

Division of Laboratory Systems



Empowering Healthcare: Bridging Gaps, Building Futures with the Clinical Laboratory Development Program

Rhiannon Clifton

October 24, 2023





Agenda

- Introduction
 - New and relevant OneLab™ Resources
 - Today's Presenter
- Empowering Healthcare: Bridging Gaps, Building Futures with the Clinical Laboratory Development Program
- Q&A
- Closing Announcements

♥ OneLab REACH™

Fundamentals of Communicating the Hazards of Laboratory Chemicals

This basic level course is designed for public health and clinical laboratory staff, safety professionals, and others who work in laboratories where hazardous chemicals are routinely used and stored. It introduces OSHA Standards and their role in providing information to laboratory staff.



NEW

P.A.C.E.[®] credit This course is 1 contact hour(s)



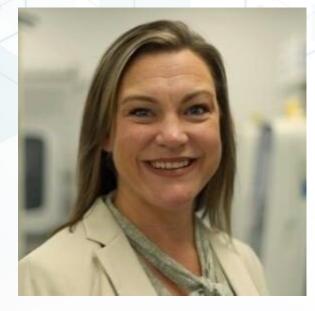
Division of Laboratory Systems

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Presenter



Rhiannon Clifton

Senior Director Clinical Laboratory Development Program University of Illinois System

CLINICAL LABORATORY DEVELOPMENT PROGRAM



BUILDING THE CLINICAL LABORATORY WORKFORCE OF TOMORROW

Agenda

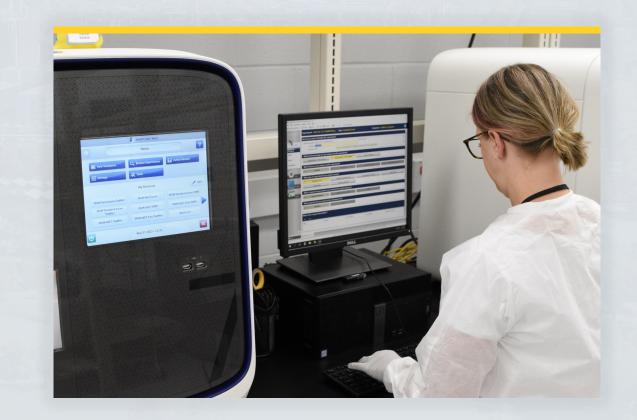
CLINICAL LABORATORY DEVELOPMENT PROGRAM



- 1. SHIELD Illinois pandemic response
- 2. What's next for public health emergency preparedness and response
- 3. CLDP Overview
- 4. How you can get involved

CLINICAL LABORATORY DEVELOPMENT PROGRAM









SHIELD Illinois is a nonprofit testing organization founded by the University of Illinois System in July 2020 to help prevent the spread of COVID-19 and save lives in Illinois.



Data as of April 24, 2023



Keys to SHIELD's success:



