APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES™

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US Public Health Laboratory Network

SARS-CoV-2 Testing Experience

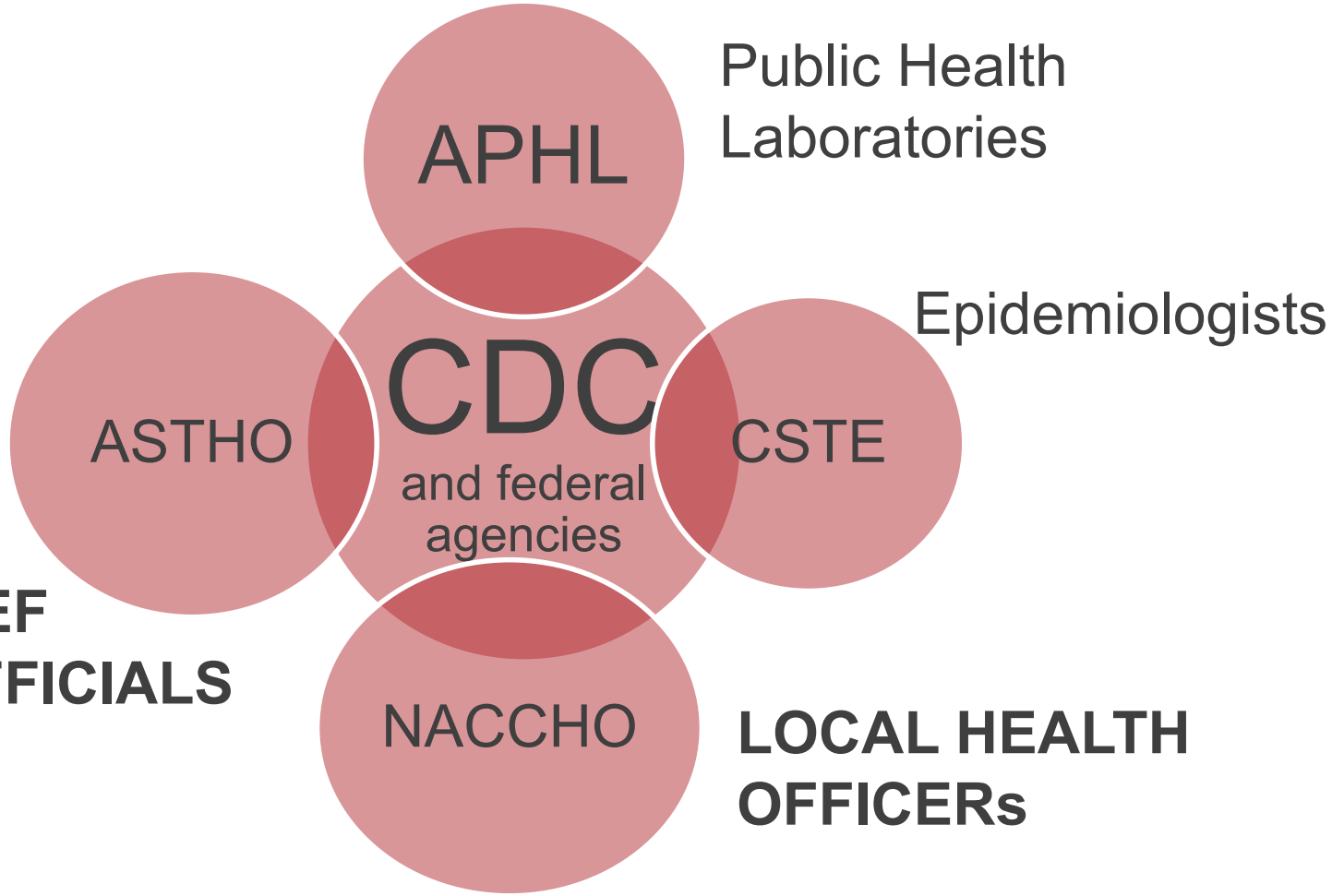
Ralph Timperi, Senior Adviser
Laboratory Practice & Management
Association of Public Health Laboratories

15 July 2020

US Public Health Laboratory Network

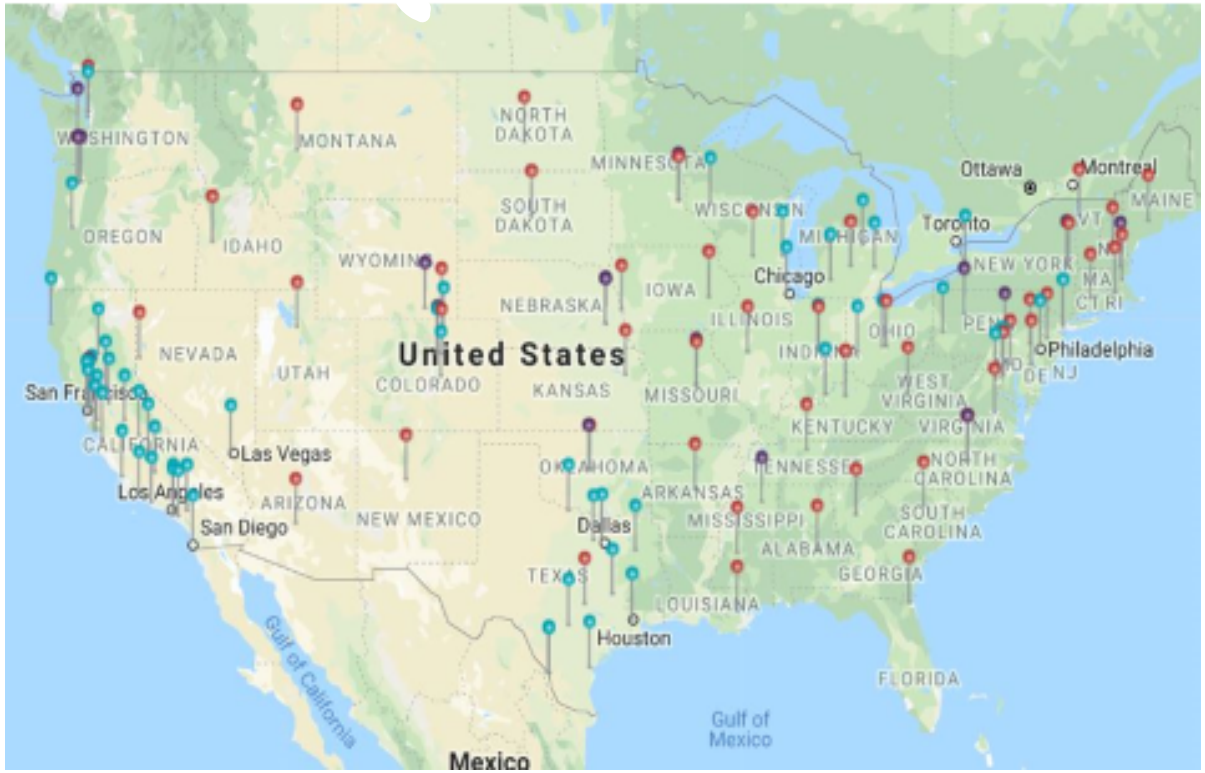
- Overview of the US laboratory network
- Role of public health laboratories
- Overview of SARS-CoV-2 Testing
- Challenges, Bottlenecks and Solutions
- Data management
- Working globally

