

Clinical Laboratory COVID-19 Response Call

Monday, June 8th, 2020 at 3:00 PM EDT

- **Welcome**
 - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Reporting and CARES Act Update**
 - Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
- **FDA Update**
 - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)
- **COVID-19 and Cytology Labs**
 - Liron Pantanowitz, Director of Anatomic Pathology, The University of Michigan
- **College of American Pathologists (CAP) Laboratory Accreditation Update**
 - Richard M. Scanlan, Chair, CAP Council on Accreditation
- **CMS Billing Update**
 - Sarah Shirey-Losso, Centers for Medicare and Medicaid Services (CMS)

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>

Share Your Feedback!

Help us improve these calls by taking a short 5-minute survey!



Take the Survey Here:

<https://www.surveymonkey.com/r/CLCR0608>



Questions? Contact DLInquiries@cdc.gov

We Want to Hear From You!

Training and Workforce Development



Questions about education and training?

Contact 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
- If you are a patient, please direct any questions to your healthcare provider



Reporting and CARES Act Update

Jason Hall

CDC Division of Preparedness and Emerging Infections (DPEI)



U.S. Department of
Health and Human Services
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**
<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

Spot Shortages of Testing Supplies: 24-Hour Support Available

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



COVID-19 & CYTOLOGY LABS



Liron Pantanowitz MD

Professor of Pathology & Biomedical Informatics

Director of Cytology UPMC Shadyside

Department of Pathology

University of Pittsburgh

Pittsburgh, PA

KEY ISSUES

- **SPECIMEN VOLUME**
- **CYTOLOGY SAMPLES**
- **ON-SITE EVALUATIONS**
- **PERFORMING FNAs**
- **WORKING FROM HOME**
- **STAFFING**



ASC SURVEY

Organized by Guliz Barkan, Stephan Pambuccian & Liron Pantanowitz



ASC SURVEY

Organized by Guliz Barkan, Stephan Pambuccian & Liron Pantanowitz

Impact on the Cytology Laboratory Specimen Volume

| SAMPLES | Paps | Non-Gyn | FNAs- NonPath | FNAs- Path | ROSEs |
|-----------------------|------|---------|------------------|---------------|-------|
| Not offered | 8% | 1% | 1% | 33% | 9% |
| Temporarily suspended | 8% | 3% | 6% | 16% | 9% |
| >2/3 reduction | 73% | 44% | 48% | 26% | 33% |
| 1/3-2/3 reduction | 6% | 40% | 34% | 11% | 31% |
| <1/3 reduction | 1% | 11% | 7% | 8% | 13% |
| Don't know | 3% | 3% | 3% | 6% | 4% |
| Other | 1% | 0% | 0% | 1% | 1% |

SPECIMEN PROCESSING

- Helpful guidance from documents for handling SARS-CoV-2 infected specimens released by the CDC and CAP & email traffic on various listservs (ASC, ADASP)
- Check patient COVID-19 status for all specimens
- Move all cytopreparation (e.g. cytospins with centrifuge) into a Class II Biosafety Cabinet
- LBC (e.g. ThinPrep, SurePath) processing can be centralized and operated by a single technologist
- Limited donning of N95 masks



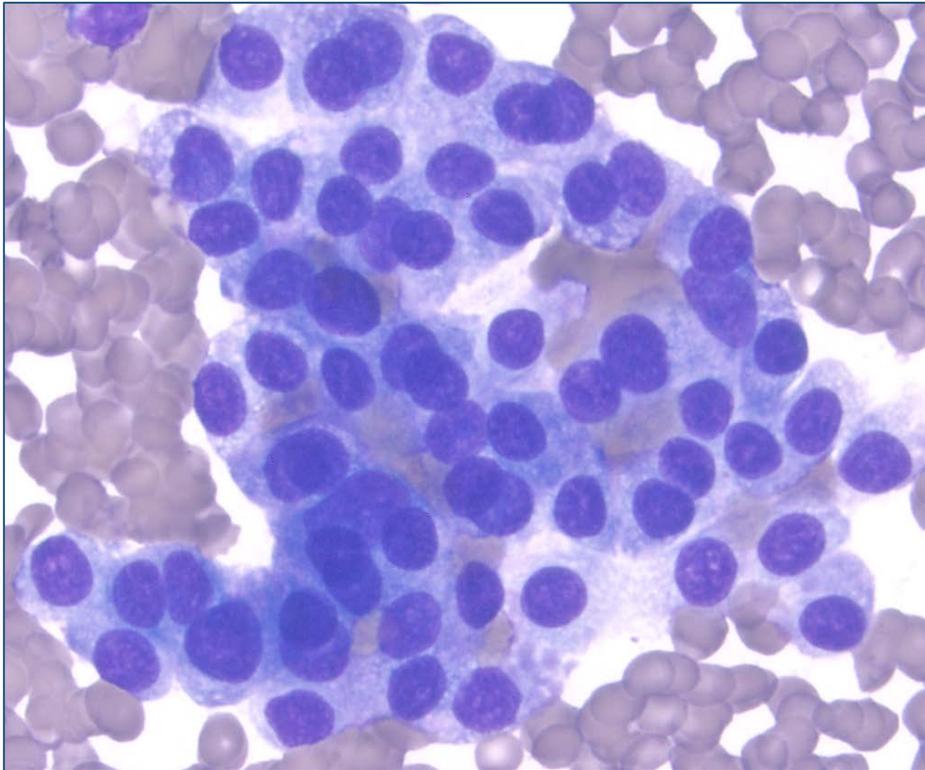
Rapid On-Site Evaluation (ROSE)

