Session II: Defining the Current Laboratory Systems, Components, and Stakeholders

Requested Focus: Commercial, independent, and academic laboratory systems; roles and responsibilities for private labs in surveillance, early detection, surge, response

Susan Van Meter
President
American Clinical Laboratory Association

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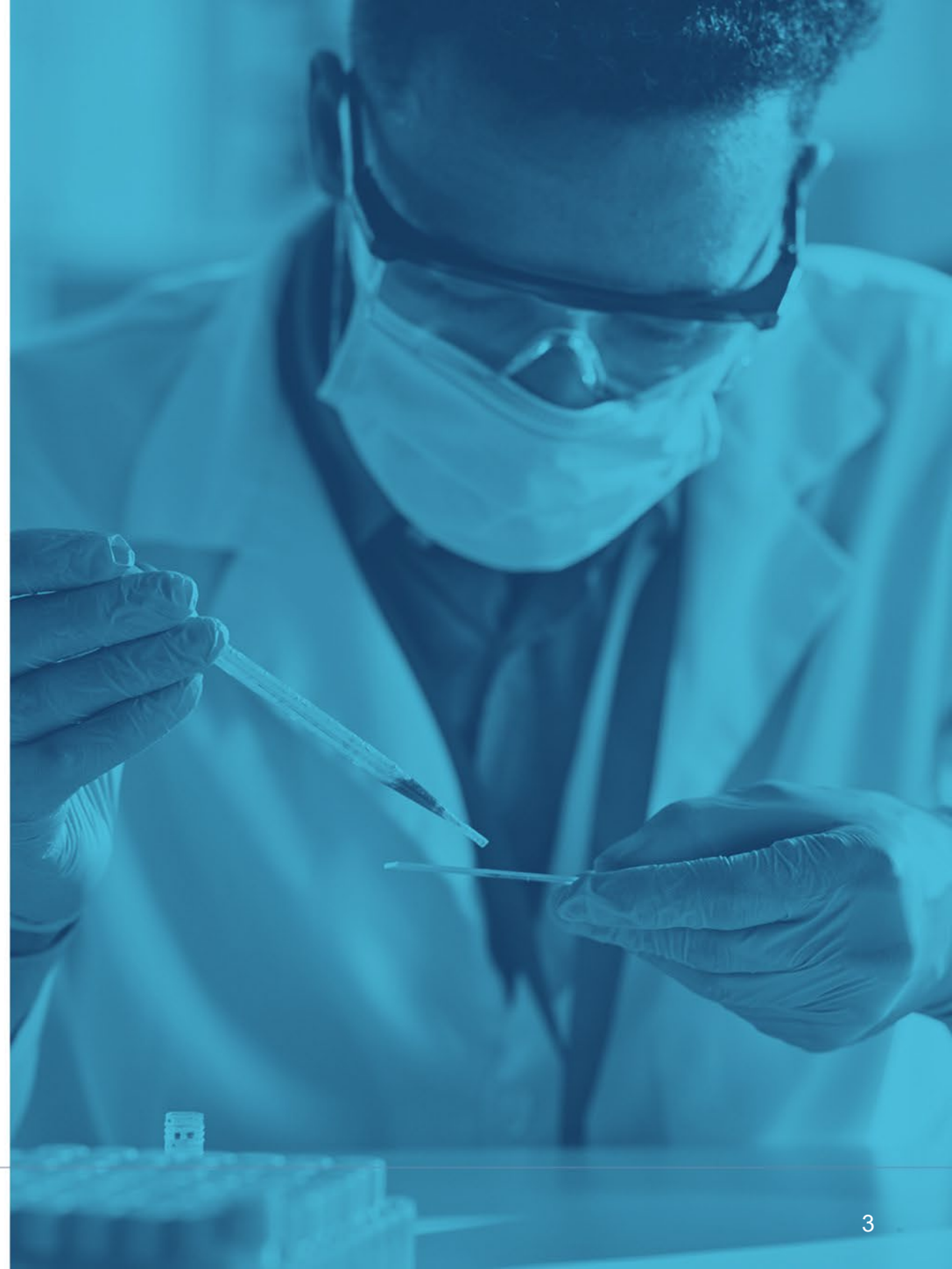
Overview of Commercial Clinical Laboratories