Primary partners in public health

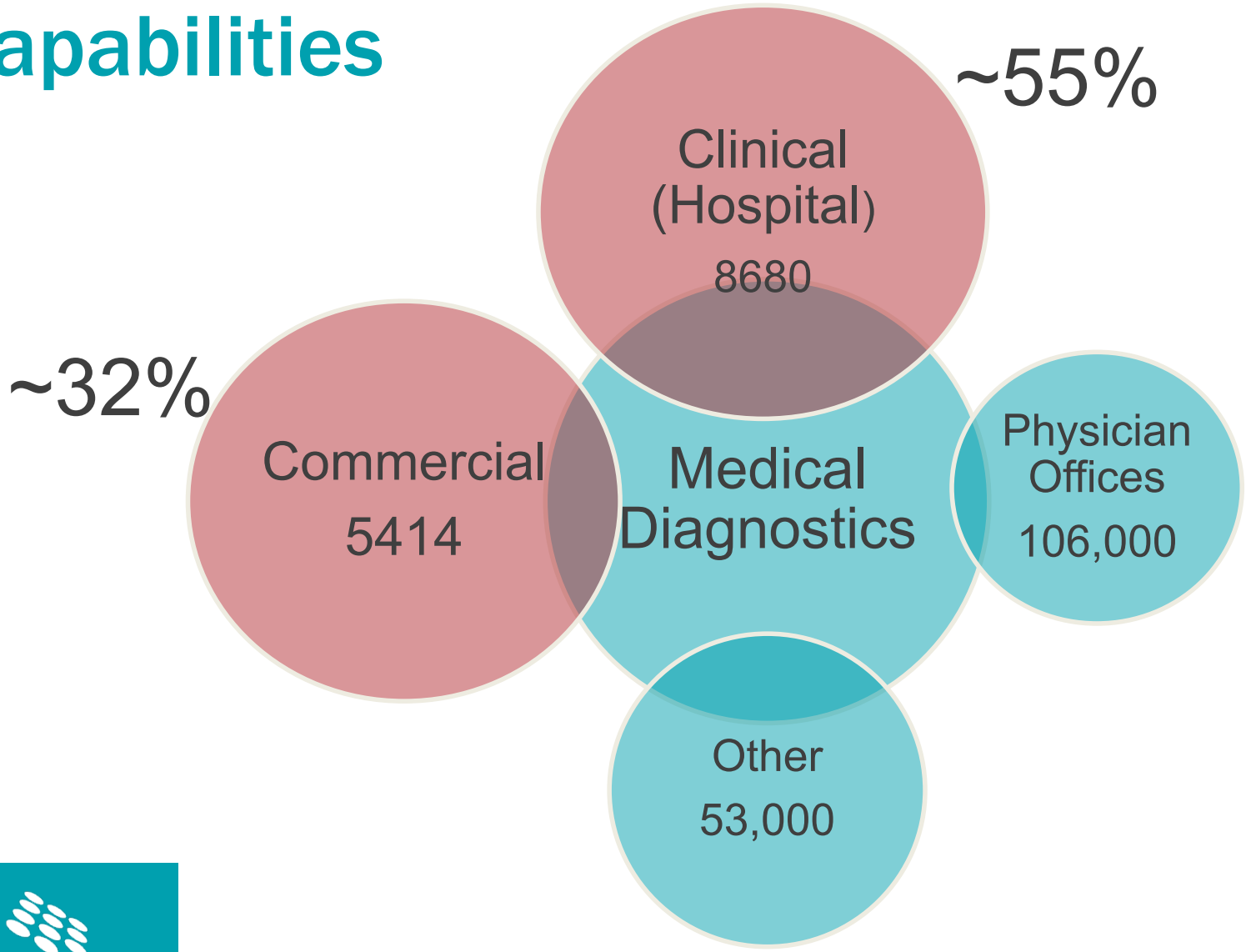


Public Health Laboratory Network

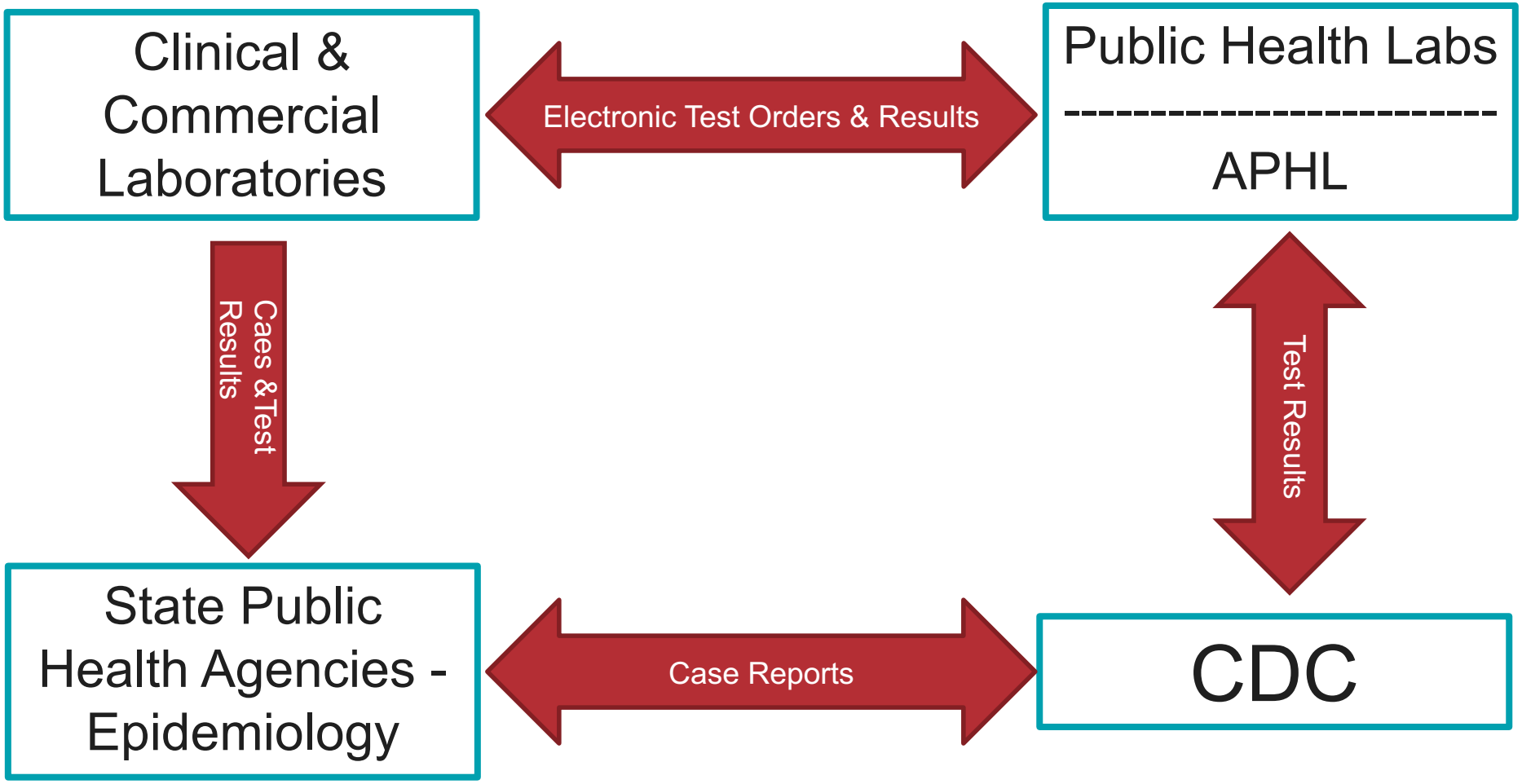
~110 Labs



Diagnostic Laboratory Testing Capabilities



Public Health Laboratory Network



Coordination is Critical

Clinical/Commercial Labs

- Diagnostic testing
- Some reference testing
- Medical management
- Individual health

Public Health Labs

- Some diagnostic testing
- Reference testing
- Surveillance, monitoring
- Public Health

Interdependent Network

Identify and Respond to Public Health Threats

U.S. Laboratory Based Networks (examples)

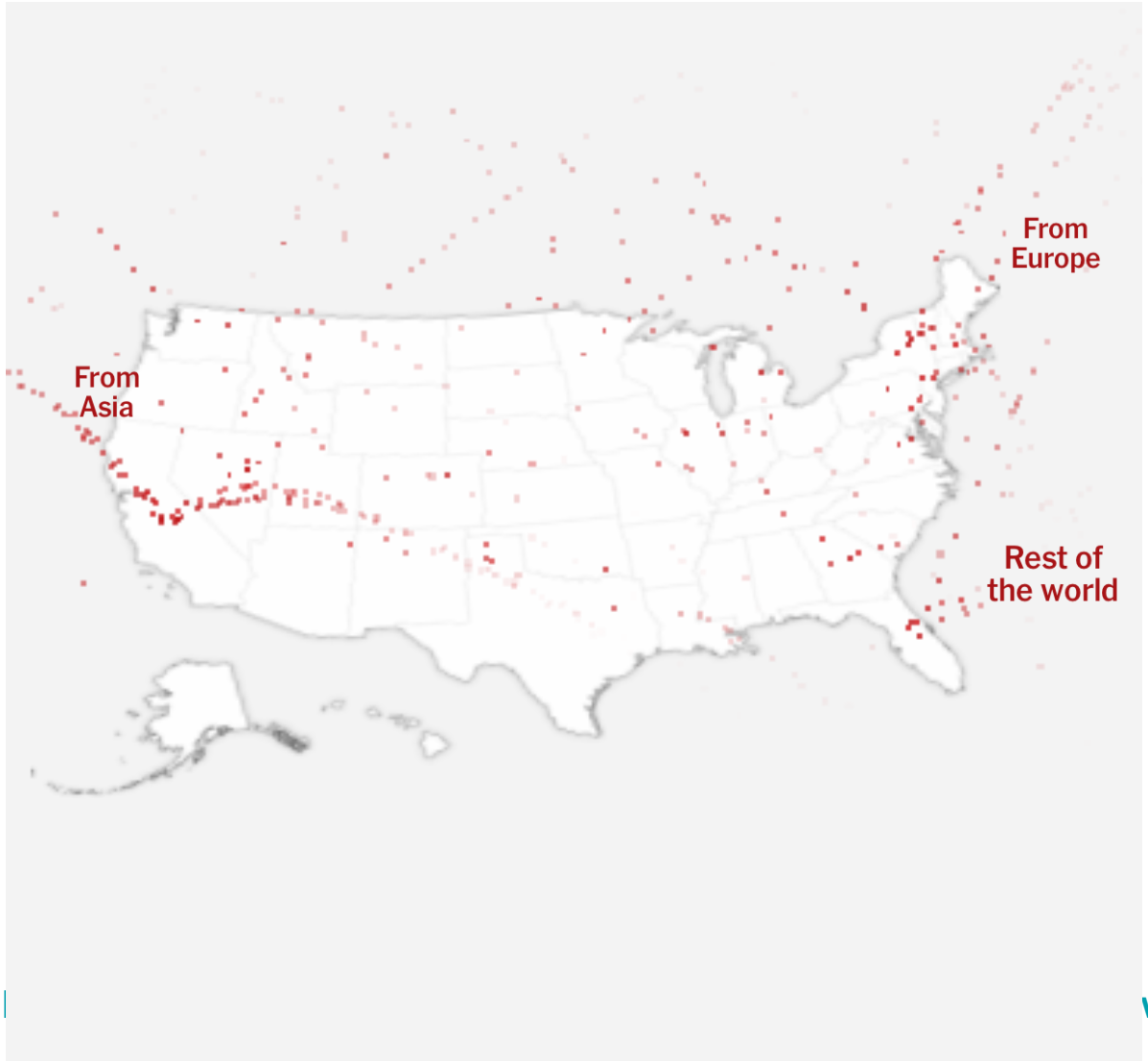
- Influenza Network
- Laboratory Response Network
- PulseNet for foodborne outbreaks
- Food Emergency Response Network
- Veterinary Laboratory Investigation and Response Network
- Environmental Response Laboratory Network
- Antibiotic Resistance Laboratory Network

