



STRONGERTOGETHER

EVALUATION OF A PANDEMIC

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CEO, American Society for Clinical Pathology

The Lab Saved My Life



**PATIENT
CHAMPIONS**

About ASCP

ASCP, founded in 1922, unites more than **100,000 members** to better improve patient care through knowledge, collaboration, and global community.

- Anatomic and Clinical Pathologists
- Residents and Fellows
- Medical Laboratory Professions
- Students
- Researchers, Friends and Family



Mission Statement

Our mission is to provide excellence in education, certification, and advocacy on behalf of the patients, pathologists, and laboratory professionals across the globe.

ASCP 2020 Virtual

6,000+
Attendees

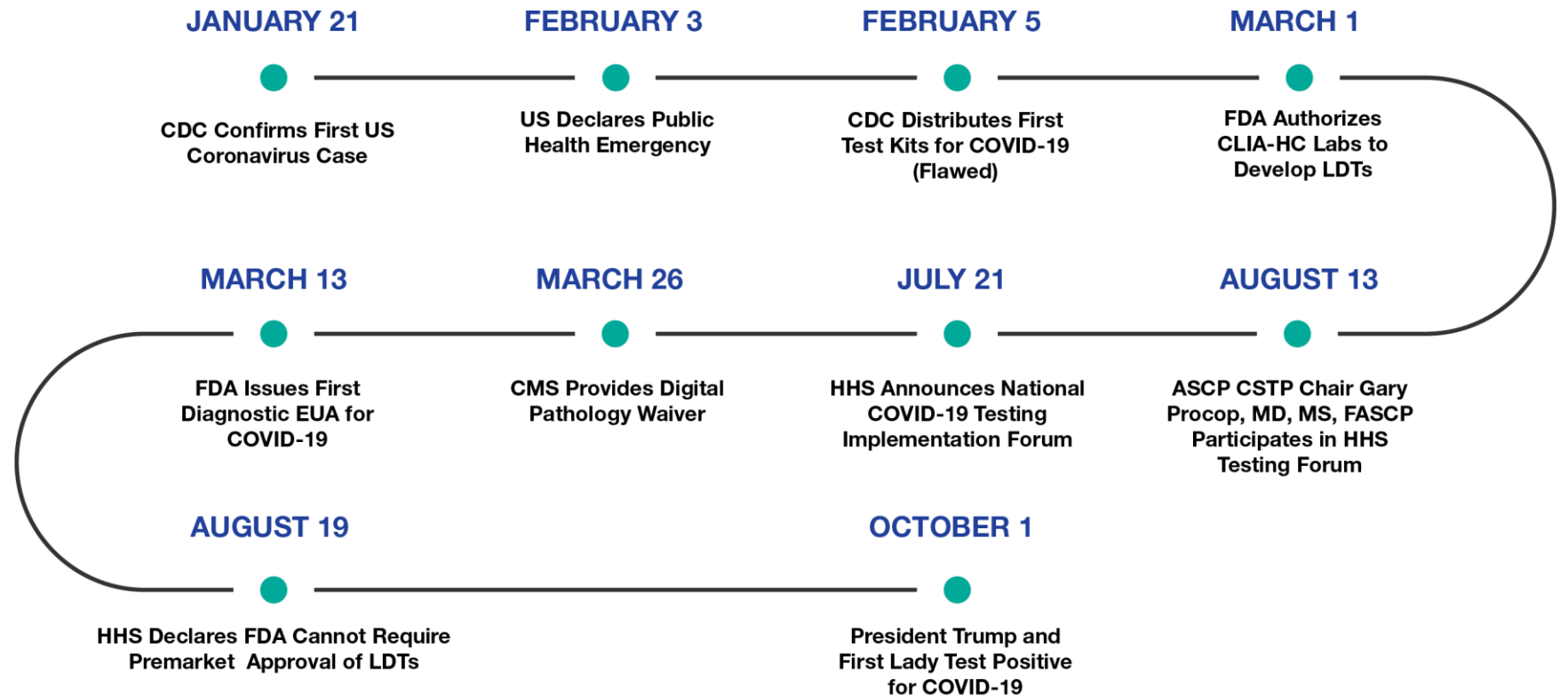
Multiple
COVID Sessions

Multiple
COVID Round Tables





U.S. COVID-19 Events



Laboratories opting to use these tests would not be eligible for Public Readiness and Emergency Preparedness Act coverage and would remain subject to regulation by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988 and its implementing regulations, HHS said. LDT developers may voluntarily apply for approval, clearance or an EUA, and FDA will adjudicate those submissions.

