Pennsylvania Department of Health Bureau of Laboratories mobilization of resources to respond to the COVID-19 pandemic



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CATEGORY: Epidemiology and Laboratory Capacity (ELC)

CATEGORY: Laboratory Data Exchange

To ensure quality and efficiency of laboratory services during the COVID-19 pandemic, the Pennsylvania Department of Health Bureau of Laboratories mobilized resources. They added personnel, managed biosafety, made technology upgrades, improved their facilities, adopted and validated new testing procedures, and formed new partnerships. All of this work ensures preparedness for future public health emergencies.

The "What"

The COVID-19 pandemic constitutes the world's largest public health crisis in the past century. As Pennsylvania's (PA) state public health laboratory, the PA Department of Health (DOH) Bureau of Laboratories (BOL) mobilized various resources to respond to the pandemic and ensure the quality and efficiency of laboratory services.

BOL has acted in the following areas:

Personnel Mobilization

With Epidemiology and Laboratory Capacity for the Prevention and Control of Emerging Infectious Diseases (ELC) funding, BOL hired contract employees by August 2020 and implemented second shift testing in November 2020. BOL also added support positions (i.e., bioinformatician, data scientist, laboratory information management system (LIMS) coordinator, on-site information technology position, quality officer, and wastewater testing staff), which greatly enhanced the workforce team.

BOL mobilized staff not only in the Division of Clinical Microbiology, but also other divisions' staff, retired staff, and volunteers to perform specimen receiving, demographic entry or testing. Staff were also trained to prepare viral transport media and build collection kits due to nationwide supply shortages. Staff were able to work overtime to perform COVID-19 testing, covering extended hours seven (7) days a week for ten (10) months.

BOL management modified standard work schedules and duties to prioritize COVID-19 response and avoided shutdowns or unacceptable turnaround times (TATs) for any other testing. All Division of Clinical Microbiology supervisors were trained to review and approve COVID-19 real-time reverse transcriptase polymerase chain reaction (RT-PCR) test results, which ensured timely reporting of test results.

Biosafety Management

The biosafety officer worked with the team closely and completed a pathogen, procedural, and site-specific biosafety risk assessment following the Centers for Disease Control and Prevention (CDC) COVID-19 guidance and using the Association of Public Health Laboratory (APHL) COVID-19 tools. They and the team incorporated safety practices into test standard operating procedures and provided safety training. They also made updates to the risk assessment, procedures, and training as more information on the disease became available.



<u>Partnerships</u>

BOL formed many partnerships and worked closely with internal and external partners during the response. PA collaborated with the PA Emergency Management Agency (PEMA) and PA COVID-19 Testing Team for logistical support. They also received technical support and participated in collaborations provided by regional and national partners such as regional support lab (Virginia Division of Consolidated Laboratory Services), APHL, State Public Health Bioinformatics Group, Technical Outreach and Assistance for States Team (TOAST), and CDC. With the federal funding support, they were able to attend training and meetings both in-person and online.

Facility Modifications

BOL used ELC funds to complete minor upgrades to laboratories to allow for the addition of new real-time PCR instruments and multiple nucleic acid extraction platforms. BOL reorganized existing space to provide additional lab work area and relocated instruments and equipment to centralize specimen extraction, testing, and storage.

In addition, BOL acquired office space after other state agency staff transitioned to work-from-home and renovated space to create a new breakroom and offices. In the meantime, BOL converted a large employee

Information Technology (IT) and LIMS Upgrades and Support

Within the first three months of the pandemic, the BOL IT team automated demographic data entry from mass testing sites and implemented ingestion of the data into the LIMS. BOL went live on the laboratory web portal (LWP) in October 2020, enabling electronic test ordering and results reporting using the APHL Informatics Messaging Services (AIMS) platform. The expanded instrument interfaces significantly reduced manual results entry into the LIMS and enhanced the ability of the LIMS to ingest the data electronically.

BOL also implemented HL7 messaging to report influenza data from the LIMS to PA-NEDSS (National Electronic Disease Surveillance System) and PHLIP (Public Health Lab Interoperability Project). Furthermore, BOL procured inventory management software is currently implementing instrument, specimen, supplies, and visitor tracking. breakroom into a laboratory space to house a large, fully automated extraction and PCR system.

Test Procedure Adoption and Validation

BOL was the first lab in Pennsylvania to perform RT-PCR to detect SARS-CoV-2 by using CDC protocols and Applied Biosystems 7500 Fast Dx thermocyclers. Manual extraction was later automated utilizing multiple nucleic acid extraction systems such as Biomerieux NucliSENS® easyMAG®, Roche MagNA Pure 96, Qiagen EZ1 Advanced XL, and ThermoFisher KingFisher TM Flex to meet the testing demand and to reduce dependence on the availability of supplies or services from individual manufacturers.

Installation of a Roche cobas ® 8800 system with a direct instrument interface to LIMS further automated RT-PCR testing through this high-throughput system. BOL also performed serology testing using Euroimmun's SARS-CoV-2 IgG ELISA kit on the Dynex DSX ® platform.

SARS-CoV-2 variants circulation in Pennsylvania was detected by whole genome sequencing started in April 2021 using Illumina's MiSeq[™] and Agena Bioscience MassARRAY® system. BOL expanded the Bioinformatics for SARS-CoV-2 sequence analysis and update in the National Database and GISAID.





The "So What"

Mobilization of resources requires significant collaboration and teamwork among internal and external partners. The successes achieved and lessons learned are invaluable in preparedness for and response to future public health crises or emergencies. Continuing to build infrastructure that did not previously exist is essential for the enhancement of future preparedness. Rapid response to increasing test capabilities and capacities is a critical role of the public health laboratory. For example, the median turnaround time for COVID-19 testing is less than one day for the past three years at BOL, which is greatly helpful for case management and disease control.

Streamlined cross-training increased the number of testing and data entry personnel across the division and prepared the lab for future emergency, surge, and outbreak response.

The "Now What"

BOL is expanding the Roche cobas ® 8800 system to create a lab-developed test to detect Candida auris colonization as well as Food and Drug Administration (FDA)-cleared testing for Chlamydia trachomatis and Neisseria gonorrhoeae. Lab instruments are being configured and interfaced with the LIMS. DOH is expanding the network infrastructure to the growing demand for bandwidth as more and more solutions are procured and implemented over the cloud. DOH modernized IT by partnering with Microsoft to implement Enterprise cloud implementation, thus enabling communication with remote partners and vendors. Work is underway to interface the current LIMS with the LWP. Expanding all tests to automated electronic test orders and reporting systems. BOL continues to evaluate the status of the current facility and make limited upgrades to improve testing capabilities. In addition, BOL is working with other state agencies to complete the design and construction of a new joint laboratory facility that will host public health, environmental, food, and forensic testing laboratories. The lab and IT newly built infrastructure would be compromised and impact laboratory public health surveillance and response activities beyond COVID-19. The established capabilities and capacities would be at risk if longterm sustainable funding is not available.

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