And many more

Surveillance for SARS-CoV-2 viruses public health testing

- Number of cases asymptomatic to fatal
- Who is infected. Testing broadly or planned studies to determine infected, ill, hospitalizations and deaths
- See Defining the Epidemiology of Covid-19 – Studies Needed, Marc Lipsitch, David Swerdlow, and Lyn Finelli, N Engl J Med 2020; 382; 1194-96.

Estimates (modeling) of earliest infections in the USA



Key laboratory factors for timely and effective response to outbreak risks

- Quality management system
- Defined testing turnaround time (an aspect of quality)
- Coordinated network
- System capability and capacity

EXAMPLES OF ESSENTIAL SYSTEM COMPONENTS

Practical capabilities scaled to pandemic

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Quality Indicator Examples

- Validation done by several PHLs of CDC 2019-Novel Coronavirus (2019-nCoV) rt RT-PCR Diagnostic Panel: initial failure and corrective action subsequently passed validation.
- Quality assessment of laboratory reagents provided by various manufacturers identify contaminated viral transport medium (VTM)
- Verification studies published on APHL Community of Practice

Why turnaround time is so important

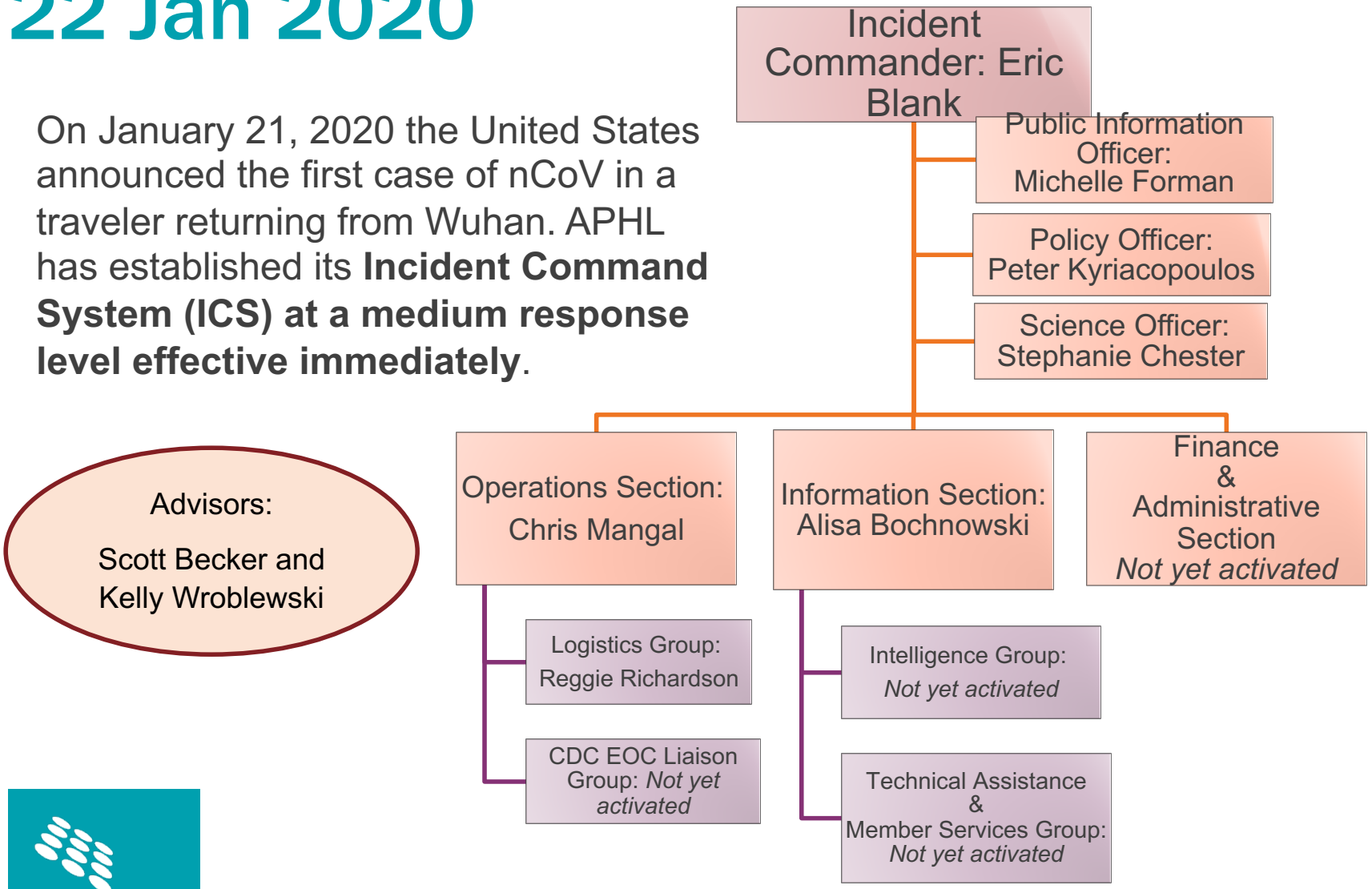
- In a previous COVID presentation by Professor Peeling, diagnostics purposes were explained. The use case for a test must be understood to know how to manage a specimen and select the appropriate test and conditions. For example, contact tracing to prevent spread of infections. If TAT is 7 days and connection with a potentially exposed persons takes further time, a “correct” test does not guarantee the desired outcome.
- Right test, right person, right place, right interpretation, right time

Communication and collaboration

- APHL organized weekly meetings
  - All public health laboratory call with FDA, CDC, presenters on current issues
  - All Laboratory call with FDA
- Community of Practice Public Health Laboratories for real-time communication and assessment of testing issues
- EOC Incident Command System for COVID-19 (24 x 7 operations)

APHL EOC Incident Command System 22 Jan 2020

On January 21, 2020 the United States announced the first case of nCoV in a traveler returning from Wuhan. APHL has established its **Incident Command System (ICS) at a medium response level effective immediately**.