- **Commercial laboratories perform laboratory services** on clinical patient samples and can be owned and operated either independently or as part of a healthcare provider or system (i.e., hospital, physician office, etc.)
  - **Independent laboratories** operate independently from a healthcare provider, such as a hospital system, and perform moderate-to-high complexity testing ranging from routine to specialized tests. These laboratories serve a broad set of providers and communities and often have national reach. They also develop, commercialize, and offer cutting-edge tests that improve patient care.
  - **Hospital laboratories** are owned and operated by the hospital or health system and perform moderate-to-high complexity testing. They typically serve the hospital system's inpatients and outpatients but may also serve other providers in the local or regional community through what are referred to as "outreach services." This also includes academic medical center laboratories, which often serve patient care, research, physician training, and test development functions.
  - **Physician office laboratories** are housed within physician offices and typically run either CLIA-waived or moderate complexity testing, serving a physician practice/group or the local community. They do not create or manufacture tests.
  - There are always exceptions and crossover, such as hospital laboratories that are operated by an independent laboratory company.

Economic Impact of Clinical Laboratories in the U.S.

WAGES	ECONOMIC IMPACT	EMPLOYMENT
$25.82 billion	**$51.14 billion**	**299,860 Jobs**
Clinical laboratories pay $25.82 billion in employee wages across the country each year. This equals an average wage of $86,100, which is about 88% higher than the national median wage.	Nationally, 55,031 clinical laboratories have a direct economic impact of $51.14 billion and a total economic impact of $118.74 billion when supplier and induced effects are included.	Clinical laboratories provide more than 299,860 high quality jobs across the U.S. and are responsible for another 352,475 related jobs.



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Commercial Laboratories: Ordering to Results

Commercial laboratories face a myriad of reporting requirements from state, county, city, and territory health agencies, including for demographic data laboratories do not hold.

Ordering, sample collection and transport

- Clinician workflow to order testing services by commercial laboratories generally efficient and well understood.
- Patient sample collection can be performed in commercial laboratory patient service centers, clinics, physician offices, hospitals, pharmacies, or other health care sites.
- Large commercial laboratories employ sophisticated logistical systems to transport samples to laboratories across the country.

Laboratory services

- Laboratory professionals and pathologists prepare and analyze samples.
- Laboratories utilize laboratory developed tests (LDTs) and tests developed and sold by manufacturers.
- Assist clinicians in assessing test results.
- Commercial laboratories have the capacity to develop and run testing at scale.

Results reporting

- Laboratories provide results to:
  - patients and ordering clinicians
  - public health authorities for certain diseases and conditions in times of non-emergency, and for the pathogen of concern during a public health emergency.