Laboratories on the Front Lines: Battling COVID-19

Institutions Featured

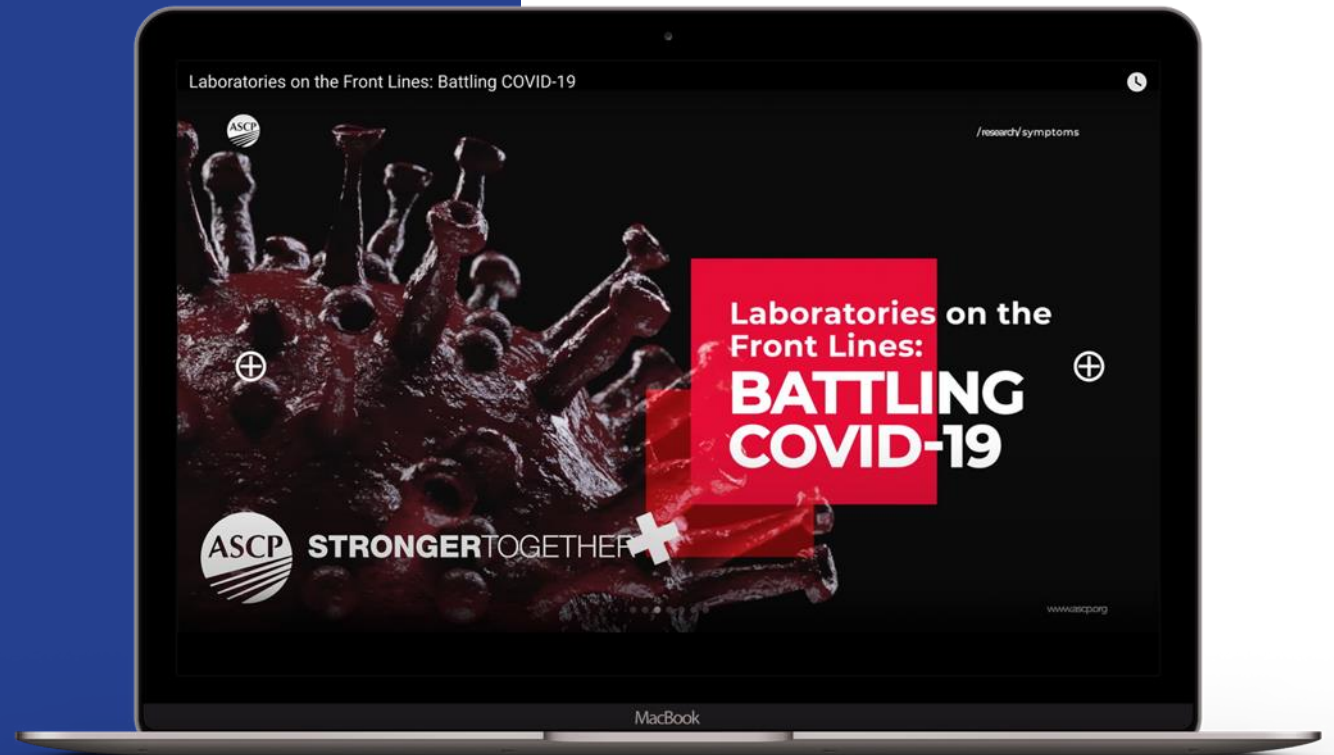
NorthShore Health System

Cleveland Clinic

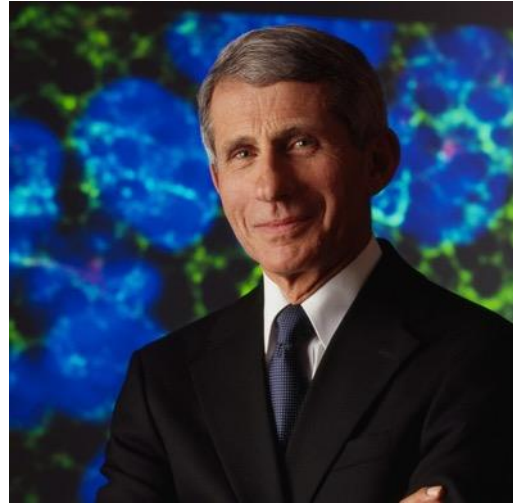
University of Washington

UCLA

University of Nebraska







ASCP Pandemic Response: Tireless Dedication to Help Patients

- Spotlight on Member Experience and Expertise including Docuseries; Town Halls; ground-breaking research in *AJCP* Journal; media outreach; resource needs, etc.
- Patient-Centered Advocacy including bi-directional communication to White House (Birx/Girot/Fauci); HHS; CMS; CDC; FDA; Public Health Labs; Congressional Staff; Partner Organizations; Diagnostic Companies; Global Partners
- Early development of a National Diagnostic Testing and Support Plan
- Mobilization of Members (Multiple Action Alerts)
66,000+ Letters to WH, Congress, HHS, Governors

COVID-19 Guidance from ASCP Experts

Gary Procop, MD, MS, MASCP, CSTP Chair

- Cleveland Clinic/ASCP Board of Directors
- ASCP representative to White House Implementation Task Force
- Multiple FDA Consultations on COVID-19
- CDC Presentation on ASCP's National Plan to over 2000 Laboratory Leaders
- Provided Consultation to AMA on COVID-19

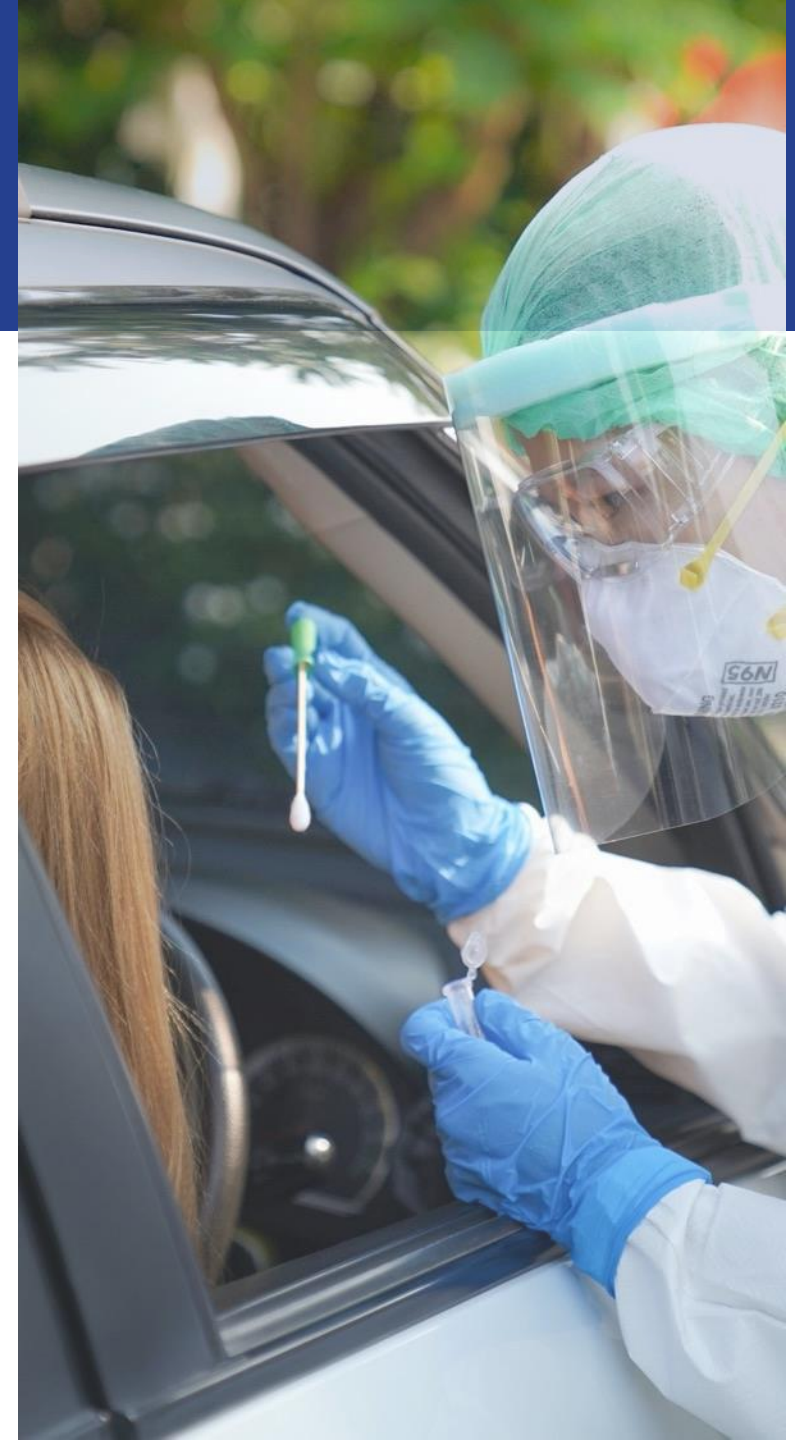


ASCP Calls for National Testing and Laboratory Support Strategy

Policy recommendations included:

- Molecular testing is the gold standard for diagnosing COVID-19
- Streamlined communications – state, federal policy makers, clinical labs
- Financial and logistics support for clinical laboratories to increase test capacity
- Grants to support innovative diagnostics development, access to testing supplies
- Provide support for the use of convalescent plasma
- Support for pathologists and laboratory professionals in the form of hazard pay, student loan support, mental health support, MIPS relief etc.

