

# Clinical Laboratory COVID-19 Response Call

Monday, August 31<sup>st</sup>, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **AMP SARS-CoV-2 Molecular Testing Follow-up Survey**
  - Robyn Temple-Smolkin, Association for Molecular Pathology (AMP)
- **CMS Update—CLIA Rule for Reporting COVID-19 Test Results**
  - Regina Van Brakle and Amy Zale, Centers for Medicare & Medicaid Services (CMS)
- **Laboratory Training Update**
  - Joe Rothschild, CDC Division of Laboratory Systems (DLS)
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

# Schedule for Clinical Laboratory COVID-19 Response Calls

The next call is scheduled for **Monday, September 14<sup>th</sup>** from 3:00 PM to 4:00 PM EDT.



# 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 – be sure to include your email address so we can get back to you
- 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



# Live Audience Poll



# 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>

# New COVID-19 Resources for Laboratories

- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>
- New Antigen Testing Guidance <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>
- New Additions to the [Frequently Asked Question \(FAQs\) about COVID-19 for Laboratories](#)
  - False Negatives and False Positives from COVID-19 Testing  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Interpreting-Results-of-Diagnostic-Tests>
  - Surveillance, Screening, and Diagnostic Testing for COVID-19  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Testing-Strategies-for-SARS-CoV-2>

# AMP SARS-CoV-2 Molecular Testing Follow-up Survey

**Robyn Temple-Smolkin**  
Association for Molecular Pathology (AMP)



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

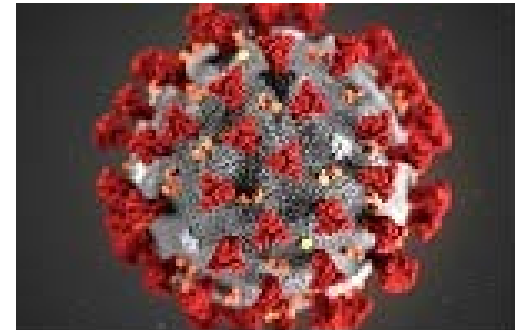


**WE NEED YOUR HELP!**

# Take AMP's NEW SARS-CoV-2 Molecular Testing Survey!

<https://www.surveymonkey.com/r/AMPCV19Testing>

Target Audience: laboratory professionals  
in clinical and public health labs  
offering SARS-CoV-2 molecular testing