- ROSE vs No ROSE
- PPE (use N95 masks)
- Especially during procedures with elevated risk of fluid aerosolization (e.g. EBUS)
- Switch air-dried slides to immediate fixation in 95% ethanol

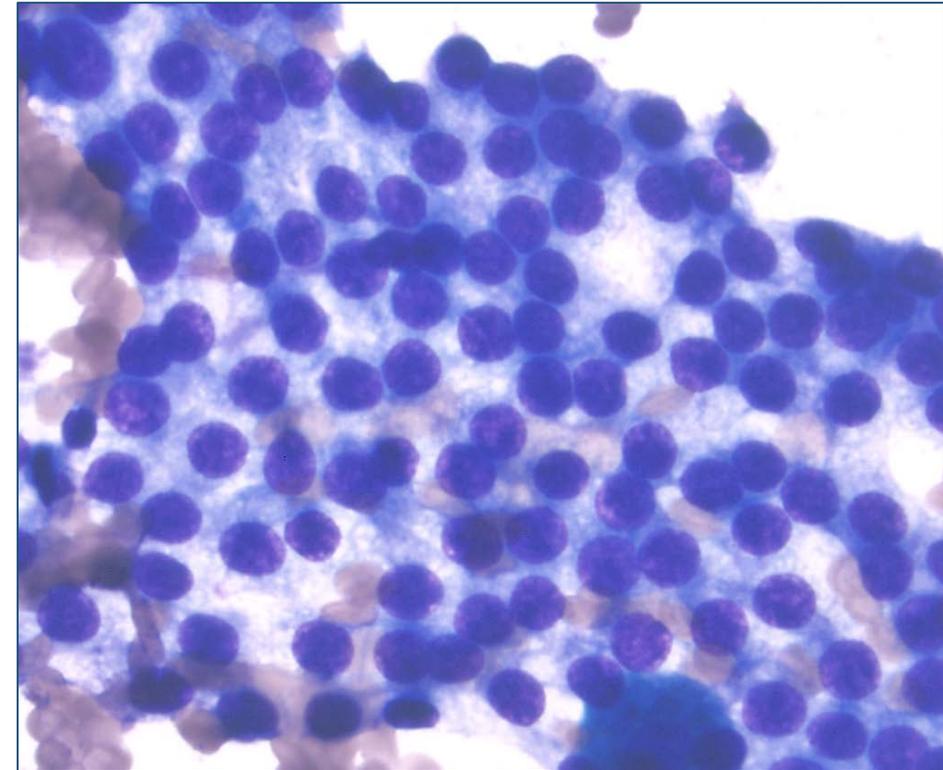


Air-Dried vs EtOH Fixed Slides

Normal lung (air-dried)

