual matrices like honeybees.
- **The Food Microbiology Laboratory** routinely tests meat samples for pathogens and sometimes fat, protein and moisture content. This lab also conducts testing during foodborne outbreaks and testing of foods and environmental swabs associated with food safety inspections and federal surveillance programs.
- **The Metrology Laboratory** is the state's arbiter of mass and volume standards, providing services to other laboratories, government agencies, service companies and industries. In accordance with international and national metric standards, the laboratory calibrates mass standards, weight carts and test measures used to calibrate other weighing and measuring devices. Errors in measurement can have real consequences. A consumer could become ill if the contents of a medication were not measured precisely.



Feed and fertilizer samples await preparation by grinding prior to analysis. Photo: KDA Lab

- **The Industrial Hemp Program** assesses the level of THC in industrial hemp samples. If the THC level is below 0.3%, the crop is deemed industrial hemp and may be used in products ranging from CBD oil to building materials. Conversely, if the THC level is 0.3% or higher, the crop is legally deemed to be marijuana and is destroyed.

Achievements

Flowers cites two achievements from her brief tenure at the KDA Lab. She has rewritten job descriptions so that staff roles are well-defined and align with agency goals and operations. She has also shared the laboratory's long-term goals with staff to show them how their daily responsibilities contribute to these ends.

Challenges

Flowers considers succession planning to be her top challenge, and she aims to be proactive rather than reactive in addressing it. She pared down the APHL Knowledge Retention Tool for use in Nebraska and has shared the revised version with her Kansas staff. Flowers also is striving to keep position descriptions up to date and is revisiting the laboratory's continuity of operations plan to be better prepared for the next emergency.

In 2020, the COVID-19 pandemic temporarily reduced the laboratory's test volume because inspectors could not go into the field to collect samples for a brief period. Without analyses to perform staff could concentrate on setting up their new facility, enabling them to progress more rapidly.

Goals

Flowers aims to build strong partnerships with Kansas State University and to create a state laboratory consortium representing commercial, government and university labs. ■

APHL 2021 Award Winners



APHL is pleased to announce the winners 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. Awardees were honored on May 19, 2021 during a virtual ceremony.

The following awards were presented:

Lifetime Achievement Award

- **Dr. Peter A. Shult**, retired, Wisconsin State Laboratory of Hygiene

Gold Standard Award

- **David Boxrud**, Minnesota Department of Health

Silver Award

- **Shondra Johnson**, Missouri State Public Health Laboratory

On the Front Line Award

- **Dr. Beverly Metchock**, US Centers of Disease Control and Prevention

Emerging Leader Award

- **Drew C. Fayram**, State Hygienic Laboratory at the University of Iowa

Leadership in Biosafety and Biosecurity Award

- **Elizabeth Weirich**, US Centers of Disease Control and Prevention

Champion of the Public Health Laboratory Award

- **Dr. Anthony S. Fauci**, National Institute of Allergy and Infectious Disease

Presidential Award

- **Rob Stein**, National Public Radio
- **APHL staff**

Healthiest Laboratory Award

- **Kentucky Public Health Laboratory**

Thomas E. Maxson Education, Training and Workforce Development Award

- **Shannon Sharp** *(posthumous)*, formerly Michigan Department of Health and Human Services, Bureau of Laboratories

DIGITAL EXTRA: **Watch the awards presentation on APHL's Facebook page.**

September is Public Health Laboratory Appreciation Month — *Let's celebrate!*

#ThanksPHLabs **www.aphl.org/ThanksPHLabs**

At APHL, we're excited to celebrate all staff in public health laboratories — everyone from microbiologists to maintenance teams, from informaticians to information technology specialists and beyond deserves to be recognized.

Whether through newborn screening, environmental testing, foodborne illness outbreak detection, infectious disease testing, biological threat monitoring or so much more, public health laboratories are working hard to keep communities safe.

And even though that work often happens behind the scenes, we want to voice our appreciation as openly and loudly as possible! Because everyone working at public health laboratories deserves to be celebrated!

Be sure to follow and subscribe so you don't miss a thing!

- Follow APHL on Twitter, Instagram and LinkedIn
- Like APHL on Facebook
- Join our Facebook Group Off the Bench
- Subscribe to the APHL Blog and *Lab Culture* Podcast

Use and follow #ThanksPHLabs throughout September to join the conversation on social media!

Celebration Toolkit
We have other creative ideas for you to get the word out, give thanks, and engage staff and the public. All of our suggestions for laboratory leaders, staff, partners and community members can be found at **www.aphl.org/ThanksPHLabs**

Use our sample graphics and posts from the toolkit on your own social networks.

