

Clinical Laboratory COVID-19 Response Call

Monday, July 6th, 2020 at 3:00 PM EDT

- **Welcome**
 - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Update on CDC Serology Guidance**
 - Lyle Peterson, National Response Coordination Center (NRCC)
- **FDA Update**
 - Sara Brenner and Tim Stenzel, U.S. Food and Drug Administration (FDA)
- **Biosafety for Autopsies and Pathophysiology**
 - Jody Hooper, Johns Hopkins University
- **COVID-19 Safety in the Laboratory Environment**
 - Reynolds (Ren) Salerno, CDC Division of Laboratory Systems (DLS)

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call is scheduled for
Monday, July 20 from 3:00 PM to 4:00 PM EDT



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/2020_July_06



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



Update on CDC Serology Guidance

Lyle Peterson
National Response Coordination Center (NRCC)



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

Spot Shortages of Testing Supplies: 24-Hour Support Available

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

Biosafety for COVID-19 Autopsies and Pathology

Jody E. Hooper, MD
Johns Hopkins University

*These slides are available upon request – email jhooper9@jhmi.edu



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

COVID-19 Safety in the Laboratory Environment

Reynolds (Ren) Salerno
CDC Division of Laboratory Systems (DLS)



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>

CDC Social Media



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

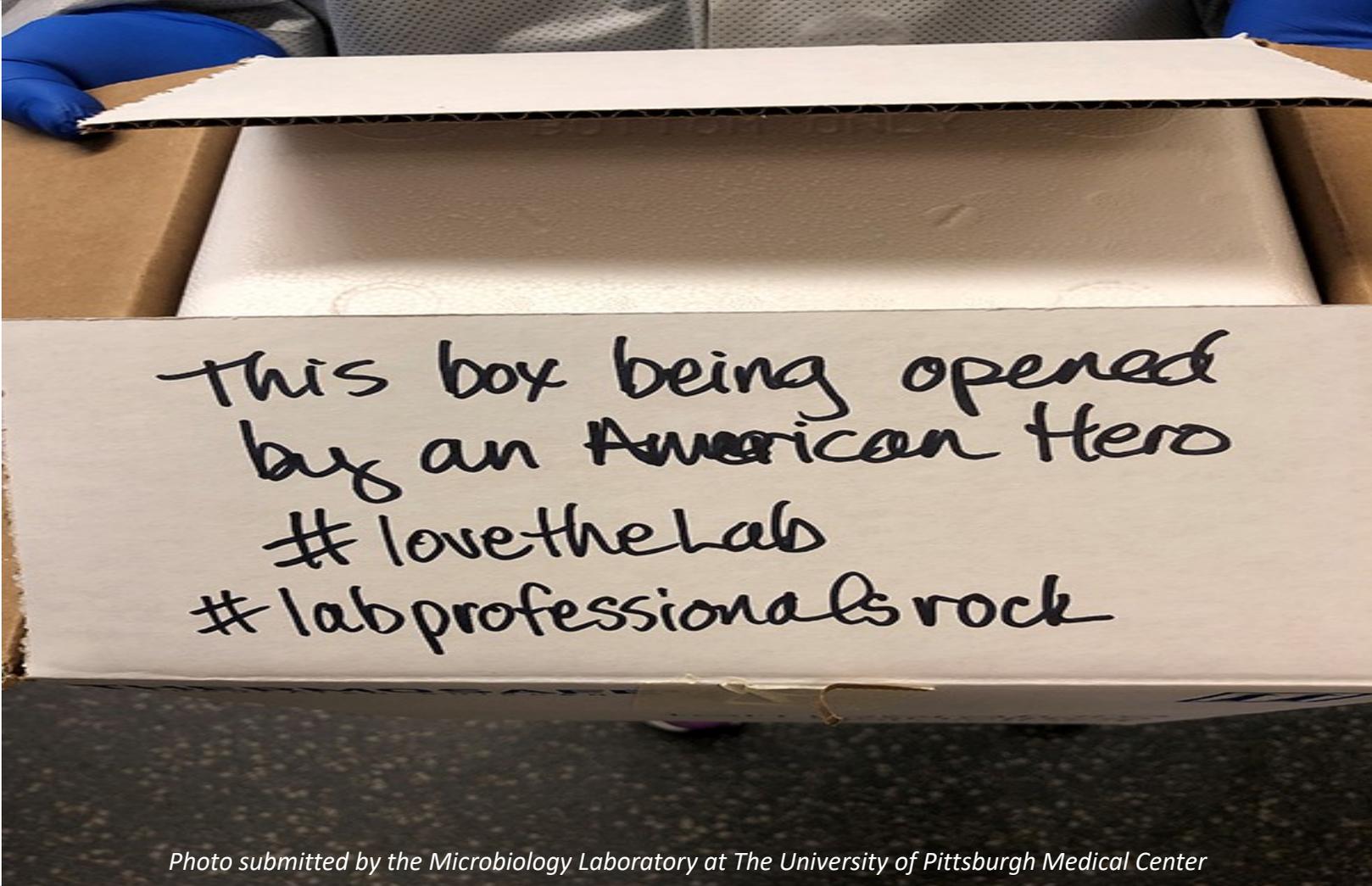


<https://twitter.com/cdcgov>



<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