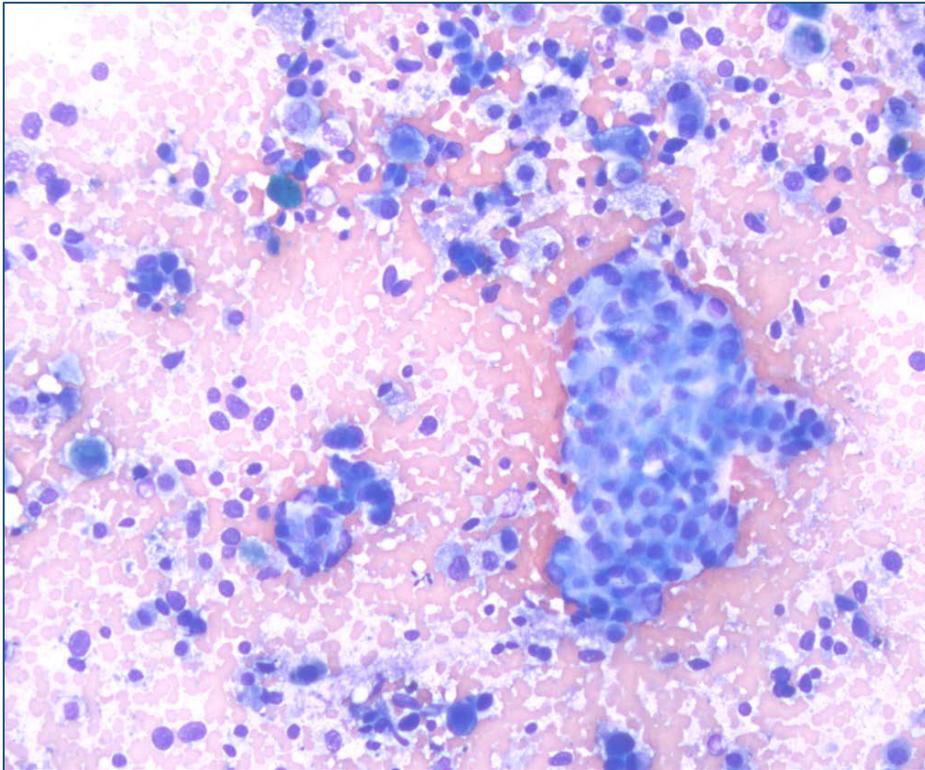


Normal lung (EtOH fixed)

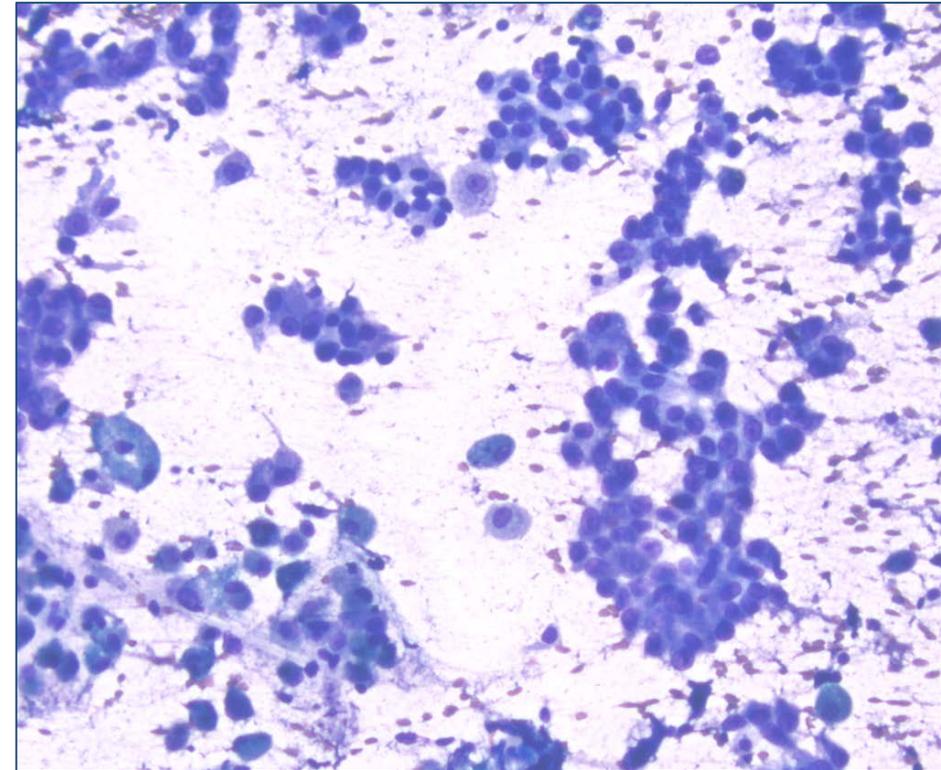


Air-Dried vs EtOH Fixed Slides

Lung NSCLC (air-dried)



Lung NSCLC (EtOH fixed)



TELECYTOLOGY

- Validated technology
- With CTs (streaming)
- Without CTs (robotic microscopy)
- CLIA suspension:
 - Pathologists permitted to work from home
- Slides for pathologist QA review can be digitized



