Roles and Responsibilities of the US Public Health Laboratory System: A Post Pandemic Evaluation

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Core Functions of Public Health Laboratories

Disease Prevention Control and Surveillance

- Outbreak investigations

- Biodefense and Select Agents

Reference and Specialized testing

- **Newborn screening and follow-up**

Integrated Data Management

Emergency Response

Food Safety

Identify chemical exposures in people and the environment

Public Health related research and assay development

Laboratory improvement and regulation

Training and education

Partnership and communication

Policy Development

Individual Health vs Population Health

Hospital, Clinical, Commercial Laboratories

- Diagnostic testing
- Reference Testing (some)
- Medical management

INDIVIDUAL HEALTH

Public Health Laboratories

- Diagnostic testing (some)
- Reference Testing
- Screening (NBS)
- Surveillance
- Outbreak investigations

POPULATION HEALTH

Parallel but Interdependent Networks

Question

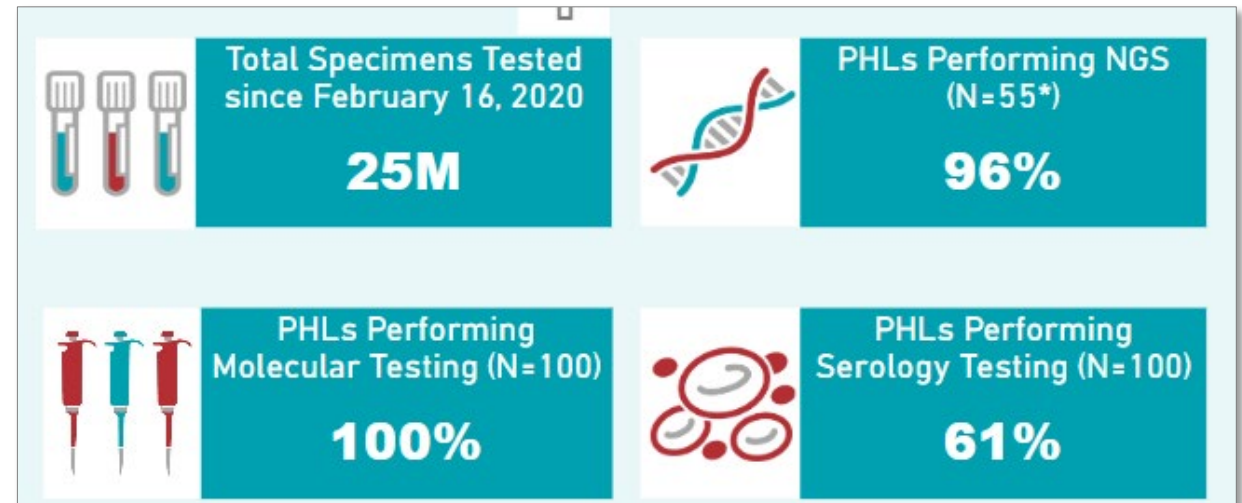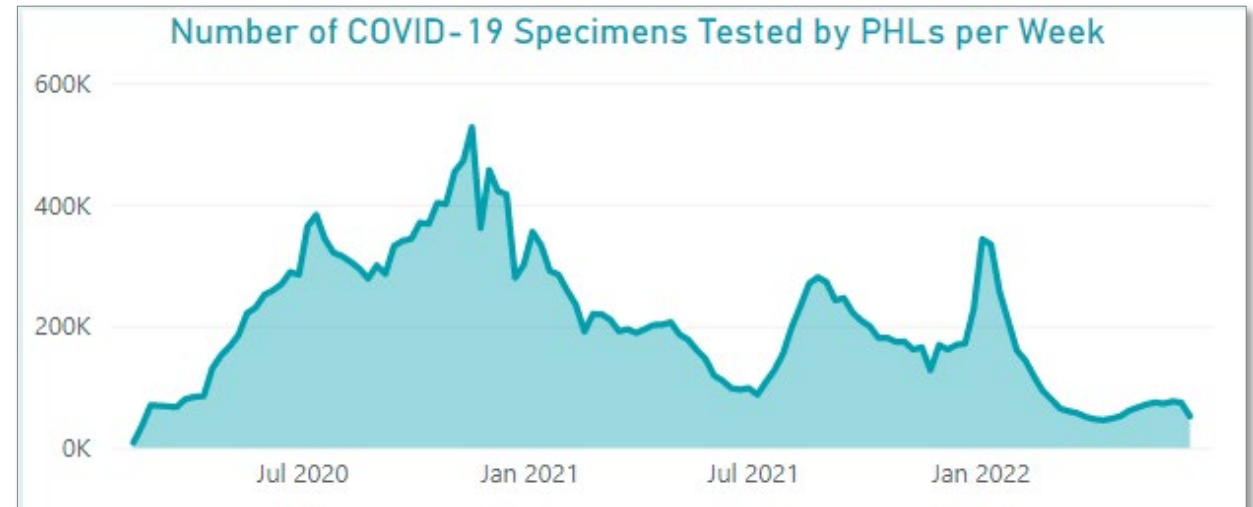What is the role of the public health laboratory system in an outbreak?