Systems organization and equipment

- Testing services: staff, instruments, supplies, facilities, access to services, specimen transport in strategic and funded implementation plan
- Data management: LIS, connectivity, instrument interfaces, interoperability with EHR, remote test order, electronic test resut report, lack of or unworkable unique identifier (policy, use case rational, implementation)

STRATEGIES, INNOVATION, ACTIONS

Providing access to quality laboratory services

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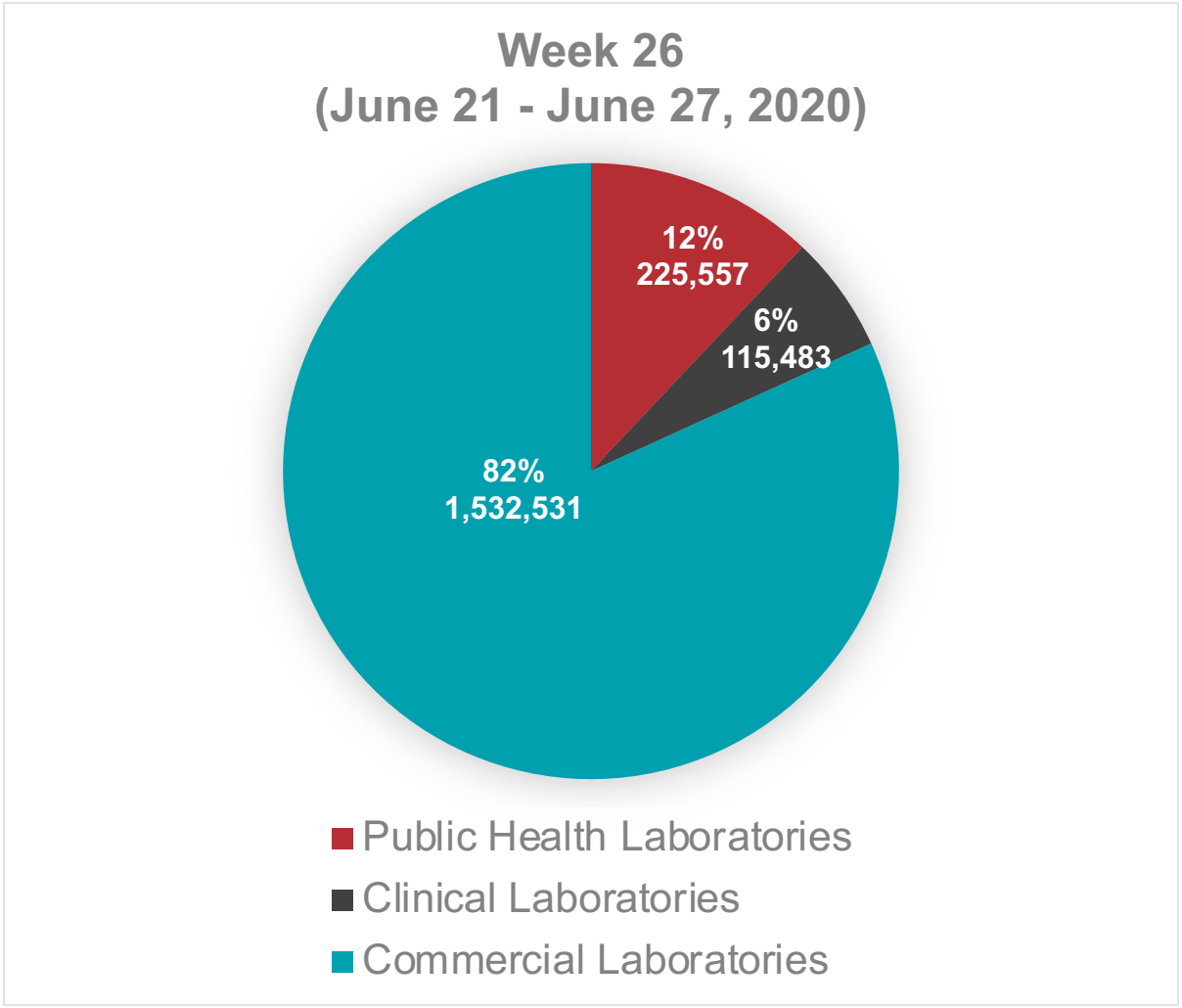
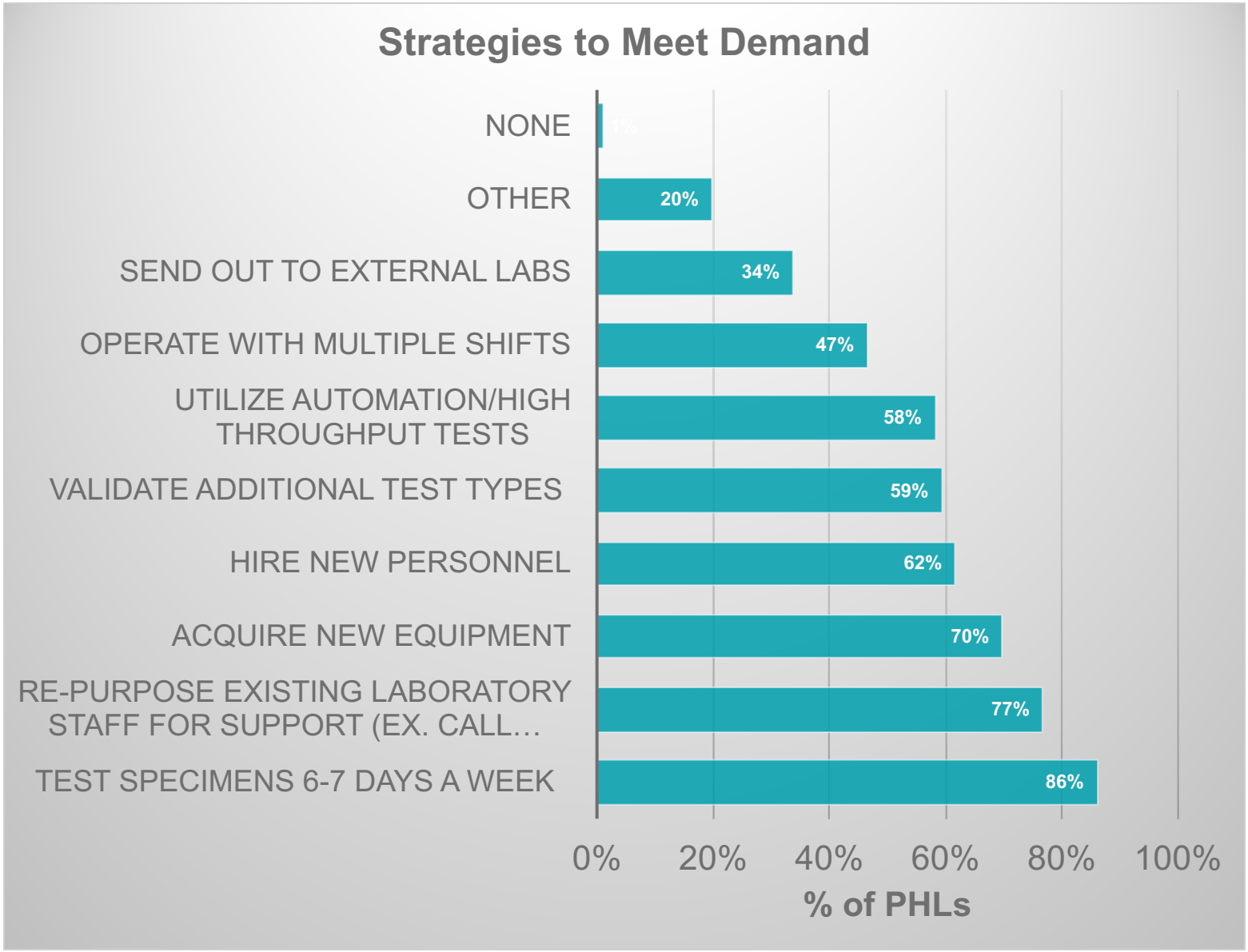
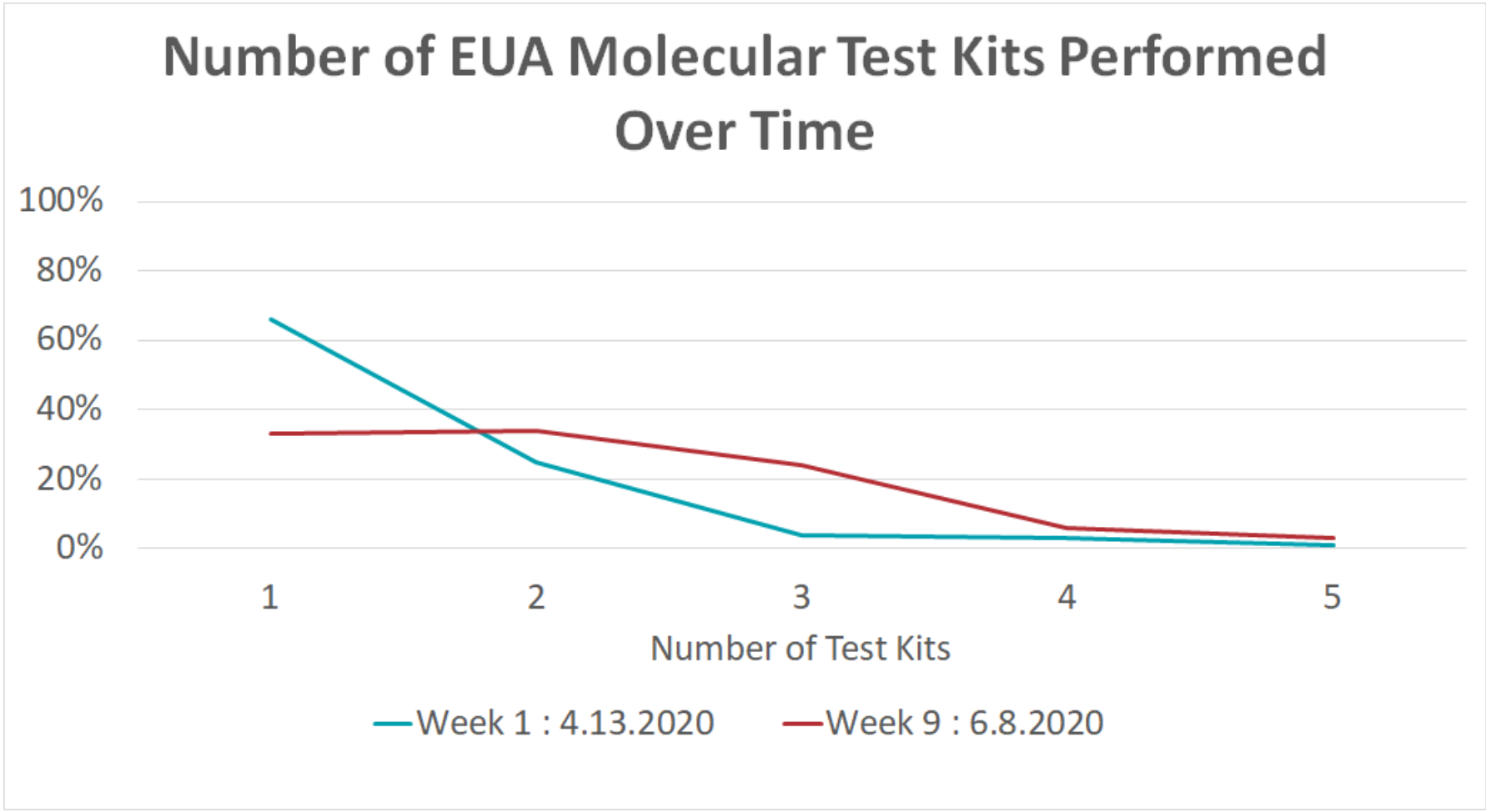
COVID-19 Testing Performed