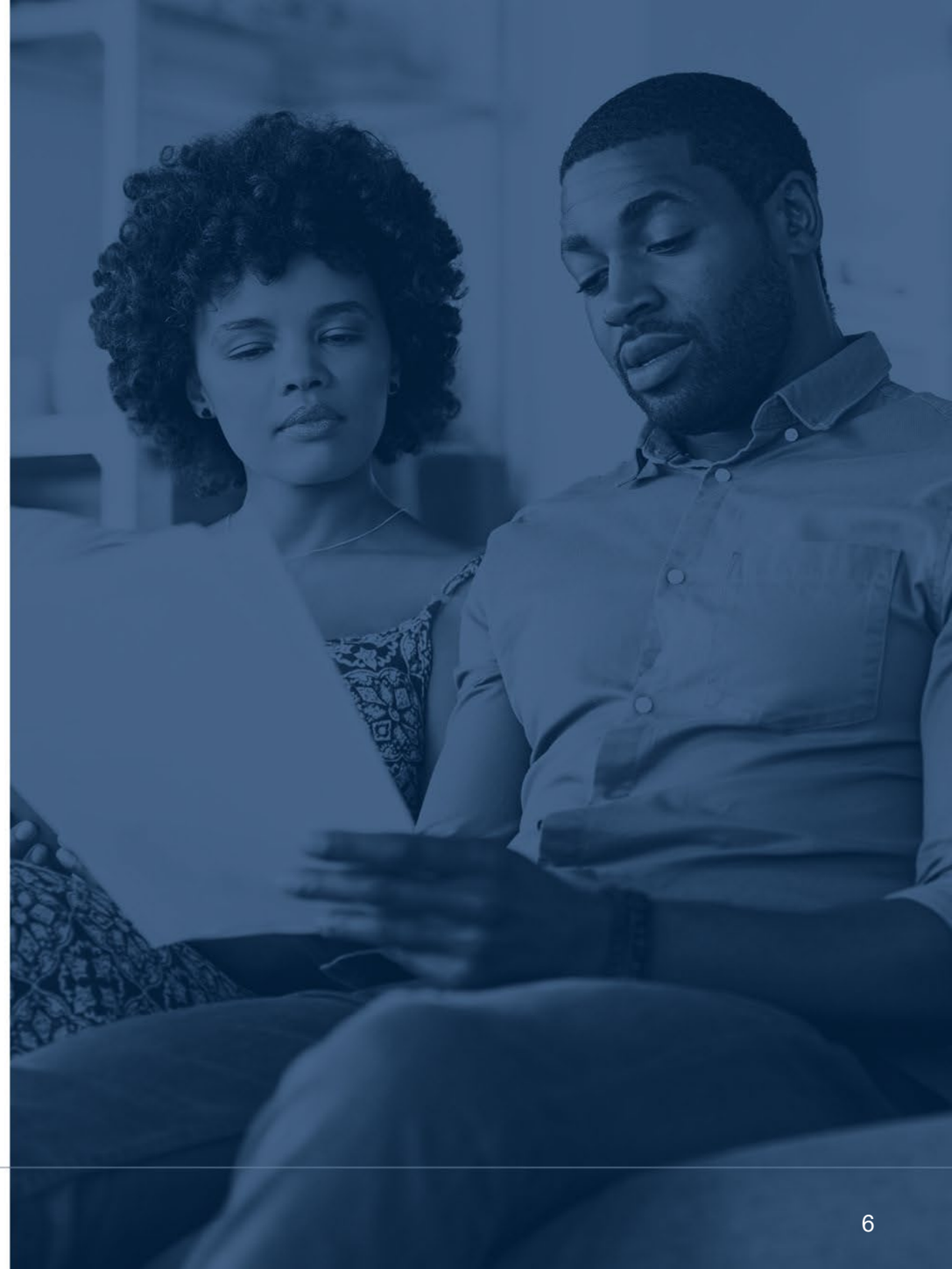
Oversight of Laboratories

- **The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA), and application of state laws.**
- The objective of the CLIA program is to ensure quality laboratory testing, providing oversight of laboratory operations and analytical validity of testing.
- Under CLIA, laboratories are certified to perform high-complexity, moderate-complexity, and/or “CLIA waived” tests.
- Among other requirements, CLIA requires laboratories to maintain adequate quality control and quality assurance programs to assure the “validity and reliability” of the tests and “the proper collection, transportation, and storage of specimens and the reporting of results.”
- All ACLA members are high-complexity CLIA laboratories accredited by the College of American Pathologists.
- **Center for Disease Control and Prevention (CDC)** advises CMS on CLIA.
- Some clinical laboratories will bring tests through the Food and Drug Administration (FDA) in times of non-emergency. **During Public Health Emergencies, clinical laboratories comply with the FDA’s requirements for Emergency Use Authorization.**

Laboratory Reimbursement & Guidelines

To ensure development of testing services, capacity for testing, and patient access to testing services, laboratories depend upon:

- Accurate **coding** for testing services to enable billing to public and private insurers;
- Broad **coverage** for testing services, by public and private payers;
- Responsible **payment** by public and private payers to reimburse laboratories for testing services (costs include sample collection, transport, analysis, results reporting, research & development, maintenance of capacity);
- Up-to-date clinical evidence and **guidelines** to inform clinician ordering.