Microbe Masterpieces Contest — Cultivate Your Creativity!
Trillions of microbes co-exist in our world, yet they are invisible to the naked eye. Their variety and hidden beauty are things scientists can showcase.

Create an artwork of a microbe or microbial colony. Sketch, paint, sculpt, photograph — use ANY technique you like! Submit your masterpiece to PHLinfo@qiagen.com and win prizes. Look for more details during the month!

Sponsored by QIAGEN, APHL Diamond Level Sustaining Member



PublicHealthLabs @APHL APHL.org

APHL Fellows: Endings and Beginnings

By **Heather Roney**, MA, manager, Fellowships

APHL's graduating fellows were honored virtually at the APHL 2021 Annual Awards. Several new groups of fellows will begin assignments in member laboratories and at CDC in the summer and fall:

- Two new laboratories will host Antimicrobial Resistance Laboratory Fellows: the Virginia Division of Consolidated Laboratory Services and the State Laboratories Division of the Hawaii Department of Health. The six fellows recruited this year will work alongside experienced mentors on dedicated AR projects to detect and respond to emerging resistant pathogens.
- There will be seven Infectious Diseases Bioinformatics Fellows in the 2021-2022 class, who will be located in a mixture of CDC labs and state public health laboratories. For the first time, we have a fellow at a local laboratory.
- The Virginia Division of Consolidated Laboratory Services and the Tennessee Newborn Screening program will host two new Newborn Screening Bioinformatics and Data Analytics Fellows.
- Four new fellows will join the newly redesigned Infectious Diseases Laboratory Fellowship. Fellows will receive training in bench-level laboratory skills and methods and assist with high-priority infectious disease testing, surveillance and control measures. Fellows are placed in disease-specifics tracks including COVID-19, influenza and vaccine preventable diseases.

COVID-19 Response Fellows continue to provide essential support during the pandemic in their respective public health laboratories. Their numerous contributions include actively participating in critical laboratory activities and training events. Fellows are developing SOPs for wastewater testing of SARS-CoV-2, assisting with evaluations of rapid antigen tests for use in public schools, collaborating with health departments to provide guidance on point-of-care tests to state National Guard personnel, and training volunteers at COVID-19 testing events.

The COVID-19 Laboratory Associate Program will continue through June 2022. Over 30 associates will continue to assist with the pandemic response in their host laboratories. The program sparked an interest in careers in public health laboratory science for some participants. Katherine Akinyemi, a current fellow in the City of Milwaukee Health Department Laboratory says that following the program, "I hope to continue working in a public health laboratory and increasing my skills and knowledge in molecular science." Her colleague Addie Skillman shares her enthusiasm about the program. "Working [in the laboratory] has been an extremely rewarding experience that has illuminated the complexities of the functions of a public health laboratory. It's astonishing to think about the scope of work performed in this laboratory, and I'm grateful for the opportunity to be a part of the exceptional COVID-19 team here!"

We look forward to supporting these APHL fellows and associates and sharing their successes. ■

As a recipient of American Rescue Plan funding, APHL is recruiting for a new fellowship and internship initiative to begin in January 2022. Applications for host laboratories are now being accepted! Read more about the new program and the application process.

Presenter: *Mimi Precit, Centers for Disease Control and Prevention/ Washington State Public Health Laboratories, Shoreline, WA, Email: mimi.precit@doh.wa.gov*

A Semi-Automated Method to Analyze and Report Data from Neisseria gonorrheae Antimicrobial Susceptibility Testing

J. Weiner, M. Khubbar and S. Bhattacharyya, City of Milwaukee Health Department Laboratory, Milwaukee, WI

Introduction: The Milwaukee Health Department Laboratory (MHDL) uses the SoftLab/SoftMic platform from Soft Computer (SCC) for all LIS-based operations in the lab. The platform includes a front-end GUI interface for daily lab operations and a back-end database that can be queried via Microsoft Access. We designed a system of two MS Access queries coupled to three simple programs in the Python programming language that together accomplish the task of compiling, analyzing and validating lab test results for both NAATs, cultures and susceptibility testing for Neisseria gonorrheae monthly.

Methods: Queries were designed in MS Access to return results based on lab test type, order #, patient ID #, dates collected, received and finalized, clinic where sample was collected, result including MIC values for AST analysis if available and other internal quality measures. Results were exported to CSV format and used as input for Python programs. Python programs were designed

Interested in more poster abstracts from APHL 2021? Visit the digital edition of Lab Matters!

to cross-check test order mismatches and SoftMic Micro Reports were used to diagnose the cause of any mismatches discovered.