*Providing global expertise in molecular testing that drives patient care.*

*Disclaimer: This survey has not been endorsed or supported by CDC*

# CMS Update—CLIA Rule for Reporting COVID-19 Test Results

**Regina Van Brakle and Amy Zale**  
Centers for Medicare and Medicaid Services (CMS)





Center for Surveillance, Epidemiology, and Laboratory Services

# DLS Laboratory Training Update

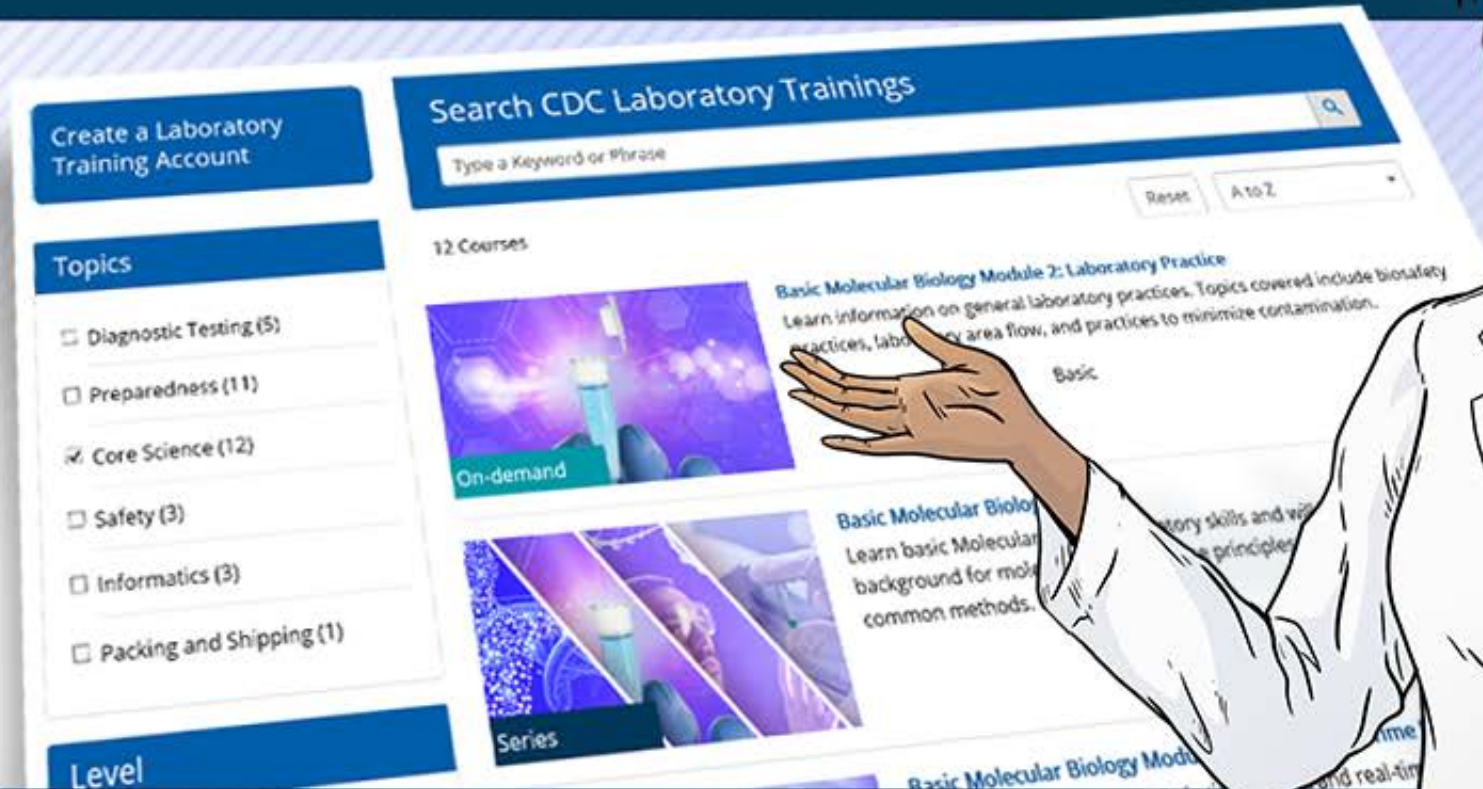
Joe Rothschild  
Health Communication Specialist  
CDC Division of Laboratory Systems

August 31, 2020



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

# CDC just made it easier to find the right lab training course for you!



New search tool, active filters, and improved course page layouts

[www.cdc.gov/labtraining](http://www.cdc.gov/labtraining)

# NOW LIVE



## PACKING AND SHIPPING DANGEROUS GOODS:

### What the Laboratory Staff Must Know



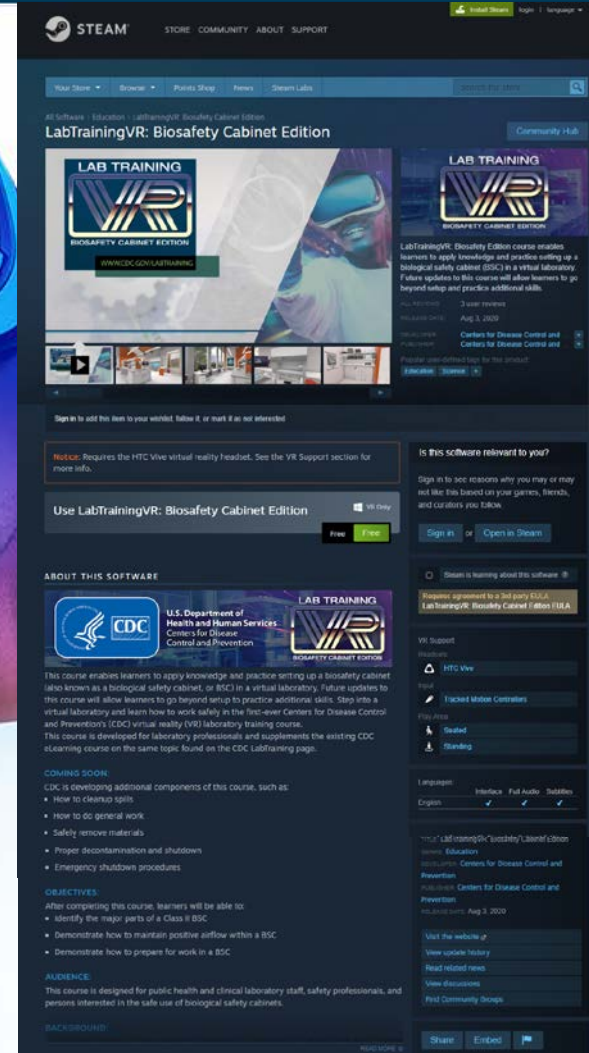
# NOW LIVE



Available on  
**CDC TRAIN**  
and  
**STEAM**




[cdc.gov/labtraining](https://cdc.gov/labtraining)