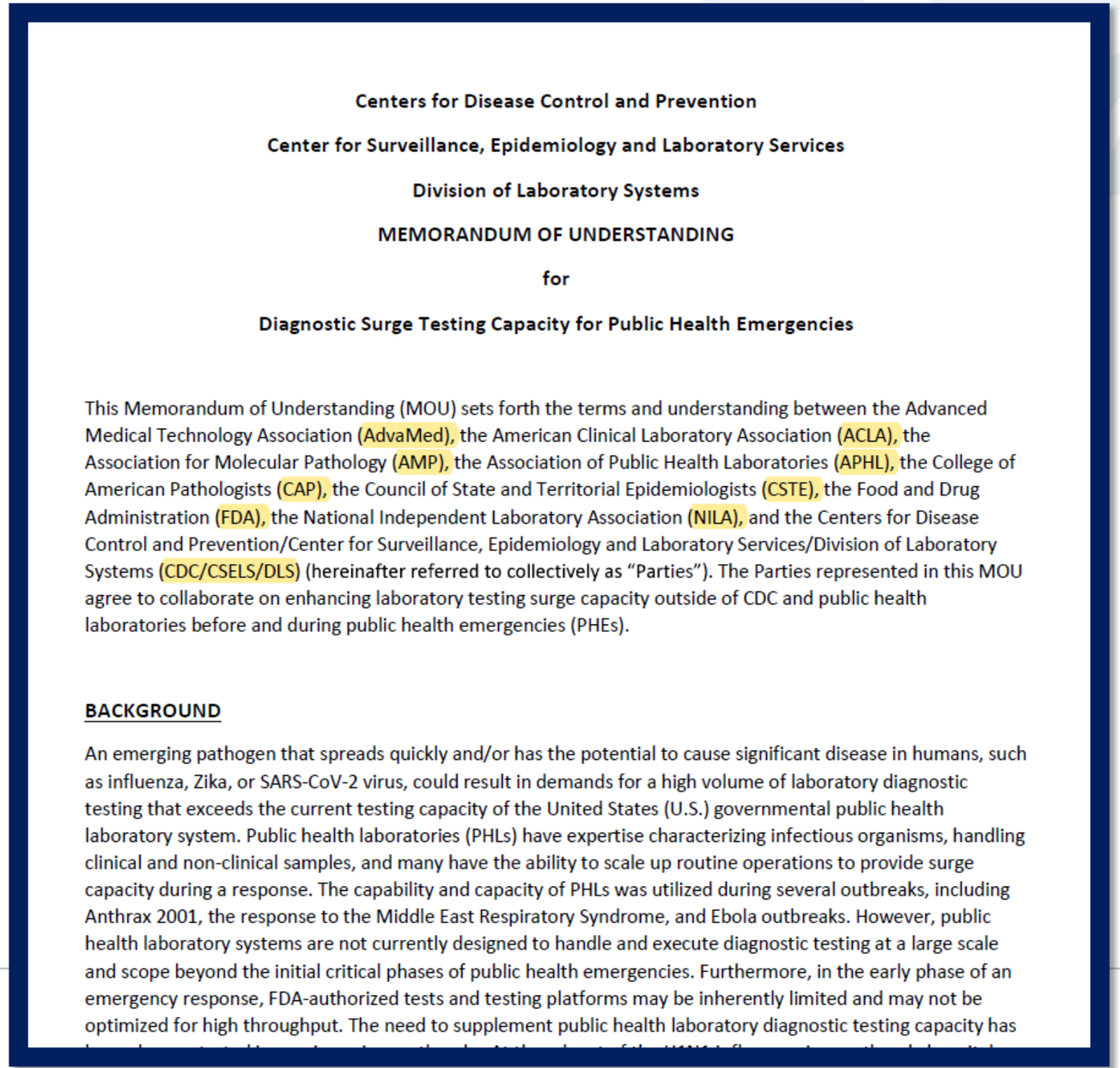
Medicare Payment Reductions Create Lack of Predictability for Laboratories

Medicare payment is determined under the Clinical Laboratory Fee Schedule (CLFS).