Answer

Readiness, for both the initial threat detection, and broad testing in the early stages of an outbreak

The Public Health Laboratory's Role During the COVID-19 Pandemic

- Testing during the initial stage of the Pandemic

- Long term, sustained high throughput testing

- Genomic sequencing to detect variants

- Standing up wastewater surveillance

- Acting as a resource for other laboratories and non-traditional testing sites

LRN

National Center for Emerging Zoonotic and Infectious Diseases
Division of Preparedness and Emerging Infections
Laboratory Preparedness and Response Branch

Legend
- Federal
- Food
- Veterinary
- Military
- Public Health

Alaska

Hawaii

There is no LRN-R for testing during nuclear or radiologic emergencies

A Diverse Laboratory Network

Federal

Laboratories at the US Centers for Disease Control and Prevention (CDC), US Department of Agriculture (USDA), Federal Bureau of Investigation (FBI).

State and Local Public Health

Laboratories run by state and local departments of health. Few are affiliated with academic institutions.

Military

Department of Defense (DoD) laboratories are operated both within the United States and abroad.

Food Testing

US Food and Drug Administration (FDA), USDA, and other laboratories that are responsible for ensuring food supply safety.

Environmental

Laboratories are capable of testing environmental samples.

Veterinary

Laboratories are responsible for animal testing, which is particularly important since animals often provide first signs of disease outbreak.

International

The LRN has several international partners with various levels of testing capabilities.

What is provided to the Network?

1. Agent specific protocols
2. Standardized reagents and controls
3. Laboratory referral directory
4. Secure website and communications
5. Electronic messaging
6. Training and technology transfer
7. Proficiency testing/Challenge exercises

Public Health Laboratory's Role During the Monkeypox Virus Outbreak

- The Massachusetts State PHL first detected the virus

- A test was available through the Laboratory Response Network (LRN)

- 79 LRN labs throughout the country have capacity and capability; other non-LRN PHLs have brought up LDTs