## CDC Laboratory Training

CDC > CDC Laboratory Training



 CDC Laboratory Training

**Virtual Reality Laboratory Training**

Virtual Reality Laboratory Training Partner Toolkit

External Training Links

FAQs

Continuing Education Units (CEU)

About Us

Contact Us

## Virtual Reality Laboratory Training

Public health emergencies demand the availability of diverse and effective distance-based education and training options for public health and clinical laboratory professionals. To keep pace with the evolving training needs, DLS has blended innovative technology and instructional design principles by adding Virtual Reality, or VR, to its laboratory training and workforce development toolbox.

VR offers laboratory professionals the opportunity to apply, assess, and improve their skills in a safe and controlled learning environment. In other words, VR simulations allow learners to make costly mistakes while learning new skills with no real-world consequences.

In 2019, DLS launched a three-year pilot project, in partnership with the Center



 [View Transcript](#)  [Low Resolution Video](#)

**NOW AVAILABLE**

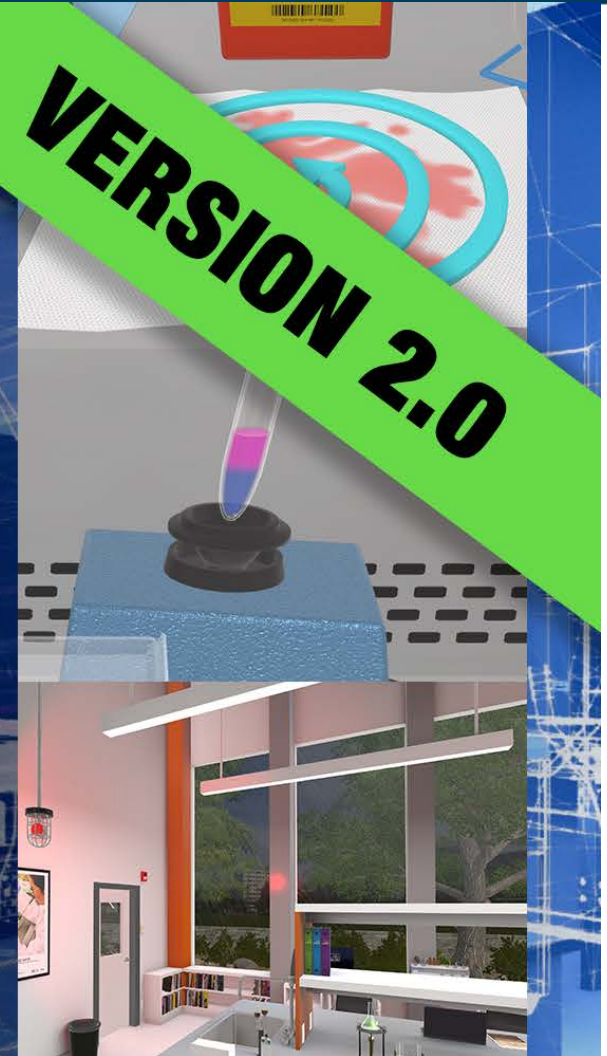
COMING SOON

LAB TRAINING



BIOSAFETY CABINET EDITION

VERSION 2.0





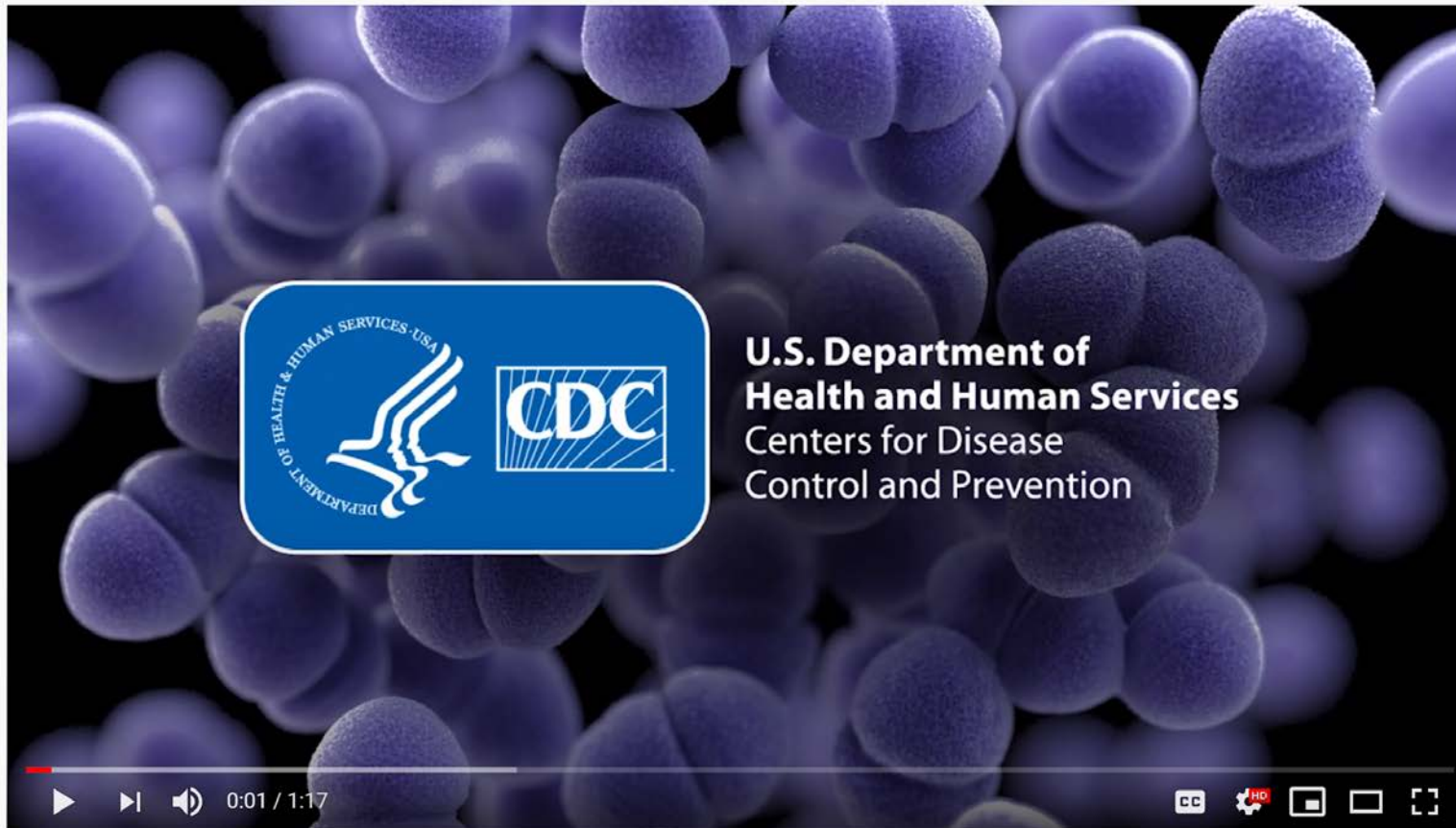
# NEW SCENARIOS & OBJECTIVES



# EMERGENCY PROCEDURES



# VIDEO DEMO (01:06)



[https://www.youtube.com/watch?v=Kmq\\_cBn\\_7Yk](https://www.youtube.com/watch?v=Kmq_cBn_7Yk)

# COMING SOON

LAB TRAINING



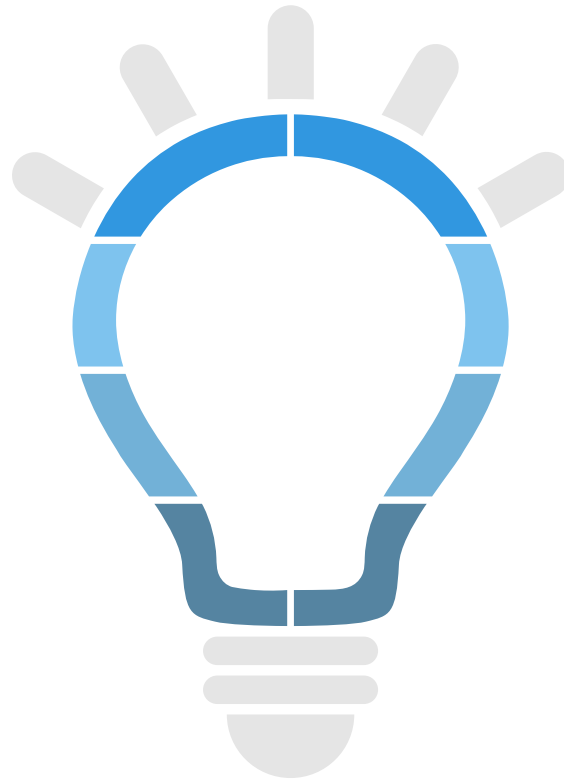
PPE EDITION

LAB TRAINING




MULTIPLAYER LAB

# SHARE YOUR TRAINING NEEDS



E-mail [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.