AMA Endorsed ASCP's Call to Develop a National Testing Strategy in early May



ASCP Member Actions: Grassroots Support

ASCP Action Alert Topic	Letters to Policy Makers
Urgent Action Alert for Remote AP Services	10,122
Urgent Action Alert for National Testing Strategy	25,296
The US Needs a COVID-19 Testing Strategy	15,653
ASCP Urges Creation of a National Testing Task Force	15,869
Total	66,980

A Voice for Our Field

Results of ASCP Advocacy Actions:

- **Flexibility and Resources to Expand Testing**
(Granted through Executive and Legislative Branch Actions)
- **Remote Read Pathology Slides** *(Granted by HHS)*
- **National Testing Strategy** *(Elements Enacted)*
- **Formation of National Task Force to Promote Reliable Testing** *(Elements Enacted)*



Key COVID-19 Legislation

Coronavirus
Preparedness and
Response Supplemental
Appropriations Act

\$1 billion
in funding

Families First
Coronavirus Response
Act

Free
testing for
uninsured

Coronavirus Aid, Relief,
and Economic Security
Act

\$4.3 billion for COVID
response

\$15 billion relief payments
for Medicaid / CHIP
Suspends PAMA cuts
for 2021

Paycheck Protection
Program and Healthcare
Enhancement Act

\$75 billion to reimburse
healthcare expenses / lost
revenues

\$25 billion to develop and
extend COVID testing

A person wearing a blue lab coat and white gloves is holding a box of face shields. The box is white with a blue label that says "FACE SHIELD". The person is also wearing a blue surgical cap. The background is a blue-tinted laboratory setting.