Ease, low cost of saliva collection & simplex PCR



Statewide logistics ensuring fast turnaround



Integrated technology platform



SHIELD

Organizational partnerships



Known, trusted brand: University of Illinois System



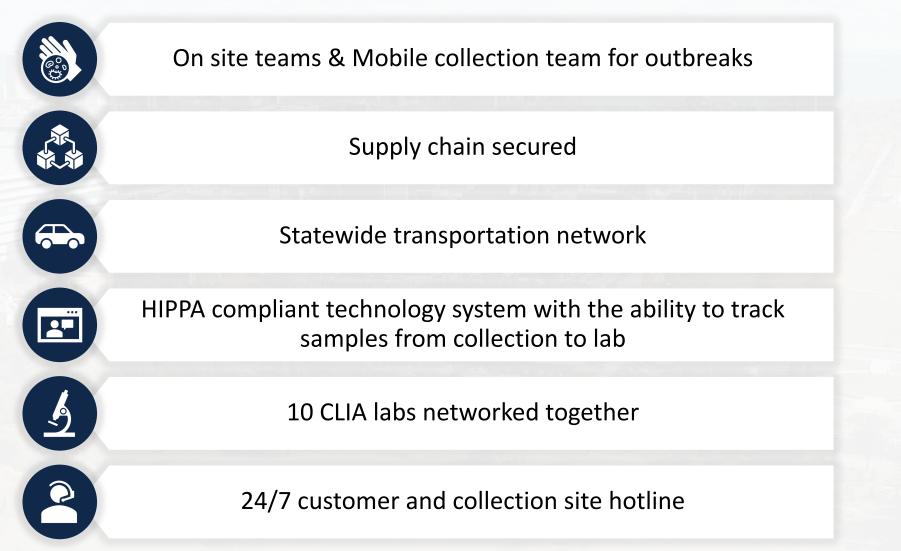




EQUITABLE STATE-WIDE PROGRAM	RESULTING TIME	CHANGING TESTING NEEDS
 Needed staff across the state Higher learning institutions K-12 schools Community testing Companies 	 Needed specimens to get to the labs efficiently Load balancing Efficient specimen collection 	 Outbreaks Variants Sequencing Wastewater testing



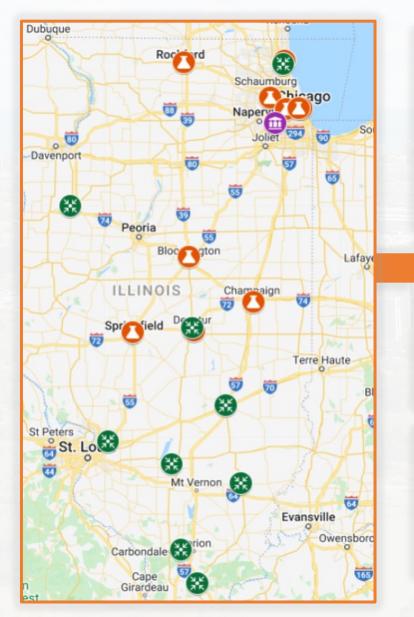
In less than 6 months:



SHIELD Illinois: Statewide Logistics Network

CLINICAL LABORATORY DEVELOPMENT PROGRAM





The key was a robust network of: SHIELD Illinois labs Funnel transportation sites That allowed testing coverage and sample transportation across the State





SHIELD Illinois: Addressing Staffing Shortages

CLINICAL LABORATORY DEVELOPMENT PROGRAM











Empowering employees

"SHIELD Illinois' commitment to professional development has been instrumental in empowering our employees to expand their skills and knowledge in critical areas such as leadership, team building, diversity, equity, inclusion, belonging, communication, health, and wellness. These newfound competencies have not only fueled their personal growth but have also paved the way for internal promotions and even post-SHIELD IL employment opportunities. Employees have repeatedly expressed their gratitude to me for the professional development opportunities offered by SHIELD IL and the University of Illinois"

A culture of learning

"By creating a culture of learning and continuous improvement in the program, Medical Laboratory Scientists can expand their knowledge base and learn new skills and techniques. This can help them develop their leadership skills and prepare them for advancement opportunities. When investing in professional development, we have the benefit of improving the quality of work, increasing productivity for the company, and boosting engagement and morale for the individual."

Ability to grow

"Professional development has allowed me the time to study molecular biology and other sciences at a slower pace to ensure I am getting a better grasp and comprehension on subjects."

Led to more opportunities

"As a Laboratory Manager, I have personally seen the impact that commitment to professional development has on our staff. It has led to more opportunities for career advancement and personal growth in a number of our laboratorians. They have been promoted to positions within the laboratory which incur more knowledge and responsibility within the field. Laboratory scientists who see their organization investing in their development are likely to be more satisfied with their jobs, leading to higher retention rates."



Journey from Lab Processor to Medical Lab Scientist

Anna Vardanyan is originally from Armenia. After completing her university studies, her scientific career in pharmaceutical research was put on hold when she immigrated to Prague, Czech Republic, in 2001 and later to Chicago, USA, in 2013. She completely changed careers, but Vardanyan never forgot her original dream of becoming a laboratory scientist. She found the opportunity to pursue her dream at SHIELD Illinois.

Anna joined SHIELD as a lab processor and was trained to receive, prepare, and process Covid-19 specimens. In addition to her hands-on training she received working in the SHIELD lab, Anna earned a Principles of Biochemistry certificate from Harvard University's online course. Her training as a processor allowed her to move up to a medical lab scientist.

"Anna is hardworking, humble, and kind...She was new to the working world of science when she came to SHIELD as a processor but through hard work and dedication, she is now a fantastic bench scientist," said Natalie Lubbers, Illinois Director of Lab Operations.