- Persistent Medicare payment cuts undermine the clinical laboratory system.
  - ~$4 billion cut since 2017 (total CLFS is ~$9b annually)
- Laboratories face up to a 15% cut to ~800 tests under the Medicare CLFS on January 1, 2024, absent congressional intervention.
- Industry has urged Congress to pass bipartisan legislation to smooth scheduled reductions and improve underlying payment determination methods.
  - Saving Access to Laboratory Services Act (introduction scheduled for March 28)
- Predictability in reimbursement is critical to laboratories making determinations on response efforts.

Surveillance, early detection, surge response

- Engagement with public and private entities on surveillance and early detection
  - *See CDC MOU on Surge Testing Capacity*
- Surge response: experience with COVID-19 and Mpox reinforce necessity of public-private collaboration for early and robust response
- Commercial laboratories are essential to scaling of testing capacity.
- During a response, laboratories are striving to engage with USG (i.e., HHS TCG, CDC, CMS, FDA, WH; at times FEMA, DoD, ASPR, HRSA) and with state, city, territory, tribal, public health agencies, providers, governments.



Centers for Disease Control and Prevention

Center for Surveillance, Epidemiology and Laboratory Services

Division of Laboratory Systems

MEMORANDUM OF UNDERSTANDING

for

Diagnostic Surge Testing Capacity for Public Health Emergencies

This Memorandum of Understanding (MOU) sets forth the terms and understanding between the Advanced Medical Technology Association (AdvaMed), the American Clinical Laboratory Association (ACLA), the Association for Molecular Pathology (AMP), the Association of Public Health Laboratories (APHL), the College of American Pathologists (CAP), the Council of State and Territorial Epidemiologists (CSTE), the Food and Drug Administration (FDA), the National Independent Laboratory Association (NILA), and the Centers for Disease Control and Prevention/Center for Surveillance, Epidemiology and Laboratory Services/Division of Laboratory Systems (CDC/CSELS/DLS) (hereinafter referred to collectively as "Parties"). The Parties represented in this MOU agree to collaborate on enhancing laboratory testing surge capacity outside of CDC and public health laboratories before and during public health emergencies (PHEs).