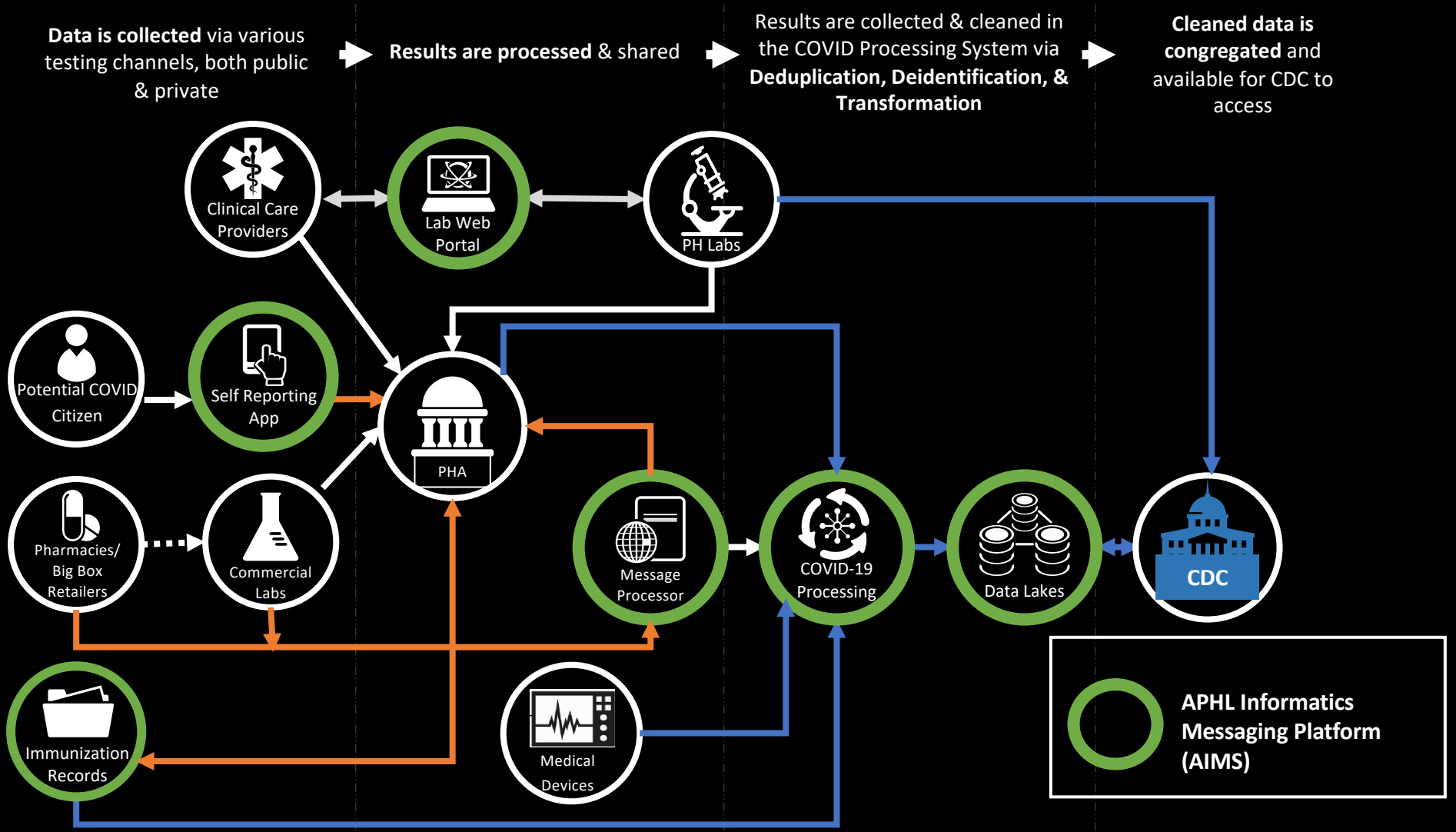


Current Strategies to Manage Workload (Week 10)



EUA Molecular Tests: Comparison Week 1 to Week 9




Data is collected via various testing channels, both public & private
Results are processed & shared
Results are collected & cleaned in the COVID Processing System via **Deduplication, Deidentification, & Transformation**
Cleaned data is congregated and available for CDC to access
Clinical Care Providers
Lab Web Portal
PH Labs
Potential COVID Citizen
Self Reporting App
PHA
Pharmacies/ Big Box Retailers
Commercial Labs
Message Processor
COVID-19 Processing
Data Lakes
CDC
Immunization Records
Medical Devices
APHL Informatics Messaging Platform (AIMS)

Molecular testing capacity SARS-CoV-2 by public health

Condition	Number of Specimens
Projected Capacity: based on **CURRENT** supplies/reagents	
Wk1: N=89	154,538
Wk2: N=88	209,020
Wk3: N=86	226,758
Wk4: N=81	203,407
Wk5: N=78	284,194
Wk6: N=82	279,141
Wk7: N=85	323,142
Wk8: N=82	336,114
Wk9: N=85	371,131
Wk10: N=86	468,479
Wk11: N=81	454,357

WHAT'S IT GOING TO TAKE TO REOPEN?

