

# Clinical Laboratory COVID-19 Response Call

Monday, June 15<sup>th</sup>, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **FDA Update**
  - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)
- **Laboratory Biosafety Update**
  - Bill Arndt, CDC Division of Laboratory Systems (DLS)
- **The Joint Commission: Ready, Relevant, Responsive**
  - Barbara Schwarzer, The Joint Commission
- **Summary of Recent SARS-CoV-2 Molecular Testing Survey**
  - Robyn Temple-Smolkin, Association for Molecular Pathology (AMP)

# CDC Information for Laboratories

- **Interim Guidance for Collecting, Handling, and Testing Clinical Specimens**  
<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>
- **Diagnostic Tools and Virus**  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html>
- **Emergency Preparedness for Laboratory Personnel**  
<https://emergency.cdc.gov/labissues/index.asp>
- **CDC's Laboratory Outreach Communication System (LOCS)**  
<https://www.cdc.gov/csels/dls/locs/>
- **IVD Industry Connectivity Consortium**  
<https://ivdconnectivity.org/livd/>
- **LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests**  
<https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>

# Live Audience Poll



# We Want to Hear From You!

## Training and Workforce Development



Questions about education and training?

Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)

# To Ask a Question?

- **Using the Webinar System**

- Click the **Q&A** button in the Zoom webinar system
- Type your question in the **Q&A** box and submit it
- Please do not submit a question using the chat button



- For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider

## FDA Update

**Tim Stenzel and Sara Brenner**  
U.S. Food and Drug Administration (FDA)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information**  
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
- **COVID-19 Frequently Asked Questions**  
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>
- **COVID-19 Updates**  
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>
- **FDA Townhall Meetings**  
<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>



# Food and Drug Administration (FDA)

**COVID-19 Diagnostic Development:** [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

## **Spot Shortages of Testing Supplies: 24-Hour Support Available**

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (\*)





# Laboratory Biosafety Update

**Bill Arndt**

CDC Division of Laboratory Systems (DLS)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention



# CDC Biosafety Resources

- COVID-19 Information for Laboratories page:  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>
- Interim Laboratory Biosafety Guidelines:  
<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>
- Laboratory Biosafety Frequently Asked Questions:  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

# The Joint Commission: Ready, Relevant, Responsive



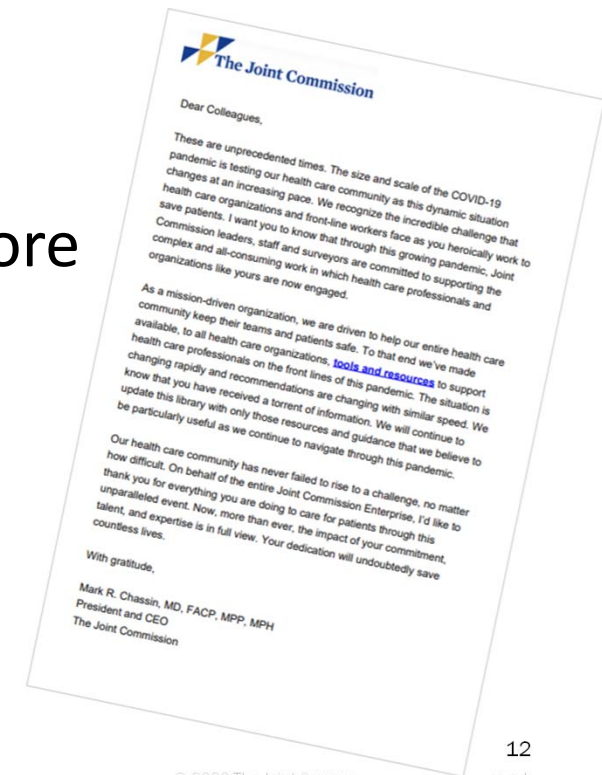
**Barbara Schwarzer, MT(ASCP), MHA, MSOL, CPHQ**

June 15, 2020



# A message from Dr. Chassin, President and CEO of The Joint Commission

- We thank you
- We commit to you
- We will all come together, stronger than before
- We advocate for you
- We are here to help you
- We ensure your safety



# We Are Ready – How We Prepared



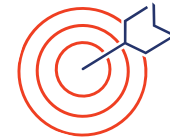
Algorithm of safety  
for survey locations



Outreach calls to  
assess readiness of  
laboratories



Training Extensive  
Emergency  
Management (EM) and  
Infection Control (IC)  
training for surveyors