## 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 for Medical Devices**  
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
- **COVID-19 In Vitro Diagnostic EUAs**  
<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>
- **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>
- **Independent Evaluations of COVID-19 Serological Tests**  
<https://open.fda.gov/apis/device/covid19serology/>



# 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 (\*)

# CDC Social Media



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

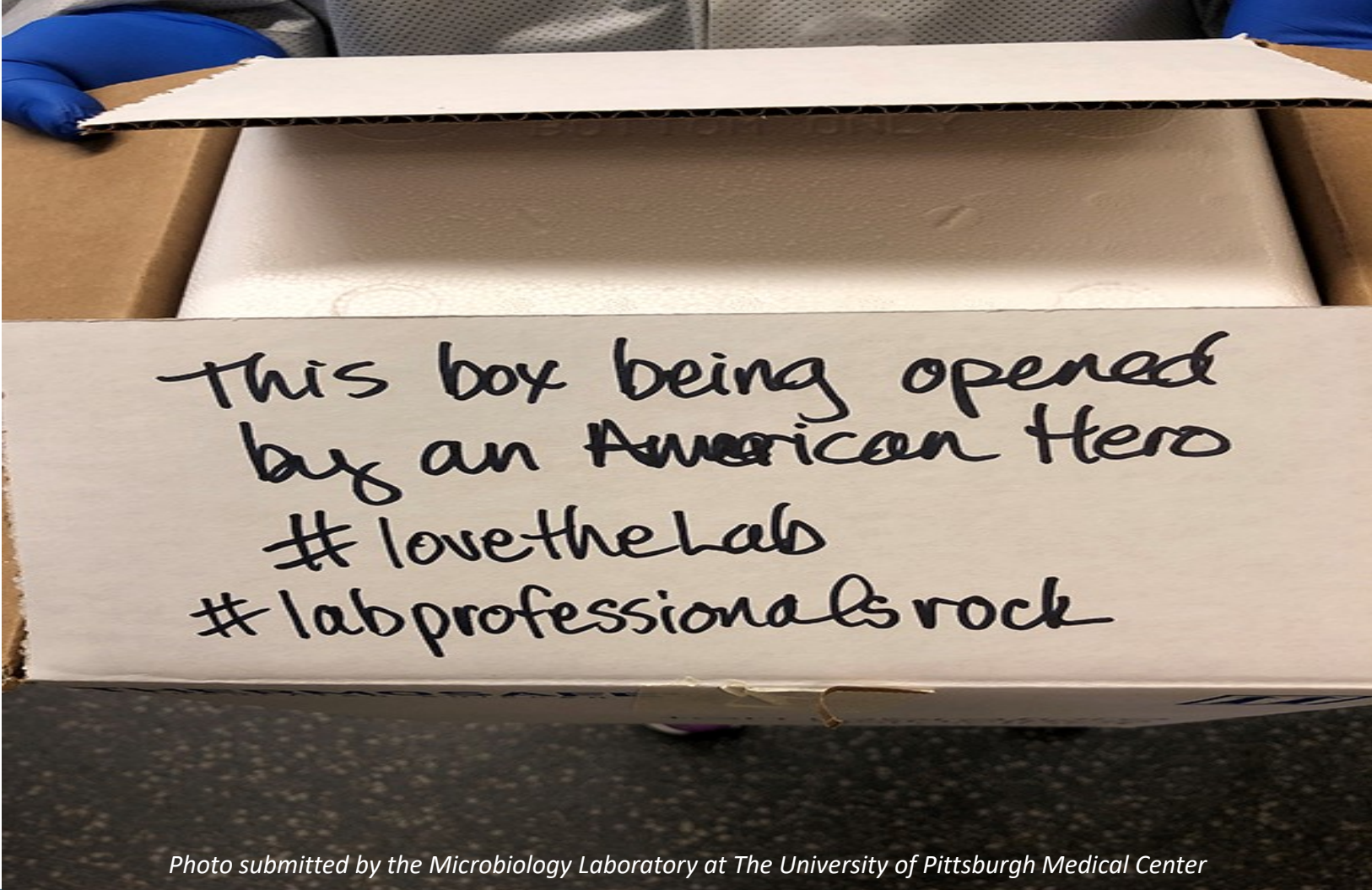


<https://twitter.com/cdcgov>



<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*