Results: Implementation of the present method eliminated lab side data entry errors for specimen and test counts, incorrect date entry and miscalculation of turnaround times. The method also flags about 5 test orders per month with incorrect clinic or collector codes. By pulling LIS values directly from the database using an SQL query, transcription errors are eliminated. Similarly, by coding in the formulae needed to compute metrics such as turnaround time in working days and tallies of infection by specimen site by clinic, calculation errors are eliminated once the code is validated.

Discussion: The task of compiling laboratory metrics was formerly done manually, requiring laboratorians to transcribe values from the LIS into an Excel spreadsheet, make calculations based on those values and report them on a separate form. This method introduced many sources of error, including data entry error, calculation errors and the propagation of errors through multiple calculations. The method also provided an unforeseen benefit by identifying test orders with incorrect clinic codes, which results in over- or underreporting of clinic metrics if left uncorrected. Overall, the method saves laboratorians' time, reduces errors and helps validate data integrity within the LIS.

Presenter: *Sanjib Bhattacharyya, PhD, City of Milwaukee Health Department Laboratory, Milwaukee, WI, Phone: 414.286.5702, Email: sbhatt@milwaukee.gov*

Pseudomonas aeruginosa Alters *Staphylococcus aureus* Sensitivity to Antibiotics

(complete abstract in Infectious Disease)

Identification of Carbapenem-Resistant Enterobacteriaceae from Rectal Swabs using the ABI 7500

M. Bashore, M. Soehnlen and K. Jones, Michigan Department of Health and Human Services, Lansing, MI

The emergence of Carbapenem-resistant Enterobacteriaceae (CRE) has become a serious concern for both clinicians and public health officials. These organisms confer antibiotic resistance through several mechanisms that often require advanced molecular methods to identify. The most common mechanism that is used to confer immunity is through the creation of extended-spectrum ß-lactamases (ESBLs). Common ESBLs that confer resistance of Carbapenems in the United States are Klebsiella pneumoniae carbapenemase (KPC), New Delhi metallo-beta-lactamase 1 (NDM-1), oxacillinase carbapenemase (Oxa) and Verona integron-encoded metallo-ß-lactamase (VIM). State public health laboratories, in correlation with the Centers for Disease Control and Prevention (CDC) have develop molecular methods that can be used to identify these enzymes. The issue of broad spectrum drug resistance in CRE organisms is especially concerning from a public health standpoint because, typically, healthy people do not acquire these

clinical laboratories due to lack of automated equipment and the use of phenotypic testing yielding low specificity of results. In order to combat this issue state public health laboratories were looked at to develop methods to transport, receive, test and report specimens from clinical sites to control the spread of these organisms. Molecular testing can be utilized to identify antimicrobial resistance genes and provide accurate and timely results for use by clinicians and infection control teams. The State of Michigan has developed methods to identify organisms containing resistance genes both from culture specimens submitted by clinical laboratories and clinical specimens in the form of rectal swabs submitted from patient care facilities. The State of Michigan, Bureau of Laboratories molecular method is based off of the use of the ABI 7500 real time PCR instrument with primers, probes and controls provided by the CDC. The validation of this method for identifying gene resistance using rectal swabs examined specimen conditions and types of swabs that could be used effectively for testing. The conditions were tested to examine acceptable specimen criteria for testing of real time clinical specimens. The Bureau of Laboratories provides collection materials to care centers and understanding which conditions affect the results of testing results is vital to ensure optimal testing. Resulting data demonstrated the effectiveness of the method at isolating DNA for multiple mechanisms of CRE under various conditions without sacrificing result quality.

Presenter: *Matthew Bashore, Michigan Department of Health and Human Services, Lansing, MI, Phone: 517.335.8373, Email: bashorem@michigan.gov*

Association of Public Health Laboratories
8515 Georgia Avenue
Suite 700
Silver Spring, MD 20910

APHL Sustaining Member Program

The following corporations partner with APHL to support the nation's public health laboratory system.

Diamond Partners

- Bio-Rad
- Cepheid
- Hologic — The Science of Sure
- PerkinElmer — For the Better
- QIAGEN
- Roche
- Ruvos
- ThermoFisher Scientific

Platinum Partners

- Abbott
- HDR
- illumina
- LightDeck Diagnostics
- Ortho Clinical Diagnostics
- PacBio
- Waters — The Science of What's Possible.

Gold Partners

- Clear Labs
- DiaSorin
- Horizon
- inductive health informatics
- Luminex
- National Jewish Health — Advanced Diagnostic Laboratories
- Promega
- SpeeDx — Diagnostics Defining Therapy
- Streck