Focus on EM and IC  
during survey  
-Assess compliance  
with current standards

# We Are Relevant

- Focus on quality and safety of patient care in this new environment
- Recognize your tireless work
- Share lessons learned by other organizations just like yours
- Begin virtual surveys
- Promote safety and efficiency during the survey



# We Are Responsive

- Seek to **understand**: tell your story and your plan to move forward
- We are here to **help** you
- **Listen** to how things have changed for you
- Provide ongoing **updates**, useful **resources**, **webinars** on The Joint Commission website

<https://www.jointcommission.org/covid-19/>

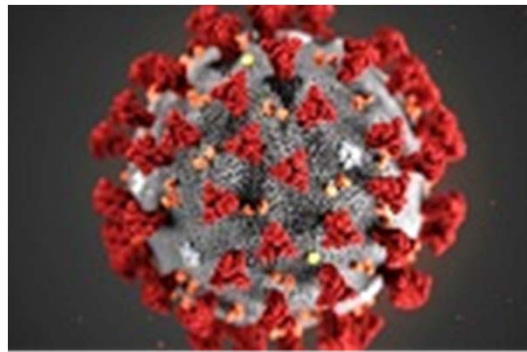
# Questions?

Contact The Joint Commission at:  
[qualitylabs@jointcommission.org](mailto:qualitylabs@jointcommission.org)



# Association for Molecular Pathology SARS-CoV-2 Molecular Testing

## Summary of Recent SARS-CoV-2 Molecular Testing Survey



AMP's COVID-19 Resources  
[www.amp.org/COVID19](http://www.amp.org/COVID19)

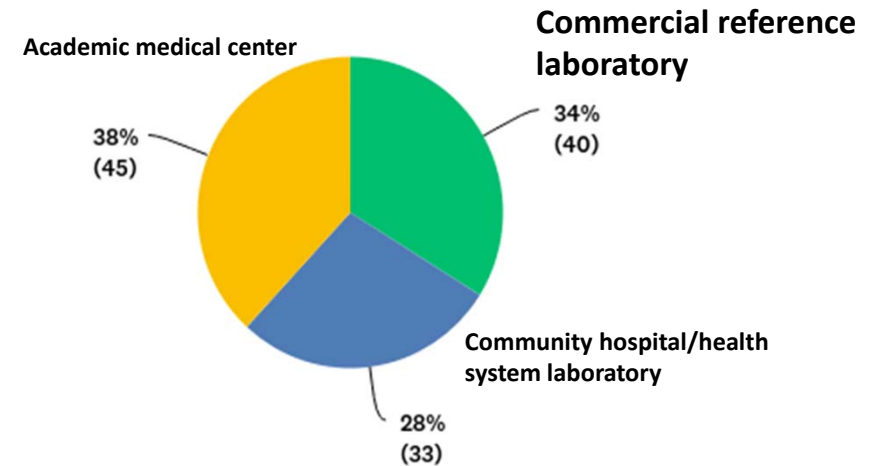
*All resources available at no cost &  
membership is not required*

# AMP SARS-CoV-2 Testing Survey

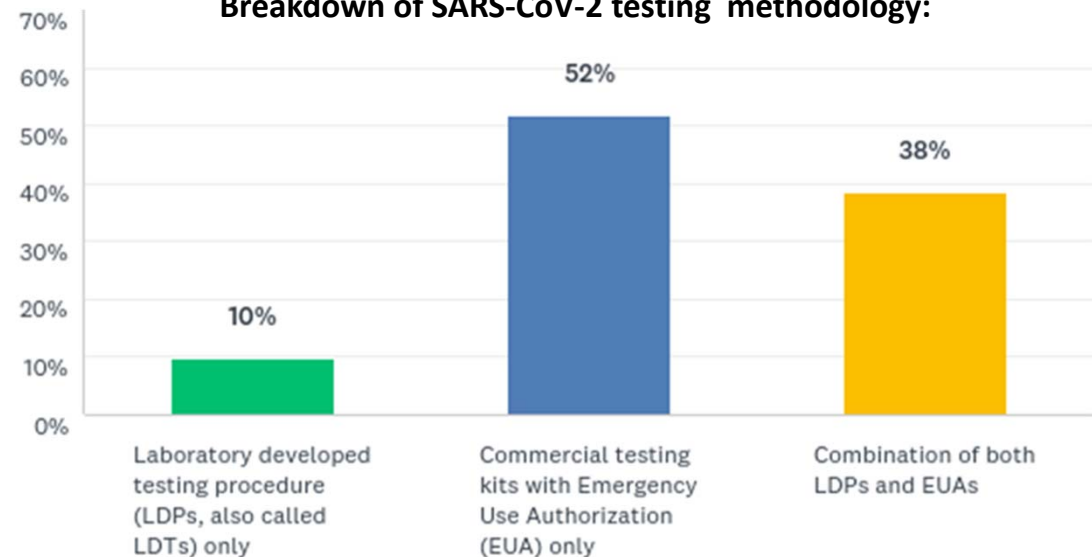
This survey was conducted between April 23 - May 5, 2020 and is second in a series of SARS-CoV-2 pandemic response surveys to AMP membership and beyond