Laboratory Challenges

Laboratory Challenges in the Time of COVID

Overwhelming volumes and surges

50 States/50 + Plans

Decreases in AP volume

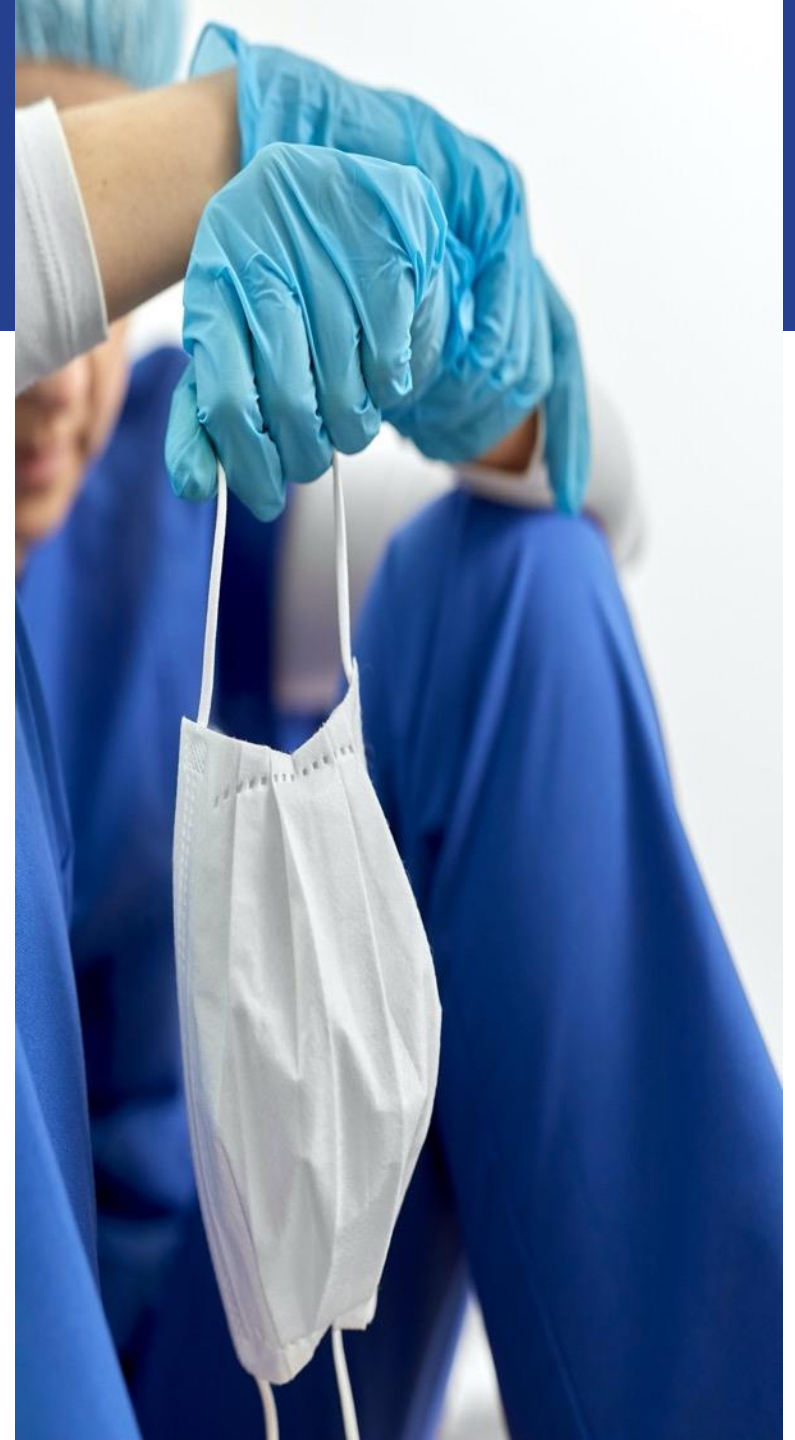
Staffing and furloughs

Reagent and supply constraints to testing

- Propriety systems, open vs closed, automation
- Multiple systems

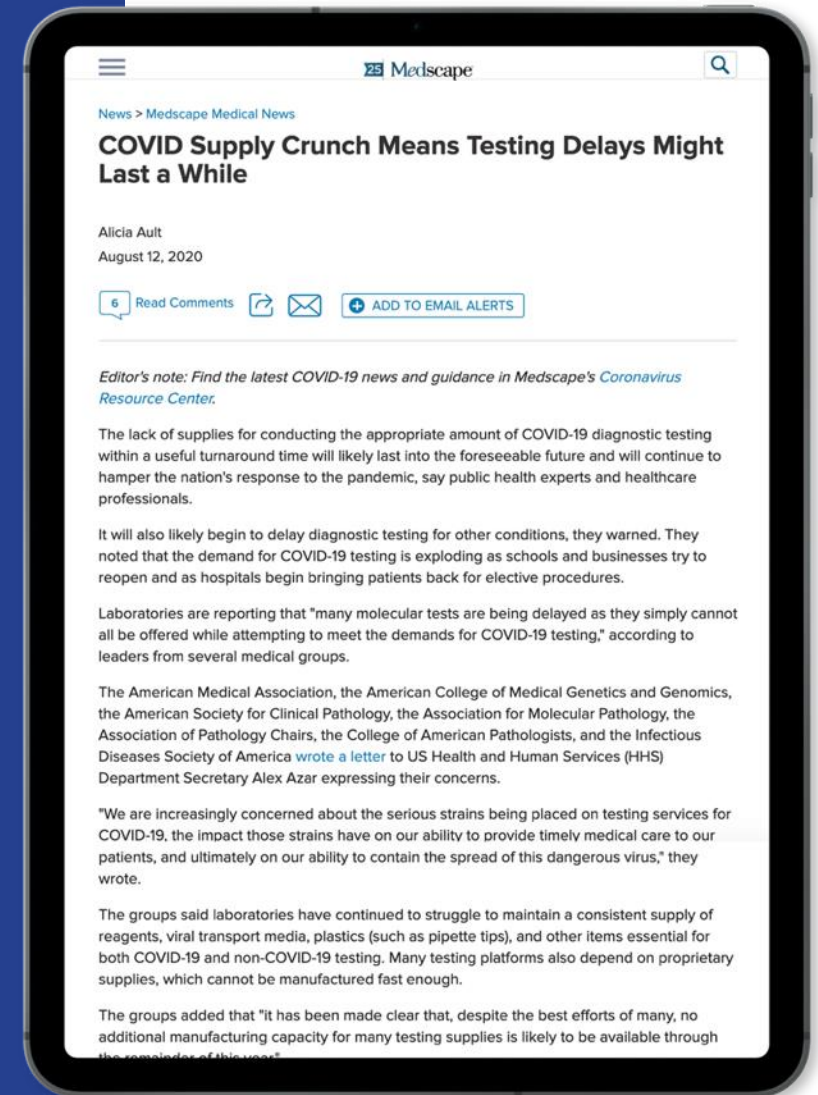
Regulatory confusion

- FDA, CDC and CMS responses
- White House and HHS is not always aligned



Laboratory Challenges in the Time of COVID

- PHLs, hospitals and private labs competing for same supplies
- Need for a national approach and updated guidelines
- TAT information is not shared publicly
- Delay in diagnostic testing for other conditions
- Lack of supplies... lasting into the foreseeable future
- No additional capacity for many supplies available for the rest of the year



Supply Chain Issues

Multiple platforms

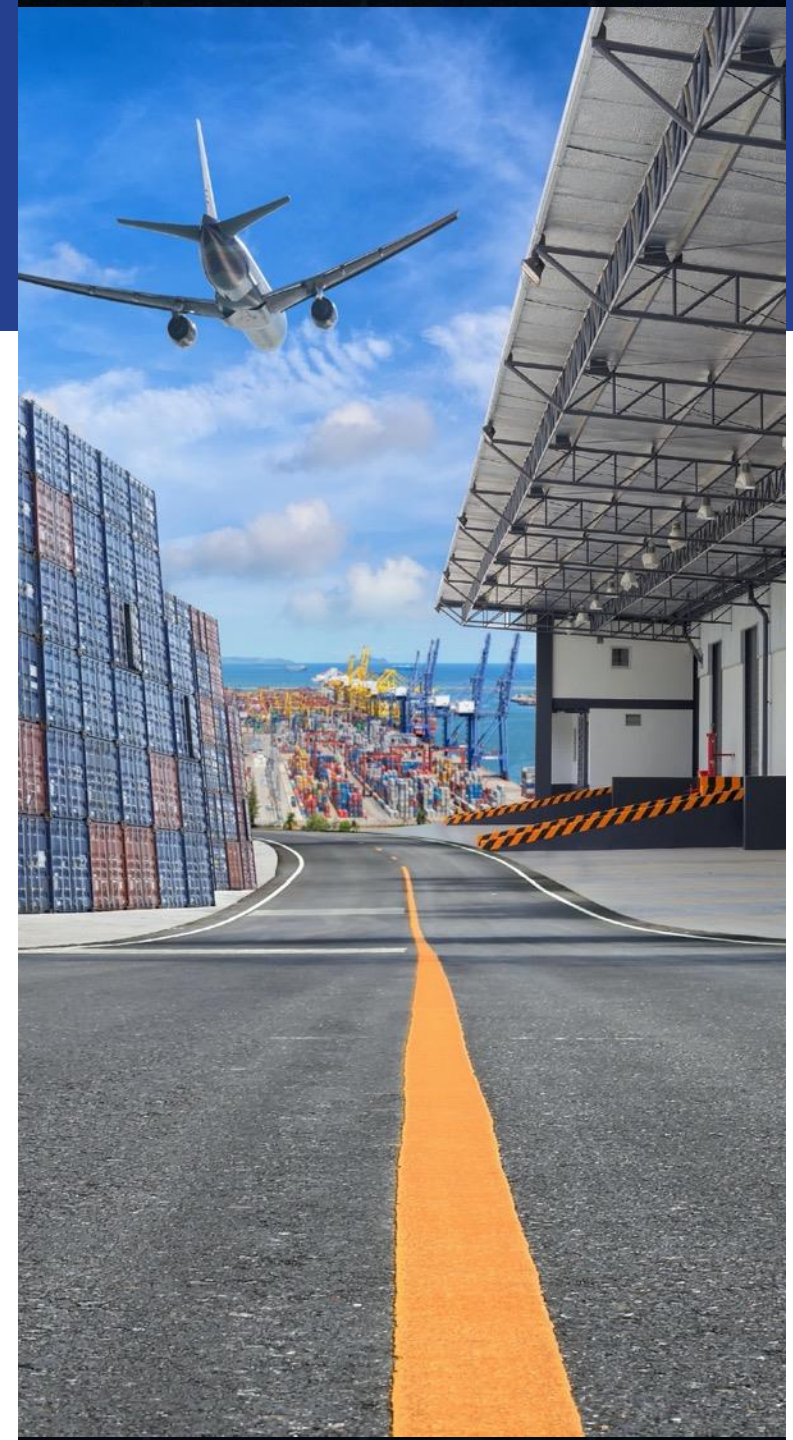
FEMA guidance (confusing) on distribution of resources

Vendor determination of resource allocation

Downstream effects (Flu testing)