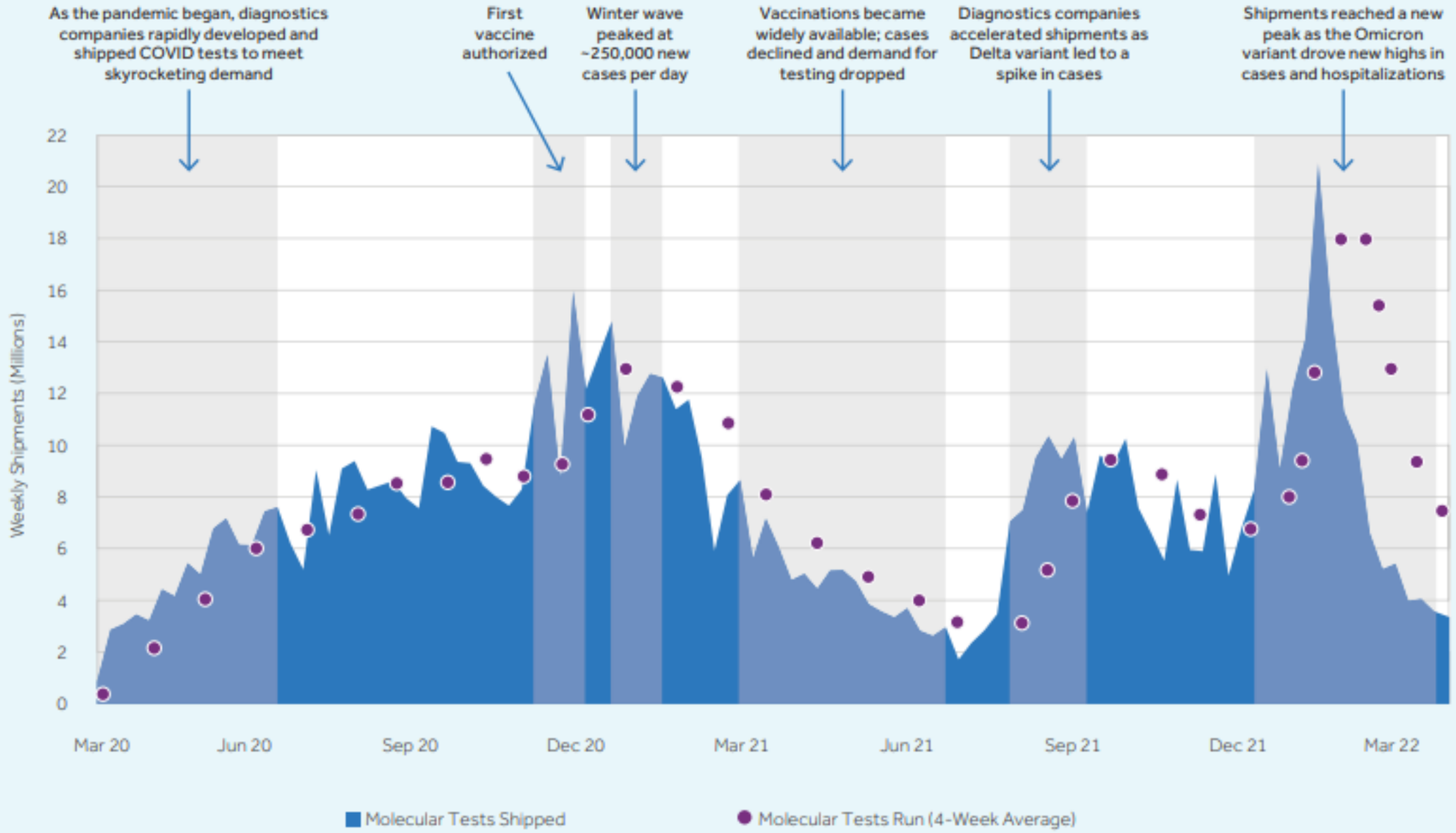
BACKGROUND

An emerging pathogen that spreads quickly and/or has the potential to cause significant disease in humans, such as influenza, Zika, or SARS-CoV-2 virus, could result in demands for a high volume of laboratory diagnostic testing that exceeds the current testing capacity of the United States (U.S.) governmental public health laboratory system. Public health laboratories (PHLs) have expertise characterizing infectious organisms, handling clinical and non-clinical samples, and many have the ability to scale up routine operations to provide surge capacity during a response. The capability and capacity of PHLs was utilized during several outbreaks, including Anthrax 2001, the response to the Middle East Respiratory Syndrome, and Ebola outbreaks. However, public health laboratory systems are not currently designed to handle and execute diagnostic testing at a large scale and scope beyond the initial critical phases of public health emergencies. Furthermore, in the early phase of an emergency response, FDA-authorized tests and testing platforms may be inherently limited and may not be optimized for high throughput. The need to supplement public health laboratory diagnostic testing capacity has

A brief look at COVID-19 & Mpox

Overview of COVID Molecular Testing Supply, Tests Run & Reported: March 2020 – May 2022