Vardanyan isn't shy about sharing her emotional attachment to her job and her co-workers. "There are two moments about SHIELD which I will never forget and they always bring tears to my eyes," she said. "First, when Amanda walked me through the lab on my first day at SHIELD. And second, the first time I was able to pipette as a Med Lab Scientist with Natalie by my side. It is hard for me to put it into words - the cascade of feelings of excitement, gratitude, and appreciation for all help and support to Natalie, Amanda, Kylie, and the entire team of SHIELD!"

Vardanyan's path to SHIELD Illinois almost reads like a Hollywood movie. "I think my story shows that sometimes old dreams [can] come true," she exclaims. "It is an amazing feeling!"



Anna Vardanyan Medical Lab Scientist



Journey from U.S. Air Force to Lead Medical Lab Scientist

The CLDP provides participants with the unique opportunity to accrue technical laboratory skills and sharpen their leadership skills in order to propel their careers to the next level. Kenyatta Selena Pierce's participation in the CLDP is a great example of this.

Kenyatta has served in the United States Air Force for over 13 years and is an aspiring physician with a bachelor's degree in health science. In 2021 during deployment she was prompted to return home to spend more time with her grandparents. Once back in Chicago, she joined the SHIELD Illinois team as a Laboratory scientist and began receiving foundational laboratory and leadership skills training.

Kenyatta immediately felt supported and welcomed into the fold by the CLDP team. As a lab scientist, she was given hands on instruction laboratory techniques, protocols, and best practices in the state-of-the-art SHIELD Illinois facilities. In addition to technical training, the CLDP provided opportunities for professional development DEI, Teamwork, and Leadership training. She quickly mastered lab techniques and flourished as both a team member and as a leader.

Upon her return from an unexpected deployment, she was encouraged to apply to a managerial position leading to her subsequent promotion to the role of Lead Medical Lab Scientist. This opportunity served as validation of the skills she acquired through the CLDP and her unwavering work ethic.

She holds deep gratitude towards the CLDP, powered by SHIELD Illinois, recognizing her journey through the CLDP has given her the tools to succeed in her future goals, "My goal is to get into medical school," shares Selena. "Applications are going to ask about any leadership experience, and I'll be able to say SHIELD offered me that opportunity."



Kenyatta Selena Pierce Medical Lab Scientist



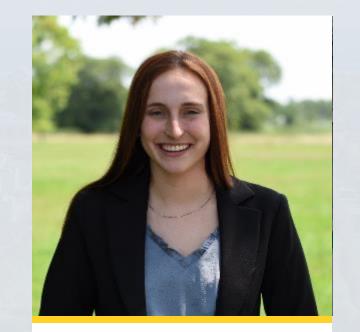
Journey from Sample Processor to Laboratory Manager at Loyola Medical

The CLDP (powered by SHIELD) program has proven to be a transformative experience for many participants, including one individual, Aubry Kusper, who expressed their gratitude for the program's impact on her career. Throughout her journey, Aubry Kusper acknowledges Natalie Lubbers, the Technical Supervisor and Director of Lab Ops at CLDP, for playing a pivotal role in shaping her early professional trajectory. Starting from an entry-level microbiology sample processor, Aubry progressed to become a Lead Molecular Technician, SHIELD Illinois General Supervisor, and eventually a Manager at Loyola Medical, thanks in part to the skills and opportunities provided by SHIELD and her former coworker, Natalie Lubbers.

"What distinguishes SHIELD is its unwavering commitment to nurturing the growth and development of its staff and trainees," explained Kusper. The CLDP program offers comprehensive training, hands-on experience and a strong foundation in laboratory practices, protocols, and state-of-the-art facilities. Aubry's exposure to a wide range of laboratory techniques and methodologies helped put her on the first track to success in her current role as the Manager of Molecular, HLA, and Flow Cytometry Laboratories at Loyola University in Maywood. "This exposure proved to be a game-changer, enabling me explore new avenues and roles within the field of molecular biology" stated Kusper.

Lubbers affirms the enduring impact of CLDP, noting that the expertise gained through the program continues to open doors for participants across diverse career paths. Kusper's remarkable achievements stand as a testament to her innate drive as well as the effectiveness of the SHIELD program in equipping highly skilled individuals to excel in real-world scenarios. Acquired skills in molecular laboratory techniques, quality control, and effective communication continue to serve as a solid foundation for the program's trainees, per Lubbers.