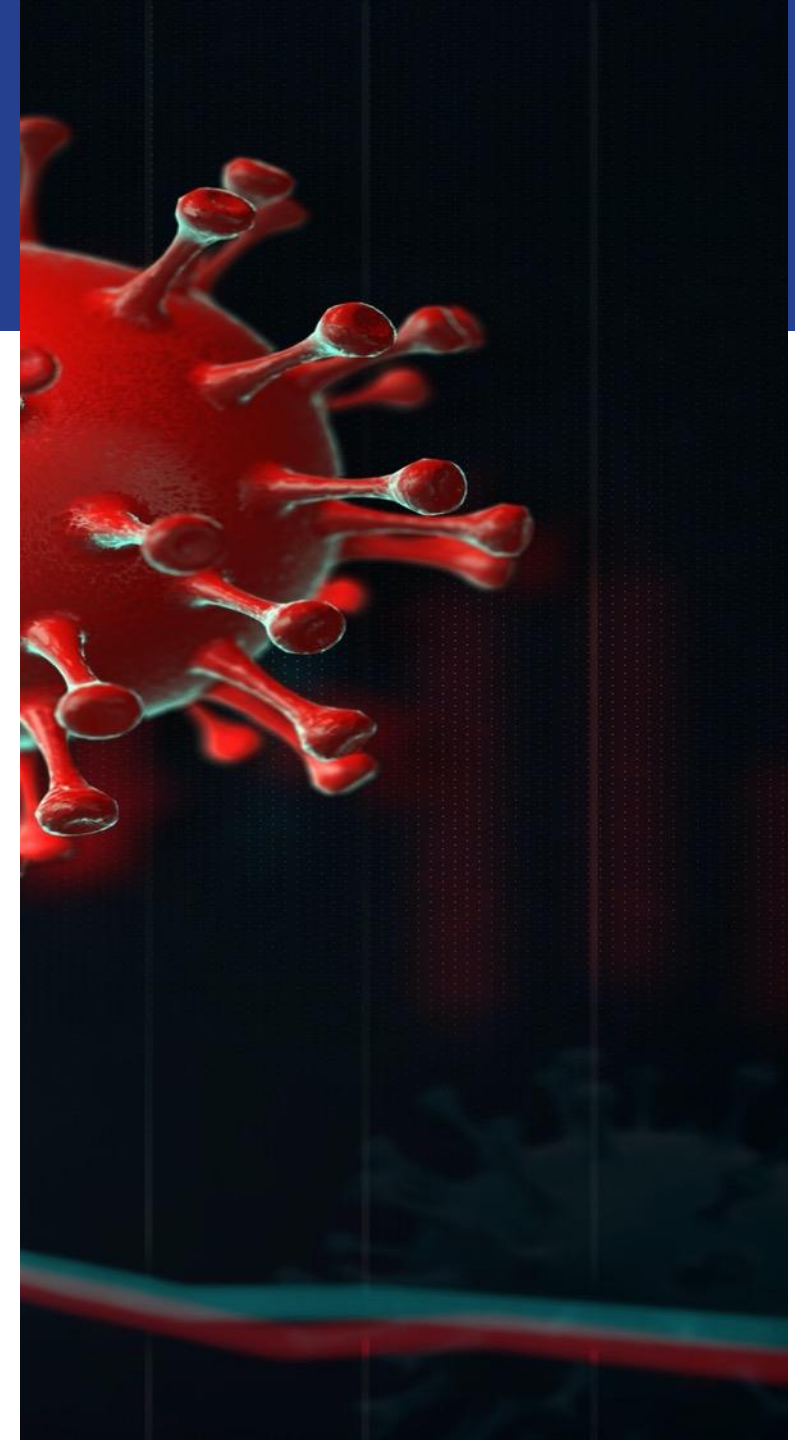
Lessons Learned

- Why labs are so important
- Labs should not be commoditized



ASCP COVID-19 Survey Data Background

- COVID-19 questions included in the 2020 ASCP Vacancy Survey
- Survey deployed from June 22 - July 24, 2020 provides a snapshot in time
- Target audience: Management-level or HR positions
- 476 responses for the COVID-19 section
- Collaboration between ASCP Institute for Science, Technology and Policy and ASCP Evaluation, Measurement, and Assessment Teams



ASCP Survey Key Findings

Testing:

61%

A majority of labs saw decreased testing volumes due to COVID-19 pandemic

60%

of laboratories saw test volume decrease by 26 percent or more

68%

Most labs were performing SARS-CoV-2 testing at their facility

ASCP Survey Key Findings

Staffing:

50%

of clinical laboratories reduced their staffs of pathologists and non-physician laboratory professionals

24%

of laboratories furloughing personnel

27%

rescinding vacant positions or requisitions for staff

7%

laying off staff

ASCP Survey Key Findings

Institutional-Level Impact:

70%

of respondents experienced a hiring freeze/slowdown during the pandemic

50%

Over half of respondents indicated that yes, staff had to be quarantined d/t COVID-19 exposure or symptoms, most of these quarantine periods lasted 14 days

ASCP Town Hall Series to Address the Challenges

COVID-19: National Testing Strategy and the Laboratories' Response

COVID-19 and the Blood Bank: What Do You Need to Know?

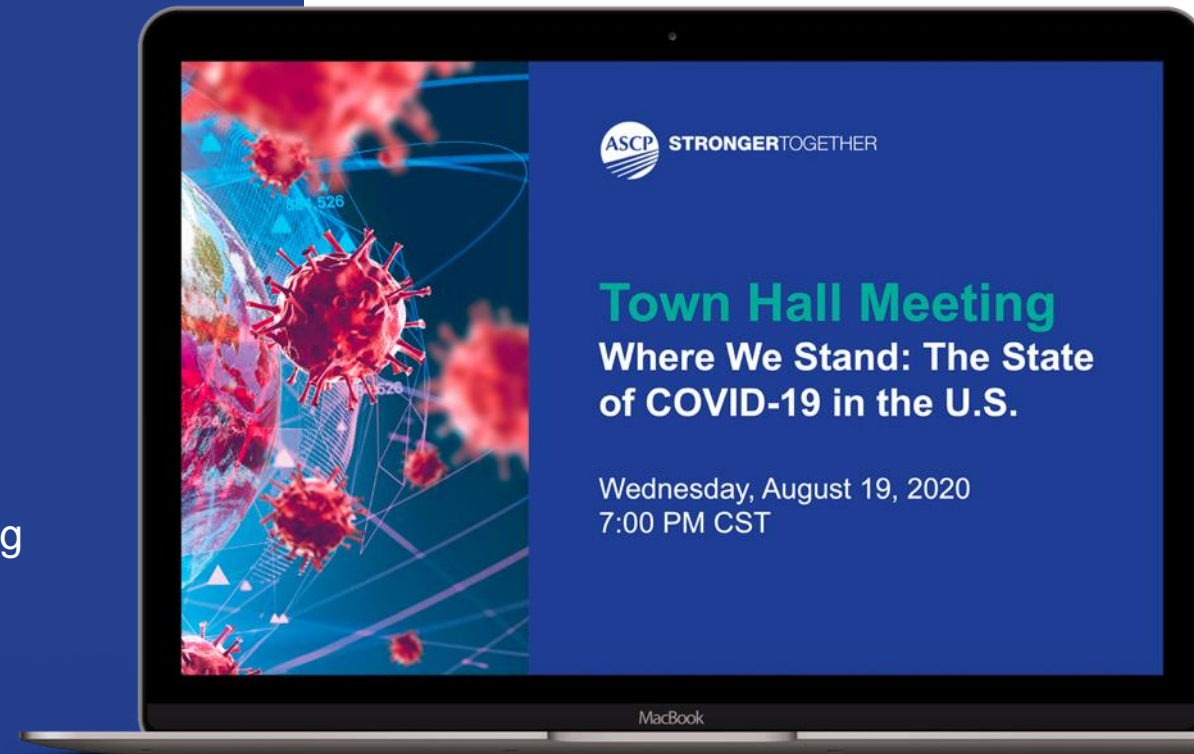
Best Practices in Adopting Multiple COVID-19 Testing Platforms

Epidemiology, Virology, and Clinical Testing Strategies for COVID-19

SARS/CoV-2
COVID-19 - Serology Testing

COVID-19 and the Patient: How the Pandemic is Escalating Health Disparities

COVID-19 and the Patient: These Unprecedented Times: Talking with Dr. Anthony Fauci





Dr. E. Blair Holladay ASCP CEO

New

“Inside the Lab Podcasts”

This podcast focuses on current topics showcasing the everyday laboratory professional and pathologist. It generates thought-provoking discussions about topics relevant to the field of pathology and laboratory medicine.

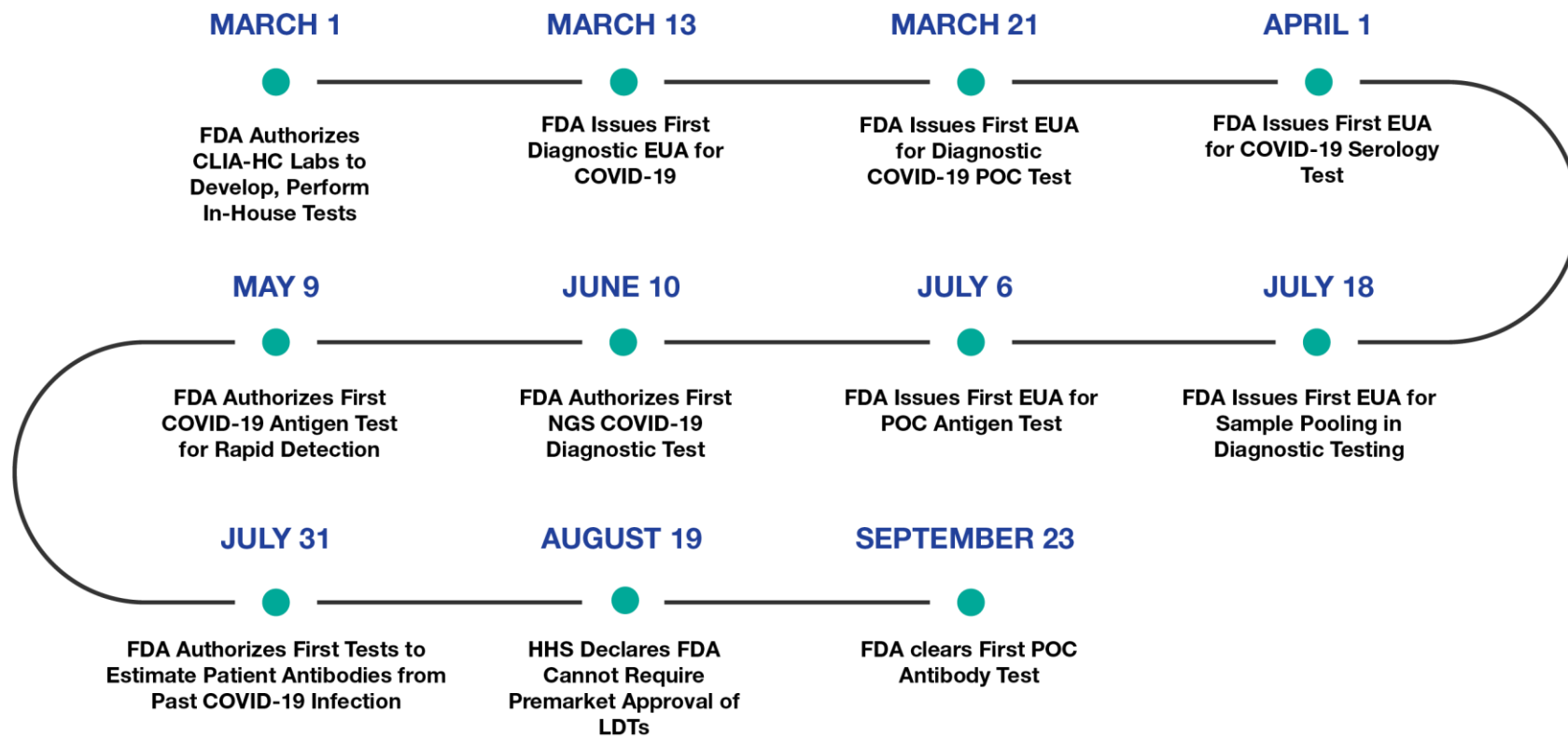


FDA Response Efforts



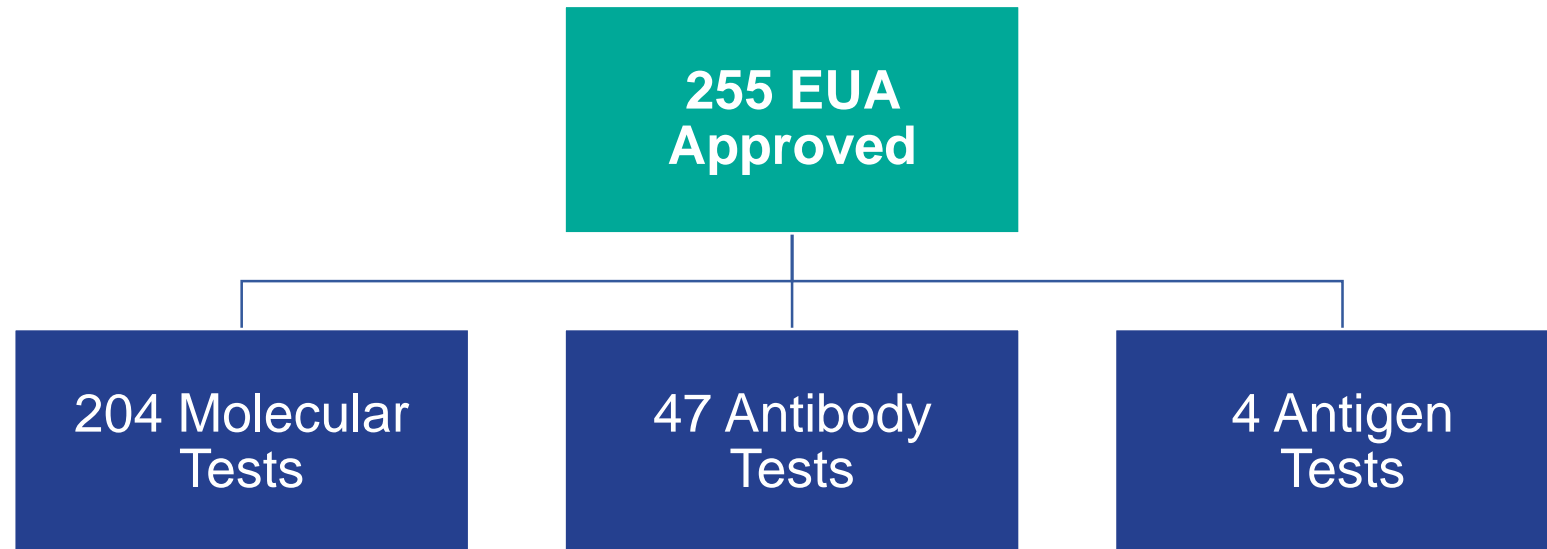
U.S. Department of Health and Human Services
Food and Drug Administration