- LRN labs provided training on the **CDC 510 (k) test** for the commercial labs
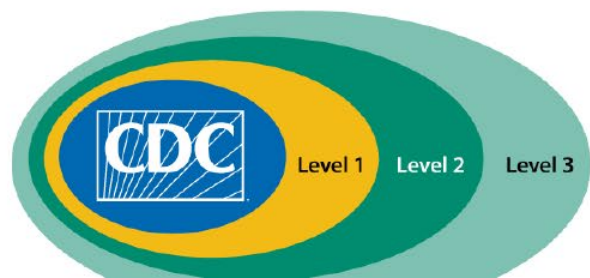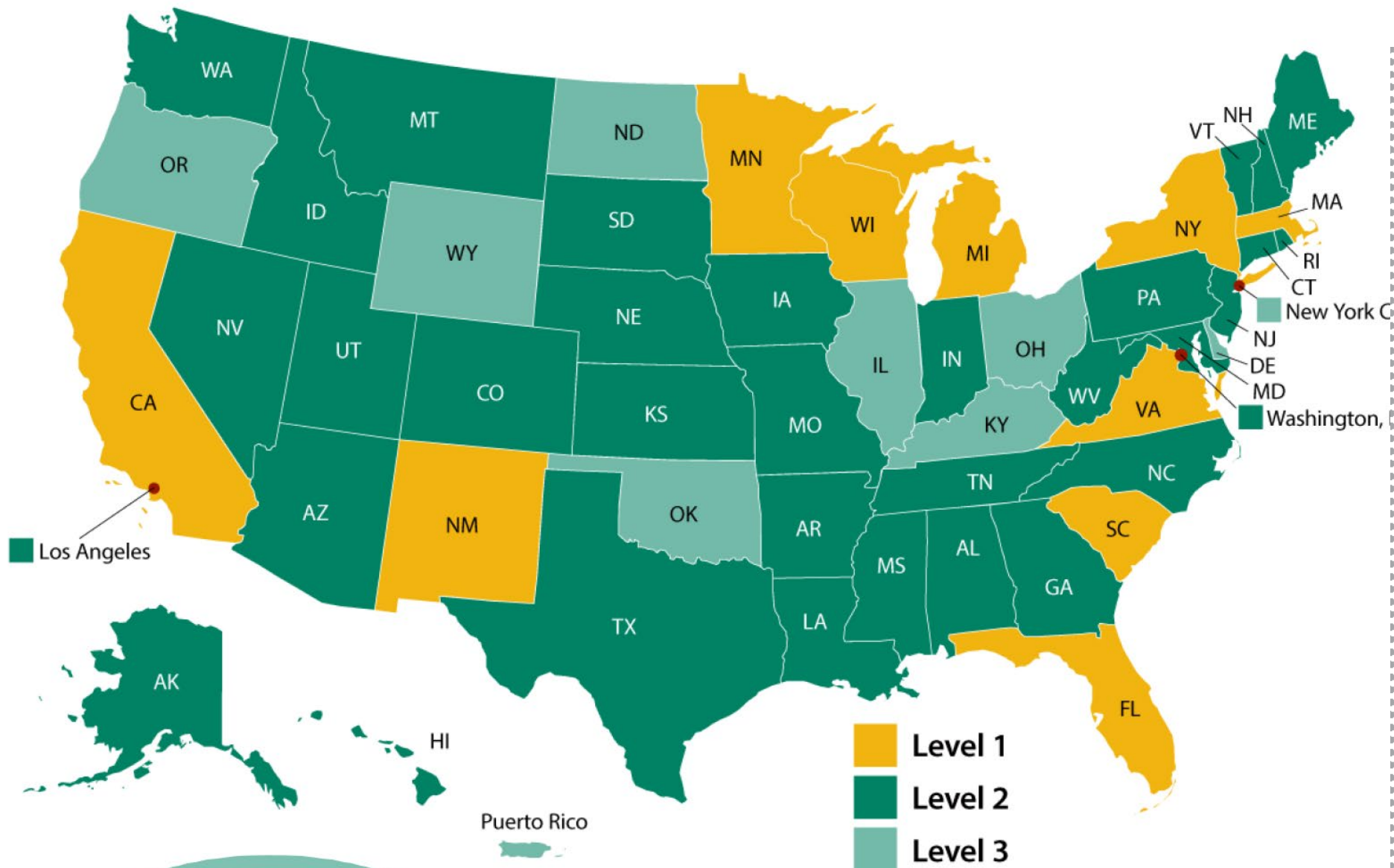
Looking Ahead

- ✓ **Biosafety -** inactivation procedures

- ✓ **Automation -** e.g., automated extraction platforms

- ✓ **High-Throughput -** multiple platforms

- ✓ **Threat Agnostic Sequencing**

- ✓ **Surge Capacity -** optimize the network model

LRN-C Laboratory Structure

By the Numbers

54
LRN-C member laboratories located in the U.S., including one U.S. territory

44
laboratories can identify exposures to toxic chemical agents such as cyanide, nerve agents, and toxic metals

