

Clinical Laboratory COVID-19 Response Call

Monday, June 1th, 2020 at 3:00 PM EDT

- **Welcome**
 - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Opening Remarks**
 - Dr. Robert Redfield, Director, CDC
- **Supply Chain Update**
 - Brad Smith, Centers for Medicare and Medicaid Services (CMS)
 - Tammy Beckham, U.S. Department of Health and Human Services (HHS)
- **FDA Update**
 - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)
- **Serology Testing Update**
 - Chris Elkins and Vicki Olson, CDC Laboratory Task Force for the COVID-19 Response
- **Maintaining Connections and Supporting Laboratories during the COVID-19 Pandemic**
 - Kathy Nucifora, COLA

Opening Remarks

Dr. Robert Redfield
Director, CDC



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

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/CLCR0601>



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.



Supply Chain Update

Brad Smith

Centers for Medicare and Medicaid Services (CMS)

Tammy Beckham

U.S. Department of Health and Human Services (HHS)



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FDA Update

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



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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 (*)



Serology Testing Update

Chris Elkins and Vicki Olson

CDC Laboratory Task Force for the COVID-19 Response



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CDC Laboratory Task Force

- **Interim Guidelines for COVID-19 Antibody Testing**

<https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>

- **COVID-19 Emergency Use Authorization (EUA) Information**

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

- **EUA Authorized Serology Test Performance**

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>

Maintaining Connections and Supporting Laboratories During the COVID-19 Pandemic

*Kathy Nucifora, MPH, MT(ASCP)
Chief Operating Officer, COLA*

June 1, 2020



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COLA is ISO 9001:2015 Certified

Laboratories have questions...we help them find answers

- Understanding Emergency Use Authorization
- Diagnostic testing vs. Antibody testing
- Availability of tests and associated supplies
- Upgrading from CLIA Certificate of Waiver to Certificate of Registration
- On-site survey delays

Connecting laboratories to resources

- Links to FDA FAQs and EUA information
- CMS guidance documents
- CDC website
- CDC weekly calls
- Laboratory Outreach Communication System (LOCS) alerts
- Webinars sponsored by laboratory professional organizations

COLA assistance

- Designated staff to respond to COVID-19 testing questions
- Technical bulletins and updates posted to customer portal
- Chat feature
- Pre-survey documentation review process
- “Soft launch” of surveys May 19

CDC Social Media



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

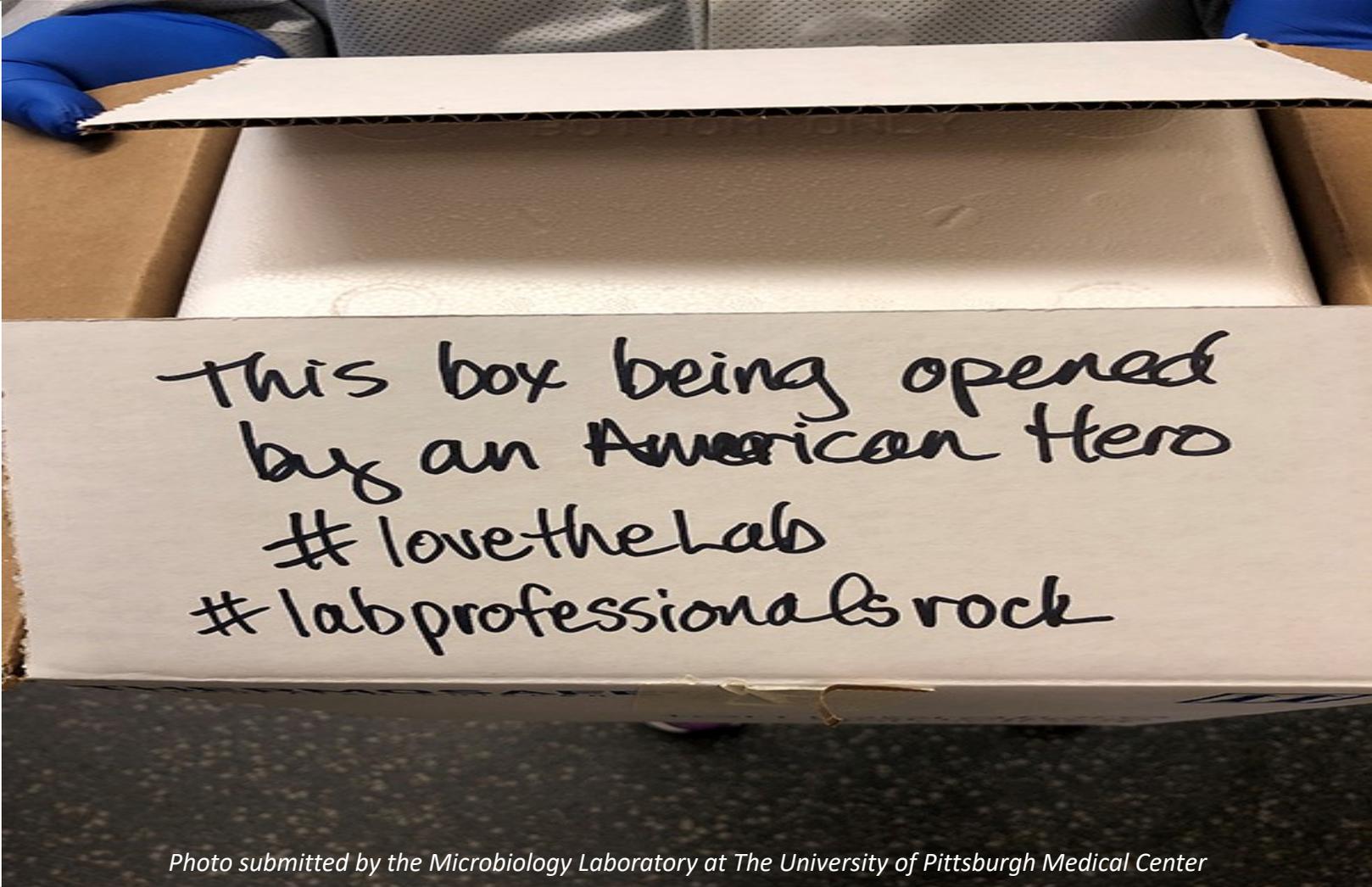


<https://twitter.com/cdcgov>



<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