In Kusper's own words, she encapsulates the significance of her journey with SHIELD and the CLDP program, saying, "SHIELD has not only transformed my career but also my outlook on what is possible. It has empowered me to embrace new opportunities, achieve beyond my expectations, and make a lasting impact in the field of molecular biology. I will forever be grateful for the invaluable support and guidance I received from Natalie Lubbers and the entire SHIELD program."



Aubry Kusper Laboratory Manager

SHIELD Illinois: What's Next?



SHIELD ILLINOIS

SHIELD Illinois closed testing operations in June 2023

SHIELD Illinois worked with 4-year universities statewide to distribute PCR/related equipment for future viral response.

- 5-year maintenance coverage on the equipment.
- Keeps 30 high throughput PCR machines in the state and active.

SHIELD Illinois' lab at UIC will be the hub of a hub-andspoke model for public health emergency response.

In the meantime, focus on access to testing and workforce development.



CLINICAL LABORATORY DEVELOPMENT PROGRAM



The mission of the CLDP is to help solve the critical shortage of qualified clinical laboratory personnel. Our team will educate and train a diverse set of apprentices to make a fundamental impact across Illinois.

"There is a critical shortage of up to 25,000 medical laboratory professionals in the U.S., with only 337,800 practicing – or roughly one medical laboratory scientist per 1,000 people."

Forbes Magazine, April 28, 2022



Companies are affected by:

- Vacant positions
- Issues attracting and retaining qualified personnel
- Increased salary and training costs

Employees are affected by:

- Heavy workload
- Professional burnout
- Fewer training opportunities

Patients are affected by:

- Delays in assay turnaround time
- Errors in resulting
- Inconsistent lab results

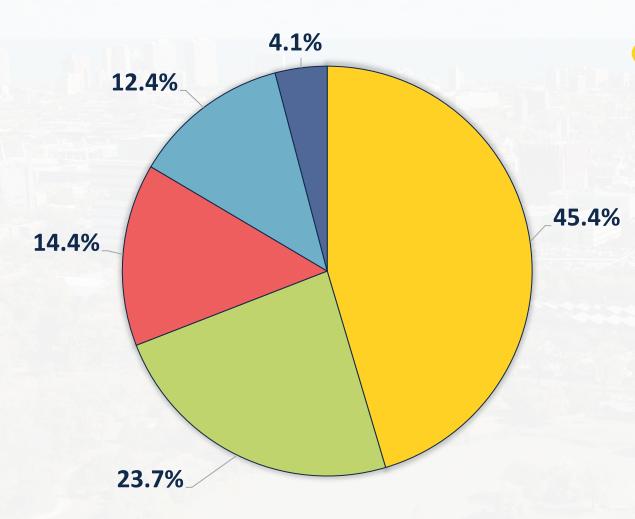
Time to fill vacant medical laboratory scientist positions in microbiology; ~67% of positions take more than 4 months to fill

Time	п	%
<1 mo	5	2.6
1–3 mo	61	31.4
4–6 mo	83	42.8
>6 mo	45	23.2

Leber et al, J. Clin. Microbiol. 2022



Obstacles in filling positions



□ Lack of qualified applicants (45.4%)

Lower compensation/benefits compared to other institutions (23.7%)

Difficult to get position re-approved (14.4%)

Lots of competition from other facilities/other lab sections within your institution (12.4%)

■ Location of the laboratory (4.1%)

Leber et al, J. Clin. Microbiol. 2022

Our Solution

Create a technical, hands-on training program to increase the supply of indispensable medical laboratory professionals.



About the Program

INICAL LABORATORY DEVELOPMENT PROGRAM



SHIELD Illinois established and managed 10 clinical laboratories, paving the way for the program.

- Hired a first-rate clinical laboratory leadership team •
- Formed an effective cohort
- Established policies, procedures, training, and competency ٠ modules

Training and assay processing will take place in our newly renovated, state-of-the-art \$3.5M facility on the campus of the University of Illinois Chicago.