10
laboratories with high threat testing capabilities for mustard agents, nerve agents, and toxic industrial chemical exposures
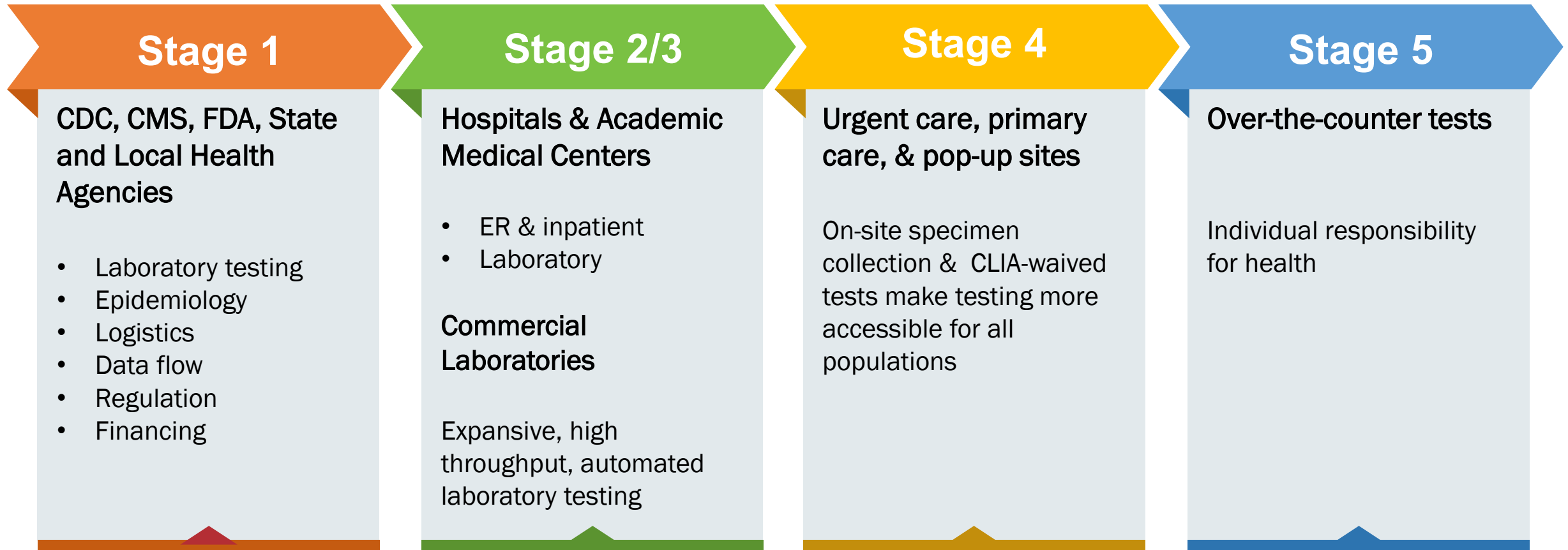
8,500
clinical samples can be processed, tested and reported to CDC within a 24 hour period
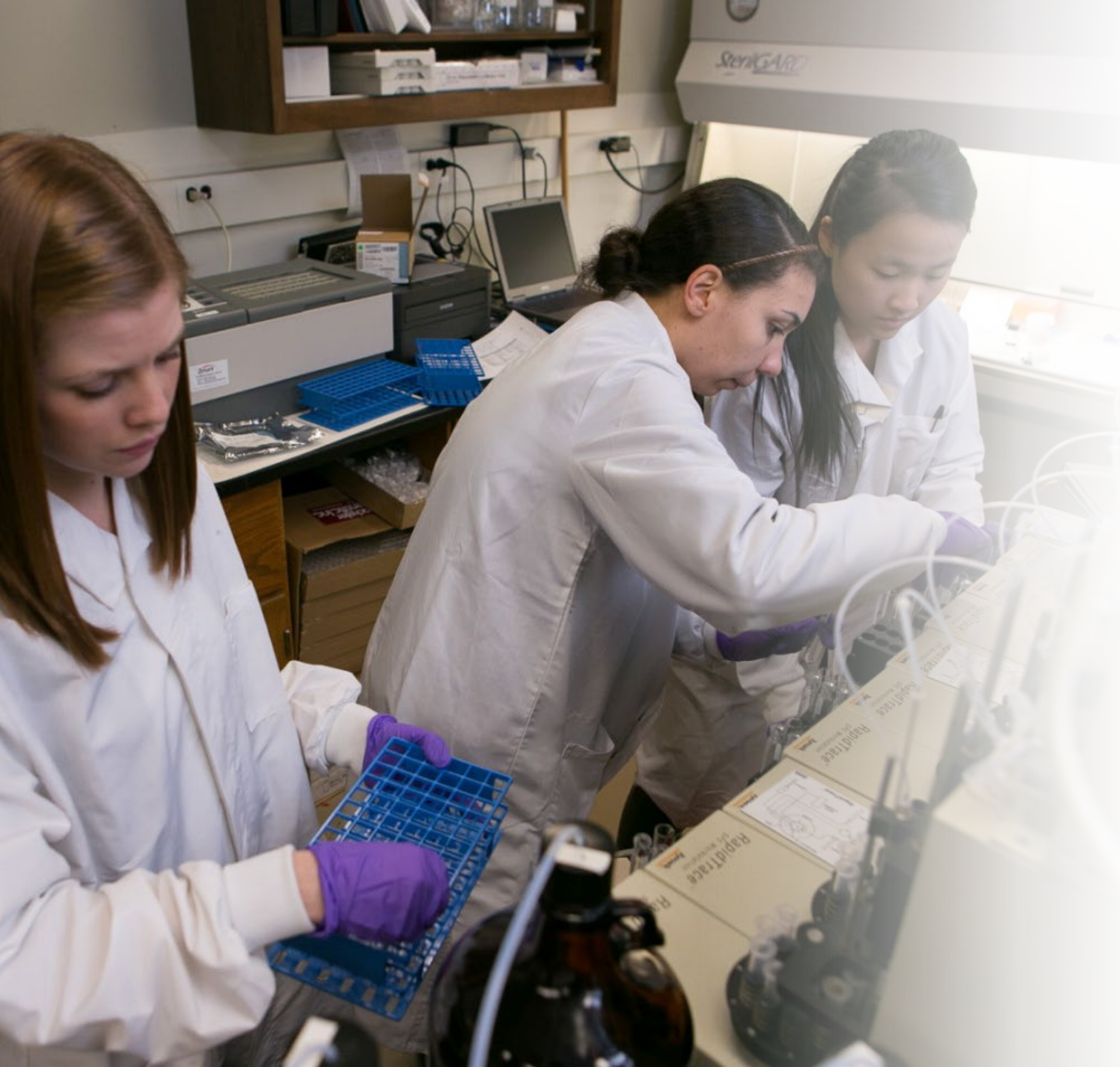
84%
of Americans live within 100 miles of an LRN-C laboratory

Legend:
- Level 1
- Level 2
- Level 3

Laboratory Sector Roles and Responsibilities During the Evolution of an Outbreak or Pandemic

Stage 1

CDC, CMS, FDA, State and Local Health Agencies

- Laboratory testing
- Epidemiology
- Logistics
- Data flow
- Regulation
- Financing

Stage 2/3

Hospitals & Academic Medical Centers

- ER & inpatient
- Laboratory

Commercial Laboratories

Expansive, high throughput, automated laboratory testing

Stage 4

Urgent care, primary care, & pop-up sites

On-site specimen collection & CLIA-waived tests make testing more accessible for all populations

Stage 5

Over-the-counter tests

Individual responsibility for health

Industry: Just-in-time Supply and Develop Rapid Tests and Tests for High Throughput Platforms

One Last Thought...

We need to re-imagine our laboratory system to encompass and engage multiple players in the public, private and health care sectors, and the academic community.