67 questions assessed different aspects of SARS-CoV-2 molecular testing:

- Laboratory demographics
- SARS-CoV-2 testing demand and current capacity
- Increasing laboratory capacity
- Agency communications regarding laboratory capacity
- SARS-CoV-2 test methodology
- Test performance & validation
- Resource and supply chain concerns
- Sample collection
- Test reimbursement
- Public health reporting requirements



Breakdown of SARS-CoV-2 testing methodology:

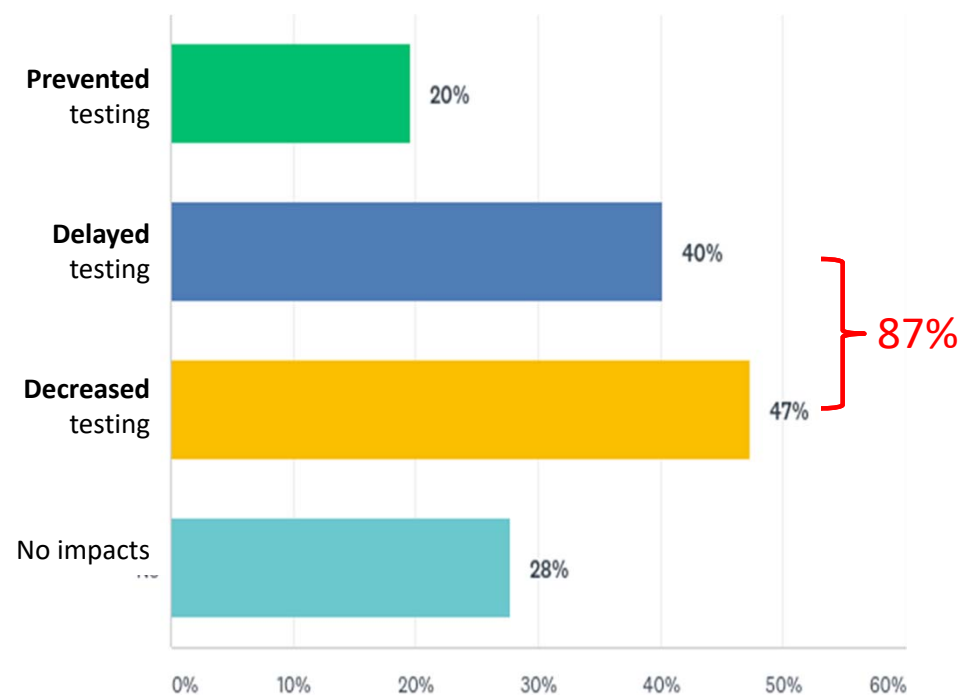


## Laboratories were quickly able to offer SARS-CoV-2 diagnostic tests but supply chain issues continue to negatively impact laboratories

TYPE OF SUPPLY CHAIN LIMITATION	CURRENTLY LIMITED	PREVIOUSLY LIMITED	NEVER LIMITED
Testing platforms (n=73)	32%	33%	36%
Testing kits (n=73)	34%	45%	21%
Reagents (RNA extraction kits, buffers, etc.; n=75)	33%	48%	19%
Swabs (n=77)	60%	31%	9%
Transport media (UTM/VTM; n=75)	53%	35%	12%
Laboratory consumables (tips, tubes, etc.; n=75)	19%	31%	51%
Personal protective equipment (n=74)	27%	31%	42%