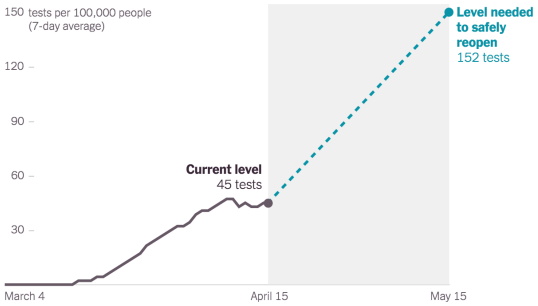
The New York Times

Coronavirus Testing Needs to Triple Before the U.S. Can Reopen, Experts Say

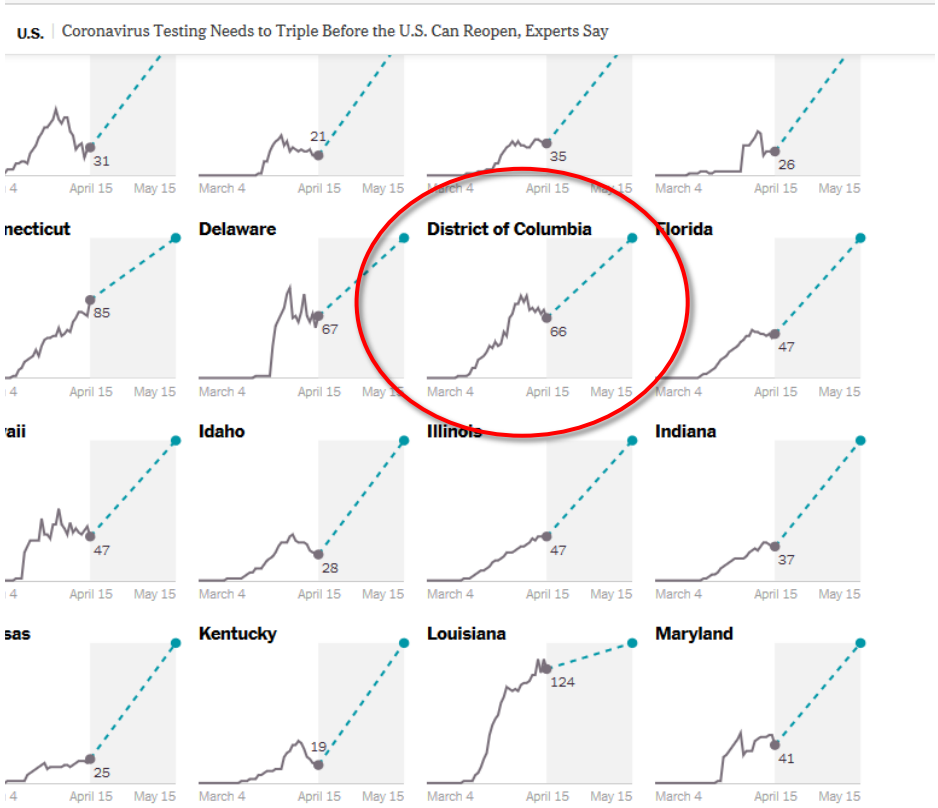
By Keith Collins April 17, 2020

As some governors consider easing social distancing restrictions, new estimates by researchers at Harvard University suggest that the United States cannot safely reopen unless it conducts more than three times the number of coronavirus tests it is currently administering over the next month.

Average Daily Coronavirus Tests in the U.S.



An average of 146,000 people per day have been tested for the coronavirus nationally so far this month, according to the COVID Tracking Project, which on Friday reported 3.6 million total tests across the country. To reopen the United States by mid-May, the number of tests performed every day should be 500,000 to 700,000, according to the Harvard estimates, which is a daily minimum of about 152 tests per 100,000 people.

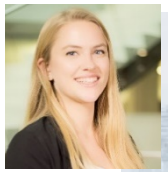


7 x 152 = **1064** samples/day

Keith Collins, NY Times April 17, 2020 https://www.nytimes.com/interactive/2020/04/17/us/coronavirus-testing-states.html

ONLINE MARCH 3RD






3x per day=180

30 Extractions


30 Extractions




25 Per Plate= 100


2 hours Capacity 50 samples per day 3 hours

Slides courtesy of Dr. Courtney

FULL AUTOMATION

Started March 30th - Panther Fusion

Staff

Capacity 300-500 samples per da

Avg daily patients = 75

2:20 hours per sample
90 samples per run
~300 samples/8 hour
Ability to run overnight

Sample to Answer
No ABI 7500 needed
Much less staffing needed
Currently limited to certain VTM brands

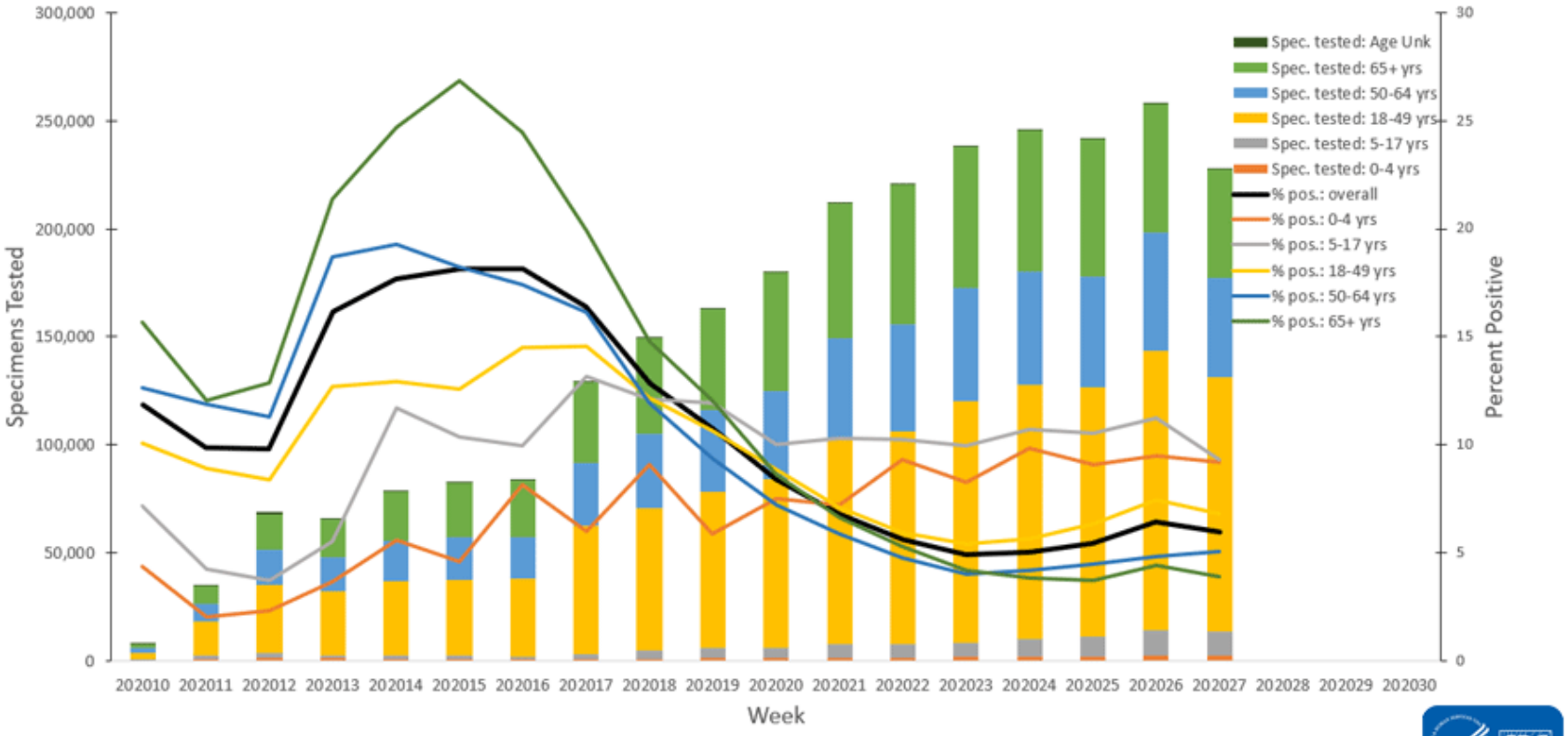
Slides courtesy of Dr. Courtney

IF THEY WON'T COME TO YOU...

Public Health Laboratories

U.S State and Local Public Health Laboratories Reporting to CDC: Number of Specimens Tested and Percent Positive for SARS-CoV-2