- Molecular diagnostic processing ٠
- Next Generation Sequencing (NGS) capabilities ٠
- 5 Real-Time Polymerase Chain Reaction (PCR) instruments ٠
- BSL3, 24/7 capabilities





Laboratory Capabilities

CLINICAL LABORATORY DEVELOPMENT PROGRAM



X	E			
Competitive turnaround time	High throughput diagnostic molecular and Next Generation Sequencing laboratory	Low-cost testing	High-speed resulting with patient care in mind	Access to testing for underserved populations
The Clinical Laboratory Development Program is led by medical laboratory professionals with extensive experience in processing high-complexity assays in CAP and CLIA laboratories. Our qualified staff has a history of producing accurate and timely results through the SHIELD Illinois testing program.	The Clinical Laboratory Development Program has a robust test menu in noninvasive prenatal testing, gastrointestinal pathogens, respiratory pathogens, STIs, and microbial resistance markers.	The Clinical Laboratory Development Program is a University of Illinois System program. Because the University of Illinois System is a 501(c)(3), we operate on a cost-recovery basis and are often able to offer tests at lower costs.	We operate with patient care in mind. Clinical laboratory staffing shortages have led to delays in assay turnaround times, leaving patients waiting for critical results. Though we do not directly work with patients, our work directly impacts the patient.	The Clinical Laboratory Development Program's goal is to provide workforce experience opportunities and access to testing to underserved populations via partnerships with local health departments, FQHCs, and other non-profit organizations.

SHIELD ILLINOIS

This one-year Clinical technician apprenticeship is a training program focused on the tactical aspects of being a laboratory technician, preparing motivated individuals from underrepresented populations for full-time roles.

Molecular assay processing with handson and virtual realitybased laboratory training

Earn-and-learn model, where apprentices earn a full-time wage

First-rate instructors and mentors, cutting-edge curriculum, and software licenses

State-of-the-art facility and equipment



Apprentices do not pay program cost or fees and will receive compensation.

PROGRAM COST	LIVING WAGE	HOUSING
\$25,000/apprentice program cost is covered by CLDP and partners	Apprentices pay starts at \$18/hour for a 40-hour work- week for moderate complexity and \$20/hour for high complexity testing	UIC campus housing provided for apprentices residing outside of Chicagoland – scholarships provided by partners

During their time at UIC, apprentices will be trained on the tactical aspects of the laboratory work, as well as troubleshooting/QAQC monitoring, and essential skills.

1:1 TRAINER TO TRAINEE	LEADERSHIP DEVELOPMENT	WEEKLY ASSESSMENTS
Led by experienced clinical laboratory professionals	Mentorship through medical laboratory scientists with significant experience processing high- complexity assays in CAP and CLIA laboratories	Confirming skill and knowledge retention, identifying areas of improvement

Apprentices will arrive at partner labs ready to contribute.

Three cohorts per year starting: Jan, May, Sept



Each term, cohorts consisting of 40-50 apprentices will follow a rigorous oneyear training schedule with CLDP.

Partners will have a preference option to select and place apprentices from each cohort into their own programs, allowing apprentices to work toward the 52-week experience needed for an ASCP certification.



Three cohorts per year starting: Jan, May, Sept

The CLDP will prepare apprentices in the clinical laboratory foundations as well as essential skills.

TECHNICAL TRAINING MODULES

Laboratory Information System (LIS) Molecular Pipetting Molecular Sterility Techniques Molecular Assay and Workflow BSL2/3 Safety Skills

PROFESSIONAL DEVELOPMENT MODULES

Equity, Diversity and Inclusion Communication Critical Thinking Problem Solving Professionalism Teamwork



Apprentices will learn tactical aspects of lab technician work through hands-on high/moderate complexity infectious disease clinical testing using molecular techniques.