FDA COVID-19 EUA Events



FDA Emergency Use Authorizations (EUAs)

- Allow use of unapproved medical products or unapproved uses of approved medical products
- Diagnose, treat, or prevent serious or life-threatening diseases in an emergency when no adequate, approved, and available alternative exists



FDA Emergency Use Authorizations (EUAs)


- FDA has also revoked EUA authority for tests due to product concerns
- FDA released guidance documents pertaining to COVID-19 testing



CDC Centers for Disease Control and Prevention Search Advanced Search

Prepared Laboratories

Clinical Laboratory COVID-19 Response Calls ▼



**Laboratory Professionals:
Find COVID-19 information from LOCS.**

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM EDT. Audio and transcripts are posted online after each call.

To submit questions for consideration, email DLInquiries@cdc.gov in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities – we are all in this together.

Participation Information
[Connect to Zoom](#) ↗

Webinar ID: 160 639 2851
 Password: 048861

Join by Phone

+1 (669) 254-5252/Passcode: 1606392851#
 +1 (646) 828-7666/Passcode: 1606392851#
 Password: 048861

[International Numbers Available](#) ↗

2020 Calls

- [September 14, 2020 Transcripts and Audio Files](#)

- [August 31, 2020 Transcripts and Audio Files](#)

- [August 17, 2020 Transcripts and Audio Files](#)

- [August 3, 2020 Transcripts and Audio Files](#)

An official website of the United States government [Here's how you know](#) Search Menu

FDA

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← Workshops & Conferences (Medical Devices)

TOWN HALL

Virtual Town Hall Series - Coronavirus (COVID-19) Test Development and Validation

OCTOBER 7, 2020

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On This Page

- [Meeting Information](#)

Date: October 7, 2020
Time: 12:15 PM - 1:15 PM ET

[TAKE OUR SURVEY](#) ↗

Tell us what you think about the town halls

Summary:

The U.S. Food and Drug Administration (FDA) will host a virtual Town Hall for SARS-CoV-2 test developers. The purpose of this Town Hall is to help answer technical questions about the development and validation of tests for SARS-CoV-2.

The FDA will also hold virtual Town Halls for test developers to help answer questions on:

- October 14, 2020 from 12:15 pm – 1:15 pm Eastern Time
- October 21, 2020 from 12:15 pm – 1:15 pm Eastern Time
- October 28, 2020 from 12:15 pm – 1:15 pm Eastern Time.

[Add this series to my Calendar](#)

Outlook users: Click link, select Open, then click Save & Close.

It's Hard for Clinicians to Understand Laboratory Testing

The NEW ENGLAND JOURNAL
of MEDICINE

Covid-19 Molecular Diagnostic Testing —
Lessons Learned Jeffrey Shuren, M.D., J.D.,
and Timothy Stenzel, M.D., PhD

The New England Journal of Medicine
September 13, 2020

“Although this approach resulted in earlier test availability, the EUA’s less-rigorous evidence standard, coupled with delayed FDA review, allowed the use of several LDTs that ultimately proved to have performance problems or to be poorly validated...The process also revealed that some clinicians have a limited understanding of test performance. No test is 100% accurate, and performance can vary within populations.”

“Even if a test were 98% sensitive and 99% specific, it would still produce a false negative result in 2 of every 100 people infected. If we test 5 million Americans daily and only 1% of them have Covid-19, a total of 1000 positive cases will be missed, which increases the risk of spread, and another 49,500 people will receive false positive results.”

Toward Optimal Test Utilization: The Long and Winding Road

Issues

- ✓ **What does it do?**
 - Define it
 - Scientific analyses
- ✓ **What can't it do?**
 - Describe boundaries
- ✓ **How to use it?**
 - Control it
 - On-label use guidance
 - Off-label hazards
 - Best Practices