March 1, 2020 – July 4, 2020

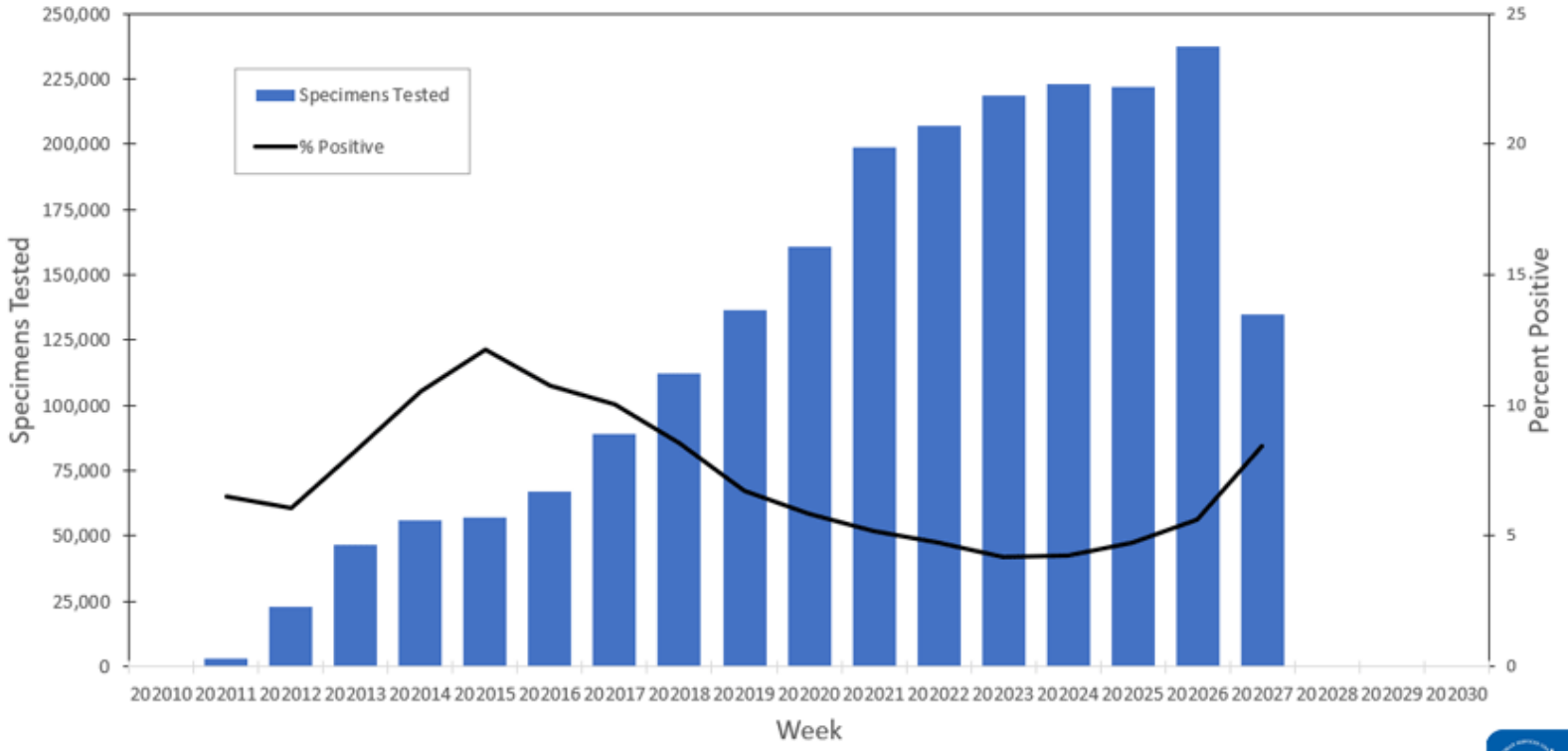


COVID View: A Weekly Surveillance Summary of U.S. COVID-19 Activity. (2020, July 10). Retrieved July 13, 2020, from https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

Clinical Laboratories

U.S. Clinical Laboratories Report to the National Respiratory and Enteric Virus Surveillance System: Number of Specimens Tested and Percent Positive for SARS-CoV-2

March 8, 2020 – July 4, 2020

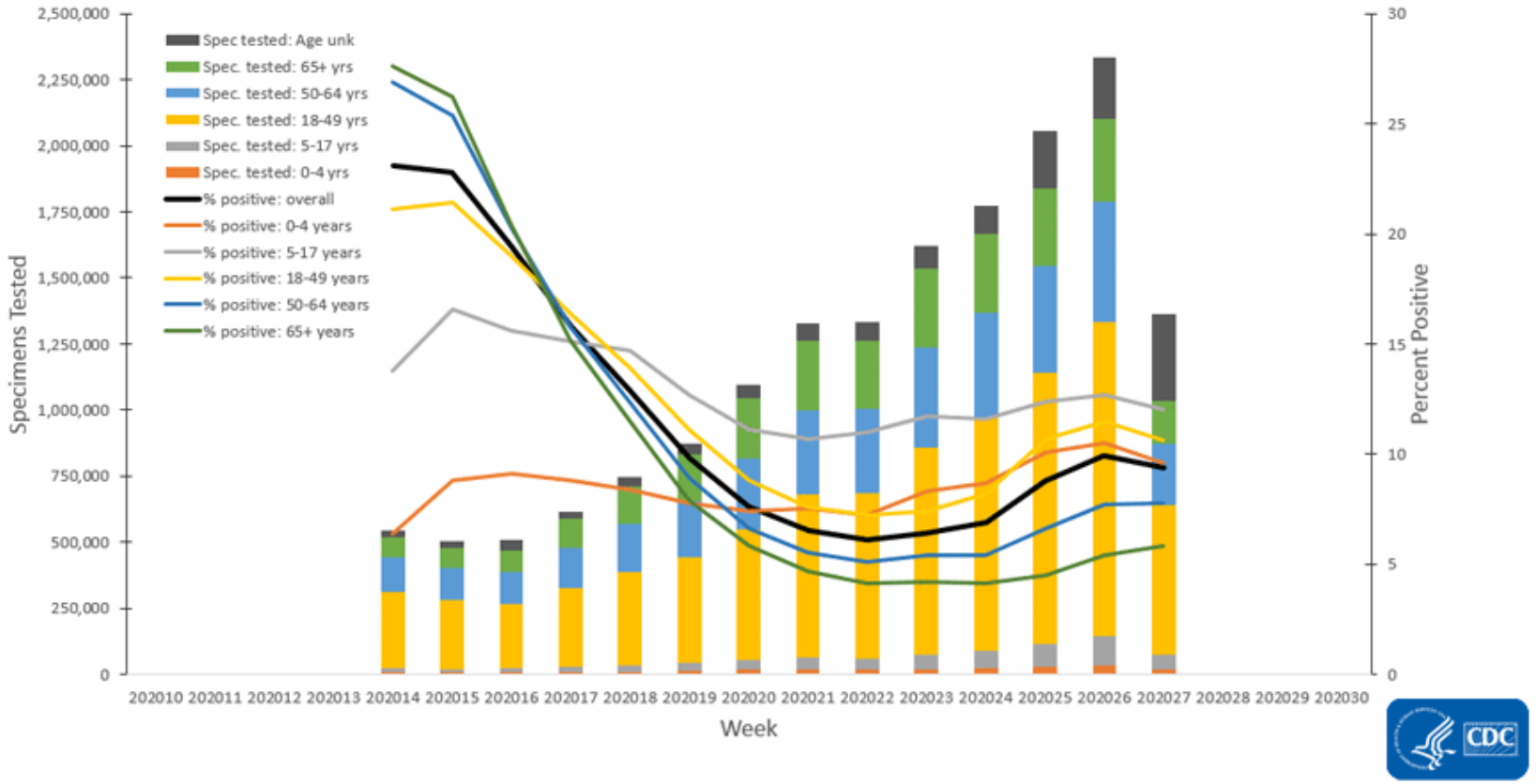


COVID View: A Weekly Surveillance Summary of U.S. COVID-19 Activity. (2020, July 10). Retrieved July 13, 2020, from https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

Commercial Laboratories

Select Commercial laboratories Reporting to CDC: Number of Specimens Tested and Percent Positive for SARS-CoV-2

March 29, 2020 – July 4, 2020



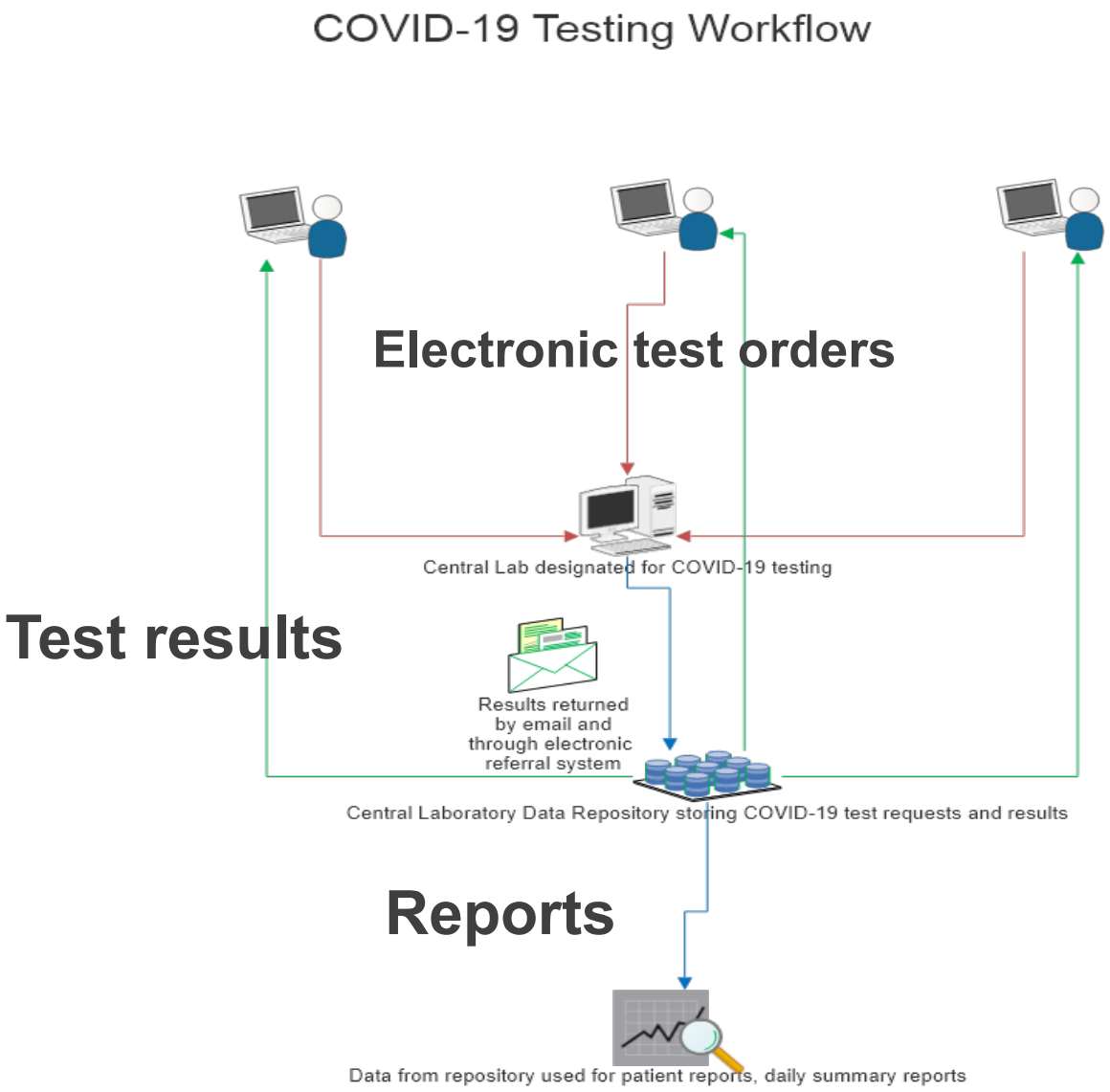
* Commercial laboratories began testing for SARS-CoV-2 in early March, but the number and geographic distribution of reporting commercial laboratories became stable enough to calculate a weekly percentage of specimens testing positive as of March 29, 2020.