HIGH COMPLEXITY

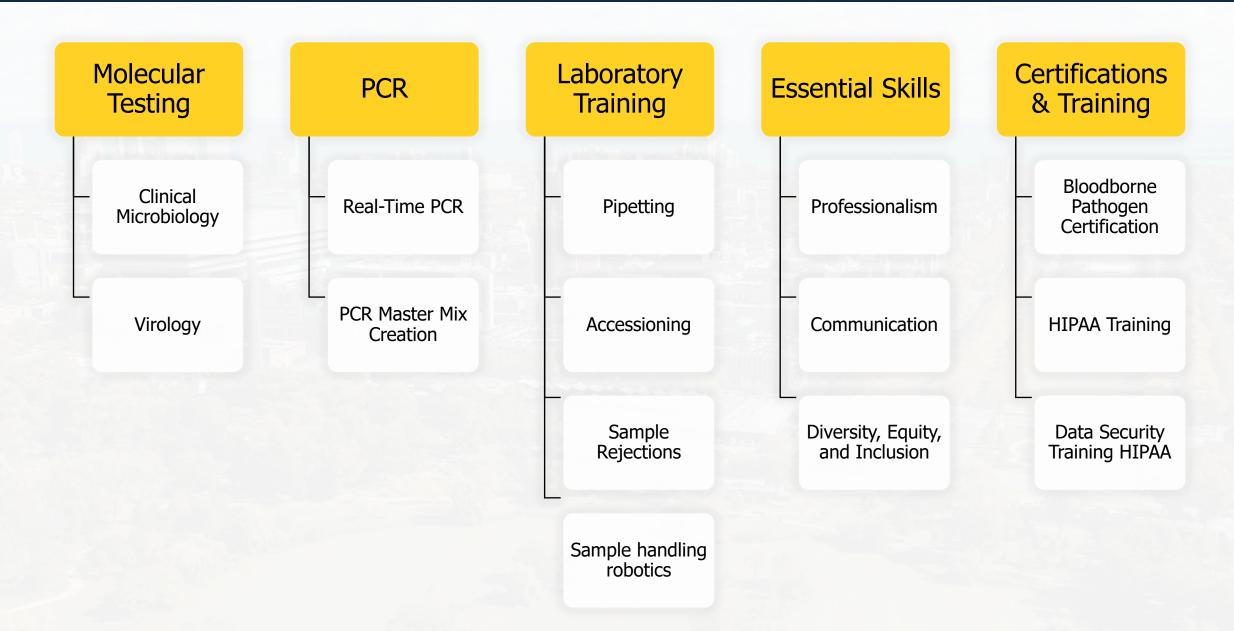
Molecular pipetting Complex reagent/master mix making Result interpretation (including troubleshooting) Analytical instrument maintenance Mechanistic training Verification of assay design training

MODERATE COMPLEXITY

Pipetting using a sample handler Simple reagent making/pipetting using automation Robotics instruments troubleshooting Robotics and other instrument maintenance/ cleaning Scanning and accessioning training Maintaining a molecular/PCR-clean environment PPE/safety training in a micro/molecular lab

CLINICAL LABORATORY DEVELOPMENT PROGRAM





Our Team



The CLDP is led by medical laboratory professionals with extensive experience in processing high-complexity assays in CAP and CLIA laboratories, developing employees, and training them in the latest methods and best practices of laboratory sciences.



Diverse laboratory leadership team are experts in their fields 1:1 apprentice to trainer ratio provides individualized feedback and mentorship Industry experts will also deliver course sessions in technical and non-technical topics