Image from Dr. S. Monaco



COLLEGE of AMERICAN
PATHOLOGISTS

CAP Laboratory Accreditation Update

CDC Laboratory Outreach Communication System (LOCS)

Richard Scanlan MD, FCAP
Chair, CAP Council on Accreditation

June 8, 2020

CAP Laboratory Accreditation Update

Two topics:

- 1) Status of CAP inspections/accreditation
- 2) Survey of CAP-accredited laboratories/COVID testing

Status of CAP inspections/accreditation

- In mid-March, we suspended all routine inspections.
- This month, we will begin to work toward on-site inspections; details being ironed out, eg, organizing inspection teams, rescheduling suspended inspections, communicating with CMS, etc.
- During this time, impacted laboratories will remain CAP accredited.
- We are giving prior notification, so inspections will be announced.



Richard Scanlan, MD, FCAP
Chair, CAP Council on
Accreditation

CAP Laboratory Accreditation Update

Survey of CAP-accredited laboratories/COVID testing

- There's no question that pathologists and laboratory professionals are under substantial amounts of pressure.
- In late April, we surveyed clinical laboratory directors (434 responded) regarding:
 - The rate of COVID-19 testing, key barriers to expanding testing, and the impact on pathologists/laboratory professionals.
- The survey confirmed that while clinical laboratories are expanding testing, over 60% of laboratory directors reported difficulties in obtaining critical supplies needed to conduct COVID-19 testing.

CAP Laboratory Accreditation Update

Survey of CAP-accredited laboratories/COVID testing

- **59% of responding CAP-accredited laboratories provide on-site COVID-19 testing, and another 9% of laboratories expected to provide testing with the next 2-4 weeks (from late April)**
- **Since March 1, the number of responding laboratories offering COVID-19 testing increased substantially**
- **Most laboratory directors reported that they have substantial excess capacity for providing COVID-19 testing**
- **Respondents expected their COVID-19 testing to increase by about 40% over the next two weeks (from late April)**

CAP Laboratory Accreditation Update

Survey of CAP-accredited laboratories/COVID testing

- **Impediments reported by laboratory directors**
 - Laboratory directors reported substantial barriers to getting the equipment needed for testing, particularly test kits (69%), swabs (66%), and transport media (62%)
 - Laboratory workforces face substantial stresses, regardless of whether the laboratory is providing COVID-19 testing.
 - Nearly all laboratories reported substantial losses in revenues and financial stress, but few had applied for federal assistance programs
- **Stresses affecting the laboratory workforce**
 - The COVID-19 pandemic is affecting pathologists and other laboratory professionals, regardless of whether the laboratory is providing COVID-19 testing.
 - The top issues reported by laboratory directors among pathologists: Reduced work hours (72%), reductions in pay (41%), increased burnout (21%), and increased work hours (20%).

CAP Laboratory Accreditation Update

Survey of CAP-accredited laboratories/COVID testing

- **Stresses affecting the laboratory workforce, continued**
 - The top issues among non-pathologist laboratory professionals are reduced work hours (69%), reduced staff capacity (36%), temporary furloughs (34%), and increased burnout (31%).
- **Financial stress on laboratories**
 - Respondents reported a median drop of 69% in AP testing and 46% in CP testing, regardless of whether they are doing COVID-19 testing.
 - Average and median laboratory revenue had decreased by about 50% among all respondents, regardless of whether they provide COVID-19 testing.
 - This adds substantial financial stresses to the laboratory. For those laboratories performing COVID-19 testing, it adds workload stresses to some pathologists and professional staff.
 - While there are federal assistance programs that could help laboratories, only slightly more than half of laboratory directors were aware of these and relatively few sought assistance or received benefits.

CAP Laboratory Accreditation Update

Resources

- **Visit [cap.org](https://www.cap.org) “COVID-19 Information” section**
 - Download survey findings/watch town hall
 - Stay up to date with what’s happening with CAP inspections
 - Review extensive COVID-19 questions and answers
 - See the CAP Statement on the Current Role of Serologic Testing for SARS-CoV-2
 - Follow the CAP’s guidance to ensure availability of reliable testing for rapid detection of the agent that causes COVID-19
 - Access best practices for Implementing a SARS-CoV-2 Test in Your Laboratory
 - See Best Practices for Using Biologic Safety Cabinets While Testing for COVID-19
 - Learn about CAP proficiency testing for both the detection of SARS CoV-2 and the detection of antibodies against SARS-COV-2