COVID View: A Weekly Surveillance Summary of U.S. COVID-19 Activity. (2020, July 10). Retrieved July 13, 2020, from https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

Reduce specimen test backlog

ROOT CAUSE	PROBLEM	SOLUTION
Paper or electronic test order request at clinic	Paper test order received at testing laboratory	Electronic test order request sent to testing laboratory
• 50 clinics with 15 specimens each • 45 minutes process time each clinic	• Testing lab receives 750 specimens (50 x 15) • 2250 minutes (37.5 hours) to process	• Testing lab scans barcodes of 750 specimens • 120 minutes to process (2 hours)

Example of electronic test order and test report (Mozambique)



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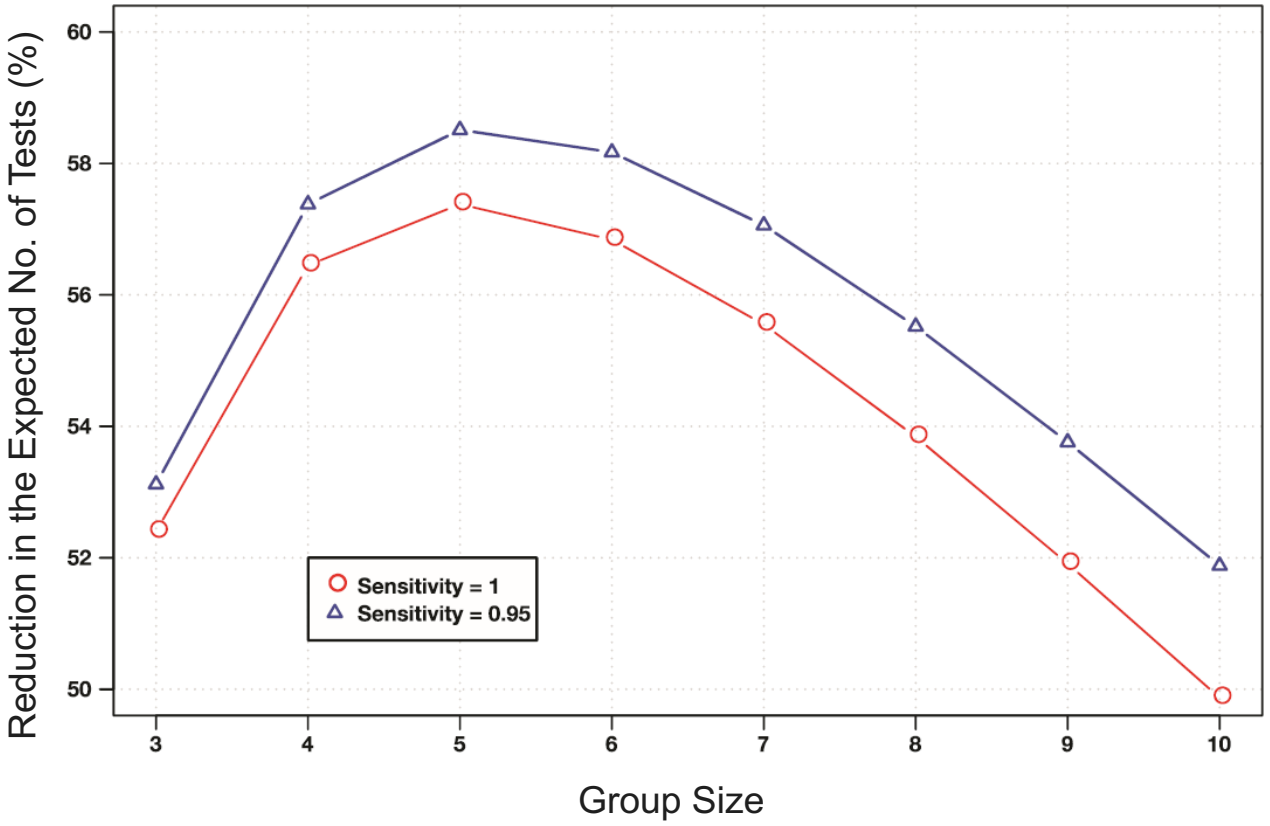
Innovation of specimen pooling

- University of Nebraska Medical Center, Nebraska Public Health Laboratory, University of Nebraska-Lincoln
- Baha Abdalhamid, Christopher Bilder, Emily McCutchen, Steven Hinrichs, Scott Koepsell and Peter Iwen

Application of Specimen Pooling to SARS-CoV-2 Testing



❙Figure 1❙ Optimal sample pool size. Graphical comparison of initial pool size compared to expected number of tests per individual using the Shiny application for pooled testing available at https://www.chrisbilder.com/shiny. The optimal sample pool size was determined based on the least number of tests and the following parameters: prevalence rate (5%), a lower limit of detection of 1 to 3 RNA copies/μL, an assay sensitivity of either 95% or 100%, and an assay specificity of 100%.

Figure borrowed with permission from: Baha Abdalhamid, MD, PhD, Christopher R Bilder, PhD, Emily L McCutchen, MS, Steven H Hinrichs, MD, Scott A Koepsell, MD, Peter C Iwen, PhD, Assessment of Specimen Pooling to Conserve SARS CoV-2 Testing Resources, *American Journal of Clinical Pathology*, Volume 153, Issue 6, June 2020, Pages 715–718, https://doi.org/10.1093/ajcp/aqaa064

Assessment of pool size for testing

- Conserve reagents and personnel time
- Optimal pool size determined
  - Assay sensitivity and specificity
  - Assay limit of detection
  - Estimated prevalence of COVID-19
- Validation of procedure
  - Prepared pools with known positive specimen
  - Testing of unknown clinical specimens

References and contact for specimen pooling

- Baha Abdalhamid et al. American Journal of Clinical Pathology, June 2020: 153: 715-718 (available free download form Internet)
- habdalhamd@unmc.edu
- Web-based application for pooling is found at https://chrisbilder.com/shiny

THANK YOU PARTICIPANTS!

Contributors

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Sudaba Parnian, Senior Specialist, Quality Systems and Analytics
Kelly Wroblewski, Director, Infectious Diseases

APHL/Mozambique, Solon Kidane, Senior Laboratory Adviser

Validation, quality assurance, data and evidence

"For every complex problem there is an answer that is clear, simple, and wrong". H. L. Mencken.

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Role of Public Health Laboratories

- Infectious disease surveillance
  - Detection and identification of priority, emerging, and re-emerging diseases
  - Syndromic surveillance by clinicians
  - Laboratory-based surveillance, quality assurance
- Diagnostic testing to support public health

Interface between LIS and testing instrument

- Automatic transfer of approved test data to LIS
  - 1 minute
  - Results sent to Central Lab Data Repository for management of test result reports sent to clinic and aggregate data for dashboard report
- Advantages to interfaced process
  - QA/QC checks automatic for test results
  - Flagged test results sent to LIS for automatic alerts
  - Timeliness of process not dependent on manual download for data from testing instrument