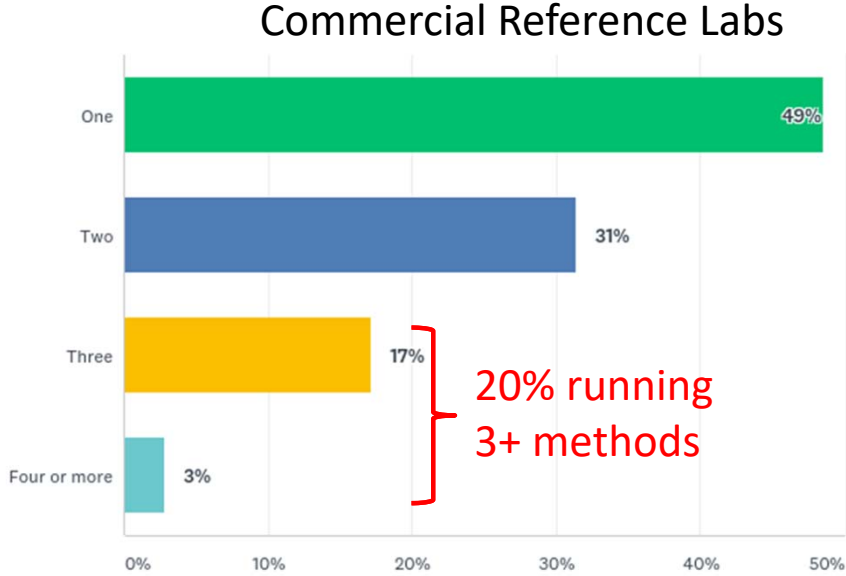
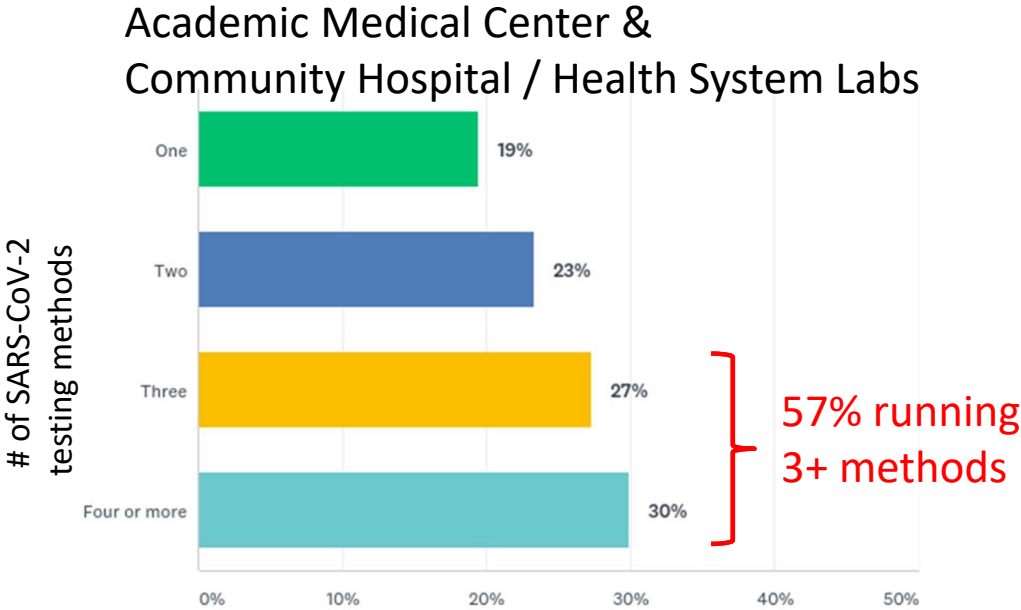
Data shown above from all laboratory types. "Select all that apply" question format, Answered: 81, Skipped: 37

### Negative impacts of supply chain interruptions or limitations on patient testing



Data shown above from all laboratory types. "Select all that apply" question format, 112 respondents, absolute # responses: Prevented (22), Delayed (45), Decreased (53), No impacts (31)