Leadership Team







Rhiannon Clifton, MBA Senior Director



Natalie Lubbers, BS Director of Lab Ops / Technical Supervisor



Heather Vatter, PhD CMS-116 Lab Director



Dawn Barding, MT Associate Director of Lab Ops / Technical Supervisor



Brianna Kelley, MBH Innovation Lab Manager

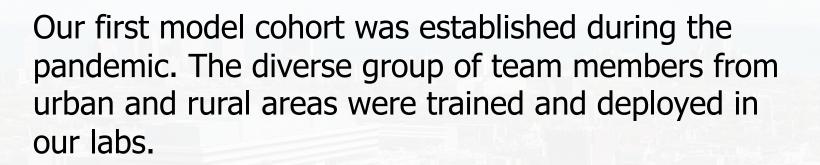


Kylie van Niekerk, BTech Diagnostic Lab Manager



Amanda Washington, MHA Lead of Lab Logistics

CLINICAL LABORATORY DEVELOPMENT PROGRAM

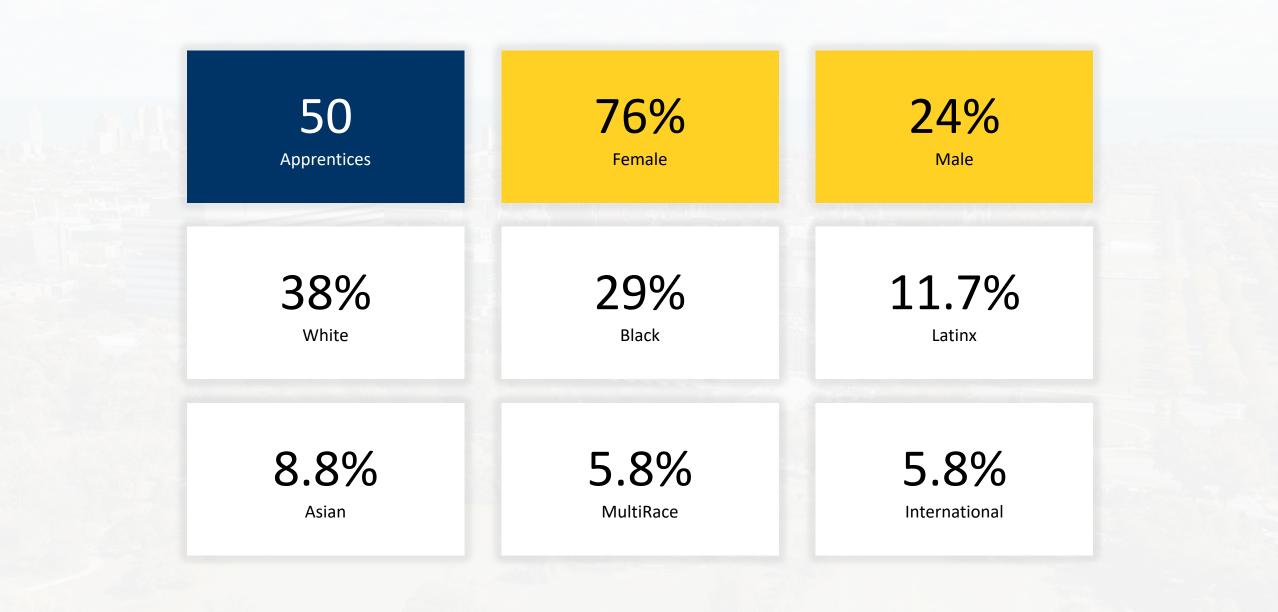


They were successfully trained in the following:

- High-complexity and moderate complexity testing experience
- Molecular testing in clinical microbiology/virology
- Real-time PCR, PCR master mix creation, PCR-clean lab environment, molecular assay-specific pipetting skills
- Accessioning, sample rejections, sample handling robotics
- Bloodborne pathogen certification, HIPAA training
- Professionalism and communication in a laboratory setting







How You Can Get Involved



We can't solve the staffing crisis alone. Partnerships are necessary to support this program, which allows us to produce a diverse and talented pool of medical laboratory professionals.

Access to skilled and diverse talent

Molecular assay processing

Support the direction of the program

Opportunity to co-develop assay training Together, our investment, both time and financial, will make this program successful.

FINANCIAL SUPPORT

Suggested sponsorship per apprentice: \$10,000 Housing scholarships per apprentice: \$6,000

Other sponsorship packages available upon request.

Partners will outsource molecular assays to the CLDP, which will process them as part of the curriculum. This CLIA-certified laboratory was designed as a highthroughput PCR and genomic sequencing facility and can adapt to support a wide variety of assays. Partners cover the assay processing costs.

ASSAY PROCESSING



	DIAGNOSTICS (EXAMPLES)		
INNOVATION (NGS)	GI PANEL	RESPIRATORY PANEL	STI PANEL
 Non-invasive prenatal testing (NIPT) from maternal blood SARS-CoV-2 from saliva SARS-CoV-2 from Wastewater Salmonella from isolate Salmonella from stool 	 <u>GI, Viruses</u>: Adenovirus 40/41, Norovirus GI/GII, Rotavirus A <u>GI, Bacteria</u>: Campylobacter, Clostridium difficile toxin A/B, Escherichia coli 0157, Enterotoxigenic E. coli (ETEC) LT/ST, Salmonella, Shiga-like Toxin producing E. coli (STEC) stx 1/stx 2, Shigella, Vibrio cholerae cholera toxin gene (ctx) <u>GI, Parasites</u>: Cryptosporidium, Entamoeba histolytica, Giardia (G. lamblia only, also known as G. intestinalis and G. duodenalis) and more 	 <u>Respiratory, Viral</u>: Influenza A Influenza A H1 Influenza A H3 Influenza B Respiratory Syncytial Virus A Respiratory Syncytial Virus B Parainfluenza virus 1 Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Human Bocavirus Human Metapneumovirus Rhinovirus/Enterovirus Adenovirus Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Coronavirus 229E <u>Respiratory, Bacteria</u>: Chlamydophila pneumoniae Mycoplasma pneumoniae 	 Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG)

If you are interested in outsourcing a particular molecular/NGS assay that isn't listed here, please let us know and we will propose pricing and TAT.





Questions?

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Clinical Laboratory Development Program

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Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov