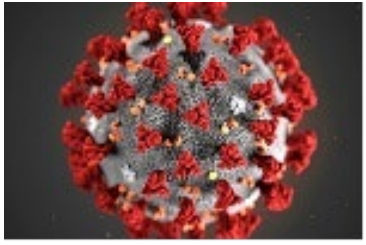
Future of the Nation's Laboratory Systems for Health Emergency Response

Session VI Part B: Identifying Short-Term Strategies To Enhance Laboratory Capabilities, Capacities, And Coordination: Acceleration, Surge, And Long-Term Response

Strategies and Recommendations from the Association for Molecular Pathology



Eric Q. Konnick, MD, MS
Chair, AMP Professional Relations Committee

Associate Professor
University of Washington
Department of Laboratory Medicine and Pathology

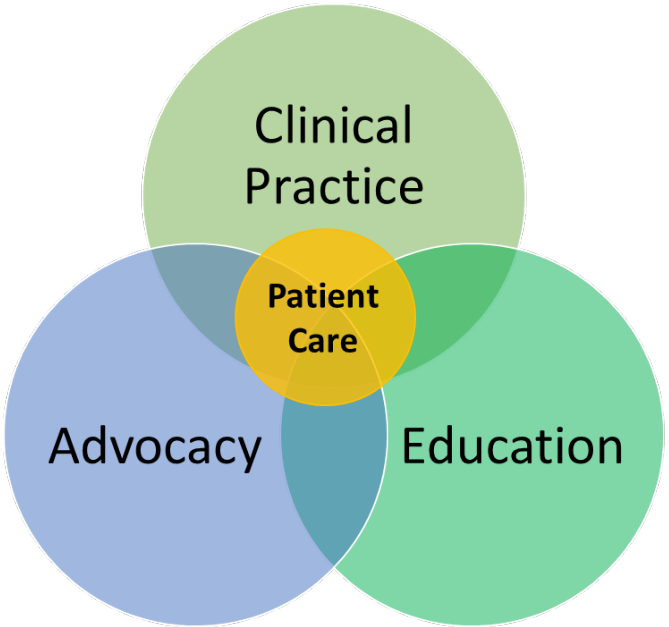
Associate Clinical Laboratory Director
Seattle Flu Alliance (Seattle Coronavirus Assessment Network)

AMP Association for Molecular Pathology

Providing global expertise in molecular testing that drives patient care.

Association for Molecular Pathology

A not-for-profit (501c3) scientific society



- Infectious Diseases
- Hematopathology
- Solid Tumors
- Inherited Disease
- Informatics

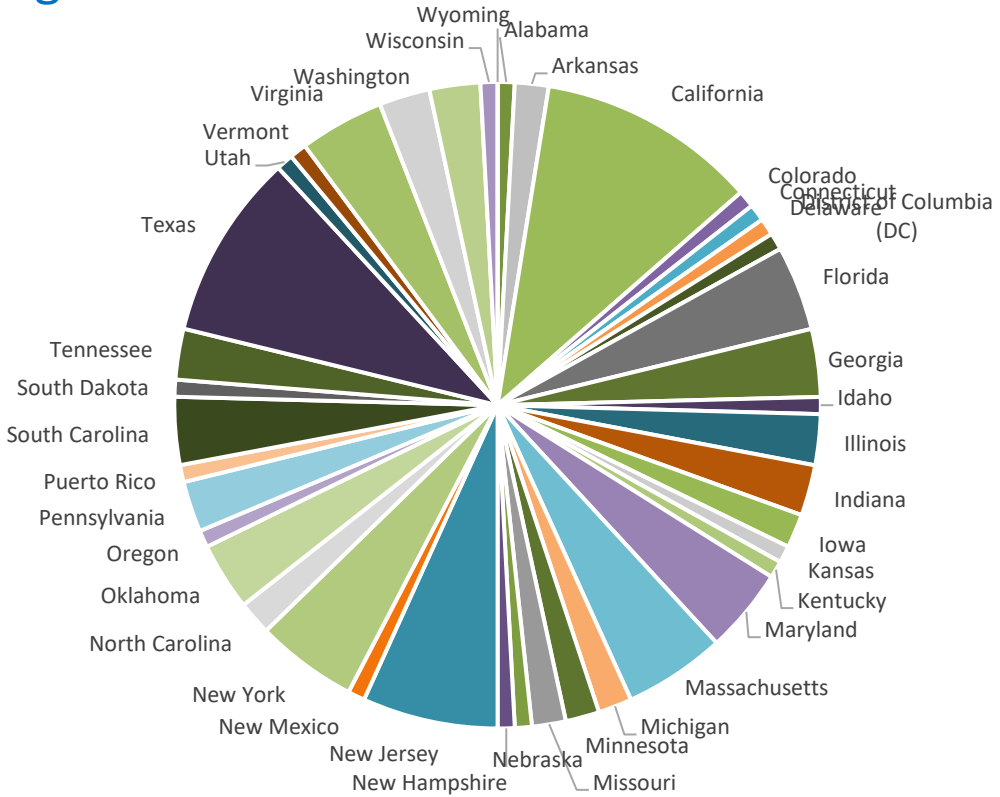
Focus and Recommendations

1) Diversity of testing locations and modalities

2) Sensible regulatory oversight of laboratories during a public health emergency

3) Consistent and predictable reimbursement for clinical testing

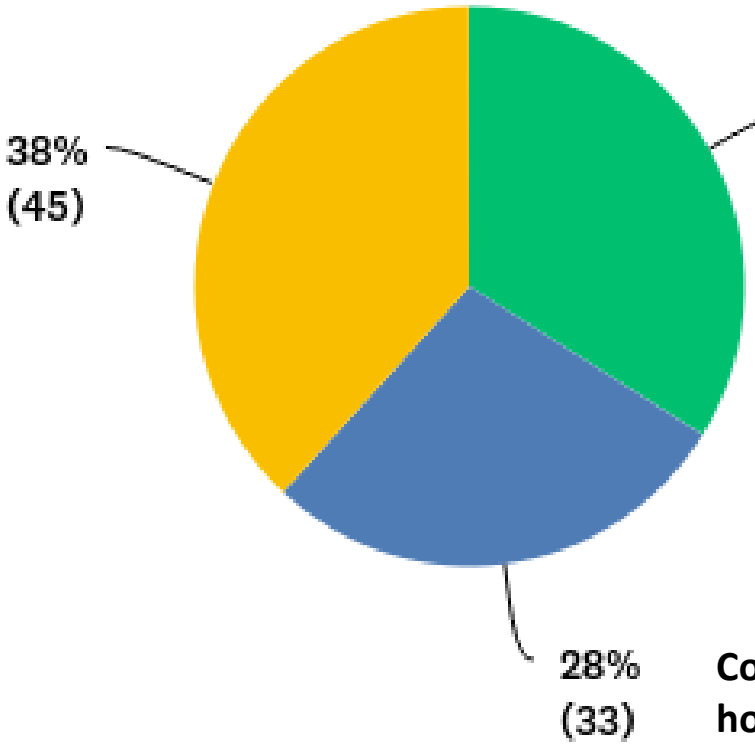
SARS-CoV-2 Molecular Testing Surveys
April & August 2020



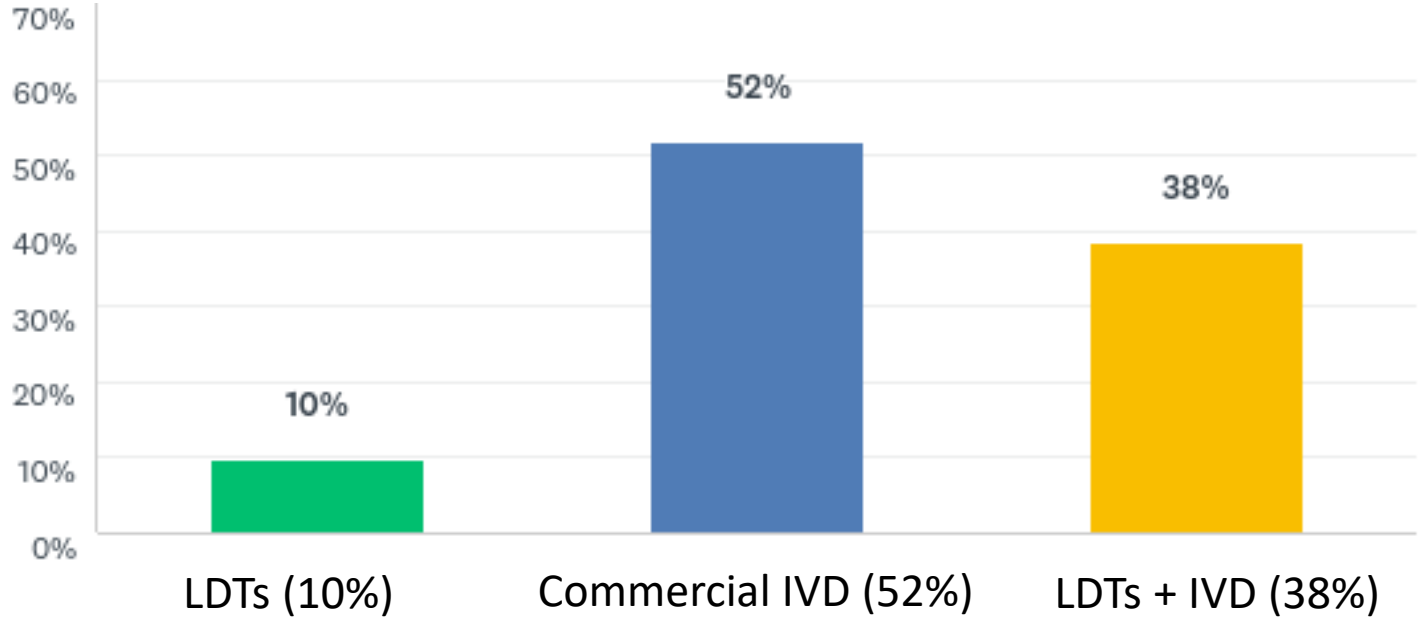
Percentage response by state

Demographics of Data Subset

- 118 US-based laboratories only
- 95 AMP members, 23 non-members

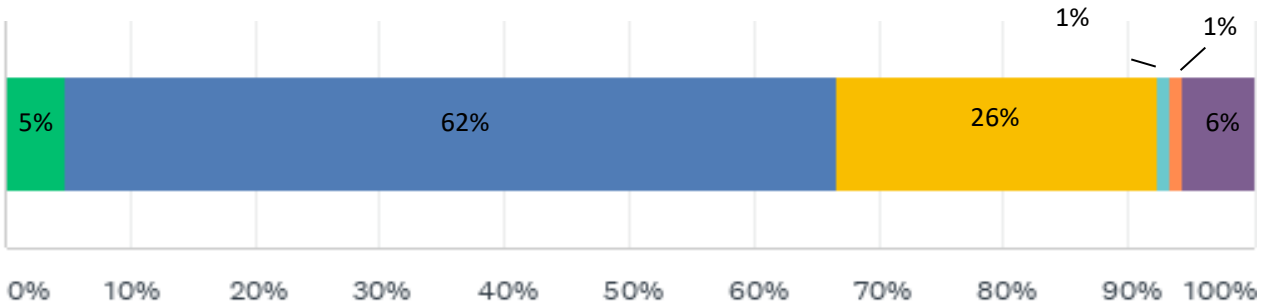


April 2020 - SARS-CoV-2 Testing Methodology



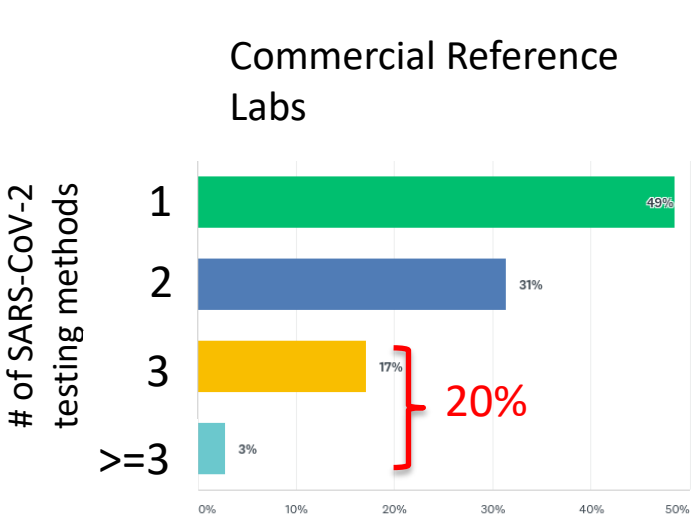
August 2020 - SARS-CoV-2 Testing Methodology

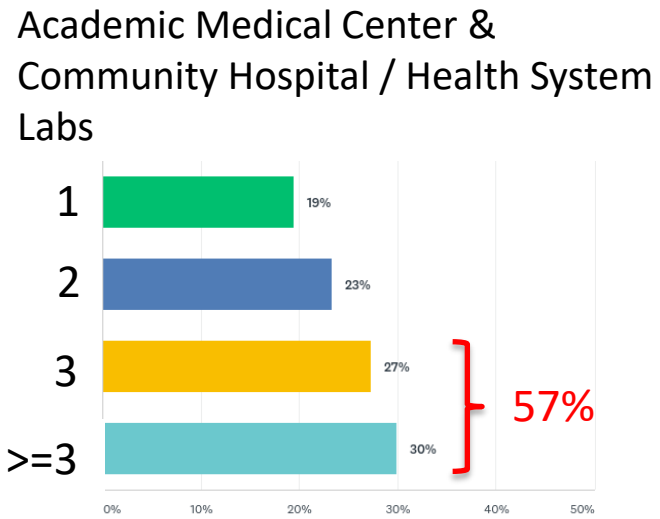
LDTs (5%) Commercial IVD (62%) LDTs + IVD (33%)



- Laboratory developed testing procedure (LDPs, also called LDTs) only
- Commercial testing kits with Emergency Use Authorization (EUA) only
- Combination of both LDPs and Commercial Kits
- Combination of both LDPs and IRB-approved/non-EUA assay
- Combination of both IRB-approved/non-EUA assay and Commercial Kits
- LDPs, IRB-approved/non-EUA assay and Commercial Kits

Laboratories deployed multiple testing methodologies due to supply shortages and uncertainties





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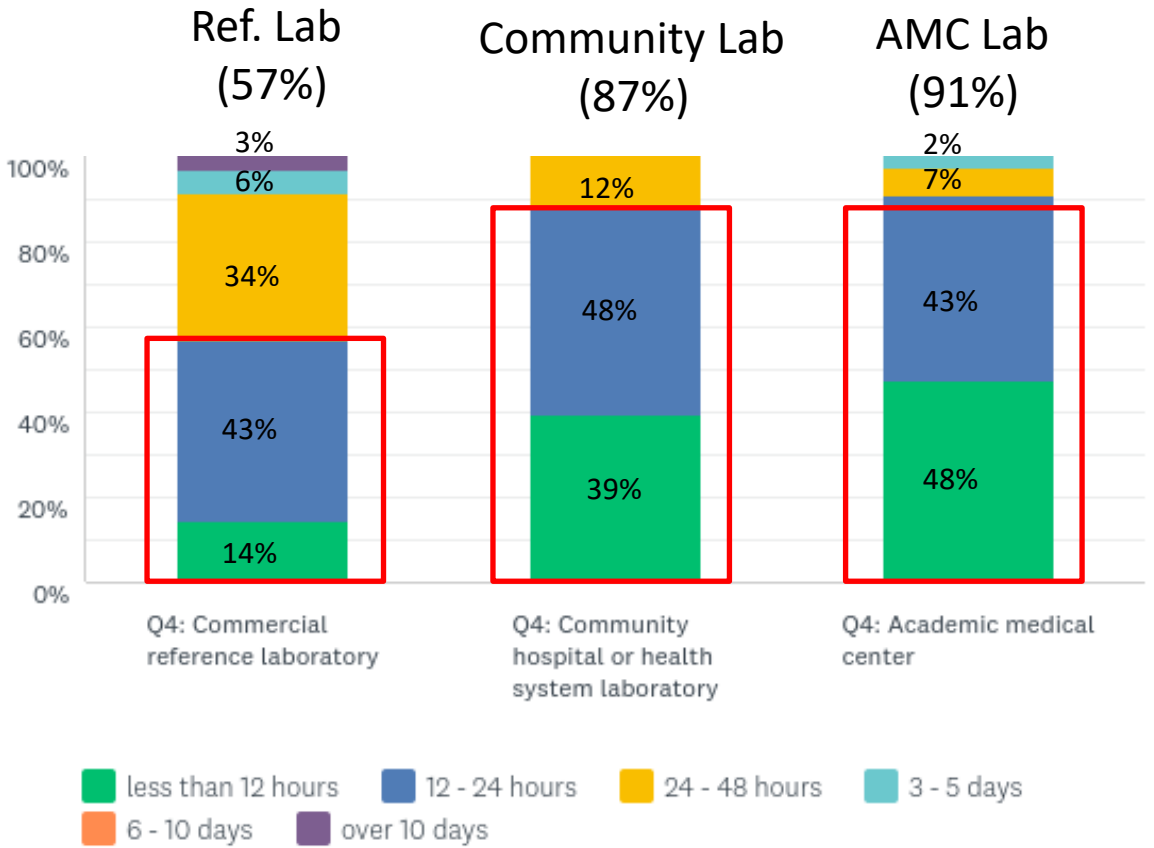
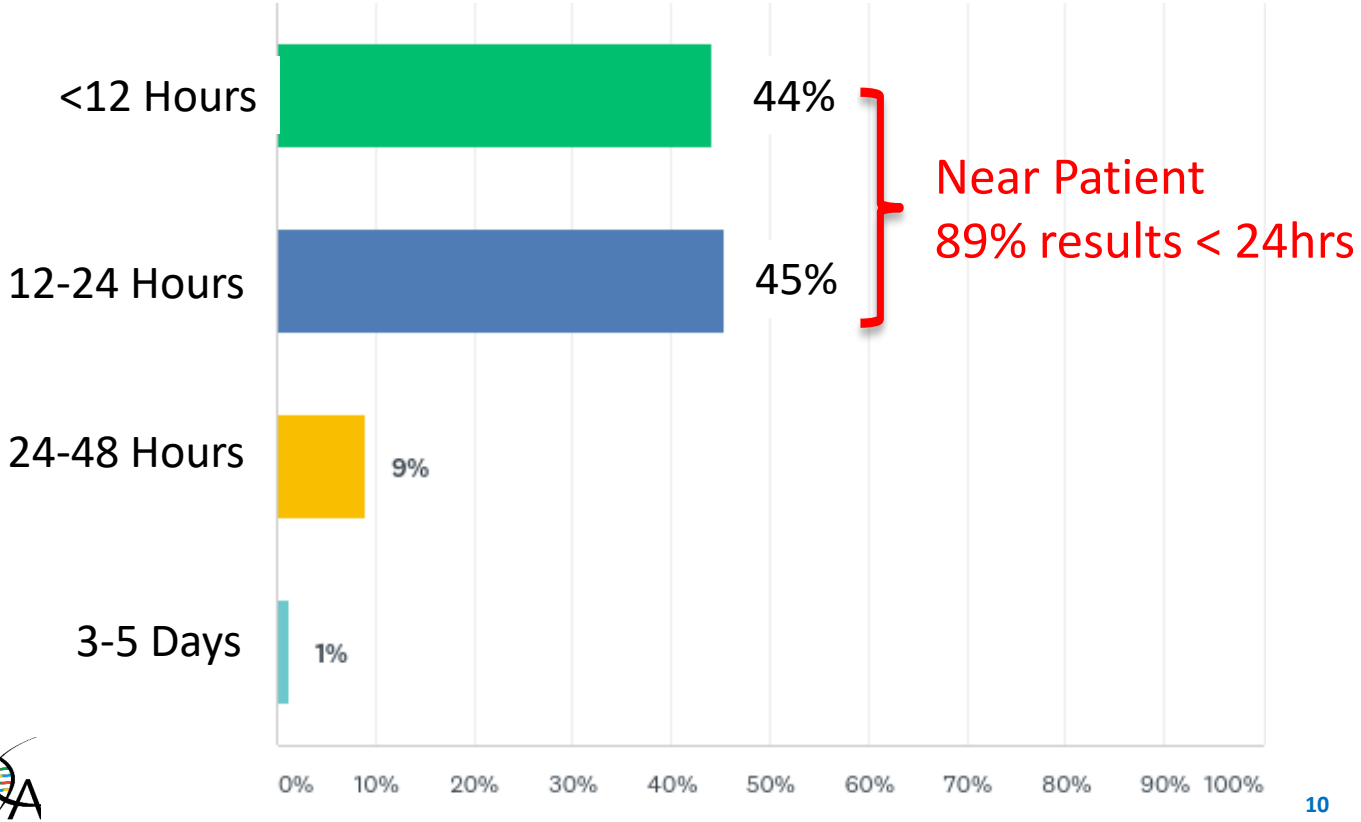
Testing close to patient = rapid turnaround time (<=24hr)



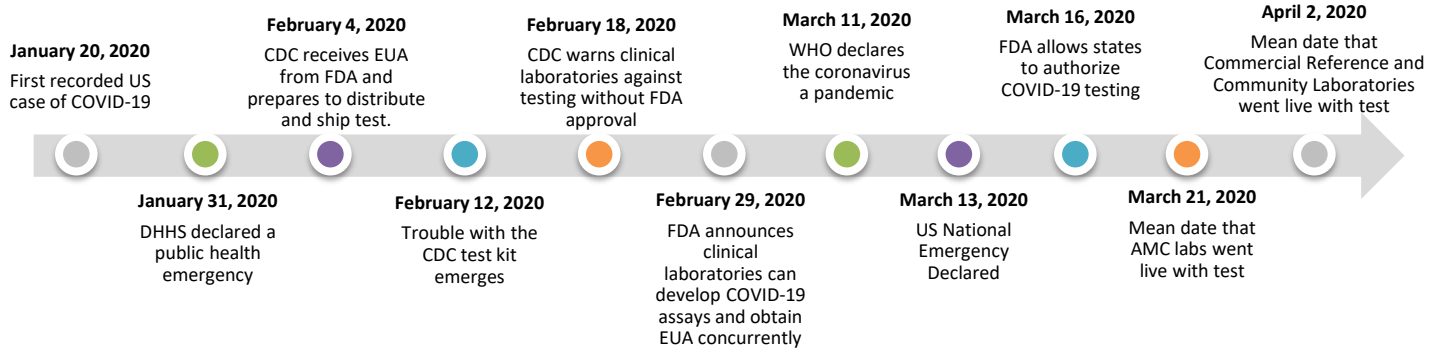
NOT INCLUDING TRANSPORT TIME

Testing close to patient = rapid turnaround time (<=24hr)



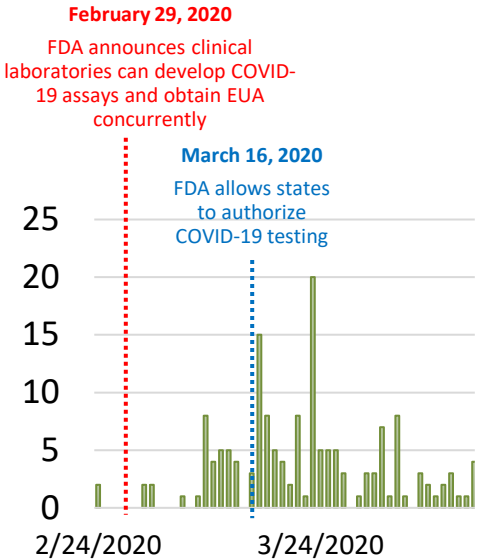
EUA Process

Laboratories acted quickly to provide testing



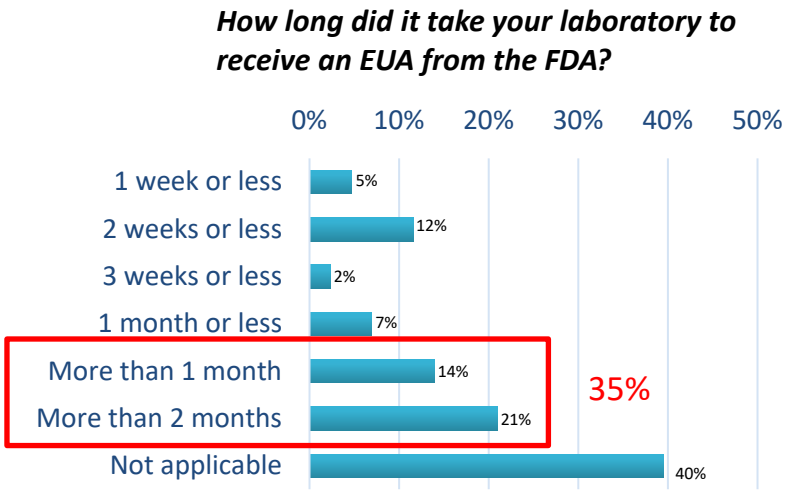
	Academic Medical Center Laboratories (n=43)	Commercial Reference Laboratories (n= 32)	Community Hospitals / Health System Laboratories (n = 31)
Mean	March 21, 2020	April 2, 2020	April 2, 2020
Median	**March 21, 2020**	**April 1, 2020**	**April 1, 2020**
Earliest date submitted	February 24, 2020	March 12, 2020	March 1, 2020

FDA EUA process severely lagged Laboratory Efforts (APRIL 2020)



First Tests Launched Per day

Data shown above combined from both April and August surveys, and represent both IVDs and LDPs from all laboratory types. 202 responses total. Data displayed through April 13, 2020 only.



Data shown above from all laboratory types. 43 responses total.

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Reimbursement

'It will bankrupt my department': How private labs are paying the price for testing

The ACLA has requested $5 billion to keep private labs up and running.

By **Olivia Rubin**
March 20, 2020, 2:59 PM

Dr. Geoff Baird, the acting chair of laboratory medicine at the University of Washington School of Medicine -- home to one of the largest COVID-19 testing labs in a state at the epi-center of the outbreak-- told ABC News his lab has spent about $10 million since it first began testing on March 1.

"It will bankrupt my department in a month," Baird said in an interview with ABC News. "But I don't have an option; it's what's needed."

https://abcnews.go.com/Health/bankrupt-department-private-labs-paying-price-testing/story?id=69707226

Focus and Recommendations

1. **Leverage all types of clinical laboratories** throughout the US
   - increase capacity and resiliency
   - support rapid turnaround times
   - including hospital and academic based laboratories, as part of the Laboratory Response Network.
2. Distribute testing supplies to locations based on disease prevalence and provide access to positive control samples to validate tests.
3. **Regulatory**
   - Allow high-complexity CLIA-certified laboratories to immediately deploy testing ahead of any regulatory submission
   - Streamline the EUA review process for IVD manufacturers to enable authorization within 4 weeks of submission.
4. Provide adequate and predictable pathways to **reimbursement** for clinical testing to ensure laboratory solvency when responding to an emergency.

RESOURCES

Access AMP's Full SARS-CoV-2 Survey Reports here:

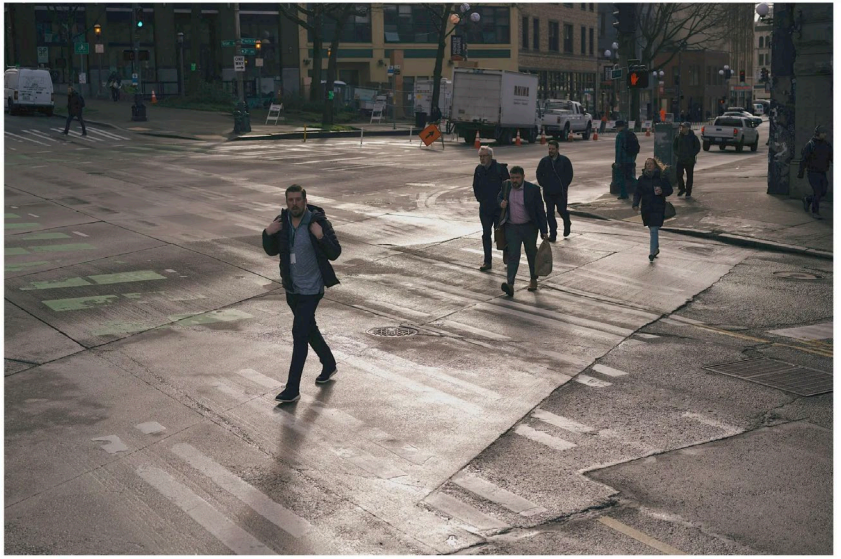
Access AMP's Whitepaper on Economics of Testing During a PHE here:

'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response

A series of missed chances by the federal government to ensure more widespread testing came during the early days of the outbreak, when containment would have been easier.


By Sheri Fink and Mike Baker

Published March 10, 2020 Updated March 16, 2021



A research project in Seattle tried to conduct early tests for the new coronavirus but ran into red tape before circumventing federal officials and confirming a case. Grant Hindsley for The New York Times

https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html

nature medicine

Correspondence | Published: 22 December 2021

The Seattle Flu Study: when regulations hinder pandemic surveillance

Michael Boeckh, Helen Y. Chu, Janet A. Englund, Christina M. Lockwood ✉, Deborah A. Nickerson, Jay Shendure & Lea Starita

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