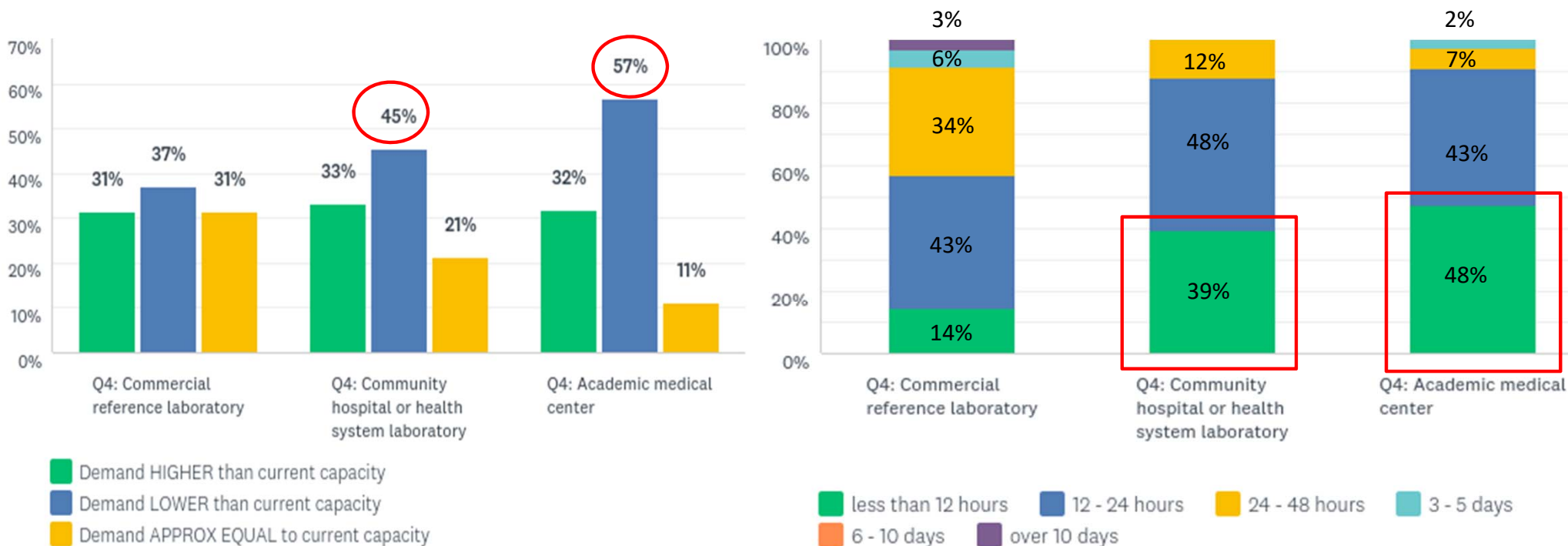
# Due to supply shortages and uncertainties, laboratories are deploying multiple testing methodologies



**Why did you choose this SARS-CoV-2 testing method?**

- “Whatever reagents were able to receive”
- “Independent supply chain”
- “Limited kit availability”
- “Supply chain issues are a major hurdle currently, which is preventing us from moving forward with this as a primary instrument.”
- “We use the [company name’s] extraction reagents and they are hard to get and the shortage affects our 24 other LDTs.”
- “We are concerned with this test and have it as a back-up for increased capacity if it needs to be deployed. The supply chain for this test has been very un-reliable.”
- “Next door (Virology Lab) is offering COVID19 testing on three platforms to minimize the risk of inventory shortage.”

Laboratories located near-to-patient have current capacity to provide SARS-CoV-2 testing with rapid turnaround times, are rapidly expanding capacity, but are underutilized & under-resourced



90% of U.S. laboratories reported planning to greatly increase testing capacity within 90 days

# Recommendations to improve the COVID-19 pandemic response and potential future pandemics

*Based on the survey findings, AMP developed 5 key recommendations. The recommendations aim to effectively leverage America's large and diverse laboratory network to best respond to both the Coronavirus pandemic and potential future pandemics.*

1. Reassess type and location of SARS-CoV-2 testing services needed
2. Reprioritize supply allocations based on clinical testing needs, which could change over time
3. Increase transparency, communication, and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government)
4. Real-time coordination amongst laboratories to leverage moments of excess capacity
5. Standardize agency reporting format and processes for reportable infectious diseases during a pandemic

## For more information

- AMP COVID-19 Virtual Town Hall - June 11, 2020 @ 1 PM Eastern
  - Dr. Jordan Laser presents key preliminary findings from the COVID-19 survey of US-based laboratories along with AMP's 5 recommendations. AMP President Dr. Karen Weck moderates a panel discussion with Drs. Laser, Frederick Nolte, and Karen Kaul along with an attendee question and answer session.
  - **Available FREE on demand:** <http://www.amp.org/COVID19>
- AMP Advocacy Hill Briefing
  - Available FREE on demand: <https://attendee.gotowebinar.com/recording/1061151173829294352>
  - Preliminary survey results: <https://www.amp.org/advocacy/sars-cov-2-survey/>
- Any requests for content for future surveys? Contact Robyn Temple-Smolkin at [rtemple@amp.org](mailto:rtemple@amp.org)