Assays

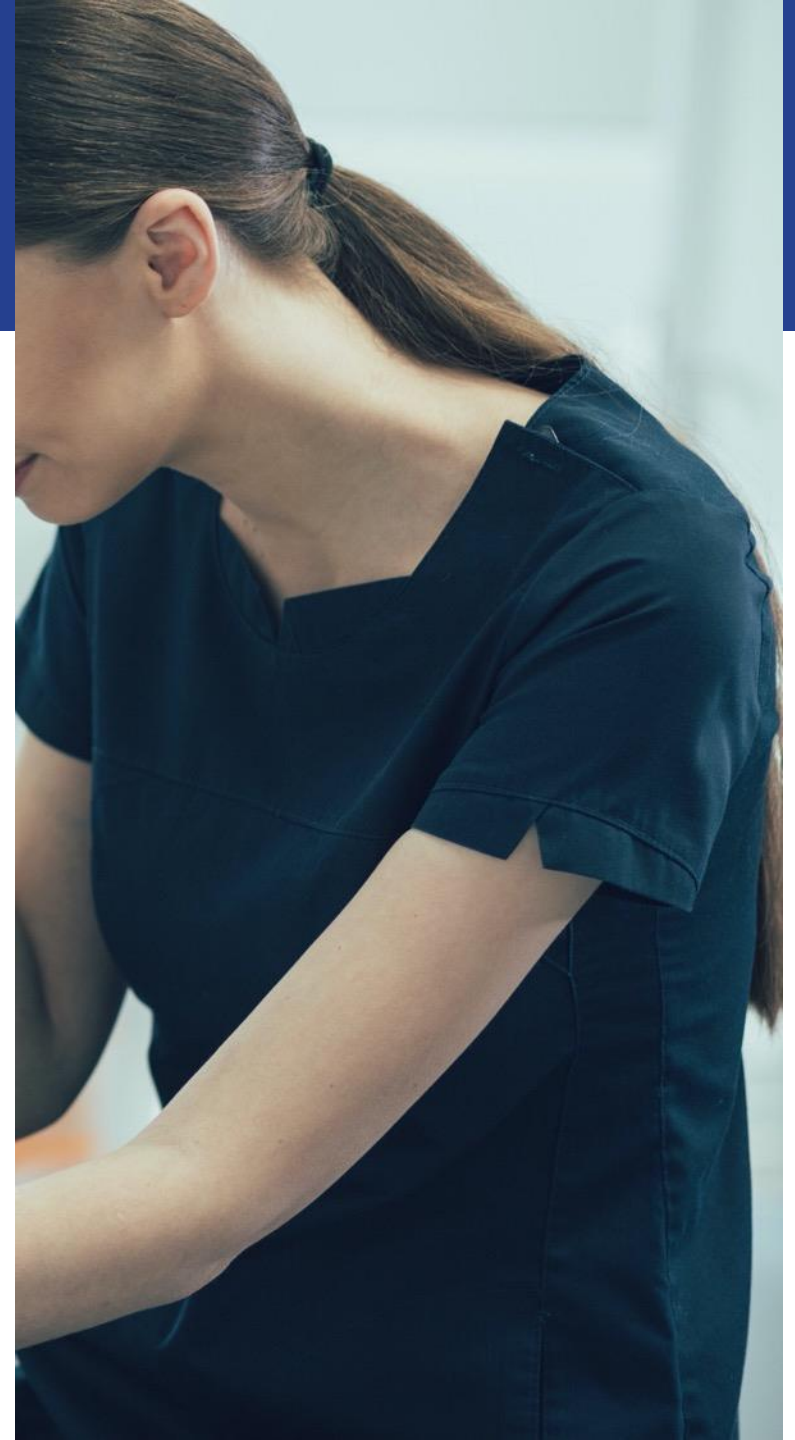
- ✓ **Direct Molecular Diagnostics**
 - Highly Sensitive
 - Not as Highly Sensitive
- ✓ **Serology**
 - Qualitative
 - Next:? Quantitative? Neutralizing
- ✓ **Antigen Detection Tests**
- ✓ **Point of Care/Home Test Kits**

A scientist in a white lab coat and blue gloves is working in a laboratory. The image is overlaid with a semi-transparent blue filter. The text is centered on the left side of the image.

**Future State:
A return to normalcy?**

The Good News

- Highlighted the importance of the laboratory
- Lab expertise is valuable and relevant
- Gained traction in not being considered a commodity
- Strengthened relationships in executive suite
- Potential leverage for additional funding for testing and clinical lab personnel



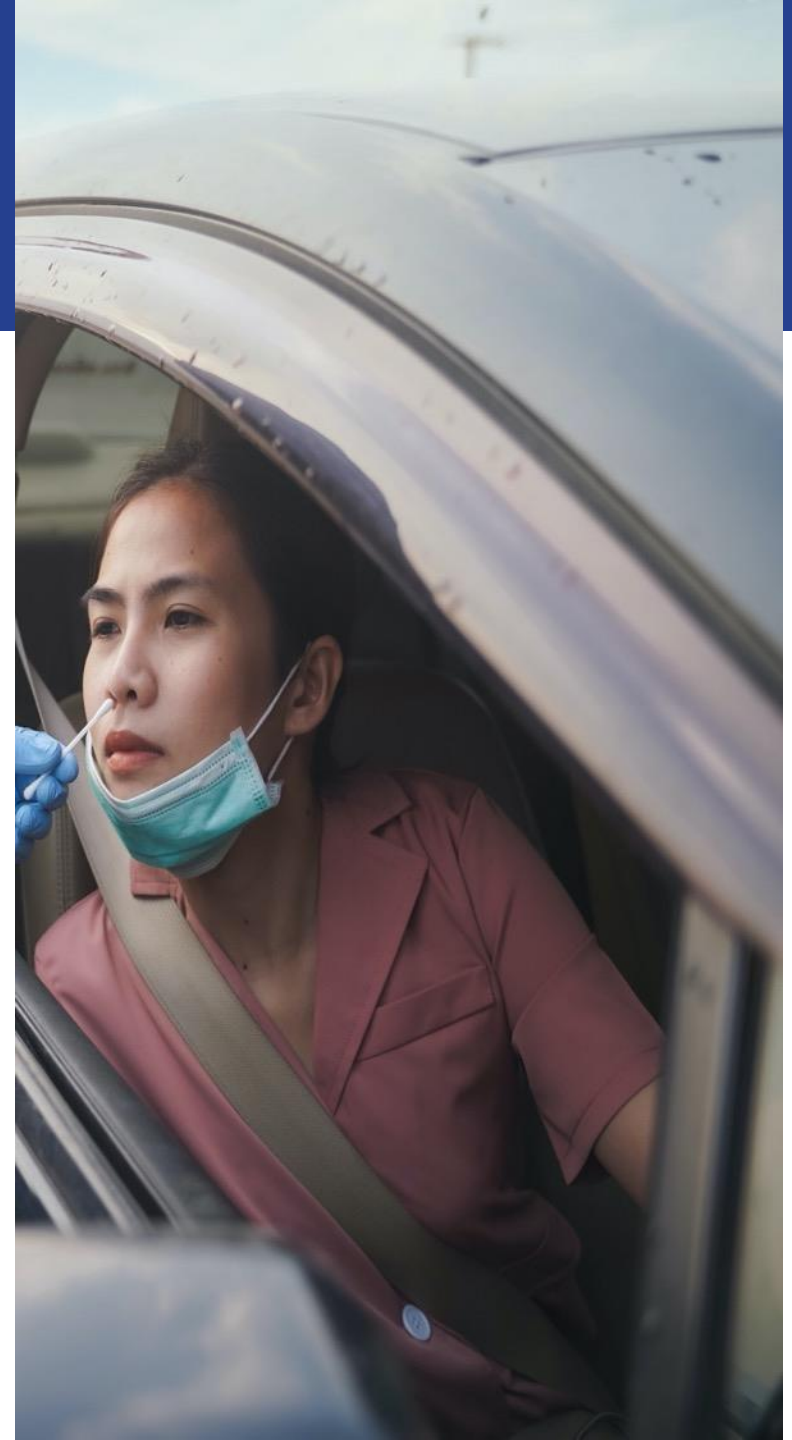
Opportunities and Lessons Learned

- Being more mindful of the origin of laboratory supplies and consumables
- Lack of a coordinated national testing strategy leading to exacerbation of competition for resources
- Supply chain constraints can lead to hoarding behaviors, exacerbating shortages



A Coherent National Test Strategy Is Still Needed

- Promote reliable tests, right time, right patient
- Disseminate accurate scientific information about testing
- Develop best practices
- Provide logistical support for improved public health and patient care outcomes related to COVID-19





**Pathology and Laboratory Medicine
Professionals are Ready to Lead and
Reduce Unnecessary Deaths**



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