COLLEGE of AMERICAN
PATHOLOGISTS

CMS Billing Update

Sarah Shirey-Losso

Centers for Medicare and Medicaid Services (CMS)



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

Centers for Medicare and Medicaid Services (CMS)

- **Medicare Fee-for-Service (FFS) FAQs**
<https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>
- **Medicare Administrative Contractor (MAC) Pricing**
<https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf>
- **Tests which do not require an order for Medicare**
<https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf>

Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**
<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>
- **FAQs Only**
<https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>

CDC Social Media



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

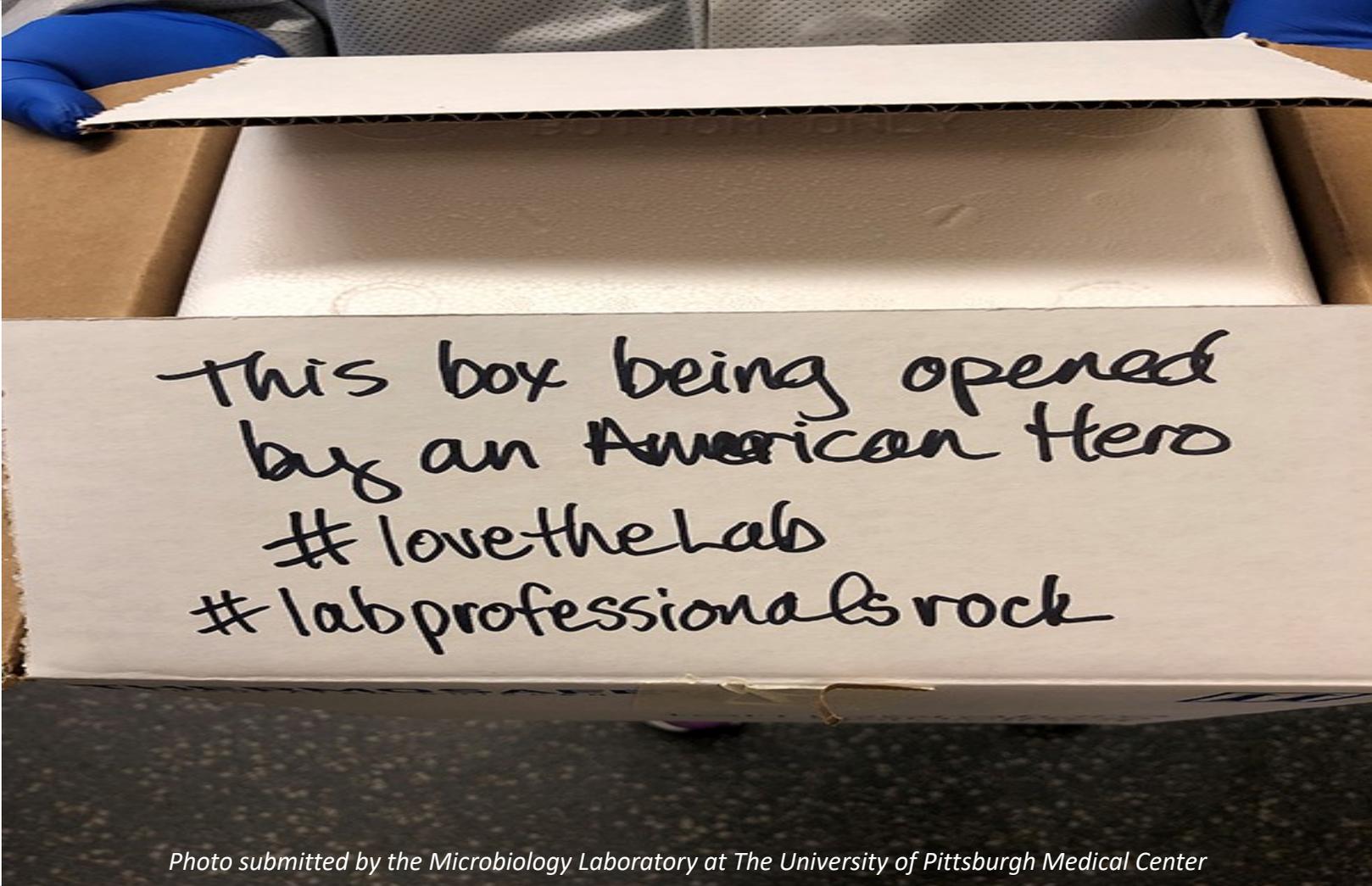


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<https://www.linkedin.com/company/cdc>

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