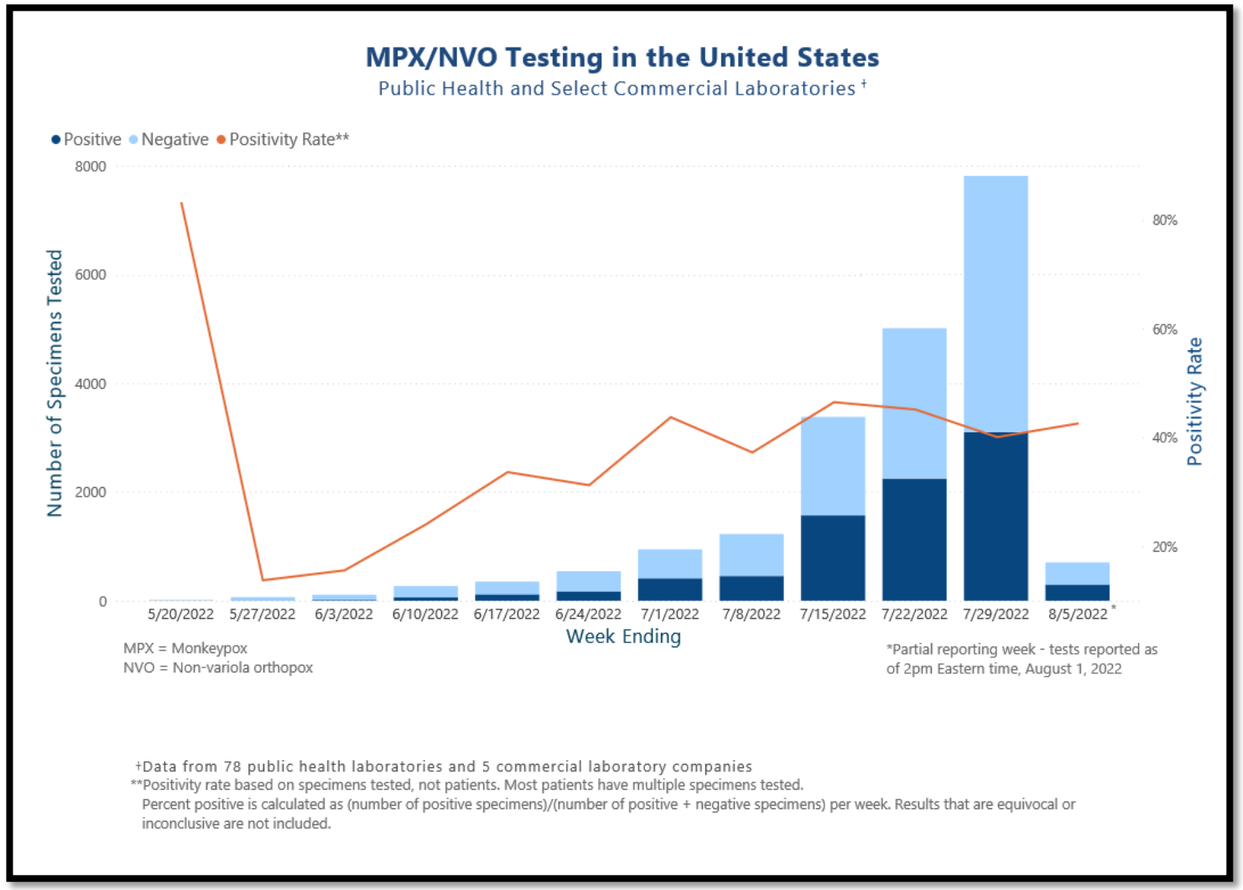
FIGURE 3: **Registry participant molecular test shipments facilitated unprecedented levels of testing**