# CDC Social Media



<https://www.facebook.com/CDC>



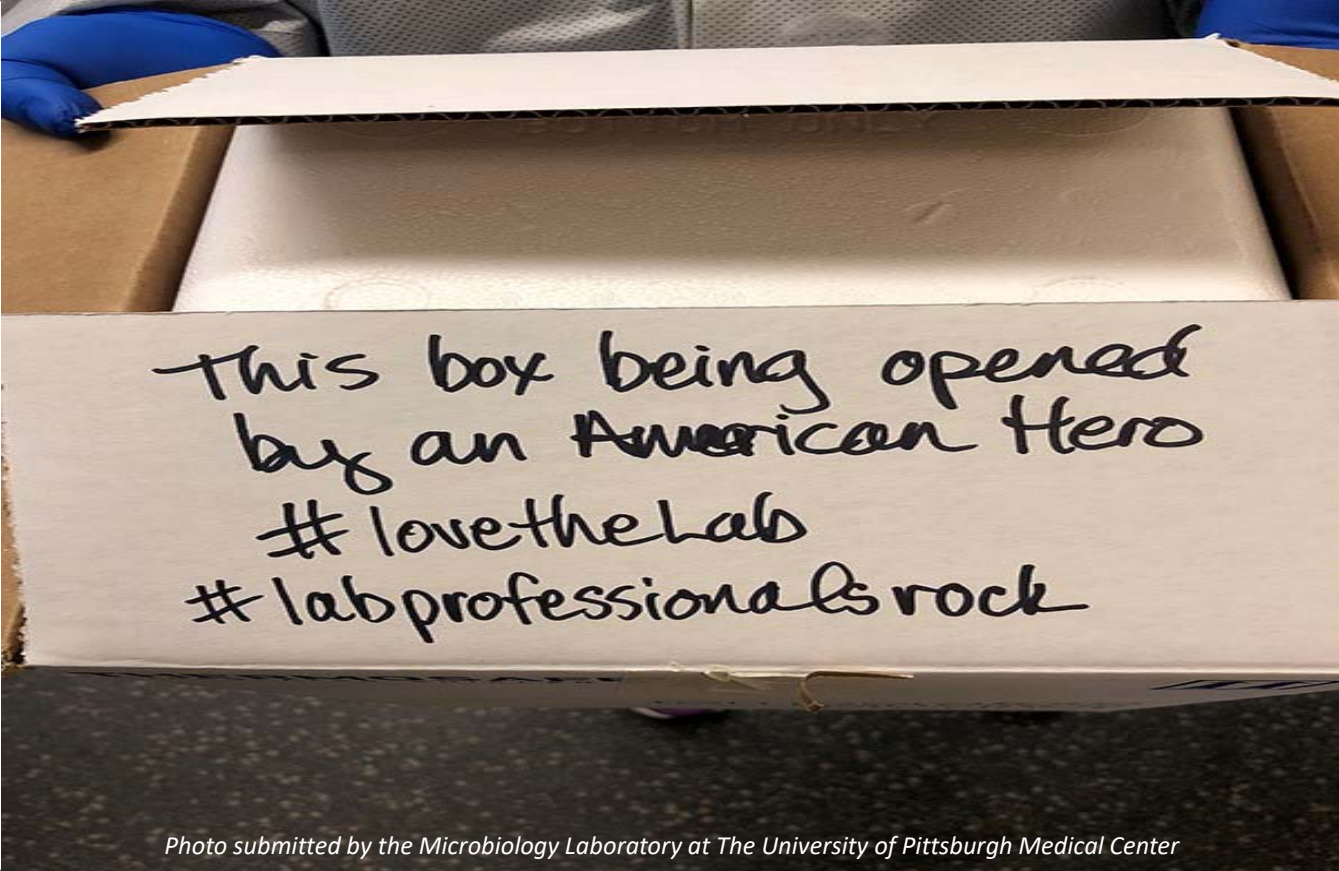
<https://twitter.com/cdcgov>



<https://www.linkedin.com/company/cdc>



# Thank You For Your Time!



This box being opened  
by an American Hero  
#lovethelab  
#labprofessionalsrock

*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*