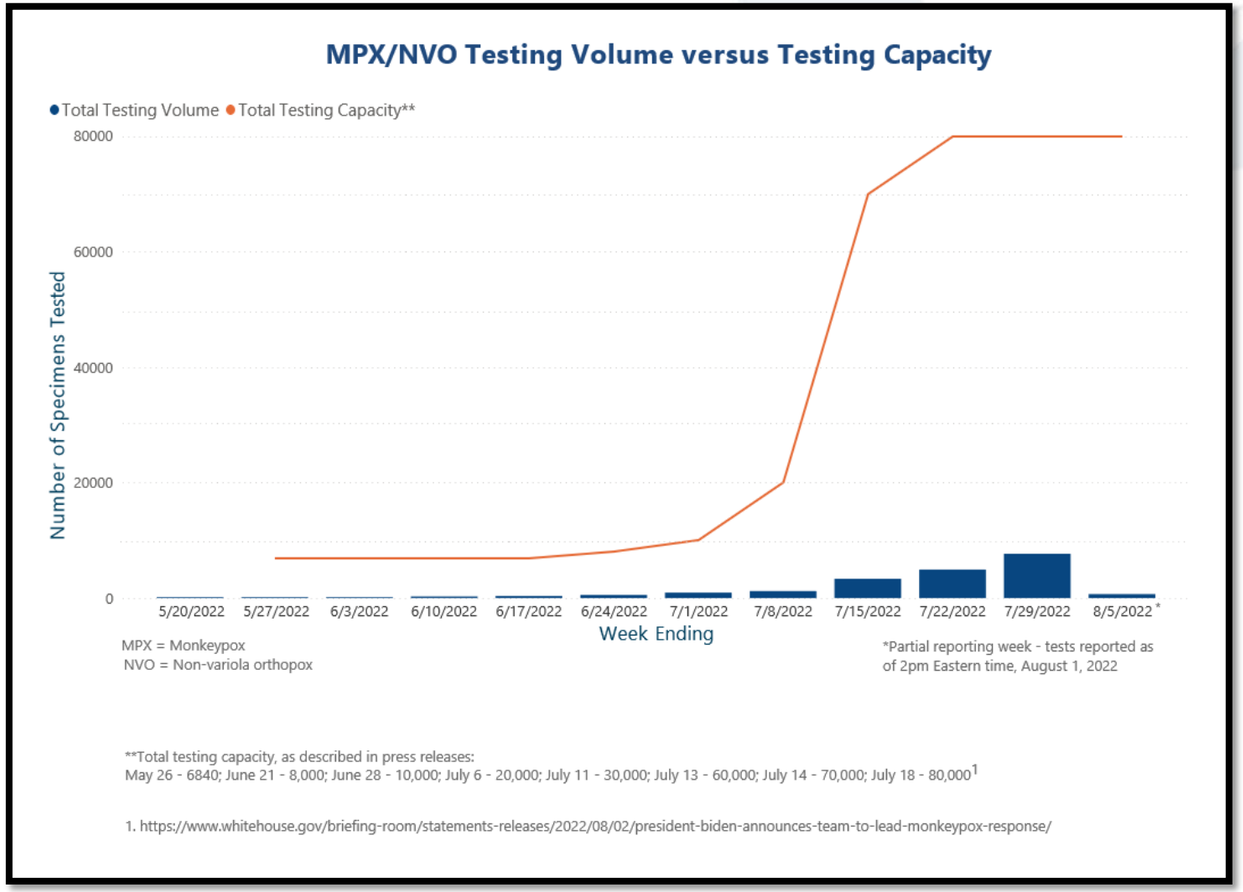


Purple dots plot the number of molecular, including PCR, tests run, principally in commercial, independent, and hospital – including academic medical center laboratories.

Source: AdvaMedDx, "Diagnostics Industry Mobilization," Analysis; https://www.advamed.org/wp-content/uploads/2022/06/AdvaMedDx-COVID-Testing-Supply-Retrospective-Report.pdf

Overview of Mpox Scale Up





Key Issues for Consideration

- Character of public-private collaboration in times of emergency and non-emergency
  - Data sharing (surveillance, early detection, testing)
  - Access to samples for test development
  - Agreements to develop tests and/or dedicate laboratory capacity
  - De-risking markets
  - Stockpiling and/or vendor managed inventory
  - Workforce
  - Sample collection and transport
  - Supply chains
  - Sharing

- Clarity on and character of regulatory landscape
- Swift establishment of predictable and robust reimbursement (coding, coverage, payment)
- USG clinical guidance on use cases for testing for public and providers

Thank you